Instructions for Use

Software

seca diagnostic 5.9

seca
Precision for health

Manufacturer:

custo med GmbH
Maria-Merian-Str. 6
85521 Ottobrunn
Ottobrunn, Germany

Phone: 0049 (0) 89 710 98 - 00
Fax: 0049 (0) 89 710 98 - 10
Email: info@customed.de
Internet: www.customed.de

custo med product names:
custo screen 300 (ABPM recorder)
custo guard holter (holter ECG device)
custo cardio 300 (12-channel PC ECG device)
custo spiro mobile (spirometry device)
custo diagnostic (medical PC software)

Distribution:

seca Ltd.
40 Barn Street
Birmingham
West Midlands
B5 5QB
Phone: 0121 643 9349
Fax: 0121 633 3403
Email: info.uk@seca.com

All contact details at www.seca.com

seca product names:
seca screen 300 (ABPM recorder)
seca guard holter (holter ECG device)
seca ct330/331 (12-channel PC ECG device)
seca spiro mobile (spirometry device)
seca diagnostic (medical PC software)

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Table of Contents

1 General notes

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

1.2 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.

1.3 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.

1.4 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.

1.5 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.

2 Safety

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.

2.2 Ambient conditions, handling of the devices

Emissions

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

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

Strong electromagnetic sources in the immediate vicinity of the seca diagnostic device/system may result in recording errors. The seca diagnostic 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 diagnostic 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.

2.3 Patient safety

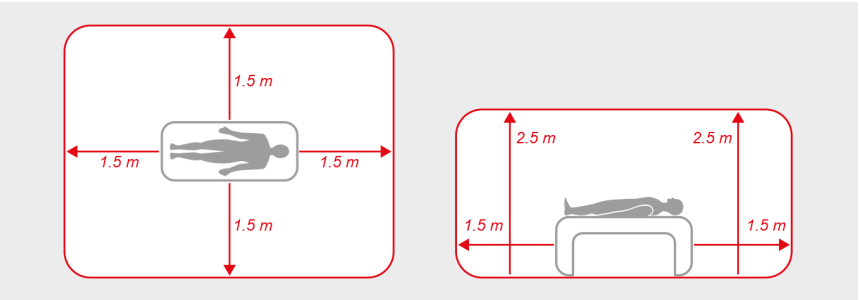


Fig. 1: Safety distances at the patient area

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.

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.

2.5 Decommissioning

IMPORTANT: Before decommissioning, ensure that all legal retention periods for medical records are known before permanently deleting data.

Archiving via the seca diagnostic service center

→ Before decommissioning, a data backup must be performed if required.
→ The data to be backed up is selected in the seca diagnostic service center and moved from there to the archiving system.
→ In the seca diagnostic service center, select the data to be backed up and move it to the corresponding archiving system.

Archiving as PDF/A

→ Alternatively, all evaluations can be exported as a PDF report (PDF/A compatible).
→ After decommissioning, evaluations and reports can be displayed with a standard PDF reader.

Deletion of data

→ All patients and evaluations that are no longer required should then be deleted either via the seca diagnostic service center or directly from the data directory of the seca diagnostic server.

3 Description of the software

3.1 Symbols used on the product 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
REF	Order number/designation
	Follow the Operating Manual!
MD	Medical device
CE 0123	CE mark
UDI	Unique Device Identifier
	Separate collection of electrical and electronic equipment, do not dispose with domestic waste.

The “Separate collection of electrical and electronic equipment” symbol is located on the seca diagnostic CD or DVD. CDs or DVDs must not be disposed of with household waste.

3.2 Intended use

seca diagnostic is software for displaying, measuring, analysing, interpreting, reporting and managing patient-related vital signs of the cardiovascular system and the lungs for diagnostic purposes.

seca diagnostic is intended for use by trained specialists or physicians in clinics, medical practices or other health care facilities.

seca diagnostic must be used only with certified medical devices for recording and measuring vital signs that have been approved by custo med.

seca diagnostic is designed to exchange data with higher-level management systems (general practice EPR system, hospital information system) or other software via defined interfaces that have been approved by custo med.

seca diagnostic is not intended for use with Class IIb or III medical devices.

seca diagnostic must be used only for diagnostic purposes. The software is not suitable for monitoring patients and their vital signs, e.g. for use in intensive care medicine.

All results obtained from automatic analysis and the resulting unconfirmed reports 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.

3.3 Indications and contraindications

3.3.1 ABPM

Mancia, G., Fagard, R., Narkiewicz, K., Redón, J., Zanchetti, A., Böhm, M., Christiaens, T., Cifkova, R., De Backer, G., Dominiczak, A., Galderisi, M., Grobbee, D. E., Jaarsma, T., Kirchhof, P., Kjeldsen, S. E., Laurent, S., Manolis, A. J., Nilsson, P. M., Ruilope, L. M., … Task Force Members. (2013). 2013 ESH/ESC Guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). Journal of Hypertension, 31(7), 1281–1357. https://doi.org/10.1097/01.hjh.0000431740.32696.cc

ABPM indications

Indications for home blood pressure measurement or ambulatory blood pressure recording:

- → Suspected white coat hypertension (isolated office hypertension)
- → Grade 1 hypertension in the office
- → Isolate office hypertension in persons without asymptomatic end-organ damage and with low overall cardiovascular risk
- → Suspected masked hypertension
- → Highly normal blood pressure values in the office
- → Normal blood pressure values in the office in patients with asymptomatic end-organ damage or high overall cardiovascular risk
- → Detection of white coat effect in hypertensive patients
- → Wide variation of office blood pressure values during one or different examinations
- → Location-dependent, postprandial or drug-induced hypotension
- → Elevated office blood pressure or suspected pre-eclampsia in pregnant women
- → Identification of resistant or pseudo-resistant hypertension

Specific indications for ambulatory blood pressure recording:

- → Lack of correspondence between office blood pressure values and home blood pressure values
- → Characterisation of circadian rhythms
- → Suspected nocturnal hypertension or suspected nondipping, e.g. in patients with sleep apnoea, chronic kidney disease or diabetes mellitus
- → Assessment of blood pressure variability

Ambulatory blood pressure contraindications and relative contraindications

The following contraindications are converse to measuring blood pressure by means of a cuff on the arm and thus against recording ambulatory blood pressure:

- → Lymphoedema
- → Paresis, plegia
- → Arterial or venous vascular access (e.g. Viggo)
- → Dialysis shunt
- → Fresh (surgical) wounds
- → Condition after ablatio mammae
- → Thrombosis of the measuring arm
- → Acute myocardial infarction

3.3.2 Holter ECG

Sauer, G., Andresen, D., Cierpka, R., Lemke, B., Mibach, F., Perings, Ch., & Vaerst, R. (2005). Positionspapier zur Durchführung von Qualitätskontrollen bei Ruhe-, Belastungs- und Langzeit-EKG. Zeitschrift für Kardiologie, 94(12), 844–857. https://doi.org/10.1007/s00392-005-0320-4

Indications for Holter ECG

- Symptoms that may be related to arrhythmias
  - Syncope
  - Presyncope
  - Dizziness with an otherwise unexplained cause
  - Recurrent palpitations or tachycardia
  - Unexplained episodes of dyspnoea, chest pain and fatigue
- In the context of antiarrhythmic therapy
  - Verification of efficacy
  - Evidence of possible proarrhythmic events
  - Verification of rate control in atrial fibrillation
- In asymptomatic patients
  - For postinfarction risk stratification
  - In patients with severe left ventricular dysfunction (dilated cardiomyopathy, secondary ischaemic cardiomyopathy)
  - For diagnosis of intermittent atrial fibrillation
  - In patients with hypertrophic obstructive cardiomyopathy
  - Therapy monitoring
- In patients with antibradycardia or antitachycardia therapy systems
  - Syncope, presyncope or frequent palpitations
  - If systemic dysfunction is suspected that cannot be diagnosed by pacemaker/ICD monitoring
- Holter ECG recording with heart rate variability analysis in
  - Post-infarction patients with left ventricular dysfunction
  - Patients with severe chronic heart failure (dilated cardiomyopathy, secondary ischaemic cardiomyopathy)
  - In patients with hypertrophic obstructive cardiomyopathy
  - Patients with cardiac involvement of another extracardiac underlying disease, e.g. diabetes

3.3.3 Resting and stress ECG

Sauer, G., Andresen, D., Cierpka, R., Lemke, B., Mibach, F., Perings, Ch., & Vaerst, R. (2005). Positionspapier zur Durchführung von Qualitätskontrollen bei Ruhe-, Belastungs- und Langzeit-EKG. Zeitschrift für Kardiologie, 94(12), 844–857. https://doi.org/10.1007/s00392-005-0320-4

Indications Resting ECG

- Suspected cardiovascular system disorder (e.g. MI, CHD, cardiac insufficiency, arterial hypertension, hypertrophy, myocarditis, pericarditis)
- Supervision and monitoring of patients with acute or chronic cardiovascular disorders (e.g. MI, CHD, cardiac insufficiency, arterial hypertension, hypertrophy, myocarditis, pericarditis)
- To assess a preoperative risk
- To assess a postoperative intervention
- To assess and supervise medication therapy (in particular for cardiologically active substances such as tricyclic antidepressants, neuroleptics, etc.)
- To assess structural heart problems with cardiac arrhythmia (especially sinus tachycardia and sinus bradycardia)
- Suspicion or monitoring of (cardiac) hypertrophy
- To check for comorbidities (for example with chronic respiratory disease)
- As part of pacemaker therapy

- → For angina pectoris
- → For suspected or diagnosed arterial sclerosis
- → For suspected or diagnosed PAD (peripheral arterial disease)
- → For diagnosed renal arterial stenosis
- → To assess patients as part of a rehabilitation program
- → Acute coronary syndrome with no ST segment elevation (NSTE-ACS)

Sauer, G., Andresen, D., Cierpka, R., Lemke, B., Mibach, F., Perings, Ch., & Vaerst, R. (2005). Positionspapier zur Durchführung von Qualitätskontrollen bei Ruhe-, Belastungs- und Langzeit-EKG. Zeitschrift für Kardiologie, 94(12), 844–857. https://doi.org/10.1007/s00392-005-0320-4

Indications Stress ECG

- → For CHD diagnosis
- → Post-myocardial infarction
- → Before and after revascularisation measures for progress monitoring
- → For patients with diagnosed or suspected arrhythmia
- → For patients with arterial hypertension
- → To record physical resilience

Contraindications Stress ECG

Absolute:

- → Acute myocardial infarction
- → Unstable angina pectoris
- → Cardiac arrhythmia with symptomatology and/or impaired haemodynamics
- → Symptomatic severe aortic stenosis
- → Decompensated cardiac insufficiency
- → Acute lung embolism
- → Acute myocarditis
- → Acute perimyocarditis
- → Acute aortic dissection

Relative:

- → Main stem stenosis
- → Moderate valvular disease
- → Diagnosed electrolyte disorder
- → Arterial hypertension (syst. 200, diast. > 110 mmHg)
- → Tachyarrhythmia or bradyarrhythmia
- → Hypertrophic obstructive cardiomyopathy and other outflow tract obstructions
- → Higher-degree atrioventricular blockage
- → Physical and/or mental impairments

3.3.4 Spirometry

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.

3.4 Approved devices and interfaces

Medical devices approved by custo med for connection to seca diagnostic:

Device name	Type	Manufacturer
seca ct330/331	Electrocardiograph	custo med GmbH
seca guard holter	Holter ECG Recorder	custo med GmbH
seca screen 300	ABPM Recorder	custo med GmbH
seca spiro mobile	Spirometer	custo med GmbH

Interface protocols to other products or systems approved by custo med:

Interface	Type	Manufacturer
HL7 Version 2.3	Exchange of data between healthcare organisations and their computer systems	Open industry standard
HL7 Version 2.5	Exchange of data between healthcare organisations and their computer systems	Open industry standard
GDT Version 2.1	Interface between general practice EPR systems and medical devices	Open industry standard
DICOM	Digital Imaging and Communications in Medicine	Open industry standard
EDF	Data format for exchange and storage of bio-signals	Open industry standard
FDA-XML	Data format for exchange and storage of bio-signals	Open industry standard
SCP ECG	Data format for exchange and storage of ECGs	Industry standard in accordance with EN 1064:2010
GE Sapphire DCAR XML Revision B	Data format for receiving ECG data from GE recorders	General Electrics
Mortara ECG XML	Data format for receiving Mortara 12-lead resting ECGs	Hillrom (formerly Welch-Allyn, Mortara)
Cosmed Omnia OCP (Omnia Communication Protocol) Version 0.7	Protocol for exchanging data and controlling the cosmed Omnia software	COSMED S.R.L.
MetaSoft® Studio	Spirometry software	Cortex Biophysik GmbH
Lode Treadmill Protocol (LTP) Version 2.3	Manufacturer interface for Lode treadmills	Lode
Communication Lode Angio, Lode Corival & Lode Excalibur ergometers Version 1.8	Manufacturer interface for Lode ergometers	Lode B.V.
h/p/cosmos® coscom® v4	Manufacturer interface for all training devices from h/p/cosmos	h/p/cosmos sports & medical gmbh
Ergoline Protokoll Version 2.2a	Manufacturer interface for Ergoline ergometers	ergoline GmbH
RAM treadmill protocol series 870 rev. 1/2022	Manufacturer interface for RAM 870 series treadmills	Medisoft RAM Italia SRL
Protocollo Trackmaster Runner Treadmill Version 1.0	Manufacturer interface for Runner treadmills	Runner SRL
custo med treadmill protocoll V1	Manufacturer interface for treadmills	custo med GmbH

3.5 System requirements

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.

Disk space requirements

Installation

- → seca diagnostic server standard installation: approx. 250 MB
- → seca diagnostic client standard installation: approx. 350 MB

Database

The setup installs a MariaDB by default. For larger installations follow the recommendations for MS-SQL databases.

- → The size of the database increases by about 1 MB per 10000 patients, 2 MB per 1000 evaluations (without evaluation data).
- → When the audit trail is enabled, the size of the database will continue to increase, about 10 MB per day, an SQL database is recommended.
- → The amount of evaluation data and its increase depends on the number of examinations carried out. Example: A clinical customer owns 5 resting ECG devices, result per day: 50 ECG evaluations (5 * 10 eval.) = 10 MB.

SQL database for patient and examination information

- → The SQL Server instance must be configured to a fixed port (default: 1433).
- → The SQL login credentials must be a SQL user-password combination.
- → The SQL user must be the database owner.
- → SQL users must have server roles: public; read on master database.
- → Location: Freely selectable (can be a dedicated, separate SQL Server).

3.6 System architecture and components

The architecture of the seca diagnostic system makes an important distinction between the seca diagnostic client and the seca diagnostic server:

seca diagnostic client:

- → Connects medical devices (e.g. ECG devices)
- → Connects GDT
- → Program for interaction with the user

seca diagnostic server:

- → Provides database and file storage
- → Connects to other seca diagnostic server installations for synchronisation or remote data transmission
- → Connects to HL7 and DICOM
- → Connects to Cloud services like custo med cloud or Letsencrypt

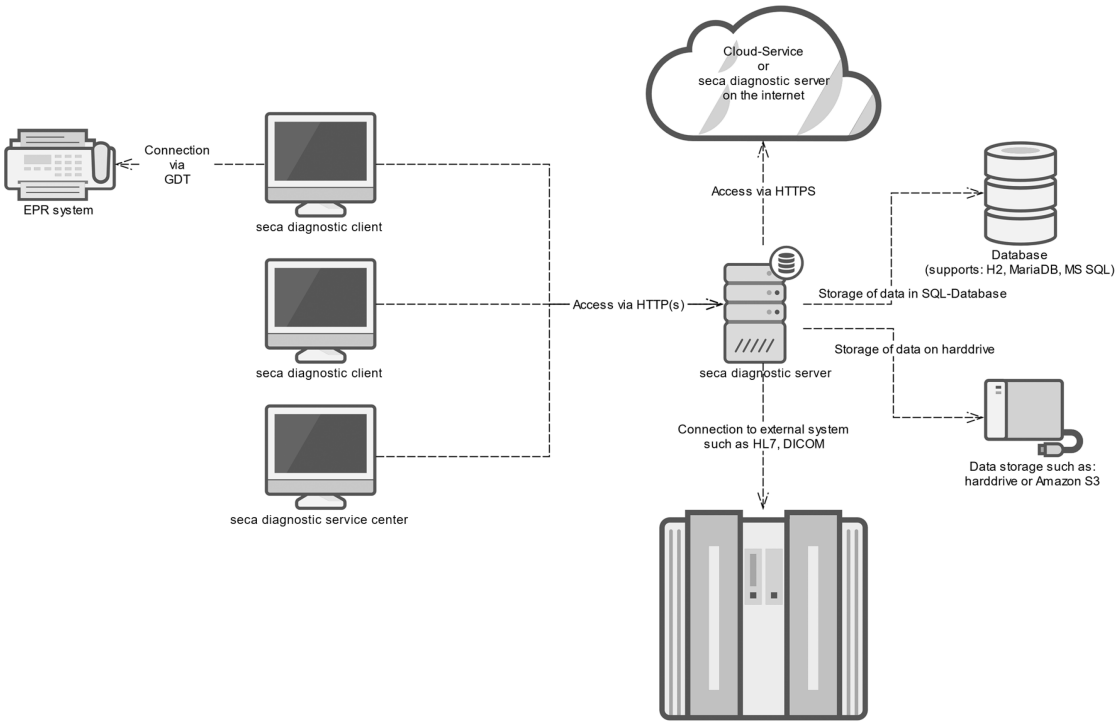


Fig. 2: Overall seca diagnostic architecture

3.7 IT security measures

The SL-C (Security Level Capability) according to 60601-4-5 for the seven Foundational Requirements (FR) is defined as follows:

FOUNDATIONAL REQUIREMENT	SECURITY LEVEL SL-C
Identification and AUTHENTICATION control (IAC)	2
Use control (UC)	2
System INTEGRITY (SI)	2
Data CONFIDENTIALITY (DC)	2
Restricted data flow (RDF)	1
Timely response to events (TRE)	3
Resource AVAILABILITY (RA)	1

To ensure secure operation, it is recommended to achieve at least an SL-T (Target) of 1 for all FRs.

In delivery state, seca diagnostic has already activated numerous measures to ensure IT security.

Requirements for secure system operation:

- → All user accounts must be password protected. The passwords must conform to a (strong) password policy.
- → Each user should have their own personalised user account.
- → Activate rights management and assign rights according to the principle of least privilege.
- → Leave the seca diagnostic automatic lock activated to ensure that unauthorised third parties cannot access the system.
- → Make sure that virus scanners and firewalls are up to date.
- → Make sure that all measures have been taken to restrict access to the computer to authorised persons only.
- → Set up a backup process for the seca diagnostic database and the data directory.

For further information, please contact custo med or your authorised seca sales partner.

4 Installation and configuration

4.1 seca diagnostic installation

IMPORTANT: Installation must be performed only by authorised and trained seca sales partners.

IMPORTANT: The PCs must meet system requirements.

For MS SQL databases:

- → If a MS SQL database is to be used, it must be installed and configured in advance.
- → Contact your IT manager.

Installation procedure:

- → The seca diagnostic software is installed using the supplied installation programs.
- → The installation programs are run on the PCs.

seca diagnostic server

- → The seca diagnostic server installation program is used to set:
  - → The language of the user interface
  - → The storage location of the evaluation files
  - → The storage location of the compressed user manual
  - → The database used
- → After the seca diagnostic server has been installed, a configuration file (CustoCfg.ini) is automatically generated and displayed in Windows Explorer.
- → The configuration file is required after the subsequent installation of the client (or clients) to establish a connection to the server.

seca diagnostic client:

- → To install a seca diagnostic client, run the installation file.
- → Place the CustoCfg.ini file that was created during the installation of the seca diagnostic server in the same directory as the installation file.
- → Start the setup.
- → Read and agree to the licence terms if you want to install the software.

4.2 Updating and upgrading

To update the seca diagnostic server, uninstall it using the corresponding Windows function and then reinstall it using the installation program. To update the seca diagnostic client, run the corresponding installation program.

4.3 Cyber security product updates (CSUP)

Updates relating to cyber security or IT security are performed in the same way as new installations. The client and server installation files also contain all SOUP components. SOUP components are always updated and cannot be deselected.

4.4 Data protection, backup

Data backup with MariaDB or H2 database

To perform a data backup when using a MariaDB or an H2 database, the corresponding task can be executed in the seca service center (Tasks, Scheduler, backupDB). The backup is created in the “backup” subfolder of the data directory set on the seca diagnostic server and can be backed up externally.

Data backup with an MS SQL database

When using an MS SQL database, a backup can be performed using the SQL server’s internal tools. The backup also saves the system's configuration items, allowing for a complete system restore from a backup. For further information, please contact your authorised seca sales partner.

4.5 Import/export interfaces

In addition to GDT for use in practices, seca diagnostic supports HL7 and DICOM as import/export interfaces for the clinical environment. These interfaces can be configured in the seca service center under “Export / Import”. The “General settings” tab contains the options for interfaces to activate the interface and to configure basic, global configurations, such as the protocol version, the code page to be used, or message backup directories.

Then, depending on the interface and workflow, the corresponding configurations for the respective communication servers (IP address, port) or the directories for file-based exchange must be configured. Individual mappings of all fields available in seca diagnostic can be set for the individual message types if the standard configuration is not sufficient. There is a tab for each interface, via which the log entries of the interface can be viewed and filtered for troubleshooting.

The individual configuration of the interfaces is strongly dependent on the customer's workflow and the on-site conditions. A detailed description of the HL7 interface and a DICOM Conformance Statement can be obtained directly from custo med.

4.6 User configuration

Access to seca diagnostic is only possible with a user account to ensure that all actions can be traced at any time. Each user should have their own personalised account (no group accounts like “Reporting station” or “Measuring station”).

4.6.1 Assignment of rights

- → The assignment of rights can be found in the seca diagnostic service center under Administration, Users.
- → Rights management is activated via the Activate user rights checkbox.
- → General system-wide rights and project-specific rights can then be activated.
  - → System-wide settings include, for example, reassigning evaluations and changing system settings.
  - → Project-specific settings include, for example, displaying evaluations and confirming evaluations.
- → According to the principle of least privilege, users should only be given the rights that are absolutely necessary for their work.
- → Profiles are created when configuring larger user groups or roles. When proceeding with profiles, the rights stored in the profile are transferred to the users of the respective profile.

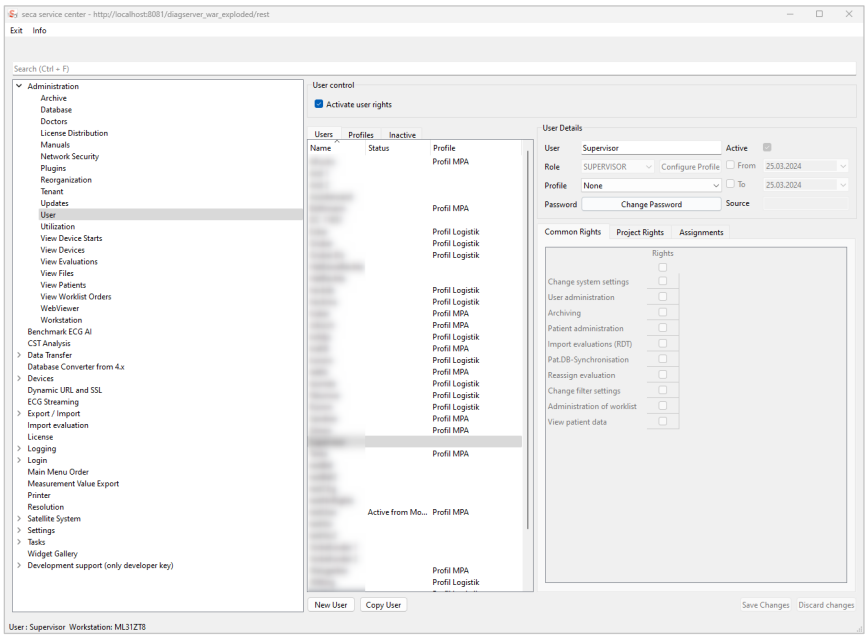


Fig. 3: System-wide rights assignment screen

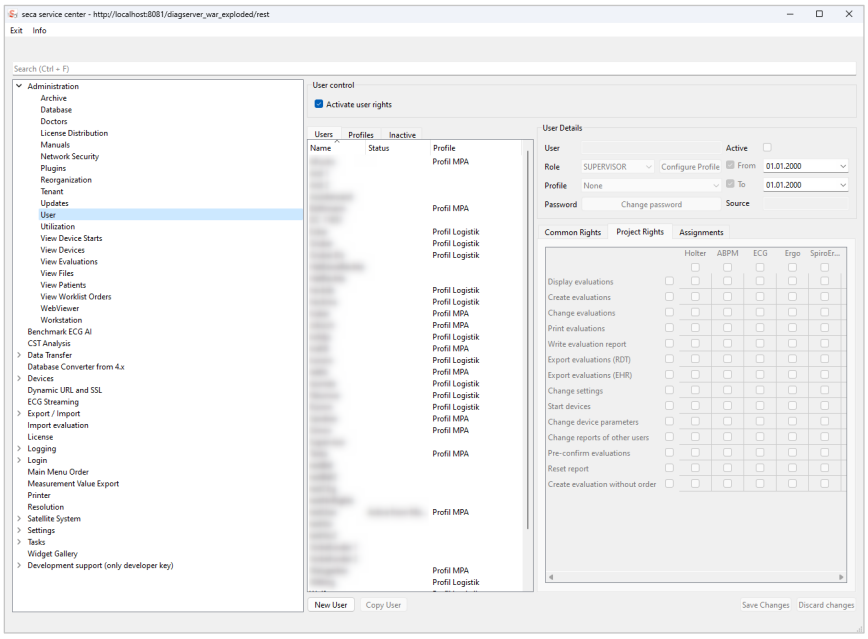


Fig. 4: Project-specific rights assignment screen

4.6.2 Password protection

Password protection is defined in the seca diagnostic service center under Login. In addition, the period of inactivity after which seca diagnostic locks itself automatically can be set there.

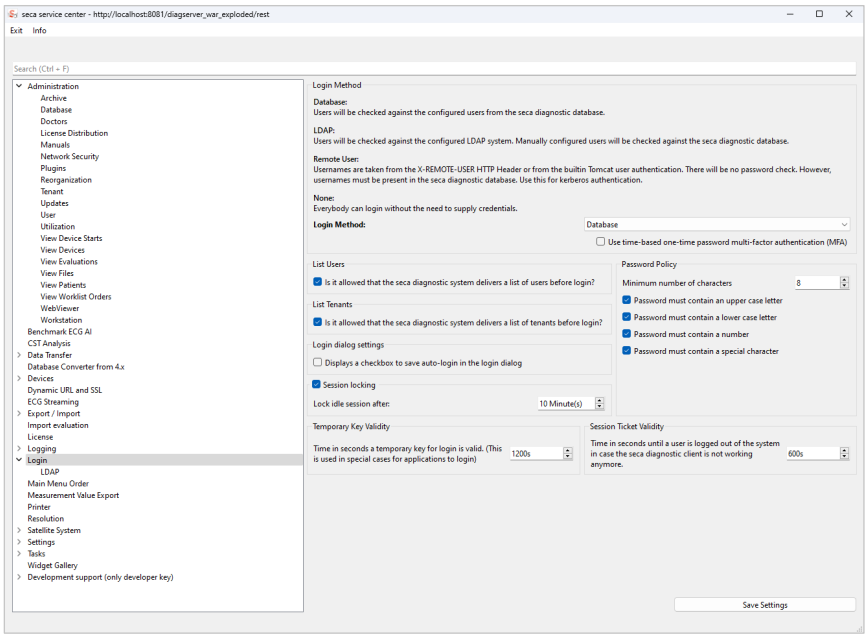


Fig. 5: seca diagnostic login settings

4.7 Setting up devices

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.

4.7.1 ABPM

Setting up the infrared connection

- → Connect the custo com IR / multi com infrared interface to the PC. The device drivers are installed automatically.
- → Start seca diagnostic.
- → In seca diagnostic, open the page Examination, ABPM, Settings, Device 1, Device connection 2.
- → If the previously connected infrared interface is not displayed in the list, click on Scan 3.
- → Select the infrared interface, e.g. custo com IR COM3 4.
- → Click Save to accept your entries.
- → The infrared interface is ready for operation. seca diagnostic can be connected to the PC via the infrared interface.

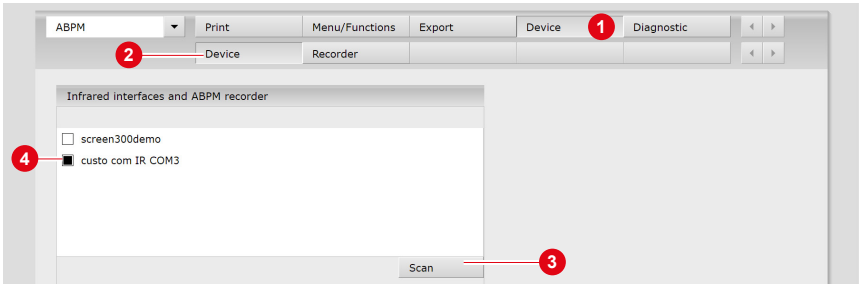


Fig. 6: Selecting a device connection

Setting up the Bluetooth connection

→ Start seca diagnostic.
→ In seca diagnostic, open the page Examination, ABPM, Settings, Device 1, Device connection 2.
→ Switch the seca diagnostic device on (the switch is set to I).
→ Click on Scan in seca diagnostic 3.
→ The device is displayed with the product name, serial number and the note “(Not configured)” 4.
→ Click on Configure Bluetooth Devices 5.
→ In the “Configure BTLE Devices” dialogue box, select the seca diagnostic device that should be connected to the PC via Bluetooth 6.
→ Click on Start 7.
→ Check whether seca diagnostic is switched on.
→ Press the function key of the seca diagnostic device until the message “Configuration successful...” appears in seca diagnostic.
→ Confirm 8 the process.
→ The display lights up blue and shows the message “PC”. seca diagnostic is now connected to the PC and seca diagnostic via Bluetooth.
→ Select the device by activating the corresponding checkbox in the list 9.
→ Click on Save to apply your settings.

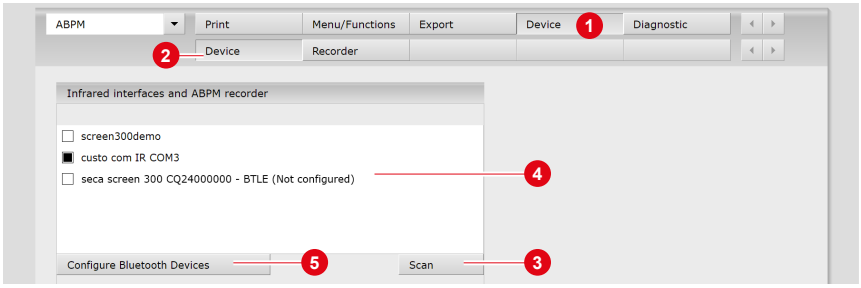


Fig. 7: Searching for Bluetooth devices

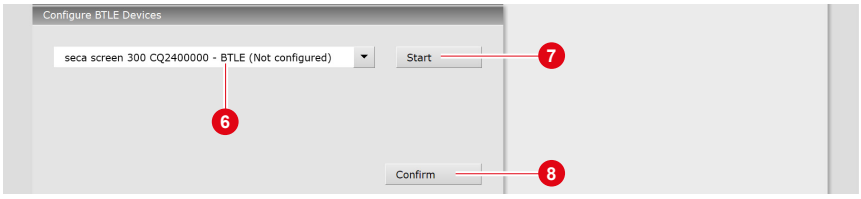


Fig. 8: Configuring the Bluetooth connection

Fig. 9: Selecting a Bluetooth device

4.7.2 Holter ECG

INFORMATION: On delivery, seca guard holter is in storage mode to conserve the battery. In storage mode, no LED display appears when charging the seca guard holter device. The storage mode is deactivated when seca guard holter is connected to seca diagnostic for the first time.

→ Connect the custo guard base charging and programming unit to the PC with the USB cable. If possible, not via a USB hub. The LED on the housing of the custo guard base charging and programming unit lights up in orange.
→ Place the seca guard holter device in the custo guard base charging and programming unit. The driver is installed automatically.
→ Start seca diagnostic and open the screen page: Examination, Holter, Settings, Device, Device-connection 1.
→ Select guard holter 2.
→ Save 3 your entries. The device is ready for operation.

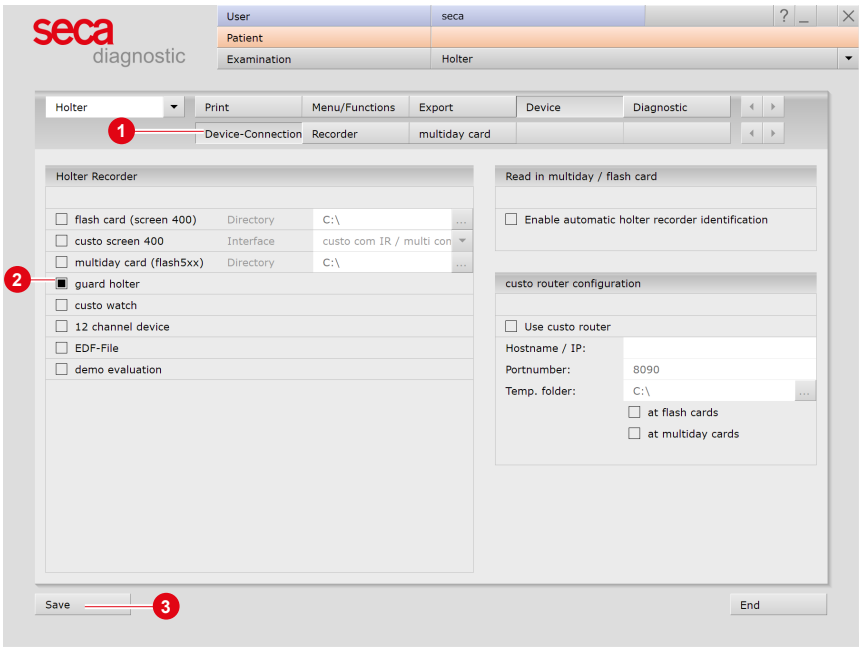


Fig. 10: Device connection in seca diagnostic

Preparing the Bluetooth connection (for monitoring)

A Bluetooth connection between the seca guard holter ECG device and the seca diagnostic workstation is required for the ECG monitoring in seca diagnostic (e.g. to check ECG quality before recording). Requirements: Windows 10 and Bluetooth Low Energy. Ensure that Bluetooth is activated.

Make sure that Bluetooth is activated. If the PC does not have Bluetooth functionality, the supplied Bluetooth USB stick can be connected to the PC. The driver installation is performed automatically. No further steps are required.

4.7.3 Resting ECG

4.7.3.1 Setting up seca ct330 (USB)

Connect the ECG device to the PC using the supplied USB cable. Power is supplied via the USB cable. This charges devices with an integrated battery. The Windows driver installation starts automatically. After the driver installation has been completed, the device is configured in seca diagnostic.

Device configuration for resting ECG

→ Start seca diagnostic.
→ Open the screen Examination, Resting ECG, Settings, Device 1, ECG Device 2.
→ The ECG device is shown in the “ECG devices” section: seca ct330 3.
→ If it is not displayed, click Scan 4 (search process).
→ Select the device: seca ct330 3.
→ A device can be identified by the serial number on the identification plate and in the software interface.
→ Later on, the ECG recording can also be started pressing a button on the device instead of using the software interface. Define the type of recording: Auto Start 5 (automatic ECG 10 s) or Start 6 (manual recording).
→ Save 7 your input. Close the screen with End 8.
→ The device is ready for operation.

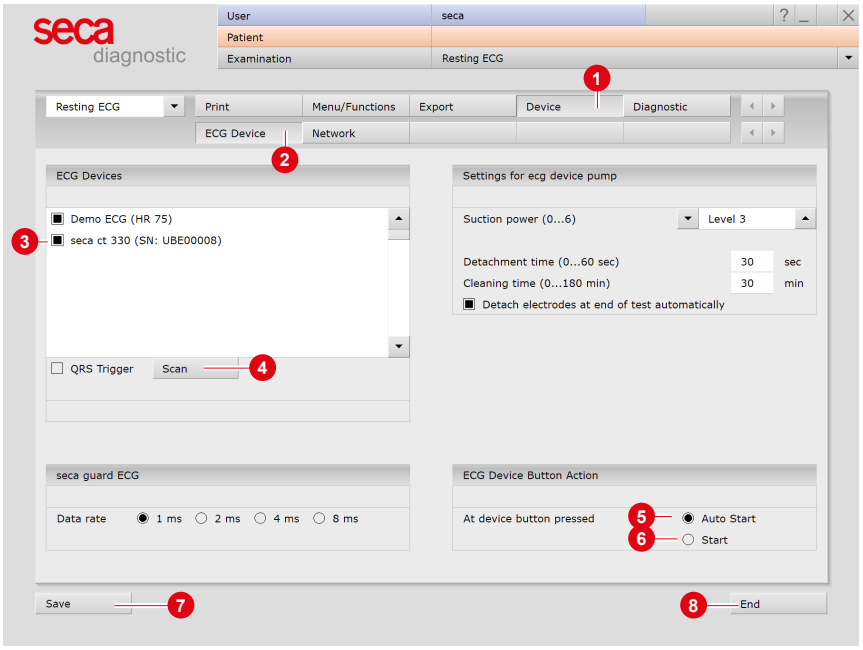


Fig. 11: Configuring the ECG device (USB) for resting ECG

4.7.3.2 Setting up seca ct331 (Bluetooth)

To use the USB port, carry out the steps described earlier to configure the USB port.

Setting up the Bluetooth connection

→ Plug the Bluetooth USB stick into the PC.
→ The driver installation starts automatically.
→ Check whether the Bluetooth driver has been installed correctly:
→ On your Windows desktop right-click on Workspace or Computer.
→ Select Manage in the context menu.
→ In the left half of the window click Device Manager.
→ In the right half of the window, open the Bluetooth Radios item.
→ Here you should see the items Broadcom BCM20702 Bluetooth 4.0 USB Device and Microsoft Bluetooth Enumerator.

Bluetooth connection between ECG device and PC

→ Switch on the device by pressing the On/Off button.
→ Open the Windows Control Panel.
→ There, click on Devices and Printers, Add Device.
→ The ECG device is found.
→ Select the entry seca ct331 in the “Add device” dialogue box and click Next.
→ The device is added without pairing code.

Device configuration for resting ECG

→ Start seca diagnostic.
→ Open the screen Examination, Resting ECG, Settings, Device ❶, ECG Device ❷.
→ The ECG device is shown in the “ECG devices” section: seca ct331 ❸.
→ If it is not displayed, click Scan ❹ (search process).
→ Select the device: seca ct331 ❸.
→ A device can be identified by the serial number on the identification plate and in the software interface.
→ Later on, the ECG recording can also be started pressing a button on the device instead of using the software interface. Define the type of recording: Auto Start ❺ (automatic ECG 10 s) or Start ❻ (manual recording).
→ Save ❼ your input. Close the screen with End ❽.
→ The device is ready for operation.

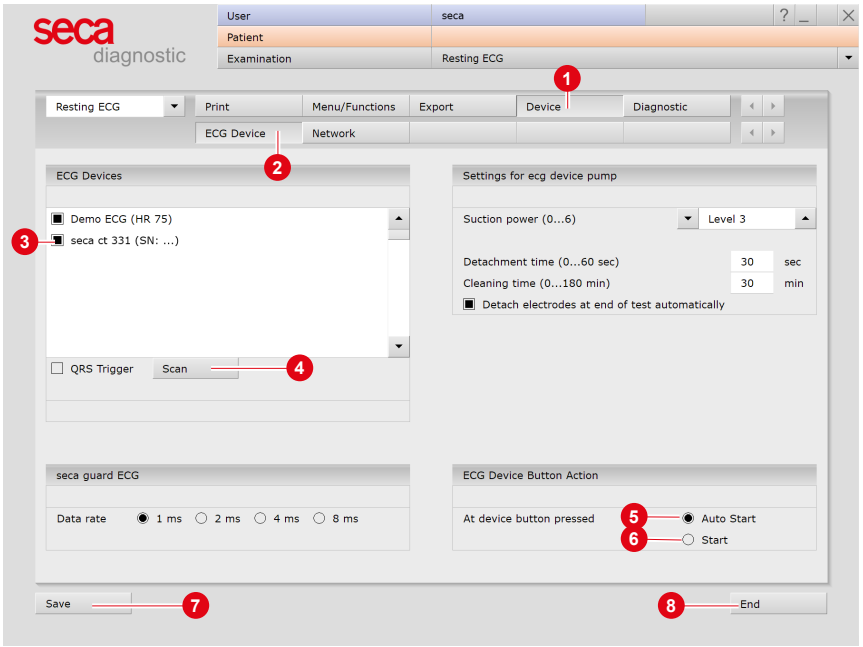


Fig. 12: Configuring the ECG device (BT) for resting ECG

4.7.4 Stress ECG

4.7.4.1 Setting up seca ct330 (USB)

Connect the ECG device to the PC using the supplied USB cable. Power is supplied via the USB cable. This charges devices with an integrated battery. The Windows driver installation starts automatically. After the driver installation has been completed, the device is configured in seca diagnostic.

Device configuration for stress ECG

→ Start seca diagnostic.
→ Open the Examination, Stress ECG, Settings, Device 1, ECG Device 2 screen.
→ The device is shown in the “ECG Devices” area: seca ct330 3.
→ If it does not appear, click Scan 4 (search operation).
→ Select the device: seca ct330 3.
→ A device can be identified by the serial number on the type plate and in the software interface (e.g. SN: EAS 0001).
→ Save 5 your input. Click on End 6 to close the screen.
→ The ECG device is ready for operation.

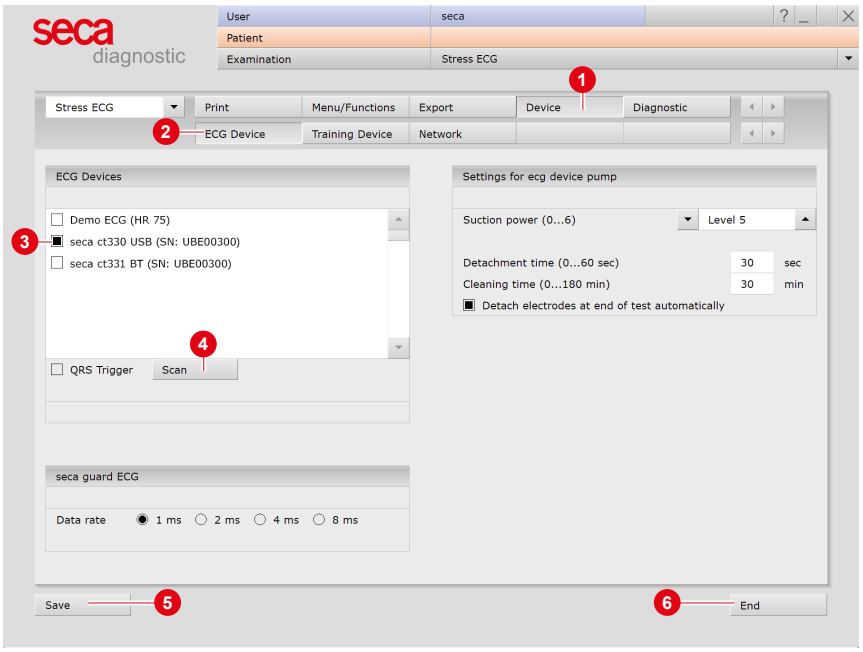


Fig. 13: Configuring an ECG device (USB) for stress ECG

4.7.4.2 Setting up seca ct331 (Bluetooth)

To use the USB port, carry out the steps described earlier to configure the USB port.

Setting up the Bluetooth connection

→ Plug the Bluetooth USB stick into the PC.
→ The driver installation starts automatically.
→ Check whether the Bluetooth driver has been installed correctly:
→ On your Windows desktop right-click on Workspace or Computer.
→ Select Manage in the context menu.
→ In the left half of the window click Device Manager.
→ In the right half of the window, open the Bluetooth Radios item.
→ Here you should see the items Broadcom BCM20702 Bluetooth 4.0 USB Device and Microsoft Bluetooth Enumerator.

Bluetooth connection between ECG device and PC

→ Switch on the device by pressing the On/Off button.
→ Open the Windows Control Panel.
→ There, click on Devices and Printers, Add Device.
→ The ECG device is found.
→ Select the entry seca ct331 in the “Add device” dialogue box and click Next.
→ The device is added without pairing code.

Device configuration for stress ECG

→ Start seca diagnostic.
→ Open the Examination, Stress ECG, Settings, Device 1, ECG Device 2 screen.
→ The device is shown in the “ECG Devices” area: seca ct331 3.
→ If it does not appear, click Scan 4 (search operation).
→ Select the device: seca ct331 3.
→ A device can be identified by the serial number on the type plate and in the software interface (e.g. SN: EAS 0001).
→ Save 5 your input. Click on End 6 to close the screen.
→ The ECG device is ready for operation.

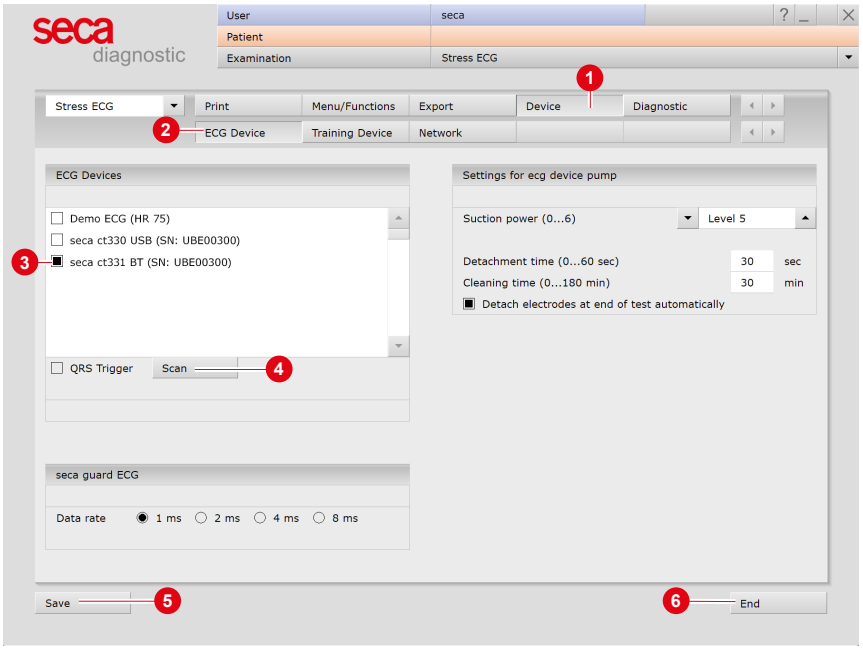


Fig. 14: Configuring an ECG device (BT) for stress ECG

4.7.4.3 Connecting training devices

1) The number of serial ports on the PC can be expanded with USB-to-serial converters or a PCI plug-in card with serial ports.

- → Connect the training device to the PC with the supplied cable (serial port)[1)].
- → Make a note of the serial port number, see Windows Device Manager. The number of the serial port will be needed later in seca diagnostic.
- → Some devices (e.g., ergometer ec5000 and treadmill er2100) can be connected to the PC using a network cable.
- → Start seca diagnostic.
- → Open the screen Examination, Settings, Interface, Devices 1.
- → In the left half of the window, select the device, e.g., Ergometers, No. 1 2.
- → In the right side of the window, change the device settings as required.
  - → If the device type is known, select the Device option 3 and in the “Device” dropdown list select the device type, e.g. ec5000 4 .
  - → If the device type is not obviously recognizable, select the Protocol option 5 and in the “Protocol” dropdown list select the connected device, e.g., customed/ergoline.
- → In the “Options” dropdown list 6, set the device options.
- → Details about the device connection are entered in the “Interface” 7 area.
- → Use the Test button 8 to check whether the connection between the device and the PC is working.
- → If the connection is successful, “Status: O.K. started” appears in the test dialogue box.
- → Save 9 your input. Close the screen with End 10.

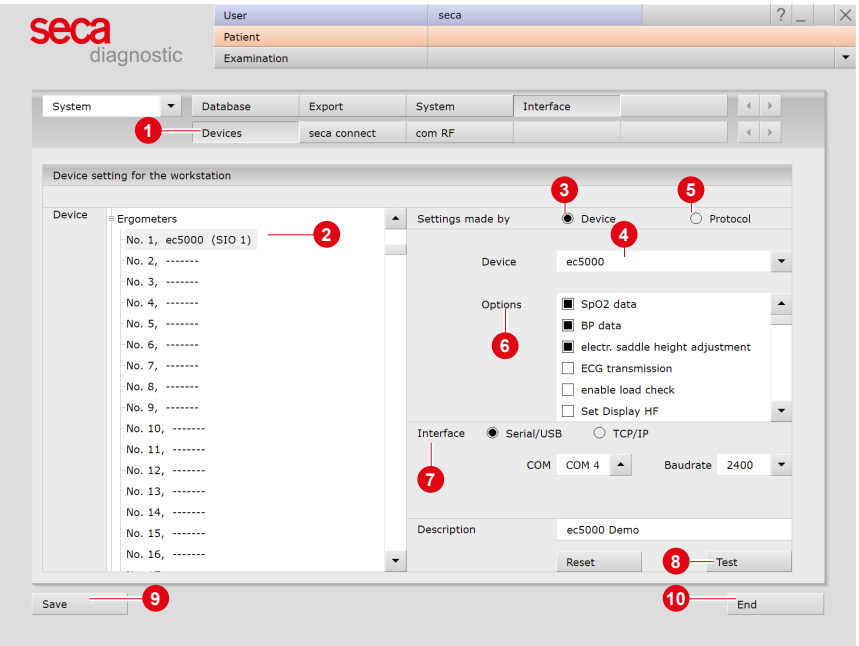


Fig. 15: Connecting training devices with seca diagnostic

4.7.4.4 Configuring a training device

→ In seca diagnostic, open the screen Examination, Stress ECG, Settings, Device 1, Training device 2.
→ Select the previously set Ergometer 3 or Treadmill 4.
→ Select the blood pressure module of the ergometer, the previously connected and set blood pressure monitor or the Manual 5 option.
→ Select the SPO2 module of the ergometer, the previously connected and set SPO2 meter or the Manual 6 option.
→ Click on Save 7 to apply your input.
→ Close the screen with End 8.
→ The training device is ready for operation.

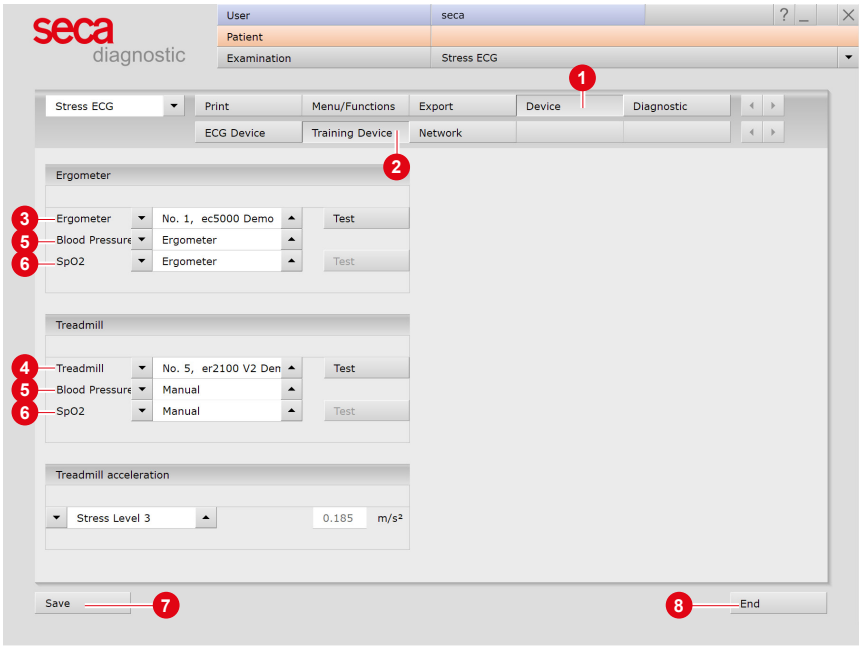


Fig. 16: Configure training devices

4.7.5 Spirometry

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.

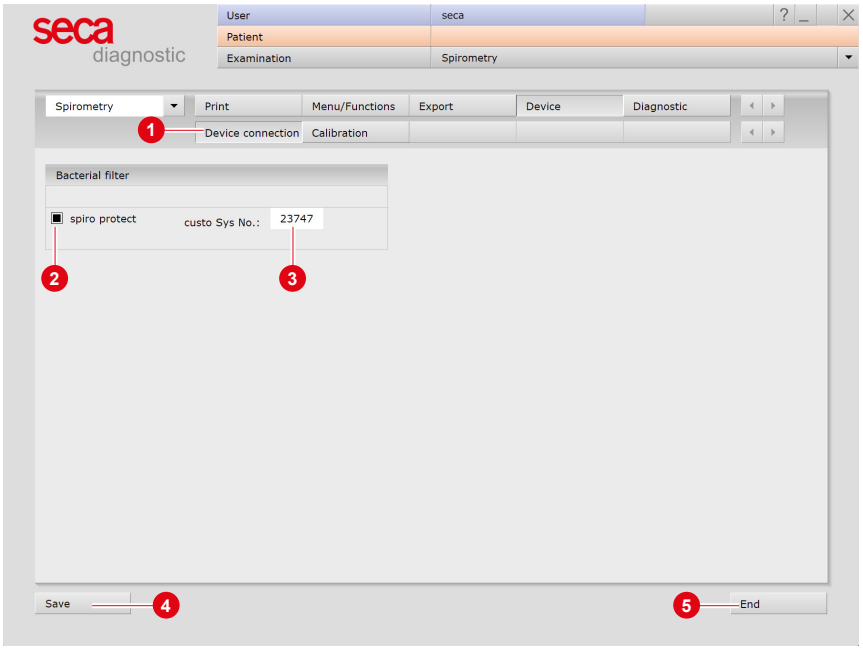


Fig. 17: Settings screen for seca spiro mobile

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 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 seca 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.

4.8 Update management

Update management can be used to update seca diagnostic quickly and easily. All available updates for the server and client are displayed in the seca diagnostic service center under Administration, Updates.

→ With the server updates (first list) there is the option to download the respective installer for the corresponding version. Updating the server requires the server to be shut down. It is not possible to work with the system until the update is completed.

→ The client updates (second list) can be downloaded directly from the Internet to the local seca diagnostic server.

→ The third list contains all the available updates. You can upload your own customised update packages here. If you select a version from the third list and click on the Update all workstations to this version button, the update is rolled out to all seca diagnostic workstations. The update is performed as soon as seca diagnostic is closed on the respective workstation.

INFORMATION:

The first list (Server Updates) shows whether the version with the current licence is valid. The second list shows after each update whether the update is compatible with the currently installed server.

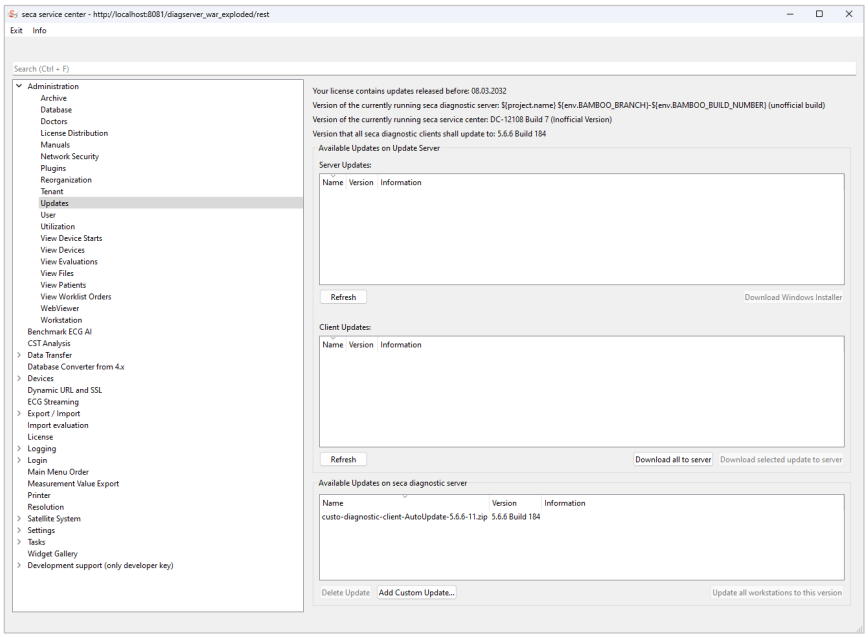


Fig. 18: Update management

→ The Administration, Workstation page shows for each seca diagnostic workstation which version was installed on this workstation at the last login to seca diagnostic. The “Target update version” column shows which version will be used for the next update.

→ A fixed update version can be defined for each workstation. To do this, select a workstation and set the corresponding version via Set Update Version.

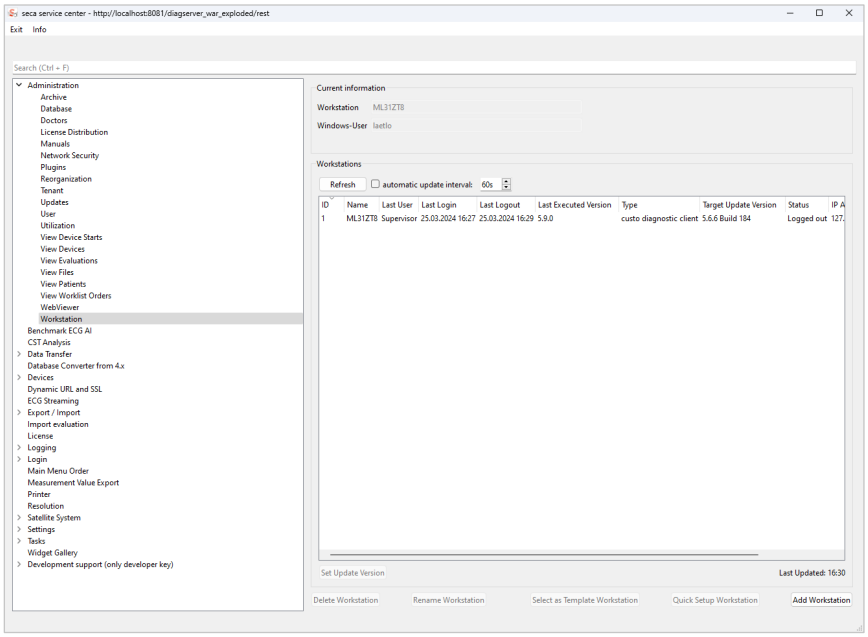


Fig. 19: Update settings for a workstation

4.9 Licence management

INFORMATION:

The seca diagnostic licence model is workstation-based. Each access to a workstation requires a separate licence.

To ensure that logging on to special workstations or for special users is possible at any time, a number of workstation licences can be assigned to a user or a workstation in the seca service center under Administration, Licence Distribution.

To do this, select the workstation or the user by double-clicking and assign the desired number of licences. The system always ensures that at least one licence is not permanently assigned so that access to the service center is possible at all times.

All licence details can be viewed under the Licence main item in the seca service center. This includes information such as the version for which this licence is valid, the licence holder and the expiry date. In the lower part, all licenced individual options are displayed, including the counter for the workstation licences.

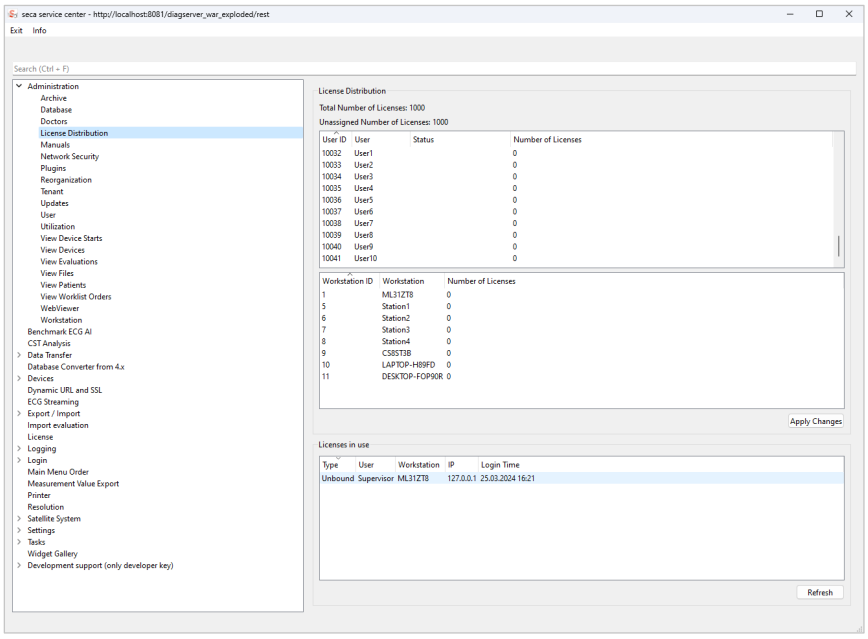


Fig. 20: Licence management in the seca service center

4.10 Audit trail

The audit trail of seca diagnostic enables the complete documentation of all user activities in the system. This option is deactivated by default and must be activated in the seca service center under Logging, Configuration. The retention period of the audit log entries is also configured here (default: 400 days).

If the audit trail is activated, the following activities, among others, are logged:

- → Logins to the system (including failed attempts)
- → Display, modification and deletion of patient data
- → Display, modification and deletion of evaluation data
- → Changes to settings

All audit log entries are read-only and always contain the workstation and the user who triggered the respective action.

5 Use

5.1 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.

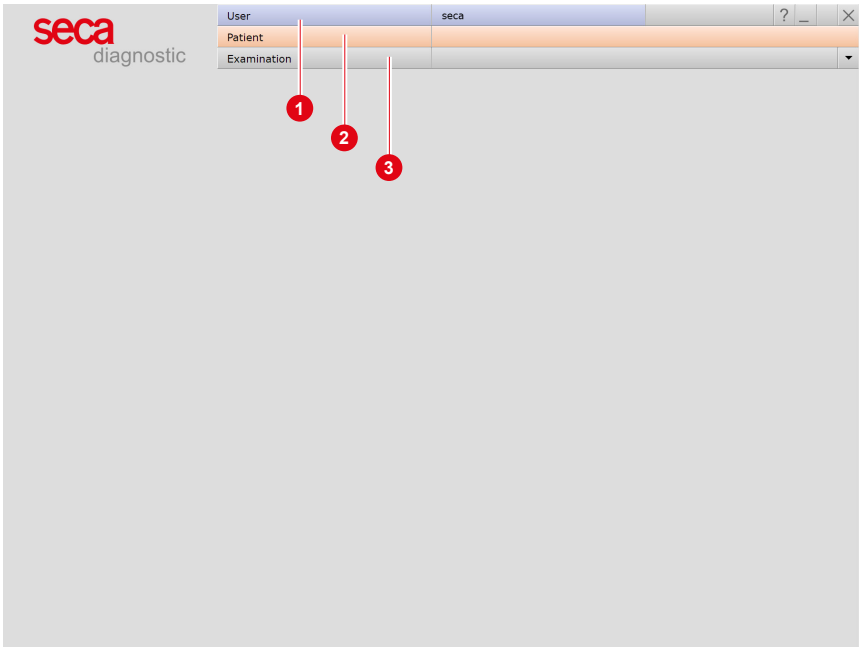


Fig. 21: seca diagnostic main menu

5.2 ABPM

5.2.1 Performing an ABPM recording

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.

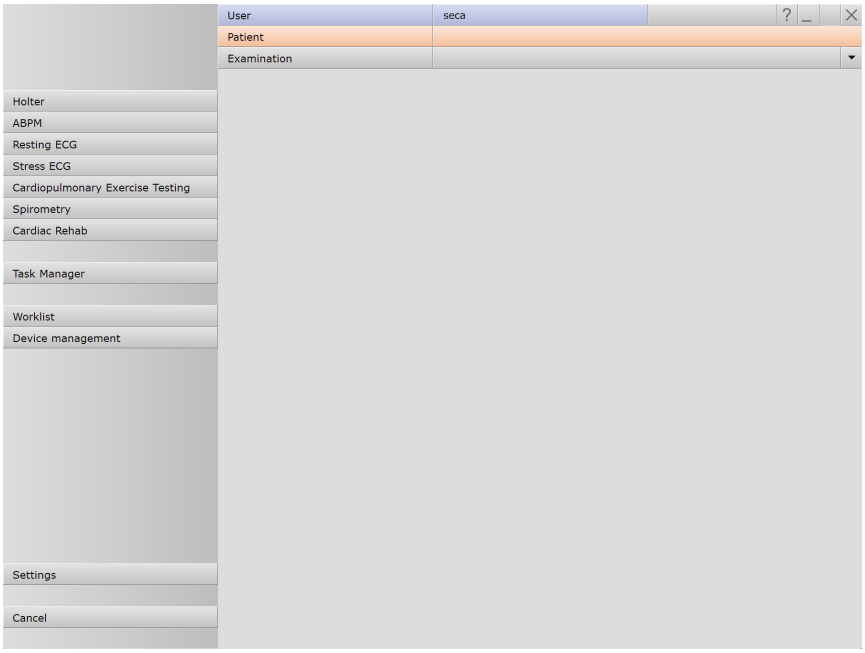


Fig. 22: seca diagnostic examination main menu

NOTE ON THE PROCEDURE: The steps necessary to carry out and evaluate an ABPM examination in seca diagnostic are shown without a surgery IT system or HIS connection.

Program start, calling the ABPM

→ If you want to start the seca diagnostic device via the infrared interface: Make sure that the infrared interface is connected to the PC and ready for operation.
→ Start seca diagnostic and log in.
→ Click on Examination ❶, ABPM ❷, New ABPM ❸.

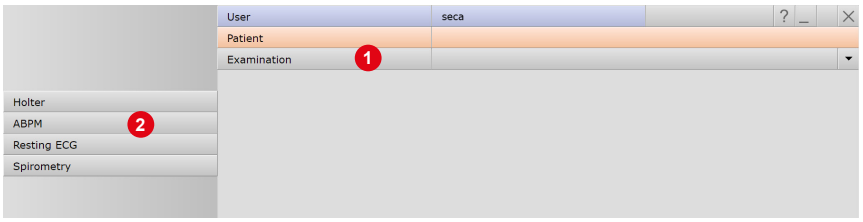


Fig. 23: Main menu Examinations

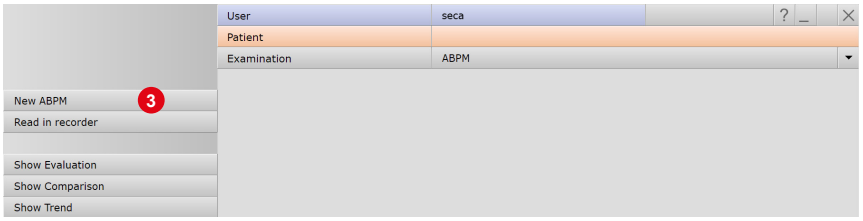


Fig. 24: Main menu ABPM

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.
→ Save the data.
→ The patient is entered into the database.
→ After the patient has been selected, the screen for configuring the start parameters opens.

Setting the start parameters

- → Select the recorder seca screen (custo screen ...).
- → Set the start parameters for the blood pressure measurements: Select previously saved start parameters, such as Standard or create new start parameters.
- → Click on Edit to change the selected start parameters. Day, night and additional phases can be set in the right half of the screen.
- → In the Repeat measurement area, you can set whether a repeat measurement should be taken if the limit values are exceeded or not reached.
- → The options can be set as required.
  - → Beep: A signal is emitted before each measurement so that the patient can prepare himself/herself accordingly.
  - → Display results: Systole, diastole and heart rate are shown on the recorder display after each measurement.
  - → Print diary: After clicking on Start, a patient diary is printed.
- → By selecting Save As, newly set start parameters can be saved under a different name and made available for further recordings.
- → By selecting Save, the originally selected start parameters will be overwritten.
- → Optional: Risk stratification (seca diagnostic professional).
- → After the start parameters have been selected, the recorder can be started.

IMPORTANT: Insert fresh batteries or freshly charged rechargeable batteries into the recorder before starting. Always use complete battery sets (do not mix weak batteries with freshly charged/new batteries).

1) During ABPM recording, the operating mode is displayed on the device before each measurement. The information ADU or PED appears briefly on the display.

Data transfer, starting the recording

→ For infrared connection: Place the switched-on recorder in front of the custo com IR / multi com interface so that the two infrared interfaces face each other (at a distance of approx. 10 – 20 cm).
→ For Bluetooth connection: Switch seca screen 300 on.
→ In seca diagnostic, click on Start (bottom left of the screen).
→ Check and confirm the data in the “Patient data entry” dialogue.
→ In the “Select device” dialogue, select which device is to be used for data transfer. Confirm the selection.
→ For infrared connection: If more than 55 seconds elapse between switching on the recorder and clicking on Start, transferring data will no longer be possible as the recorder is in idle mode. To activate the recorder, press the function key.
→ If “PC” appears on the display of the recorder, the device is in data transfer mode.
→ If the patient is a child between 3 and 12 years of age, you can select whether the device should be started in “pediatric” mode (3 to 12 years) or in “adult” mode (10 years and older)[1)]. Confirm the selection.
→ The data is transferred to the device.
→ Put the recorder on the patient.
→ Carry out a sample measurement (press the function key).
→ Instruct the patient on how to use the recorder.
→ The patient and the recorder are ready for recording.

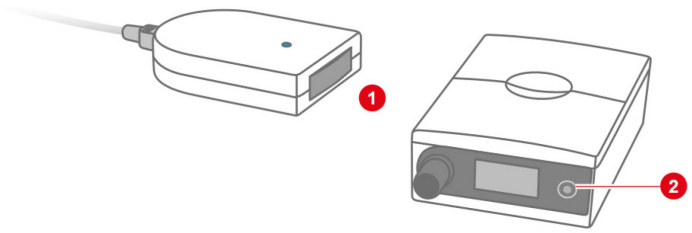
5.2.2 Downloading the ABPM recorder

Remove the recorder from the patient:

→ detach the cuff tube from the recorder.
→ take the recorder out of its case and switch it off.
→ Remove the carrying belt, cuff and fixing aids.

Reading in a recording via the infrared connection

→ Make sure that the infrared interface is connected to the PC and ready for operation.
→ Start seca diagnostic and log in.
→ Place the switched-on recorder in front of the custo com IR / multi com interface so that the two infrared interfaces are opposite each other (approx. 10 - 20 cm) 1.
→ Click on Examination, ABPM, Read in recorder.
→ If more than one interface has been configured for data transfer: In the “Select device” dialogue, select which device is to be used for data transfer. Confirm the selection.
→ The dialogue box for data transfer is displayed.
→ If more than 55 seconds elapse between switching on the recorder and clicking on Start, data transfer is no longer possible because the recorder is in idle mode. To activate the recorder, press the function key 2.
→ If “PC” appears on the display of the recorder, the device is in data transfer mode.
→ The recording is downloaded and displayed as an evaluation.



Reading in a recording via the Bluetooth connection

→ Start seca diagnostic and log in.
→ Switch seca diagnostic on, click on Examination, ABPM, Read in recorder.
→ If more than one interface has been configured for data transfer: In the “Select device” dialogue, select which device is to be used for data transfer. Confirm the selection.
→ The dialogue box for data transfer is displayed.
→ If “PC” appears on the display of the recorder, the device is in data transfer mode. When connected via Bluetooth, the display also lights up blue.
→ The recording is downloaded and displayed as an evaluation.

5.2.3 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 ❶.
→ With factory settings, the search screen ❷ 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 ❸.
→ 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 ❹.
→ If no filter set is active yet, select a set ❺.
→ Open an evaluation by double-clicking on the corresponding line or via the Show button ❻.

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 ❼.

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. 25: 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.

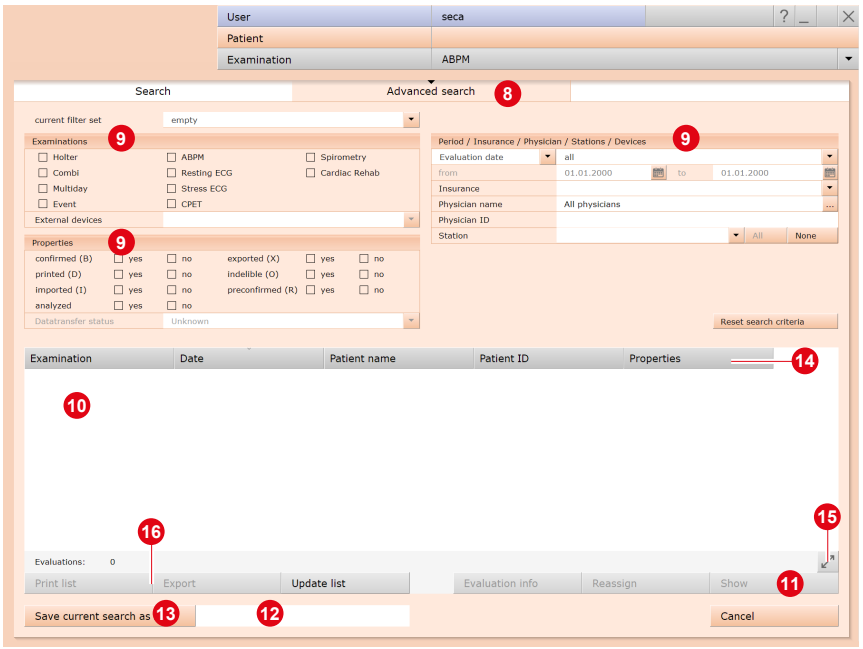


Fig. 26: Evaluation search, extended search

5.2.4 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 examination main menu via Examination, ABPM.
→ Click on Show evaluation 1.
→ The patient search screen appears. Select the patient whose evaluation you would like to open. Enter the name of the patient in the input fields of the search screen 2.
→ Select the patient from the list below the input fields 3 and confirm the selection with the Select patient button 4 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.

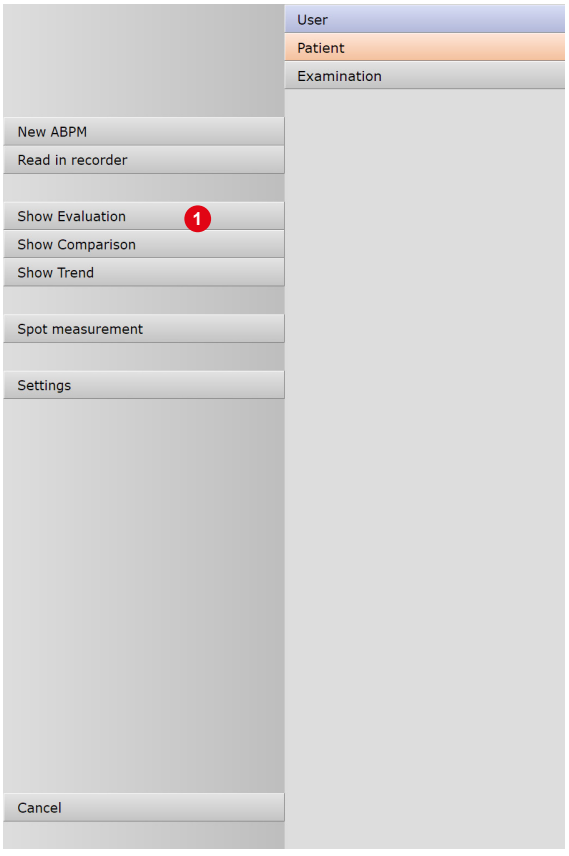


Fig. 27: ABPM main menu

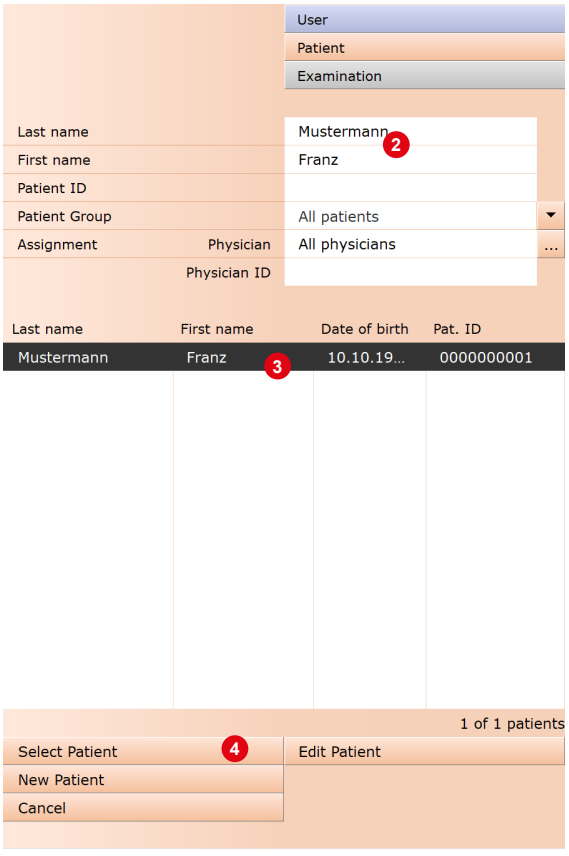


Fig. 28: Select patient

5.2.5 Evaluation structure

The most important screen pages of an ABPM evaluation are the Overview, the Table of measured values and the Diagrams. From these three screen pages, the Comparison can be opened at any time to compare the current evaluation with a previous one. The Options menu can be used to open additional screen pages, for example the Trend or a list of Erroneous measurements.

Start screen "Overview, Standard"

with the heart rate trend, blood pressure trend and the most important measured values;

if additional software options are used, further evaluation views are possible: e.g. risk stratification or phenotypes[1)].

Table:	**Diagram:**	**Comparison:**	**Options menu**
Tabular overview of all measured values. View with single values or hourly average values.	Representation of measurement results as pie charts, different view modes. Systolic & diastolic values or Systolic values or Diastolic values	of two evaluations of the patient, e.g. current and previous	additional screens:

Erroneous measurements:
List of all erroneous measurements with error codes.

Recorder information:
Recording parameters, battery trend of the recorder

Trend:
Long-term trend of all ABPM evaluations of the patient as bar chart.

1) The "Risk stratification" and "Phenotypes" software options are part of seca diagnostic professional and therefore not included in the standard scope of the software.

5.2.6 Screens of the evaluation

5.2.6.1 Overview “Standard”

Fig. 29: Overview, Standard

1. Set view: single values/hourly values and screen page content, here standard (or risk stratification, or phenotypes)
2. Measured values curves - all measured values as a progression over time: top HR heart rate (orange), bottom BP blood pressure (green)
3. Slider to change the night phase (grey area)
4. Cursor for selection of points in the measured values curves, move by “drag & drop”, values see column “current”
5. Measured values table with “current” values (cursor), average blood pressure values (total, day, night), day/night drop, and number of measurements
6. Showing and hiding of limit values lines in the blood pressure curve
7. Buttons for opening additional evaluation screen pages
8. Options menu
9. Printout according to system settings
10. Button for closing the evaluation

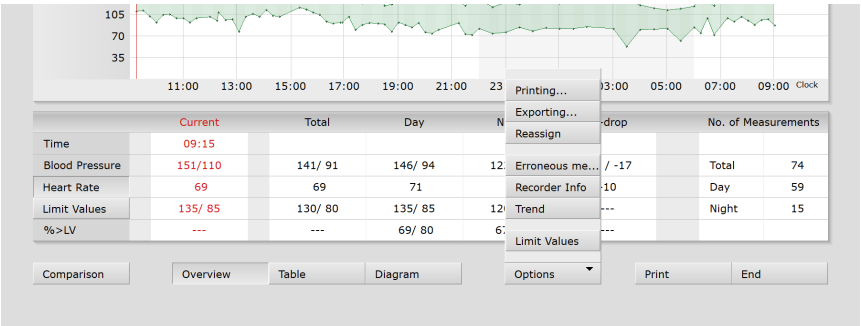


Fig. 30: Options menu

Options menu

- → Print...: Change print settings for the current printout
- → Export of the evaluation, e.g., Excel, PDF, e-mail or to a directory
- → Assign: If necessary, assign evaluation to another patient
- → Erroneous measurement: List of incorrect measurements with error codes (check if recording is incomplete)
- → Recorder info: Recording parameters and battery voltage of the recorder
- → Trend for evaluation of blood pressure behaviour over a longer period of time
- → Limit values: Dialogue for changing the limit values for the current evaluation

5.2.6.2 Evaluation screen “Table”

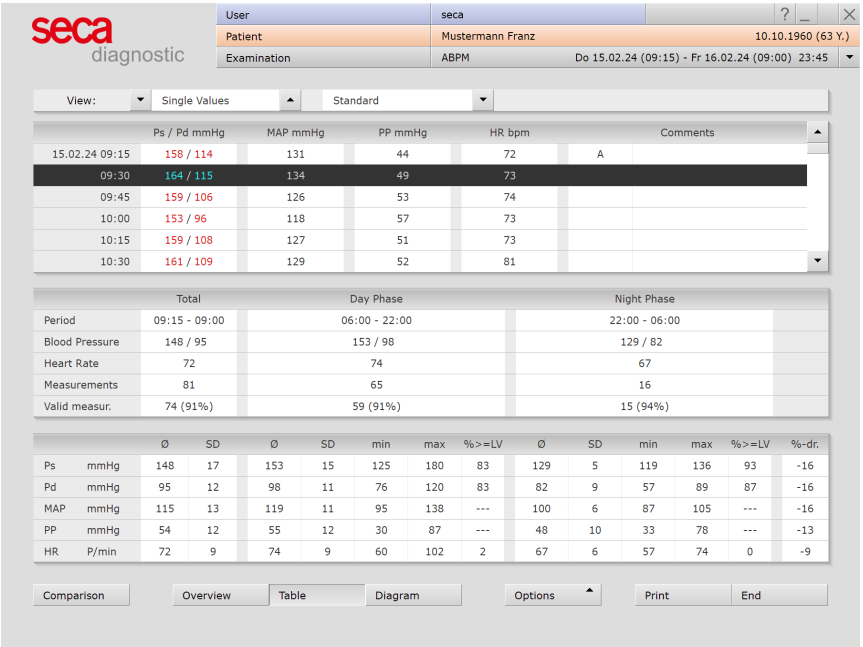


Fig. 31: Measured value table Standard

List of all single measurements (or average values per hour), summary total/day/night (the line “valid measurements” shows proportion of valid measurements), average, minimum and maximum values for the entire recording.

Transfer patient diary to the software

→ Click on the desired line in the Comments column.
→ There you can enter the text.

Delete measurements

→ Click on the measurement to be deleted in the upper table.
→ Right-click to open the context menu.
→ Select Delete measurement there.

Abbreviations in the third table:

→ Ps = Brachial systolic blood pressure
→ Pd = Brachial diastolic blood pressure
→ MAP = mean arterial pressure
→ PP = Pulse pressure
→ HR = Heart rate
→ EC = Error message recorder
→ R = Repeat measurement
→ A = Additional measurement

5.2.6.3 Evaluation screen “Diagram”

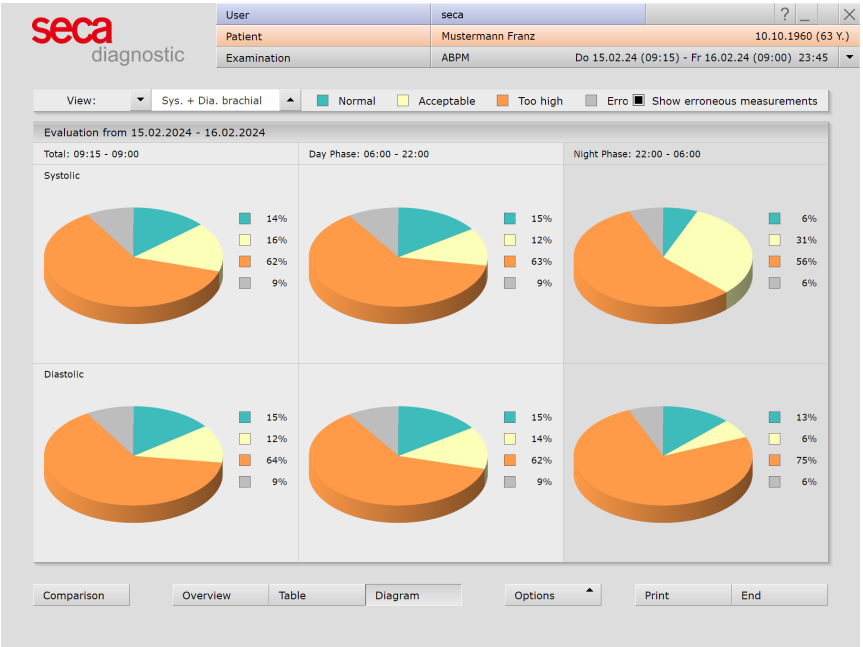


Fig. 32: Diagrams

Here you can see at a glance how large the percentage of measurements inside (green) and outside (orange) the limit values is. The percentage of erroneous measurements (grey) can optionally be shown.

Definition of the limit values (default setting)

→ Normal (green): day 135/85 mmHg, night 120/70 mmHg
→ Acceptable (yellow): up to 10 mmHg above the normal values
→ Too high (orange): more than 10 mmHg above the normal values

Change limit values

→ These values can be set under: Examination, ABPM, Settings, Diagnostic, Limit Values.
→ Click Save to apply your input.

5.2.6.4 Evaluation screen “Comparison”

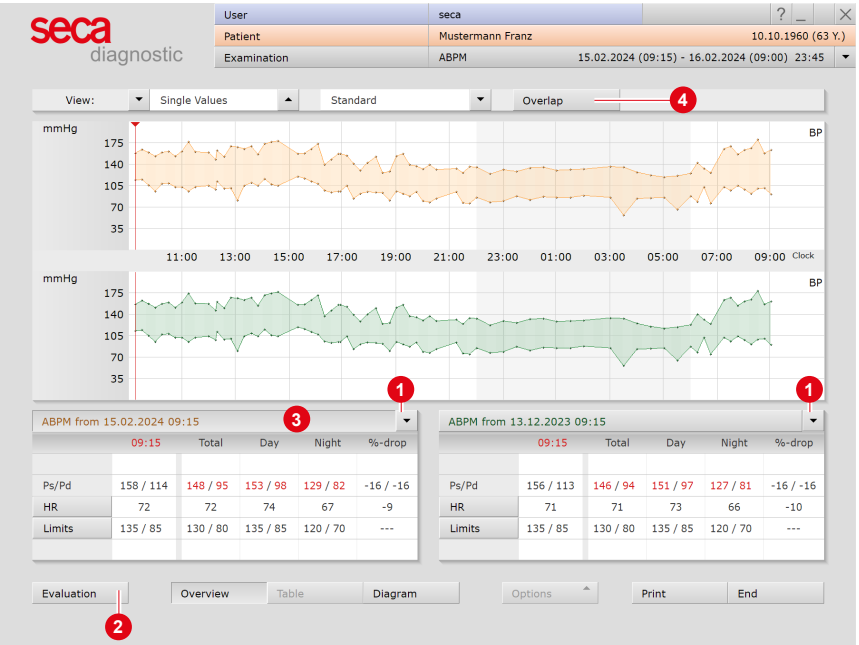


Fig. 33: Comparison

Comparison of two evaluations for a patient. More evaluations can be selected using the arrow keys 1. Click on the Evaluation 2 button to open the single view of the selected evaluation 3. Click on Overlap 4 to superimpose the measurement curves for direct comparison.

__TIP__ for printing the comparison view: The Comparison screen can be printed with the Print button. The contents of the printout correspond to the display on the screen. For example, if the blood pressure curves were superimposed (Overlap button), the blood pressure curves are also superimposed in the printout.

5.2.6.5 Evaluation screen “Trend”

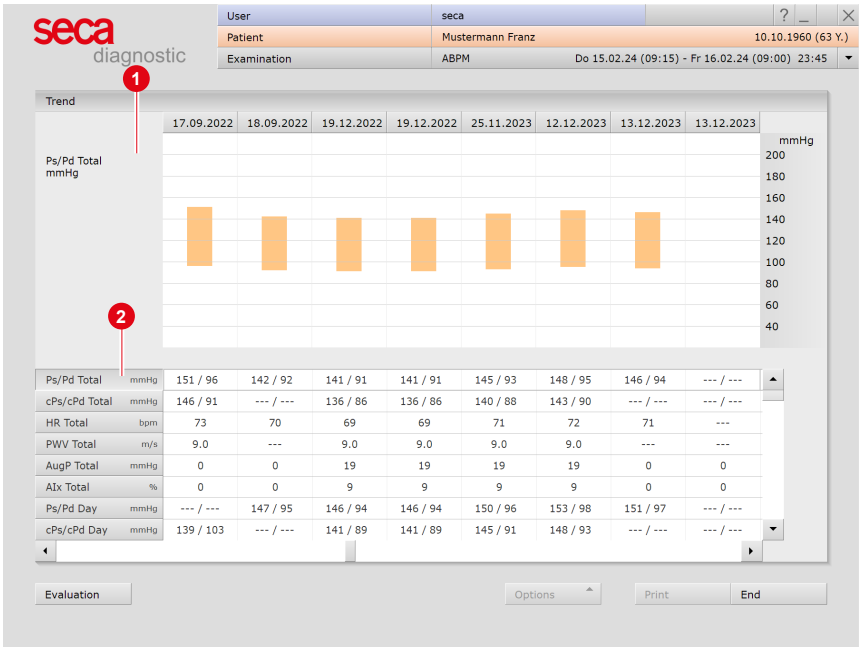


Fig. 34: Trend

To be opened via Options, Trend. Long-term trend displaying all blood pressure evaluations for a patient. The selected value, e.g. Ps/Pd total ❶, is graphically displayed for all evaluations ❷. In this way, the development of the individual values can be viewed at a glance.

Abbreviations in the table:

- → Ps = Brachial systolic blood pressure
- → Pd = Brachial diastolic blood pressure
- → cPs = central systolic blood pressure
- → cPd = central diastolic blood pressure
- → HR = Heart rate
- → PWV = Pulse wave velocity
- → ... Drop = percentage of drop from day to night average; (daily average - night average = 10 to 15 %)

If you are using the “Phenotypes” software option, this screen also displays measured values from the phenotypes area. These are marked with the prefix “PT”.

5.2.6.6 Dialogue “Automatic report”

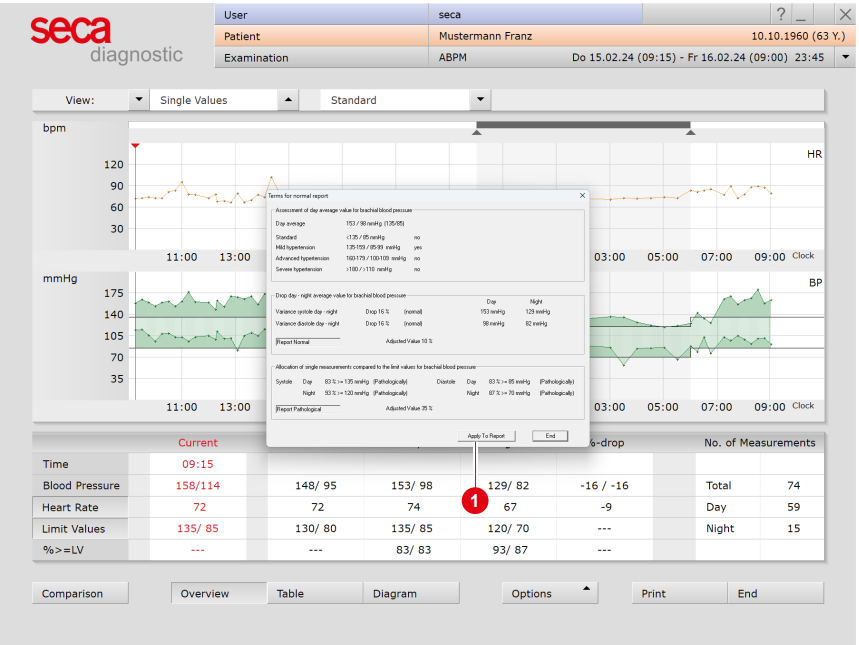


Fig. 35: Automatic report

To be opened via Context menu, Auto. Report. The automatic report is created from the day average values, the drop of the day-night average values and the proportion of measurements that are above the limit values. Click on Apply To Report 1 to transmit the results into the unconfirmed report.

INFORMATION:

The Automatic report option is not available if you are working with risk stratification.

5.2.7 Printing the evaluation

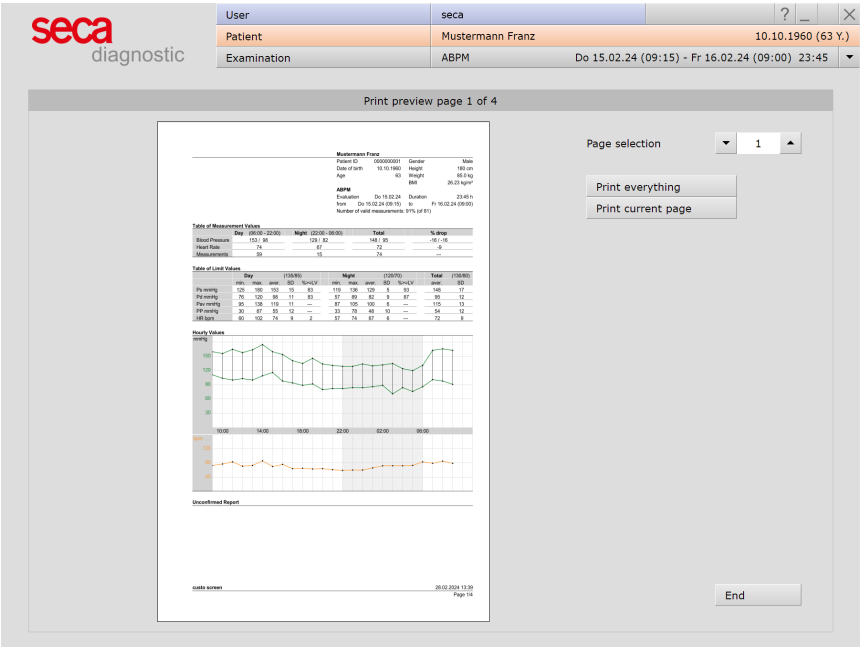


Fig. 36: Print preview

The printout is done via the Print button or via Options, Printing ... (print menu of the evaluation, to change the contents for the current printout). The Print preview can be opened via the print menu (Printing ...).

5.2.8 Confirming the evaluation

Unconfirmed report and report

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

Text modules – an aid for writing reports

Select Examination, examination type (e.g. Holter ECG, ABPM, Resting ECG, Stress ECG, ...), Settings, Diagnostic, Reports to configure text modules for reporting an evaluation. A total of four groups with up to eight text modules can be created. The text modules are called in the unconfirmed report dialogue via the keyboard (F5 to F12).

A text module can be created from normal text and variables. When you use a text module in the unconfirmed report, the actual value from the evaluation is inserted in the report text instead of a variable. The structure of a variable is {VARIABLE}. The Shortcuts for export values button provides you with a list with all variables. If the text modules should be shown in the unconfirmed report dialogue, make sure that the Enabled option is activated. Alternatively, the text modules can be shown in the unconfirmed report dialogue by selecting Options, Texts on. There is also the option of writing a text that is automatically displayed in each unconfirmed report (text suggestion or user-defined unconfirmed report). The text can be changed later in the unconfirmed report dialogue. Save your input.

5.2.9 Ending the evaluation

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

This is where the status of an evaluation is defined. Assigning properties (evaluation status) in the End dialogue makes it easier to find evaluations in the evaluation search.

→ Evaluation preconfirmed: If a user with the reporting right “Preconfirm evaluations” has confirmed the unconfirmed report.
→ Evaluation confirmed: If a user with the reporting right “Confirm evaluations” has confirmed the unconfirmed report. The “Evaluation confirmed” status can be reset if required.
→ Printed: Indicates if the evaluation has been printed.
→ Indelible: Can be selected after reporting has been completed. The evaluation can only be viewed and can no longer be changed.
→ Click on Confirm to close the evaluation.

5.2.10 Evaluation with phenotypes

IMPORTANT: The “Phenotypes” function can only be applied to patients aged 18 and over.

INFORMATION: The calculation of phenotypes refers to the first 24 hours of a recording. There must be at least 20 valid measurements in the day phase and 7 valid measurements in the night phase.

The “Phenotypes” software function is not included in the standard scope of delivery of the software and is available as an option.

Evaluating ABPM recordings based on haemodynamic phenotypes provides information about the cause of a patient‘s pathological blood pressure behaviour. seca diagnostic differentiates between five haemodynamic phenotypes with different pathological focuses[1)].

- → Cardiogenic phenotype: affecting the heart
- → Neurogenic phenotype: affecting the sympathetic/parasympathetic balance
- → Volumetric phenotype: affecting the kidneys and fluid balance
- → Vasoconstriction phenotype: affecting systemic vascular resistance
- → Arterial stiffness phenotype: affecting aortic elasticity

The haemodynamic and cardiovascular parameters for determining the five phenotypes are partly included in the ABPM recording or are calculated from the measured values. The phenotypes result from the interaction and expression of the following haemodynamic and cardiovascular parameters:

- → MAD Mean Arterial Pressure
- → PD Pulse Pressure
- → CO Cardiac Output
- → CI Cardiac Index
- → SV Stroke Volume
- → SVR Systemic Vascular Resistance
- → PWV Pulse Wave Velocity
- → SAI Sympathetic Activity Index
- → ABA Afferent Baroreflex Activity

Information on the methodology, reliability and treatment success of this approach can be found in the following sources:

Álvarez-Montoya D, Madrid-Muñoz C, Escobar-Robledo L, Gallo-Villegas J, Aristizábal-Ocampo D. A novel method for the noninvasive estimation of cardiac output with brachial oscillometric blood pressure measurements through an assessment of arterial compliance. Blood Press Monit. 2021 Dec 1;26(6):426-434. doi: 10.1097/MBP.0000000000000553. PMID: 34128491.

Aristizábal-Ocampo D, Álvarez-Montoya D, Madrid-Muñoz C, Fallon-Giraldo S, Gallo-Villegas J. Hemodynamic profiles of arterial hypertension with ambulatory blood pressure monitoring. Hypertens Res. 2023 Jun;46(6):1482-1492. doi: 10.1038/s41440-023-01196-z. Epub 2023 Mar 8. PMID: 36890272; PMCID: PMC10239728.

5.2.10.1 Accessing haemodynamic phenotypes

In seca diagnostic, the phenotype analysis is called up via the Overview screen. In the “View” line (above the trends), select Phenotypes in the second menu. The “Phenotype analysis” dialogue appears. In the “Phenotype analysis” dialogue, you will be informed of the existing analysis quota[1)]. The dialogue shows how many analyses are still available. By pressing Confirm, the phenotype analysis is carried out (and deducted from the quota).

1) custo med offers various quota models for phenotype analysis, e.g. 25 phenotype analyses per month (analyses that are not used expire at the end of the month).

“Phenotypes” overview

To access the evaluation view with calculation of the phenotype, open the menu at the top of the screen and select Phenotypes 1. The phenotypes result from the interaction and expression of various haemodynamic parameters, see table “Parameters” 2. The value ranges of the parameters are shown in the form of coloured bars 3 – green shows the setpoint range, red shows the areas outside the setpoints. The patient's values are shown with black lines 4.

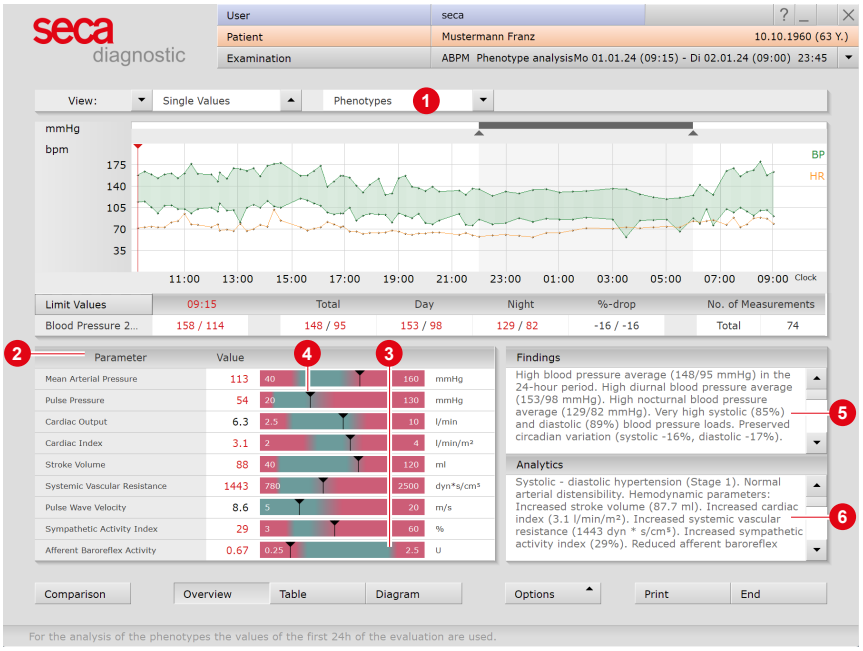


Fig. 37: Overview, phenotypes

Tip for creating text modules: To create text modules, open the Examination, ABPM, Settings, Diagnostics, Report screen in seca diagnostic. You can find more information on this in the Confirming the evaluation chapter.

The results are summarised in words in the “Findings” text field 5. In the “Analytics” text field 6, the phenotype is derived, which in turn indicates the cause of the hypertension. These texts can be included in the unconfirmed report. To do this, enter the variable {PT_FINDINGS} or {PT_ANALYTICS} in the opened unconfirmed report. Click on Confirm to apply your input. For efficient creation of report texts, seca diagnostic allows you to create text modules from your own text and a large number of variables relevant to the examination, see tip.

The Comparison button can be used to compare the current phenotype determination with a previous one.

5.2.10.2 Expression of the haemodynamic parameters

IMPORTANT: The parameters shown in seca diagnostic for determining the haemodynamic phenotypes may only be considered in the context of the seca diagnostic “Phenotypes” function. The parameters for determining the haemodynamic phenotypes must not be used separately or for other purposes.

Each haemodynamic phenotype is characterised by a specific expression of the parameters shown here, see table:

	Cardiovascular parameters				
Phenotype	**TPR**	**HR**	**PP**	**ePWV**	**CI**
Vasoconstriction PT	> 1300	< 80	≤ 50	–	–
Cardiogenic PT	≤ 1300	≥ 80	≤ 50	–	> 30
Neurogenic PT	> 1300	≥ 80	–	–	–
Volumetric PT	–	–	≥ 50	≤ 10	–
Arterial stiffness PT	–	–	≥ 50	> 10	–

Key: TPR = Total Peripheral Resistance; HR = Heart Rate; PP = Pulse Pressure; ePWV = Estimated Pulse Wave Velocity; CI = Cardiac Index

5.2.10.3 Description of the phenotypes

Cardiogenic phenotype

- → High stroke volume and high cardiac index
- → Frequently increased heart rate
- → Normal to reduced vascular resistance and baroreflex activity

Neurogenic phenotype

- → High sympathetic activity index
- → Slightly increased stroke volume, cardiac index and vascular resistance
- → Normal pulse pressure (PP) and pulse wave velocity (PWV)
- → Low afferent baroreflex activity

Vasoconstriction phenotype

- → High systemic vascular resistance
- → Normal stroke volume and cardiac index
- → Normal PWV
- → Normal pulse pressure and sympathetic activity index

Volumetric phenotype

- → Significantly increased stroke volume and pulse pressure
- → Frequently increased systemic vascular resistance
- → PWV in the normal range

Arterial stiffness phenotype

- → High PWV and high pulse pressure
- → Frequently increased vascular resistance
- → Normal stroke volume and normal cardiac index
- → Slightly increased sympathetic activity index and reduced afferent baroreflex activity

5.2.11 Risk stratification

IMPORTANT: Risk stratification can only be applied to patients over 16 years of age.

The “Risk stratification” software module is part of the “professional” software and is not included in the standard version.

The seca diagnostic software function “Risk stratification” is used to determine the patient's 10-year risk of serious cardiovascular disease. The result is displayed as a graphic in the evaluation.

The risk is calculated from the blood pressure severity and the cardiovascular risk factors of the patient. The blood pressure severity is calculated from the ABPM recording. The risk factors have to be entered manually in seca diagnostic.

5.2.11.1 Configuring workflows

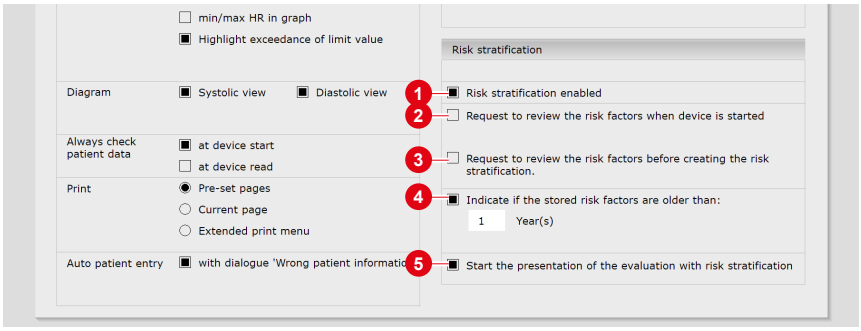


Fig. 38: Settings for risk stratification

→ Start seca diagnostic and open the screen page Examination, ABPM, Settings, Menu/Functions, Workflow.

→ ❶ Enable or disable risk stratification. If the option is not selected, seca diagnostic will not perform risk stratification.

→ ❷ If this option is selected, the dialogue for entering the risk factors opens automatically when starting the recorder. If the option is not selected, the input dialogue can be opened via Set Risk Factors.

→ ❸ If this option is selected, a prompt to check the previously set risk factors appears in the evaluation before risk stratification is performed. If the option is not selected, risk stratification is performed automatically without any prompt to check the risk factors.

→ ❹ If this option is selected, a prompt to check the existing risk factors appears if these are older than the set time period (e.g., 1 year). This is to ensure that the existing risk factors also correspond to the acute condition of the patient during follow-up examinations. If no check is performed when starting the recorder, the prompt appears again in the evaluation before the risk assessment is created.

→ ❺ If this option is selected, risk stratification is automatically displayed in the overview when opening an evaluation. If the option is deactivated, the standard view without risk stratification is displayed. Risk stratification can be opened manually.

→ Click on Save (bottom left) to apply your settings.

5.2.11.2 Defining evaluation guidelines

With the seca diagnostic standard configuration, risk stratification is carried out based on German Hypertension League (DHL) guidelines. Risk stratification according to international guidelines is also possible.

→ To do this, open the screen page Examination, ABPM, Settings, Diagnostic, Limit values in seca diagnostic.
→ In the “Categories of Blood Pressure” area, select the International option.
→ Click on Save (bottom left) to apply your settings.

The German and the international risk stratification differ with respect to the blood pressure severity grades and the classification of the risk factors. 14 valid measurements during day phase are required for risk stratification according to international criteria.

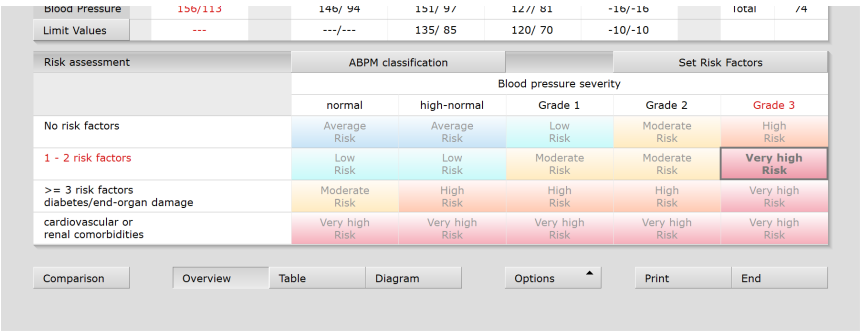


Fig. 39: Risk stratification according to DHL.

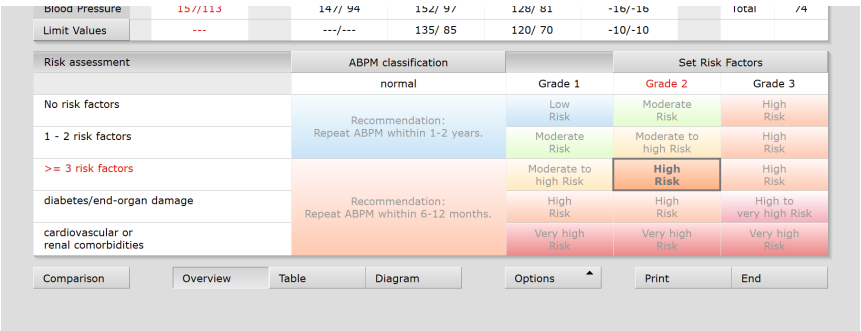


Fig. 40: Risk stratification according to international criteria

5.2.11.3 Print settings for risk stratification

The contents of the ABPM print pages are defined under Examination, ABPM, Settings, Print, Printed pages in seca diagnostic. To print the results of risk stratification, select the Summary with risk stratification option (= physician's printout) ❷. In addition, the Summary standard ❶ without risk stratification can be printed. With the Patient printout risk stratification option ❸, the results are summarized in a simplified form for the patient on an A4 page. Click on Save (bottom left) to apply your settings.

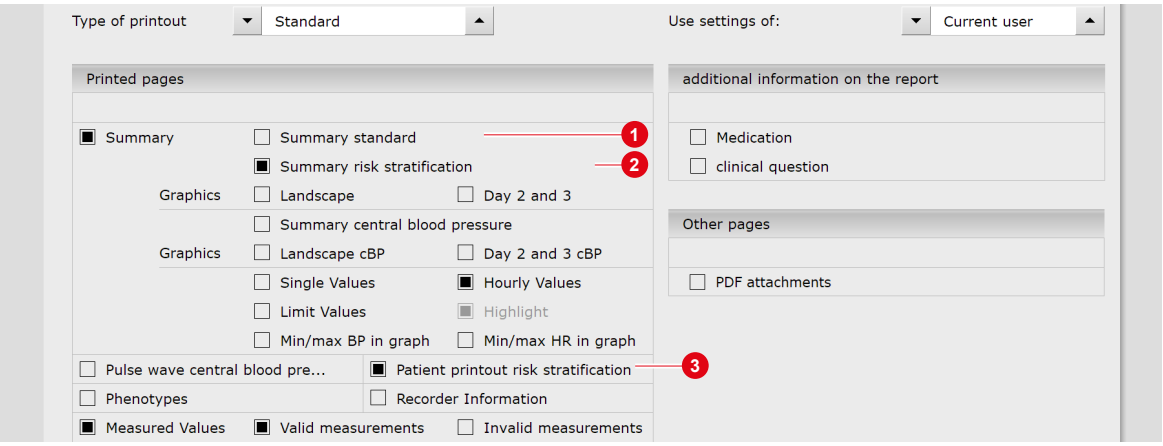


Fig. 41: Settings for the printout

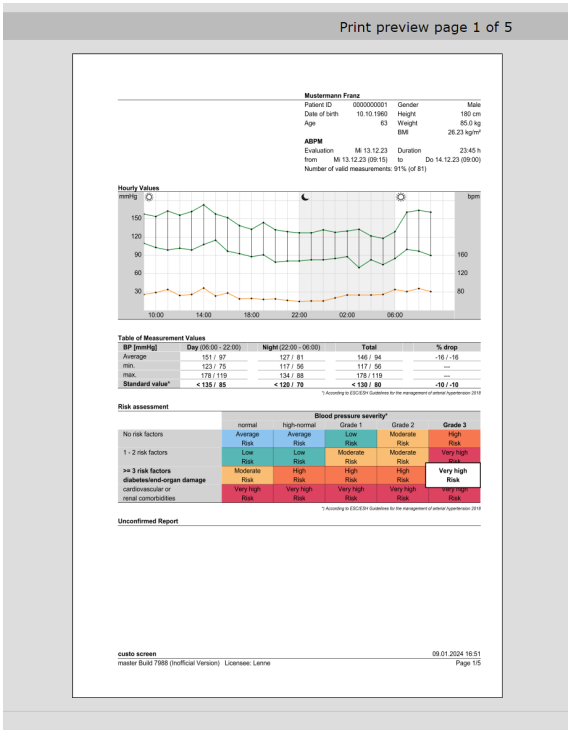


Fig. 42: Print preview of physician's printout with risk stratification

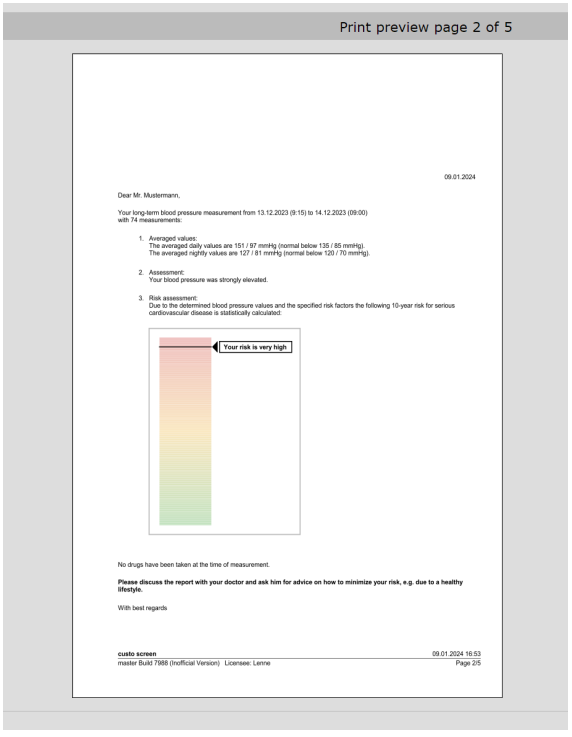


Fig. 43: Print preview of patient's printout with risk stratification

5.2.11.4 Recorder start with risk stratification

INFORMATION: If the risk factors are not entered or checked at this point, this step must be carried out later.

The start procedure for a recording with risk stratification corresponds to the standard procedure, *see 5.2.1 Performing an ABPM recording, p. 53*. In addition, the patient's cardiovascular risk factors must be entered.

- → On the screen page Examination, ABPM, New ABPM click on Set risk factors ❶ to enter them.
- → The dialogue for entering the risk factors is displayed. Select the appropriate risks ❷.
- → If the patient does not have any of these risks, no further risks must be selected.
- → Click on Confirm ❸ to save your settings and close the dialogue.
- → The recorder can then be started via the Start button.
- → If the risk factors are not entered or checked at this point, this step must be carried out later.

***TIP:** Information on the risk factors*

Place the mouse pointer over an entry in the "Select risk factors for risk stratification" dialogue to obtain a short description of the respective risk. On mouse-over, the so-called "tool tip" with the desired information is displayed.

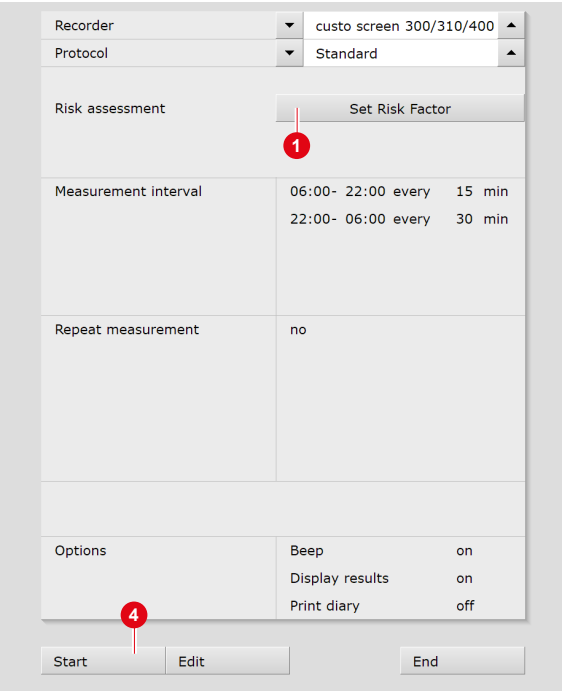


Fig. 44: Start parameters, set risk factors

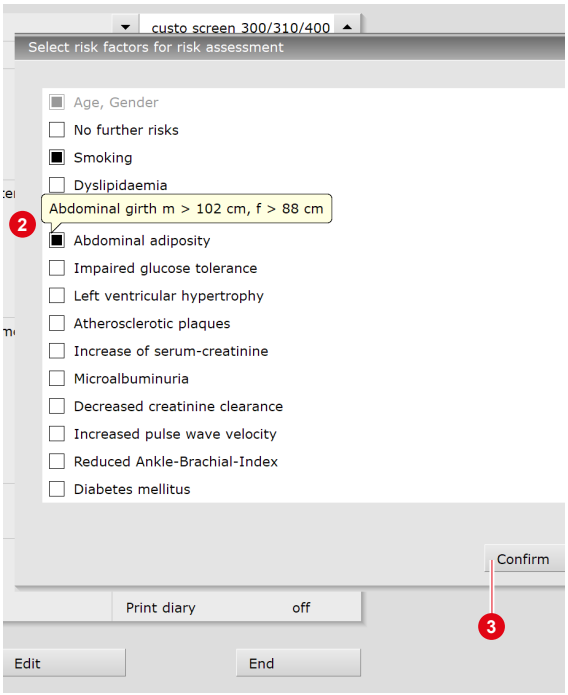


Fig. 45: Select risk factors

5.2.11.5 Downloading an evaluation with risk stratification

The download procedure corresponds to the standard procedure, *see 5.2.2 Downloading the ABPM recorder, p. 57*. After the download the evaluation overview is displayed. This contains, in addition to the standard contents, the risk stratification with indication of the 10-year risk of severe cardiovascular disease. The risk stratification is only displayed if the risk factors were set when starting the recorder. Otherwise, you will be prompted to enter them.

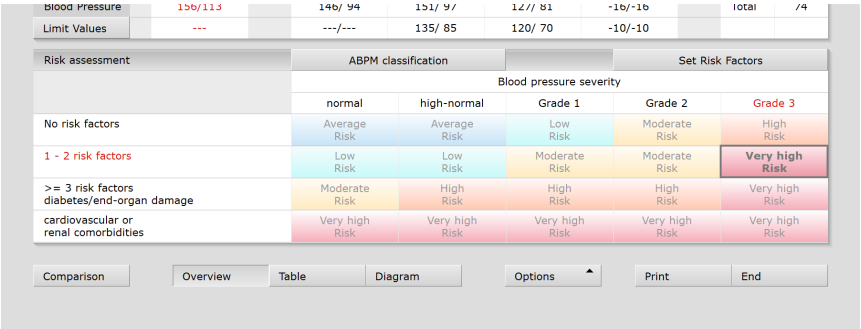


Fig. 46: Evaluation with risk stratification

5.2.11.6 Evaluation overview with risk stratification

Opening an ABPM evaluation with risk stratification works in the same way as a standard evaluation. The evaluation overview contains the following display and operating elements:

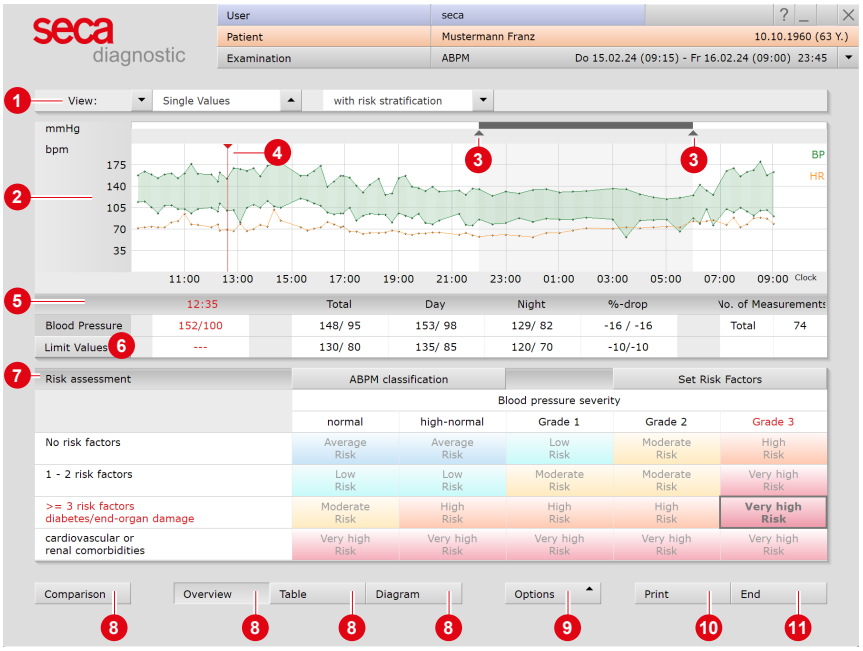


Fig. 47: Evaluation with risk stratification

1. Set view: single values/hourly values, with/without risk stratification
2. Blood pressure curve (green) and heart rate curve (orange)
3. Slider to change the night phase (grey area)
4. Cursor for selection of points in the measured values curves, move by “drag & drop”, values see column “current”
5. Table with blood pressure average values and number of measurements
6. Showing and hiding of limit values lines in the blood pressure curve
7. Risk stratification with indication of 10-year risk of severe cardiovascular disease of the patient[1)]. The field with the applicable risk is enlarged and has a stronger colour. The present number of risk factors (left column of the table) and the patient's blood pressure severity (second row of the table) are shown in red font.
8. Buttons for opening additional evaluation screen pages
9. Options menu with further evaluation screen pages
10. Printout according to system settings
11. Button for closing the evaluation

1) The risk is calculated from the patient's blood pressure severity and cardiovascular risk factors. The blood pressure severity is derived from the ABPM recording. The risk factors must be entered manually in seca diagnostic. This is done via the Set risk factors button. The ABPM Classification button can be used to open a tabular overview with definition and classification of the blood pressure severity levels. The applicable severity level is highlighted.

5.2.11.7 Problems with risk stratification

If the evaluation does not yet contain risk stratification, this may be because:

- → Not enough valid blood pressure measurements are available. In this case, risk stratification is not possible (14 valid measurements during day phase are required for the risk stratification).
- → The cardiovascular risk factors of the patient were not entered when starting the recorder. You will be prompted to enter them see 1.
- → seca diagnostic is configured such that the saved risk factors always have to be checked prior to each risk stratification. You will be prompted to check them see 2.
- → seca diagnostic is configured such that the correctness of risk factors that were entered more than a year ago has to be checked. You will be prompted to check them.

Entering or checking the risk factors

- → To enter or check the risk factors, click Set risk factors 3.
- → The dialogue for entering the risk factors is displayed.
- → Select the appropriate risks.
- → If the patient does not have any of these risks, no further risks must be selected.
- → Click on Confirm 4 to save your settings and close the dialogue.
- → The risk stratification is displayed.

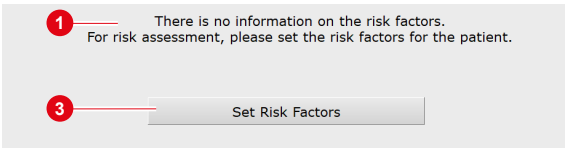


Fig. 48: No risk factors entered

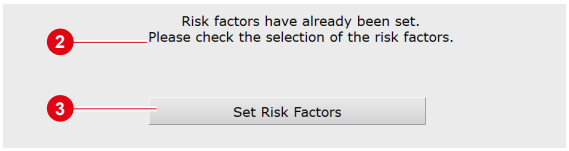


Fig. 49: Check existing risk factors

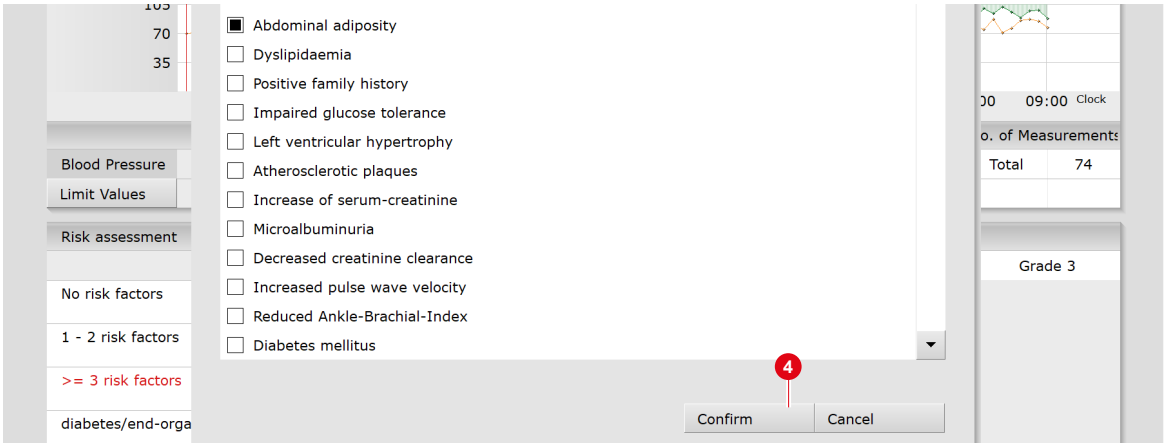


Fig. 50: Confirm risk factors

5.2.11.8 Unconfirmed report with risk stratification

To open the unconfirmed report, right-click on the evaluation interface. In the context menu, select Report.

The unconfirmed report contains a summary of the blood pressure behaviour, the results of the risk stratification and a trend analysis which compares the current results with the previous report (if available). It is possible to add information to the text and change it. Click on Confirm to save your changes and close the dialogue.

The procedures in connection with the unconfirmed report are the same as in the standard procedure.

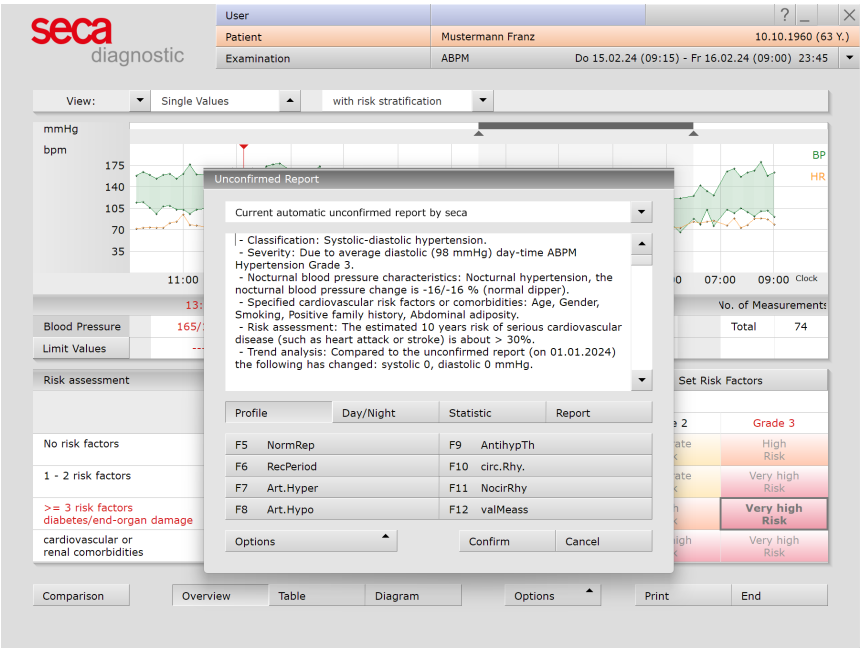


Fig. 51: Unconfirmed report with risk stratification

5.2.11.9 Definition of the blood pressure severity grades

Risk stratification is performed based on the risk factors of the patient and the blood pressure severity calculated from the recorded values. A table with the blood pressure severity grades can be viewed by clicking on the ABPM Classification button.

Classification of blood pressure ranges according to DHL

	Systolic [mmHg]		Diastolic [mmHg]	
	Office blood pressure	Daily average	Office blood pressure	Daily average
Optimum	< 120	< 115	< 80	< 75
Normal	120 – 129	115 - 124	90 – 94	75 - 79
High-normal	130 – 139	125 - 134	85 - 89	80 – 84
Grade 1	140 – 159	135 - 146	90 – 99	85 – 89
Grade 2	160 – 179	147 - 156	100 – 109	90 - 95
Grade 3	≥ 180	≥ 157	≥ 110	≥ 96
Isolated syst. hypertension	≥ 140	≥ 135	< 90	< 85

The “Optimum” and “Isolated systolic hypertension” ranges provide additional information; they are not listed in the risk assessment table in this form. Example: If a patient's daily average values lie within the optimum range (< 115/75 mmHg), the blood pressure severity is classified as “Normal” in the risk assessment table (better assessment not possible). In the definition and classification table (ABPM Classification button) the “Optimum” and “Normal” lines are highlighted in this case.

Classification of blood pressure ranges according to international guidelines

	Systolic [mmHg]		Diastolic [mmHg]	
	Office blood pressure	Daily average	Office blood pressure	Daily average
Normal	< 140	< 135	< 90	< 85
Grade 1	140 – 159	135 - 149	90 – 99	85 – 94
Grade 2	160 – 179	150 - 169	100 – 109	95 - 104
Grade 3	≥ 180	≥ 170	≥ 110	≥ 105
Isolated syst. hypertension	≥ 140	≥ 135	< 90	< 85

5.3 Holter ECG

5.3.1 Performing a holter recording

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.

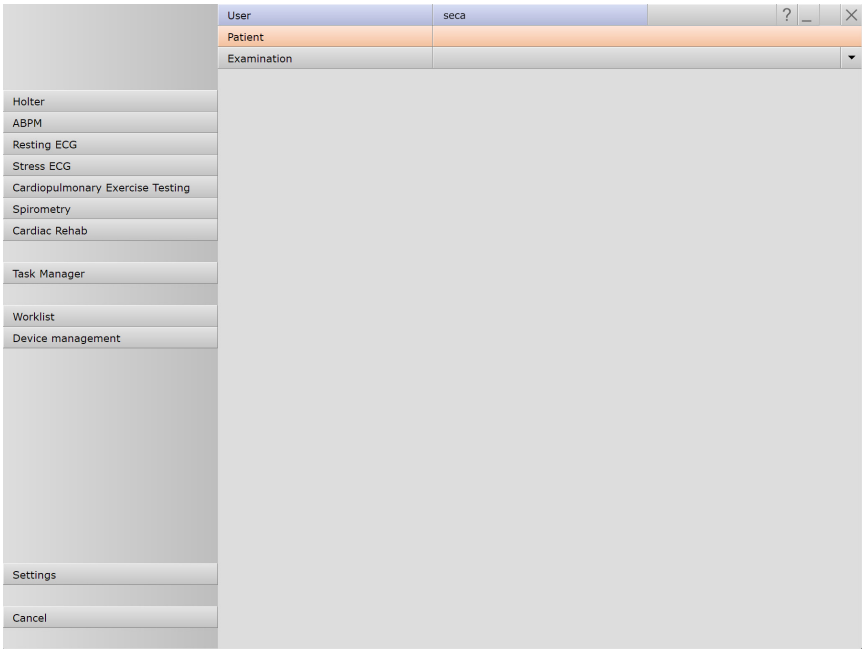


Fig. 52: seca diagnostic examination main menu

NOTE ON THE PROCEDURE: The steps necessary to carry out and evaluate a holter examination in seca diagnostic are shown without a surgery IT system or HIS connection.

Program start, calling the Holter ECG

- → Make sure that the card reader or the communication unit is connected to the PC and ready for operation.
- → Start seca diagnostic and log in.
- → Click on Examination, Holter, New Holter.
- → In the Holter ECG recorder list, select the guard holter device for Holter ECG recording.
- → Place the guard holter device on the communication unit.

Setting the start parameters

- → Select a set of Holter ECG parameters, e.g. Standard or create a new set: Edit.
- → Edit: Buttons 1 – 5 open additional screens with analysis parameters.
- → The options can be set as required:
  - → Pacemaker detection
  - → Print diary: Printout of the patient diary during the start procedure (to document events during recording).
  - → Start with Patient: Allows a patient to be selected when starting the recorder. This option is always active.
- → By selecting Save As, the changed parameters can be saved under a new name.
- → By selecting Save, the current set is overwritten.
- → Click Close to close the parameter configuration.
- → Next, select the lead type, start options and recording parameters.

IMPORTANT when working without selecting a patient:

Medical personnel must ensure clear and reliable assignment of device and patient so that a recording can be assigned to the correct patient when it is later read into seca diagnostic (e.g. labelling, keeping a daily updated list of device numbers and patients).

1) seca guard holter leads in seca diagnostic: with custo belt: F, T1, T2; with ECG cable guard 3: I, II, III; with custo wing: A, B, C; with ECG cable guard 4: A, B, C.

For seca guard holter: Defining the leads, start type and duration

→ Depending on the attachment method, the ECG leads[1)] are calculated differently. Specify how the seca guard holter is attached to the patient:
  → with custo belt (electrode belt)
  → with ECG cable guard 3 (adapter for adhesive electrodes)
  → with custo wing/ECG cable guard 4 (four disposable adhesive electrodes)
→ Set when the recorder should start:
  → Start now
  → Start later (manually at any time)
  → Start at date/time (automatic start at a defined time)
→ Set the recording duration:
  → 24 h
  → 48 h
  → 72 h
  → 5 days
  → 7 days
  → unlimited
→ Click on the Start button.
→ The patient selection screen appears.

If the Start with Patient option was previously deactivated, there is no need to select a patient at this point. The seca guard holter device is prepared for recording without patient data. Medical personnel must ensure clear and reliable assignment of device and patient so that a recording can be assigned to the correct patient when it is later read into seca diagnostic (e.g. labelling, keeping a daily updated list of device numbers and patients).

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.
→ Save the data.
→ The patient is entered into the database.

Data transmission

→ The recording parameters and patient data are then transferred to the seca guard holter device.
→ Check for feedback from seca diagnostic or the Holter ECG recorder.
→ For seca guard holter and Start now option: Recording is started and monitoring is displayed in seca diagnostic.
→ For seca guard holter and Start later option: A dialogue with information on the recorder start is displayed in seca diagnostic. Confirm the dialogue.

INFORMATION - HANDLING THE SECA DIAGNOSTIC WARNING ABOUT THE CHARGE STATUS: If a warning about insufficient battery capacity appears in seca diagnostic during the start procedure (charge status is not sufficient for the selected recording duration), seca guard holter can still be started (Start anyway button), e.g. if a shorter recording duration is sufficient. Otherwise, cancel the start procedure (Cancel button) and recharge seca guard holter.

Monitoring with seca guard holter – checking the electrode positions

→ The Monitoring screen either automatically appears after the start (Start now with patient option) or can be opened via Examination, Holter ECG, Monitoring in all other cases.
→ Put the seca guard holter device on the patient. When putting the device on the patient, the lead type previously selected must be used (custo belt/ECG cable guard/custo wing). Otherwise, inaccuracies may occur in the analysis.
→ Check the ECG signal on the screen. Correct the electrode positions if necessary. If QRS complexes are detected, the ECG LED on the seca guard holter device will light up in green at regular intervals.
→ If the Start later option has been selected, start recording at the desired time by tapping the device twice on the centre of the front panel or already during Monitoring with the Start button. Recording begins after a short beep. Checking the quality of the ECG signal is also possible without monitoring. If the ECG quality is insufficient, the ECG LED on the seca guard holter device will light up in red at regular intervals. Correct the electrode positions until the ECG LED lights up in green.
→ If the Start at a specified time option has been selected, recording will automatically start at the preset time. Recording begins after a short beep.

Monitoring duration

Start option	Recording duration	Max. monitoring duration
start now	24 h, 48 h, 72 h	1 h after start
start now	120 h, 168 h, unlimited	15 min after start
start later, at a specified time	24 h, 48 h, 72 h	1 h before and after start
start later, at a specified time	120 h, 168 h, unlimited	15 min before and after start

The shortened duration of monitoring for recordings with 120 h or unlimited duration serves to extend the battery life of the seca guard holter or to conserve the battery charge in advance.

5.3.2 Read in and display the recording

Work steps after the Holter ECG recording

→ Remove the Holter ECG recorder and all accessories (e.g. protective bags, carrying belt, electrodes...) from the patient.
→ Connect the Holter ECG recorder to the PC so that the recording can be downloaded.

Program start, downloading the Holter ECG recording

→ Start seca diagnostic and select: Examination, Holter ECG, Read in recorder.
→ The “Workflow after download data” dialogue appears. You can analyse and display the recording now or later.
  → Later button: The recording is stored without analysis in the Job Manager. The Job Manager is suitable for downloading several recorders in a short period of time. To make recordings from the Job Manager available, open the Job Manager via the Examination main menu. Activate the Analysis option and start the process (Start). After the analysis, the recordings can be opened.
  → Now button: The recording is evaluated during the download and then displayed.
→ When using different Holter ECG recorders, the “Select Data Source” dialogue appears. Select the appropriate device type.
→ If the seca guard holter was selected as the device type, a dialogue for selecting the seca guard holter device appears. The seca guard holter devices connected to the PC (USB connection via custo guard base) are displayed in a list. Select the seca guard holter device to be read in with a mouse click on the corresponding list entry. When the list entry is clicked, the battery LED of the seca guard holter device will flash quickly for approx. 30 seconds (to check and identify whether it is the correct seca guard holter device). Confirm the selection.
→ Recording without patient data: If the Holter ECG device has been started without patient data, the recording must be assigned to a patient at this point.
→ Optional additional dialogues: Additional dialogues may follow, depending on the device type or software version, for example: “Evaluation start time” to check and correct the recording period or “Evaluation type” to specify whether a recording is read in as a Holter ECG or as an event recorder. With the Event recorder option, only the events in the recording are downloaded and analysed.
→ The data is read into seca diagnostic.
→ If the recording is opened after it has been read in, it can be closed via End (bottom right).
→ Click on Confirm in the End dialogue.

5.3.3 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. 53: 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.

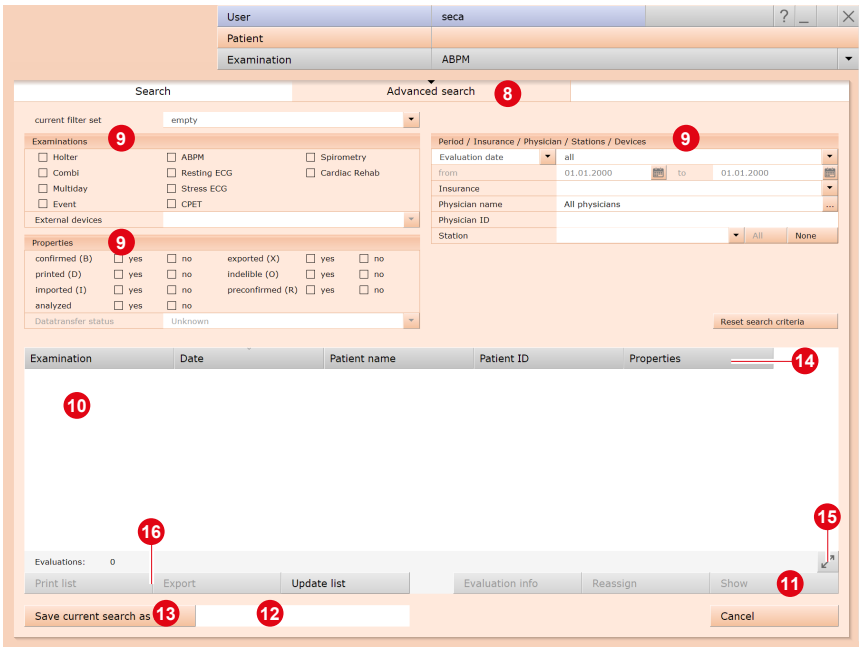


Fig. 54: Evaluation search, extended search

5.3.4 Opening an evaluation via the evaluation menu

Tip for making entries in the patient menu: Press the Tab key to jump to the next entry field with the cursor.

→ Open the examination main menu via Examination, Holter ECG.
→ Click on Show Evaluation.
→ The patient search screen appears. In this screen, select the patient whose evaluation you want to open. Enter the patient's name in the input fields in the search screen.
→ Select the patient from the list below the input fields and confirm your selection using the Select Patient button 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.

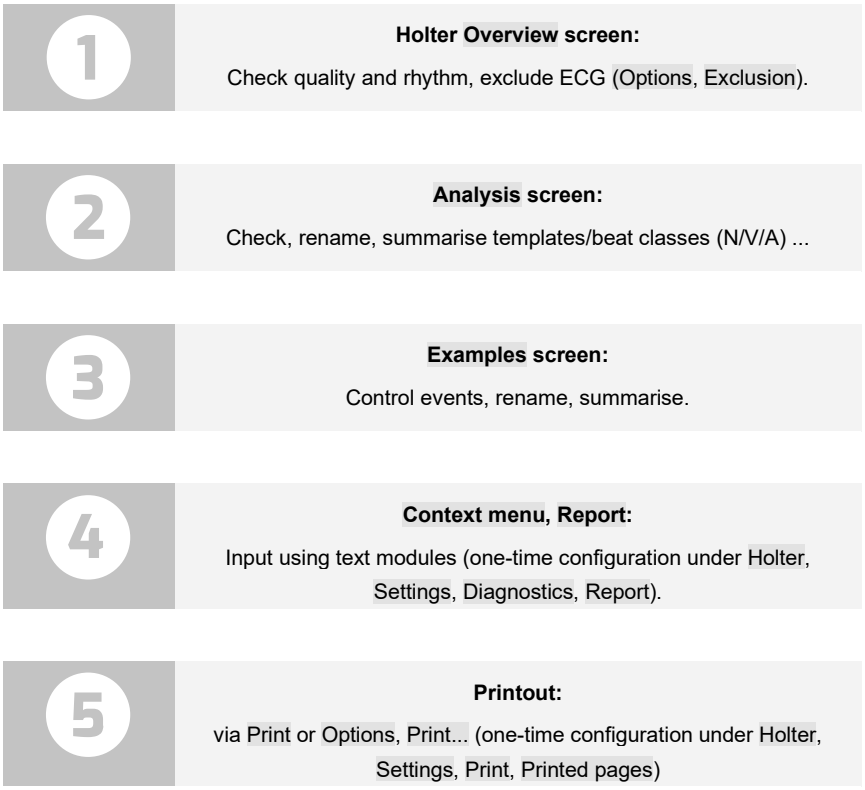
5.3.5 Evaluation structure

Start screen page "holter overview": 24-hour graph (trend) with a tabular summary of all events. Further screen pages of the evaluation:				
Beat class analysis: representation of all beat classes, divided into Normal, VPB, Artefact and Pacemaker	**Trend & ECG:** 24 h graph and ECG according to the cursor position in the 24 h graph, event-related navigation in the ECG	**ECG examples:** overview with example sections for the VPB classes and each event	**Evaluation comparison:** comparison of the current evaluation with an additional one	**Options menu** further screen pages
Compressed classes: beat classes within the previously selected class		**VPB selected, all VPB:** each single VPB as an example		ABPM[1)]
Single complexes: single beats of the previously selected class		**VPB selected, all templates:** All VPB classes, one example for each class		ANS diagnostics[2)]
		Show all: all VPB examples of the previously selected VPB class		Total ECG
		Show all: all examples of the previously selected event		Trend overview
				multiday

1) A suitable recorder is required
2) Optional

5.3.5.1 Workflow for writing the report for an evaluation

Getting to the report in five steps



5.3.5.2 Context menu

The context menu is opened by right-clicking on the evaluation. The contents of the context menu change depending on the evaluation page.

The report dialogue is always accessible via the context menu.

If you open the context menu on the Overview screen, you can manually insert events via Change if you should find events that were not detected by the program. In all evaluation pages where the ECG is visible, you can manually edit beats or events in the ECG using the Change function.

In the context menu of the Overview screen, the contents of the Overview or summary can be set using the Properties dialogue. For example, in episodes with atrial fibrillation, other atrial arrhythmias can be hidden (activate the Atrial fibrillation (no SVES, arrhythmia, SVT) option and Apply).

In the context menu of the Analysis, Trend/ ECG and Total ECG screens, specific points in time in the recording can be displayed using the Select time function. These are stored in the dialogue with the “Select Time” designation and are always available.

5.3.5.3 Options menu

The contents of the Options menu can vary depending on the evaluation screen. The Print, Export, Total ECG, Trend Overview and Service functions are available on every evaluation screen. Other functions or evaluation screens are available depending on the recording device and software version:

- → Print...
  Temporary change of print settings for the current evaluation.
- → Export...
  Excel and PDF export of the evaluation.
- → ABPM
  Combined recording of the Holter ECG and ABPM.
  Only with seca screen 300 in combination with a seca Holter ECG device
- → ANS diagnostics (vegetative diagnostics)[2)]
  Overview of the balance of the autonomic nervous system with graphical representation of stress and regeneration phases.
- → multiday (summary of multi-day recordings)
  Multi-day recordings with seca guard holter.
- → Total ECG
  Full-page representation of the ECG, view of the complete recording
- → Trend overview
  Graphical representation of all heart rate-related and ventricular events over the entire recording period
- → Invert
  The Invert function results in the reversal of the respective ECG channel

→ New analysis
Recalculation of the evaluation after manual changes have been made in the beat analysis
→ Exclusion
Exclusion of specific ECG sections, e.g. when the signal is interrupted
→ Parameters...
Setting pages for changing the analysis parameters of the respective area
→ Assign new
The evaluation can be assigned to another patient
→ Service
Technical details about the recorder and recording

1) seca diagnostic professional
2) optional

INFORMATION on applying or resetting changed parameters: Clicking on the Analysis button (at the bottom of the screen) applies the settings and the ECG is analysed again taking your changes into account.
With the Exit button, you leave the parameter settings screen and changes are not taken into account.
The Restore defaults button can be used to restore the default settings. This applies to all parameter setting pages in the Holter ECG evaluation.

5.3.6 Screens of the evaluation

5.3.6.1 Holter overview

1) *The present events are sorted by severity in descending order. For each event, it is indicated how often it occurred during the recording, partly with indication of the maximum value and time of the maximum value.*

Tips for navigation in the trend: Double-clicking on any point in the trend takes you to the Trend/ECG page. The clicked point is displayed enlarged. This procedure is suitable for targeted viewing of events in the ECG. Click on Overview to return to the Holter overview.

In the tables: Double-click on any event button to open the Trend/ECG screen page. Clicking on Number, Maximum value, Time of an event opens all examples of the event. The examples are ECG sections containing the corresponding event.

1. 24 hours graph (trend)
2. HR average (dark blue, between HR maximum and minimum), results from average heart rate per minute
3. HR maximum, HR minimum (light blue above and below HR average) show the highest and lowest value within one minute
4. Movement data (e.g., upright, resting (right), walking, ...)
5. Zoom: one hour of the graph enlarged
6. Selected event – button pressed, font orange.
   A selected event is displayed in the form of vertical orange lines, at the top, in the trend 1. The height of the lines in combination with the scale on the right-hand side of the screen provides information on the number of occurrences within a minute.
7. Night phase – adjust by dragging the grey arrows
8. Summary with number of all cardiac activities and HR
9. Listing of the heart rate related events[1)]
10. Listing of the ventricular events[1)]
11. Buttons to open further evaluation screen pages.
12. If it is a multi-day recording (longer than 24 hours and up to max. 3 or 7 days), two arrows for scrolling within the present recording days are displayed to the left of the Analysis button.
13. Options menu with further evaluation screen pages and editing functions
14. Printout according to system settings
15. Button for closing the evaluation

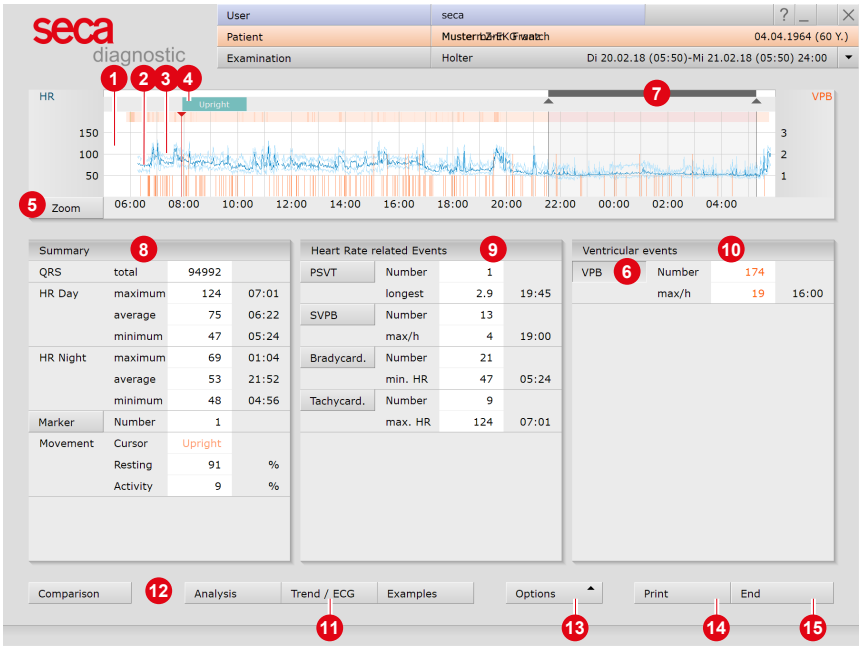


Fig. 55: Holter overview

5.3.6.2 Analysis

On the Analysis page, the beat classes of the recording can be checked, summarized and reassigned. All recorded QRS complexes are summarized into beat classes. The method of beat class calculation or its accuracy is defined in the settings1).

1. Beat classes with normal QRS complexes (N);
2. Beat classes with modified QRS complexes (V);
3. Artefact classes (A) and if applicable an additional button for showing the pacemaker classes (P)
4. Occurrences of the selected class are marked in colour in the ECG
5. Marking/saving changes for analysis
6. Display of all classes or beats of the selected class
7. Scroll forward one step at a time
8. Scroll backwards or forwards page by page
9. Scroll bar to navigate through the entire recording
10. Jump to the next single complex of the selected class
11. Continuous scrolling in the ECG
12. Numbering of the class (numbered in ascending order)
13. Annotation: normal (N), VES (V), artefact (A), pacemaker (P)
14. Number of single complexes of a class
15. Percentage related to the number of all QRS complexes.

Fig. 56: Analysis

Beat identification

Beat identification in seca diagnostic is carried out using the VES identification algorithm from Kraft et al (2023): Kraft, D., Bieber, G., Jokisch, P., & Rumm, P. (2023). End-to-End Premature Ventricular Contraction Detection Using Deep Neural Networks. Sensors, 23(20), Article 20. https://doi.org/10.3390/s23208573.

1) seca diagnostic settings for beat classes: To specify the number of beat classes in an evaluation, open the screen page: Examination, Holter, Settings, Diagnostics, Analysis, Beat identification. In the "Compress templates for analysis" area, the following options are available:

Disabled: No compression.

Compress: The beat classes are compressed according to the set sensitivity (by default "4").

Auto-Compress: With this option, the beat classes are reduced until either a sensitivity has been reached for which there is no change compared to the previous value or until fewer than 30 classes has been reached.

Tip for controlling beat classes: The QRS complexes of a beat class can be displayed superimposed. That is, all QRS complexes of a class are superimposed and deviations within a class can be quickly identified. If the central complex is displayed clearly and without deviations, the QRS complexes of the class match. If many deviations can be detected, the sensitivity of the beat class analysis may need to be adjusted. Overlay on/off function: Examination, Holter, Settings, Menu/Functions, Workflow, Show template superimposition option.

Editing options on the Analysis page

Display and editing levels:

→ Analysis screen page: all beat classes of the evaluation
→ Compressed class: selected class with assigned classes
→ Single complexes: single beats of the previously selected class

The individual levels are opened by double-clicking on a class or by clicking on the Show all button. With Back the parent level is displayed again.

Selection of several beat classes for further processing:

→ Keep left mouse button pressed and drag
or Shift + left click = selection of several classes next to each other (range)
→ Ctrl + left-click = specific selection of several classes

Combine or move several classes

→ If multiple classes are selected, left-clicking on the numbering (top left number) of any class in the selection will combine all selected classes into the class with the lowest numbering.
→ If multiple classes are selected, left-clicking on the annotation (N/V/A/P) will move all selected classes to the corresponding category.

Combining or moving single classes

→ Left-click on the numbering (number in the upper left corner) opens the dialogue for “Merging templates”. Here a new target can be defined for the previously selected class.
→ Left-click on the annotation (N/V/A/P) changes the assignment, alternatively enter the letter via the keyboard.

Moving single complexes of a beat class

For this step, the lowest navigation level of a beat class must be open (double-click on a class and its subclasses or repeatedly press the Show all button). Double-click on the numbering of a single beat to open the dialogue for moving single complexes. The selected beat (source) can be assigned to another class (target).

Applying changes

With the OK button (top right in the Analysis overview) the previous changes are marked. Via Options, New analysis the ECG is recalculated taking into account the changes. If the new analysis is not triggered manually, this is done automatically when another screen page is called up. With Confirm you start the process. With Cancel the changes are discarded.

5.3.6.3 Trend/ECG

1) *About the mouse functions: Measure RR intervals: By clicking in the ECG signal, a line appears, the starting point of the measurement. By dragging the mouse to the left or right, more lines appear. Another click fixes the distances between the lines. By clicking again, the lines disappear. Marking ECG sections: To mark an ECG section, drag the cursor in the ECG signal over an ECG section. When you release the cursor, a dialogue opens in which you can name the marking and then print it or save it as an episode in the evaluation. Episodes are stored with the examples. Changing events: To edit a beat or an event (e.g., change VES to artefact), make a double click on the corresponding place in the ECG. A dialogue opens in which you can correct the original assignment. Confirm to apply the change.*

1. 24 hours graphic (trend) with zoom function
2. Movement data (e.g., upright, resting (right), walking, ...)
3. ECG matching the cursor position in the upper graph
4. Menu for selecting an event
5. The selected event is highlighted in colour on the ECG
6. The centrally positioned letters show the type of event
7. In the trend the selected event is marked with lines
8. the height of the lines in combination with the scale on the right side of the screen shows the number of occurrences per minute
9. Mouse functions Mark, Change, Time or Measure; the selected tool can be applied in the ECG[1)]
10. ECG overview – reduced ECG (e.g., 15 min/page) with marking of the selected event
11. Tabular display of events
12. ST measurement
13. Scroll bar for navigating the ECG signal; by dragging the scroll bar across the entire length of the recording, artefacts and areas without a signal can be quickly detected and checked
14. By clicking on 14: The program automatically jumps to the previous or next occurrence of the selected event
15. By clicking on 15: The ECG runs constantly across the screen
16. Changing the amplitude magnitude, moving the zero line, resetting the changes
17. Display of RR distances, heart rate or beat classes (Templ.) below the ECG signal

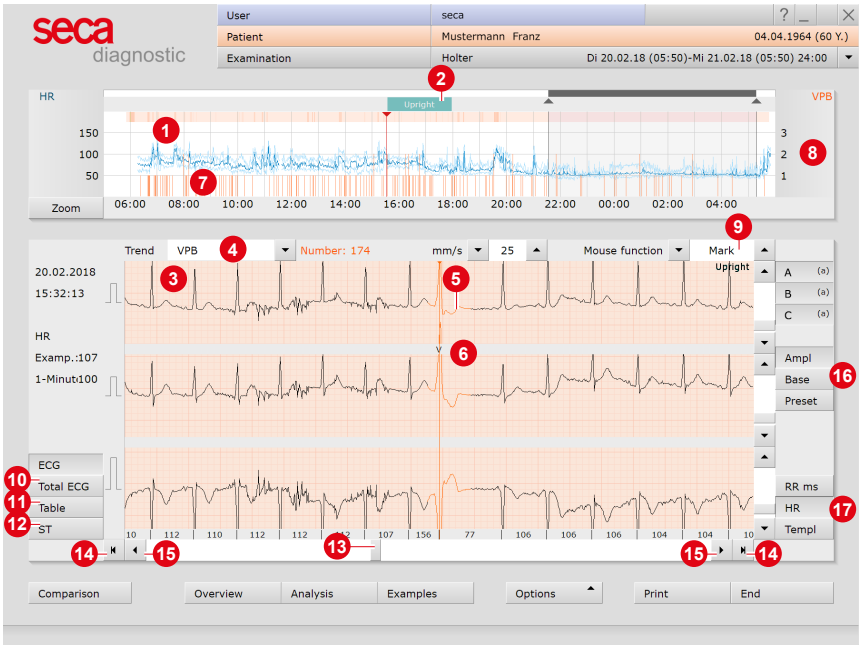


Fig. 57: Trend/ECG

5.3.6.4 Examples

1. Sample preview with an ECG example for every event
2. Additional information on the selected example. Selection by mouse click.
3. The header of the selected example has a black background.
4. Delete the selected example[1)]
5. To view and edit the examples in detail...
   all VPB: display of all VPB examples of the evaluation
6. all templates: display examples of all VPB classes
   or show all: display all examples of an event class

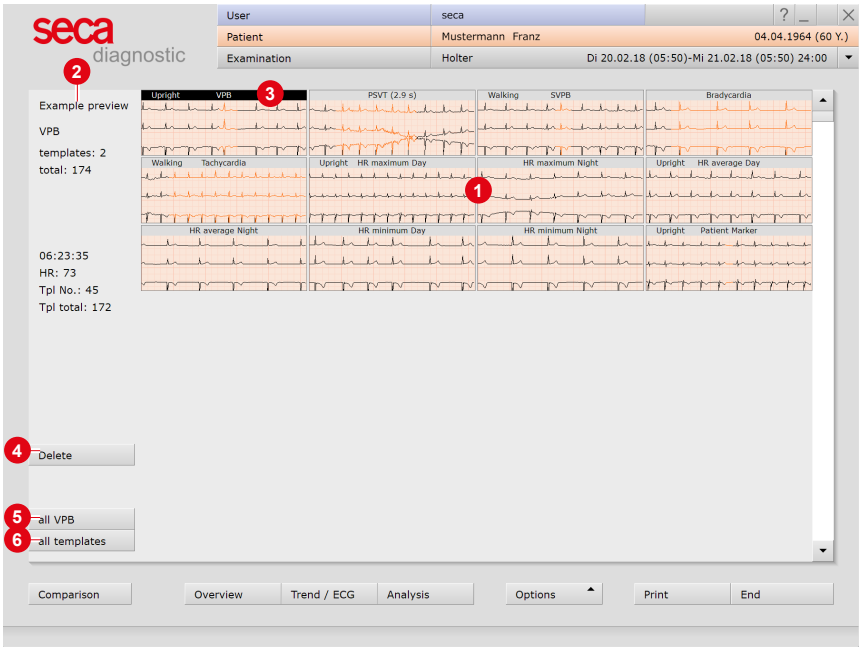


Fig. 58: Example preview

Considering ECG examples in context

The examples can be viewed either on the Trend/ECG screen page or in the ECG environment in context, i.e. in the ECG recording[2)]. This is done by double-clicking on an example. Additionally opening the ECG recording is only possible on the lowest navigation level in the example area – to be reached via Example preview, selecting the example and clicking on all VPB or Show all, depending on whether a VPB or another event has been selected (alternatively, it is also possible to navigate in depth by double-clicking on an example). The Example Preview button opens the higher-level screen page again.

Changing the allocation of examples

→ Select an example,
→ open the context menu and click Change there.
→ In the “Edit beat” dialogue, select the desired event.
→ Confirm to apply the changes

1) Editing, deleting and restoring examples: After you Delete examples, the undo function is available to restore deleted examples. Via Options, Edited examples, you can display all the previously deleted examples and restore them from this page (undo). In the lower navigation levels of the example preview, you can delete all the examples of an event at once (delete all).

2) seca diagnostic can be set to display the ECG Environment dialogue instead of the Trend/ECG screen page when an example is double-clicked. The difference in this procedure is that the Example preview screen page remains open while the ECG example is viewed in context. To activate the ECG Environment dialogue, open the context menu and click Properties there. Select the option “Display selected example in ECG environment”. Apply the settings.

5.3.6.5 Further standard functions

Comparison

Comparison (button always bottom left) of two evaluations of a patient, each with trend, HR summary and events.
By clicking on an event button, the event is displayed in the graphic. The date lines above the tables can be opened with a mouse click to display further evaluations of the patient.

Fig. 59: Comparison

Total ECG

Minimised representation of the entire recording. To mark ECG sections, drag the cursor over the ECG. When you release the mouse button, a dialogue opens for further editing of the selection. By clicking the double arrow buttons the ECG automatically runs in the corresponding direction, clicking again = increased speed.

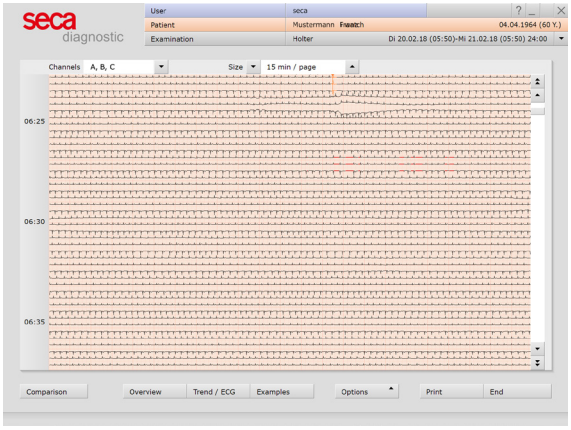


Fig. 60: Total ECG

Trend overview

An interactive table detailing all events over the entire recording period and ECG in relation to the cursor position in the table. Each event is represented in the form of a black line in the table. Click on the black lines to display the corresponding position in the ECG.

Fig. 61: Trend overview

multiday evaluations

A multiday evaluation is an evaluation over several days. When opening a multiday evaluation, the previously selected recording day is displayed. The arrow keys to the left of the Analysis button can be used to scroll within the recording days.

The multiday summary (overview of all recording days) is opened via Options, multiday. The multiday summary is a graphical overview of all recording days with a tabular summary of all values and events for the entire recording period. In the upper graphic of the summary, individual days can be selected with the cursor. Double-click to display the corresponding day as an evaluation.

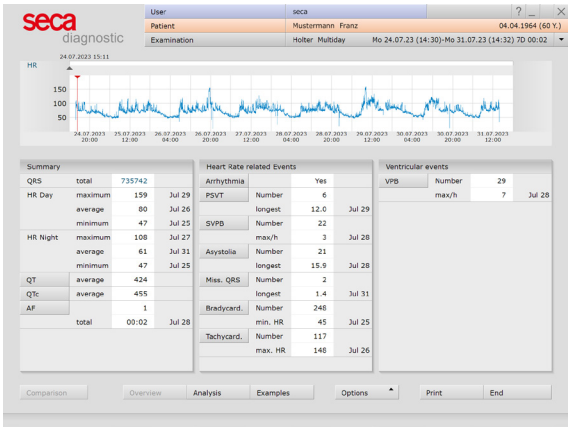


Fig. 62: multiday summary

Holter-ABPM evaluation

If you perform an ABPM recording in addition to the holter recording, you can open both recordings as a combined evaluation in seca diagnostic (time offset < 12 h).

The blood pressure curve (green) is displayed in the trend via the BP (Blood Pressure) button in the summary. Open the ABPM evaluation via Options, ABPM.

In the ABPM evaluation, the unconfirmed report is opened by right-clicking on the evaluation surface. Select Report in the context menu. The ABPM report is automatically transferred to the Holter-ABPM view when you exit the ABPM evaluation.

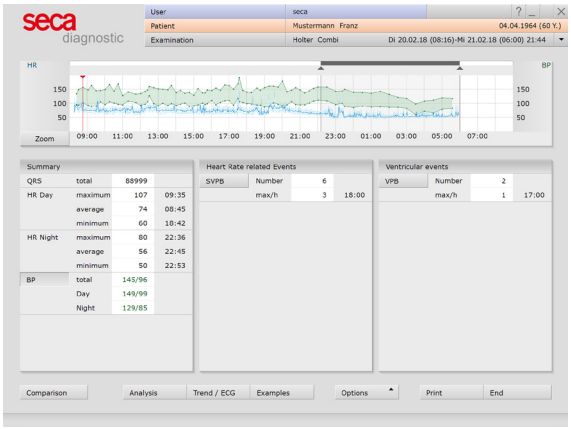


Fig. 63: Holter-ABDM evaluation

5.3.6.6 Optional functions

1) The relationship between the two areas of influence during the night can be interpreted as a measure of sleep quality.

2) Values for the heart rate, the standard deviation from normal beats, the logarithm of the respiratory sinus arrhythmia, the natural logarithm of the "very low/low/high frequency" and the autonomic quotient of LF/HF. For these areas, the average values and the normal range are indicated – once within 24 hours – and also as a wake and sleep phase.

ANS diagnostics (Options menu, ANS diagnostics)

ANS diagnostics provides an overview of the balance of the autonomic nervous system. Stress and regeneration phases are displayed graphically. The trend (graph above) also shows the movement data.

1. Chronocardiogram with spectral analysis of HRV, based on 24 h
   horizontal: time axis (h),
   vertical: frequency axis in Hertz (Hz)

   The frequency ranges show the dynamics of various vegetative-mediated activities, such as blood flow rhythm, blood pressure variability, respiration and others. The colours indicate the intensity of the degree of the respective vegetative activities:
   red = very high,
   white/yellow = weak and
   blue = virtually no effect.

2. Distribution of the stress and regeneration phases during the recording, shows stress and regeneration phases[1)]
3. Drop-down menu for opening the variability/vagal activity diagram.
   Standard deviation from the average heartbeat (purple band) and a representation of the decadic logarithm of the respiratory sinus arrhythmia (light blue band).
4. Measured value table[2)]

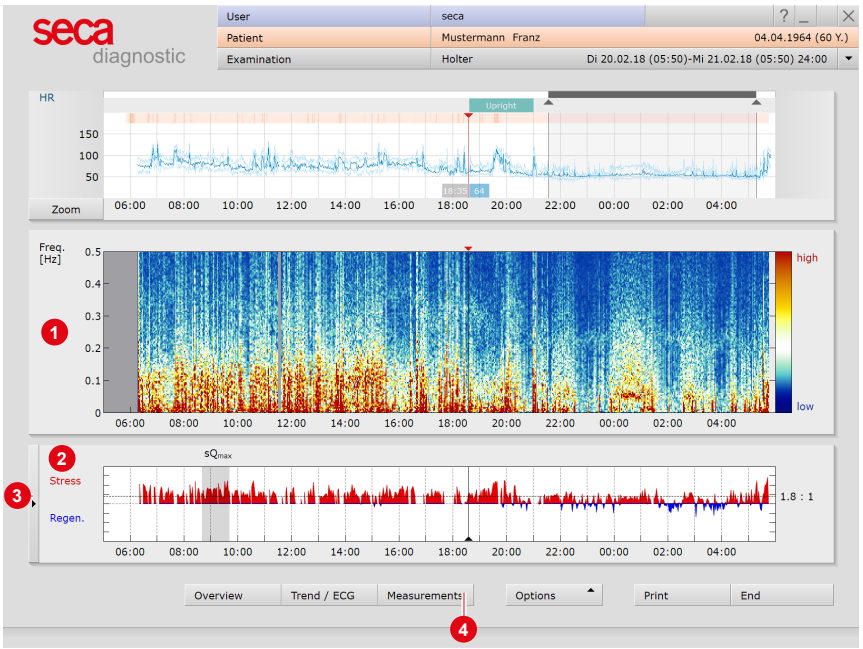


Fig. 64: ANS diagnostics

5.3.7 Printing the evaluation

1) To execute print jobs saved in the Job Manager, click on Examination, Job Manager, Execute or Execute All.

Alternative ways to create a printout:

→ Printout according to the system settings using the Print button.
→ Individually compiled print pages for the current printout via Options, Print... (settings are not permanently applied)
→ Collect print jobs in the Job Manager for later batch processing[1)]

Options menu, Print... screen

1. Compiling the contents
2. Amplitude size of the ECG signal in the printout
3. Selection and setting of the printer on the General page
4. Button for saving the print job in the Job Manager
5. Preview of the compiled print pages
6. Button for starting the printout
7. Button for closing the print menu

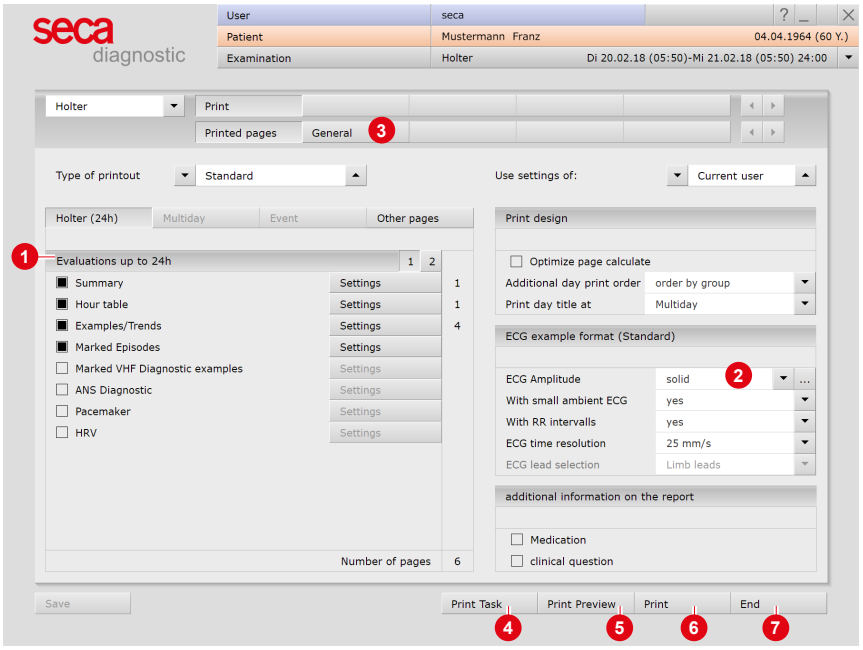


Fig. 65: Print... screen

The system settings for the printout of holter evaluations can be found under Examination, Holter, Settings, Print. To apply changes in the system settings, click on Save.

5.3.8 Confirming the evaluation

Unconfirmed report and report

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

Text modules – an aid for writing reports

Select Examination, examination type (e.g. Holter ECG, ABPM, Resting ECG, Stress ECG, ...), Settings, Diagnostic, Reports to configure text modules for reporting an evaluation. A total of four groups with up to eight text modules can be created. The text modules are called in the unconfirmed report dialogue via the keyboard (F5 to F12).

A text module can be created from normal text and variables. When you use a text module in the unconfirmed report, the actual value from the evaluation is inserted in the report text instead of a variable. The structure of a variable is {VARIABLE}. The Shortcuts for export values button provides you with a list with all variables. If the text modules should be shown in the unconfirmed report dialogue, make sure that the Enabled option is activated. Alternatively, the text modules can be shown in the unconfirmed report dialogue by selecting Options, Texts on. There is also the option of writing a text that is automatically displayed in each unconfirmed report (text suggestion or user-defined unconfirmed report). The text can be changed later in the unconfirmed report dialogue. Save your input.

5.3.9 Ending the evaluation

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

This is where the status of an evaluation is defined. Assigning properties (evaluation status) in the End dialogue makes it easier to find evaluations in the evaluation search.

→ Evaluation preconfirmed: If a user with the reporting right “Preconfirm evaluations” has confirmed the unconfirmed report.
→ Evaluation confirmed: If a user with the reporting right “Confirm evaluations” has confirmed the unconfirmed report. The “Evaluation confirmed” status can be reset if required.
→ Printed: Indicates if the evaluation has been printed.
→ Indelible: Can be selected after reporting has been completed. The evaluation can only be viewed and can no longer be changed.
→ Click on Confirm to close the evaluation.

5.4 Resting ECG

5.4.1 Perform resting ECG recording

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.

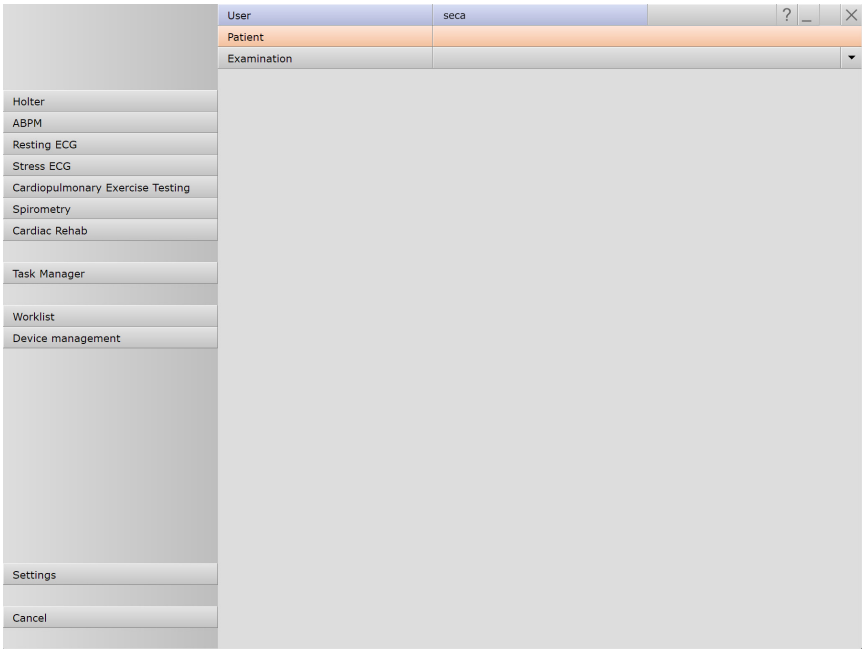


Fig. 66: seca diagnostic examination main menu

INFORMATION: The necessary steps for recording and analysing ECG data in seca diagnostic are shown without a surgery IT system or HIS connection

→ Apply the ECG device to the patient.
→ Observe the correct sequence of work steps.

Starting the program, calling up resting ECG

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

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.
→ Save the data.
→ The patient is entered into the database.

Selecting ECG device

→ If several ECG devices are connected to the workstation, the “Select ECG Device” dialogue box 1 is displayed.
→ Select the ECG device 2 and click on Confirm 3.
→ If only one ECG device is connected, this step can be omitted.

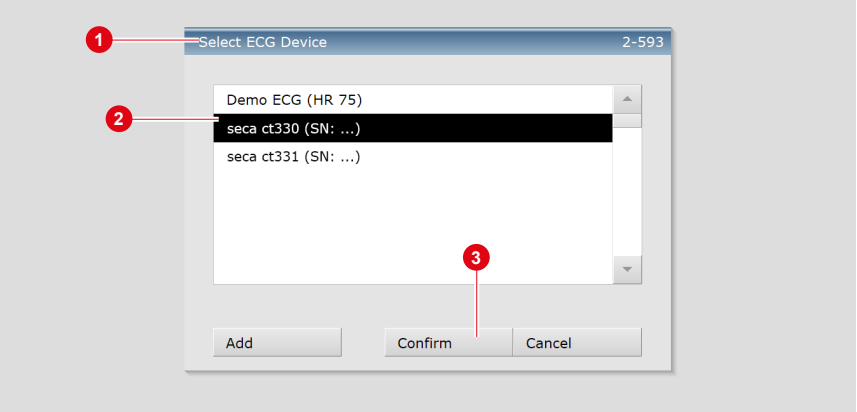


Fig. 67: Select ECG device

Monitoring and electrode control

The patient's ECG signal is displayed on the screen, but not yet recorded (monitoring). Work steps before starting:

→ Change the type of Lead ❶ if necessary.
→ Check whether the electrodes are in optimal contact. If red lines are visible on the screen, there is insufficient contact between the skin and the electrode(s). The corresponding electrodes must be reattached.
→ Set the desired Filters ❷ (Options menu ❸).

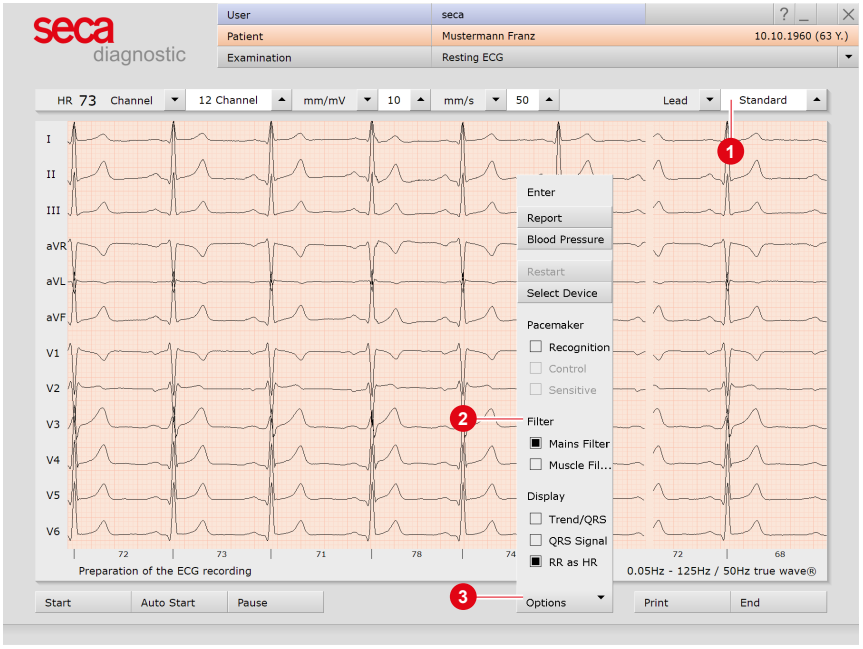


Fig. 68: Monitoring and electrode control, resting ECG

INFORMATION

ECG filters limit the signal range and can suppress diagnostically relevant portions of the ECG signal. Muscle filters (45 Hz) and ergo filters in particular reduce the transmission range of the ECG signal. Information for the ECG analysis may be lost as a result.

Therefore, do not always switch on ECG filters, but only in specific cases where an ECG filter is required.

Automatic ECG - Autostart button

→ Click on Autostart ❶ to start the automatic recording.
→ The default setting for the duration of automatic recording is ten seconds.
→ After the ten seconds have elapsed, the recording is automatically ended, saved, measured and printed out.

Manual recording – Start button or Enter key:

→ If you want to perform a recording without a time limit (e.g., if you suspect irregularities), trigger the recording with Start ❷.
→ At least ten seconds of the ECG must be recorded before a recording can be ended.
→ Use Stop to end the recording, the ECG interface remains open.
→ Use Start and Stop to record additional sections.
→ End ❸ closes the recording.
→ Click Confirm in the End dialogue so that the recording is saved, measured and displayed as an evaluation.

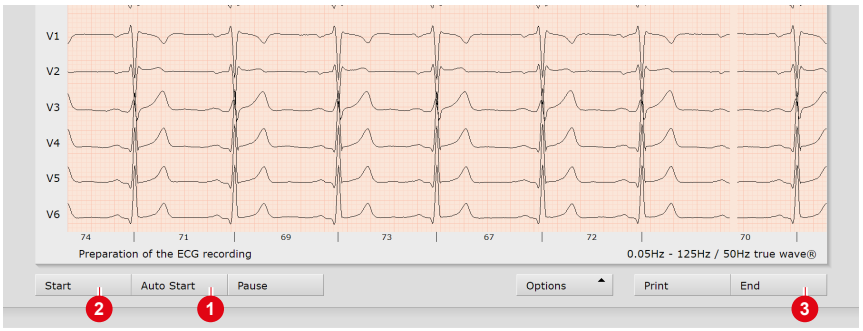


Fig. 69: Start resting ECG recording

IMPORTANT

Note on recording with a tablet PC: Before starting a recording, the system asks for the battery capacity. If this is less than 15%, no new recording can be performed.

INFORMATION:

The preset standard work steps for automatic ECG and manual recordings are described here. This workflow can be changed in the seca diagnostic settings, see Examination, Settings, Resting ECG, Menu/Functions, Workflow.

Tip: Keyboard shortcut “Change amplitude (mm/mV)”.

Editing options during the recording process

→ Mark ECG automatically: Clicking the Mark button 1 automatically marks the last six seconds of the recording. A dialogue box opens for naming, printing and saving the marking 2.

→ Mark the ECG manually: With Start marking 3, you can determine the length of the marker yourself. The marker runs until you click on Stop marking. A dialogue for naming, printing and saving the marked ECG section 2 opens.

→ Viewing ECG, marking and measuring HR during a Pause: Clicking on Pause 4 stops the screen display. The recording continues and is displayed on one channel. The scroll bar can be used to view the current recording. The “Mouse function” area (top right) contains the Mark, Measure HR and Measure tools. By dragging the red cursor in the ECG (Mark mouse function), you can mark sections. A dialogue box opens for naming, printing and saving the marking. Click on Continue to return to the normal view.

→ Online ECG print (print ECG): With the Print button 5, a page of ECG is printed out from the point of clicking. The printout contains 4.5 to 9 seconds of ECG depending on the display speed.
Under Examination, Resting ECG, Settings, Print, General you can specify in the area “Online ECG print settings” whether the ECG should be printed as it is displayed on the monitor or whether the online print should be done according to the already specified print settings for analysed ECG.

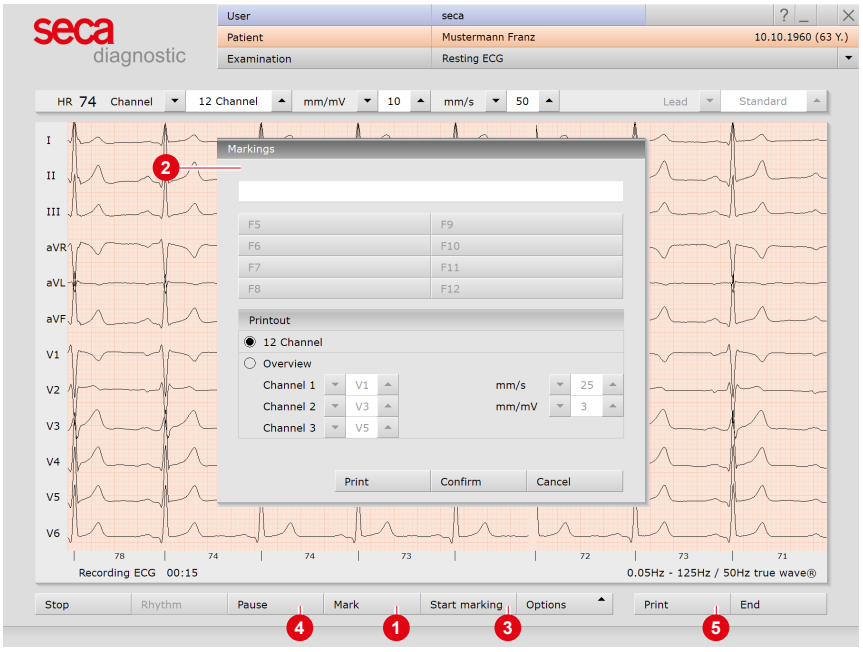


Fig. 70: Resting ECG recording, editing functions

5.4.2 Resting ECG rhythm strips

During resting ECG recordings, additional rhythm strips can be recorded. These are ECG sections of any duration during which the recording can be manually controlled. The “Rhythm strip” function can be activated under Examination, Resting ECG, Settings, Menu/Functions, Workflow 1. Specify whether the recording is to be stopped manually 2 or after a certain duration 3. Save 4 your input.

The recording of a rhythm strip is triggered with the Rhythm button in the ECG interface. If the recording duration is free, the recording of the rhythm strip is stopped with the Stop button.

In the evaluation, the available rhythm strips can be called up and displayed via the menu at the top left 5. It is possible to print out the rhythm strips. Under Examination, Resting ECG, Settings, Print, Printed pages activate Rhythm 6. Save your input.

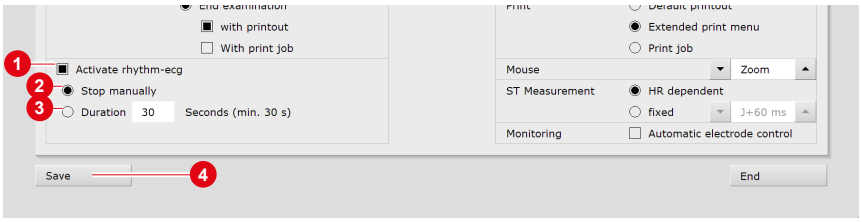


Fig. 71: Rhythm strip settings

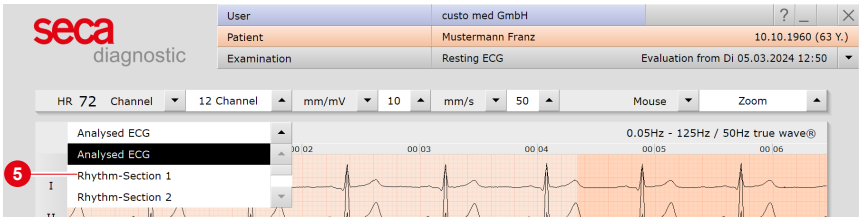


Fig. 72: Resting ECG evaluation with rhythm strips

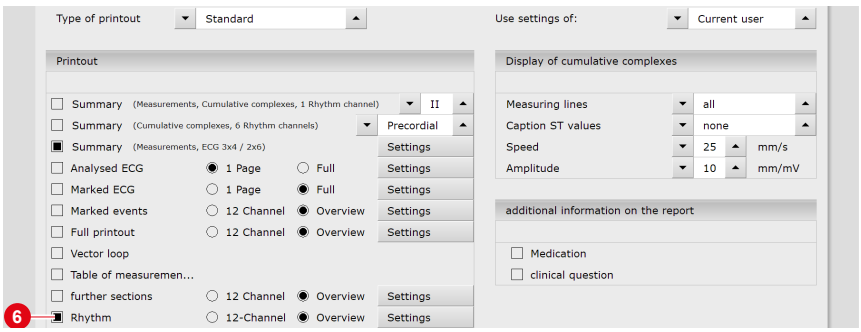


Fig. 73: Rhythm strip printout

5.4.3 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. 74: 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.

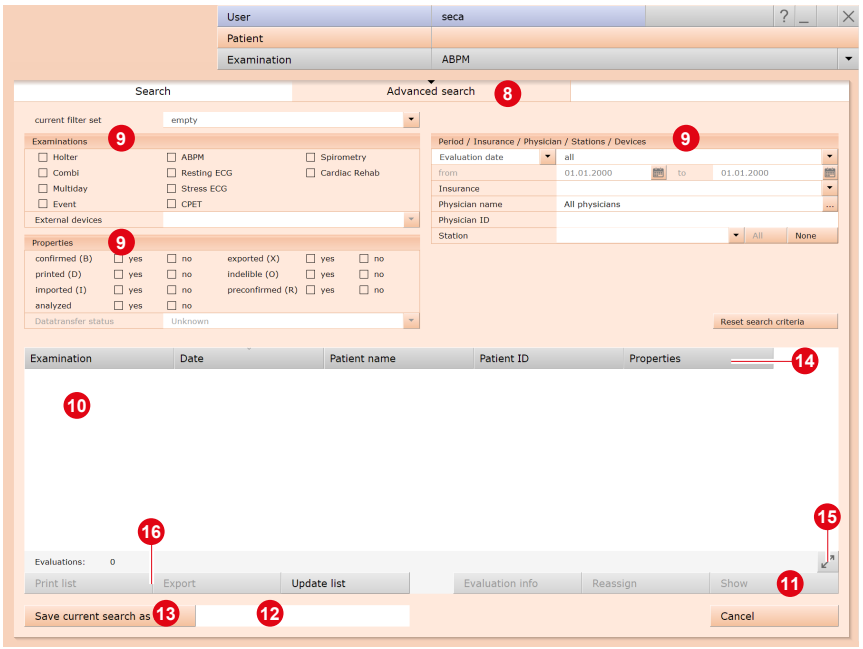


Fig. 75: Evaluation search, extended search

5.4.4 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 examination main menu via Examination, Resting ECG.
→ Click on Show evaluation 1.
→ The patient search screen appears. Select the patient whose evaluation you would like to open. Enter the name of the patient in the input fields of the search screen 2.
→ Select the patient from the list below the input fields 3 and confirm the selection with the Select patient button 4 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.

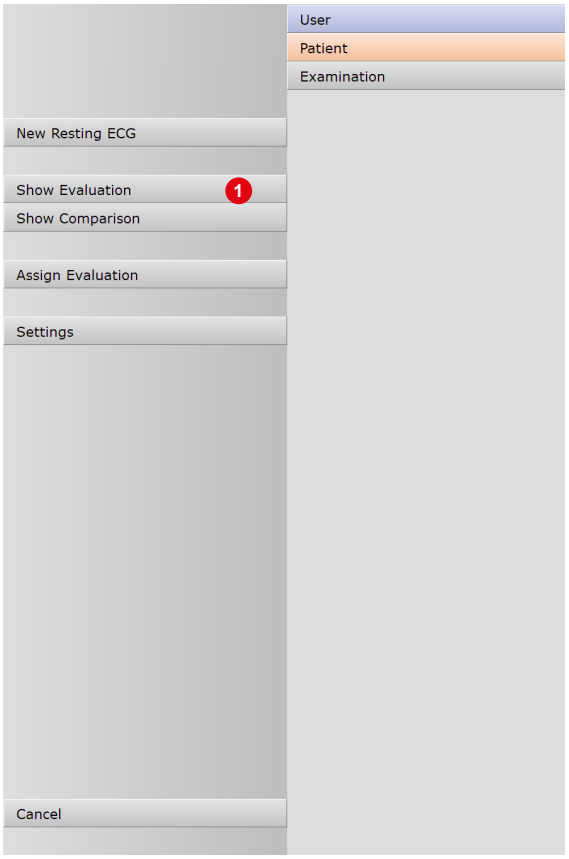


Fig. 76: Resting ECG main menu

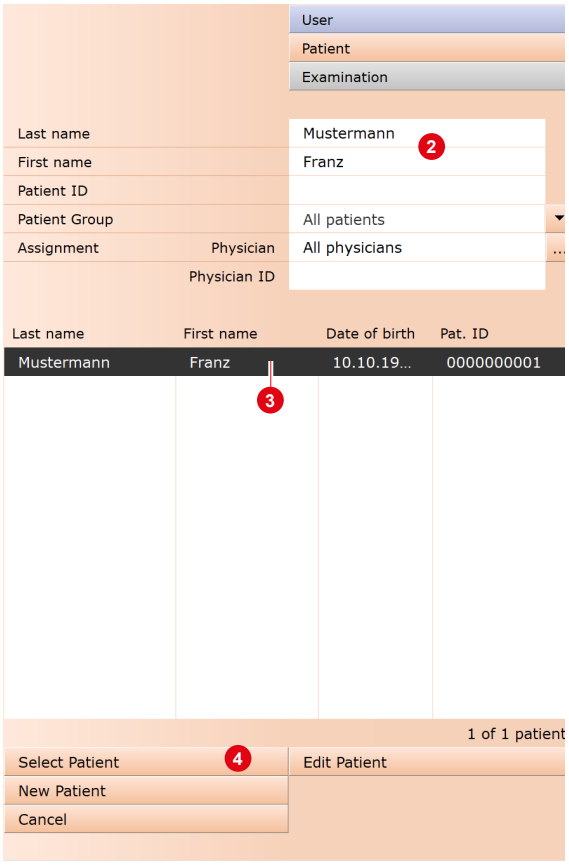
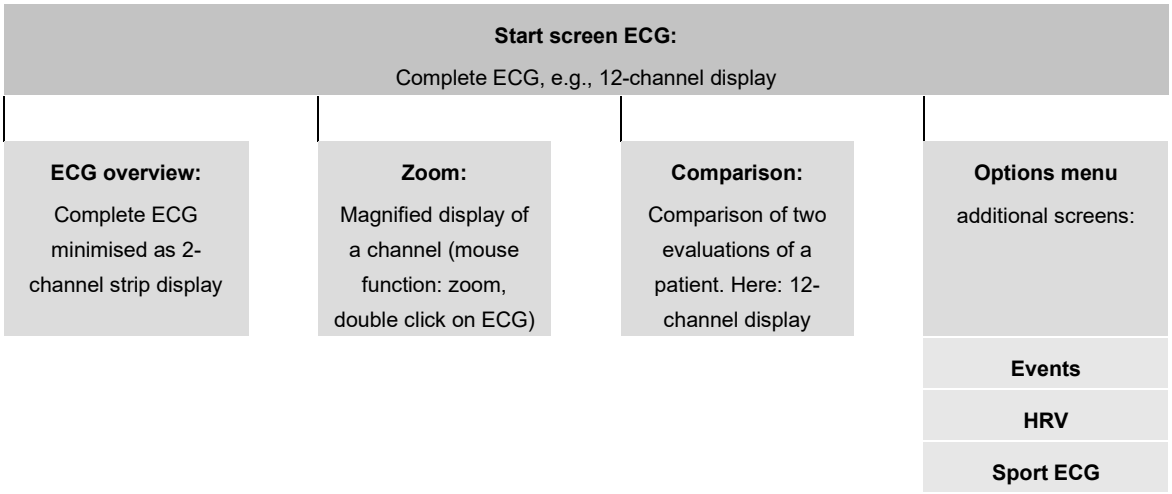


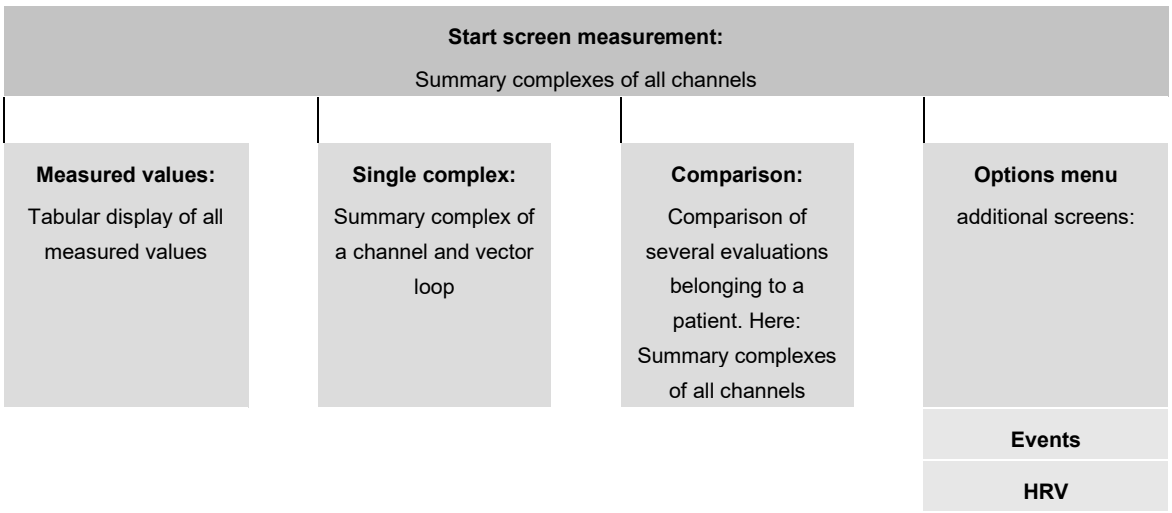
Fig. 77: Select patient

5.4.5 Evaluation structure

ECG evaluation is divided into two main areas: ECG and Measurement. The ECG screen is preset as the start screen, and the Measurement screen can be set as the start screen as an alternative if required. From the sub-screens of the two areas, the main screen of the other area can be reached at any time.

The evaluation start screen can be set under Examination, Resting ECG, Settings, Menu/Functions, Workflow in the “Menu/Functions, Show evaluation” area.





Tip: Keyboard shortcuts

Blood pressure input

F9

Deletes a marking if it was previously selected by mouse click

Delete

5.4.6 Screens of the evaluation

ECG start screen

1. Setting options for the ECG display
2. Mouse functions for precise viewing and measuring of the ECG signal (Zoom, Analysis, Measure HR, Measure, Marking)
3. Further evaluation screens
4. Print evaluation
5. Button for closing the evaluation

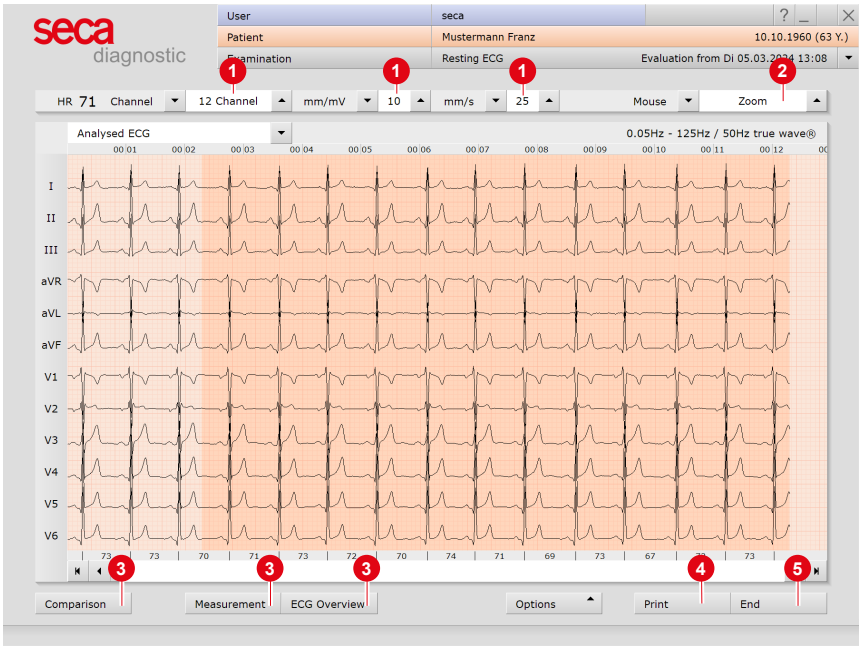


Fig. 78: Evaluation Resting ECG, ECG start screen

If the Measurement view is set as the start screen, you will find the same operating and navigation elements (1 to 5) there.

The evaluation start screen can be set under Examination, Resting ECG, Settings, Menu/Functions, Workflow in the “Menu/Functions, Show evaluation” area.

Settings for the Print button: On the Examination, Resting ECG, Settings, Menu/Functions, Workflow screen, in the “Workflow, Print” area, you can specify whether the advanced print menu is displayed when the Print button is clicked (default) or whether printing is performed automatically and without further settings, according to the default print settings (= defined printout). The standard print settings for Resting ECG can be found under Examination, Resting ECG, Settings, Print, Printed pages. Click on Save to apply your input.

Options menu

The scope and contents of the options menu change depending on which screen of the evaluation you are on. On the Measurement screen, for example, you can activate the display of ST values in the options menu and set which markers are to be displayed in the summary complexes.

1) For the RR variability to be displayed, at least five minutes of ECG needs to be recorded!

1. Print menu for temporary changes to the print settings
2. Export of the evaluation (e.g., as Excel, PDF, DICOM...)
3. If necessary, assign evaluation to another patient
4. Manual blood pressure input (F9 key)
5. HR trend, display of events in ECG (e.g., VBP)
6. Tables and graphics for heart rate variability[1)]
7. Deletes the ECG outside the marked and analysed sections
8. New analysis of ECG signal for resetting manual changes in ECG, additions to the report remain available
9. Automatic creation of a new report after manual changes have been made in the ECG recording
10. Analysis of the ECG according to criteria for competitive athletes
11. Switching on and off filters in the ECG (options: Display ECG as saved, unfiltered or filtered ECG - mains filter, muscle filter
12. Show and hide additional content on the right-hand side of the screen: e.g. cumulative complexes and report
13. Show or hide pacemaker spikes
14. Graphic flattening of ECG signal
15. In the bar below the ECG the heart rate is displayed instead of RR intervals in milliseconds

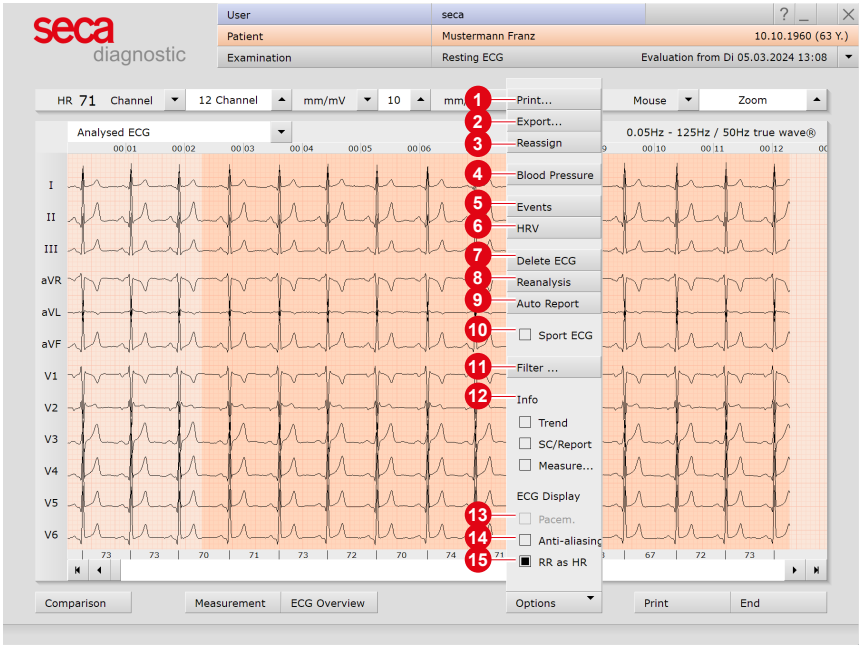


Fig. 79: Resting ECG evaluation, Options menu

5.4.7 Resting ECG with additional function Sport ECG

The Sport ECG function is not part of the standard software and can be purchased optionally.

A resting ECG recording can be viewed in the context of a “sports ECG” in the case of competitive sports patients. In seca diagnostic, it is taken into account that competitive athletes may have a different heart anatomy. The results of the automatic analysis are evaluated differently for competitive athletes than for patients who do not fall into the category of competitive athletes. The diagnostic approach is based on the following publication: “International recommendations for electrocardiograph interpretation in athletes, ESC 2018”.

View resting ECG evaluation in the context of Sport ECG:

→ In the resting ECG evaluation, click on Options, Sport ECG.
→ The “Criteria for competitive athletes” dialogue box opens. Select the applicable items here. Confirm the selection.
→ If the selection meets the criteria for competitive athletes, a new automatic report is generated. For this purpose, Confirm the “Report” dialogue box.
→ If the selection does NOT meet the criteria for competitive athletes, the standard view is displayed again.

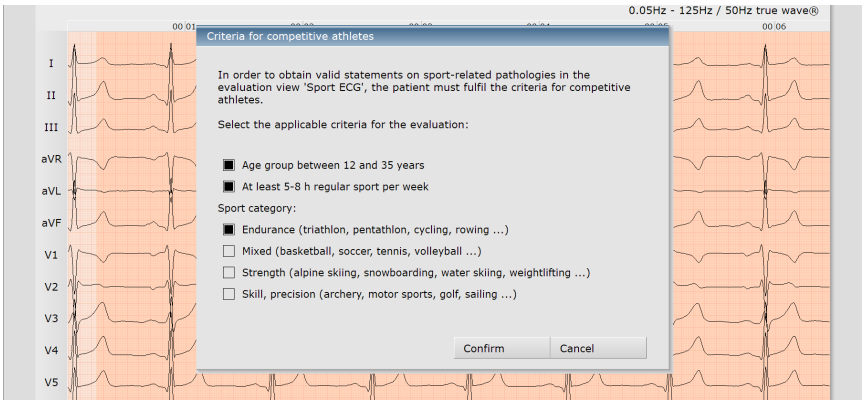


Fig. 80: “Criteria for competitive athletes” dialogue box

Display and control elements in the Sport ECG

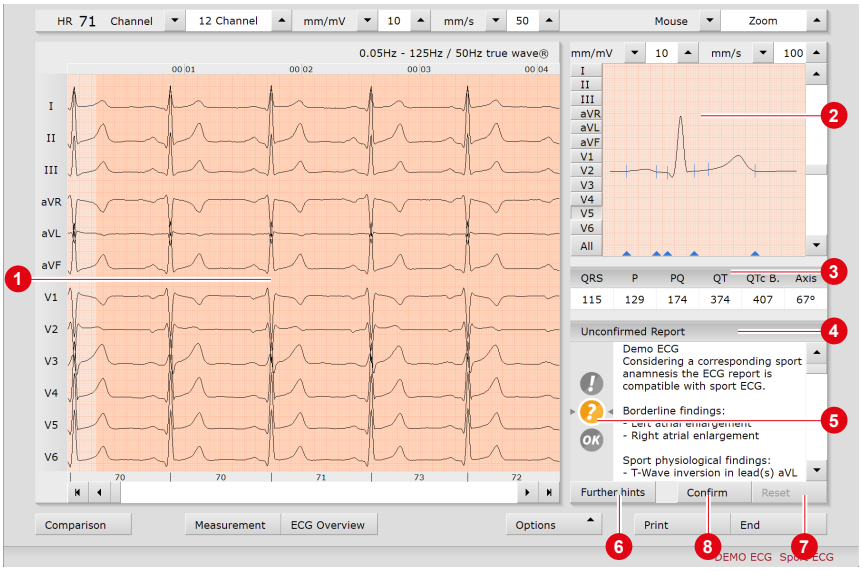


Fig. 81: Sport ECG evaluation view

1. Recorded ECG
2. Sum complex
3. Table of measured values
4. Unconfirmed report
5. Status indicator with graphical representation of the evaluation
6. Notes on further recommended examinations
7. Reset changes in the unconfirmed report
8. Confirm the unconfirmed report and adopt as report

Meanings of the status indicator in the unconfirmed report	
Red with exclamation mark	Abnormal ECG changes, clarification required
Yellow with question mark	Two or more ECG changes, clarification required
Green and OK	Asymptomatic, no further clarification required

Create Sport ECG report

→ Check the unconfirmed report of the system.
→ If necessary, change the information in the unconfirmed report. Click with the mouse in the text field 4 and make the changes.
→ Use Reset 7 to undo the changes in the unconfirmed report.
→ Click on Confirm 8 to apply the entries.
→ In the “Status modification” dialogue box (double-click on status indicator 5), check whether the status indicator matches the unconfirmed report.
→ If the status indicator does NOT match the unconfirmed report, adjust the status indicator.
→ Confirm the “Status modification” dialogue box.

Return to the standard view

→ Click on Options.
→ Deactivate the Sport ECG option.

5.4.8 Confirming the evaluation

Unconfirmed report and report

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

Text modules – an aid for writing reports

Select Examination, examination type (e.g. Holter ECG, ABPM, Resting ECG, Stress ECG, ...), Settings, Diagnostic, Reports to configure text modules for reporting an evaluation. A total of four groups with up to eight text modules can be created. The text modules are called in the unconfirmed report dialogue via the keyboard (F5 to F12).

A text module can be created from normal text and variables. When you use a text module in the unconfirmed report, the actual value from the evaluation is inserted in the report text instead of a variable. The structure of a variable is {VARIABLE}. The Shortcuts for export values button provides you with a list with all variables. If the text modules should be shown in the unconfirmed report dialogue, make sure that the Enabled option is activated. Alternatively, the text modules can be shown in the unconfirmed report dialogue by selecting Options, Texts on. There is also the option of writing a text that is automatically displayed in each unconfirmed report (text suggestion or user-defined unconfirmed report). The text can be changed later in the unconfirmed report dialogue. Save your input.

5.4.9 Ending the evaluation

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

This is where the status of an evaluation is defined. Assigning properties (evaluation status) in the End dialogue makes it easier to find evaluations in the evaluation search.

→ Evaluation preconfirmed: If a user with the reporting right “Preconfirm evaluations” has confirmed the unconfirmed report.
→ Evaluation confirmed: If a user with the reporting right “Confirm evaluations” has confirmed the unconfirmed report. The “Evaluation confirmed” status can be reset if required.
→ Printed: Indicates if the evaluation has been printed.
→ Indelible: Can be selected after reporting has been completed. The evaluation can only be viewed and can no longer be changed.
→ Click on Confirm to close the evaluation.

5.4.10 Extended ECG settings for resting ECG

Changing the ECG colour scheme:

The ECG colours are preset in seca diagnostic and can be changed under Examination, Settings, System, ECG colour. Click on Save to apply your changes.

ECG Grid:

The ECG grid in seca diagnostic corresponds to normal ECG paper. The small boxes measure 1 * 1 mm, the large boxes 5 * 5 mm. To ensure the graph paper is correctly displayed on the screen, the screen diagonal of the monitor must be specified in the seca service center. Contact seca.

Resting ECG, automatic ECG procedures:

Under Examination, Resting ECG, Settings, Menu/Functions, Workflow procedures for automatic ECG recordings can be set in the “Automatic ECG” area. For example, recording duration and procedures after recording. Click on Save to apply your changes.

Procedures for manual resting ECG recordings:

Under Examination, Resting ECG, Settings, Menu/Functions, Workflow procedures after recording and the display options in the evaluation can be set in the “Workflow” area. Click on Save to apply your changes

Print settings for resting ECG:

On the Examination, Resting ECG, Settings, Print, Printed pages screen, you can set the contents for various printouts. Select the desired entry in the “Type of printout” list, for example automatic printout (Automatic ECG). In the “Printout” area, select the contents for the printout after an automatic ECG. Click Save to apply your changes.

5.5 Stress ECG

5.5.1 Perform stress ECG recording

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.

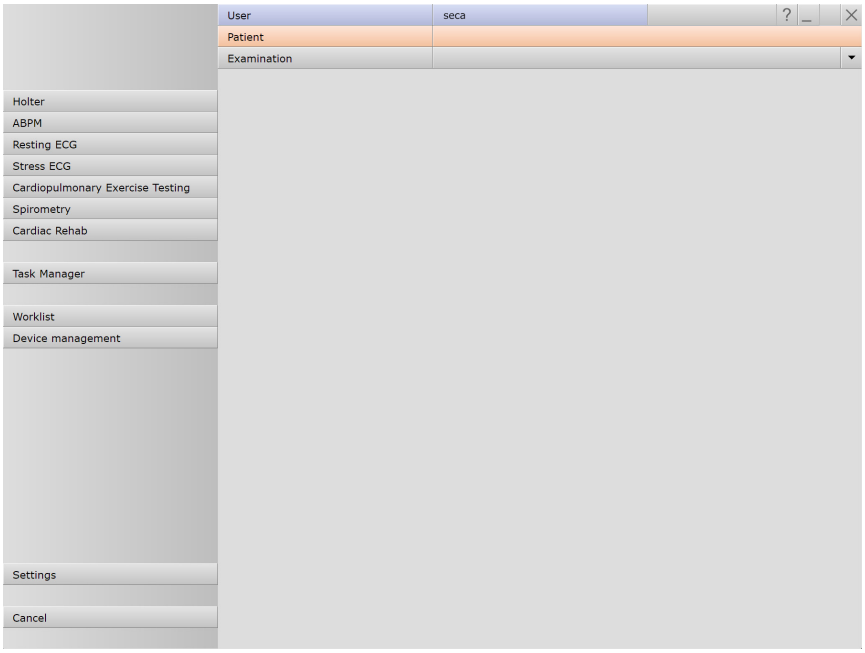


Fig. 82: seca diagnostic examination main menu

INFORMATION: The necessary steps for recording and analysing ECG data in seca diagnostic are shown without a surgery IT system or HIS connection

→ Apply the ECG device to the patient.
→ Observe the correct sequence of work steps.

Starting the program, calling up stress ECG

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

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.
→ Save the data.
→ The patient is entered into the database.

Profile selection

→ The profile selection opens.
→ Select a stress profile 1. The list contains predefined profiles for ergometer (with watt specifications) and treadmill.
→ Set the training device 2 for the recording.
→ The predefined load profiles can be changed and adjusted if necessary 3.
→ With Save 4, the modified load profile can be saved under a new name.
→ With New 5 new profiles can be created (types: ergometer, free, treadmill).
→ The values in the Notes area 6 are freely adjustable and can be activated if required. If you want to use the Notes function, the Notes values must be set correctly during profile selection before clicking Start 7. The Notes values cannot be activated and changed later.
→ After selecting and configuring the load profile, click the Start 7 button to access the recording screen.

Additional information: Steady State option for ergometer profiles

With Steady State 8 the load profile can be controlled manually during recording. If Steady State 8 is selected, entries can no longer be made for the stage duration, increase and end in the input mask. The profile continues to run unchanged during the recording until a manual change is made. To define the end of a load level during the recording, click on the Measurement button. The last ten seconds will be measured. Then set the load for the new load level.

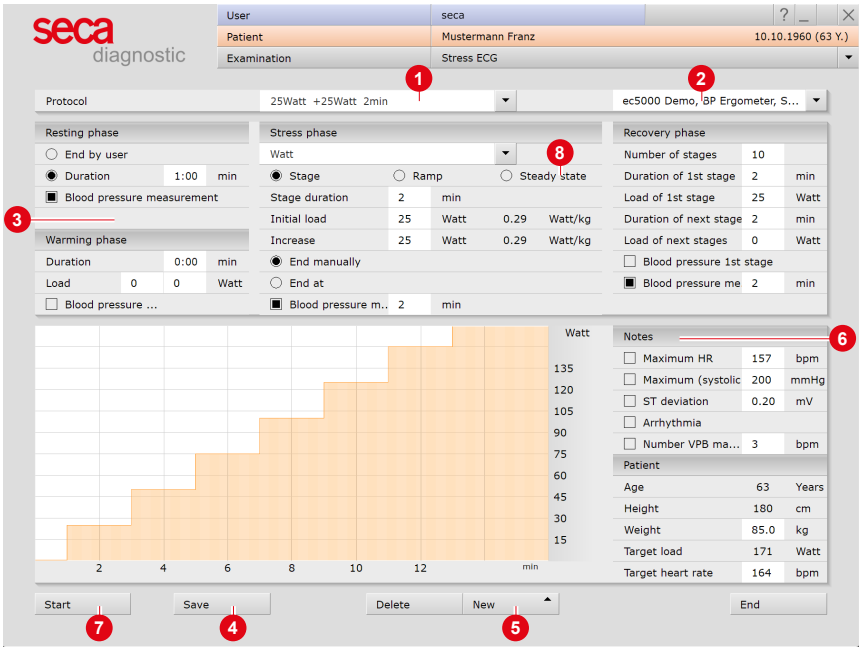


Fig. 83: Profile selection stress ECG

Selecting the ECG device

→ If several ECG devices are connected to the workstation, the “Select ECG Device” dialogue will be displayed.
→ Select the ECG Device and click on Confirm.
→ If only one ECG device is connected, this step is not necessary.

Monitoring and electrode control

The patient's ECG signal will be shown on the display but not yet recorded (monitoring). Work steps before the start:

→ Change the lead type (top right) if necessary.
→ Check if all electrodes are attached optimally. If red lines appear on the screen, there is insufficient contact between the skin and the electrode(s). The corresponding electrodes will need to be reattached.
→ Set the required filters (Options menu).

INFORMATION

ECG filters limit the signal range and can suppress diagnostically relevant portions of the ECG signal. Muscle filters (45 Hz) and ergo filters in particular reduce the transmission range of the ECG signal. Information for the ECG analysis may be lost as a result.

Therefore, do not always switch on ECG filters, but only in specific cases where an ECG filter is required.

Recommended settings for a stress ECG with treadmill:

→ Under Options activate: Mains Filter and Ergo-Filter. The Ergo-Filter is only needed when strong movement artefacts are to be expected, e.g. when using a treadmill.
→ ECG display Precordial, 5 mm/mV and 25 mm/s.

Starting the recording

→ Click on Start or Enter to start the recording.

Tip: Keyboard shortcuts

Additional BP measurement

F7

End and measure a load level for steady state profile

F8

Blood pressure input

F9

Lactate input

F10

SPO2 input

F11

Borg input

F12

Options menu

1. Turning on and off the automatic blood pressure measurement
2. Trigger an additional BP measurement or F7
3. Dialogue box for entering an unconfirmed report
4. Dialogue box for entering the blood pressure (with manual measurement) or F9
5. Dialogue box for entering lactate values or F10
6. Dialogue box for entering SPO2 values or F11
7. Input of Borg values to document the subjective feeling of a patient (e.g., strenuous) or F12
8. Restart of ergometry without previous profile selection
9. Extending the current level (only possible after starting)
10. Detection of pacemaker spikes, if the patient has a pacemaker
11. Filter for removing interferences caused by the power supply unit
12. Filter for flattening the ECG signal (e.g., in the event of amyostasia)
13. Ergo filter for compensating strong movement artefacts
14. Signal tone with each heart beat
15. Switching on and off of signals when Notes limits are exceeded
16. In the bar below the ECG the heart rate is displayed instead of RR intervals in milliseconds

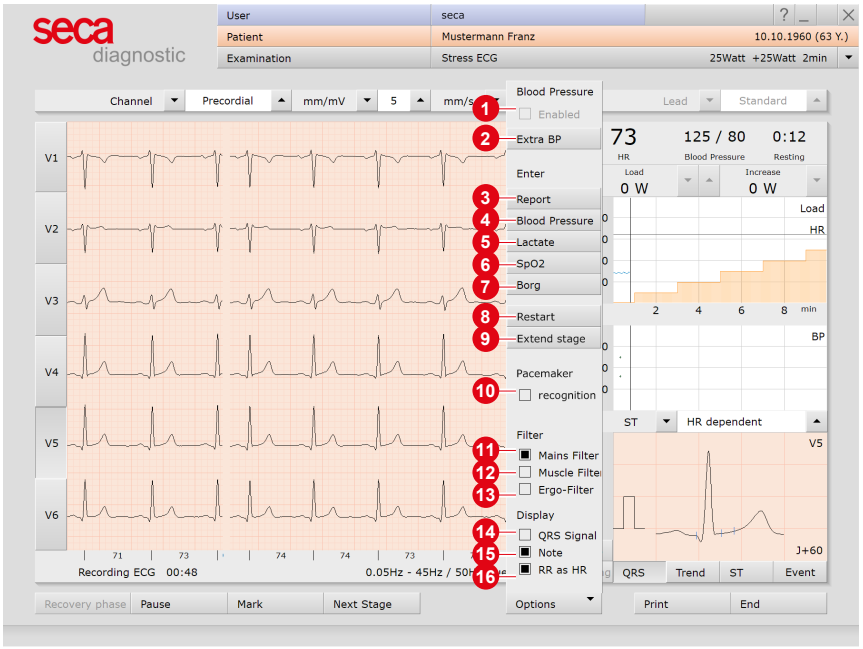
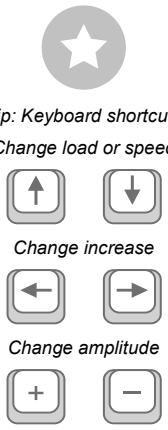


Fig. 84: Options stress ECG, during recording

For stress ECG with a treadmill, the Constant speed and Constant slope options are also displayed. These options can be used to set the speed and slope at the current level. The speed and slope remain the same throughout the rest of the recording and are no longer increased. These options can be used to prevent the patient being subject to excessive stress.



Display and control elements (view after starting)

1. Setting options for ECG display
2. Buttons for controlling and editing the ECG recording
3. Heart rate and blood pressure, countdown of the current level
4. Change current load and increase for ergometer profiles or speed and slope for treadmill profiles
5. Load profile (orange) with heart rate curve (blue)
6. Blood pressure curve (green)
7. Setting of the ST point
8. Display of summary complexes (selection of the channel with the buttons on the left side in front of the ECG signal)
9. Display of ST trend curve, ST values and event overview (online arrhythmia detection); button in the area 9 flashes red when the limits are exceeded

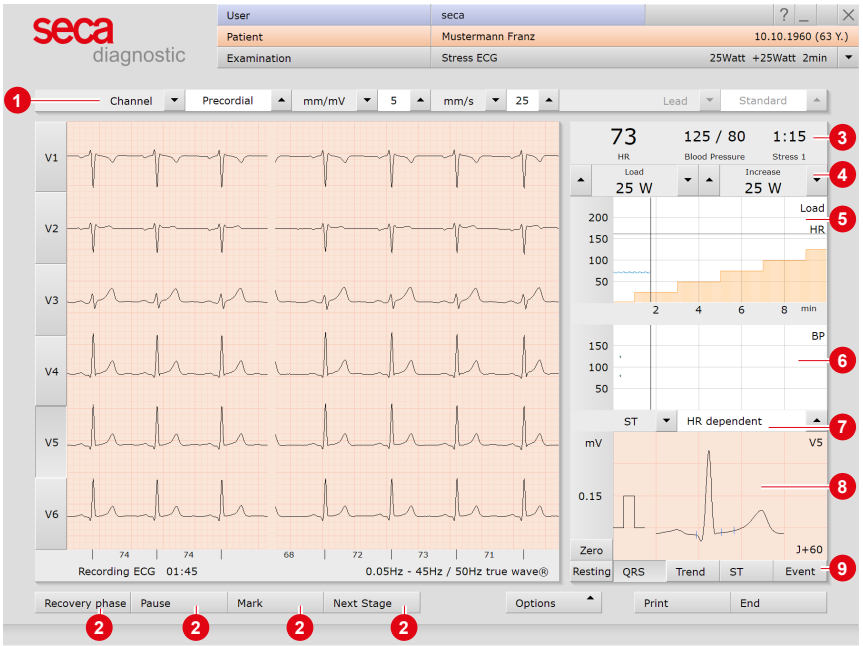


Fig. 85: Stress ECG recording

Load change settings 4:

You can define by how many watts load and increase should change each time the arrow buttons are pressed. This setting can be found under Examination, Stress ECG, Settings, Menu/Functions, ECG view in the “Manual load change” area.

Manual blood pressure measurement

You are regularly requested to measure blood pressure. Enter the values in seca diagnostic. Click on Blood pressure or the “F9” in the Options menu and enter the values. Confirm to apply your input. Entering lactate (“F10”), SPO2 (“F11”) and Borg (“F12”) values works in the same way.

Resting phase

The resting phase begins after Start. This phase proceeds according to the settings in the profile selection, it has a minimum duration of ten seconds.

Stress phase

The stress phase then begins. This phase proceeds according to the profile. Manual load changes can be made at any time. The Next Stage button can be used to end the current load level and start the next load level.

Note on treadmill profiles: The treadmill can be stopped using the Stop button, e.g. if a lactate measurement should be conducted. The treadmill will be restarted by clicking on the button again. Always warn the patient before you stop or start the treadmill!

Entering an unconfirmed report during recording

Open the Context menu and select Report. Enter the unconfirmed report in the large text field. To save your input, click on Confirm. By pressing Cancel, the unconfirmed report is closed without any changes being applied.

If the Unconfirmed report option is active in the Settings, seca diagnostic generates an automatic unconfirmed report which is displayed in the evaluation. This option is enabled by default and can be disabled under Stress ECG, Settings, Diagnostic, Reports.

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.

Recovery phase, ending the recording

The recovery phase can be started using the Recovery phase button, e.g., when the Manual end option was selected in the profile selection or as a result of a premature termination. Define the end of the stress phase (immediately or at the end of the load stage). The dialogue for entering the reason for end is then opened. The reason for end can be displayed in the evaluation.

If the end of the stress phase is defined in the profile, the recovery phase starts automatically after the last load level has expired. The recovery phase proceeds according to the profile.

If you would like to end the ECG recording but the ECG signal should still be displayed on the screen, click on Stop. Otherwise, the recording will be automatically saved, measured and displayed as an evaluation by clicking on the End button (bottom right).

Editing options during the recording process

→ Mark ECG automatically: Clicking the Mark button ❶ automatically marks the last six seconds of the recording. A dialogue box opens for naming, printing and saving the marking ❷.

→ Viewing and marking ECGs and measuring HR during a Pause: Clicking on Pause will stop the screen display. he recording continues to run and is displayed on one channel ❸. The scroll bar ❹ can be used to view the current recording. In the “Mouse Function” ❺ area, the tools Mark, Measure HR and Measure can be found. By dragging the red cursor ❻ in the ECG (using the Mark function), you can mark sections. A dialogue appears for specifying, printing and saving the marked part. With Continue ❼ you return to the normal view.

→ Online ECG printing (printing ECG): By clicking on the Print button ❽ a screen page of the ECG is printed from the point of clicking. The printout contains 4.5 to 9 seconds of the ECG, depending on the display speed.
Select Examination, Stress ECG, Settings, Print, General o define in the “Online ECG print settings” area whether the ECG should be printed as it appears on the monitor or if online printing should be carried out according to previously defined print settings for the analysed ECG.

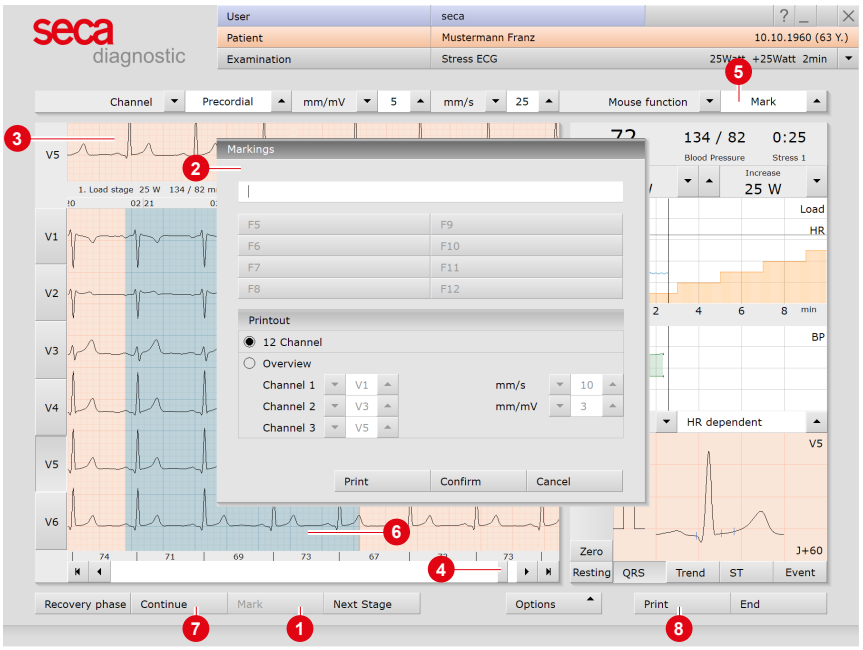


Fig. 86: Stress ECG recording, editing options

5.5.2 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. 87: 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.

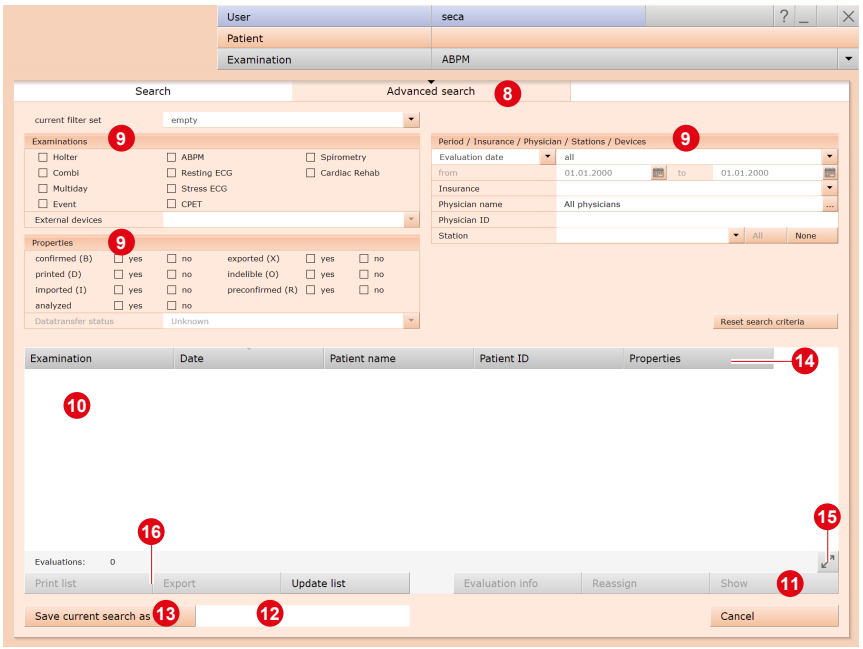


Fig. 88: Evaluation search, extended search

5.5.3 Opening an evaluation via the evaluation menu

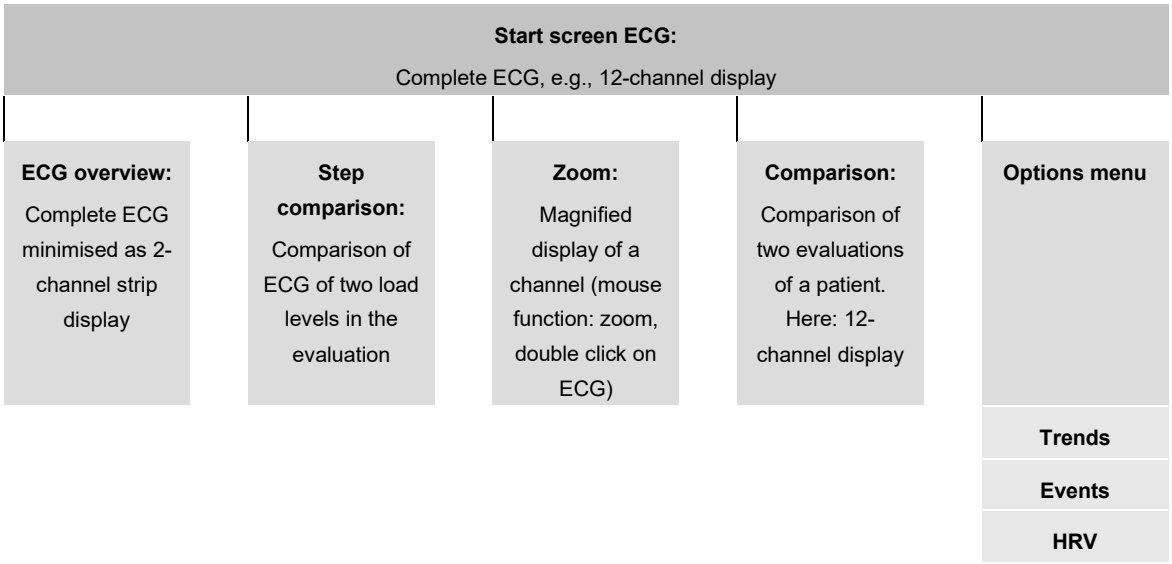
Tip for making entries in the patient menu: Press the Tab key to jump to the next entry field with the cursor.

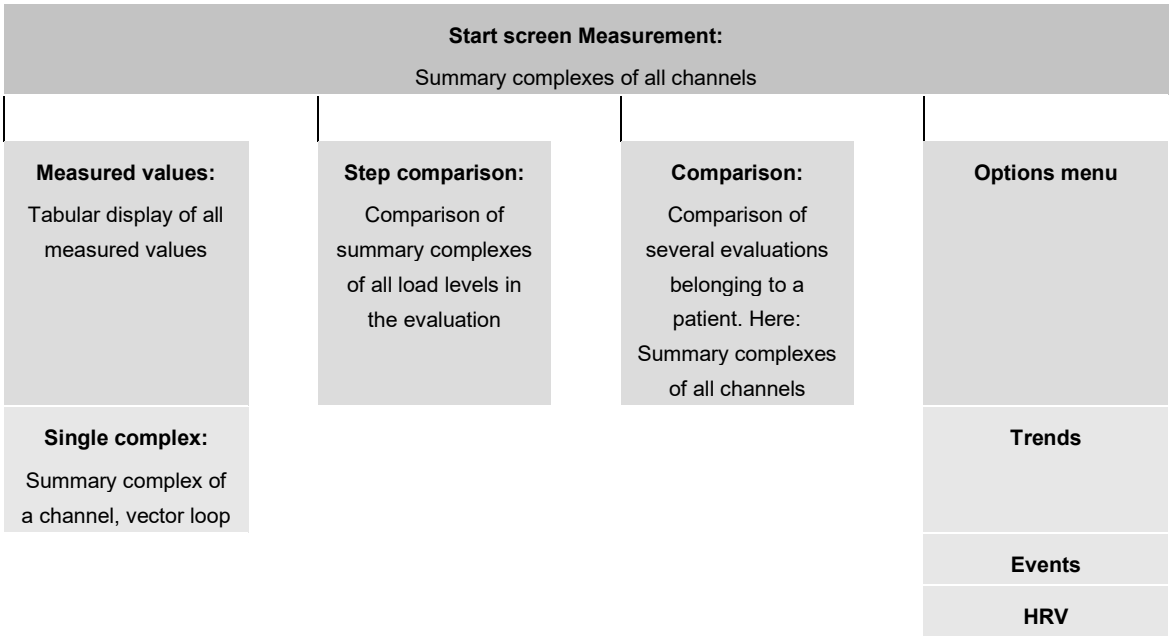
→ Open the examination main menu via Examination, Stress ECG.
→ Click on Show Evaluation.
→ The patient search screen appears. In this screen, select the patient whose evaluation you want to open. Enter the patient's name in the input fields in the search screen.
→ Select the patient from the list below the input fields and confirm your selection using the Select Patient button 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.

5.5.4 Evaluation structure

ECG evaluation is divided into two main areas: ECG and Measurement. The ECG screen is preset as the start screen, and the Measurement screen can be set as the start screen as an alternative if required. From the sub-screens of the two areas, the main screen of the other area can be reached at any time.

The evaluation start screen can be set under Examination, Stress ECG, Settings, Menu/Functions, Workflow in the “Workflow, Show evaluation” area.





5.5.5 Screens of the evaluation

1) The PWC predicted values are preset in seca diagnostic and can be changed on the screen Examination, Stress ECG, Settings, Diagnostic, Reference values. Click on Save to apply your input.

ECG start screen

1. Setting options for ECG display
2. Mouse functions for precise viewing and measuring of the ECG signal (Zoom, Analysis, Measure HR, Measure, Marking)
3. Stress profile with heart rate and blood pressure curve
4. Tabular display of PWC (Physical Working Capacity[1)]) and MET (Metabolic Equivalent); further information on PWC and MET can be found in the appendix.
5. Further evaluation screens
6. Print evaluation
7. Button for closing the evaluation

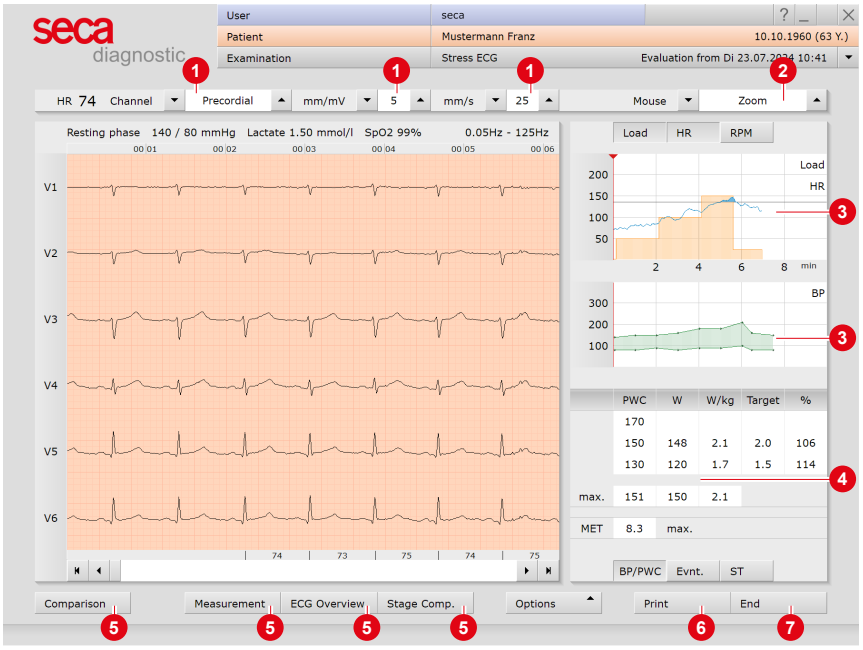


Fig. 89: Evaluation Stress ECG, ECG start screen

If the Measurement view is set as the start screen, you will find the same operating and navigation elements (1 to 7) there.

The evaluation start screen can be set under Examination, Stress ECG, Settings, Menu/Functions, Workflow in the “Workflow, Show evaluation” area.

Settings for the Print button: On the Examination, Stress ECG, Settings, Menu/Functions, Workflow screen, in the “Workflow, Print” area, you can specify whether the advanced print menu is displayed when the Print button is clicked (default) or whether printing is performed automatically and without further settings, according to the default print settings (= defined printout). The standard print settings for Stress ECG can be found under Examination, Stress ECG, Settings, Print, Printed pages. Click on Save to apply your input.

Tip: Keyboard shortcuts

Blood pressure input

F9

Lactate input

F10

SPO2 input

F11

Deletes a marking if it was previously selected by mouse click

Delete

Options menu

The scope and contents of the options menu change depending on which screen of the evaluation you are on. On the Measurement screen, for example, you can activate the display of ST values in the options menu and set which markers are to be displayed in the summary complexes.

1) For the RR variability to be displayed, at least five minutes of ECG needs to be recorded!

1. Print menu for temporary changes to the print settings
2. Export of the evaluation (e.g., as Excel, PDF, DICOM...)
3. If necessary, assign evaluation to another patient
4. Display of blood pressure (F9), lactate (F10), SPO2 (F11) and Borg values (F12)
5. Trend graphics, e.g., for load, HR, ST, RPM, blood pressure, lactate, SPO2...
6. HR trend, display of events in ECG (e.g., VES)
7. Tables and graphics for heart rate variability[1)]
8. Delete ECG: unmarked ECG will be deleted
9. New analysis of ECG signal for resetting manual changes in ECG, additions to the report remain available
10. Switching on and off filters in ECG (options: Display ECG as saved, unfiltered or filtered ECG - mains filter, muscle filter, ergo filter).
11. Showing and hiding of additional contents in the right half of the screen: summary complexes and report or measured value table (preset: Trend = stress profile with HR and blood pressure curve, PWC and MET).
12. Show or hide pacemaker spikes
13. Graphic flattening of ECG signal
14. In the bar below the ECG the heart rate is displayed instead of RR intervals in milliseconds

Fig. 90: Evaluation of stress ECG, Options menu

5.5.6 Confirming the evaluation

Unconfirmed report and report

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

Text modules – an aid for writing reports

Select Examination, examination type (e.g. Holter ECG, ABPM, Resting ECG, Stress ECG, ...), Settings, Diagnostic, Reports to configure text modules for reporting an evaluation. A total of four groups with up to eight text modules can be created. The text modules are called in the unconfirmed report dialogue via the keyboard (F5 to F12).

A text module can be created from normal text and variables. When you use a text module in the unconfirmed report, the actual value from the evaluation is inserted in the report text instead of a variable. The structure of a variable is {VARIABLE}. The Shortcuts for export values button provides you with a list with all variables. If the text modules should be shown in the unconfirmed report dialogue, make sure that the Enabled option is activated. Alternatively, the text modules can be shown in the unconfirmed report dialogue by selecting Options, Texts on. There is also the option of writing a text that is automatically displayed in each unconfirmed report (text suggestion or user-defined unconfirmed report). The text can be changed later in the unconfirmed report dialogue. Save your input.

For Stress ECG: Unconfirmed report with Duke Treadmill Score

In order to display the Duke Treadmill Score, some settings are required in seca diagnostic, _RS. Information on calculating the Duke Treadmill Score can be found in the appendix, _RS.

In order to display the Duke Treadmill Score in seca diagnostic, the Treadmill Angina Index (TAI) must first be specified. If the TAI has not yet been entered during the recording of the stress ECG, carry out the following steps in the evaluation. Open the context menu (right-click on the evaluation interface) and click there on Reason for end. Select the appropriate entry from the drop-down menu at the bottom of the “Reason for termination” dialogue: No angina pectoris/pain, Typical angina pectoris or Training cancelled due to angina pectoris. The Duke Treadmill Score is calculated using this information and other measured values from the stress ECG.

To display the Duke Treadmill Score, call up in the unconfirmed report dialogue in the stress ECG evaluation. Open the context menu in the evaluation (right-click on the evaluation interface) and click there on Unconfirmed report. In the unconfirmed report dialogue, select the text module that contains the variable for outputting the Duke Treadmill Score. If there is no text module for this, enter the export elements or variables directly into the white text field of the unconfirmed report dialogue: {DUKE_SCORE} and {TREADMILL_ANGINA_INDEX}. The values are displayed in the unconfirmed report. Click on Confirm to apply your input.

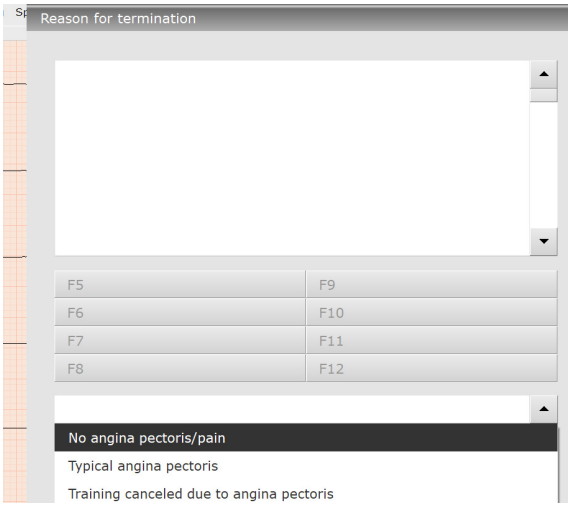


Fig. 91: Specifying the TAI in the “Reason for termination” dialogue

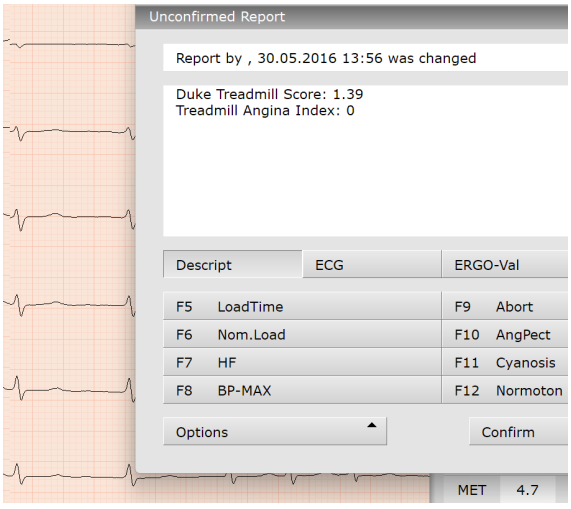


Fig. 92: Unconfirmed report text with the Duke Treadmill Score

5.5.7 Ending the evaluation

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

This is where the status of an evaluation is defined. Assigning properties (evaluation status) in the End dialogue makes it easier to find evaluations in the evaluation search.

→ Evaluation preconfirmed: If a user with the reporting right “Preconfirm evaluations” has confirmed the unconfirmed report.
→ Evaluation confirmed: If a user with the reporting right “Confirm evaluations” has confirmed the unconfirmed report. The “Evaluation confirmed” status can be reset if required.
→ Printed: Indicates if the evaluation has been printed.
→ Indelible: Can be selected after reporting has been completed. The evaluation can only be viewed and can no longer be changed.
→ Click on Confirm to close the evaluation.

5.5.8 Extended ECG settings for stress ECG

Changing the ECG colour scheme:

The ECG colours are preset in seca diagnostic and can be changed under Examination, Settings, System, ECG colour. Click on Save to apply your changes.

ECG Grid:

The ECG grid in seca diagnostic corresponds to normal ECG paper. The small boxes measure 1 * 1 mm, the large boxes 5 * 5 mm. To ensure the graph paper is correctly displayed on the screen, the screen diagonal of the monitor must be specified in the seca service center. Contact your authorized seca dealer.

Workflows for stress ECG:

Under Examination, Stress ECG, Settings, Menu/Functions, Workflow you can set workflows after recording and display options in the evaluation in the “Menu/Functions” area. Click on Save to apply your changes.

Print settings for stress ECG:

On the Examination, Stress ECG, Settings, Print, Print pages screen, you can define the contents for various printouts. In the “Type of printout” list, select the desired entry and compile the contents of the printout. Important: This setting is only necessary if the selected printout (see “Type of printout”) should contain different content than the standard printout (see “Type of printout” Standard). Click on Save to apply your changes.

Maximum load:

The maximum load achieved is displayed in the evaluation and in the printout and is used for comparison with the target load. The criteria for determining the maximum load are defined on the Examination, Stress ECG, Settings, Diagnostic, Calculation screen. For example, load levels that fall below a certain duration can be excluded.

Duke Treadmill Score

The Duke Treadmill Score is used to predict the risk of ischemia or infarction. This value is output in the unconfirmed report dialogue of a stress ECG evaluation. To display the Duke Treadmill Score in the unconfirmed report dialogue, the following settings are required.

Activating the Duke Treadmill Score option in seca diagnostic:

→ In seca diagnostic, open the Examination, Stress ECG, Settings, Diagnostic, Reason for End screen.
→ In the “Duke Score”, select the with Duke Score according to Gibbons et al. (1997) option.
→ Save your input.

Creating text modules for outputting the Duke Treadmill Score:

→ In seca diagnostic, open the Examination, Stress ECG, Settings, Diagnostic, Reports screen.
→ In the “Text modules for reporting” area, use the arrow keys next to “Group” and “Button” to select the text module that should contain the Duke Treadmill Score.
→ In the white text field below, enter the variables for the Duke Treadmill Score and the Treadmill Angina Index (TAI):
  → Duke Treadmill Score: {DUKE_SCORE}
  → Treadmill Angina Index: {TREADMILL_ANGINA_INDEX}
→ Save your input.
→ The text modules can be called up later in the unconfirmed report dialogue of an evaluation. Instead of the export elements or variables {DUKE_SCORE} and {TREADMILL_ANGINA_INDEX}, the actual values of the evaluation are displayed.

Displaying the Duke Treadmill Score in the unconfirmed report dialogue is described in the chapter on reporting a stress ECG.

5.6 Spirometry

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.

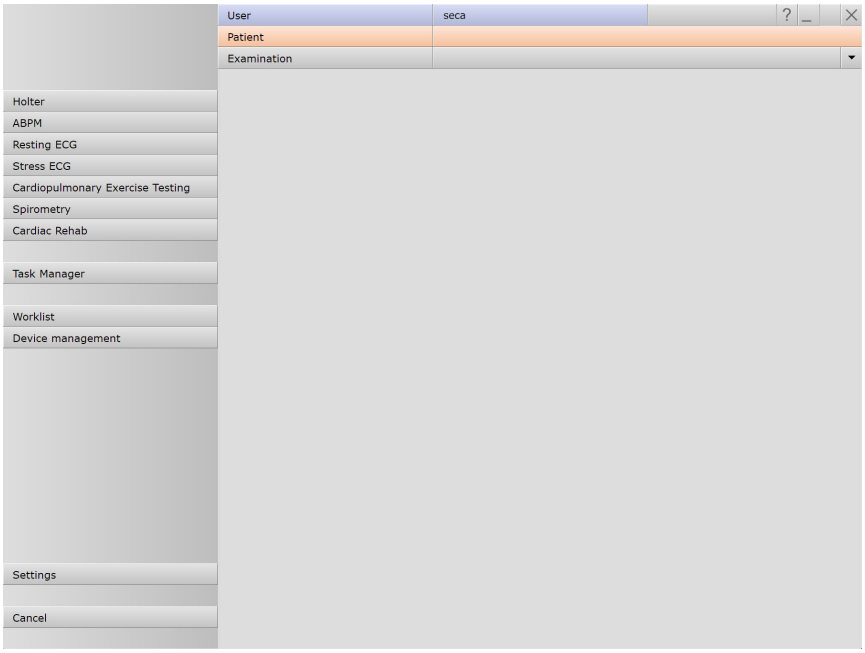


Fig. 93: seca diagnostic examination main menu

INFORMATION:

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

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

→ Measurement type ❸: 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 ❹ and dosage ❺: 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 ❻: Specify whether bacterial and viral filters are used.

→ Environment data ❼: Set the environmental data correctly.

→ Confirm ❽ your input.

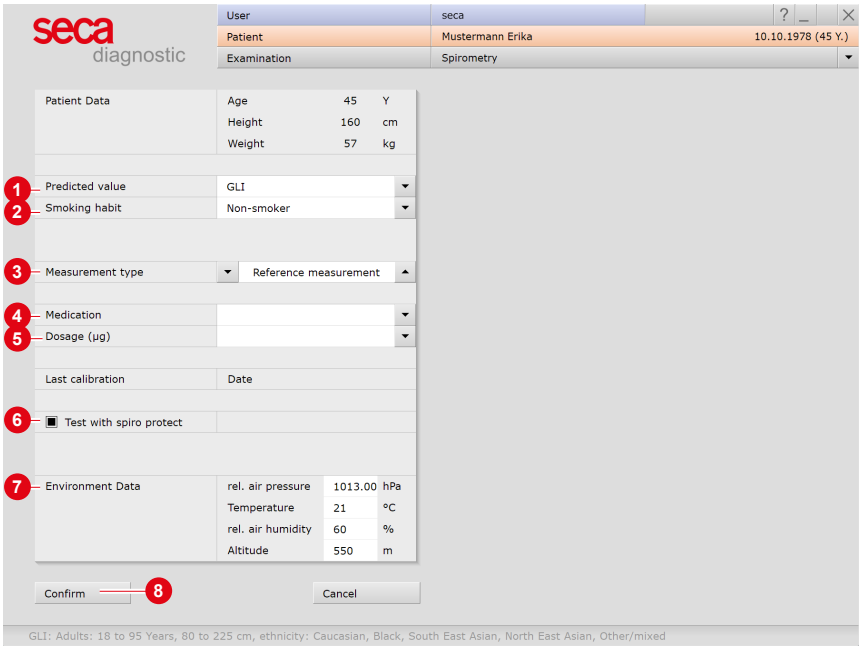


Fig. 94: Settings for the reference measurement

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

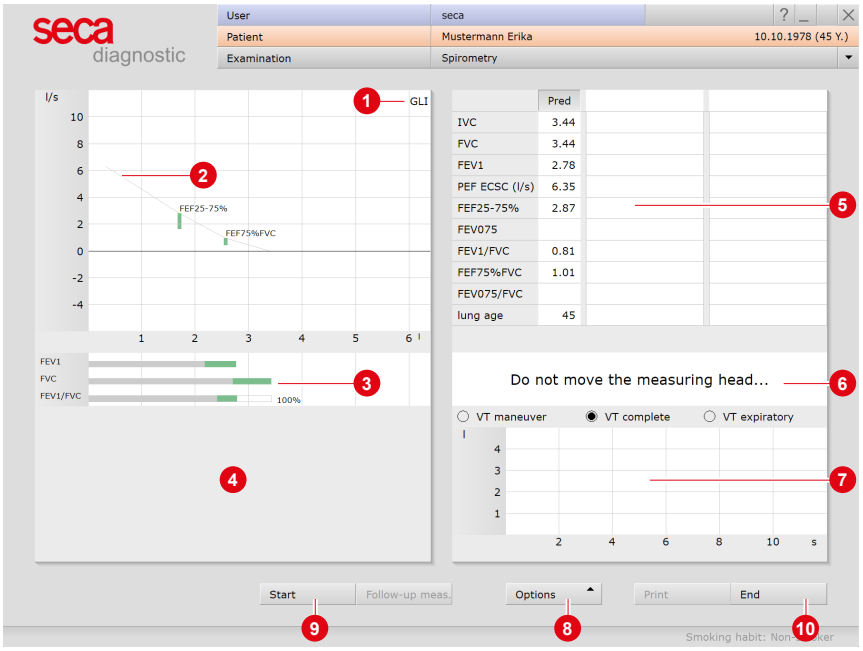


Fig. 95: Measurement interface

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).

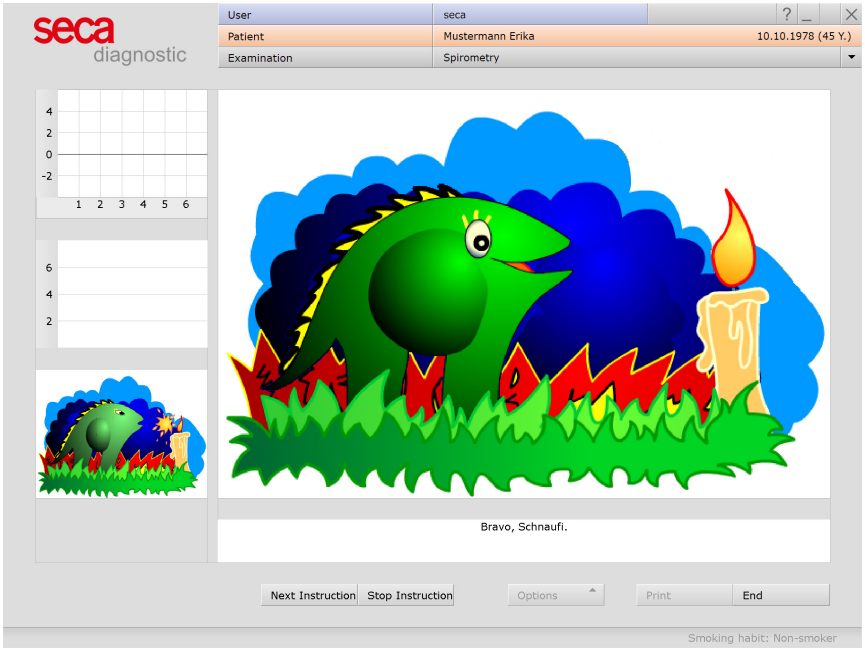


Fig. 96: Spirometry measurement with animation for children

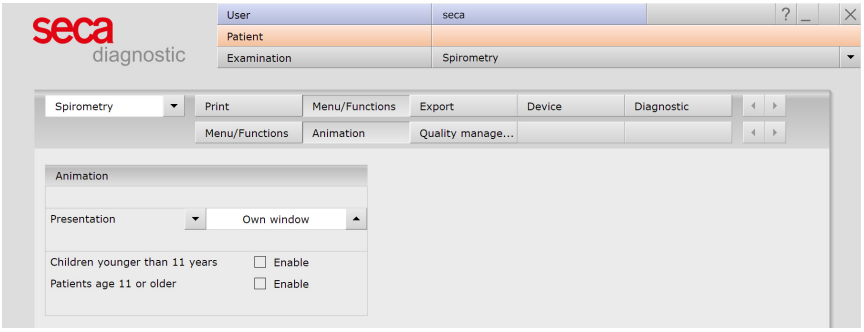


Fig. 97: Animation for children settings

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.

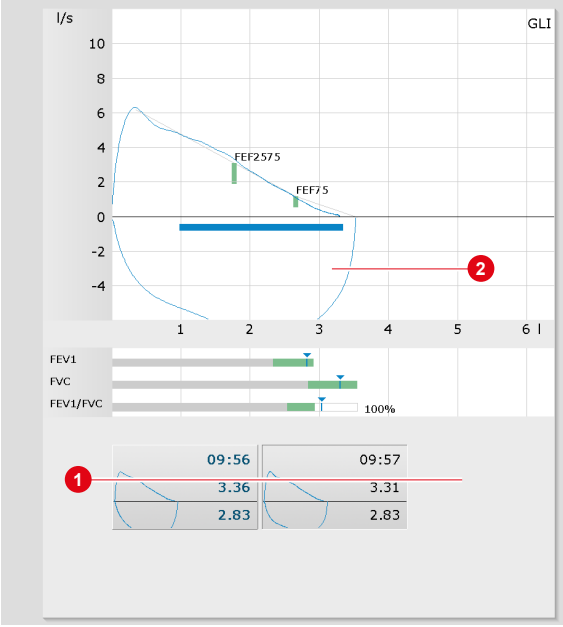


Fig. 98: Reference measurement, miniature views

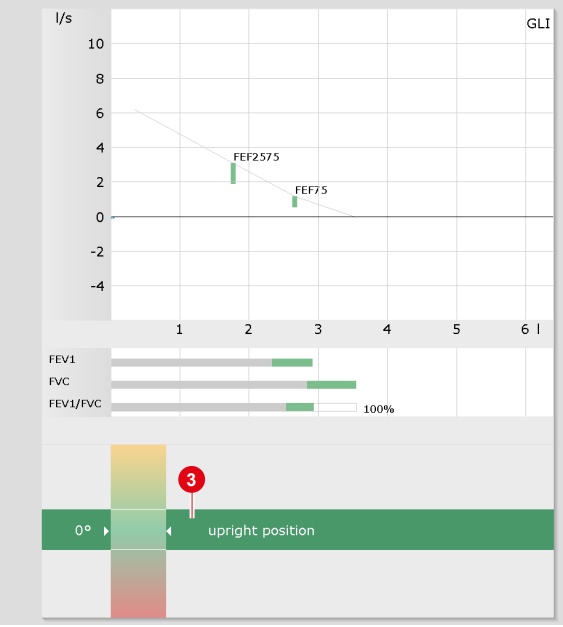


Fig. 99: Reference measurement, inclination sensor

Additional function inclination sensor[2)]

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

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

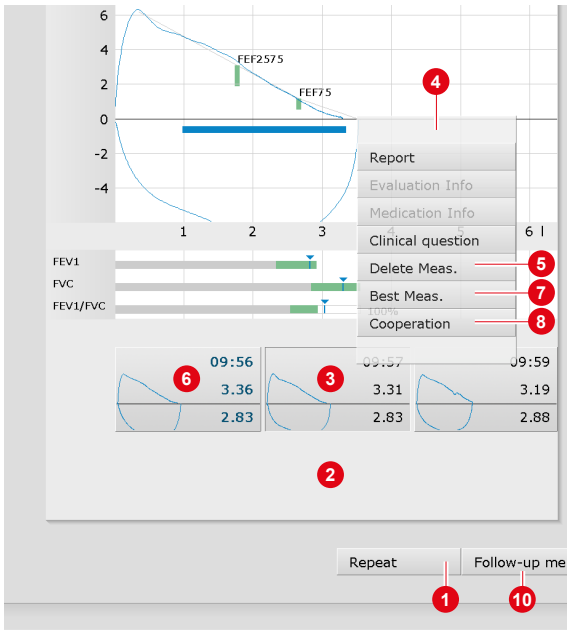


Fig. 100: Context menu of a measurement

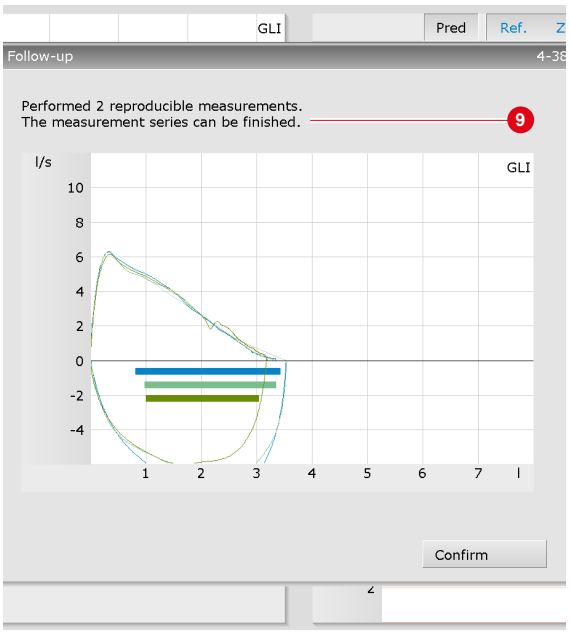


Fig. 101: Process control, reproducibility of a measurement.

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.

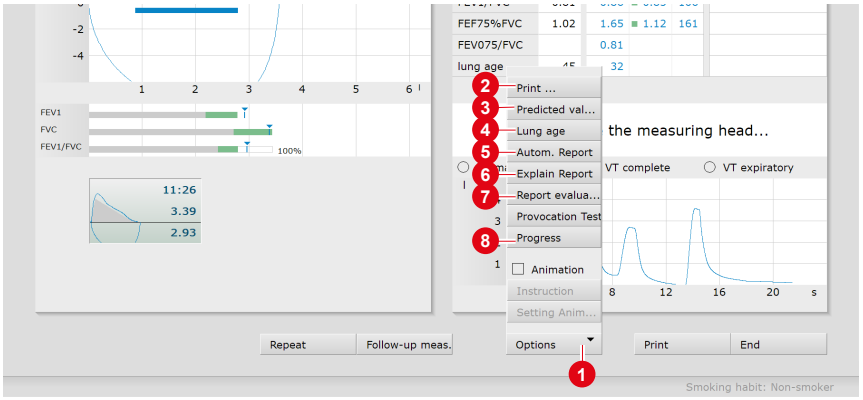


Fig. 102: Reference measurement, options

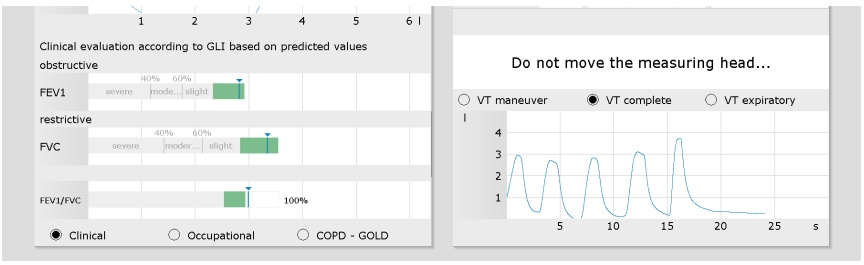


Fig. 103: Reference measurement, evaluation of measurement results

5.6.2 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.

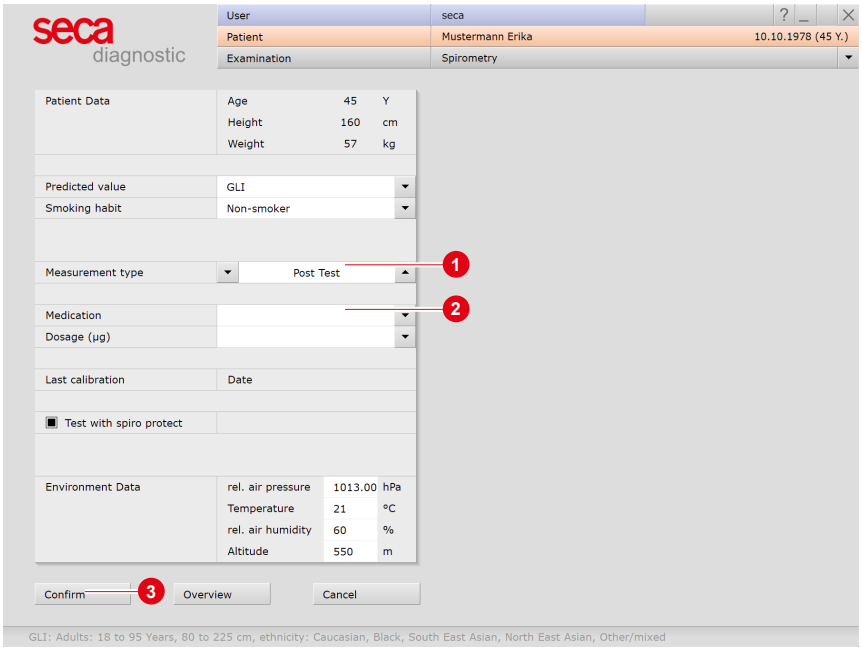


Fig. 104: Follow-up measurement, settings

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.

5.6.3 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.

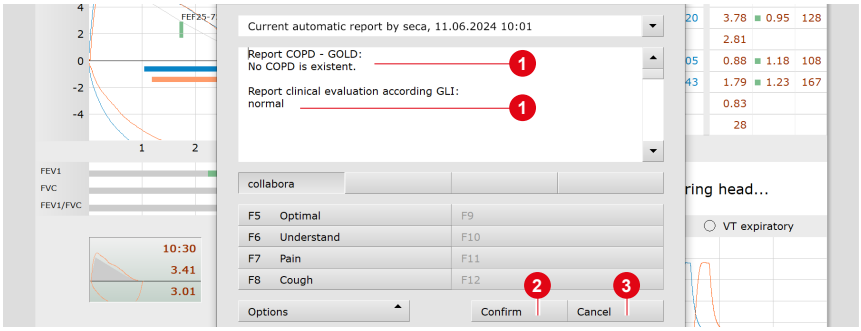


Fig. 105: Unconfirmed report, directly after a measurement

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.

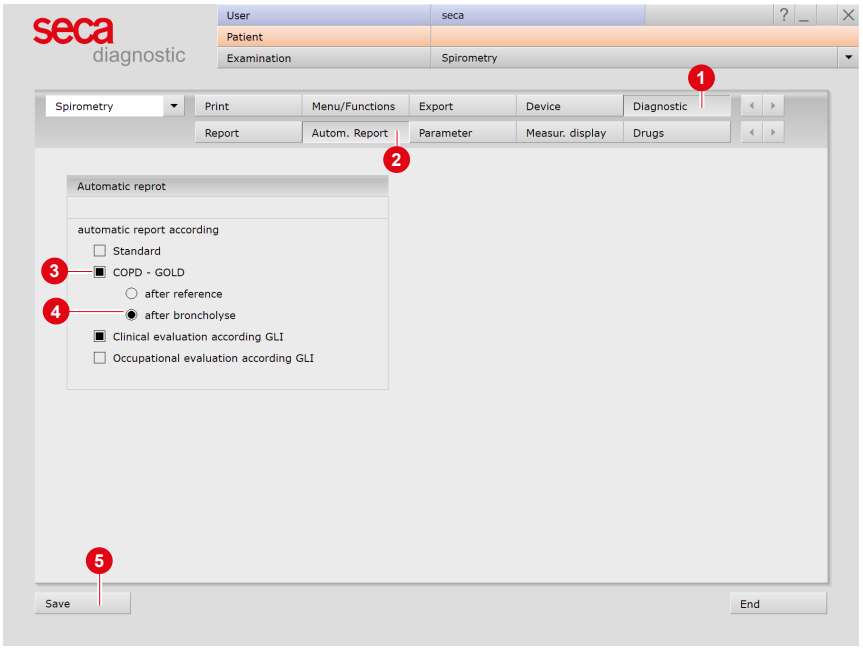


Fig. 106: Settings, automatic report

5.6.4 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.

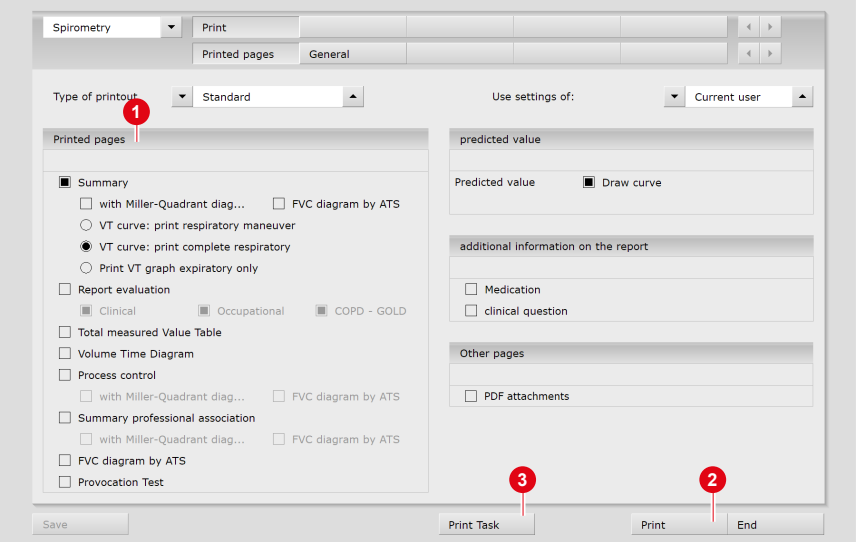


Fig. 107: Options, Print...

5.6.5 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. 108: 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.

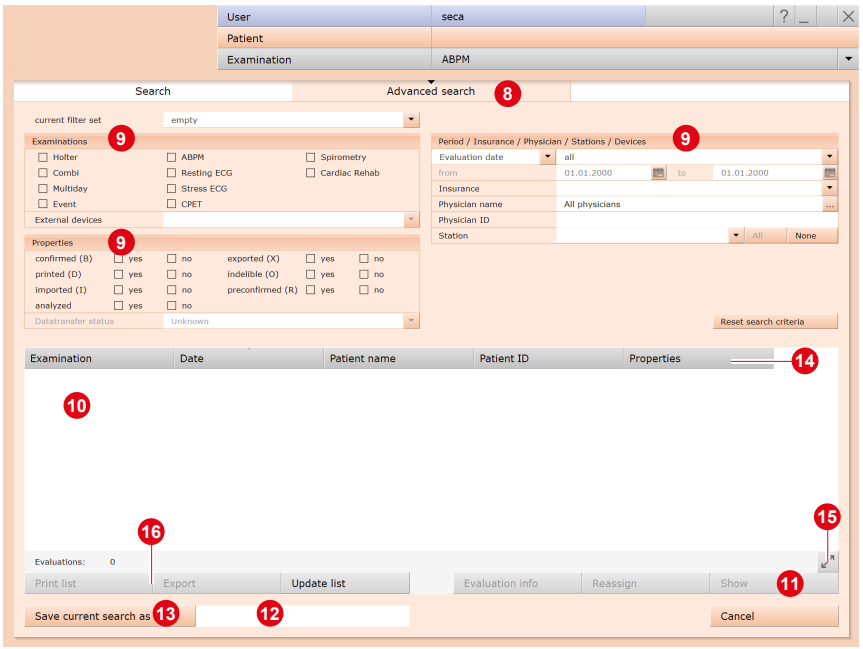


Fig. 109: Evaluation search, extended search

5.6.6 Opening an evaluation via the evaluation menu

Tip for making entries in the patient menu: Press the Tab key to jump to the next entry field with the cursor.

→ Open the examination main menu via Examination, Pulmonary Function.
→ Click on Show Evaluation.
→ The patient search screen appears. In this screen, select the patient whose evaluation you want to open. Enter the patient's name in the input fields in the search screen.
→ Select the patient from the list below the input fields and confirm your selection using the Select Patient button 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.

5.6.7 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.

5.6.8 Screens of the evaluation

5.6.8.1 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).

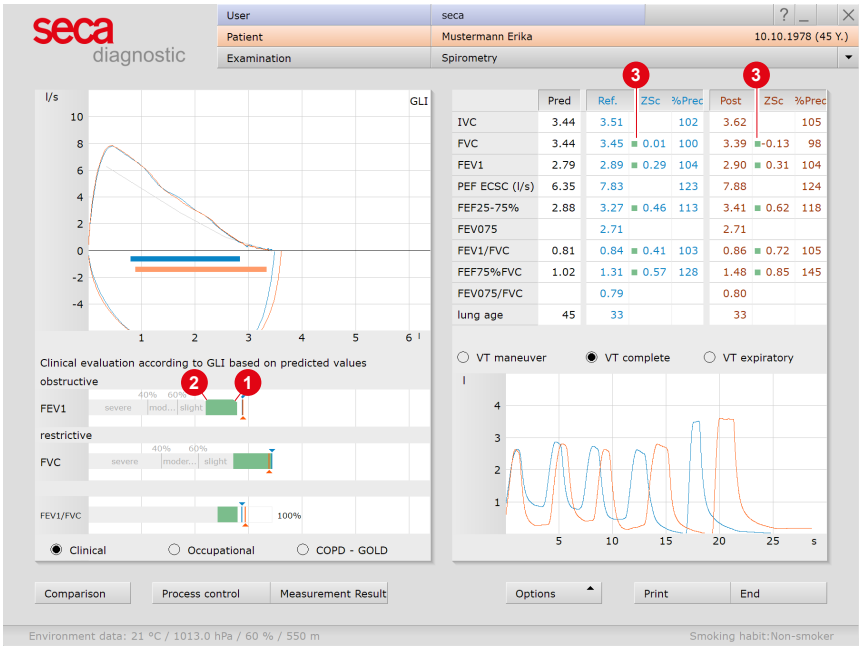


Fig. 110: Lower limit of normal and Z-score.

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.

5.6.8.2 Reference measurement and spasmolysis

Fig. 111: 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.

5.6.8.3 Provocation measurement series

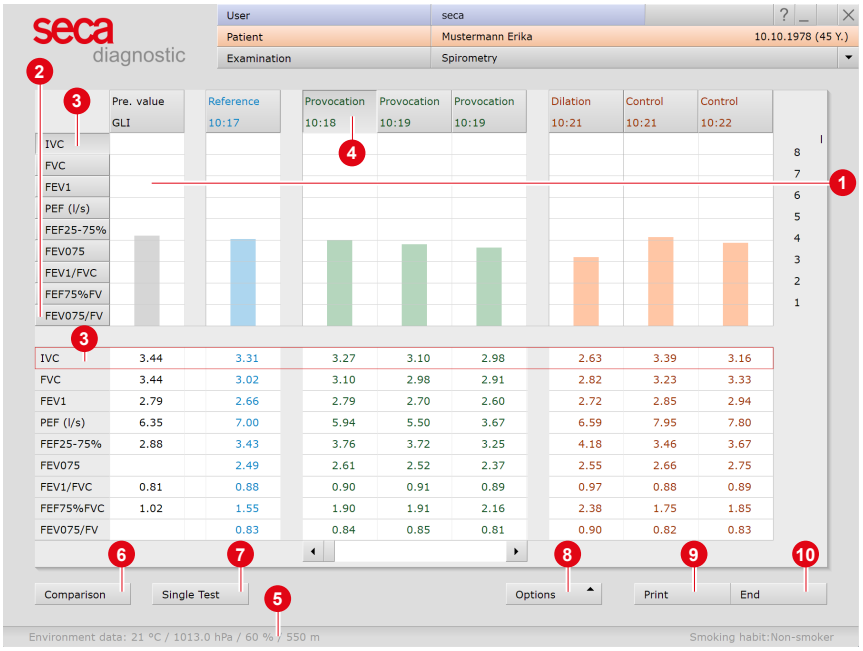


Fig. 112: Evaluation, provocation

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

5.6.8.4 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.

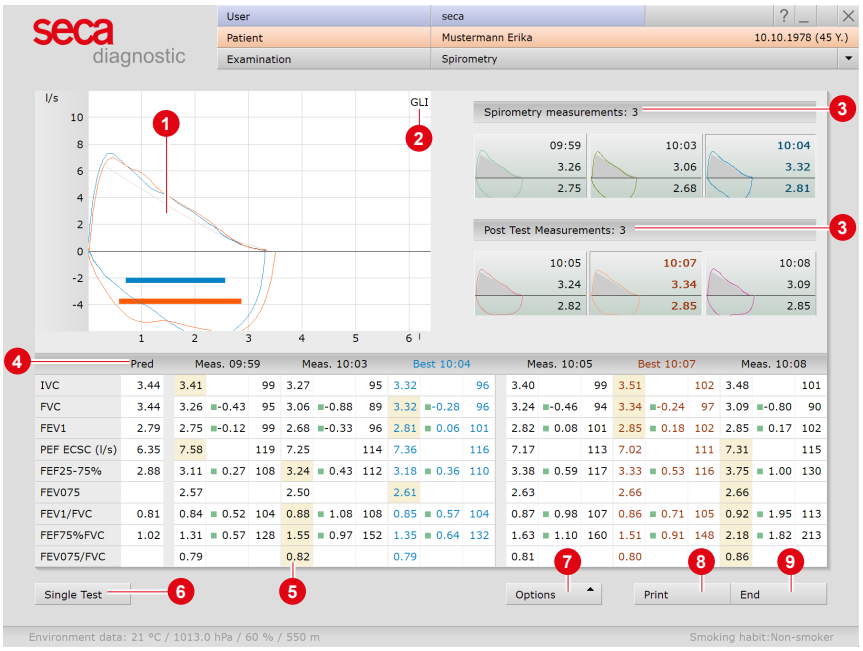


Fig. 113: Evaluation, process control

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

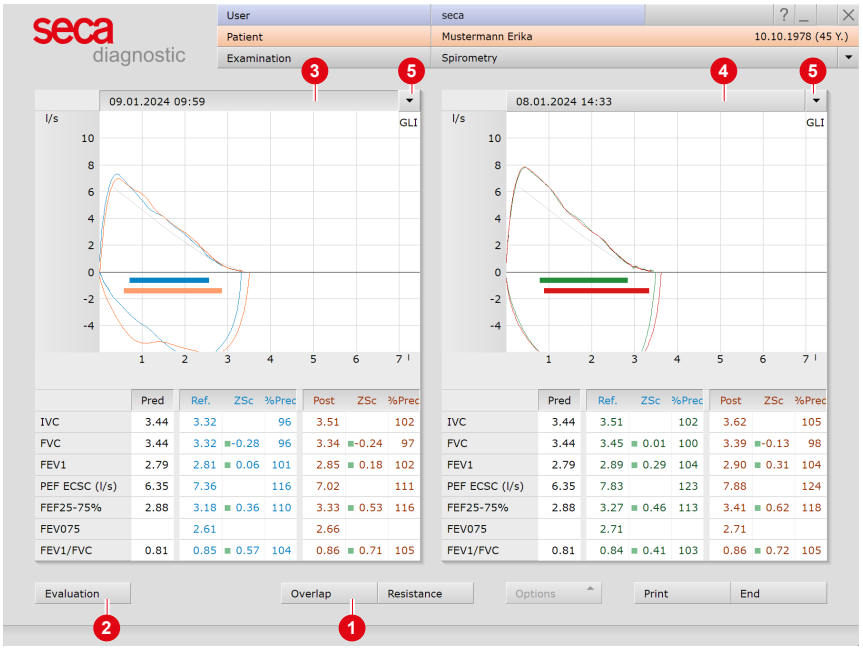


Fig. 114: Evaluation, comparison

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

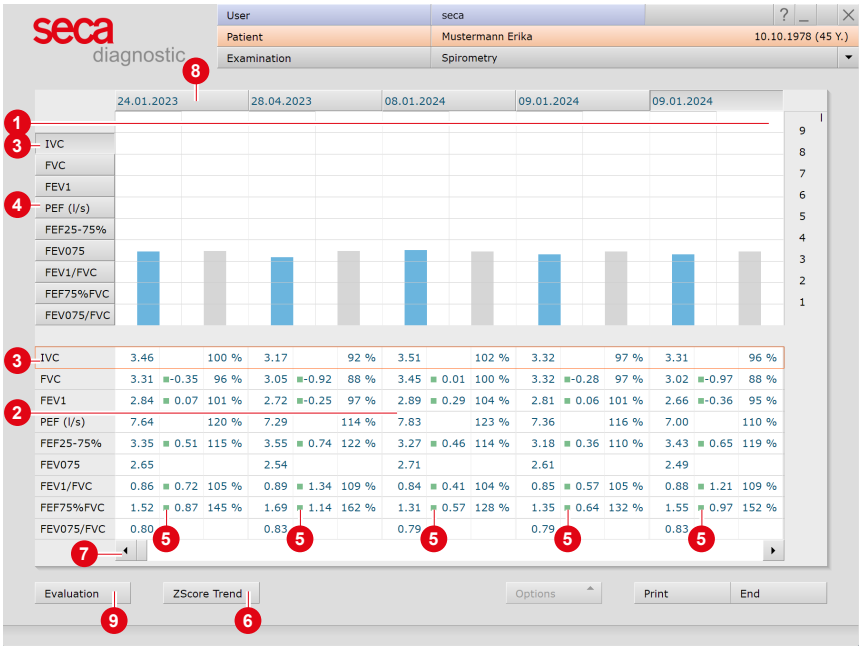


Fig. 115: Evaluation, trend view

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

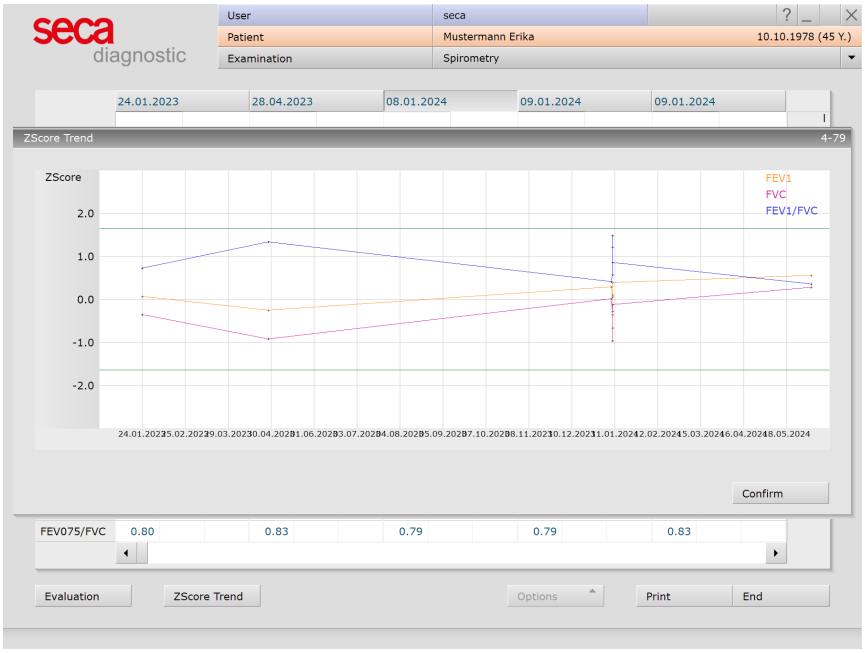


Fig. 116: Evaluation, Z-Score Trend

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

5.6.9 Confirming the evaluation

Unconfirmed report and report

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

Text modules – an aid for writing reports

Select Examination, examination type (e.g. Holter ECG, ABPM, Resting ECG, Stress ECG, ...), Settings, Diagnostic, Reports to configure text modules for reporting an evaluation. A total of four groups with up to eight text modules can be created. The text modules are called in the unconfirmed report dialogue via the keyboard (F5 to F12).

A text module can be created from normal text and variables. When you use a text module in the unconfirmed report, the actual value from the evaluation is inserted in the report text instead of a variable. The structure of a variable is {VARIABLE}. The Shortcuts for export values button provides you with a list with all variables. If the text modules should be shown in the unconfirmed report dialogue, make sure that the Enabled option is activated. Alternatively, the text modules can be shown in the unconfirmed report dialogue by selecting Options, Texts on. There is also the option of writing a text that is automatically displayed in each unconfirmed report (text suggestion or user-defined unconfirmed report). The text can be changed later in the unconfirmed report dialogue. Save your input.

5.6.10 Ending the evaluation

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

This is where the status of an evaluation is defined. Assigning properties (evaluation status) in the End dialogue makes it easier to find evaluations in the evaluation search.

→ Evaluation preconfirmed: If a user with the reporting right “Preconfirm evaluations” has confirmed the unconfirmed report.
→ Evaluation confirmed: If a user with the reporting right “Confirm evaluations” has confirmed the unconfirmed report. The “Evaluation confirmed” status can be reset if required.
→ Printed: Indicates if the evaluation has been printed.
→ Indelible: Can be selected after reporting has been completed. The evaluation can only be viewed and can no longer be changed.
→ Click on Confirm to close the evaluation.

5.6.11 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.

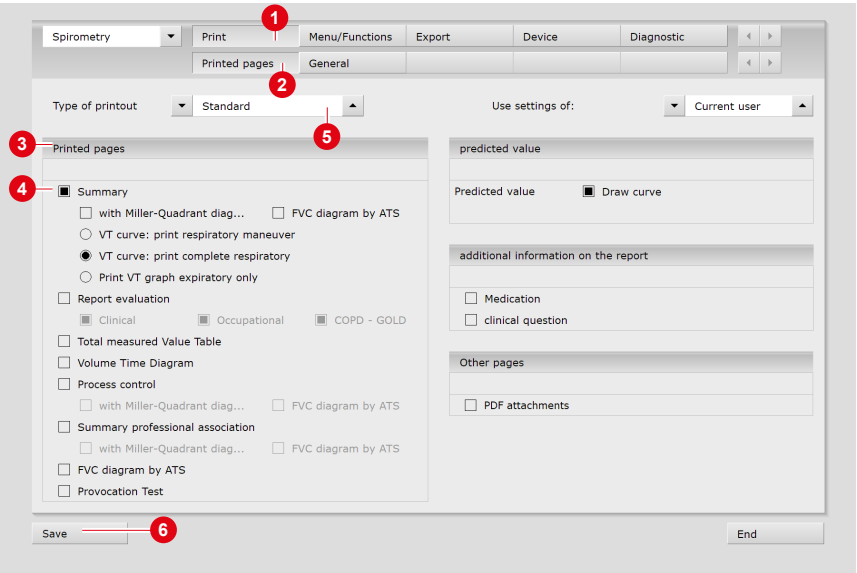


Fig. 117: Contents for the preset pages option

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.

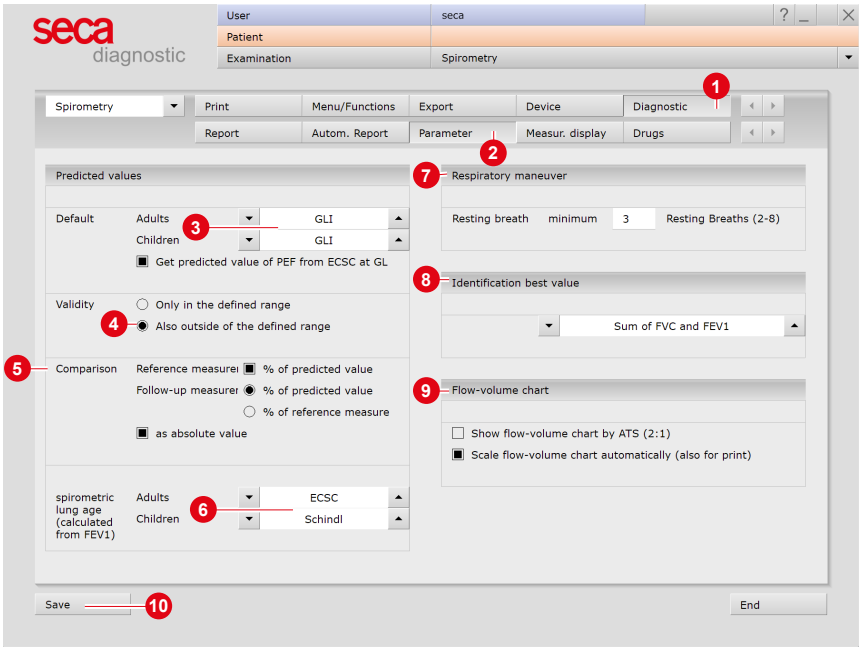


Fig. 118: Parameters for spirometry measurement

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.

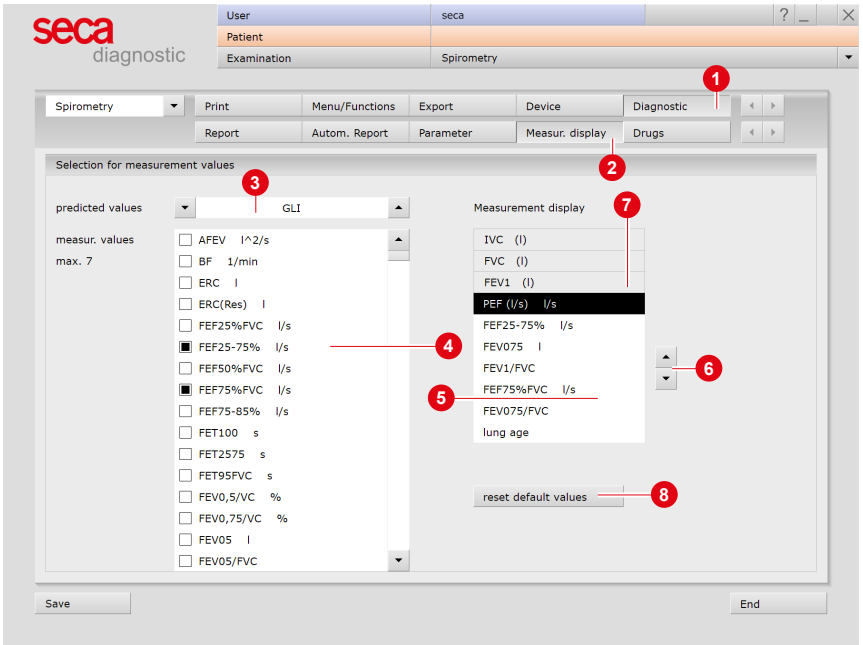


Fig. 119: Settings for displaying the measured values

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.

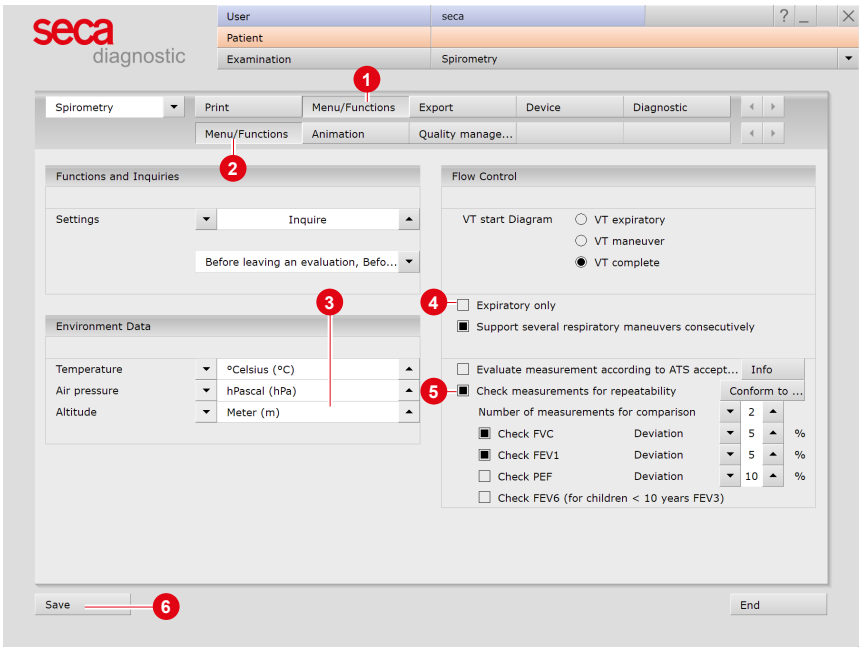


Fig. 120: Settings for prodedures during the measurement

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 diagnostic 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.

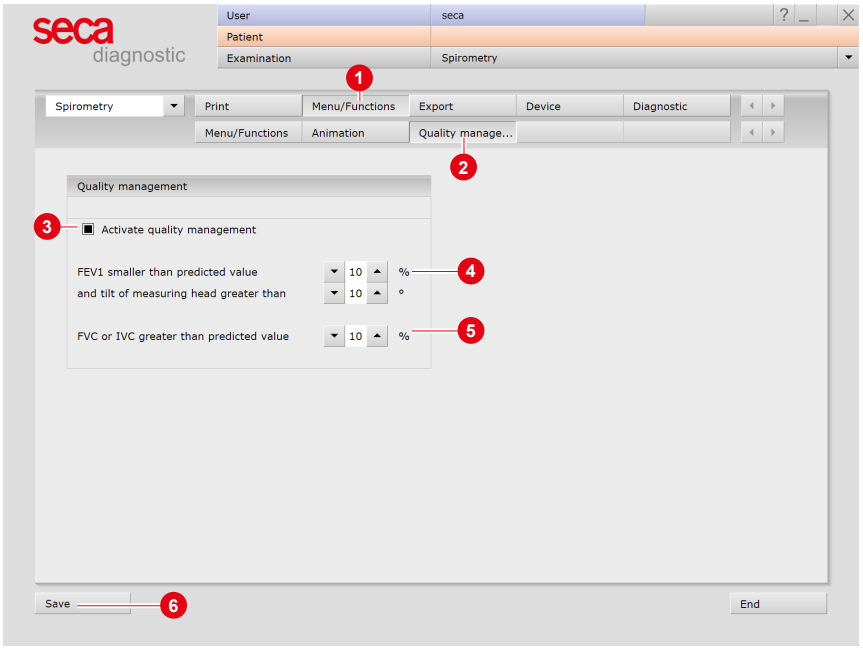


Fig. 121: Quality management settings

5.6.12 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!

6 Appendix

6.1 Calculation methods, formulas and limit values

6.1.1 ABPM

6.1.1.1 Abbreviations in the evaluation

Ps	Brachial systolic blood pressure
Pd	Brachial diastolic blood pressure
MAP	Mean arterial pressure: MAP = Dias + (Syst - Dias) * 0.38
PP	Pulse pressure: PD = Ps - Pd
HR	Heart rate
Average	Average value of the measured values over the total measurement period, calculated as a weighted arithmetic average: Arithmetic mean = (Σ single values) : number of measurements.
SD	Standard deviation: $SD = \sqrt{\frac{\Sigma(\text{Single Value} - \text{Average Value})^2}{\text{Number of Measured Values}}}$
Min	Minimum, lowest measured value
Max	Maximum, highest measured value
% > LV	Percentage of measurements exceeding the limit value
%-drop	drop: decrease in terms of percentage between day and night average values; (daily average value - night average value = 10 to 15%)
A	Additional measurement, identifies measurements that were triggered manually with the function key.
R	Repeat measurement: identifies measurements that were triggered if the set values for repeat measurements were exceeded in the previous measurement or the previous measurement was erroneous.

Phenotype analysis values and abbreviations

MAD	Mean Arterial Pressure
PP	Pulse Pressure
CO	Cardiac Output
CI	Cardiac Index
SV	Stroke Volume
SVR	Systematic Vascular Resistance
PWG	Pulse Wave Velocity
SAI	Sympathetic Activity Index
ABA	Afferent Baroreflex Activity

6.1.1.2 Limit values for adults

Limit values brachial (Ps/Pd)			
Day phase		**Night phase**	
Systole	Diastole	Systole	Diastole
135 mmHg	85 mmHg	120 mmHg	70 mmHg

Measurements in which these values were exceeded are shown in red in the evaluation 1. The limit values can be changed for the current evaluation via Options, Limit values. To change the limit values permanently, open the Examination, ABPM, Settings, Diagnostic, Limits values screen.

In the ABPM graphic, you can use the Limit values button 2 to display guide lines at the level of the defined limit values 3. Values outside the defined limits are thus immediately visible.

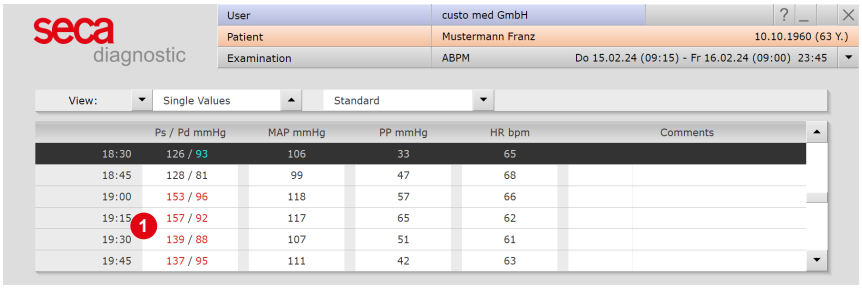


Fig. 122: Exceeded limit values in the table

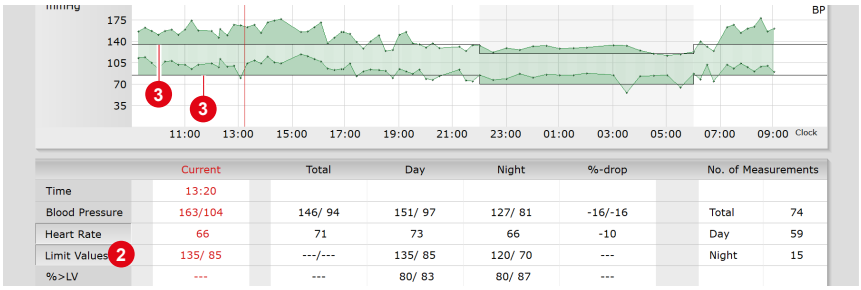


Fig. 123: Limit Values button in the overview

6.1.1.3 Limit values for children and adolescents

To work with limit values for children and adolescents up to 16 years[1)], they must be selected on the Examination, ABPM, Settings, Diagnostic, Limit values screen page.

1) S2k Leitlinie Pädiatrische Nephrologie und Pädiatrie: Arterielle Hypertonie (2013)

→ Select the Use limit values for children up to 16 years option.
→ A distinction is made between:
  → Limit values for gender and height[1)] (Table 1) and
  → Limit values for sex and age[1)] (Table 2).
→ Click Save to apply your input.

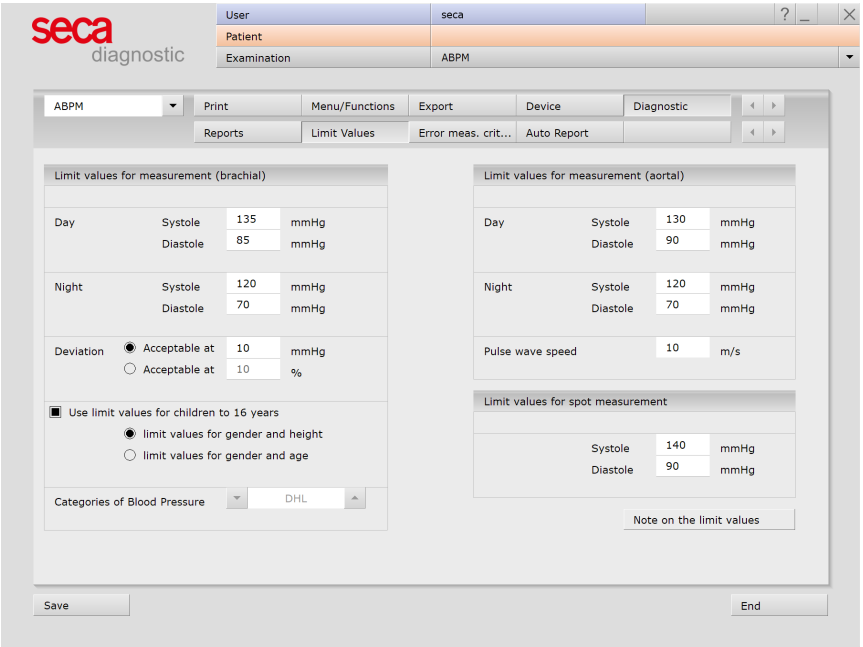


Fig. 124: Limit values for children and adolescents

1) S2k Leitlinie Pädiatrische Nephrologie und Pädiatrie: Arterielle Hypertonie (2013)

2) 2016 European Society of Hypertension guidelines for the management of high blood pressure in children and adolescent.

Definition of hypertension in automatic findings

Based on the limit values described on the following pages, the following classification[1), 2)] is used in the automatic report in seca diagnostic:

→ Normal/high normal: < 95th percentile.
→ Hypertension 1st degree: 5th to (99th percentile + 5 mmHg)
→ Hypertension 2nd degree: > (99th percentile + 5 mmHg)

The classifications can be viewed in seca diagnostic on the screen page Examination, ABPM, Settings, Diagnostic, Auto. Report. Click on Tip for the assessment with children.

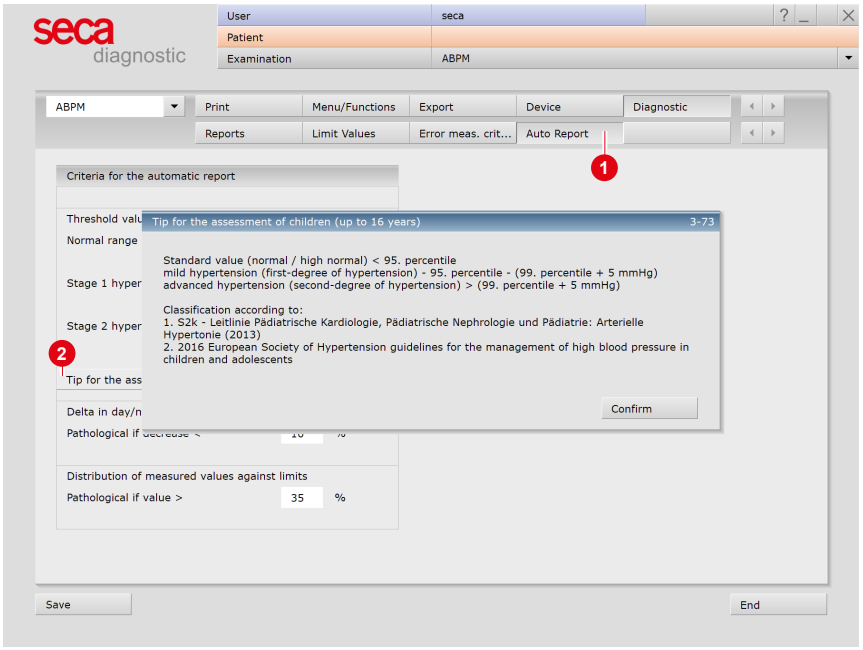


Fig. 125: Note for the assessment of children up to 16 years of age

Table 1:

Standard values for oscillometric ABPM in children by gender and body length.

Boys																											
Height [cm]	Systolic blood pressure [mmHg]									Diastolic blood pressure [mmHg]										Mean arterial pressure (MAP) [mmHg]								
	24-hours			Day			Night			24-hours			Day			Night			24-hours			Day			Night		
	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99
120	114	117	123	122	125	133	103	106	112	74	77	83	80	82	87	61	63	66	86	89	96	93	96	101	76	79	88
125	115	118	124	122	125	132	105	108	114	74	77	82	80	82	86	61	63	67	87	90	96	93	96	101	77	80	88
130	116	119	125	122	126	132	106	110	116	74	77	82	80	82	86	62	64	68	87	90	95	93	96	100	77	81	88
135	117	120	126	122	126	132	108	111	119	74	77	82	80	82	86	63	65	69	88	90	95	93	96	100	78	81	88
140	118	121	127	123	126	132	109	113	121	75	77	82	80	82	85	64	65	70	88	91	95	93	95	100	78	81	87
145	119	123	129	124	127	133	111	114	123	75	77	82	79	81	85	64	66	70	89	91	96	93	95	100	79	81	87
150	121	124	130	125	128	134	112	116	124	75	77	82	79	81	85	64	66	70	89	91	96	93	96	100	79	81	86
155	123	126	132	127	130	136	112	117	125	75	77	82	79	81	85	64	66	70	90	92	96	94	96	100	79	82	86
160	124	127	133	129	133	139	114	118	126	75	77	82	79	81	85	64	66	70	90	93	97	95	91	101	80	82	86
165	126	129	135	132	135	142	116	119	127	75	77	82	80	82	85	64	66	70	91	93	97	95	89	102	80	82	86
170	128	131	137	134	138	145	117	121	128	75	78	82	80	82	86	64	66	70	92	94	98	97	99	103	81	83	86
175	130	133	138	136	140	147	119	122	130	75	78	83	80	83	87	64	66	70	93	95	99	98	100	104	81	83	87
180	131	134	139	138	142	149	120	124	131	76	78	83	81	83	87	64	66	70	94	96	99	99	101	106	82	84	87
185	133	135	141	140	143	151	122	125	132	76	78	83	81	84	88	64	66	70	94	96	100	100	103	107	83	84	87

Girls																											
Height [cm]	Systolic blood pressure [mmHg]									Diastolic blood pressure [mmHg]										Mean arterial pressure (MAP) [mmHg]								
	24-hours			Day			Night			24-hours			Day			Night			24-hours			Day			Night		
	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99
120	112	114	119	118	120	125	103	106	110	71	72	75	80	82	85	63	65	69	84	85	88	91	93	97	77	79	85
125	113	116	120	119	121	125	104	107	111	71	73	75	80	82	85	63	65	70	84	86	89	91	94	97	77	79	84
130	114	117	121	120	122	126	106	108	113	72	73	76	80	82	85	63	66	70	85	87	90	92	94	98	77	80	84
135	115	118	122	120	123	127	107	109	115	72	74	77	80	82	86	63	66	70	86	87	91	92	94	98	77	80	85
140	116	119	123	121	124	129	107	110	116	73	75	78	80	82	86	63	66	71	86	88	91	92	95	99	77	80	85
145	117	120	125	122	125	130	108	112	118	73	75	79	80	82	86	63	66	71	87	89	92	93	95	99	78	80	85
150	119	121	126	124	127	132	110	113	119	74	76	79	80	82	86	63	66	71	87	89	93	93	95	99	78	80	85
155	120	122	127	125	128	133	110	114	120	74	76	80	80	82	86	63	66	71	88	90	93	93	95	99	78	81	85
160	121	123	128	126	129	134	111	114	120	74	76	80	80	82	86	63	65	71	88	90	93	94	96	99	79	81	85
165	122	124	128	127	130	135	112	114	119	74	76	80	80	82	85	63	65	71	89	91	94	94	96	99	79	81	85
170	123	125	129	128	130	135	112	115	119	74	76	80	80	82	85	67	71	79	90	91	94	94	96	99	80	82	85
175	124	126	129	129	131	135	113	115	119	74	76	80	80	82	85	63	65	70	90	92	94	95	96	99	80	82	86

Table 2:

Standard values for oscillometric ABPM in children by gender and age.

Boys																											
Age [years]	Systolic blood pressure [mmHg]									Diastolic blood pressure [mmHg]									Mean arterial pressure (MAP) [mmHg]								
	24-hours			Day			Night			24-hours			Day			Night			24-hours			Day			Night		
	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99
5,0	113	116	123	120	123	129	103	106	112	72	74	79	79	81	85	62	65	72	86	88	94	91	94	98	75	78	84
5,5	114	117	123	121	123	129	104	107	113	72	75	79	79	81	85	63	66	72	86	88	94	92	94	99	75	78	85
6,0	115	118	124	121	124	130	105	108	115	73	75	79	79	81	85	63	66	73	86	89	95	92	95	99	76	79	86
6,5	115	118	125	121	124	130	106	109	116	73	75	79	80	81	85	64	66	73	86	89	95	92	95	100	77	80	86
7,0	116	119	125	122	125	131	106	110	117	73	75	79	80	82	85	64	67	73	87	89	95	93	95	100	77	80	87
7,5	116	119	126	122	125	131	107	110	118	73	75	79	80	82	85	64	67	73	87	90	95	93	96	100	78	81	87
8,0	117	120	127	122	125	132	107	111	118	73	75	79	80	82	85	64	67	74	87	90	95	93	96	101	78	81	88
8,5	117	121	127	123	126	132	108	112	119	73	75	79	80	82	85	64	67	73	88	90	95	93	96	101	78	81	88
9,0	118	121	128	123	126	132	109	112	120	73	75	79	80	82	85	64	67	73	88	90	96	94	96	101	79	82	88
9,5	118	122	128	123	127	133	109	113	120	73	75	79	80	82	85	64	67	73	88	91	96	94	96	101	79	82	88
10,0	119	123	129	124	127	134	110	113	121	73	75	79	80	82	85	64	67	73	88	91	96	94	96	101	79	82	88
10,5	120	123	130	125	128	135	110	114	121	74	76	79	79	82	85	64	67	72	89	91	96	94	96	101	79	82	88
11,0	121	125	131	126	129	136	111	115	122	74	76	79	79	82	85	64	67	72	89	91	96	94	97	101	79	82	87
11,5	122	126	133	127	130	137	112	115	123	74	76	79	79	82	85	64	67	72	89	92	96	94	97	101	79	82	87
12,0	124	127	134	128	132	139	113	116	124	74	76	80	80	82	85	64	66	71	90	92	96	95	97	102	80	82	87
12,5	125	129	135	130	133	140	114	117	125	74	76	80	80	82	85	64	66	71	90	92	96	95	98	102	80	82	87
13,0	126	130	137	131	135	141	115	119	127	74	76	80	80	82	86	64	66	71	91	93	97	96	98	102	80	83	87
13,5	128	131	138	133	136	143	116	120	128	74	76	80	80	82	86	64	66	71	91	93	97	96	99	103	81	83	87
14,0	120	133	140	134	138	144	118	121	129	75	77	80	80	82	86	64	66	71	92	94	97	97	99	103	81	83	87
14,5	131	134	141	136	139	146	119	122	130	75	77	80	80	82	86	64	66	71	92	94	98	98	100	104	81	83	87
15,0	132	135	142	137	141	147	120	123	130	75	77	81	81	83	87	64	66	71	93	95	98	98	101	105	81	83	87
15,5	133	137	143	139	142	149	121	125	131	75	77	81	81	83	87	64	66	70	93	95	99	99	101	105	81	83	86
16,0	135	138	145	140	144	150	122	126	132	76	78	81	81	83	88	64	66	70	94	96	99	100	102	106	82	83	86

Girls																											
Age [years]	Systolic blood pressure [mmHg]									Diastolic blood pressure [mmHg]									Mean arterial pressure (MAP) [mmHg]								
	24-hours			Day			Night			24-hours			Day			Night			24-hours			Day			Night		
	P90	P95	P99	P90	P95	P99	P90	P95	P90	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99	P90	P95	P99
5,0	112	115	120	118	121	126	105	108	115	72	74	78	80	82	86	66	69	74	85	87	91	92	95	99	77	79	84
5,5	113	116	121	119	122	126	106	109	115	72	74	78	80	82	86	65	68	74	85	87	91	92	95	99	77	79	84
6,0	114	116	122	120	122	127	106	110	116	72	74	78	80	82	86	65	68	74	85	87	91	92	94	99	77	79	84
6,5	114	117	122	120	123	128	107	110	117	72	74	78	80	82	86	65	68	73	85	87	91	92	94	99	77	80	84
7,0	115	118	123	121	123	128	107	111	117	72	74	78	80	82	86	65	67	73	85	87	91	92	94	98	77	80	84
7,5	116	118	124	121	124	129	108	111	118	72	74	78	80	82	86	64	67	73	86	87	91	92	94	98	77	80	84
8,0	116	119	124	122	124	130	108	111	118	72	74	78	80	82	85	64	67	72	86	88	91	92	94	98	77	80	84
8,5	117	119	125	122	125	130	108	112	119	72	74	78	80	82	85	64	67	72	86	88	91	92	94	98	77	80	84
9,0	117	120	125	122	125	131	109	112	119	73	74	78	80	82	85	64	67	72	86	88	91	92	94	98	77	80	84
9,5	118	121	126	123	126	131	109	113	120	73	75	78	79	81	85	64	67	72	86	88	91	92	94	98	78	80	85
10,0	118	121	127	123	126	132	109	113	120	73	75	78	79	81	85	64	66	72	86	88	92	92	94	98	78	80	85
10,5	119	122	127	124	127	132	110	113	120	73	75	78	79	81	85	64	66	72	87	89	92	92	94	98	78	80	85
11,0	119	122	128	124	127	133	110	113	120	73	75	78	79	81	85	63	66	72	87	89	92	92	94	98	78	80	85
11,5	120	123	128	125	128	133	110	114	120	73	75	79	79	81	85	63	66	72	88	89	93	93	95	98	78	80	85
12,0	120	123	128	125	128	134	110	114	120	74	76	79	80	82	85	63	66	71	88	90	93	93	95	99	78	80	85
12,5	121	123	129	126	129	134	111	114	120	74	76	79	80	82	85	63	66	71	88	90	93	93	95	99	78	80	85
13,0	121	124	129	126	129	135	111	114	119	74	76	80	80	82	86	63	66	71	89	90	94	94	96	99	78	81	85
13,5	122	124	129	127	130	135	111	114	119	74	76	80	80	82	86	63	66	71	89	91	94	94	96	99	78	81	85
14,0	122	125	129	127	130	135	111	114	119	74	76	80	80	82	86	63	65	71	89	91	94	94	96	100	79	81	85
14,5	122	125	130	128	130	135	111	114	118	75	77	80	80	82	86	63	65	71	89	91	94	95	97	100	79	81	85
15,0	123	125	130	128	130	135	111	114	118	75	77	80	80	82	86	63	65	70	90	91	95	95	97	100	79	81	85
15,5	123	125	130	128	131	135	111	114	118	75	77	80	80	82	86	63	65	70	90	92	95	95	97	100	79	81	85
16,0	123	126	130	128	131	135	111	114	118	75	77	81	80	82	85	63	65	70	90	92	95	95	97	101	79	81	85

6.1.2 Holter ECG

Beat identification

Beat detection in seca diagnostic is performed using the VPB detection algorithm by Kraft et al (2023): Kraft, D., Bieber, G., Jokisch, P., & Rumm, P. (2023). End-to-End Premature Ventricular Contraction Detection Using Deep Neural Networks. Sensors, 23(20), Article 20. https://doi.org/10.3390/s23208573.

Method for calculating the heart rate

seca diagnostic displays different heart rates, all based on one minute:

HR/minute	Per minute, only the disturbance-free time is considered. Sum of the normal beats and the VPB beats divided by the disturbance-free time [in s] * 60 s
HR example	Sum of the normal beats and the VES beats divided by the length of the example [in s] * 60 s.
HR beat	60 s divided by the interval to the previous beat (RR interval) [in s].
HR max	The highest value of all “HR/minute” during the monitoring time.
HR average	The average value of all “HR/minute” during the monitoring time.
HR min	The lowest value of all “HR/minute” during the monitoring time.
HR day max	The highest value of all “HR/minute” during the day phase of the monitoring period
HR day average	The average value of all “HR/minute” during the day phase of the monitoring time
HR day min	The lowest value of all “HR/minute” during the day phase of the monitoring period
HR Night max	The highest value of all “HR/minute” during the night phase of the monitoring time
HR night average	The average value of all “HR/minute” during the night phase of the monitoring time
HR night min	The lowest value of all “HR/minute” during the night phase of the monitoring time.
HR event	Sum of normal beats and VES beats divided by the length of the event [in s] * 60 s.

If the “HR max. linked with Tachycardia/VT” option is activated (context menu, Properties), the HR of the tachycardia/VT is used for the “HR max” calculation if its heart rate is the highest.

If the “HR min. linked with Bradycardia” option is activated (context menu, Properties), the heart rate of the bradycardia is used for the “HR min” calculation if its heart rate is the lowest.

Method for determining a heart action break

The basis is the ECG analysis that automatically detects the beats and disturbances. If there is no disturbance and the break between two normal beats becomes greater than 2.0 s (for VES 2.5 s), the holter software shows this break as an asystole. The asystole must be shorter than 60 s.

All values can be adjusted in the holter software. The values used here correspond to the factory settings.

6.1.3 Resting ECG

Isoelectric segments within the QRS complex.

The isoelectric segments within the QRS complex are included in the Q, R, or S waves.

The duration of each spike/wave is the same in all 12 channels and is determined by the channel where the first event (this refers to the beginning or end of a spike/wave) occurs.

Calculation of QTc duration

Formula according to Bazett:

$$QTc\text{-}Duration = QT * \sqrt{\frac{HR}{60}}$$

Formula according to Fridericia:

$$QTc\text{-}Duration = QT * \sqrt[3]{\frac{HR}{60}}$$

Beat identification

Beat detection in seca diagnostic is performed using the VPB detection algorithm by Kraft et al (2023): Kraft, D., Bieber, G., Jokisch, P., & Rumm, P. (2023). End-to-End Premature Ventricular Contraction Detection Using Deep Neural Networks. Sensors, 23(20), Article 20. https://doi.org/10.3390/s23208573.

6.1.4 Stress ECG

Isoelectric segments within the QRS complex.

The isoelectric segments within the QRS complex are included in the Q, R, or S waves.

The duration of each spike/wave is the same in all 12 channels and is determined by the channel where the first event (this refers to the beginning or end of a spike/wave) occurs.

PWC (physical working capacity)

The PWC values indicates the physical ability of a patient at a specific heart rate. The PWC value is specified in watt/kg (body weight). In seca diagnostic, the PWC value is determined for a heart rate of 130, 150 and 170. To determine the PWC value, the patient must have a heart rate of +/- 10 to the reference rate (130, 150 and 170). If the heart rate has not been precisely achieved, the PWC value will be calculated using interpolation or extrapolation. Example: If a patient who weighs 100 kg reaches a heart rate of 170 to 200, the PWC value will be calculated as follows:

PWC170 = 200 W : 100 kg = 2 W/kg

The PWC predicted values are preset in seca diagnostic and can be changed under Examination, Stress ECG, Settings, Diagnostic, Reference values. Click on Save to apply your changes.

MET (metabolic equivalent)

The metabolic equivalent is used to determine the expenditure of energy during the maximum load. In seca diagnostic, the metabolic equivalent is calculated as follows:

Treadmill ergometry:

v = max. speed in miles per hour, m = gradient in %.

*MET = 1 + (v * 26.8 * (0.1 + m * 0.018)) : 3.5*

Bicycle ergometry:

L = max. load in watts, G = weight in kg

*MET = 1 + (12 * L) : (3.5 * G)*

Calculation of QTc duration

Formula according to Bazett:

$$QTc\text{-}Duration = QT * \sqrt{\frac{HR}{60}}$$

Formula according to Fridericia:

$$QTc\text{-}Duration = QT * \sqrt[3]{\frac{HR}{60}}$$

Calculation of the target load

seca diagnostic offers three different calculation options for calculating the target load at maximum workload: “according to Rost & Hollmann”, “according to Wonisch et al.” and “according to Reiterer”. The setting can be found on the Examination, Stress ECG, Settings, Diagnostic, Reference values screen.

Calculation of the target load according to Rost & Hollmann

Male, under 30 years of age:

*Target load = 3 * weight*

Female, under 30 years of age:

*Target load = 2.5 * weight*

Male, over 30 years of age:

*Target load = 3 * weight * ((130 - age) : 100)*

Female, over 30 years of age:

*Target load = 2.5 * weight * ((130 - age) : 100)*

Source: Rost, R. & Hollmann, W. (1982): Belastungsuntersuchungen in der Praxis, Georg Thieme Verlag, Stuttgart, New York. 164 p.

Calculation of the target load according to Wonisch et al.

female:

*3.933 + (86.641 * body surface) - (0.015 * age) - (0.346 * body surface * age)*

male:

*6.773 + (136.141 * body surface area) - (0.064 * age) - (0.916 * body surface area * age)*

Source: Wonisch M., Berent R., Klicpera M., Laimer H., Marko C., Pokan R., Schmid P., Schwann H. (2008): Praxisleitlinien Ergometrie. Journal für Kardiologie - Austrian Journal of Cardiology. 15(A): 3-17.

Body surface area according to DuBois & DuBois

*BSA = 0.007184 * height [cm] 0.725 * weight [kg] 0.425*

Source: DuBois, D. & DuBois, E.F. (1916): A formula to estimate the approximate surface area if height and weight be known. Arch Intern Med, 17: 863

Target load according to Reiterer (1975), for men

Men									
Age (years)	**20 – 24**	**25 – 29**	**30 – 34**	**35 – 39**	**40 – 44**	**45 – 49**	**50 – 54**	**55 – 59**	**60 – 64**
Weight (kg)	**Load in watts**								
60 – 61	215	205	195	184	174	164	152	143	133
62 – 63	218	207	197	187	177	166	156	146	134
64 – 65	220	210	200	184	179	169	159	148	138
66 – 67	223	213	202	192	182	172	161	151	141
68 – 69	226	215	205	195	184	174	164	154	143
70 – 71	228	218	208	197	187	177	166	156	146
72 – 73	231	221	210	200	190	179	169	159	148
74 – 75	234	223	213	203	192	182	172	161	151
76 – 77	236	226	216	205	195	185	174	164	154
78 – 79	239	228	218	208	198	187	177	167	156
80 – 81	241	230	221	210	200	190	180	169	159
82 – 83	244	234	223	213	203	193	182	172	162
84 – 85	248	236	226	216	205	195	185	175	164
86 – 87	249	239	230	218	208	198	187	177	167
88 – 89	252	243	231	221	211	200	190	180	170
90 – 91	256	244	234	225	213	203	193	182	172
92 – 93	257	248	238	226	216	207	195	185	175
94 – 95	261	249	239	230	220	208	198	189	177
96 – 97	262	252	243	233	221	211	202	190	180
98 – 99	266	256	244	234	225	215	203	193	184
100 – 101	269	257	248	238	226	216	207	197	185
102 – 103	270	261	251	239	230	220	208	198	189
104 – 105	274	264	252	243	233	221	211	202	192
106 – 107	277	266	256	246	234	225	215	197	193
108 – 109	279	269	259	248	238	228	216	207	197

Reiterer, W. (1975). Methodik eines rektangulär-triangulären Belastungstestes. Herz Kreislauf Zeitschrift für Kardiologie und Angiologie in Klinik und Praxis, Herz/Kreisl. (7), 457–462.

Target load according to Reiterer (1975), for women

Women									
Age (years)	**20 – 24**	**25 – 29**	**30 – 34**	**35 – 39**	**40 – 44**	**45 – 49**	**50 – 54**	**55 – 59**	**60 – 64**
Weight (kg)	**Load in watts**								
40 – 41	107	102	96	95	90	87	82	79	74
42 – 43	108	105	102	97	93	89	85	82	77
44 – 45	111	108	103	100	95	92	89	84	80
46 – 47	115	110	107	102	98	95	90	87	82
48 – 49	116	113	110	105	102	97	93	90	85
50 – 51	120	116	111	108	103	100	97	92	89
52 – 53	123	118	115	110	107	103	98	95	90
54 – 55	125	121	118	113	110	105	102	98	93
56 – 57	128	125	120	116	111	108	105	100	97
58 – 59	131	126	123	118	115	111	107	103	98
60 – 61	133	130	126	121	118	113	110	107	102
62 – 63	136	133	128	125	120	116	113	108	105
64 – 65	139	134	131	126	123	120	115	111	107
66 – 67	141	138	134	130	126	121	118	115	110
68 – 69	144	141	136	133	128	125	121	116	113
70 – 71	148	143	139	134	131	128	123	120	115
72 – 73	149	146	143	138	134	130	126	123	118
74 – 75	152	149	144	141	136	133	130	125	121
76 – 77	156	151	148	143	139	136	131	128	123
78 – 79	157	154	151	146	143	138	134	131	126
80 – 81	161	157	152	149	144	141	138	133	130
82 – 83	164	159	156	151	148	144	139	136	131
84 – 85	166	162	159	154	151	146	143	139	134
86 – 87	169	166	161	157	152	149	146	141	138
88 – 89	172	167	164	159	156	152	148	144	139

Reiterer, W. (1975). Methodik eines rektangulär-triangulären Belastungstestes. Herz Kreislauf Zeitschrift für Kardiologie und Angiologie in Klinik und Praxis, Herz/Kreisl. (7), 457–462.

BORG values for stress ECG

When performing a stress ECG, BORG values can be entered during the recording. BORG values are used to evaluate the subjective perceived exertion and were established by the Swedish physiologist Gunnar Borg in the Borg scale named after him. Classification is carried out either by the physician or by the patients themselves.

Borg values are entered in seca diagnostic during the stress test. This can either be done for each load stage or for the entire test. The dialogue for entering the Borg values is called up via Options, Borg or by pressing the F12 key. Values between 0 and 30 can be entered for each of the musculature, breathing and pain categories. This can be based on, for example, the CR10 Borg scale or the RPE Borg scale. seca diagnostic does not specify a specific Borg scale.

Maximum heart rate during the stress test (HR max)

You can set how the maximum heart rate should be calculated during the examination on the Examination, Stress ECG, Settings, Menu/Functions, Menu/Functions screen. Four options are offered in the “Load” area: manual entry, 100 % of 200 minus the patient's age, calculation according to Tanaka et al. (2001), calculation according to Arena et al. (2016).

Maximum heart rate according to Tanaka et al. (2001):

*208 – 0.7 * Age (in years)*

Tanaka, H., Monahan, K. D., & Seals, D. R. (2001). Age-predicted maximal heart rate revisited. Journal of the American College of Cardiology, 37(1), 153–156. https://doi.org/10.1016/S0735-1097(00)01054-8

Maximum heart rate according to Arena et al. (2016):

*209.3 – 0.72 * Age (in years)*

Arena, R., Myers, J., & Kaminsky, L. A. (2016). Revisiting age-predicted maximal heart rate: Can it be used as a valid measure of effort? American Heart Journal, 173, 49–56. https://doi.org/10.1016/j.ahj.2015.12.006

Duke Treadmill Score

In order to display this value in seca diagnostic, some settings are required, _RS.

Calculation

*Duke score = Test duration - 5 * ST segment deviation - 4 * TAI*

Explanations of the values in the equation:

- → Test duration: the duration of the stress test in minutes
- → ST segment deviation: maximum net ST segment deviation in millimetres. ST deviation refers to the maximum ST change (elevation or depression) in each lead except the aVR lead
- → TAI is the Treadmill Angina Index:
  - → 0: no angina pectoris/pain
  - → 1: Typical angina pectoris (pain that is limited to the period of exertion)
  - → 2: Training canceled due to angina pectoris

Duke Treadmill Score	Risk assessment
≥ 5	Low
-10 to +4	Medium
Less than -10	High

Mark, D. B., Shaw, L., Harrell, F. E., Hlatky, M. A., Lee, K. L., Bengtson, J. R., McCants, C. B., Califf, R. M., & Pryor, D. B. (1991). Prognostic value of a treadmill exercise score in outpatients with suspected coronary artery disease. The New England Journal of Medicine, 325(12), 849–853. https://doi.org/10.1056/NEJM199109193251204

Gibbons, R. J., Balady, G. J., Beasley, J. W., Bricker, J. T., Duvernoy, W. F., Froelicher, V. F., Mark, D. B., Marwick, T. H., McCallister, B. D., Thompson, P. D., Winters, W. L., Yanowitz, F. G., Ritchie, J. L., Gibbons, R. J., Cheitlin, M. D., Eagle, K. A., Gardner, T. J., Garson, A., Lewis, R. P., … Ryan, T. J. (1997). ACC/AHA Guidelines for Exercise Testing. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Exercise Testing). Journal of the American College of Cardiology, 30(1), 260–311. https://doi.org/10.1016/s0735-1097(97)00150-2

Beat identification

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6.1.5 Spirometry

6.1.5.1 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
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).

Abbreviation	Unit	Description
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

6.1.5.2 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.

6.2 Keyboard navigation and shortcuts

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

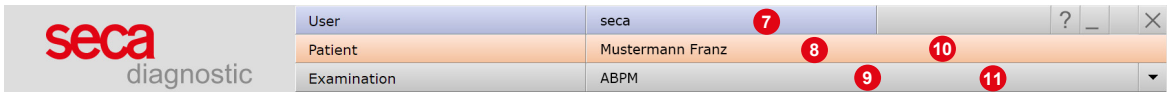
Quick links in the main navigation

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

6.3 EC Declaration of Conformity

Simplified declaration of conformity

seca diagnostic 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 types custo screen 300 (seca screen 300), custo guard holter (seca guard holter) and custo cardio 300 BT (seca ct331) 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.

6.4 List of applied standards

Generally applied standards	DIN EN ISO 13485 DIN EN ISO 14971 DIN EN ISO 20417 DIN EN ISO 15223-1 DIN EN 60601-1 DIN IEC 60601-1-6 DIN EN 62304 DIN EN 62366-1
Product-specific standards	DIN EN 60601-2-25 DIN EN 60601-2-47 DIN EN 80601-2-30 DIN EN ISO 23747 DIN EN ISO 26782 PD IEC/TR 60601-4-5 IEC 81001-5-1 EN 80601-2-61 DIN EN 82304-1 EN 1064
Regulations, guidelines	2017/745 2021/2226

6.5 List of Figures

Manufacturer:

custo med GmbH
Maria-Merian-Str. 6
85521 Ottobrunn
Ottobrunn, Germany

Phone: 0049 (0) 89 710 98 - 00
Fax: 0049 (0) 89 710 98 - 10
Email: info@customed.de
Internet: www.customed.de

custo med product names:
custo screen 300 (ABPM recorder)
custo guard holter (holter ECG device)
custo cardio 300 (12-channel PC ECG device)
custo spiro mobile (spirometry device)
custo diagnostic (medical PC software)

Distribution:

seca Ltd.
40 Barn Street
Birmingham
West Midlands
B5 5QB
Phone: 0121 643 9349
Fax: 0121 633 3403
Email: info.uk@seca.com

All contact details at www.seca.com

seca product names:
seca screen 300 (ABPM recorder)
seca guard holter (holter ECG device)
seca ct330/331 (12-channel PC ECG device)
seca spiro mobile (spirometry device)
seca diagnostic (medical PC software)

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