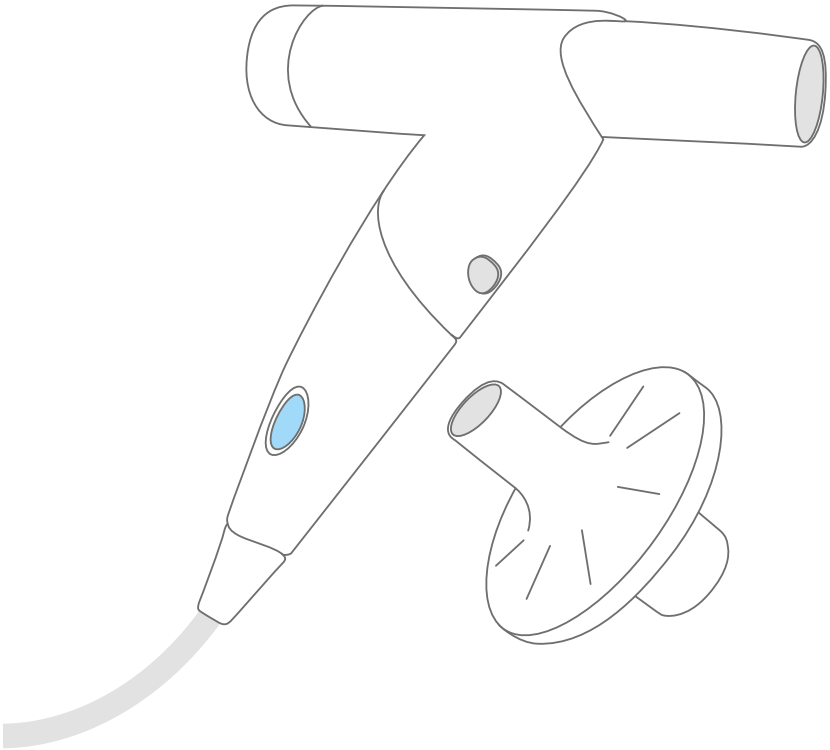
Instructions for Use

Spirometry with seca spiro mobile and seca diagnostic 5.9



seca®
Precision for health

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custo diagnostic (medical PC software)

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seca product names:
seca spiro mobile (spirometry device)
seca diagnostic (medical PC software)

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1 Safety

1.1 General notes

1.1.1 Symbols used in this Operating Manual

	Safety warning symbol, in case of dangerous situations with high and medium risk level, which may result in personal injuries
	**IMPORTANT:** absolutely necessary working steps
	**INFORMATION:** for the correct and safe use of the system.
	**TIP:** contains practical information to assist you with your work
seca	Words highlighted in colour indicate buttons or click paths to the corresponding program point, e.g.: Examination, Settings

1.1.2 Laws and regulations applicable to the product

INFORMATION:

Strict compliance with the safety instructions protects against personal injury and property damage during device operation. These Instructions for Use are designed to accompany the product and must be kept ready to hand close to the device. As either the operator or user of this device you should have read and understood the Instructions for Use, in particular the safety instructions.

Should serious incidents occur in connection with the product, they must be reported by the user and/or patient to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

This system is designed in accordance with Regulation (EU) 2017/745 on medical devices, Medical Device Regulation (MDR), Class IIa and corresponds to protection class I or II, depending on the power supply unit, or it is a device with an internal power supply, type BF or CF in accordance with DIN EN 60601-1. Other devices that are part of the system must comply with the standard for information technology equipment (DIN EN 62368) or the standard for electromedical devices (DIN EN 60601-1).

The electrical installations in the rooms in which the system is used must meet the requirements of the applicable safety standards.

For users outside the Federal Republic of Germany, the respective national accident prevention measures, regulations and requirements apply.

1.1.3 Disclaimer

The manufacturer will not be held liable for improper operation, non-compliance with safety instructions and negligently skipped instructions.

custo med only accepts responsibility for the safety and reliability of the device if all modifications, extensions, repairs and other work on the device or system are carried out by an authorised seca sales partner and the instructions for use are observed during use.

1.1.4 Warranty

Our product philosophy is committed to providing you with faultless products which meet your expectations. Should you have reason to complain we aim to rectify any defects immediately or provide a replacement delivery.

This does not include damage that can be attributed to usual wear and tear, improper use, unauthorised modification of parts and the use of violent force.

After the warranty period has expired, only use original spare parts and accessories supplied by custo med. Only this will ensure the safe and problem-free operation of your device.

1.1.5 Support

If you have any questions or problems that are not covered here, please contact your authorised seca sales partner. The contact details can be found on the second and last page of these instructions for use.

You can also contact custo med GmbH directly at any time. We will be happy to put you in touch with your authorised seca sales partner and forward your request.

1.2 Safety installations and safe working

1.2.1 Putting into operation, setup

The system must only be used in a technically perfect condition. Regularly carry out a visual inspection of the devices and their associated components. Only use accessories approved by custo med. The use of accessories other than those specified may result in increased emissions or decreased immunity.

A PC with peripherals is required to operate the seca device. For assembly it is recommended to use portable multiple socket outlets approved by custo med. The following must be noted:

- → Portable socket outlets must not be laid on the ground.
- → Portable multiple socket outlets which are supplied with the system are to be used only for supplying devices which are part of the system.
- → Additional portable multiple socket outlets, lines and other equipment, which are not part of the system, must not be connected to the system.
- → When using a multiple socket outlet, the maximum permitted load is 3200 VA.
- → Slots which are not used in the delivered system (portable multiple socket outlets) must be provided with covers.

1.2.2 Ambient conditions, handling of the devices

Emissions

The seca spiro mobile device/system is not suitable for use in rooms or areas with a risk of explosion.

For installation and operation of the seca spiro mobile device/system, the EMC (electromagnetic compatibility) instructions in this manual must be observed.

Strong electromagnetic sources in the immediate vicinity of the seca spiro mobile device/system may result in recording errors. The seca spiro mobile device/system must not be stored or used in the vicinity of X-ray equipment, diathermy units or magnetic resonance devices (MRT). Other electrical devices such as mobile phones or radio transceivers may impair the quality of the recording.

Other devices may interfere with the seca spiro mobile device/system, even if the other devices comply with the applicable emissions requirements according to CISPR.

Mechanical impact

No modifications may be made to the seca devices/systems. For repairs, please contact your authorised seca sales partner.

seca devices for outpatient use (recorder, transmitter) must be protected from heat, moisture, dust and dirt. The devices may not function properly if they come into contact with liquid.

It is not permitted to wear the devices in a swimming pool, in the sauna, bathtub, shower or similar wet rooms. Do not submerge the seca devices.

seca devices must be protected from mechanical impact, such as falls or transport damage. Avoid heavy mechanical loads.

Rechargeable batteries

seca ct330/331 (12-channel PC ECG device) and seca guard holter (holter ECG device) contain an integrated lithium polymer rechargeable battery (permanently installed in the housing). Any mechanical stress which is beyond the intended use must be avoided. Do not use force to open the devices.

seca screen 300 (ABPM recorder) contains batteries or rechargeable batteries that can be removed. Remove the batteries or rechargeable batteries when the device is not in use. Batteries and rechargeable batteries must be protected from extreme temperatures, fire and moisture. Immersion in liquids is prohibited. Observe the operating and storage conditions. Avoid strong impacts. Batteries and rechargeable batteries must not be modified or short-circuited. Only use the charger supplied to charge the rechargeable batteries. Do not remove any battery compartment covers or other covers during operation.

USB cable

seca ct330/331 (12-channel PC ECG device) and seca spiro mobile (spirometry device) both have a USB cable. This cable must not be kinked. Do not step on the USB cable, only roll up the cable loosely and allow it to hang freely during operation. Always hold the USB cable by the plug in order to disconnect it from the PC.

1.2.3 Patient safety

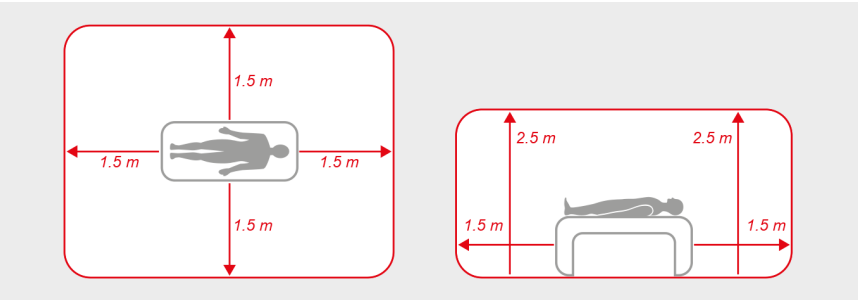


Fig. 1: Safety distances at the patient area

Without medical protective devices, for example medical protector, the PC and all the non-medical devices connected to the system (e.g. the monitor and printer) must be set up and used at a distance of at least 1.5 m to the patient unit (see the orange area in the figure) as leakage currents can occur.

During examination or routine maintenance, do not touch non-medical equipment and the patient at the same time (risk of electric shock). Make sure that the electrode contacts do not come into contact with other conductive parts.

All results achieved by automatic analysis and the resulting unconfirmed reports produced by the system must be considered as suggestions only. For diagnosis and therapy purposes it is essential that the results are checked and assessed by a qualified physician.

1.2.4 System and data security

IMPORTANT: Patient data must be handled in accordance with the legal requirements of the respective country (this includes the General Data Protection Regulation (GDPR)). seca diagnostic offers functions to help you meet these requirements (e.g., user administration, password assignment).

Manufacturer's note for users/customers for the integration of programmable electronic medical systems (PEMS) into existing IT networks

The seca products and systems are programmable electronic medical systems (PEMS). The integration of seca products into an IT network that includes other devices can lead to risks for patients, operators or third parties that were not previously known. The responsible organisation should identify, analyse, evaluate and control these risks. Subsequent changes to the IT network can lead to new risks, and therefore require additional analysis.

Changes to the IT network include the following: Changes to the IT network configuration, connecting additional items to the IT network, removing items from the IT network, updates/upgrades of devices that are connected to the IT network.

seca diagnostic

The device must only be used with the supplied seca software (seca diagnostic).

As the operator you are responsible for ensuring regular data backups (patient databases, evaluations etc.) and system backups. We recommend that you backup the data at the latest before new installations, updates and far-reaching system configurations.

seca diagnostic new installations, updates and system configurations may only be performed by your authorised seca dealer.

Only change data generated in seca diagnostic within seca diagnostic itself and not in your surgery IT system or your hospital information system (HIS). seca does not accept any responsibility for any changes to data in your IT system or your HIS which were made after the export from seca diagnostic.

To ensure the safe operation of seca diagnostic, deactivate the screensaver and energy management options on your PC. Set up your operating system in such a way to prevent the PC from being switched off either accidentally or automatically during the examination (standby mode/idle mode).

Allocation of case and job numbers

If case or job numbers are manually entered into the system or they are changed in the system, there is a risk of confusing patients and subsequent misdiagnosis if an incorrect entry is made by a user. Always make sure that case or job numbers are entered correctly!

Scanning or manually entering patient, case or job numbers does not relieve the user of the obligation to check the patient to be physically treated.

Data management in seca diagnostic: Assign evaluation

If an examination was conducted with incorrect patient data, the evaluation can be subsequently allocated to the correct patient. Make sure that the evaluation is definitely allocated to the correct patient. Incorrect allocation can lead to misdiagnosis. Please note that data which has already been exported to an external system (e.g., surgery IT system) cannot be changed.

seca diagnostic is preset with the Assign evaluation function deactivated; however, it can be reactivated via user rights if necessary. Only the Supervisor can configure user rights. If the Assign evaluation function is activated, it can be found in the evaluation search or in open evaluations in the Options menu.

We recommend configuring user rights in seca diagnostic so that only authorised persons can execute the Assign evaluation function.

1.2.5 Information on EMC (Electromagnetic Compatibility)

The use of other accessories, other converters and leads than those indicated, except for the converters and leads sold by custo med as spare parts for inner components, can lead to increased electromagnetic emissions or to a reduced electromagnetic immunity of the system. For connecting the device to other equipment, only specially screened cables supplied by custo med or seca must be used.

1.2.6 Maintenance (regular safety checks)

The operator is responsible for maintenance.

Observe the legal regulations for checking electrical systems and equipment (e.g., Regulation 3 “Accident Prevention Regulation” of the German Social Accident Insurance (DGUV) in the Federal Republic of Germany).

The functionality and the state of accessories must be checked at regular intervals. If damaged or heavily soiled, the complete system must no longer be used.

After each system or device repair, modification or conversion, your authorised seca dealer must perform a safety and conformity assessment.

1.3 Safety instructions for spirometry

If seca spiro mobile is transported at temperatures below freezing point, the device must only be put into operation when it has reached ambient room temperature. Observe the operating conditions

To ensure precise measuring results, the environmental data in seca diagnostic must be adapted to local conditions (air humidity, temperature, etc.). Otherwise, this may falsify the measurement data obtained.

Only use bacterial and viral filters approved by custo med, such as spiro protect. Unsuitable filters may falsify the measurement data obtained.

spiro protect is a single-use article. Make sure that it is disposed of after each examination in a safe and environmentally responsible manner.

1.4 Residual risks spirometry

CAUTION

Cross-contamination and falsification of measured values due to soiling in the filter

→ Dispose of the spiro protect bacterial and viral filters after each examination. Do not reuse!

CAUTION

Risk of contamination from used bacterial and viral filters

→ A spiro protect bacterial and viral filter may only be used for one patient.

→ Dispose of the spiro protect bacterial and viral filter safely and properly after the examination.

2 Hardware

2.1 Intended use

seca spiro mobile is a pulmonary function testing device designed for measuring and evaluating a patient's pulmonary function. seca spiro mobile measures respiratory flow rates and lung volumes and displays them graphically in the software interface. The type and status of a lung disease can be diagnosed on the basis of the derived measured values. The quality of the evaluation depends largely on the patient's cooperation.

seca spiro mobile is perfectly safe for patients with a pacemaker. The operator has to decide himself/herself whether to use seca spiro mobile for a patient in certain situations (e.g. in the case of disablement). The system is intended for use by trained specialist staff or physicians in clinics and medical practices.

2.1.1 Indications and contraindications

Graham, B. L., Steenbruggen, I., Miller, M. R., Barjaktarevic, I. Z., Cooper, B. G., Hall, G. L., Hallstrand, T. S., Kaminsky, D. A., McCarthy, K., McCormack, M. C., Oropez, C. E., Rosenfeld, M., Stanojevic, S., Swanney, M. P., & Thompson, B. R. (2019). Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement. American Journal of Respiratory and Critical Care Medicine, 200(8), e70–e88. https://doi.org/10.1164/rccm.201908-1590ST

Indications spirometry

Diagnosis
- → To evaluate symptoms, signs, or abnormal laboratory test results
- → To measure the physiologic effect of disease or disorder
- → To screen individuals at risk of having pulmonary disease
- → To assess preoperative risk
- → To assess prognosis

Monitoring
- → To assess response to therapeutic intervention
- → To monitor disease progression
- → To monitor patients for exacerbations of disease and recovery from exacerbations
- → To monitor persons for adverse effects of exposure to injurious agents
- → To monitor for adverse reactions to medications with known pulmonary toxicity

Disability/impairment evaluations
- → To assess patients as part of a rehabilitation program
- → To assess risks as part of an insurance evaluation
- → To assess individuals for legal reasons

Other
- → Research and clinical studies
- → Epidemiological surveys
- → Derivation of reference equations
- → Preemployment and lung health monitoring for at-risk occupations
- → To assess health status before beginning at-risk physical activities

Relative contraindications spirometry

Due to increased myocardial stress or changes in blood pressure
- → Acute myocardial infarction within one week
- → Systemic hypotension or severe hypertension
- → Significant atrial/ventricular arrhythmia
- → Non-compensated heart failure
- → Uncontrolled pulmonary hypertension
- → Acute cor pulmonale
- → Clinically unstable pulmonary embolism
- → History of syncope related to forced expiration/cough

Due to increases in intracranial/intraocular pressure
- → Cerebral aneurysm
- → Brain surgery within four weeks
- → Recent concussion with continuing symptoms
- → Eye surgery within one week

Due to increases in sinus and middle ear pressures
- → Sinus or middle ear surgery or infection within one week

Due to increases in intrathoracic and intraabdominal pressure
- → Presence of pneumothorax
- → Thoracic surgery within four weeks
- → Abdominal surgery within four weeks

→ Late-term pregnancy

Infection control issues

→ Active or suspected transmissible respiratory or systemic infection, including tuberculosis. Physical conditions predisposing to transmission of infections, such as hemoptysis, significant secretions, or oral lesions or oral bleeding.

Spirometry should be discontinued if the patient experiences pain during the manoeuvre. Relative contraindications do not preclude spirometry but should be considered when ordering spirometry. The decision to conduct spirometry is determined by the ordering healthcare professional on the basis of their evaluation of the risks and benefits of spirometry for the particular patient. Potential contraindications should be included in the request form for spirometry.

2.2 Symbols on the devices and packaging

	Manufacturer: custo med GmbH, Maria-Merian-Str. 6, 85521 Ottobrunn, Germany
distributed by seca	Distributor: seca Ltd., 40 Barn Street, Birmingham, West Midlands, B5 5QB, UK
	Order number/designation
	Lot designation
	Serial number
	Unique Device Identifier
	Medical device
	Date of manufacture (YYYY-MM, e.g., 2022-01)
	CE mark
	CE mark
	Follow the Operating Manual!
	Safety class classification of medical electrical equipment according to DIN EN 60601-1 (Type BF)
	Separate collection of electrical and electronic equipment, do not dispose with domestic waste.
	Observe the Operating Manual
	Observe accompanying documents.
	Minimum shelf life, for use until (MM YYYY, e.g. 10 2021)

	Single-use article, do not reuse
	Temperature limit
	Latex-free
	PHT-free
	Prescription only. Caution: US Federal law restricts this device to sale by or on the order of a physician or dentist.
	Do not use if package or product is damaged.

2.3 Technical data and system requirements

seca spiro mobile	
Measuring sensor	Differential pressure gauge with laminar element
Display of measured values	BTPS (Body Temperature Pressure Saturated)
Measurement range according to ISO 23747	1.00l/s – 14.5 l/s (peak expiratory flow)
Measurement range according to ISO 26782	0l – 8l (time forced expired volume)
Error of measurement according to ISO 23747	±3% (peak expiratory flow)
Error of measurement according to ISO 26782	3% or ±0,05l (time forced expired volume)
Linearity according to ISO 23747	1% (peak expiratory flow)
Linearity according to ISO 26782	3% (time forced expired volume)
Repeatability according to ISO 26782	0.02l (time forced expired volume)
Flow resistance according to ISO 23747	Maximum value: 0.21 kPa/l/s at 14.5 l/s (peak expiratory flow)
Flow resistance according to ISO 26782	Maximum value: 0.17 kPa/l/s at 7.0 l/s Average value: 0.14 kPa/l/s (time forced expired volume)
Frequency response	Maximum value 9%
Time zero	Time zero is determined by the back-extrapolation method
Resting breathing detection	> 300 ml
End of measurement detection	< 150 ml/sec for 5 sec
Resolution	12 Bit
Power supply	USB (Universal Serial Bus), Standard USB port on the PC
Dimensions	140 * 150 * 45 mm (L * B * H)
Weight	approx. 330 g
Operating conditions	Temperature +10°C ... +40°C Humidity 10 ... 95 % rH Air pressure 700 ... 1060 hPa
Transport and storage conditions	Temperature -20°C ... +45°C Humidity 10 ... 95 % rH Air pressure 700 ... 1060 hPa Only for storage in a medical environment, under consideration of the conditions mentioned here.
Classification	Protection class II Type BF Class IIa
Applied standards	DIN EN ISO 13485, DIN EN ISO 14971, DIN EN 20417, DIN EN ISO 15223-1, DIN EN 60601-1, DIN EN 60601-1-2, DIN IEC 60601-1-6, DIN EN 62304, DIN EN 62366-1, DIN EN ISO 10993-1, DIN EN ISO 26782, DIN EN ISO 23747, DIN EN ISO 10993-10, ISO 10993-5

Technical requirements for the operation of seca diagnostic

seca diagnostic SERVER, hardware and operating system

- → The seca diagnostic server is designed for operation on any hardware or virtualized systems.
- → The hardware or the virtualised environment must meet the minimum requirements of the operating system used.
- → The seca diagnostic server is based on Tomcat 9.0. Please note the system requirements for Tomcat.
- → The PC or hardware must comply with the DIN EN 62368 safety standard for information technology equipment.

seca diagnostic SERVER, minimum requirements

- → 2x vCPU each with 1.5 GHz
- → 4 GB RAM
- → HDD 500 GB

seca diagnostic SERVER, recommendations

- → 4x vCPU each with 2.5 GHz
- → 8 GB RAM
- → HDD 1TB (depending on use, two partitions 100 GB (system) and 900 GB user data)

seca diagnostic CLIENT, hardware and operating system

- → The seca diagnostic client is designed for operation on any hardware or virtualized systems.
- → The hardware or the virtualised environment must meet the minimum requirements of the operating system used.
- → The PC or hardware must comply with the DIN EN 62368 safety standard for information technology equipment.

seca diagnostic CLIENT, minimum requirements

- → 6th Generation Intel Core-i processor or later
- → 4 GB RAM
- → At least 5 GB of free hard drive space

seca diagnostic CLIENT, recommendations

- → 9th Generation Intel Core-i processor or later
- → 8 GB RAM
- → At least 5 GB of free hard drive space
- → One of the following graphics cards:
  - → NVIDIA Kepler (GTX 600 series) and above
  - → AMD GCN 1st Gen (Radeon HD 7000 series) and above
  - → Intel Haswell (4th-gen core) HD Integrated Graphics and above
- → USB connection
- → DVD or CD-ROM drive
- → One COM port each for ergometers and treadmills

Software requirements for the operation of seca diagnostic

seca diagnostic SERVER

Approved operating systems (64-bit Windows only):
- → Microsoft Windows 11 64 bit (for small environments only)
- → Microsoft Windows Server 2019
- → Microsoft Windows Server 2022
- → Older versions are not supported.

Supported database systems and database servers:
- → Microsoft SQL Server 2016 or higher, provided the version is still within the lifecycle policy. All editions: Enterprise, Datacenter, Business Intelligence, Standard, Workgroup, Web. Express Edition is not recommended due to database size limitations!
- → MariaDB (seca diagnostic Installer is delivered with MariaDB)

seca diagnostic CLIENT

Approved operating systems (64-bit Windows only):
- → Microsoft Windows 10 1809 – 22H2
- → Microsoft Windows 11
- → Microsoft Windows Server 2019
- → Microsoft Windows Server 2022
- → Older versions are not supported.

The operating system or database system used must be up to date with the latest security patches.

2.4 Shutdown, storage, transport, disposal

Shutdown and storage

→ Clean and disinfect the devices and their components before putting them out of operation.
→ Make sure that the storage location is dust-free, dry and away from direct sunlight.
→ After a long period of non-operation, the device may only be used again if a technical safety check has been carried out by your authorised seca dealer.

Transport

→ Clean and disinfect the devices and their components before transport.
→ Use the original packaging for transport. These devices are sensitive pieces of electronic equipment. If the original packaging is not available, pack the devices in such a way that they are protected against impact, moisture and dust.
→ The devices must comply with the operating conditions when they are put into operation again, e.g. operating temperature.

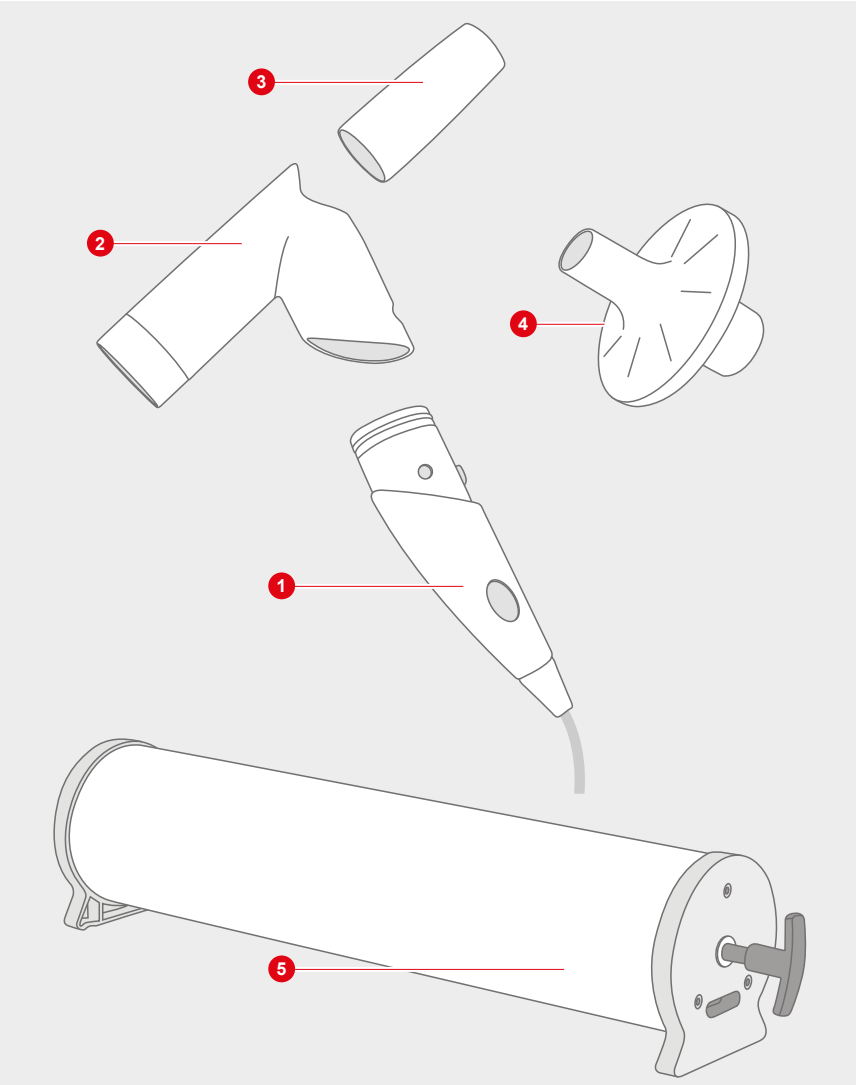
Disposal

→ The devices and all their components must be disposed of in a proper manner in compliance with applicable regulations (that is, in accordance with the valid laws governing waste electrical and electronic equipment).
→ The devices must not be disposed of as normal domestic waste.
→ Observe the disposal instructions for consumables.
→ The original packaging is recyclable (cardboard/waste paper).

Symbols for transport, storage and disposal

	Fragile, handle with care
	Keep dry
	Protect from sunlight
	Separate collection of electrical and electronic equipment, do not dispose with domestic waste.

2.5 Components for the recording



1. seca spiro mobile
2. seca spiro mobile measuring unit
3. seca spiro mobile adapter
4. seca spiro protect bacterial and viral filter
5. Calibration pump 3 liters

Not shown

→ Nasal clip (not depicted)

2.6 Device operation

2.6.1 Function display

The LED in the handle of the device lights up 1 when seca spiro mobile is connected to the PC - connection via USB cable 2. The device is ready for operation.

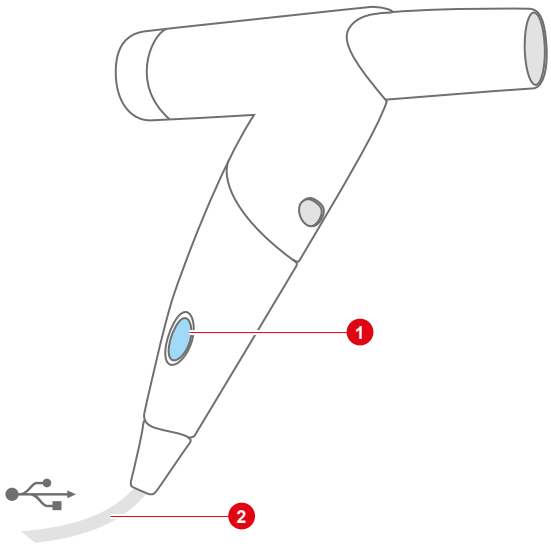


Fig. 2: seca spiro mobile function display

2.6.2 Using the bacterial and viral filters

The seca spiro mobile pulmonary function testing device must only be operated with spiro protect bacterial and viral filters 1!

spiro protect bacterial and viral filters 1 are fitted on the mouthpiece 2 before the measurement.

A filter is only to be used for a single patient and, after the examination, it must be disposed of in a safe and environmentally responsible manner.

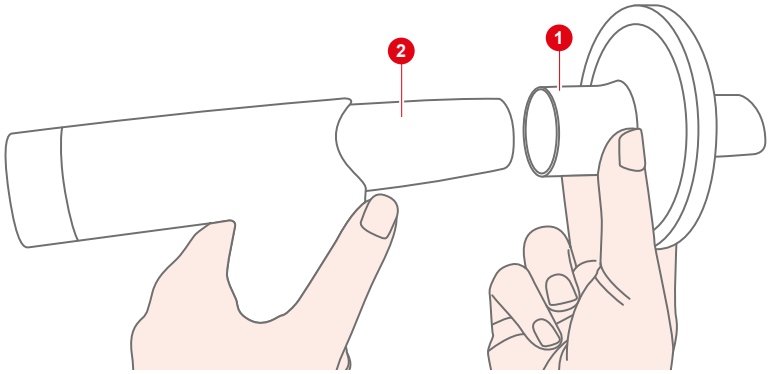


Fig. 3: Attaching the spiro protect bacterial and viral filter

CAUTION

Cross-contamination and falsification of measured values due to soiling in the filter

→ Dispose of the spiro protect bacterial and viral filters after each examination. Do not reuse!

2.6.3 Disassembling and assembling the device

To disassemble the seca spiro mobile:

→ Press firmly on the release key 1.
→ Pull the measuring unit 2 upwards.
→ Pull the mouthpiece 3 out of the measuring unit 2 by rotating it slightly.

When assembling:

→ When reassembling, make sure that the measuring unit 2 and handle 4 lock into place.

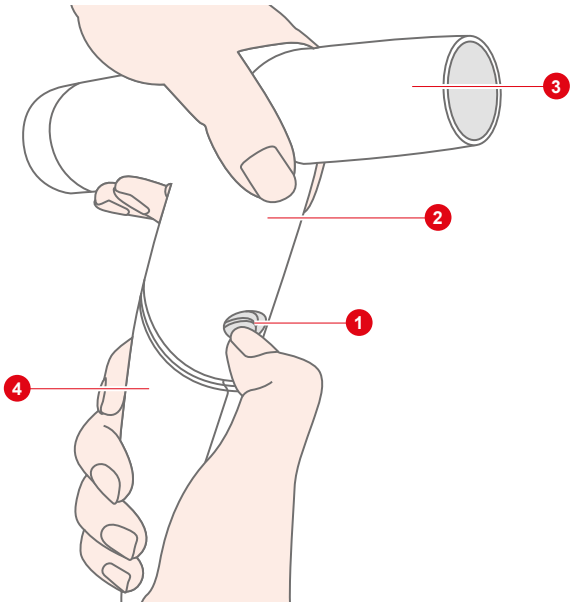


Fig. 4: Disassembling seca spiro mobile

2.6.4 Notes on calibration

Calibration intervals

The seca spiro mobile pulmonary function testing devices are pre-calibrated at custo med (10-stage calibration).

Before putting the device into operation another calibration with seca diagnostic 5.9 has to be carried out – in the process system and device are matched, taking the environmental conditions into account. The procedure is shown in the software description for spirometry.

When using a new measuring unit, a new calibration must be carried out immediately before use.

In the event of mechanical impact, a calibration must be carried out immediately in order to check the functioning and precision of the pulmonary function testing device.

In the further course, daily calibration of the device is not necessary.

The use of spiro protect bacterial and viral filters reduces the need for cleaning and disinfection and, as a result, the formation of deposits in the measuring unit. Deposits in the measuring unit may falsify the measurement data obtained.

Calibrate seca spiro mobile weekly or after 100 examinations, following disinfection of the device.

If you own a gauged calibration pump, you can carry out the calibration yourself. Otherwise please contact your authorised dealer. Calibration pumps are available as accessories.

Instructions for performing calibration

Using a non-calibrated device will falsify the measurement data obtained. To ensure correct results, a calibration essential.

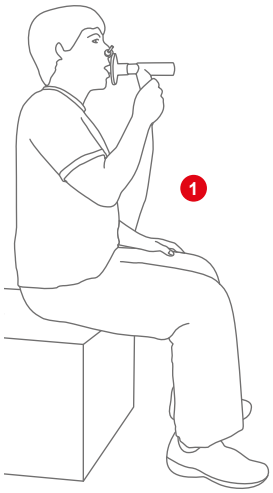
Calibration is to be performed without a spiro protect bacterial and viral filter.

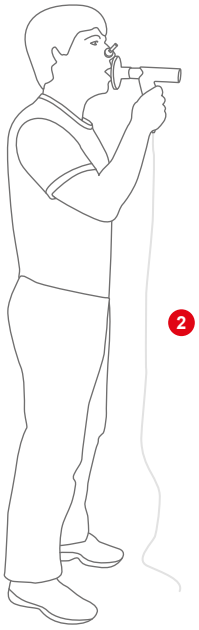
Only use gauged calibration pumps.

The best results can be achieved by using 2l or 3l pumps. 1l pumps may result in inaccuracies.

For calibration make sure to specify the correct pump volume. An incorrect pump volume will result in an incorrect calibration and falsify the measurement data obtained.

2.7 Procedure of an examination





Preparing for the measurement, seca spiro mobile

- → Check to make sure that seca spiro mobile is connected to the PC.
- → When the LED in the handle lights up, the device is ready for operation.
- → Fit a new spiro protect bacterial and viral filter.

Patient's posture during measurement

- → The patient must be sitting 1 or standing 2 upright for the measurement.
- → The patient places the mouthpiece of the measuring device as follows:
  - → The teeth are placed on the mouthpiece,
  - → the tongue is below the mouthpiece.
  - → The lips must firmly enclose the mouthpiece.
- → No air should escape from the corners of the mouth during the measurement.
- → Explain the breathing manoeuvre in advance and encourage the patient to cooperate loudly during the procedure! Use short, clear instructions: e.g., BREATH IN - CONTINUE - CONTINUE - BREATH OUT ... Precise instructions improve the quality of the measurement. The quality of the evaluation depends largely on the patient's cooperation.
- → Immediately before the measurement, put the nasal clip on the patient so that the patient cannot breathe through the nose.

seca diagnostic

- → Start seca diagnostic and click on Examination, Spirometry, New Spirometry, *see 3.4 Performing the spirometry measurement, p. 33*.
- → The measurement is started with the Start button.

Performing a breathing manoeuvre

- → The patient must start by taking a few quiet breaths.
- → During the last quiet breath before the actual breathing manoeuvre the patient must exhale as deeply as possible (signal tone and system indication).
- → Next the patient must inhale as deeply as possible,
- → if necessary, holding his/her breath (max. 1 second),
- → and then exhale again as deeply as possible.
- → During the measurement the patient must sit upright or stand. Ensure the patient's upper body is not bent forward otherwise the measurement data obtained will be falsified.
- → After the last breath, the device is put down.

Checking options, troubleshooting in case of unusual measured values...

- → Is the device calibrated?
- → Correct posture of the patient during measurement?
- → Detectable damage to the device?
- → Use of the correct bacterial and viral filter?
- → Gross contamination of the measuring unit?

3 Software

3.1 seca diagnostic program structure

The seca diagnostic program is divided into three areas: User, Patient and Examination. This structure ensures that you can always recognise who (which user) is carrying out what type of examination with whom (which patient).

The main menus of each area can be reached by clicking on User ❶, Patient ❷ or Examination ❸.

The user of the system can be selected in the main menu of the User ❶ area. User administration is performed in the seca service center (create user, user rights, user-specific settings).

Patient administration takes place in the main menu of the Patient area ❷. The most important functions include Find patient, New patient and Find evaluation

In the main menu of the Examination area ❸, all examination types that are possible with seca diagnostic are listed. Modules that have already been purchased are active (black font), all others are inactive (light grey font). This menu is also linked to the Settings area. This area is for making cross-program, examination-related and user-specific settings.

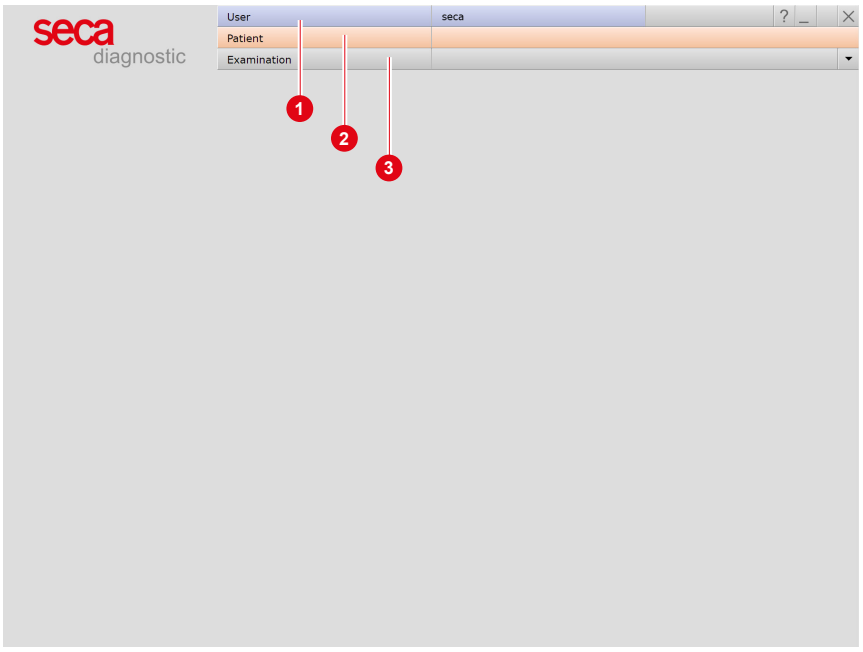


Fig. 5: seca diagnostic main menu

3.2 seca spiro mobile connection to the PC

IMPORTANT: Prerequisite - seca diagnostic is installed on your PC and ready for operation. The seca devices and components may only be connected to the PC after seca diagnostic has been installed. The required device drivers are installed on the PC via the seca diagnostic standard setup or by specific selection during the seca diagnostic setup.

Connecting to the PC, configuring

→ Connect seca spiro mobile to the PC.
→ The driver is installed automatically.
→ Wait until the installation is complete.

If you are working with spiro protect bacterial and viral filters, perform the following steps:

→ Start seca diagnostic. Open the screen page Examination, Spirometry, Settings, Device, Device connection 1.
→ Activate the spiro protect option 2.
→ Enter the code of the spiro protect bacterial and viral filters 3. The five-digit code can be found on the packaging of the filters (line Cat. No.).
→ Click on Save 4 to apply your input.
→ Click on End 5 to close the settings.

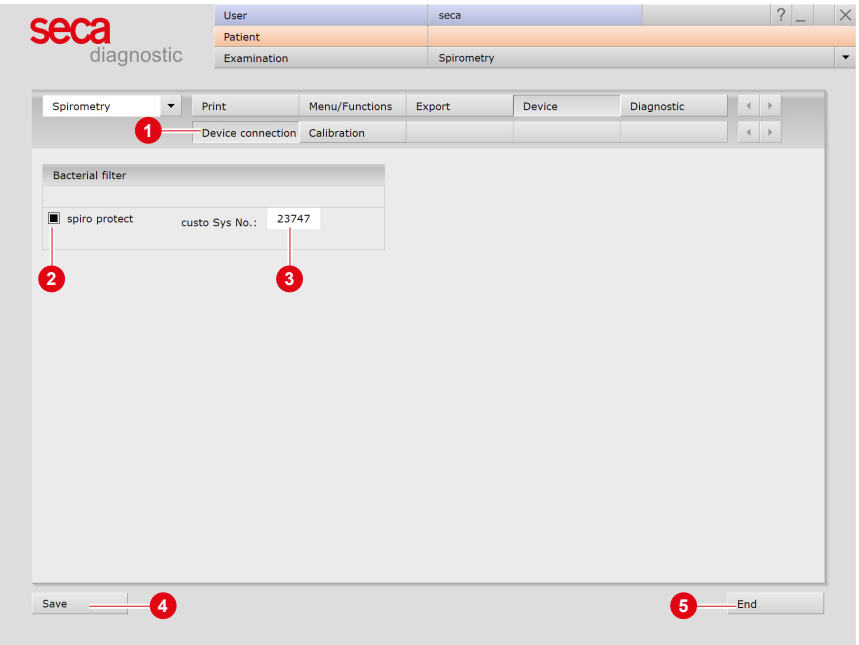


Fig. 6: Settings screen for seca spiro mobile

3.3 Calibrating seca spiro mobile

IMPORTANT: Before using the device for the first time, a calibration must be carried out.

- → Connect seca spiro mobile to the PC.
- → Assemble the devices as shown 1.
- → Start seca diagnostic and open the page Examination, Spirometry, Calibration 2.
- → Enter the volume of your pump 3.
- → Enter your name in the “performed by” field 4.
- → Click on Start calibration 5.
- → Follow the working instructions of the system 6.
- → Pump briskly from stop to stop.
- → After measurement of the pump volume, the calibration is ended.
- → The calibrations are displayed under “Documentation, ...” 7.
- → With the button Print calibration entries 8 a list of the calibrations performed so far can be printed.
- → The Delete calibration entries button 9 can be used to delete older entries from the list.

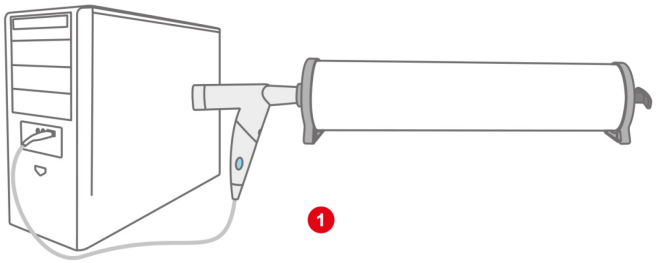


Fig. 7: Calibration pump with seca spiro mobile

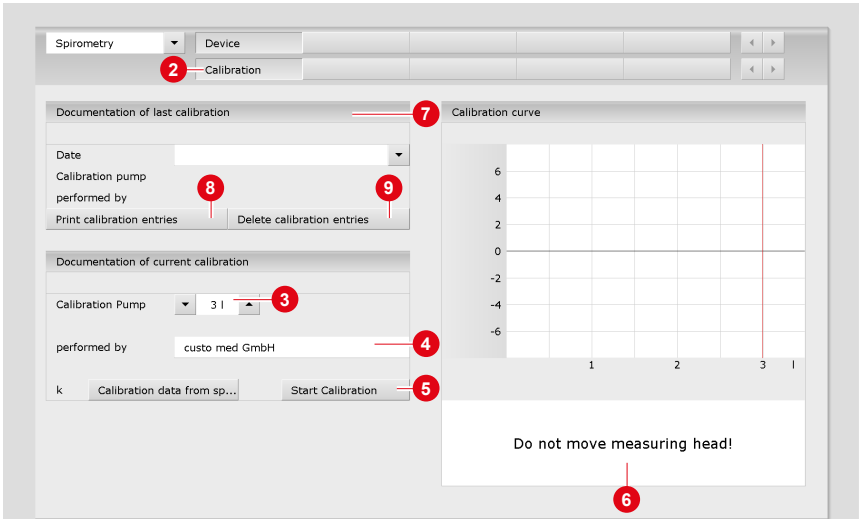


Fig. 8: Calibration screen

3.4 Performing the spirometry measurement

Procedure with SystmOne or EMIS Health connection

seca diagnostic can be connected to the SystmOne or EMIS Health practice management software. In this case, the first steps for performing an examination are carried out in SystmOne or EMIS Health, e.g. selecting the patient. Then seca diagnostic is started manually. There are two options for the next steps of the process:

→ If seca diagnostic is only used for one type of examination, seca diagnostic directly displays the screen for starting the recording for the previously selected patient.
→ If seca diagnostic is used for several types of examination, the previously selected patient is transferred from SystmOne or EMIS Health and the seca diagnostic examination main menu is displayed. Here you can select which examination is to be performed on the patient.

When a recording is ended, seca diagnostic exports the recording as a PDF file to SystmOne or EMIS Health. seca diagnostic is automatically closed after the PDF export.

The connection to SystmOne or EMIS Health is optional and can be configured in the seca diagnostic settings if required. Please contact your authorised seca sales partner for this.

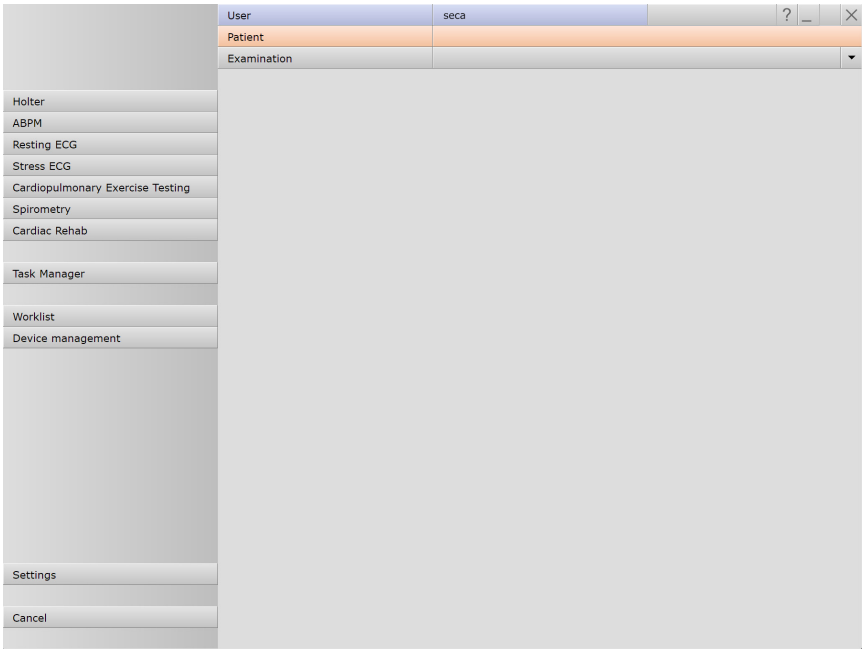


Fig. 9: seca diagnostic examination main menu

INFORMATION:

The steps necessary to perform and evaluate a spirometry measurement in seca diagnostic are shown without a surgery IT system or HIS connection.

3.4.1 Reference measurement

Program start, calling the pulmonary function

→ Start seca diagnostic and log in.
→ Click on Examination, Spirometry, New Spirometry.

Tip for entries in the patient menu: Press the tab key to move the cursor to the next input field.

Selecting a patient

→ Select a patient for the examination. Enter the patient's name into the input fields in the search mask.
→ Select the patient from the list.
→ Confirm the selection with Select Patient. The patient can also be selected by double-clicking on the name.

Creating a new patient

→ If the patient does not yet exist in your database:
Click on New Patient.
→ Enter the patient data. The fields marked with an asterisk are mandatory.
→ For a spirometry measurement, the values age, gender, height, weight and ethnicity must be entered. This information is used to determine the predicted values author and to calculate the predicted values individually. If the required information has not been stored, you will be prompted to enter it later.
→ Save the data.
→ The patient is entered into the database.

Settings for the reference measurement

→ Predicted value 1: the default setting is GLI (Global Lung Initiative)[1)]. The area of validity is displayed at the bottom of the screen page. If the patient data deviate from the area of validity, the system will propose a suitable predicted value author. If no suitable predicted value author is available, “none” is displayed in the “Predicted value” field. In this case, select a predicted value author yourself from the menu. The determined predicted values are displayed in brackets during the measurement and may be incomplete.

→ Smoking habit 2: Select the corresponding entry from the menu. The “Smoking habit” option is included on the printout in the “Unconfirmed report” field.

→ Measurement type 3: The first measurement on a patient is always a reference measurement. The measurement type can only be changed during follow-up measurements (spasmolysis or provocation).

→ Optional medication 4 and dosage 5: Here you can specify which medication was administered to the patient. In order to use this function, a selection of possible medications must be saved in seca diagnostic in advance. To do this, open the screen page Examination, Spirometry, Settings, Diagnostic, Drugs. Enter the medication in the “Drugs” area and click on Add. The procedure is identical in the “Dosage” area. Save your input.

→ Measurement with spiro protect 6: Specify whether bacterial and viral filters are used.

→ Environment data 7: Set the environmental data correctly.

→ Confirm 8 your input.

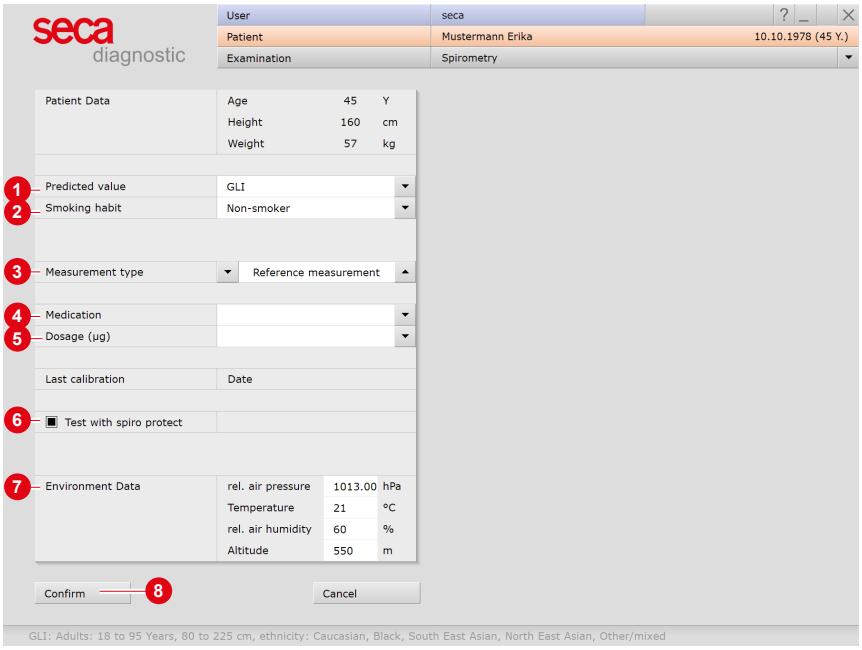


Fig. 10: Settings for the reference measurement

1) The preset predicted values author can be changed in the seca diagnostic settings.

GLI is characterised by the following features: The underlying population for the predicted values is much more extensive and broader than for other predicted values. The equation for determining the average predicted values is more accurate than for other predicted values. There is no noticeable transition from childhood to adulthood.

For the correct use of the predicted values author GLI, the ethnicity of a patient must be specified in the patient master data. If this information is not yet specified, you will be prompted to enter it (White, Coloured, Latin, South East Asian, North East Asian, other/mixed). The following countries and regions are assigned to these groups:

• Caucasians (white, Latin, North African): Europe, Israel, Australia, USA, Canada, Mexican Americans, Brazil, Chile, Mexico, Uruguay, Venezuela, Algeria, Tunisia

• Black (coloured): African-Americans

• South East Asians: Thailand, Taiwan and China (including Hong Kong) south of the Huaihe River and the Qinling Mountains

• North East Asians: Korea and China north of the Huaihe River and the Qinling Mountains

Called on 23.10.2020 from https://www.ers-education.org/guidelines/global-lung-function-initiative/faq/what-reference-equations-do-i-apply-for-non-caucasians/

1) LLN (Lower Limit of Normal) is the lower limit value, used to assess "normal" or "pathological". LLN corresponds to the 5% percentile of a healthy population. This means that if a measured value is below the 5% percentile, there is a 95% probability that a pathological finding exists or a patient with the corresponding value is healthy in only 5% of the cases. The green bars in the area of the measurement curve or in the coordinate system – orientation aid (b) – are formed from the predicted value (upper edge) and LLN (lower edge). Measurement curves above or within the green bars can be considered acceptable. The same applies to all other green bars in the spirometry surface. Measured values ≥ LLN, i.e. within the green range, are considered acceptable.

The Z-score indicates by how many standard deviations a certain measured value deviates from the average predicted value. For example, Z = 0 corresponds exactly to the average predicted value and Z = -2 means that the measured value is two standard deviations below the average predicted value.

A specific percentile can always be assigned to each Z-score. A Z-score of -1.645 corresponds to the 5% percentile (LLN). If the Z-score is greater than or equal to -1,645, the measured value is not in the pathological range. The Z-score for the corresponding measured value is marked with a green square in the table of measured values. If the Z-score is smaller than -1.645, the value is marked with an orange-coloured square (see the guideline on spirometry. Pulmonology. 2015; 69: 146-163).

Overview of the measurement interface

1. The predicted value that has been selected for the measurement series, in this case GLI.
2. Orientation aid (only for GLI, otherwise predicted value curve) constructed from FVC and FEF25-75, with the display of the predicted value range (green bars) formed from the predicted value and LLN[1)].
3. Display of the results for FEV, FVC and FEV1/FVC in a bar diagram; arrows mark the respective result after the measurement. Values within the green ranges can be considered as acceptable. Values located in the grey areas of the bars are considered pathological, divided into light, moderate and severe.
4. During the measurement: tilt sensor to control the posture (part of the software version professional, not included in the standard scope). After the measurement: miniature views of the performed measurements.
5. Table of measured values with predicted values, measured values obtained, Z-score[2)] and measured value deviations in percentage from the predicted values
6. Instructions for performing the breathing manoeuvre
7. Time volume curve in real-time display
8. Settings for the measurement
9. Starting or stopping the measurement
10. Ending the measurement, closing the measurement interface

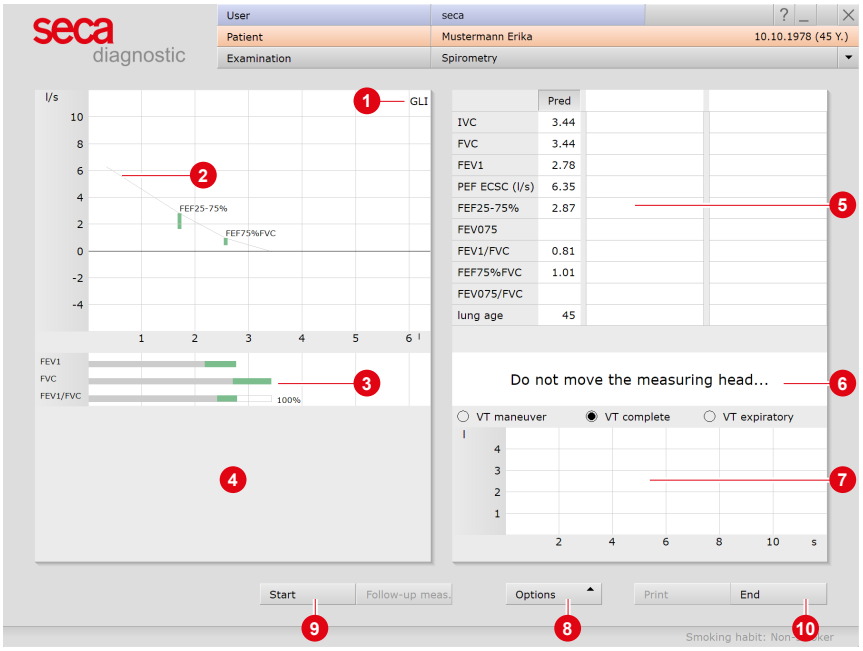


Fig. 11: Measurement interface

The Z-score, LLN, report assessment and the explanation according to clinical and occupational criteria are only available for measurements with the GLI predicted value.

The “Animation for children” function is part of the “professional” software and not included in the standard scope of supply.

Under Options, Setting Animation, you can define the exhalation level (PEF) at which the candle is lit. The lower the percentage, the easier it is to light the candle. Confirm to apply the changes.

Optional: Spirometry measurement with animation for children[1)]

To perform a measurement with animation for children, click on Options, Animation. In this case, the sequence of a spirometry measurement is shown with animated drawings: the little dragon tries to spit fire in order to light a candle. With his/her breathing, the patient supports the dragon to light the candle[2)]. The procedure with animation can be shown and explained before starting the measurement via Options, Instruction.

The animation should run on an extra screen for the patient. To set an extra screen, open the screen page Examination, Spirometry, Settings, Menu/Functions, Animation and select Own window in the “Animation” area. In addition, you can set on this screen page for which age groups the animation should be displayed automatically. Save your input (bottom left button).

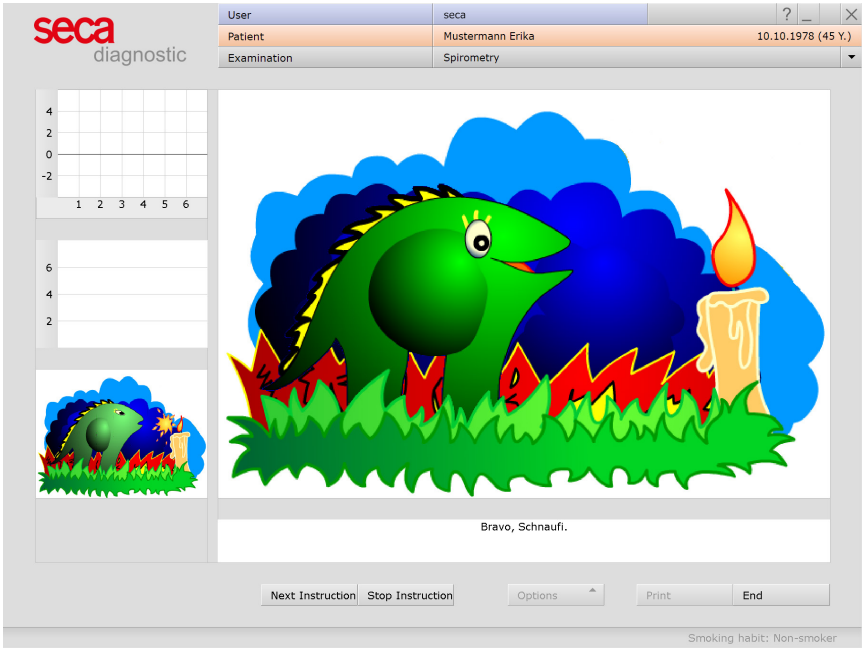


Fig. 12: Spirometry measurement with animation for children

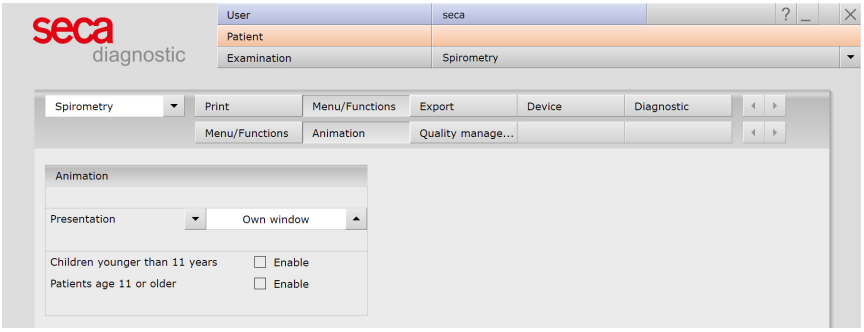


Fig. 13: Animation for children settings

Performing a reference measurement

1) *The number of resting breaths before the breathing manoeuvre can be changed in the settings. To do this, open the Examination, Spirometry, Settings, Diagnostics, Parameters screen page. The setting can be found in the "Breathing manoeuvre" area. Save your input.*

- → Put the nasal clip on the patient.
- → Click on Start.
- → Next, the patient places the mouthpiece of the device into his/her mouth.
- → The lips must firmly enclose the mouthpiece.
- → Give clear instructions on how to perform the breathing manoeuvre[1)].
- → The maximum recording time is two minutes.
- → Remove the device from the patient after the breathing manoeuvre.
- → To cancel a measurement in progress, e.g., in the event of incorrect handling of the device or incorrect execution of the breathing manoeuvre, click the Stop button.
- → Performed measurements are displayed as miniature views 1 (several if the Repeat function was used).
- → The last measurement is displayed in the coordinate system 2.
- → Other measurements can be displayed by clicking on the corresponding miniature view 1.

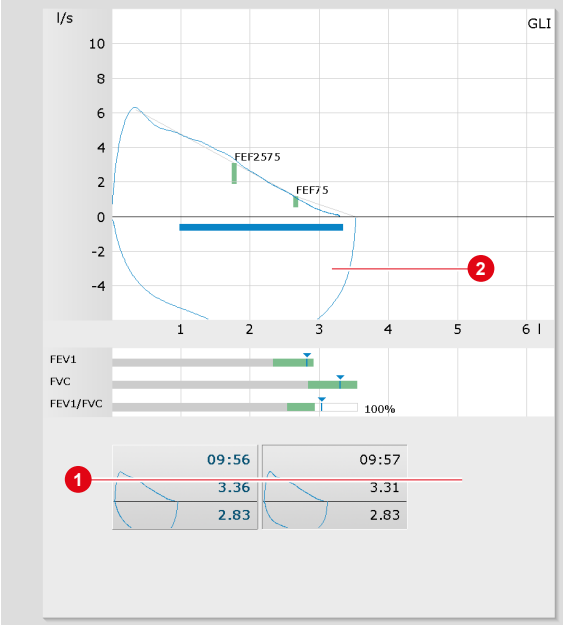


Fig. 14: Reference measurement, miniature views

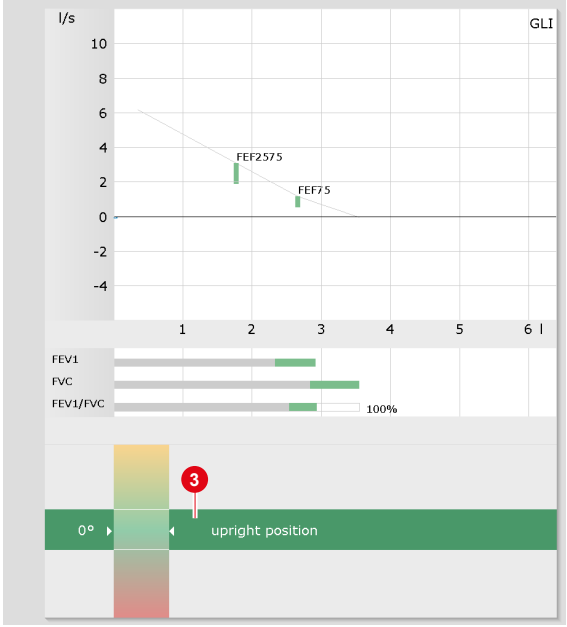


Fig. 15: Reference measurement, inclination sensor

2) *Part of the software version professional, not included in the standard scope of delivery.*

Additional function inclination sensor[2)]

The inclination sensor is displayed after pressing the Start button. This function is used to control the patient's posture during the measurement. An upright body posture improves the quality of the measurement and enables a more accurate determination of the measured values, especially FEV1. The white arrows of the inclination sensor should be in the middle, green area of the display 3. If the patient leans too far to the front or rear, the arrows will move into the red or yellow area, which may affect the determination of the measured values. The miniature views of the measurements taken are highlighted in green, yellow or red to provide information about the body posture during the measurement.

Green: upright body posture (-10° to +10°), yellow: inclined too far back, red: inclined too far forward.

Further functions within the reference measurement

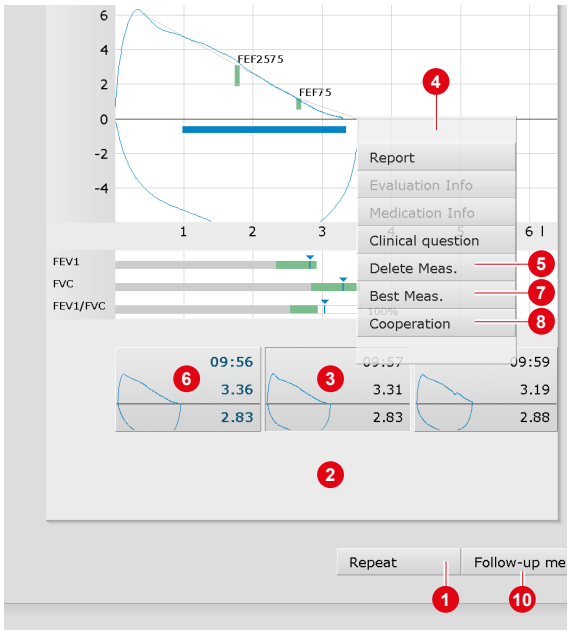


Fig. 16: Context menu of a measurement

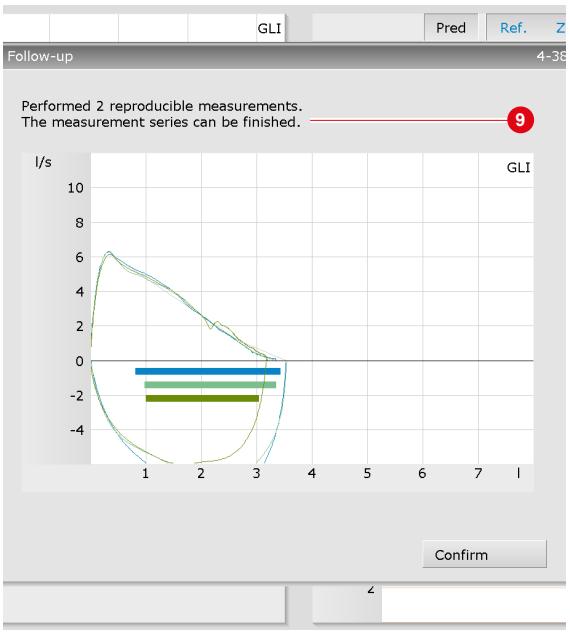


Fig. 17: Process control, reproducibility of a measurement.

Repeating measurement

→ Click Repeat 1 to perform another reference measurement. Up to six repeat measurements are possible.
→ If further repeat measurements are to be performed (more than six), measurements in the miniature view area must be deleted 2.
→ To do this, left-click on the measurement you want to delete 3,
→ right-click to open the Context menu 4
→ and click on Delete Measurement 5.

Defining the best measurement

The best measurement of a measurement series is marked with bold letters, in the same colour as the measurement curve 6. This measurement will be displayed later when opening the evaluation.

→ To set another measurement as the best measurement, left-click on the miniature view of the desired measurement,
→ right-click to open the Context menu 4
→ and click Best Measurement 7.

TIP: The best measurement is determined based on the sum of FVC and FEV1. The determination of the best measurement can also be made using other values. This setting is located on the Examination, Spirometry, Settings, Diagnostic, Parameter page in the "Identification best value" area.

Documenting patient cooperation

→ Open the Context menu 4 with a right click,
→ select the item Cooperation 8 and evaluate the patient cooperation.
→ Confirm to transfer the information into the unconfirmed report.

Ending and closing the measurement

→ With the default settings, the measurements are checked for reproducibility. If two reproducible measurements are available, a corresponding note 9 appears and the measurement can be ended.
→ Starting a follow-up measurement: If a spasmolysis or provocation is to be performed immediately following the reference measurement, click on Follow-up measurement 10.
→ Click on End (bottom right) and in the End dialogue click on Confirm.

__TIP:__ Checking measurements for reproducibility can be switched on and off in the settings. The settings for checking reproducibility are located on the Examination, Spirometry, Settings page, Menu/Functions in the "Flow Control" area at the very bottom. There, the required number of reproducible measurements can be changed and the criteria for reproducibility can be adjusted.

It can also be set whether the reproducibility is to be checked against ATS criteria (ATS compliant button) and/or whether only ATS compliant measurements are accepted. The ATS criteria can be viewed via the Info button. Save your input.

Options during the reference measurement

During the reference measurement, the following functions are available for editing and reporting in the Options menu:

1. Button for opening the Options menu
2. Print...: Print menu for compiling a printout
3. Changing the Predicted values
4. Information on spirometric lung age: The spirometric lung age is determined using the FEV1 value if FEV1 is calculated as a function of age (not for all predicted values authors). The spirometric lung age is calculated based on the deviation from the predicted value. Under Examination, Spirmetry, Settings, Diagnostic, Parameter, you can set which predicted values author is used to calculate the spirometric lung age.
5. Autom. Report: The following types of unconfirmed reports can be selected - Standard (70% rule for FEV1/FVC and 80% rule for IVC and FVC), COPD-GOLD, clinical or occupational evaluation according to GLI.
6. Explain Report: Table with measured values, predicted values, limit values and the Z-score. Explanation of the assessment criteria underlying the assessment functions clinical, occupational and COPD-GOLD.
7. Report evaluation on/off: Assessment of the measurement results in a bar diagram below the measurement curve.
8. Progress: Superimposition of the measurement curves for plausibility check.

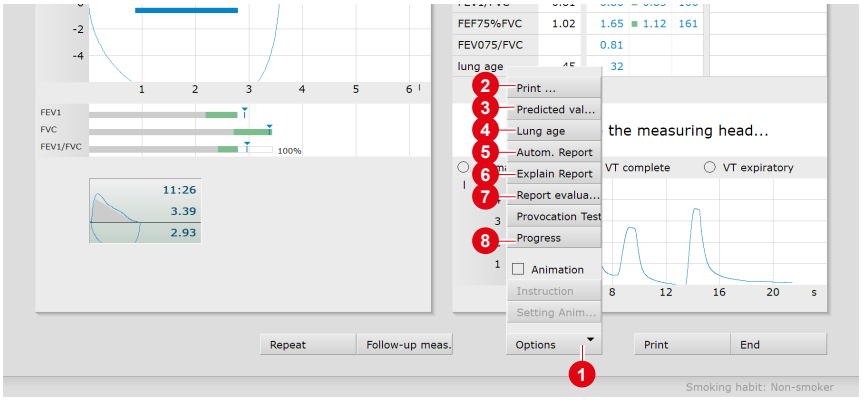


Fig. 18: Reference measurement, options

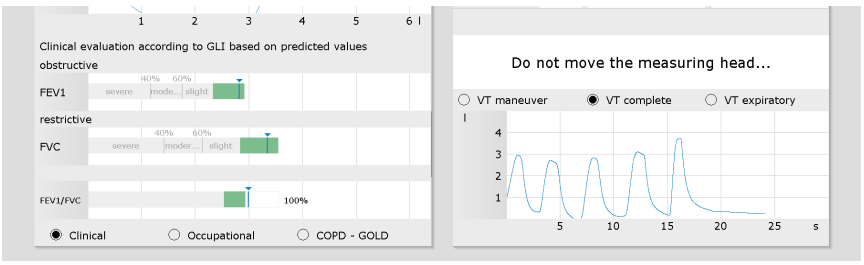


Fig. 19: Reference measurement, evaluation of measurement results

3.4.2 Follow-up measurements: Spasmolysis and provocation

Spasmolysis and provocation are referred to as follow-up measurements. Follow-up measurements are only possible after a reference measurement.

Calling up a follow-up measurement

→ Click on Examination, Spirometry, Follow-up measurement.
→ A list of patients for whom a reference measurement was performed opens (spirometry group).
→ Select the patient from the list.
→ Confirm with Select patient or double-click on the name.

INFORMATION on the spirometry group:

A patient is deleted from the spirometry group when a follow-up measurement has been saved, a new measurement has been created (via Examination, Spirometry, New Spirometry) or on the next day.

Sequential measurement settings

→ Make the settings for the follow-up measurement.
→ Check and change if necessary.
→ Select the measurement type 1 - spasmolysis or provocation.
→ The measurement is possible without medication information 2.
→ Medication information 2 is only possible if a list of medications has been created (under Examination, Spirometry, Settings, Diagnostic, Drugs).
→ Click on Confirm 3 to continue.

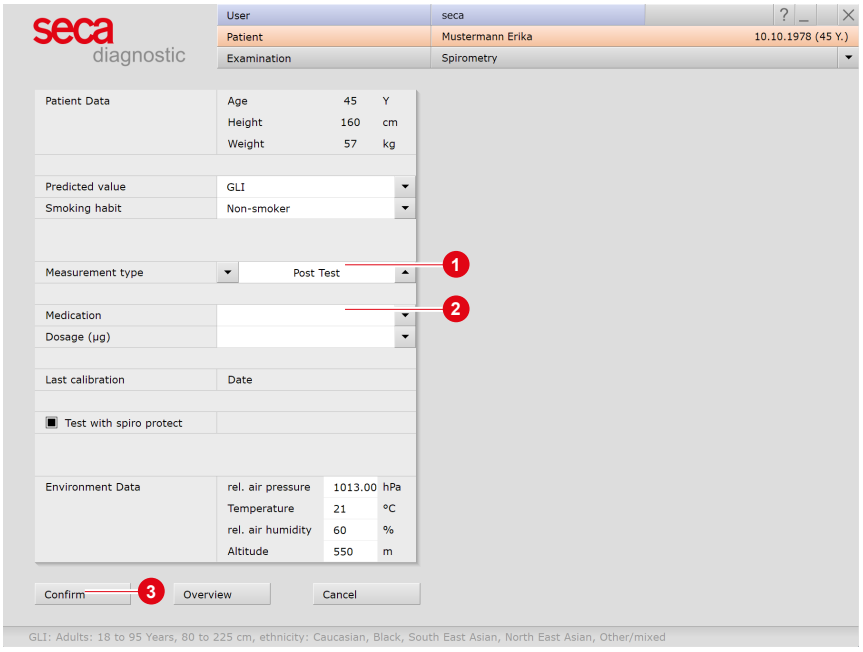


Fig. 20: Follow-up measurement, settings

INFORMATION on follow-up measurements:

The setting options and operating elements of the follow-up measurements correspond to those of a reference measurement, e.g. Start, Repeat and Best Measurement.

Performing a spasmolysis

- → Put the nasal clip on the patient.
- → Click on Start.
- → Next, the patient places the mouthpiece into his/her mouth.
- → The lips must firmly enclose the mouthpiece.
- → Give clear instructions for the breathing manoeuvre.
- → The maximum recording time is two minutes.
- → Remove the device from the patient after the breathing manoeuvre.
- → Repeat the measurement if necessary.
- → Performed measurements are displayed on the bottom left in the form of miniature views.
- → The results of the spasmolysis (orange) are displayed together with the results of the reference measurement (blue) for direct comparison.
- → To close the measurement interface, click End (bottom right).

Performing a provocation test

Procedure of a provocation test: a maximum of eight provocation measurements are followed by a dilatation measurement and up to eight control measurements. For better differentiation, the different measurement types of a provocation test are colour-coded in seca diagnostic. Reference measurement: blue, provocation: green, dilation: orange-brown, control measurement: orange-brown.

- → Put the nasal clip on the patient.
- → Click on Start.
- → Next, the patient places the mouthpiece into his/her mouth.
- → The lips must firmly enclose the mouthpiece.
- → Give clear instructions for the breathing manoeuvre.
- → The maximum recording time is two minutes.
- → Remove the device from the patient after the breathing manoeuvre.
- → Repeat the measurement if necessary.
- → The results of the provocation (green) are displayed together with the results of the reference measurement (blue) for direct comparison.
- → Under Options, Provocation test, the PD20 provocation dose[1)] is displayed.
- → The next measurement is triggered via the Follow-up measurement button (or later via Examination, Spirometry, Follow-up measurement.
- → To close the measurement interface, click End.

1) PD20 provocation dosage: Medication dosage for the 20 percent drop of FEV1 in a provocation measurement compared to the initial value in the reference measurement.

3.4.3 Unconfirmed report

IMPORTANT: All unconfirmed reports produced by the system should be considered as suggestions only. For diagnosis and therapy purposes it is essential that the results are checked and assessed by a qualified physician.

To open the Unconfirmed report dialogue, right-click on the measurement interface and select Report in the Context menu.

If the Unconfirmed report option is activated in the system settings, the unconfirmed report dialogue already contains an automatic report of the system ❶. This option is activated by default and can be deactivated under Spirometry, Settings, Diagnostic, Reports. You can modify and supplement the text in the report dialogue. To save your entries, click Confirm ❷. Cancel ❸ closes the unconfirmed report without saving any changes.

If you save your entries with Confirm ❷, the unconfirmed report becomes a (preliminary) report, depending on the reporting rights of the current user. The evaluation is thus (pre-)confirmed. If the evaluation is not to be classified as (pre-)confirmed at this point, reset the status in the End dialogue box.

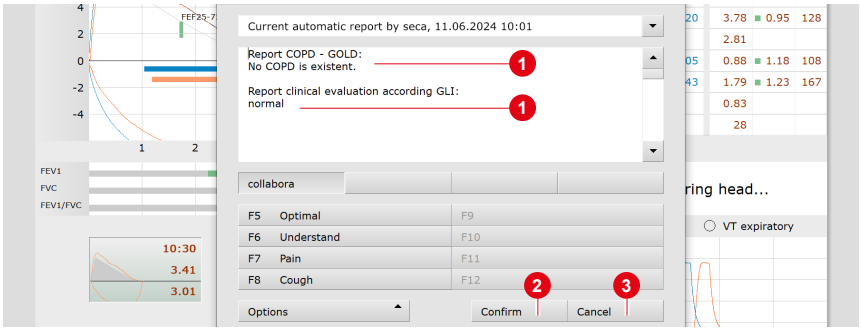


Fig. 21: Unconfirmed report, directly after a measurement

Displaying further automatic reports

Via Options, Autom. Report, the following evaluations can be added to the report:

→ Standard, according to 70% rule for FEV1/FVC and 80% rule for IVC and FVC,
→ COPD-GOLD, statement on presence and severity of Chronic Obstructive Pulmonary Disease,
→ Clinical evaluation according to GLI,
→ Occupational evaluation according to GLI.

Transferring the automatic reports into the report

seca diagnostic can be set so that the different types of automatic reports are transferred to the report.

→ To do this, open the screen page Examination, Spirometry, Settings, Diagnostic 1, Autom. Report 2.
→ Activate the desired option, for example COPD-GOLD 3.
→ For COPD-GOLD 3, specify whether the COPD-GOLD finding should be transferred to the report after a reference measurement or after a spasmolysis 4.
→ Save 5 your input.

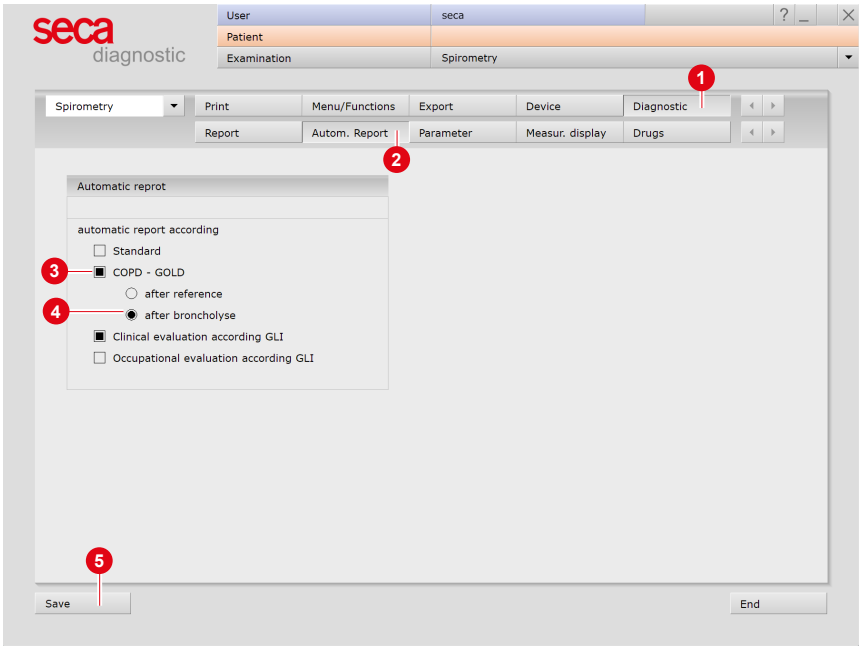


Fig. 22: Settings, automatic report

3.4.4 Printing the measurement

Printing with system settings:

→ Click on the Print button in the measurement interface.

The system settings for the print pages of a spirometry measurement can be found in seca diagnostic on the screen page Examination, Spirometry, Settings, Print, Printed pages. On the screen page Examination, Spirometry, Settings, Print, General, you can define in the “Print sequence control” area which pages are printed when the Print button is pressed (Current page, Pre-set pages or Total Printout PA).

Printing with temporarily changed print settings:

→ If you do not want to print according to the system settings, open the Options, Print.... screen page in the measurement interface.
→ Make your print settings there 1.
→ Changes in this print menu only affect the current printout.
→ Start the printout with the Print button 2.

Printing with the Job Manager:

→ The print jobs are stored in the job manager and can be printed there collectively at a later time.
→ To store print jobs in the job manager, open the Options, Print.... screen page.
→ Click on Print Task 3.
→ The existing print jobs are started on the screen page Examination, Job Manager via the Execute/Execute all button.

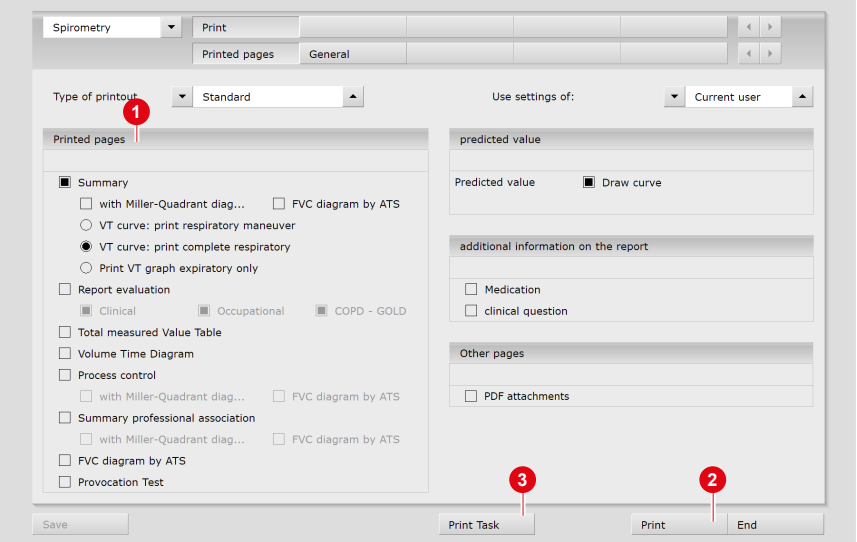


Fig. 23: Options, Print...

3.5 Opening evaluations

3.5.1 Opening an evaluation via the evaluation search

1) The evaluation search can be configured in the seca diagnostic settings, see *Examination, Settings, Database, Eval. search.*

→ To open the evaluation search[1] right-click on the Patient button 1.
→ With factory settings, the search screen 2 is displayed. Here, previously saved search criteria, so-called filter sets, can be used to search for evaluations. Filter sets can be created on the Advanced search screen 3.
→ Depending on the default setting of the system, a filter set is already active and the search results are displayed here full-screen as a list 4.
→ If no filter set is active yet, select a set 5.
→ Open an evaluation by double-clicking on the corresponding line or via the Show button 6.

Configuring the list of search results

→ Right-click on the screen to open the context menu. There click on Select columns and set the required columns. Click on Confirm to apply your changes.
→ By clicking on a column heading, the list is sorted by this column and the sorting within the column can be reversed.
→ The list can be printed and exported 7.

Renaming filter sets, deleting filter sets

→ Right-click on the screen to open the context menu. There, click on Rename filter set or Delete filter sets.
→ Follow the instructions.

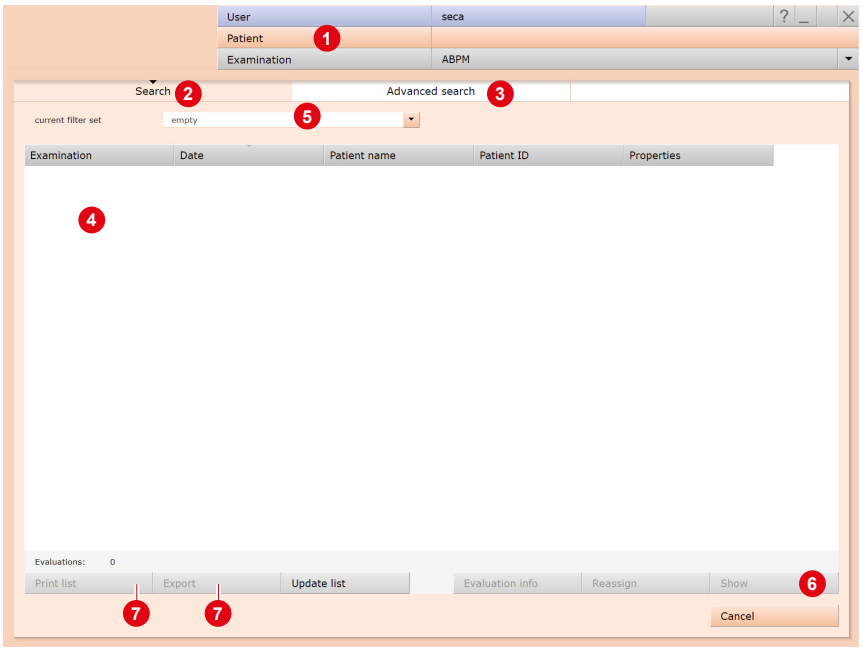


Fig. 24: Evaluation search, search with filter sets

Reference between the end dialogue and the evaluation search - In order to make proper use of the evaluation search, the status of the evaluation must be set correctly in the end dialogue when you exit an evaluation. Example: An evaluation can only be found in the evaluation search with the property confirmed "No" if the status "Evaluation confirmed" is NOT selected in the end dialogue.

Advanced search, creating filter sets

- → The Advanced search 8 is used to create filter sets and to quickly select search criteria (e.g., examination, properties, time period) 9. By setting certain search criteria, the search is narrowed down.
- → The search results are displayed as a list 10.
- → An evaluation is opened by double-clicking on the corresponding line or via the Show button 11.
- → The selected search criteria can be saved as a filter set with a corresponding name. Enter the name in the input field 12 and click Save current search as set 13.

Editing filter sets

- → Select the filter set to be edited, (current filter set).
- → Adjust the search parameters (e.g. examination, time period).
- → Save current search as set 13 overwrites the previous set.
- → If a new name is assigned beforehand, a new set is created.

Configuring the list of search results

- → Right-click on the screen to open the context menu. There click on Select columns and set the required columns. Click on Confirm to apply your changes.
- → By clicking on a column heading 14, the list is sorted by this column and the sorting within the column can be reversed.
- → With the arrow button 15 at the bottom right of the list, the list can be enlarged or reduced.
- → The list can be printed and exported 16.

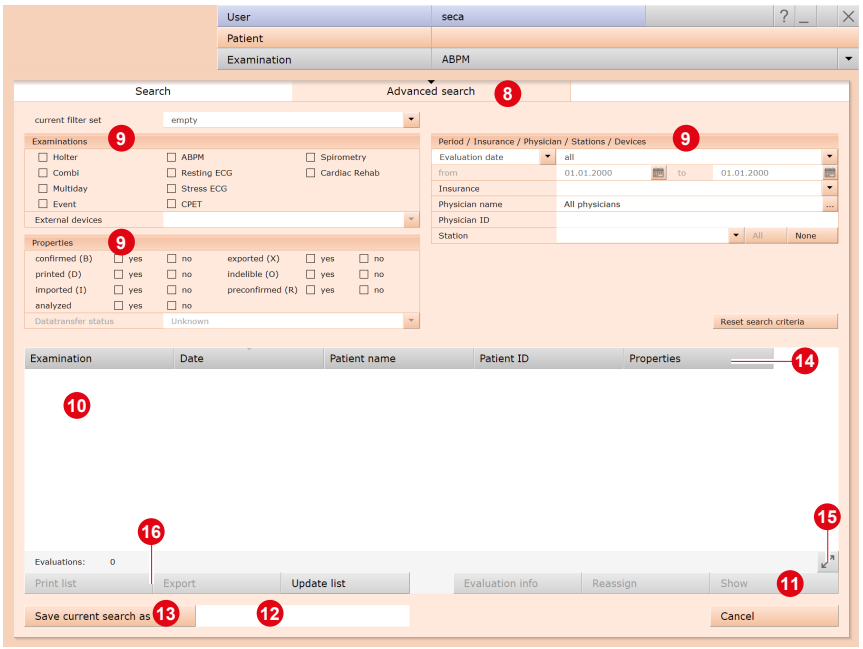


Fig. 25: Evaluation search, extended search

3.5.2 Opening an evaluation via the evaluation menu

Tip for entries in the patient menu: Press the tab key to move the cursor to the next input field.

→ Open the main examination menu via Examination, Pulmonary function.
→ Click on Show evaluation ❶.
→ The patient search screen appears. Select the patient whose evaluation you want to open. Enter the name of the patient in the input fields of the search screen ❷.
→ Select the patient from the list below the input fields ❸ and confirm the selection with the Select patient button ❹ or by double-clicking on the name.
→ A list with all of the patient's evaluations is then displayed. Select the desired evaluation from the list and open it with a double-click or via the Show Evaluation button.

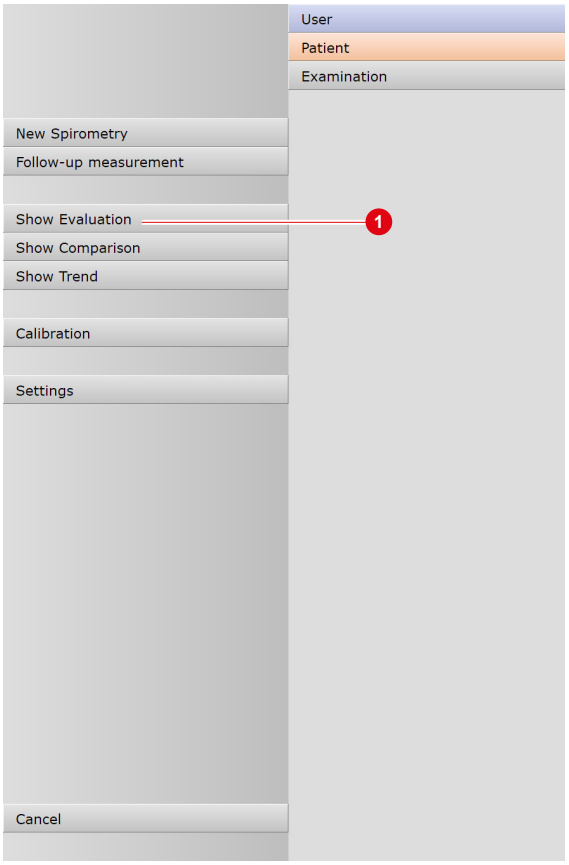


Fig. 26: Spirometry main menu

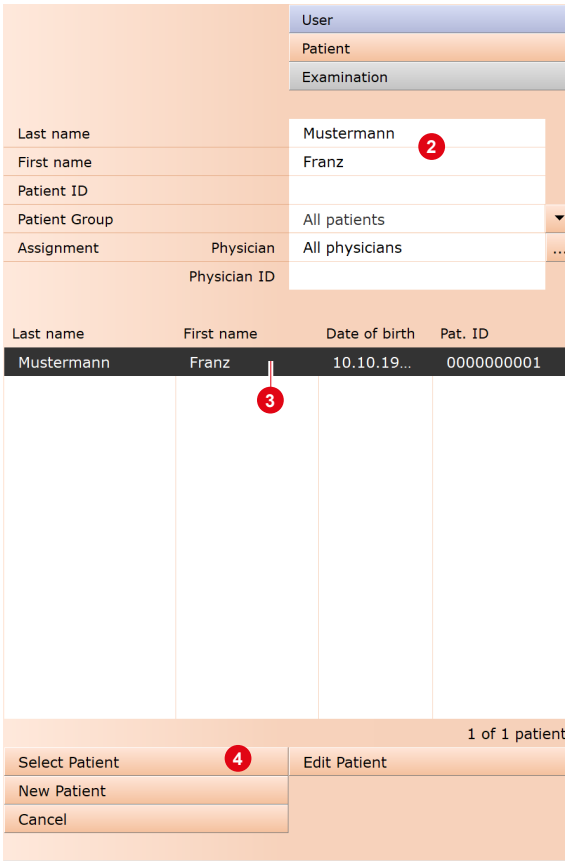


Fig. 27: Select patient

3.6 Evaluation structure

Structure of reference and spasmolysis measurements

INFORMATION on the scope of functions:
The Z-score, LLN, report assessment and the explanation according to clinical and occupational criteria are only available for measurements with the GLI predicted value.

Overview of reference and spasmolysis measurement: Display of the best measurement(s) each with a measurement curve(s) and a table of measured values		
Comparison of 2 evaluations of one patient	**Process control:** Three reference and spasmolysis measurements with measured values and measurement curves for direct comparison.	**Options menu:**
Overlay the measurement curves	**Options menu:**	**Print...**
	Print...	**Trend**[1)]
	Export...	**Export...**
	Predicted value	**Predicted value**
	Medications	**Medications**
	allocate new	**Miller Quadrant**[2)]
	Repeatability	**Lung age**[3)]
		Autom. Report[4)]
		Explain Report[5)]
		allocate new

1) All evaluations of a patient as bar chart with table of measured values.
In addition, the Z-score trend can be displayed for each measured value.

2) Indicates the probability of developing a disease and its severity.

3) Specified in years, calculated based on FEV1 depending on age, not possible for all predicted values.

4) The following types of unconfirmed reports can be selected and added to the report text: Standard (70% rule for FEV1/FVC and 80% rule for IVC and FVC), COPD-GOLD, clinical or occupational evaluation according to GLI.

5) Assessment criteria for clinical, occupational and COPD-GOLD reports.

Structure of provocation measurements

INFORMATION on the scope of functions:
The Z-score, LLN, report assessment and the explanation according to clinical and occupational criteria are only available for measurements with the GLI predicted value.

Provocation overview:
Bar diagram and table of measured values with reference, provocation, dilatation and control measurement.
Other screen pages:

Comparison of 2 evaluations of one patient	**Single test:** Measurement selected in the overview with measurement curve and measurement value table.	**Options menu:**
Overlay the measurement curves	**Options menu:**	**Print...**
	Print...	**Trend**[1)]
	Trend[1)]	**Export...**
	Export	**Predicted value**
	Predicted value	**Medications**
	Medications	**Lung age**[3)]
	Miller quadrant[2)]	**Provocation test**
	Lung age[3)]	**allocate new**
	Autom. Report[4)]	
	Explain Report[5)]	
	allocate new	

1) All evaluations of a patient as bar chart with table of measured values.
In addition, the Z-score trend can be displayed for each measured value.

2) Indicates the probability of developing a disease and its severity.

3) Specified in years, calculated based on FEV1 depending on age, not possible for all predicted values.

4) The following types of unconfirmed reports can be selected and added to the report text: Standard (70% rule for FEV1/FVC and 80% rule for IVC and FVC), COPD-GOLD, clinical or occupational evaluation according to GLI.

5) Assessment criteria for clinical, occupational and COPD-GOLD reports.

6) PD20 provocation dosage: Medication dosage for the 20 percent drop of FEV1 in a provocation measurement compared to the initial value.

3.7 Navigation in the evaluation

The buttons for opening the various evaluation screens are located at the bottom of the screen. By pressing one of the buttons, e.g., Comparison 1, the comparison view is opened and the name of the button changes to Evaluation 2 (name of previous screen page). Clicking the Evaluation 2 button takes you back to the Overview screen page.

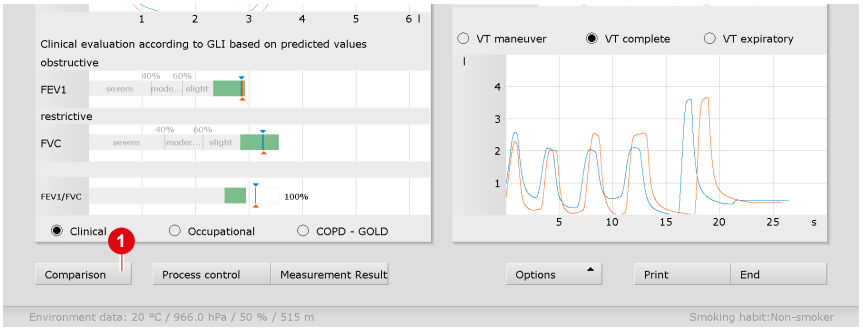


Fig. 28: Overview

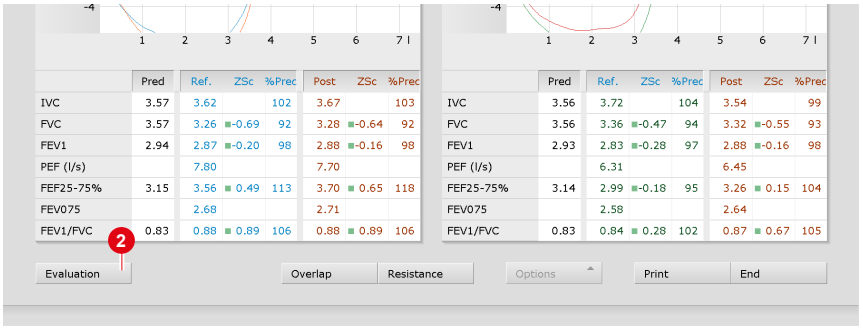


Fig. 29: Comparison

3.8 Diagnostic terms in the evaluation

Lower Limit of Normal (LLN)

The green ranges in the bar diagram are defined by the predicted value (upper limit/right end) ❶ and LLN - Lower Limit of Normal (lower limit/left end) ❷. LLN is the lower limit value used to assess “normal” or “pathological”. LLN corresponds to the 5% percentile of a healthy population. This means that if a measured value is below the 5% percentile, there is a 95% probability that a pathological finding exists or a patient with the corresponding value is healthy in only 5% of the cases.

Z-score

The Z-score indicates by how many standard deviations a certain measured value deviates from the average predicted value. For example, Z = 0 corresponds exactly to the average predicted value and Z = -2 means that the measured value is two standard deviations below the average predicted value.

A specific percentile can always be assigned to each Z-score. A Z-score of -1.645 corresponds to the 5% percentile (LLN). If the Z-score is greater than or equal to -1,645, the measured value is not in the pathological range. The Z-score for the corresponding measured value is marked with a green square in the table of measured values ❸. If the Z-score is smaller than -1.645, the value is marked with an orange-coloured square (see the guideline on spirometry. Pulmonology. 2015; 69: 146-163).

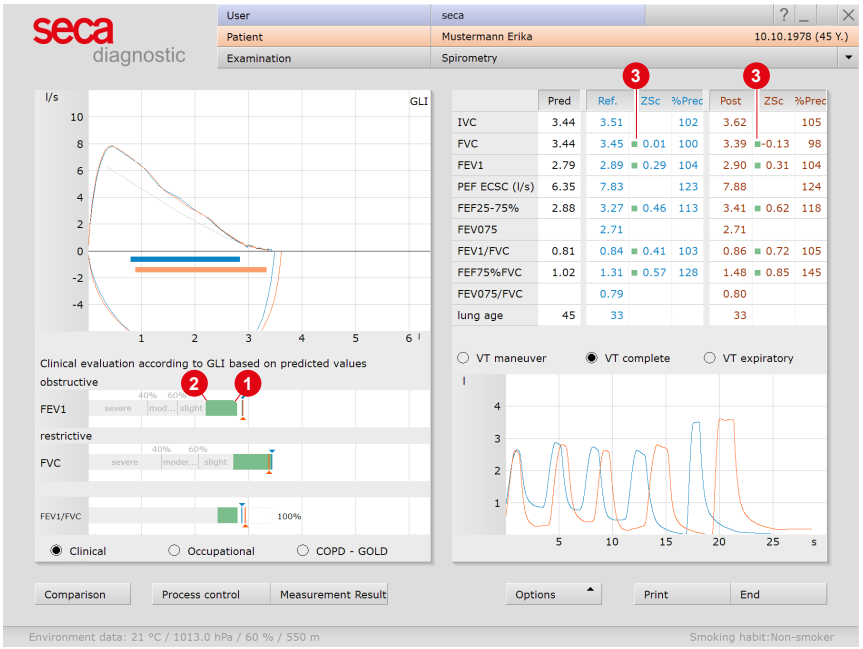


Fig. 30: Lower limit of normal and Z-score.

Miller quadrant

The Miller Quadrant indicates the probability of the existence of a disease and its severity. The relationship between FEV1%VC and FVC is determined and the result is entered in the coordinate system. The coordinate system is divided into the four areas Obstruction, Obstruction & Restriction, Restriction and Normal. The FEV1%VC value is entered as a percentage on the x-axis, the FVC value achieved in comparison to the predicted value is entered as a percentage on the y-axis. The intersection of these values is marked with a cross. The marking crosses are in the colour of the measurement type.

Lung age

The spirometric lung age is determined using the FEV1 value, if FEV1 is calculated depending on age (not for all predicted values). The spirometric lung age is calculated based on the deviation from the predicted value. The spirometric lung age can be displayed via Options, Lung age. On the Examination, Spirometry, Settings, Diagnostic, Parameter screen you can define which predicted value should be used to calculate the spirometric lung age.

Types of reports

The following types of reports can be selected: Standard (70% rule for FEV1/FVC and 80% rule for IVC and FVC), COPD-GOLD, clinical or occupational evaluation according to GLI.

Provocation measurement series, PD20 provocation dosage

Medication dosage for the 20 percent drop of FEV1 in a provocation measurement compared to the initial value in the reference measurement.

3.9 Reference measurement and spasmolysis

Fig. 31: Evaluation, overview

1. Flow-volume curves (reference measurement: blue, spasmolysis: orange)
2. Predicted values, in this case GLI
3. Display of results for FEV, FVC and FEV1/FVC in a bar chart
4. Table of measured values with predicted values, measured values, Z-score and deviations in percentage; clicking on the column header shows or hides the corresponding curve
5. Volume time curve
6. Environmental data input before the measurement
7. Comparison of current and further evaluation of the patient
8. Comparison of individual measurements of a measurement series (plausibility check)
9. Reduced report assessment and, if applicable, resistance results
10. Options menu with print menu, trend, export, predicted value, medication, etc.
11. Printout according to system settings
12. End evaluation

To the results display 3

Blue or orange arrows mark the respective result. Values within the green areas can be considered acceptable. Values located in the gray areas of the bars are considered pathological, classified as mild, moderate and severe. The evaluation can be done according to the criteria clinical, occupational or COPD-GOLD, see options below the diagram.

3.10 Provocation measurement series

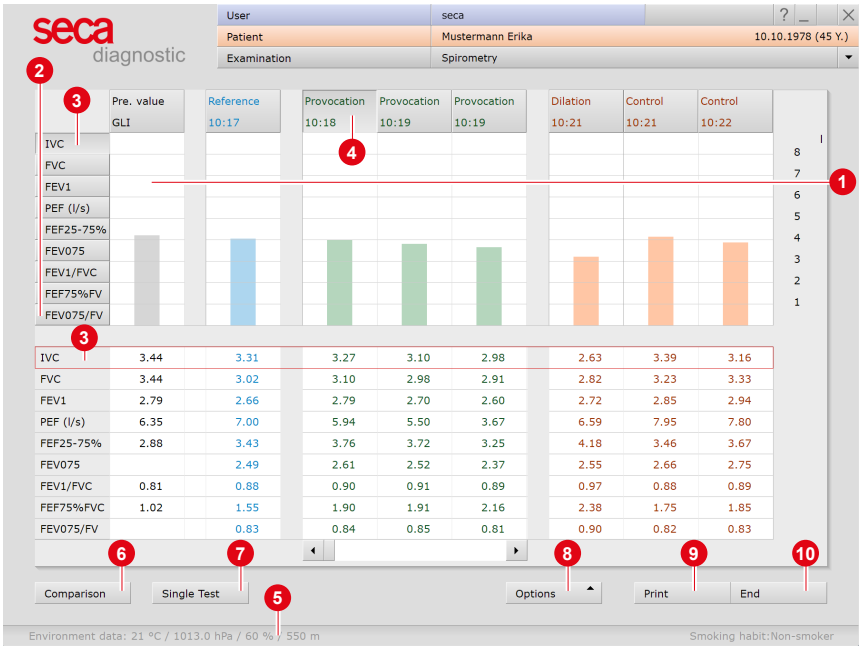


Fig. 32: Evaluation, provocation

1. Graphical representation of all the measurements of the measurement series with the selected measured value displayed as a bar, here IVC
2. Measured value buttons for displaying a different measured value
3. Table of measured values - the selected measured value is outlined in red
4. Buttons for selecting a measurement of the measurement series, e.g., to open the selected measurement in the single view
5. Environmental data input before the measurement
6. Comparison of current and further evaluation of the patient
7. The selected measurement is displayed as a single measurement
8. Options menu with print menu, trend, export, predicted value, medication, etc.
9. Printout according to system settings
10. End evaluation

3.11 Further screens of an evaluation

History control (only for reference and spasmolysis evaluations).

This screen is opened via the Process Control button. The process control is used to compare a series of reference and/or spasmolysis measurements in order to check the quality of the patient's cooperation well as the plausibility of the results. It is a precondition that the measurements have been made in direct succession.

By clicking on the miniature views of the curves, the measurements can be superimposed. Clicking on the miniature view again deactivates the overlay. Strong deviations between the measurement curves show that the patient did not cooperate correctly.

The best values of all measurements are highlighted in light yellow on the Progress control screen. You can use Options, Composite values to call up a table that combines the best measured values, regardless of which measurement in the measurement series a value comes from.

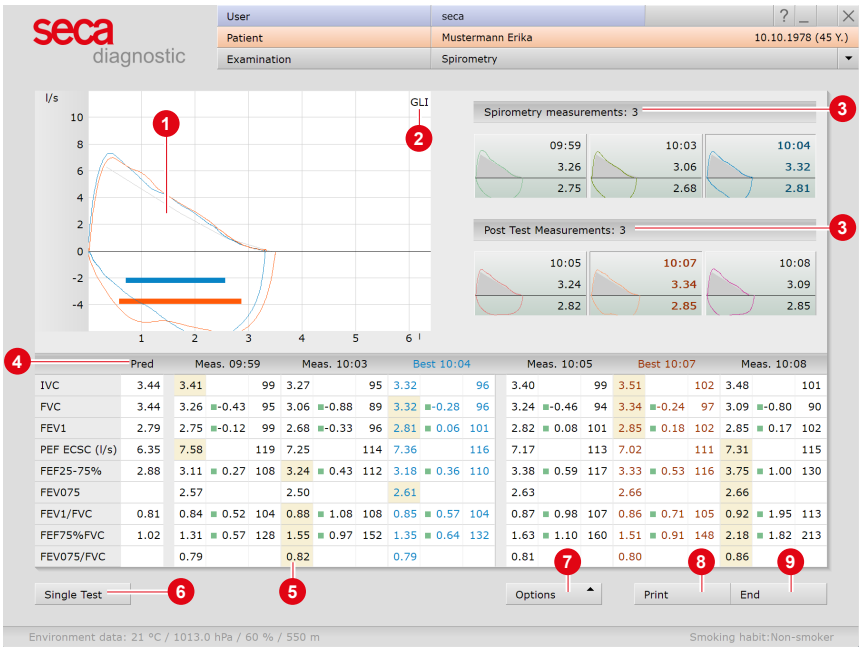


Fig. 33: Evaluation, process control

1. Flow-volume curves (reference: blue, spasmolysis: orange)
2. Predicted values, in this case GLI
3. Miniature views of the available measurements, by clicking the respective measurement curve is displayed in area 1
4. Table of measured values with predicted values, measured values, Z-score and deviations in percentage
5. Highlighting the best values in all measurements of a series
6. The selected measurement is displayed as a single measurement
7. Options menu with print menu, export, setpoint author, medication list, composite values, etc.
8. Printout according to system settings
9. End evaluation

Options menu, Repeatability

In order to make a statement on the quality and plausibility of a measurement series, the FEV1 values of a measurement series and the FVC values of a measurement series are compared with each other. If the deviation is less than 5%, the reproducibility criteria are met. The measured values and limits on which the check is based can be adjusted on the Examination, Spirometry, Settings, Menu/Functions screen page if required. Save your input.

Comparison

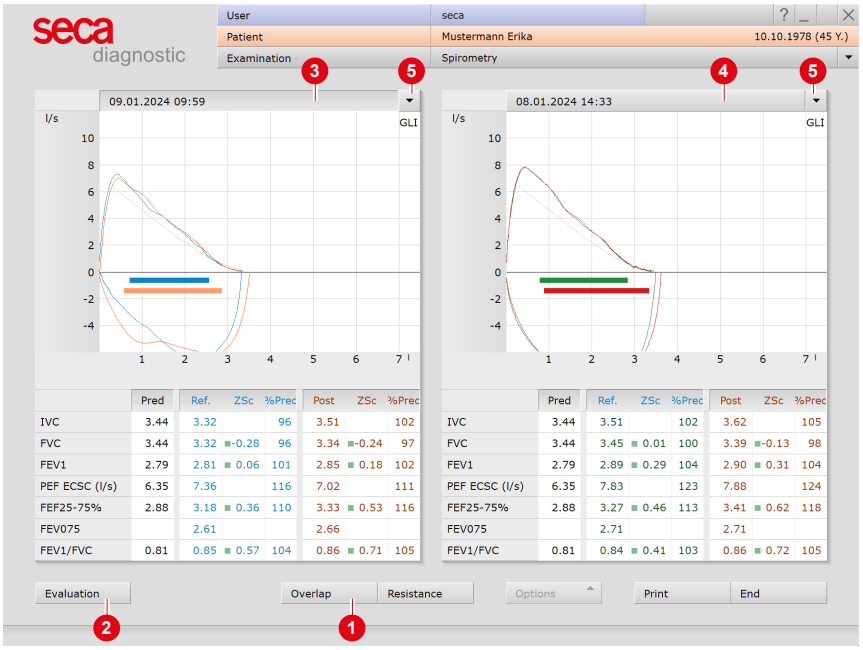


Fig. 34: Evaluation, comparison

The Comparison function (bottom left in the evaluation overview) can be used to compare the open evaluation with another evaluation of the patient. The comparison can also be called up via the Spirometry main menu with Show Comparison.

Clicking on Overlap ❶ superimposes the measurement curves of the two evaluations. The Evaluation button ❷ leads back to the single view of the selected evaluation (pressed date line) ❸.

The comparison measurement can also be displayed as a single measurement. To do this, click in the date line above the measurement curve ❹ and on Evaluation ❷. The arrow buttons ❺ provide lists with all available evaluations of the patient. To open one of these evaluations, select the desired evaluation and click on the Evaluation button ❷.

Trend

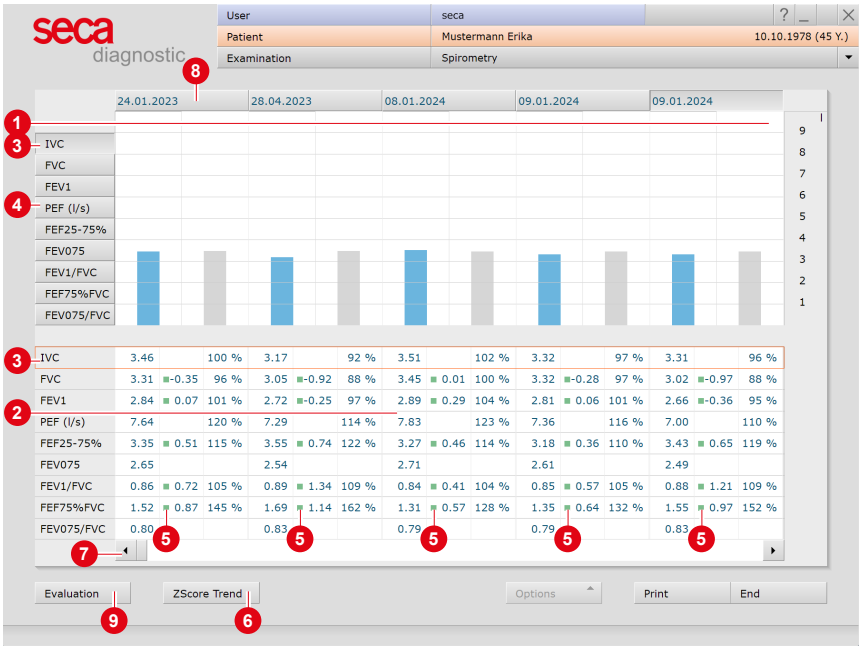


Fig. 35: Evaluation, trend view

The trend view is opened via the Spirometry main menu with Show trend or in the evaluation via Options, Trend. The trend view is used to display developments over a longer period of time. All measurements of a patient are shown as a bar chart ❶ with a table of measured values ❷. The selected measured value ❸ is displayed in the chart ❶ (measured value: blue, setpoint: grey). The line with the corresponding measured values is marked in colour in the table of measured values ❸. To display a different measured value, click on the desired measured value button ❹.

The table of measured values shows the Z-score values for the patient ❺. Values with a green marking are ≥ -1.645 and therefore acceptable; values with an orange-coloured marking are < -1.645 and probably to be considered as pathological. The development of the Z-score for the FEV1, FVC and FEV1/FVC values can be displayed using the ZScore Trend ❻ button.

Additional measurements can be viewed using the scroll bar at the bottom of the screen ❼. To open a measurement from the trend, select the measurement by clicking on the button with the date of creation ❽. Then click on Evaluation ❾. The trend view also considers the results of already deleted and archived measurements. These results can no longer be shown in the single view.

Z-Score Trend

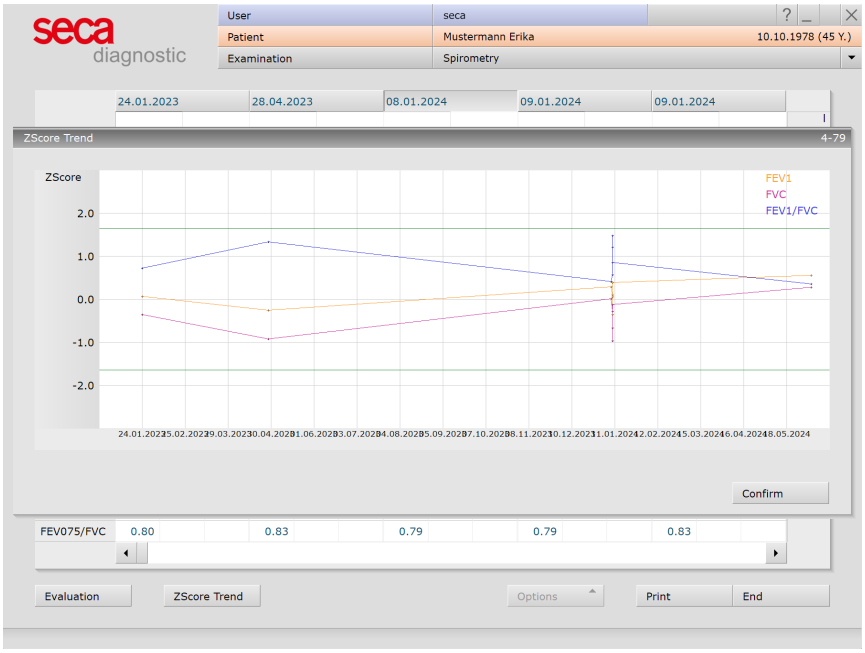


Fig. 36: Evaluation, Z-Score Trend

The Z-score trend can be called up in the trend view of an evaluation (Open evaluation, Options, Trend). The Z-score values of a measured value are plotted as a trend over time (y-axis: Z-score, x-axis: date). The normal value range is within the green lines. Values below the lower green line are considered pathological.

Colour coding of the measured values in the Z-score trend:

→ FEV1: orange
→ FVC: pink
→ FEV1/FVC: blue

3.12 Confirming the evaluation

1) In addition, further automatic reports may already be included, e.g., according to the criteria clinical, occupational or COPD-GOLD. These automatic reports can be added via Options, Autom. Report. In the settings, you can specify which automatic reports are to be included in the unconfirmed report by default. To do this, open the screen page Examination, Spirometry, Settings, Diagnostic, Autom. Report findings. Save your input.

Unconfirmed report and report

To open the unconfirmed report, right-click on the evaluation interface. In the context menu select Report. Enter your data in the text field 1. If the Unconfirmed report or Interpretation option is selected in the system settings, an automatic system unconfirmed report is already present in the text field[1)]. If necessary, older reports can be displayed via the report history (collapsible list above the text input field). When you click on Confirm 2 your input is saved and the unconfirmed report becomes a (preliminary) report, depending on the report rights of the current user. If your (unconfirmed) report is not yet complete but you want to save it nevertheless without reaching the “Evaluation (pre)confirmed” status, the report status is reset upon ending (End) the evaluation.

Text modules – an aid for writing reports

On the Examination, Spirometry, Settings, Diagnostic, Report screen page, you can create text modules for confirming an evaluation 3. A total of four groups 4 with up to eight text modules 5 can be created. The text modules are called up in the unconfirmed report dialogue box via the keyboard (F5 to F12) 6.
A text module can be composed of normal text and variables. Instead of a variable, the actual value from the evaluation is inserted into the report text when using a text module in the report text. The structure of a variable is {VARIABLE}. Via the button Shortcuts for export values 7 you receive a list with all variables. If the text modules are to be displayed in the unconfirmed report dialogue box, make sure that the Enabled 8 option is activated. Otherwise, the text modules can be displayed in the unconfirmed report dialogue box via Options 9, Texts on. It is also possible to write a text that is automatically displayed in each unconfirmed report 10. The text can be changed later in the unconfirmed report dialogue box. Save your entries.

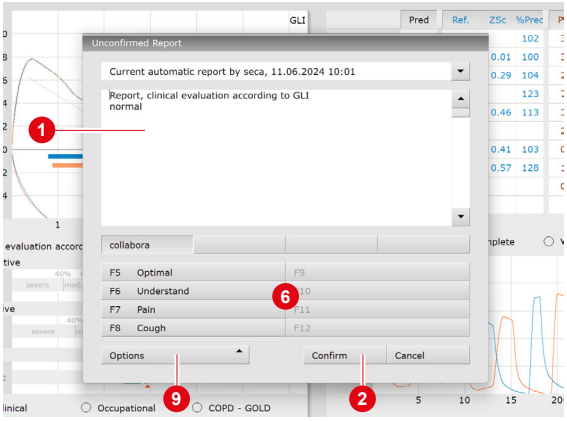


Fig. 37: Unconfirmed report

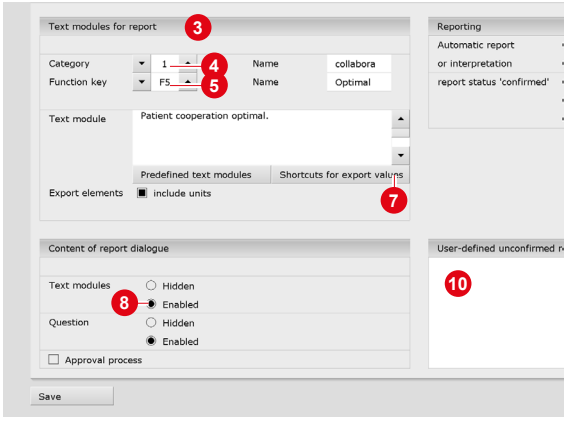


Fig. 38: Text modules

3.13 Optional: Reporting with approval process

If seca diagnostic is used with approval process, authorised persons with corresponding user rights can save pre-reports of other persons as a report without having to close the evaluation already opened by the previous examiner (shortened workflow) or enter pre-reports/reports directly if the evaluation was created by a person without reporting rights.

The approval process is visible in the unconfirmed report dialogue 1 of an evaluation. The user can be changed there: User name 2, Password 3, Enter. During the login process, the user rights of the respective user are checked and the software interface is adapted accordingly 4. The reporting is documented in the evaluation information 5 (context menu).

The approval process must be activated in the Settings and in the seca service center for each user and project. The user rights must be set to match the workflow. Contact seca.

INFORMATION: Pre-reporting physicians must have the user right Preconfirm evaluations, reporting physicians must have the user rights Confirm evaluations and Change reports of other users.

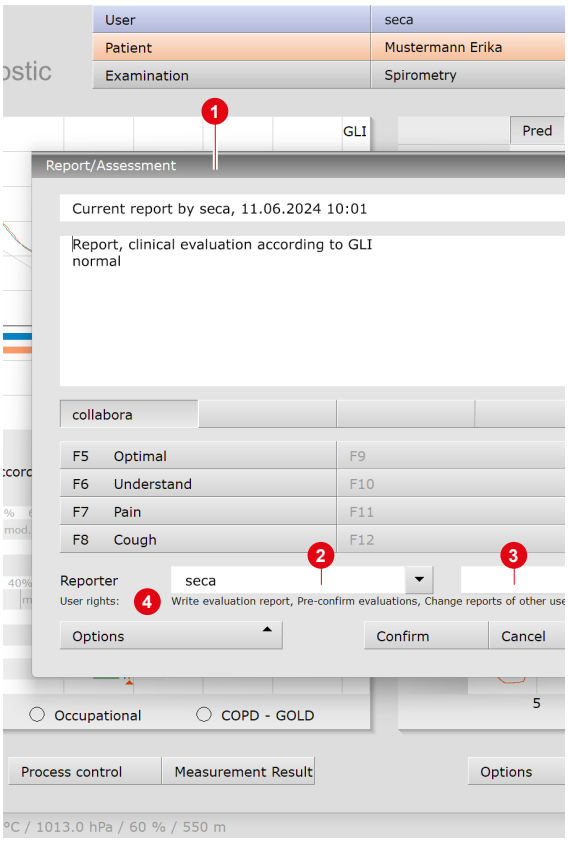


Fig. 39: Unconfirmed report dialogue with approval process

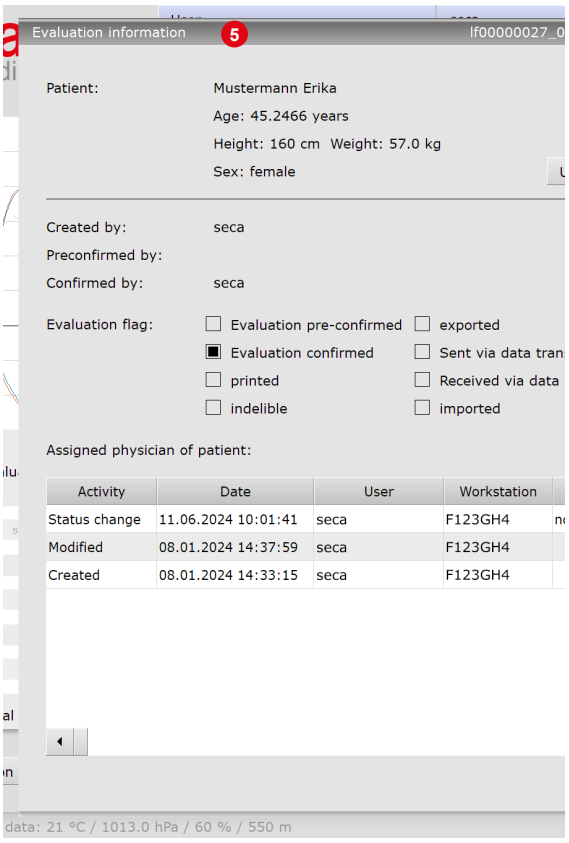


Fig. 40: Evaluation information

3.14 Ending the evaluation

Click on End (bottom right) in the evaluation. The End dialogue opens.

1. The status of an evaluation is defined here. Assigning properties (status of the evaluation) in the End dialogue makes it easier to find evaluations in the evaluation search.
2. Evaluation pre-confirmed: active if a user with the reporting right “Preconfirm evaluations” has confirmed the unconfirmed report of an evaluation.
3. Confirmed: active if a user with the reporting right “Confirm evaluations” has confirmed the unconfirmed report. The “confirmed” status can be reset if required.
4. Printed: indicates whether the evaluation has been printed.
5. Indelible: can be selected after reporting has been completed. The evaluation can now only be viewed and can no longer be changed.
6. Click on Confirm to close the evaluation.

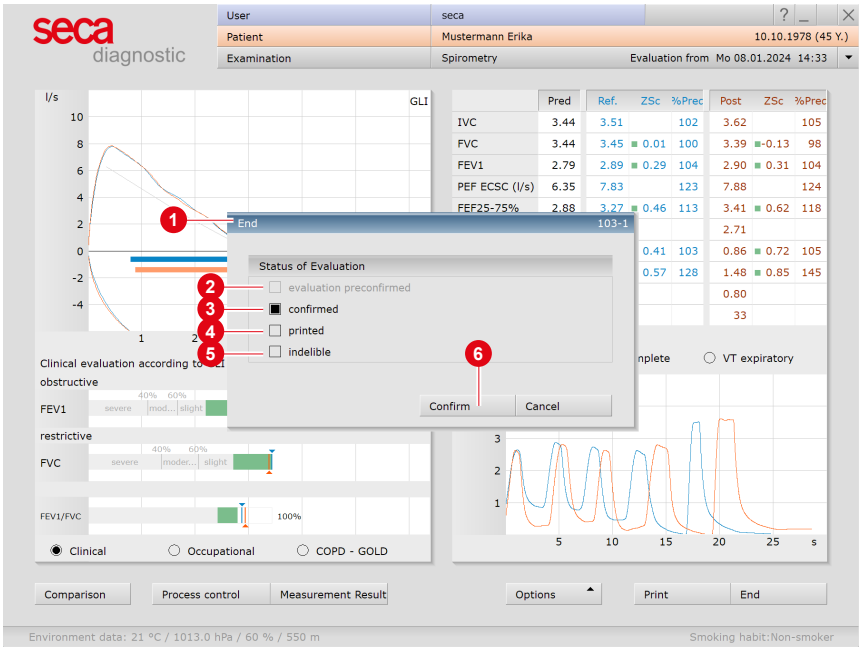


Fig. 41: End dialogue

3.15 Settings for spirometry

Configuring the printout

On the Examination, Spirometry, Settings, Print, General screen page, you define which print pages are printed when the Print button is pressed. In the “Print sequence...” area, select either:

→ Current page (creates a printout of the open evaluation screen),
→ Pre-set pages (for configuration see next paragraph)
→ or Total printout PA (professional association).

On this screen page you also select the printer (right half of the screen). Save your input.

Defining the contents for the Pre-set pages option:

→ The settings for the print pages can be found on the Examination, Spirometry, Settings, Print, ❶ Printed Pages ❷ screen page.
→ In the “Printed pages” area ❸, the contents of the printout can be compiled.
→ The default setting is the Summary option ❹. This contains a table of measured values, a flow-volume chart, a volume-time curve and an unconfirmed report. The summary can be combined with all other options (report assessment, total table of measured values etc.).
→ The steps shown are the definition of your standard print settings. The default print settings automatically apply automatically to all other types of printout (print job via the Job Manager, PDF export).
→ To change the print settings for further printout types, select the desired printout type in the “Type of printout” area ❺ and define the page contents as described above.
→ Save ❻ your input.

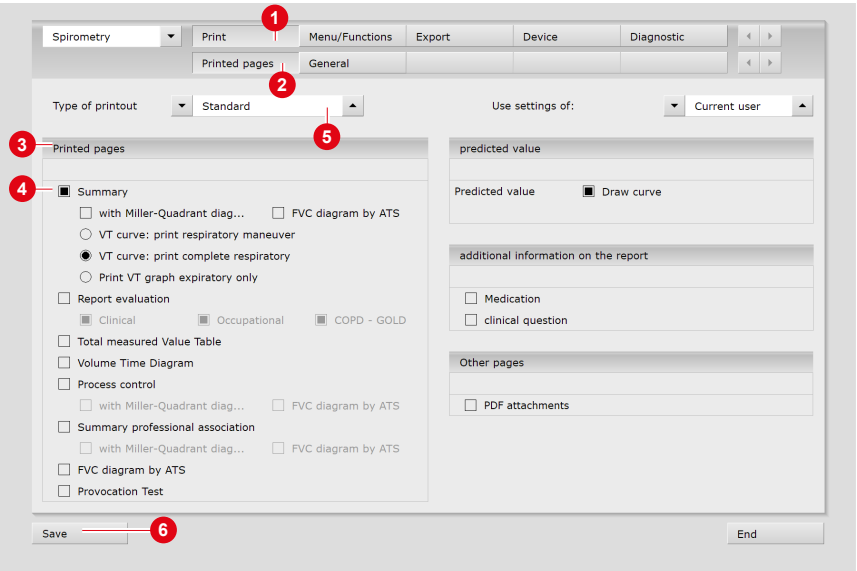


Fig. 42: Contents for the preset pages option

Parameters for the spirometry measurement

On the Examination, Spirometry, Settings, Diagnostic 1, Parameter 2 screen page, various parameters can be set for the measurement:

- → Predicted values and area of validity: Define which predicted values should be proposed by default for children and adults 3. If you activate the option also outside 4 in the “Validity” area, the predicted values will also be suggested if the patient data does not match the validity range of the predicted values. In this case, the predicted values are displayed in brackets in the software interface.
- → Comparison 5: Here you can specify whether the percentage deviation of the measured values in comparison to the predicted values is to be specified for reference measurements and whether the percentage deviation of the measured values in comparison to the reference or predicted values is to be specified for follow-up measurements.
- → Spirometric lung age 6: Select the predicted value according to which the spirometric lung age is to be calculated. The spirometric lung age is determined using the FEV1 value, if FEV1 is calculated depending on age.
- → Breathing manoeuvre 7: Adjust the required resting breaths before the breathing manoeuvre.
- → Determination of best value 8: Set which measurement value is used to determine the best measurement of a measurement series. Select Sum of FVC and FEV1, FEV1, FVC or IVC.
- → Flow-volume curve 9: To display the flow-volume curve in conformity with ATS, activate the option Show flow-volume chart by ATS....
- → Save 10 your input.

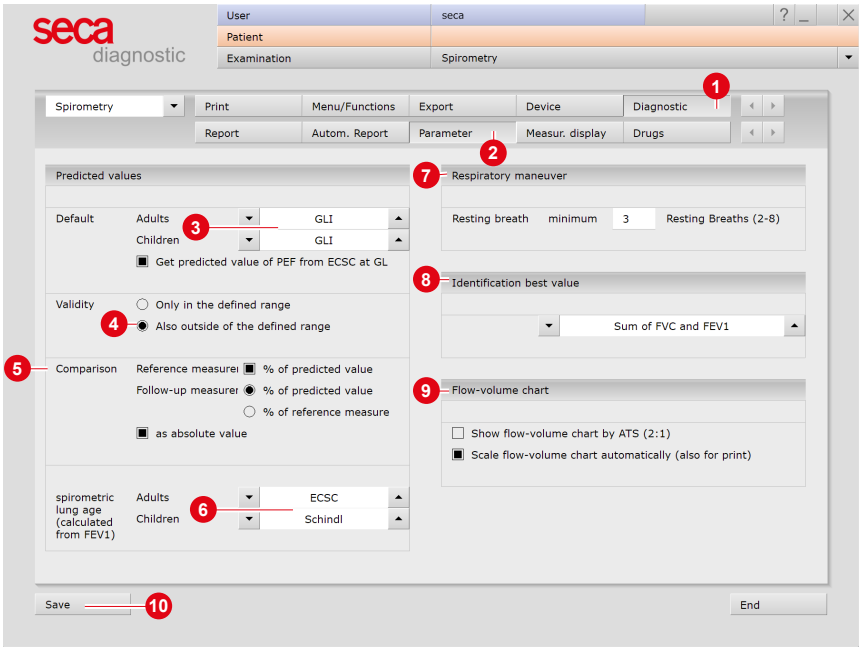


Fig. 43: Parameters for spirometry measurement

Display of measured values in the software interface and in the printout

On the Examination, Spirometry, Settings, Diagnostic 1, Measur. Display 2 screen page, you can set for each set of predicted values which measured values are to be displayed in the software interface and in the printout (if a different display from the default setting is desired).

- → Select the predicted values 3 in the “predicted values” area.
- → Then up to seven measured values can be selected for display 4.
- → The selected measured values are displayed in the right half of the screen, in the “Measurement display” area 5.
- → The order of the selected measured values can be changed using the arrow keys 6.
- → The measured values IVC, FVC and FEV1 7 are always displayed and cannot be changed.
- → Use the reset default values button 8 to display the factory settings again.
- → Save 9 your input.

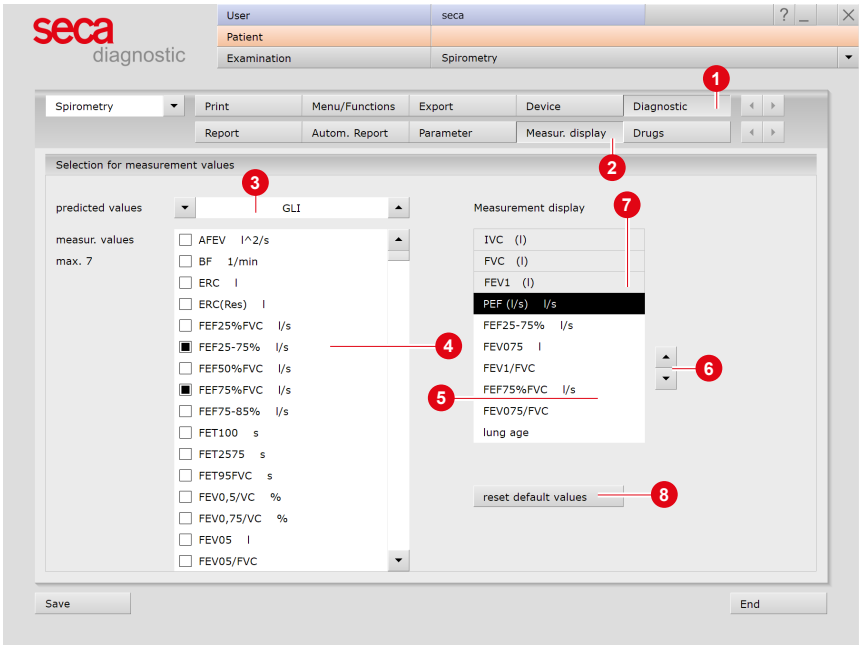


Fig. 44: Settings for displaying the measured values

Procedures and functions for the spirometry measurement

These settings can be found on the Examination, Spirometry, Settings, Menu/Functions 1, Menu/Functions 2 screen page.

→ Measurement units for the environmental data 3: In the “Environmental data” area, you can change the units of the environmental data. Preset units are °Celsius (°C), hPascal (hPa) and meter (m).
→ Flow control, Expiratory only 4: If this option is enabled, the patient has to exhale forcefully into the device only once for the spirometry measurement (no resting breathing).
→ Flow control, Check measurements for repeatability 5: In order to make a statement on the quality and plausibility of a measurement series, the FEV1 values of a measurement series and the FVC values of a measurement series are compared with each other. If the deviation is less than 5%, the reproducibility criteria are met. If there are three measurements within the specified limits, a message appears indicating that the measurement series can be ended.
→ Save 6 your input.

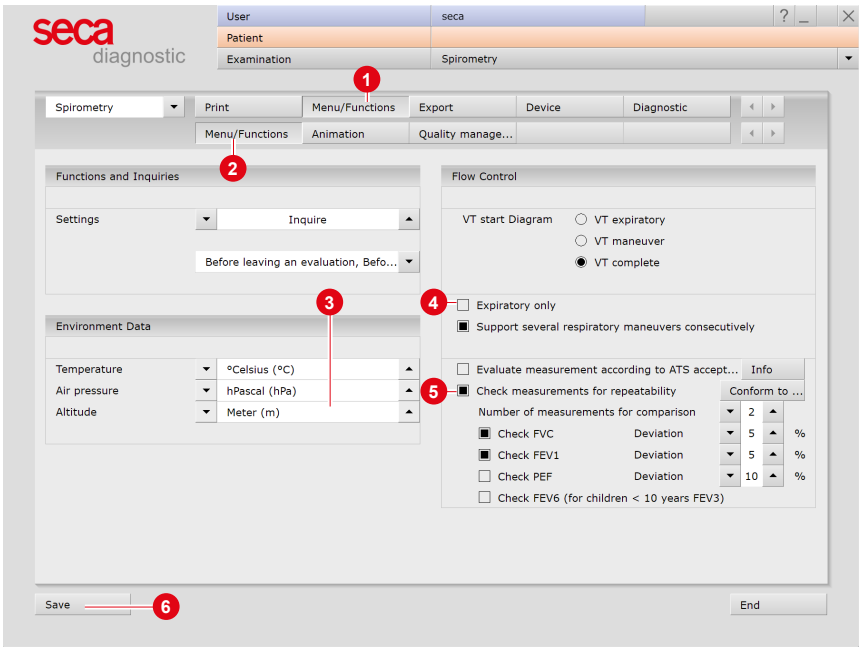


Fig. 45: Settings for prodedures during the measurement

Quality management

These settings can be found on the Examination, Spirometry, Settings, Menu/Functions 1, Quality management 2 screen page. The Quality management function 3 can be switched on and off as required.

The function supports the correct use of the seca spiro mobile measuring device as well as its maintenance and care in order to permanently ensure the quality of the measurements. The review mechanism examines the best reference measurements from five consecutive patients. If there are deviations from the set limits in five consecutive patients, the system displays corresponding information.

The limits are preset as follows:

→ If FEV1 is 10 % smaller than the predicted value and the tilt of the measuring unit is simultaneously in the red range (> 10°) 4, seca diagnostic displays the message “... Please make sure that the patient is in an upright position during the measurement...”.

→ If IVC or FVC are 10 % greater than the predicted value 5, seca diagnostic displays the message “... The value for FVC or IVC was more than 10% above the predicted value. We therefore recommend to clean the measuring unit and to check the calibration”.

→ The values for checking can be adjusted if necessary.

→ Save your input.

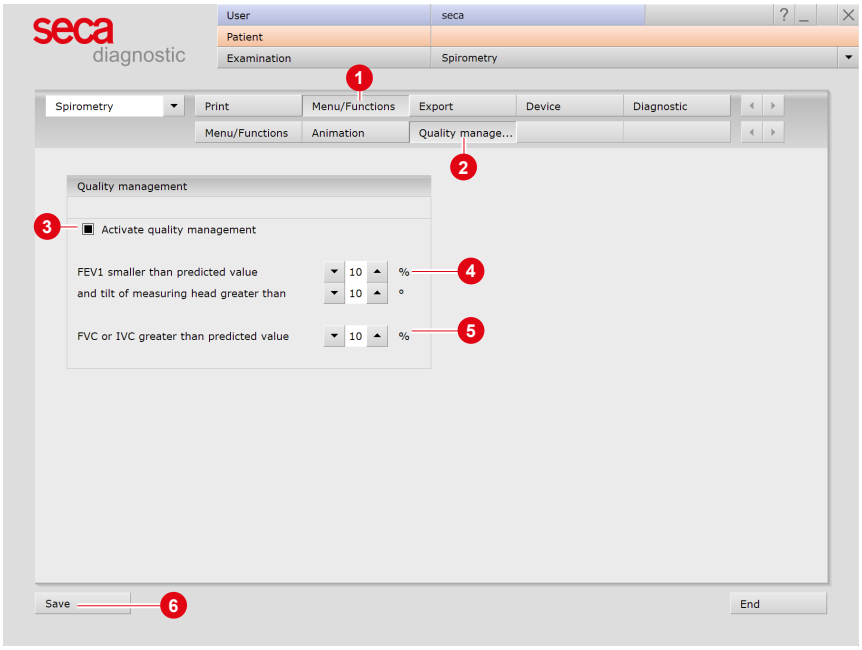


Fig. 46: Quality management settings

3.16 Error messages and solutions

Error message: Spirometry device not ready for use

→ Confirm the error message, close the spirometry software if necessary.
→ Disconnect the USB plug of the spirometry testing device from the PC.
→ After a few seconds, reconnect the device to the PC.
→ When the LED in the handle lights up, the device is ready for operation.
→ Call the spirometry software again.
→ This re-initialises the device.
→ You can then continue with the examination.
→ If the system still does not recognise your device, seca diagnostic must be restarted.

Error message: Breathing manoeuvre could not be recognised

→ If the patient's breathing is too weak or incorrect during the measurement, seca diagnostic might not be able to recognise the breathing manoeuvre. Without a breathing manoeuvre the system cannot create an evaluation.
→ Confirm the error message.
→ Repeat the measurement, give the patient clear breathing instructions and pay attention to the system instructions on breathing.
→ Important: The patient may only breathe into the device after you have clicked the Start button!

4 Hygiene

4.1 Important notes

Only use cleaning agents and disinfectants recommended by custo med. Unsuitable agents may damage the device.

The handle of the device ❷ must not be immersed in liquids.

The measuring unit ❶ and the mouthpiece ❹ are suitable for cleaning in an ultrasonic bath.

The measuring unit ❶ must be completely dry before the next measurement.

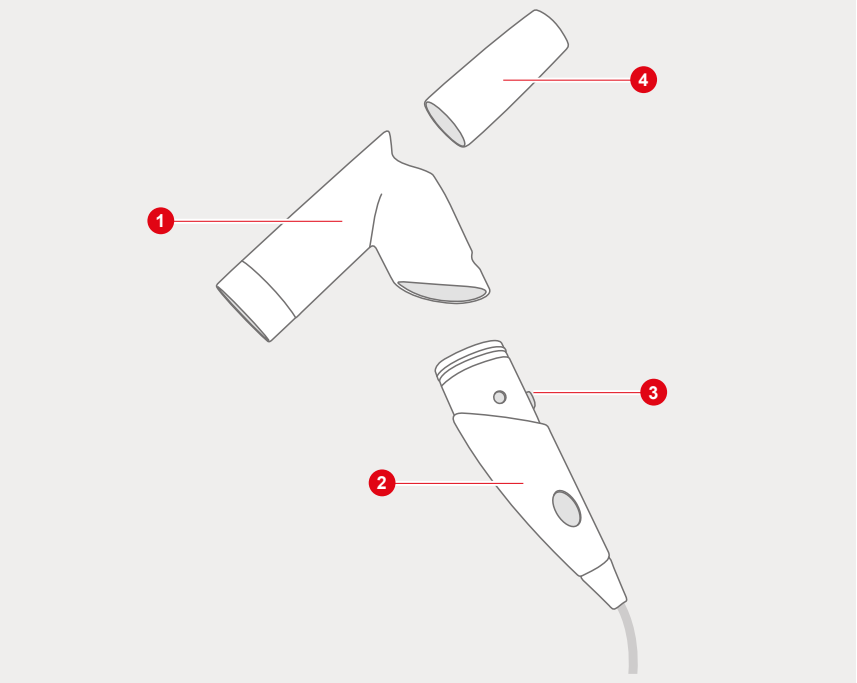


Fig. 47: seca spiro mobile components

spiro protect bacterial and viral filters

When using spiro protect bacterial and viral filters, the need for cleaning and disinfection of the device is minimized, but not eliminated.

CAUTION

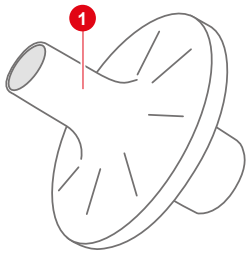
Risk of contamination from used bacterial and viral filters

→ A spiro protect bacterial and viral filter may only be used for one patient.

→ Dispose of the spiro protect bacterial and viral filter safely and properly after the examination.

4.2 Hygienic reprocessing

4.2.1 Procedure and frequency of reprocessing



After each examination:

→ Properly dispose of spiro protect bacterial and viral filters 1. For infectious patients *see 4.4 Contaminated consumables, p. 77*.
→ Disinfect seca spiro mobile and all associated components/parts that have come into contact with the patient from the outside, *see 4.2.3 Wipe disinfection, after each examination, p. 74*.
→ Properly dispose of nasal clips. For infectious patients *see 4.4 Contaminated consumables, p. 77*.

Weekly or after 100 examinations:

→ Clean and disinfect measuring unit and mouthpiece inside and out, *see 4.2.4 Instrument disinfection: weekly or after 100 examinations, p. 75*.
→ Check device for linearity and function and calibrate.

4.2.2 Disassembling the device for reprocessing

→ Remove the spiro protect bacterial and viral filter and dispose of it properly.
→ Press firmly on the release key 1.
→ Pull the measuring unit 2 upwards.
→ Pull the mouthpiece 3 out of the measuring unit 2 by rotating it slightly.
→ Make sure that the sealing ring in the handle 4 is not damaged.
→ If possible, clean or disinfect immediately after use.

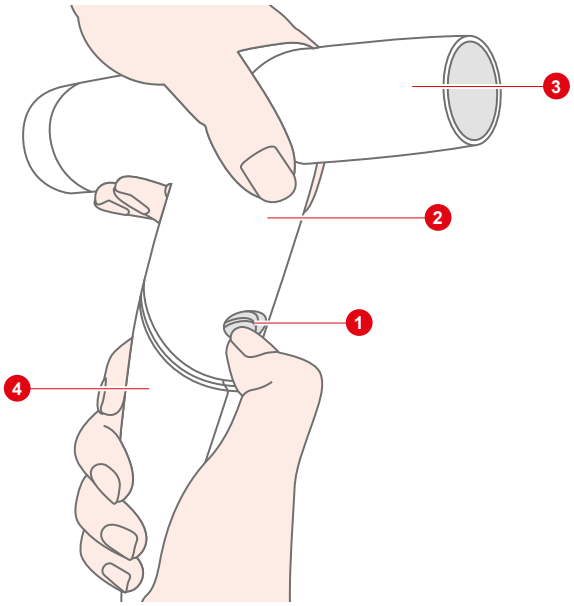


Fig. 48: Disassembling seca spiro mobile

4.2.3 Wipe disinfection, after each examination

Applies to seca spiro mobile and all associated components (1 to 4).

Reprocessing type: Wipe disinfection

- → Suitable agents *see 4.3 Recommended cleaning agents and disinfectants, p. 76*.
- → No moisture may get into the handle 2 (e.g. via the sensor).
- → When all parts of the seca spiro mobile device have been cleaned, disinfected and dried, reassemble the device.
- → The release button must engage with a click when placing the measuring unit.

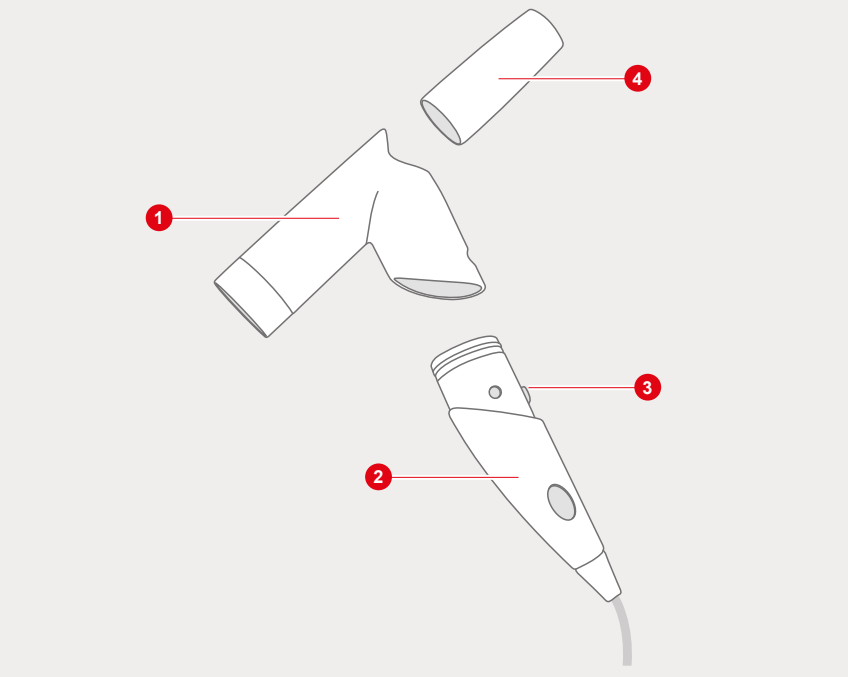


Fig. 49: seca spiro mobile components

4.2.4 Instrument disinfection: weekly or after 100 examinations

Measuring unit and mouthpiece

→ Perform a preliminary cleaning of the measuring unit and mouthpiece. To do this, rinse the measuring unit and mouthpiece with water or clean them in an ultrasonic bath (for coarse contamination), depending on the degree of contamination.
→ Then disinfect the measuring unit and mouthpiece.
→ Reprocessing type: Instrument disinfection. Suitable agents *see 4.3 Recommended cleaning agents and disinfectants, p. 76*.
→ NEVER subject the handle to instrument disinfection. Do not allow moisture to enter the handle.
→ After instrument disinfection, rinse the measuring unit and mouthpiece thoroughly with water.
→ If possible, use low-lime water (deionised, distilled).
→ Disinfectant residues must be completely removed.
→ Then dry the measuring unit and mouthpiece thoroughly. Shake the water out of the measuring unit and rub the surfaces with a disposable cloth.

Handle

→ Reprocessing method: Wipe disinfection. Suitable agents *see 4.3 Recommended cleaning agents and disinfectants, p. 76*.
→ No moisture must get into the handle (e.g., via the sensor).
→ When all parts of the seca spiro mobile device have been cleaned, disinfected and dried, reassemble the device. The release button must engage when the measuring unit is put on.

4.3 Recommended cleaning agents and disinfectants

Wipe disinfection:

- → Meliseptol® Wipes sensitive (B.Braun)
- → Meliseptol® Foam pure (B.Braun), use a soft, lint-free cloth for this purpose.
- → Observe the manufacturer's instructions!

Instrument disinfection:

- → Helipur H plus N (B.Braun) as a solution of max. 4%
- → Observe the manufacturer's instructions!

INFORMATION:

The recommended disinfectants can be replaced by products from other manufacturers provided they are equivalent in terms of disinfection and material compatibility. For more information, contact your partner for hygiene and disinfection.

4.4 Contaminated consumables

Concerns spiro protect bacterial and viral filters and nasal clips.

In principle, the country-specific local rules and regulations apply. For the Federal Republic of Germany as follows: According to the Waste Catalogue Ordinance (AVV), infectiously contaminated bacterial and viral filters (and nasal clips) are wastes whose collection and disposal are subject to special requirements from an infection prevention point of view and are to be assigned to waste code AS 18 01 03. Disposal also depends on the amount of contaminated waste.

In clinics and in medical practices that treat patients with corresponding diseases (e.g., active tuberculosis) on a regular basis (i.e., not only in sporadic individual cases), the filter and the nasal clip must be disposed of in an extra container (tear-proof, labelled with “biohazard symbol”). Observe the Infection Protection Act (§17 IfSG: objects contaminated with notifiable pathogens).

In principle, this requirement also applies to the accumulation of small quantities of contaminated waste. However, disinfection is possible in the case of single items (any disinfectant, the part does not require any further consideration). Afterwards, the filter and nasal clip can be disposed of with the general waste (for practices, household waste). See the “Directive on the proper disposal of waste from health care facilities”.

5 Appendix

5.1 Abbreviations of the spirometry values

Abbreviation	Unit	Description
AFEV	l2/s	Area under flow volume curve
BF	l/min	Breathing frequency at rest (Breathing Frequency)
ERC	l	Expiratory reserve volume
FEF25%FVC	l/s	= MEF75%FVC
FEF25-75%	l/s	Average forced expiratory flow between 25% and 75% of FVC
FEF50%FVC	l/s	= MEF50%FVC
FEF75%FVC	l/s	= MEF25%FVC
FEF75-85%	l/s	Average forced expiratory flow between 75% and 85% of FVC
FET100	s	Forced expiratory time for the total FVC
FET25-75	s	Forced expiratory time between 25 and 75% of FVC
FET95%FVC	s	Forced expiratory time at 95% of FVC
FEV0.5	l	0.5 second capacity (forced expiratory volume in 0.5 seconds)
FEV0.5%FVC	%	Relative 0.5 second capacity of forced vital capacity in percent
FEV0.5/FVC	---	Relative 0.5 second capacity of forced vital capacity
FEV0.5/VC	%	Relative 0.5 second capacity of VC
FEV0.75	l	0.75 second capacity (forced expiratory volume in 0.75 seconds)
FEV0.75/FVC	---	Relative 0.75 second capacity of forced vital capacity
FEV0.75/VC	%	Relative 0.75 second capacity of VC
FEV1	l	Absolute second capacity
FEV1%VC	%	Relative second capacity of vital capacity in percent
FEV1.5	l	1.5 second capacity (Forced expiratory volume in 1.5 seconds)
FEV1.5/FVC	---	Relative 1.5 second capacity of forced vital capacity
FEV1.5/VC	%	Relative 1.5 second capacity of VC
FEV1/FEV6	---	Ratio of forced expiratory volume in the first to sixth second
FEV1/FVC	---	Relative second capacity of forced vital capacity
FEV1/VC	%	Relative second capacity of VC
FEV2	l	2 second capacity (forced expiratory volume in 2 seconds)
FEV2/FVC	---	Relative 2 second capacity of forced vital capacity
FEV2/VC	%	Relative 2 second capacity of VC
FEV3	l	3 second capacity (forced expiratory volume in 3 seconds)
FEV3/FVC	---	Relative 3 second capacity of forced vital capacity
FEV3/VC	%	Relative 3 second capacity of VC
FEV6	l	6 second capacity (forced expiratory volume in 6 seconds)
FEV6/FVC	---	Relative 6 second capacity of forced vital capacity
FEV6/VC	%	Relative 6 second capacity of VC
FIF25-75%	l/s	Average forced expiratory flow between 25% and 75% of FVC
FIT100	s	Forced inspiratory time for the total FVC
FIV0.5	l	0.5 second capacity (forced inspiratory volume in 0.5 seconds)
FIV0.5/VC	%	Relative 0.5 second capacity of VC (inspirat.) in percent
FIV0.75	l	0.75 second capacity (forced inspiratory volume in 0.75 seconds)
FIV0.75/VC	%	Relative 0.75 second capacity of VC (inspirat.) in percent
FIV1	l	Second capacity (forced inspiratory volume in 1 second)
FIV1%VC	%	Relative second capacity of VC (inspirat.) in percent
FIV1.5	l	1.5 second capacity (forced inspiratory volume in 1.5 seconds)
FIV1.5/VC	%	Relative 1.5 second capacity of VC (inspirat.) in percent
FIV2	l	2 second capacity (forced inspiratory volume in 2 seconds)
FIV2/VC	%	Relative 2 second capacity of VC (inspirat.) in percent
FIV3	l	3 second capacity (forced inspiratory volume in 3 seconds)
FIV3/VC	%	Relative 3 second capacity of VC (inspirat.) in percent
FVC	l	Forced vital capacity
IC	[l]	Inspiratory capacity (volume of air that can be inhaled after normal expiration) IRC + T
IRC	l	Inspiratory reserve volume
IVC	l	Inspiratory vital capacity

Abbreviation	Unit	Description
Lung age	Years	The patient's spirometric lung age is determined using the measured FEV1, if FEV1 is calculated depending on age (different depending on the predicted value).
MEF25%FVC	l/s	Forced expiratory flow at 75% of FVC.
MEF50%FVC	l/s	Forced expiratory flow at 50% of FVC
MEF75%FVC	l/s	Forced expiratory flow at 25% of FVC
MIF25%FVC	l/s	Forced inspiratory flow at 25% of FVC
MIF50%FVC	l/s	Forced inspiratory flow at 50% of FVC
MIF75%FVC	l/s	Forced inspiratory flow at 75% of FVC
MVV	l	Maximum voluntary ventilation
OBQ		Obstruction quotient
PEF	l/s	Peak flow, maximum expiratory flow
PIF	l/s	Peak flow, maximum inspiratory flow
tE	s	Average time of expiration at rest
tI	s	Average time of inspiration at rest
TV	l	Tidal volume
VCmax	l	Maximum vital capacity, inspiratory or expiratory
VTtI	l/s	Average inspiratory flow at rest

5.2 Calculation tables for predicted values

The predicted values define their areas of validity using age, height, weight, ethnicity etc. A suitable predicted value for the measurement is allocated to the patient according to his/her data. The standard setting for children and adults is GLI.

Abbreviations in the calculation tables

- A = Age
- H = Height
- G = Weight
- B = Broca index = weight : (height - 100)
- Fi = Obesity = H : $\sqrt[3]{W}$
- M = Predicted value
- S = Coefficient of variation
- AfrAm = Afro-American ethnicity
- NEAsia = North-East Asian ethnicity
- SEAsia = South-East Asian ethnicity
- Other = other ethnic groups

Multicèntrico di Barcelona		**Boys** **H = 85 - 180 cm | A = 6 - 20 years**	**Girls** **H = 85 - 180 cm | A = 6 - 20 years**
FVC	[l]	0.02800 * H + 0.03451 * G + 0.05728 * A - 3.21	0.03049 * H + 0.02220 * G + 0.03550 * A - 3.04
FEV1	[l]	0.02483 * H + 0.02266 * G + 0.07148 * A - 2.91	0.02866 * H + 0.01713 * G + 0.02955 * A - 2.87
MVV	[l]	(0.02483 * H + 0.02266 * G + 0.07148 * A - 2.91) * 37.5	(0.02866 * H + 0.01713 * G + 0.02955 * A - 2.87) * 37.5
FEF25-75%	[l/s]	0.038 * H + 0.140 * A - 4.33	0.046 * H + 0.051 * A - 4.30
PEF	[l/s]	0.075 * H + 0.275 * A - 9.08	0.073 * H + 0.134 * A - 7.57
MEF25%FVC	[l/s]	0.024 * H + 0.066 * A - 2.61	0.027 * H + 0.032 * A - 2.68
MEF50%FVC	[l/s]	0.017 * H + 0.157 * A + 0.029 * G - 2.17	0.046 * H + 0.067 * A - 4.17
FEV1%VC	[%]	-0.1902 * A + 85.58	-0.224 * A - 0.1126 * G + 94.88
		Men **H = 150 - 200 cm | A = >20 years**	**Women** **H = 150 - 200 cm | A = > 20 years**
FVC	[l]	0.0678 * H - 0.0147 * A - 6.05	0.0454 * H - 0.0221 * A - 2.83
FEV1	[l]	0.0499 * H - 0.0211 * A - 3.84	0.0317 * H - 0.0250 * A - 1.23
MVV	[l]	(0.0499 * H - 0.0211 * A - 3.84) * 37.5	(0.0317 * H - 0.0250 * A - 1.23) * 37.5
FEF25-75%	[l/s]	0.0392 * H - 0.0430 * A - 1.16	0.0230 * H - 0.0456 * A - 1.11
PEF	[l/s]	0.0945 * H - 0.0209 * A - 5.77	0.0448 * H - 0.0304 * A - 0.35
MEF25%FVC	[l/s]	0.0190 * H - 0.0356 * A - 0.14	0.02 * H - 0.031 * A - 0.0062 * G - 0.21
MEF50%FVC	[l/s]	0.0517 * H - 0.0397 * A - 2.40	0.0242 * H - 0.0418 * A - 1.62
FEV1%VC	[%]	-0.1902 * A + 85.58	-0.224 * A - 0.1126 * G + 94.88

Polgar79		**Boys** **H = 85 - 180 cm | A = 4 - 17 years**	**Girls** **H = 85 - 180 cm | A = 4 - 18 years**
		Men **H = 150 - 200 cm | A = 18 - 120 years**	**Women** **H = 150 - 200 cm | A = 18 - 120 years**
FVC	[l]	$2.12 * 0.000001 * H^{2.81}$	$2.34 * 0.000001 * H^{2.78}$
IVC	[l]	$2.12 * 0.000001 * H^{2.81}$	$2.34 * 0.000001 * H^{2.78}$
FEF25-75%	[l/s]	(219.66 + 2.72 * H) : 60	(219.66 + 2.72 * H) : 60
PEF	[l/s]	(467.96 + 5.59 * H) : 60	(376.51 + 4.85 * H) : 60

Polgar71		**Boys** **H = 85 - 180 cm | A = 4 - 17 years**	**Girls** **H = 85 - 180 cm | A = 4 - 18 years**
		Men **H = 150 - 200 cm | A = 18 - 120 years**	**Women** **H = 150 - 200 cm | A = 18 - 120 years**
FVC	[l]	$4.4 * 0.000001 * H^{2.67}$	$3.3 * 0.000001 * H^{2.72}$
IVC	[l]	$4.4 * 0.000001 * H^{2.67}$	$3.3 * 0.000001 * H^{2.72}$
FEV1	[l]	$2.1 * 0.000001 * H^{2.8}$	$2.1 * 0.000001 * H^{2.8}$
MVV	[l]	99.507 + 1.276 * H	99.507 + 1.276 * H
FEF25-75%	[l/s]	(207.7 + 2.621 * H) : 60	(207.7 + 2.621 * H) : 60
PEF	[l/s]	(425.5714 + 5.2428 * H) : 60	(-425.5714 + 5.2428 * H) : 60
PIF	[l/s]	5.26 + 0.06 * H	5.26 + 0.06 * H

Crapo		**Men**	**Women**
		H = 150 - 220 cm | A = 18 - 120 years	**H = 150 - 220 cm | A = 18 - 120 years**
FVC	[l]	6.00 * H - 0.0214 * A - 4.650	4.91 * H - 0.0216 * A - 3.590
IVC	[l]	6.00 * H - 0.0214 * A - 4.650	4.91 * H - 0.0216 * A - 3.590
FEV0.5	[l]	3.27 * H - 0.0152 * A - 1.914	2.38 * H - 0.0185 * A - 0.809
FEV1	[l]	4.14 * H - 0.0244 * A - 2.190	3.42 * H - 0.0255 * A - 1.578
MVV	[l]	(4.14 * H - 0.0244 * A - 2.190) * 37.5	(3.42 * H - 0.0255 * A - 1.578) * 37.5
FEV3	[l]	5.35 * H - 0.0271 * A - 3.512	4.42 * H - 0.0257 * A - 2.745
FEV1%VC	[%]	13.0 * H - 0.152 * A + 110.49	20.20 * H - 0.252 * A + 126.58
FEV3/VC	[%]	6.27 * H - 0.145 * A + 112.09	9.37 * H - 0.163 * A + 118.16
FEF25-75%	[l/s]	2.04 * H - 0.038 * A + 2.133	1.54 * H - 0.046 * A + 2.683

Morris		**Men**	**Women**
		H = 150 - 220 cm | A = 20 - 120 years	**H = 150 - 220 cm | A = 20 - 120 years**
FVC	[l]	5.83 * H - 0.025 * A - 4.241	4.52 * H - 0.024 * A - 2.852
IVC	[l]	5.83 * H - 0.025 * A - 4.241	4.52 * H - 0.024 * A - 2.852
FEV1	[l]	3.62 * H - 0.032 * A - 1.260	3.50 * H - 0.025 * A - 1.932
MVV	[l]	3.62 * H - 0.032 * A 1.260 * 37.5	3.50 * H - 0.025 * A - 1.932 * 37.5
FEV1%VC	[%]	107.12 - 12.28 * H - 0.2422 * A	88.70 - 2.67 * H - 0.1815 * A
FEF25-75%	[l/s]	1.85 * H - 0.045 * A + 2.513	2.36 * H - 0.030 * A + 0.551

Austrian reference values[1)]		**Men** **H = 1.44 - 2.00 m | A = 18 - 90 years**	**Women** **H = 1.40 - 1.90 m | A = 16 - 90 years**
FVC	[l]	-11.606 + 8.172H - 0.0339A * H + 1.2869 ln(A)	-10.815 + 6.640H - 0.0408A * H + 1.7293 ln(A)
FEV1	[l]	-8.125 + 6.212H - 0.0300A * H + 0.9770 ln(A)	-6.995 + 5.174 - 0.0314A * H + 1.0251 ln(A)
PEF	[l/s]	$(1.798 + 2.311 \ln(H) + 0.0159A - 0.000248A2)^2$	$(1.832 + 1.838 \ln(H) + 0.0078A - 0.000172A2)^2$
MEF75%FVC	[l/s]	$(1.581 + 1.854 \ln(H) + 0.0213A - 0.000283A2)^2$	$(1.779 + 1.421 \ln(H) + 0.0096A - 0.000179A2)^2$
MEF50%FVC	[l/s]	$(1.490 + 1.290 \ln(H) + 0.0125A - 0.000218A2)^2$	$(1.561 + 1.177 \ln(H) + 0.0045A - 0.000140A2)^2$
MEF25%FVC	[l/s]	$(1.314 + 0.898 \ln(H) - 0.0083A - 0.000026A2)^2$	$(1.372 + 0.938 \ln(H) - 0.0152A + 0.000036A2)^2$
FEV1%VC	[%]	101.99 - 1.191H2 - 3.962 ln(A)	118.993 - 3.0320H2 - 6.9053 ln(A)
		Boys **H = 1.09 - 1.96 m | A = 5 - 17.99 years**	**Girls** **H = 1.10 - 1.82 m | A = 5 - 15.99 years**
FVC	[l]	exp(-1.142 + 1.259H + 0.004070A vW)	exp(-3.842 + 4.1632 vH + 0.1341 vA - 1.614Fi)
FEV1	[l]	exp(-1.178 + 1.221H + 0.003841A vW)	exp(-3.877 + 3.9808 vH + 0.1485 vA - 1.322Fi)
PEF	[l/s]	exp(-0.214 + 0.921H + 0.0467A + 0.0020W)	exp(0.411 + 1.793 ln(H) + 0.4251 ln(A) - 0.910Fi)
MEF75%FVC	[l/s]	exp(-0.077 + 0.770H + 0.0373A + 0.0025W)	exp(0.455 + 1.616 ln(H) + 0.3738 ln(A) - 0.861Fi)
MEF50%FVC	[l/s]	exp(-0.522 + 0.843H + 0.0300A + 0.0035W)	exp(0.256 + 1.643 ln(H) + 0.3481 ln(A) - 1.089Fi)
MEF25%FVC	[l/s]	exp(-1.576 + 1.166H + 0.0219A + 0.0021W)	exp(-0.772 + 2.002 ln(H) + 0.3063 ln(A) - 0.409Fi)
FEV1%VC	[%]	$(101.99 - 1.191H^2 - 3.962\ln(A))$	92

Cherniak[2)]		**Men** **H = 150 - 190 cm | A = 15 - 79 years**	**Women** **H = 150 - 190 cm | A = 15 - 79 years**
FVC	[ml]	47.6 * H - 14 * A - 3180	30.7 * H - 15 * A - 1310
FEV1	[ml]	35.9 * H - 23 * A - 1510	23.7 * H - 19 * A - 0190
MVV	[ml]	(35.9 * H - 23 * A - 1510) * 37.5	(23.7 * H - 19 * A - 0190) * 37.5
PEF	[ml/s]	57.6 * H - 24 * A + 0230	35.9 * H - 18 * A + 1130
MEF75%FVC	[ml/s]	35.6 * H - 20 * A + 2730	27.1 * H - 19 * A + 2150
MEF50%FVC	[ml/s]	25.7 * H - 30 * A + 2400	24.5 * H - 23 * A + 1430
MEF25%FVC	[ml/s]	14.1 * H - 41 * A + 1610	09.2 * H - 35 * A +2220
		Boys **H = 75 - 180 cm | A = 3 - 17 years**	**Girls** **H = 75 - 180 cm | A = 3 - 17 years**
FVC	[ml]	40.53 * H + 51.34 * A - 3655	27.86 * H + 90.96 * A - 2554

Knudson[3)]		**Men** **H = 150 - 195 cm | A = 25 - 80 years**	**Women** **H = 150 - 195 cm | A = 25 - 80 years**
FVC	[ml]	65 * H - 29 * A - 5460	37 * H - 22 * A - 1770
FEV1	[ml]	52 * H - 27 * A - 4200	27 * H - 21 * A - 790
MVV	[ml]	(52 * H - 27 * A - 4200) * 37.5	(27 * H - 21 * A - 790) * 37.5
FEV1%VC	[%]	0.087 * H - 0.14 * A + 103.64	0.111 * H - 0.109 * A + 107.38
PEF	[ml/s]	94 * H - 35 * A - 5993	49 * H - 25 * A - 735
MEF75%FVC	[ml/s]	88 * H - 35 * A - 5620	43 * H - 25 * A - 130
MEF50%FVC	[ml/s]	69 * H - 15 * A - 5400	35 * H - 13 * A - 440
MEF25%FVC	[ml/s]	44 * H - 12 * A - 4140	-14 * A + 3040
		Boys **H = 140 - 193 cm | A = 12 - 25 years**	**Girls** **H = 140 - 193 cm | A = 12 - 25 years**
FVC	[ml]	59.0 * H - 73.9 * A - 6887	41.6 * H + 69.9 * A - 4447
FEV1	[ml]	51.9 * H - 6118	35.1 * H + 6.94 * A - 3762
MVV	[ml]	(51.9 * H - 6118) * 37.5	(35.1 * H + 6.94 * A - 3762) * 37.5
FEV1%VC	[%]	-0.0813 * H + 100.439	-0.1909 * H + 0.6655 * A + 109.97
PEF	[ml/s]	78.0 * H + 166 * A - 8060	49.0 * H + 157 * A - 3916
MEF75%FVC	[ml/s]	70.0 * H + 147 * A - 7054	44.0 * H + 144 * A - 3365
MEF50%FVC	[ml/s]	54.3 * H + 115 * A - 6385	28.8 * H + 111 * A - 2304
MEF25%FVC	[ml/s]	39.7 * H - 5.7 * A - 4242	24.3 * H + 292.3 * A - 7.5 * A2 - 4400.9
		Boys **H = 112 - 155 cm | A = 6 - 12 years**	**Girls** **H = 112 - 155 cm | A = 6 - 12 years**
FVC	[ml]	40.9 * H - 3376	43.0 * H - 3749
FEV1	[ml]	34.0 * H - 2814	33.6 * H - 2758
MVV	[ml]	(34.0 * H - 2814) * 37.5	(33.6 * H - 2758) * 37.5
FEV1%VC	[%]	0.0813 * H + 100.439	-0.1909 * H + 0.6655 * A + 109.97
PEF	[ml/s]	78.0 * H + 166 * A - 8060	49.9 * H + 157 * A - 3916
MEF75%FVC	[ml/s]	70.0 * H + 147 * A - 7054	44.0 * H + 144 * A - 3365
MEF50%FVC	[ml/s]	37.8 * H + 2545	184.6 * A + 736
MEF25%FVC	[ml/s]	17.1 * H - 1014.9	10.9 * H - 165.7

Ulmer[4)]		**Men** **H = 150 - 195 cm | A = 15 - 75 years** **G = 40 - 170 kg**	**Women** **H = 150 - 195 cm | A = 15 - 75 years** **G = 40 - 170 kg**
IVC	[ml]	82.243 * H - 20.4 * A - 8420.5 - 69.8 * B	56.695 * H - 19.4 * A - 5096 - 69.7 * B
IRC	[ml]	47.291 * H - 11.3 * A - 6632 + 1297.3 * B	35.751 * H - 6.4 * A - 4241.4 - 1016.1 * B
ERC	[ml]	41.995 * H - 7.8 * A - 3523.8 - 1875 * B	12.126 * H - 14.4 * A + 136 - 624.6 * B
FVC	[ml]	77.576 * H - 21.7 * A - 7769.5 - 151.3 * B	52.467 * H - 19.9 * A - 4412.3 - 400.4 * B
FEV1	[ml]	53.212 * H - 26.1 * A - 4234 - 71.8 * B	23.939 * H - 20.7 * A - 641.6 - 209 * B
MVV	[ml]	(53.212 * H - 26.1 * A - 4234 - 71.8 * B) * 37.5	(23.939 * H - 20.7 * A - 641.6 - 209 * B) * 37.5
PEF	[ml/s]	66.067 * H - 20.8 * A - 2981.3 - 1249.3 * B	55.175 * H - 31.4 * A - 1683.4 - 115.1 * B
MEF50%FVC	[ml/s]	30.584 * H - 44 * A + 672.3 + 668.5 * B	26.181 * H - 22.4 * A + 2618.1 + 124 * B
MEF25%FVC	[ml/s]	25.108 * H - 39 * A - 1254.2 + 697.4 * B	20.129 * H - 35.2 * A - 438.6 + 593.6 * B

Baur[5]		Men H = 1.55 - 1.95 m | A = 18 - 70 years	Women H = 1.45 - 1.80 m | A = 18 - 70 years
FVC	[l]	6.00 * H - 0.0214 * A - 4.650	4.91 * H - 0.0216 * A - 3.590
FEV1	[l]	4.14 * H - 0.0244 * A - 2.190	3.42 * H - 0.0255 * A - 1.578
MVV	[l]	(4.14 * H - 0.0244 * A - 2.190) * 37.5	(3.42 * H - 0.0255 * A - 1.578) * 37.5
PEF	[l/s]	6.14 * H - 0.043 * A + 0.15	5.50 * H - 0.030 * A - 1.11
MEF75%FVC	[l/s]	5.46 * H - 0.029 * A - 0.47	3.22 * H - 0.025 * A + 1.60
MEF50%FVC	[l/s]	3.79 * H - 0.031 * A - 0.35	2.45 * H - 0.025 * A + 1.16
MEF25%FVC	[l/s]	2.61 * H - 0.026 * A - 1.34	1.05 * H - 0.025 * A + 1.11

ECCS/Quanjer[6]		Men H = 150 - 195 cm | A = 25 - 75 years	Women H= 150 - 190 cm | A= 25 - 75 years
IVC	[ml]	61.03 * H - 28 * A - 4654	46.64 * H - 26 * A - 3284
FVC	[ml]	57.57 * H - 26 * A - 4345	44.26 * H - 26 * A - 2887
FEV1	[ml]	43.01 * H - 29 * A - 2492	39.53 * H - 25 * A - 2604
MVV	[ml]	(43.01 * H - 29 * A - 2492) * 37.5	(39.53 * H - 25 * A - 2604) * 37.5
FEV1%VC	[%]	87.21 * H - 0.179 * A	89.10 * H - 0.192 * A
PEF	[ml/s]	61.46 * H - 43 * A + 154	55.01 * H - 30 * A -1106
MEF75%FVC	[ml/s]	54.59 * H - 29 * A - 470	32.18 * H - 25 * A + 1596
MEF50%FVC	[ml/s]	37.94 * H - 31 * A - 352	24.50 * H - 25 * A + 1156
MEF25%FVC	[ml/s]	26.05 * H - 26 * A - 1336	10.50 * H - 25 * A + 1107
FEF25-75%	[ml/s]	19.4 * H - 43.0 * A + 2700.0	12.5 * H - 34.0 * A + 2920.0

Hankinson		Boys Caucasian/Asian H = 75 - 180 cm | A = 4 - 19 years
FEV1%VC	[%]	88.066 + (-0. 2066 * A)
FEV1	[l]	0.7453 + (-0.04106 * A) + (0.004477 * A * A) + (0.00014098 * H * H)
MVV	[l]	(0.7453 + (-0.04106 * A) + (0.004477 * A * A) + (0.00014098 * H * H)) * 37.5
FEV6	[l]	-0.3119 + (-0.18612 * A) + (0.009717 * A * A) + (0.00018188 * H * H)
FVC	[l]	-0.2584 + (-0.20415 * A) + (0.010133 * A * A) + (0.00018642 * H * H)
IVC	[l]	-0.2584 + (-0.20415 * A) + (0.010133 * A * A) + (0.00018642 * H * H)
PEF	[l/s]	-0.5962 + (-0.12357 * A) + (0.013135 * A * A) + (0.00024962 * H * H)
FEF25-75%	[l/s]	-1.0863 + (0.13939 * A) + (0.00010345 * H * H)
		Boys Afro-American **H = 75 - 180 cm | A = 4 - 19 years old**
FEV1%VC	[%]	89.239 + (-0.1828 * A)
FEV1	[l]	-0.7048 + (-0.05711 * A) + (0.004316 * A * A) + (0.00013194 * H * H)
MVV	[l]	((-0.7048 + (-0.05711 * A) + (0.004316 * A * A) + (0.00013194 * H * H)) * 37.5
FEV6	[l]	-0.5525 + (-0.14107 * A) + (0.007241 * A * A) + (0.00016429 * H * H)
FVC	[l]	-0.4971 + (-0.15497 * A) + (0.007701 * A * A) + (0.00016643 * H * H)
IVC	[l]	-0.4971 + (-0.15497 * A) + (0.007701 * A * A) + (0.00016643 * H * H)
PEF	[l/s]	-0.2684 + (-0.28016 * A) + (0.018202 * A * A) + (0.00027333 * H * H)
FEF25-75%	[l/s]	-1.1627 + (0.12314 * A) + (0.00010461 * H * H)
		Boys Latin-American **H = 75 - 180 cm | A = 4 - 19 years**
FEV1%VC	[%]	90.024 + (-0.2186 * A)
FEV1	[l]	-0.8218 + (-0.04248 * A) + (0.004291 * A * A) + (0.00015104 * H * H)
MVV	[l]	(-0.8218 + (-0.04248 * A) + (0.004291 * A * A) + (0.00015104 * H * H)) * 37.5
FEV6	[l]	-0.6646 + (-0.11270 * A) + (0.007306 * A * A) + (0.00017840 * H * H)
FVC	[l]	-0.7571 + (-0.09520 * A) + (0.006619 * A * A) + (0.00017823 * H * H)
IVC	[l]	-0.7571 + (-0.09520 * A) + (0.006619 * A * A) + (0.00017823 * H * H)
PEF	[l/s]	-0.9537 + (-0.19602 * A) + (0.014497 * A * A) + (0.00030243 * H * H)
FEF25-75%	[l/s]	-1.3592 + (0.10529 * A) + (0.00014473 * H * H)

Hankinson		**Girls Caucasian/Asian** **H = 75 - 180 cm | A = 4 - 17 years**
FEV1%VC	[%]	90.809 + (-0.2125 * A)
FEV1	[l]	-0.8710 + (0.06537 * A) + (0.00011496 * H * H)
MVV	[l]	(-0.8710 + (0.06537 * A) + (0.00011496 * H * H)) * 37.5
FEV6	[l]	-1.1925 + (0.06544 * A) + (0.00014395 * H * H)
FVC	[l]	-1.2082 + (0.05916 * A) + (0.00014815 * H * H)
IVC	[l]	-1.2082 + (0.05916 * A) + (0.00014815 * H * H)
PEF	[l/s]	-3.6181 + (0.60644 * A) + (-0.016846 * A * A) + (0.00018623 * H * H)
FEF25-75%	[l/s]	-2.5284 + (0.52490 * A) + (-0.015309 * A * A) + (0.00006982 * H * H)
		Girls Afro-American **H = 75 - 180 cm | A = 4 - 17 years**
FEV1%VC	[%]	91.655 + (-0.2039 * A)
FEV1	[l]	-0.9630 + (0.05799 * A) + (0.00010846 * H * H)
MVV	[l]	((-0.9630 + (0.05799 * A) + (0.00010846 * H * H)) * 37.5
FEV6	[l]	0.6370 + (-0.04243 * A) + (0.003508 * A * A) + (0.00013497 * H * H)
FVC	[l]	-0.6166+(-0.04687 * A) + (0.003602 * A * A) + (0.00013606 * H * H)
IVC	[l]	-0.6166+(-0.04687 * A) + (0.003602 * A * A) + (0.00013606 * H * H)
PEF	[l/s]	-1.2398 + (0.16375*A) + (0.00019746 * H * H)
FEF25-75%	[l/s]	-2.5379 + (0.43755 * A) + (-0.012154 * A * A) + (0.00008572 * H * H)
		Girls Latin-American **H = 75 - 180 cm | A = 4 - 17 years**
FEV1%VC	[%]	92.360 + (-0.2248 * A)
FEV1	[l]	-0.9641 + (0.06490 * A) + (0.00012154 * H * H)
MVV	[l]	((-0.9641 + (0.06490 * A) + (0.00012154 * H * H)) * 37.5
FEV6	[l]	-1.2410 + (0.07625 * A) + (0.00014106 * H * H)
FVC	[l]	-1.2507 + (0.07501 * A) + (0.00014246 * H * H)
IVC	[l]	-1.2507 + (0.07501 * A) + (0.00014246 * H * H)
PEF	[l/s]	-3.2549 + (0.47495 * A) + (-0.013193 * A * A) + (0.00022203 * H * H)
FEF25-75%	[l/s]	-2.1825 + (0.42451 * A) + (-0.012415 * A * A) + (0.00009610 * H * H)

Hankinson		**Men Caucasian/Asian** **H = 150 - 200 cm | A = 20 - 120 years**
FEV1%VC	[%]	88.066 + (-0.2066 * A)
FEV1	[l]	0.5536 + (-0.01303 * A) + (-0.000172 * A * A) + (0.00014098 * H * H)
MVV	[l]	(0.5536 + (-0.01303 * A) + (-0.000172 * A * A) + (0.00014098 * H * H)) * 37.5
FEV6	[l]	0.1102+(-0.00842 * A) + (-0.000223 * A * A) + (0.00018188 * H * H)
FVC	[l]	-0.1933 + (0.00064 * A) + (-0.000269 * A * A) + (0.00018642 * H * H)
IVC	[l]	-0.1933 + (0.00064 * A) + (-0.000269 * A * A) + (0.00018642 * H * H)
PEF	[l/s]	1.0523 + (0.08272 * A) + (-0.001301 * A * A) + (0.00024962 * H * H)
FEF25-75%	[l/s]	2.7006 + (-0.04995 * A) + (0.00010345 * H * H)
		Men Afro-American **H = 150 - 200 cm | A = 20 - 120 years**
FEV1%VC	[%]	89.239 + (-0.1828 * A)
FEV1	[l]	0.3411 + (-0.02309 * A) + (0.00013194 * H * H)
MVV	[l]	(0.3411 + (-0.02309 * A) + (0.00013194 * H * H)) * 37.5
FEV6	[l]	-0.0547 + (-0.02114 * A) + (0.00016429 * H * H)
FVC	[l]	-0.1517 + (-0.01821 * A) + (0.00016643 * H * H)
IVC	[l]	-0.1517 + (-0.01821 * A) + (0.00016643 * H * H)
PEF	[l/s]	2.2257 + (-0.04082 * A) + (0.00027333 * H * H)
FEF25-75%	[l/s]	2.1477 + (-0.04238 * A) + (0.00010461 * H * H)
		Men Latin-American **H = 150 - 200 cm | A = 20 - 120 years**
FEV1%VC	[%]	90.024 + (-0.2186 * A)
FEV1	[l]	0.6306 + (-0.02928 * A) + (0.00015104 * H * H)
MVV	[l]	(0.6306 + (-0.02928 * A) + (0.00015104 * H * H)) * 37.5
FEV6	[l]	0.5757 + (-0.02860 * A) + (0.00017840 * H * H)
FVC	[l]	0.2376 + (-0.00891 * A) + (-0.000182 * A * A) + (0.00017823 * H * H)
IVC	[l]	0.2376 + (-0.00891 * A) + (-0.000182 * A * A) + (0.00017823 * H * H)
PEF	[l/s]	0.0870 + (0.06580 * A) + (-0.001195 * A * A) + (0.00030243 * H * H)
FEF25-75%	[l/s]	1.7503 + (-0.05018 * A) + (0.00014473 * H * H)

Hankinson		**Women Caucasian/Asian** **H = 140 - 200 cm | A = 18 - 120 years**
FEV1%VC	[%]	90.809 + (-0.2125 * A)
FEV1	[l]	0.4333 + (-0.00361 * A) + (-0.000194 * A * A) + (0.00011496 * H * H)
MVV	[l]	(0.4333 + (-0.00361 * A) + (-0.000194 * A * A) + (0.00011496 * H * H)) * 37.5
FEV6	[l]	-0.1373 + (0.01317 * A) + (-0.000352 * A * A) + (0.00014395 * H * H)
FVC	[l]	-0.3560 + (0.01870 * A) + (-0.000382 * A * A) + (0.00014815 * H * H)
IVC	[l]	-0.3560 + (0.01870 * A) + (-0.000382 * A * A) + (0.00014815 * H * H)
PEF	[l/s]	0.9267 + (0.06929 * A) + (-0.001031 * A * A) + (0.00018623 * H * H)
FEF25-75%	[l/s]	2.3670 + (-0.01904 * A) + (-0.000200 * A * A) + (0.00006982 * H * H)
		Women Afro-American **H = 140 - 200 cm | A = 18 - 120 years**
FEV1%VC	[%]	91.655 + (-0.2039 * A)
FEV1	[l]	0.3433 + (-0.01283 * A) + (-0.000097 * A * A) + (0.00010846 * H * H)
MVV	[l]	(0.3433 + (-0.01283 * A) + (-0.000097 * A * A) + (0.00010846 * H * H)) * 37.5
FEV6	[l]	-0.1981 + (0.00047 * A) + (-0.000230 * A * A) + (0.00013497 * H * H)
FVC	[l]	-0.3039 + (0.00536 * A) + (-0.000265 * A * A) + (0.00013606 * H * H)
IVC	[l]	-0.3039 + (0.00536 * A) + (-0.000265 * A * A) + (0.00013606 * H * H)
PEF	[l/s]	1.3597 + (0.03458 * A) + (-0.000847 * A * A) + (0.00019746 * H * H)
FEF25-75%	[l/s]	2.0828 + (-0.03793 * A) + (0.00008572 * H * H)
		Women Latin-American **H = 140 - 200 cm | A = 18 - 120 years**
FEV1%VC	[%]	92.360 + (-0.2248 * A)
FEV1	[l]	0.4529 + (-0.01178 * A) + (-0.000113 * A * A) + (0.00012154 * H * H)
MVV	[l]	(0.4529 + (-0.01178 * A) + (-0.000113 * A * A) + (0.00012154 * H * H)) * 37.5
FEV6	[l]	0.2033 + (0.00020 * A) + (-0.000232 * A * A) + (0.00014106 * H * H)
FVC	[l]	0.1210 + (0.00307 * A) + (-0.000237 * A * A) + (0.00014246 * H * H)
IVC	[l]	0.1210 + (0.00307 * A) + (-0.000237 * A * A) + (0.00014246 * H * H)
PEF	[l/s]	0.2401 + (0.06174 * A) + (-0.001023 * A * A) + (0.00022203 * H * H)
FEF25-75%	[l/s]	1.7456 + (-0.01195 * A) + (-0.000291 * A * A) + (0.00009610 * H * H)

HSU		**Boys** **H = 75 - 180 cm | A = 7 - 18 years**	**Girls** **H = 75 - 180 cm | A = 7 - 18 years**
FVC	[l]	(3.58 : 10000) * $H^{3.18}$: 1000	(2.57 : 1000) * $H^{2.78}$: 1000
IVC	[l]	(3.58 : 10000) * $H^{3.18}$: 1000	(2.57 : 1000) * $H^{2.78}$: 1000
FEV1	[l]	(7.74 : 10000) * $H^{3.00}$: 1000	(3.79 : 1000) * $H^{2.68}$: 1000
MVV	[l]	(7.74 : 10000) * $H^{3.00}$: 1000 * 37.5	(3.79 : 1000) * $H^{2.68}$: 1000 * 37.5
PEF	[l/s]	((3.35 : 10000) * $H^{2.79}$) : 60	((2.58 : 1000) * $H^{2.37}$) : 60
FEF25-75%	[l/s]	((7.98 : 10000) * $H^{2.46}$) : 60	((3.79 : 1000) * $H^{2.16}$) : 60

Schindl[7)]		**Boys**	**Girls**
		H = 110 - 180 cm | A = 10 - 18 years	H = 110 - 180 cm | A = 10 - 18 years
FVC	[ml]	49.2 * H + 118.2 * A - 6006.0	41.7 * H + 91.3 * A - 4660.6
FEV1	[ml]	41.9 * H + 79.0 * A 4674.4	41.9 * H + 70.6 * A - 4176.1
PEF	[ml/s]	76.8 * H + 224.2 * A 8381.5	62.1 * H + 176.3 * A - 5623.2
MEF75%FVC	[ml/s]	56.2 * H + 175.4 * A - 5530.3	46.5 * H + 154.7 * A - 3627.9
MEF50%FVC	[ml/s]	41.5 * H + 109.5 * A - 3988.0	48.3 * H + 115.6 * A - 4896.6
MEF25%FVC	[ml/s]	30.3 * H + 39.0 * A - 3059.9	38.8 * H + 51.4 * A - 4331.9

ECCS Children/Quanjer		Boys H = 75 - 180 cm | A = 4 - 17 years	Girls H = 75 - 180 cm | A = 4 - 17 years
FVC	[l]	$H^{2.7}$	0.95 * $H^{2.7}$
IVC	[l]	$H^{2.7}$	0. 95 * $H^{2.7}$
FEV1	[l]	0.84 * $H^{2.7}$	0.81 * $H^{2.7}$
MVV	[l]	0.84 * $H^{2.7}$ * 37.5	0.81 * $H^{2.7}$ * 37.5
FEV1%VC	[%]	84	84
PEF	[l/s]	8.2 * H - 6.8	6.7 * H - 5.3
FEF50%FVC	[l/s]	5.6 * H - 4.4	4.6 * H - 3.3
MEF50%FVC	[l/s]	5.6 * H - 4.4	4.6 * H - 3.3

Zapletal[8)]		Boys H = 115 - 180 cm | A = 6 - 17 years	Girls H = 115 - 180 cm | A = 6 - 17 years
logVC	[ml]	-2.5768 + 2.7799 log(H)	-2.2970 + 2.6361 log(H)
logIRC	[ml]	-2.79590 + 2.73794 log(H)	-2.69813 + 2.67126 log(H)
logERC	[ml]	-3.81064 + 3.12550 log(H)	-2.74262 + 2.61668 log(H)
logVT	[ml]	-1.3956 + 1.8643 log(H)	-1.3956 + 1.843 log(H)
logFVC	[ml]	-2.9239 + 2.9360 log(H)	-2.7040 + 2.8181 log(H)
logFEV1	[ml]	-2.86521 + 2.87294 log(H)	-2.60565 + 2.74136 log(H)
FEV1%VC	[%]	90.6043 - 0.04104 * H	90.6043 - 0.0410 * H
logPEF	[l/s]	-4.37221 + 2.34275 log(H)	-4.37221 + 2.34275 log(H)
logMEF75%FVC	[l/s]	-4.01648 + 2.1541 log(H)	-4.01648 + 2.15414 log(H)
logMEF50%FVC	[l/s]	-4.21684 + 2.17719 log(H)	-4.21684 + 2.17719 log(H)
logMEF25%FVC	[l/s]	-4.58082 + 2.21169 log(H)	-4.58082 + 2.21169 log(H)
MVV	[ml]	-1.9178 + 3.0388 log(H)	-1.9178 + 3.0388 log(H)

GLI - Global Lung Function Initiative[9)]	Men and women Age = 3 - 95 years FEF25-75% and MEF25%FVC: 3 to 90 years of age
	The predicted values are calculated for: FVC, FEV1, FEV1/FVC, FEF25-75%, FEF75%FVC, FEV075 (only children 3 to 7 years, Caucasian), FEV075/FVC (only children 3 to 7 years, Caucasian) The predicted values are calculated depending on age, gender, height and ethnicity (African American, North-East Asian, South-East Asian, Caucasian and other/mixed). The predicted values are calculated using this formula: M = exp(a0 + a1 * ln(Height) + a2 * ln(Age) + a3 * AfrAm + a4 * NEAsia + a5 * SEAsia + a6 * Other + Mspline) For the coefficients a1, a2, a3 etc. there are defined value tables for each measured value of GLI from which the corresponding values are inserted into the calculation formula. The calculation formula remains the same for all the measured values mentioned above. Mspline is an age and measured value-dependent coefficient which is also taken from a value table defined by GLI. The value PEF is not calculated when using the predicted value GLI. Therefore, no predicted value curve can be mapped in the coordinate system in seca diagnostic.

Kainu (Finland)[10)]	**Men and women** **Age = 18 - 83.99 years, ethnicity: none**
	The predicted values are calculated for: FEV1, FVC, FEV1FVC, MEF75, MEF50, MEF25, MMEF (FEF25-75), PEF, FEV6, FEV1FEV6. The predicted values are calculated depending on gender, height and age. The predicted values are calculated using these formulas: M = exp(a0 + a1 * ln(height) + a2 * ln(age) + Mspline) S = exp(b0 + b1 * ln(Age) + Sspline) LLN = M - 1.645 * S For the coefficients a0, a1, a2, b0 and b1, there are defined values for each measured value of Kainu, which are inserted into the calculation formula to calculate the respective predicted value. The calculation formula remains the same for all the measured values mentioned above. Mspline and Sspline are age and measured value-dependent coefficients which are also taken from a value table defined by Kainu.

Siriraj. Thailand[11)]		**Men** **H = 155 - 185 cm | A = 18 - 80 years**
FVC	[l]	-2.601 + 0.122 * A - 0.00046 * A^2 + 0.00023 * H^2 - 0.00061 * A * H
FEV1	[l]	-7.914 + 0.123 * A + 0.067 * H - 0.00034 * A^2 - 0.0007 * A * H
FEF25-75%	[l/s]	-19.049 + 0.201 * A + 0.207 * H - 0.00042 * A^2 - 0.00039 * H^2 - 0.0012 * A * H
PEF	[l/s]	-16.895 + 0.307 * A + 0.141 * H - 0.0018 * A^2 - 0.001 * A * H
FEV1/FVC	---	19.362 + 0.49 * A + 0.829 * H - 0.0023 * H^2 - 0.0041 * A * H
		Women **H = 155 - 185 cm | A = 18 - 80 years**
FVC	[l]	-5.914 + 0.088 * A + 0.056 * H - 0.0003 * A^2 - 0.0005 * A * H
FEV1	[l]	-10.6 + 0.085 * A + 0.12 * H - 0.00019 * A^2 - 0.00022 * H^2 - 0.00056 * A * H
FEF25-75%	[l/s]	-21.528 + 0.11 * A + 0.272 * H - 0.00017 * A^2 - 0.0007 * H^2 - 0.00082 * A * H
PEF	[l/s]	-31.355 + 0.162 * A + 0.391 * H - 0.00084 * A^2 - 0.00099 * H^2 - 0.00072 * A * H
FEV1/FVC	---	83.126 + 0.243 * A + 0.084 * H + 0.002 * A^2 - 0.0036 * A * H

Danish Reference Values[12)]		**Men** **H = 155 - 200 cm | A = 20 - 90 years**
FVC	[l]	-2.87615 - 0.00026 * A2 + 0.04201 * H
FEV1	[l]	-5.17591 - 0.00026 * A2 + 0.06015 * H
FEV1/FVC	---	105.77443 - 0.00126 * A2 - 0.12261 * H
		Women **H = 150 - 195 cm | A = 20 - 90 years**
FVC	[l]	-1.35015 - 0.00024 * A2 + 0.02923 * H
FEV1	[l]	-2.80132 - 0.00023 * A2 + 0.04203 * H
FEV1/FVC	---	105.57449 - 0.00165 * A2 - 0.12431 * H FVC

References for predicted values

1) Austrian reference values – sources: Skriptum SPIROMETRIE Der Österreichischen Gesellschaft für Pneumologie; Prepared by the members of the Working Group for Clinical Respiratory Physiology, Standardization and Assessment.

2) Cherniak – sources: PH. H. Quanjer et al. "Lung Volumes and Forced Ventilatory Flows" Report Working Party, Standardization of Lung Function Tests, European Community of Steel and Coal; The European Respiratory Journal 1993, Volume 6, Supplement 16, 5 - 40; "Standardization of Lung Function Tests in Paediatrics" The European Respiratory Journal, Volume 2, Supplement 4, March 1989, ISBN 87-16-14801-0; R.M. Cherniak, M.B. Raber "Normal standards of ventilatory function..." Am. Rev. Respir. Dis. 1972; R.M. Cherniak "Ventilatory function in normal children" Canad. Med. Assoc. 1962;

3) Knudson – sources: PH. H. Quanjer et al. "Lung Volumes and Forced Ventilatory Flows" Report Working Party, Standardization of Lung Function Tests, European Community of Steel and Coal; The European Respiratory Journal 1993, Volume 6, Supplement 16, 5 - 40; "Standardization of Lung Function Tests in Paediatrics" The European Respiratory Journal, Volume 2, Supplement 4, March 1989, ISBN 87-16-14801-0; R. J. Knudson, M.D. Lebowitz, R.C. Slatin "Normal standards variability, and effects of age" AM. Rev. Respir. Dis. 1983;

4) Ulmer – sources: PH. H. Quanjer et al. "Lung Volumes and Forced Ventilatory Flows" Report Working Party, Standardization of Lung Function Tests, European Community of Steel and Coal; The European Respiratory Journal 1993, Volume 6, Supplement 16, 5 - 40; W.T. Ulmer et al. "Lungenfunktion: Physiologie und Pathophysiologie" Methodology, 2nd Edition, Thieme Stuttgart, 1983; W.T. Ulmer, G. Reichel, D. Nolte, M.S. Islam "Die Lungenfunktion" 3rd Edition, Thieme-Verlag Stuttgart, 1983;

5) Baur – sources: X. Baur "Lungenfunktionsprüfung und Allergiediagnostik" Dustri-Verlag, Dr. Karl Feistle, 1998, ISBN 3-87185-270-8;

6) ECCS – sources: PH. H. Quanjer et al. "Lung Volumes and Forced Ventilatory Flows" Report Working Party, Standardization of Lung Function Tests, European Community of Steel and Coal; The European Respiratory Journal 1993, Volume 6, Supplement 16, 5 - 40; W. Schmidt "Angewandte Lungenfunktions-Prüfung" 3rd Edition, 1987, Dustri-Verlag, ISBN 3-87185-130-2; G. J. Tammeling, PH. H. Quanjer: "Physiologie der Atmung" Thomae; H. Löllgen "Kardiopulmonale Funktionsdiagnostik" CIBA-GEIGY GmbH;

7) Schindl – sources: R. Schindl, K. Aigner "Atemfunktionsscreening und Sollwertebezug bei Kindern und Jugendlichen";

8) Zapletal – sources: A. Zapletal., M. Samánek, T. Paul "Lung Function in Children and Adolescents" Progress in Respiration Research, Volume 22, Kager-Verlag, ISBN 3-8055-4495-2; PH. H. Quanjer et al. "Lung Volumes and Forced Ventilatory Flows" Report Working Party, Standardization of Lung Function Tests, European Community of Steel and Coal; The European Respiratory Journal 1993, Volume 6, Supplement 16, 5 - 40; "Standardization of Lung Function Tests in Paediatrics" The European Respiratory Journal, Volume 2, Supplement 4, March 1989, ISBN 87-16-14801-0;

9) www.lungfunction.org

10) Reference values of spirometry for Finnish adults: A. Kainu, K.L. Timonen, J. Toikka, B. Quaiser, J. Pitkäniemi, J. T. Kotaniemi, A. Lindqvist, E. Vanninen, E. Länsinies and A. R. A. Sovijärvi

11) Siriraj, Thailand: Dejsomritrutal W., Nana A., Maranetra N., et al. Reference spirometric values for healthy lifetime nonsmokers in Thailand. J Med Assoc Thai 2000; 83:457-466.

12) Danish Reference Values: Løkke A, Marott JL, Mortensen J, Nordestgaard BG, Dahl M and Lange P. New Danish reference values for spirometry. Clin Respir J DOI:10.1111/j.1752-699X.2012.00297.x.

5.3 Keyboard navigation and shortcuts

Use the quick access, keyboard control and keyboard shortcuts to work quickly and conveniently.

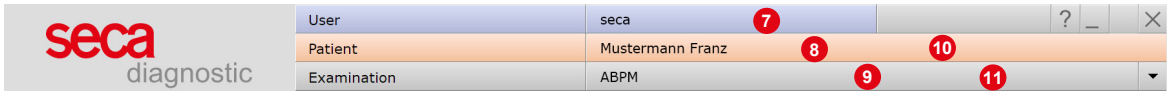
Quick links in the main navigation

Left click

→ 1 Change user password
→ 2 Call last patient
→ 3 Examination main menu

Right click

→ 4 Evaluation search
→ 5 Call last patient
→ 6 Most recently opened evaluation



Left click

→ 7 Change user password
→ 8 Patient master data
→ 9 Menu of the current examination

Right click

→ 10 All evaluations of the patient
→ 11 Last opened evaluations of this examination

Keyboard navigation

Pressing the Alt key underlines the first letter of a screen button. Pressing an initial letter again triggers the corresponding button.

Keyboard shortcuts

General shortcuts

Enter	Confirm
Tabulator	Cursor jumps to next input field (patient menu)
Ctrl H	User main menu
Ctrl P	Patient main menu
Ctrl U	Examination main menu
Ctrl A	All examinations of the selected patient
Ctrl G	List of last opened evaluations (same as clicking on the arrow button at top right)
Ctrl L	Evaluation search
Ctrl W	Work list
Ctrl Q	Device list

Generally valid keyboard shortcuts in an open evaluation

Ctrl N	Unconfirmed report input dialogue
Ctrl K	Medication input dialogue
Ctrl T	Call trend
Ctrl D	Call print dialogue
Ctrl O	Call options menu

5.4 Manufacturer’s declaration regarding EMC

Electromagnetic compatibility (EMC) according to DIN EN 60601-1-2:2022-01

Lead lengths

USB cable:	approx. 3000 mm

Manufacturer's declaration – electromagnetic emissions

Emission measurements	EMC standard / test method	Compliance
RF emissions	CISPR11	Group 1
RF emissions	CISPR11	Class B
Harmonics	IEC 61000-3-2	Not applicable
Voltage fluctuations/flickers	IEC 61000-3-3	Not applicable

Manufacturer’s declaration – electromagnetic immunity

seca spiro mobile meets the test levels specified here.

Phenomenon	EMC standard / test method	IMMUNITY TEST LEVEL
Static electricity discharge (ESD)	IEC 61000-4-2	± 8 kV contact; ± 2 kV, ± 4 kV, ± 8 kV air
Radio-frequency electromagnetic fields	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz
Radiofrequency electromagnetic fields in the in the immediate vicinity of wireless communication devices	IEC 61000-4-3	Conforms to the standard, for the immunity test level refer to the table on the next page
Quick transient electric interference factors / bursts	IEC 61000-4-4	± 2 kV 100 kHz Repetition frequency
Surges line against line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges line against earth	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances, induced by high-frequency fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM frequency bands between 0.15 MHz and 80 MHz[1)] 80 % AM at 1 kHz
Power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz
Voltage drops	IEC 61000-4-11	0% UT; ½ period[2)] Mains 100V/50Hz and 240V/50Hz
		0% UT; 1 period[2)] and 70% UT; 25/30 periods[2)] Mains 100V/50Hz and 240V/50Hz
Voltage interruptions	IEC 61000-4-11	0% UT; 250/300 periods[2)] Mains 100V/50Hz and 240V/50Hz
Magnetic fields in close proximity	IEC 61000-4-39	Not applicable

1) The ISM bands (EN: Industrial, Scientific and Medical, i.e., frequency bands used for industrial, scientific and medical purposes) between 0.15 MHz and 80 MHz are 6.765 to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz; 3.5 MHz to 4.0 MHz; 5.3 MHz to 5.4 MHz; 7 MHz to 7.3 MHz; 10.1 MHz to 10.15 MHz; 14 MHz to 14.2 MHz; 18.07 MHz to 18.17 MHz; 21 MHz to 21.4 MHz; 24.89 MHz to 24.99 MHz; 28 MHz to 29.7 MHz and 50 MHz to 54.0 MHz.

2) UT is the alternating supply voltage prior to application of test levels

Recommended protective distances between portable and mobile RF telecommunication devices and seca spiro mobile

seca spiro mobile is designed for use in an electromagnetic environment in which the RF transients can be controlled. The user can help avoid electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the device - depending on the power output of the communication device, as indicated below.

Portable RF communication devices (radios) (including their accessories such as antenna cables and external antennas) should not be used within 12 inches (30 cm) of the manufacturer's designated parts and leads of the seca spiro mobile device. Failure to observe this warning can compromise the performance of the device.

Use of this device directly next to other devices or stacked together with other devices should be avoided, as this could result in fault operation. If the devices must nonetheless be used as described above, this device and the other devices should be monitored to ensure proper functionality.

Frequency band[a)]	MHz radio service[a)]	Maximum output in W	Clearance in m	Immunity test level in V/m
380 to 390	TETRA 400	1.8	0.3	27
430 to 470	GMRS 460, FRS 460	2	0.3	28
704 to 787	LTE Band 13, 17	0.2	0.3	9
800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	2	0.3	28
1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	2	0.3	28
2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	2	0.3	17
5100 to 5800	WLAN 802.11 a/n	0.2	0.3	9

a) For some radio services, only the frequencies for the radio link from the mobile communication device to the base station (EN: uplink) have been included in the table.

NOTE Protective distances: The minimum distances for higher immunity test levels must be calculated using the following equation: $E = 6/d * \sqrt{P}$

P is the maximum output in Watt (W), d the minimum clearance in metres (m) and E the immunity test level in Volts per metre (V/m).

General COMMENTS: These guidelines may not apply in every case. The propagation of electromagnetic variables is influenced by absorptions and reflections of buildings, objects and people.

5.5 EC Declaration of Conformity

Simplified declaration of conformity

seca spiro mobile complies with the requirements of the Medical Device Regulation (EU) 2017/745 and Directive 2011/65/EU.

Hereby, custo med declares that the radio device type(s) custo screen 300 (seca screen 300), custo guard holter (seca guard holter) and custo cardio 300 BT (seca ct331) is/are in compliance with Directive 2014/53/EU.

The full text of the EC declaration of conformity is available at the following internet address:
https://www.customed.de/information/zertifizierung/konformitaetserklaerungen

Declarations of Conformity for accessories and supplementary parts, if applicable, can also be found there.

5.6 Product components and accessories

Description	Product designation	Part no.	Quantity/pc.
	seca spiro mobile	11055	1

Description	Accessories	Part no.	Quantity/pc.
	seca spiro mobile measuring unit	11036	1
	seca spiro mobile adapter	11037	1
	spiro protect bacterial and viral filter	21026	Box of 200 pieces

Description	Complementary parts	Part no.	Quantity/pc.
	Nasal clip	21002	10 pieces
	Calibration pump 3 liters	21299	1

All parts listed here are available separately.

We recommend the following:

- → seca spiro mobile
- → seca spiro mobile measuring unit
- → seca spiro mobile adapter
- → spiro protect bacterial and viral filter
- → Nasal clip
- → Calibration pump

5.7 List of Figures

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custo diagnostic (medical PC software)

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seca product names:
seca spiro mobile (spirometry device)
seca diagnostic (medical PC software)

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