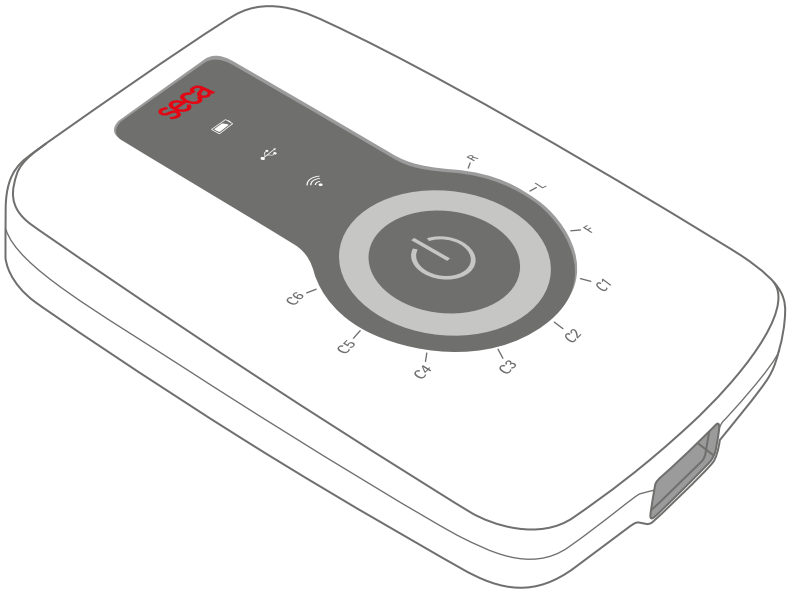
Instructions for Use

Resting & Stress ECG with seca ct330/331 and 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 cardio 300 (12-channel PC ECG 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 ct330/331 (12-lead PC ECG device)
seca diagnostic (medical PC software)

seca®
Precision for health

Table of Contents

1 Safety

1.1 General notes

1.1.1 Symbols used in this Operating Manual

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

1.1.2 Laws and regulations applicable to the product

INFORMATION:

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

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

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

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

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

1.1.3 Disclaimer

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

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

1.1.4 Warranty

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

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

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

1.1.5 Support

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

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

1.2 Safety installations and safe working

1.2.1 Putting into operation, setup

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

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

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

1.2.2 Ambient conditions, handling of the devices

Emissions

The seca ct330/331 device/system is not suitable for use in rooms or areas with a risk of explosion.

For installation and operation of the seca ct330/331 device/system, the EMC (electromagnetic compatibility) instructions in this manual must be observed.

Strong electromagnetic sources in the immediate vicinity of the seca ct330/331 device/system may result in recording errors. The seca ct330/331 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 ct330/331 device/system, even if the other devices comply with the applicable emissions requirements according to CISPR.

Mechanical impact

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

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

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

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

Rechargeable batteries

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

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

USB cable

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

1.2.3 Patient safety

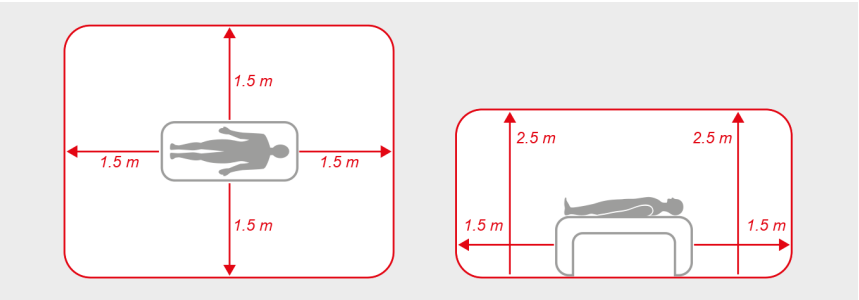


Fig. 1: Safety distances at the patient area

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

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

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

1.2.4 System and data security

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

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

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

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

seca diagnostic

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

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

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

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

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

Allocation of case and job numbers

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

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

Data management in seca diagnostic: Assign evaluation

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

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

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

1.2.5 Information on EMC (Electromagnetic Compatibility)

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

1.2.6 Maintenance (regular safety checks)

The operator is responsible for maintenance.

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

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

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

1.3 Safety instructions for resting and stress ECGs

The device must be protected from dust and liquids.

seca ct330/331 is only defibrillation-protected with the manufacturer's patient cable.

Only use patient cables with 10 or 100 KΩ defibrillation protection resistance for seca ct330/331.

In the event of defibrillation, observe the manufacturer's instructions regarding the safe and proper use of the defibrillator.

Defibrillation interferes with the ECG recording. The recovery time of seca ECG devices is less than five seconds.

Make sure that the electrode contacts do not come into contact with other conductive parts.

If electrodes become detached from the patient during an ECG recording or the electrode contact is too weak, a red signal line is displayed on the corresponding ECG channel in seca diagnostic. A note appears below the ECG recording (in red) indicating which electrodes are affected. Attach these again. Red signal lines in seca diagnostic do not indicate that the patient has an asystole.

seca diagnostic offers pacemaker detection. The pacemaker impulse is detected from the ECG signal (at least in two channels) and projected into the ECG recording as an (artificial) spike with precise timing.

seca ct330/331 is not suitable for intracardiac use.

seca ct330/331 has no protection against possible influences from high-frequency (HF) surgical devices.

seca ct330/331 must not be used in the vicinity of HF surgical devices.

Use of the seca ct330/331 in conjunction with life-support equipment is not permitted. The device is not suitable for intensive care or as an alarm system for life-sustaining body functions.

1.4 Residual risks resting and stress ECG

CAUTION

Allergic reactions on the skin due to substances in adhesive electrodes (acrylate adhesive, Ag/AgCl).

→ Clarify further procedure with the physician before recording.

WARNING

Risk of injury due to changes in acceleration, speed or incline of the treadmill.

Unexpected, abrupt stopping or starting of the treadmill can cause injury to the patient. Bruises, strains or fractures from tripping and falling.

→ Inform patient before making any change in acceleration, speed or incline.

→ Do not make changes until the patient has adjusted.

2 Hardware

2.1 Intended use

seca ct330/331 is a 12-channel PC ECG device designed for the creation, analysis and evaluation of ECG recordings in medical practices and hospitals.

Users are trained specialists in medical practices, laboratories, rehabilitation facilities or hospitals. These include doctors and medical-technical assistants in particular.

seca ct330/331 can be used safely on patients with pacemakers.

seca ct330/331 is not suitable for intracardiac use.

Use of the seca ct330/331 in conjunction with life-support equipment is not permitted. The device is not suitable for intensive care or as an alarm system for life-sustaining body functions.

2.1.1 Indications and contraindications

Indications Resting 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

- → 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)

Indications 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

- → 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

2.1.2 Device types and functions

Type	Connection to PC	Power supply
seca ct330	USB cable	USB cable
seca ct331	USB cable and Bluetooth	Lithium-ion battery

2.2 Symbols on the devices and packaging

	Manufacturer: custo med GmbH, Maria-Merian-Str. 6, 85521 Ottobrunn, Germany
distributed by seca	Distributor: seca Ltd., 40 Barn Street, Birmingham, West Midlands, B5 5QB, UK
SN	Serial number
REF	Order number/designation
UDI	Unique Device Identifier
LOT	Lot designation
MD	Medical device
	Follow the Operating Manual!
	Observe the Operating Manual
	Protection class designation of a medical electrical device according to DIN EN 60601-1 (type CF, defibrillation protected)
	Separate collection of electrical and electronic equipment, do not dispose with domestic waste.
CE 0123	CE mark
CE	CE mark
	Date of manufacture (YYYY-MM, e.g., 2022-01)

2.3 Technical data and system requirements

seca ct330/331	
Number of ECG channels	12
Frequency response	0 to 0.262 * Sampling frequency [HZ]
Sampling frequency	1000, 2000, 4000, 8000, 16000 (USB), 32000 (USB) [Hz]
Sampling rate	1.0 / 0.5 / 0.25 / 0.125 / 0.0625 (USB) / 0.03125 (USB) [ms]
Deviation	< 1.5%
A/D converter	24 bit
Input impedance	10 MΩ when electrode recognition is active 1000 MΩ when electrode recognition is inactive
Amplitude quantification	1.525 µV/bit
CMRR	> 93 dB
Impedance measurement	At all electrode leads (not N) with automatic quality indication
Defibrillation protection	Electrical strength 5000 V
Recovery time after defibrillation	< 5 s
Power supply	USB cable (standard connection on PC) Lithium-ion battery
Max. Energy consumption	1.5 watts
Operating time Li-Ion battery	with Bluetooth operation and 4 kHz: max. 10 hours
Battery charging time	max. 3 hours in pure charging mode
Operating life	approx. 5 years
IT connection	USB (cable length 3000 mm), Bluetooth
Patient connection	Patient cable 10-lead with HDMI connection
Bluetooth frequency	2.4 GHz ISM frequency band
Bluetooth range	typ. 10 m, depending on ambient conditions
Dimensions	approx. 118 * 78 * 23 mm (L * W * H)
Weight	approx. 130 g
Cable lengths of patient cables[1)]	approx. 1050 mm (R, L, N, F), 700 mm (C1 - C6)
Operating conditions	Temperature +10°C ... +40°C Humidity 25 ... 95 % rH Air pressure 700 ... 1060 hPa
Transport and storage conditions	Temperature +5°C ... +45°C Humidity 30 ... 93 % rH Air pressure 700 ... 1060 hPa
Classification	seca ct330: Protection class II, seca ct331: Device with internal power supply, class IIa, type CF
Applied standards	DIN EN ISO 13485, DIN EN ISO 14971, DIN EN ISO 20417, DIN EN ISO 15223-1, DIN EN 60601-1, DIN EN 60601-1-2, DIN EN 60601-1-6, DIN EN 62304, DIN EN 62366-1, DIN EN ISO 10993-1, EN 60601-2-25, DIN EN 10993-5, DIN EN 10993-10

Technical requirements for the operation of seca diagnostic

seca diagnostic SERVER, hardware and operating system

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

seca diagnostic SERVER, minimum requirements

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

seca diagnostic SERVER, recommendations

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

seca diagnostic CLIENT, hardware and operating system

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

seca diagnostic CLIENT, minimum requirements

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

seca diagnostic CLIENT, recommendations

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

Software requirements for the operation of seca diagnostic

seca diagnostic SERVER

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

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

seca diagnostic CLIENT

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

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

2.4 Shutdown, storage, transport, disposal

Shutdown and storage

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

Transport

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

Disposal

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

Symbols for transport, storage and disposal

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

2.5 Components for the recording

seca ct330 (with USB connectivity)

→ seca ct330 (with USB connectivity), ECG device
→ with 10-wire patient cable with banana plugs

Not shown:

→ seca diagnostic medical PC software for ECG diagnostic assistance
→ Carrying case with belt
→ USB connection cable A-A, 3 m
→ ECG electrodes

seca ct331 (with Bluetooth connectivity)

→ seca ct331 (with Bluetooth connectivity), ECG device
→ with 10-wire patient cable with banana plugs

Not shown:

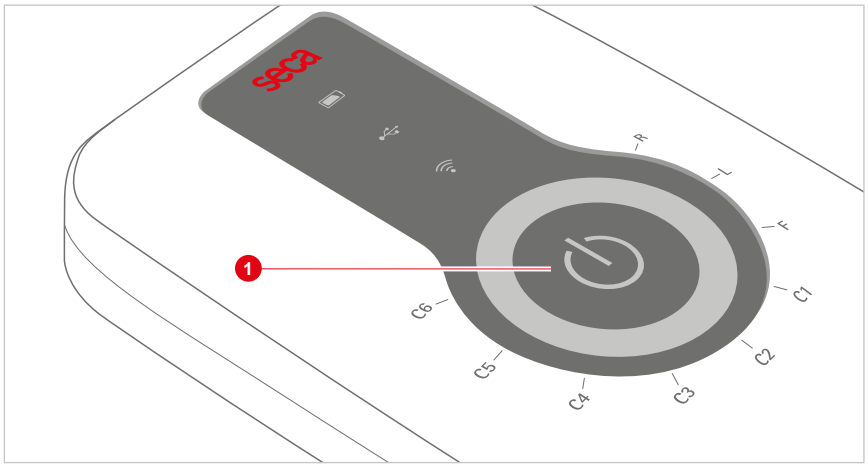
→ seca diagnostic medical PC software for ECG diagnostic assistance
→ Carrying case with belt
→ USB connection cable A-A, 3 m
→ Bluetooth 4.0 USB adapter
→ USB extension cable A-A, 1.8 m
→ ECG electrodes

2.6 Device operation

2.6.1 Display and control elements

On/off button

The device is switched on and off with the large button in the middle 1. To switch on, keep the button 1 pressed for at least one second. Only switch the device on shortly before recording. Switching off takes place automatically after 15 minutes of inactivity or manually by pressing the on/off button 1 for at least three seconds



1) Operating time rechargeable battery & Bluetooth operation, 4 kHz sampling rate: max. 10 h.

Status display

Information about the device status is displayed via LEDs ❶, ❷, ❸ when the device is switched on:

❶ charge status of rechargeable battery
→ green: good
→ yellow: medium
→ red: low

If seca ct331 (device with rechargeable battery) is being charged, the LED ❶ flashes and indicates the charging status with the corresponding colour. If the LED ❶ flashes red quickly: recharge battery[1)].

❷ USB connection between device and PC: if the connection is established, the LED lights up green. If not connected, the LED is off.

❸ Radio connection between device and PC: In radio mode, the LED lights up blue. The device can now be connected via Bluetooth or WLAN (depending on the version) or is already connected. During data transfer, the LED flashes. If not connected, the LED is off. For a change of connection, e.g. from Bluetooth to USB, the device must first be switched off and on again.

❹ LED ring: Quality control of the electrode attachment or display of the recording progress, *see 2.6.2 Sequences after switching on, p. 26*.

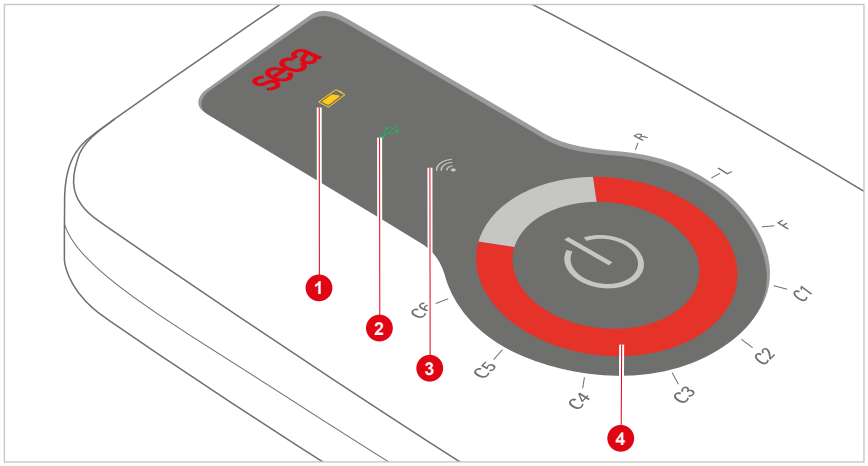


Fig. 2: seca ct330/331 Status display

2.6.2 Sequences after switching on

Immediately after switching on (keep the on/off button 1 pressed for at least 1 s), all LEDs light up. The device starts and can be used.

Electrode control

After switching on, the LED ring indicates the quality of the electrode application. If the electrodes are not applied to the patient, all LEDs light up red. If the electrodes are correctly attached to the patient, the corresponding LEDs light up green 2. This check also works without a connection to seca diagnostic.

Starting/stopping recording on the device

An ECG recording can be triggered not only via the software interface, but also by pressing the on/off button 1 on the device. For this, seca diagnostic must be configured accordingly, a patient must be selected and seca ct330/331 must be connected to seca diagnostic. The following recording types are possible:

- → Automatic ECG by pressing the on/off button 1: For automatic ECG, recording duration (at least 10 s) and procedures after recording are preset. After pressing the On/Off button 1, the recording starts. The LED ring lights up blue and shows the progress of the recording. When the recording time has elapsed, the entire LED ring lights up blue 3.
- → Manual ECG by pressing the On/Off button 1: In manual ECG, the recording is performed in any length. The recording must be started and stopped manually with the On/Off button. During the first 10 seconds, the blue LED ring behaves in the same way as for an automatic ECG recording. From then on, the LED ring lights up inverted and takes 10 s per further run. The recording can be stopped by pressing the on/off button.

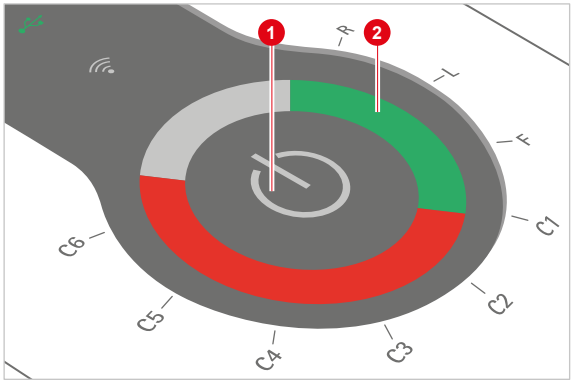


Fig. 3: Electrode control after switching on

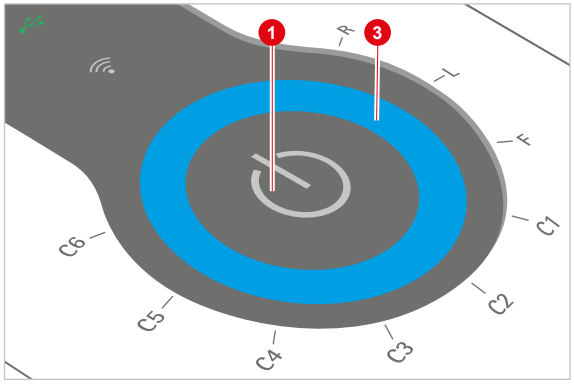


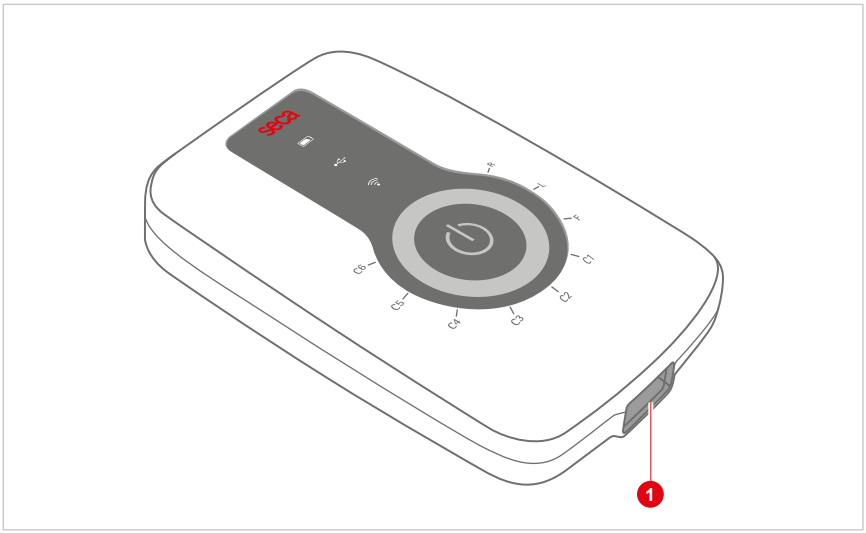
Fig. 4: Recording progress

2.6.3 Power supply

Recharge seca ct331 (version with rechargeable battery)

seca ct331 with integrated rechargeable battery is charged via the USB cable. The connection is located on the lower edge of the device housing 1.

If seca ct331 is connected to a switched-on PC via USB cable, the device is charged automatically. Charging via USB universal power supply is also possible. Connect the seca ct331 to the universal USB power supply and plug in the power adapter. The battery symbol indicates the charging status. In pure charging mode (without ECG recording), the maximum charging time is 3 hours.



2.7 Procedure of an examination

INFORMATION

Prerequisite for an examination: proper installation, configuration and commissioning of the system by your authorized seca dealer.

Resting ECG

- → Ensure that the ECG device is connected to the PC and that power is supplied to the device.
- → Check that your patient is lying comfortably and is not cold.
- → Shave, clean and dry the electrode contact points thoroughly.
- → Apply the electrodes to the patient according to the application diagram, *see 2.8.1 Positions of the electrodes, p. 29*.
- → Connect the patient leads to the electrodes.
- → Start seca diagnostic and click on Examination, Resting ECG, New Resting ECG, *see 3.3 Perform resting ECG recording, p. 41*.
- → Start the recording.
- → The patient should remain calm during the recording.

Stress ECG

- → Ensure that the ECG device is connected to the PC and that power is supplied to the device.
- → When using an ergometer, make sure that the patient is in the optimal sitting position (the outstretched leg slightly bent).
- → When using a treadmill, be sure to follow the instructions for stress ECG with treadmill, *see 2.8.2 Notes on stress with treadmill, p. 30*.
- → Shave, clean and dry the electrode contact points thoroughly.
- → Apply the electrodes to the patient according to the application diagram, *see 2.8.1 Positions of the electrodes, p. 29*.
- → Connect the patient leads to the electrodes.
- → Wait a few minutes so that the contact between the skin and the electrodes can develop optimally.
- → Apply the blood pressure cuff.
- → Start seca diagnostic and click on Examination, Stress ECG, New Stress ECG, *see 3.5 Perform stress ECG recording, p. 48*.
- → Start the recording.

CAUTION

Allergic reactions on the skin due to substances in adhesive electrodes (acrylate adhesive, Ag/AgCl).

- → Clarify further procedure with the physician before recording.

2.8 Attaching the recorder to the patient

2.8.1 Positions of the electrodes

Thoracic wall resting and stress ECG, standard according to Wilson		
V1 (C1)	red	4th intercostal space at the right sternal border
V2 (C2)	yellow	4th intercostal space at the left sternal border
V3 (C3)	green	On the left on the 5th rib between C2 and C4
V4 (C4)	brown	5th intercostal space on the left midclavicular line
V5 (C5)	black	On the left on the anterior axillary line, on the level of C4
V6 (C6)	purple	On the left on the midaxillary, on the level of C4
Resting ECG extremities		
R	red	Right arm
L	yellow	Left arm
F	green	Left leg
N	black	Right leg
Stress ECG (lying or sitting position): extremities		
R	red	On the right below the collarbone
L	yellow	On the left below the collarbone
F	green	On the left above the hip
N	black	On the right above the hip
Stress ECG (sitting position): extremities		
R	red	Attach to the deltoid muscle on the right
L	yellow	Attach to the deltoid muscle on the left
F	green	9th rib left
N	black	9th rib right

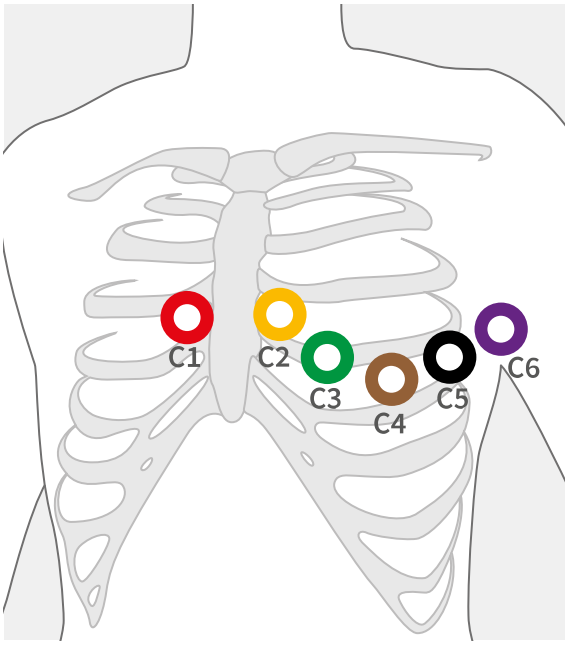


Fig. 5: C1 to C6

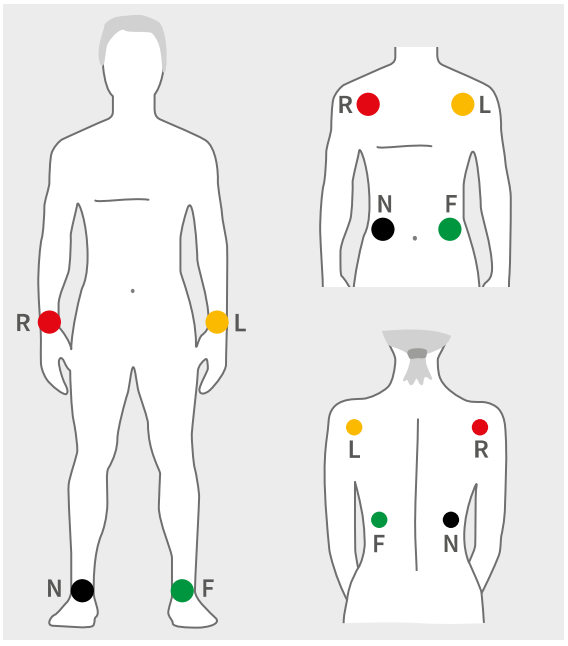


Fig. 6: R, L, F, N

2.8.2 Notes on stress with treadmill

- → The patient should ideally be wearing running shoes or trainers.
- → The patient should not hold on to the handles of the treadmill during recording. This causes muscle tension which affects the ECG signal.
- → Missing skin tension, in interaction with shoulder movement, will increase artefacts in the ECG signal.
- → The extremity leads should if possible be applied on taut skin areas in order to avoid excessive movement artefacts and therefore interference in the other terminal lines.
- → The electrode cables should not touch the patient, the treadmill or other objects during ECG recording.
- → Fix any overlong trailing leads to the carrying case. No tension must be exerted on the electrodes. Make sure that no lead passes over the contact of an electrode.
- → Tip: To fix electrodes and cables to the patient's body and therefore reduce interference in the ECG signal, the patient should wear a stretchable ECG mesh shirt.

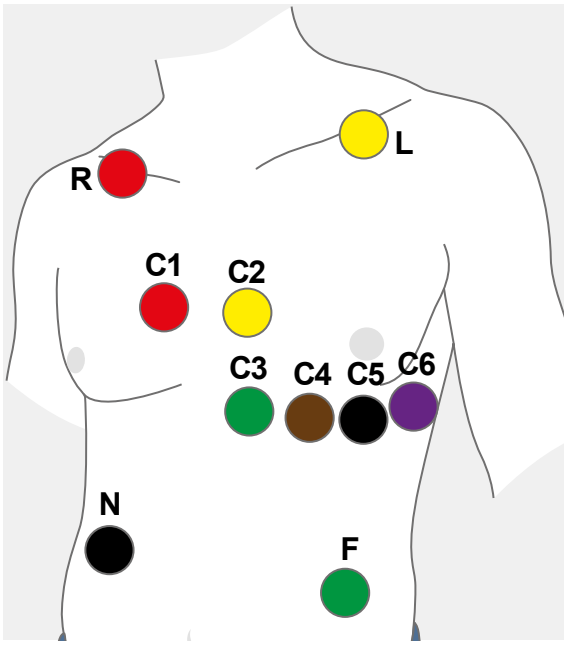


Fig. 7: Normal electrode application

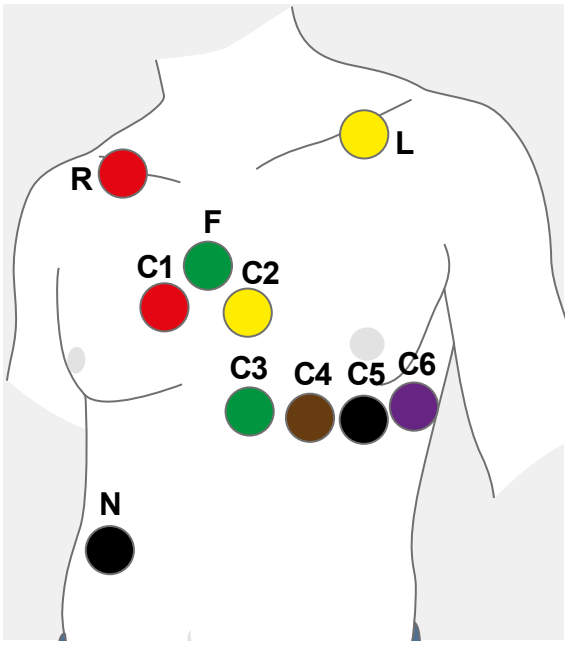


Fig. 8: Artefact reduced electrode application

***TIP:** Artefact reduced electrode application results in smaller amplitudes in the extremity derivations.*

2.8.3 Safe use of treadmills

WARNING

Risk of injury due to changes in acceleration, speed or incline of the treadmill.

Unexpected, abrupt stopping or starting of the treadmill can cause injury to the patient. Bruises, strains or fractures from tripping and falling.

→ Inform patient before making any change in acceleration, speed or incline.

→ Do not make changes until the patient has adjusted.

IMPORTANT:

Always set the treadmill so that the patient can safely move on the device. Ensure that the acceleration, speed and inclination of the treadmill are adjusted to the patient's physical constitution, stamina and skill. Observe the manufacturer's safety instructions.

3 Software

3.1 seca diagnostic program structure

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

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

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

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

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

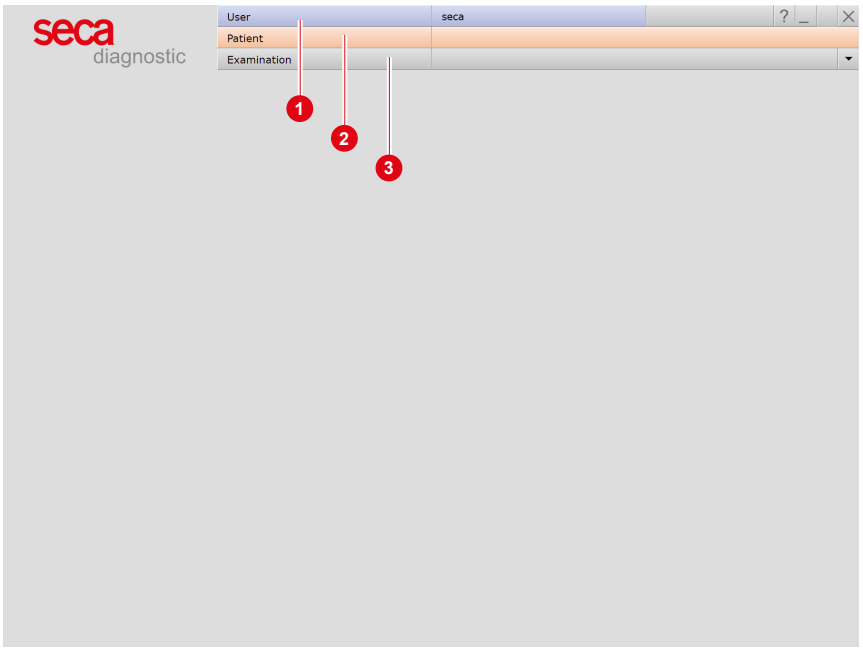


Fig. 9: seca diagnostic main menu

3.2 seca ct330/331 connection to the PC

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

3.2.1 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 and stress ECG

→ Start seca diagnostic.
→ Open the screen Examination, Resting ECG or Stress 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 (e.g., SN: EAS 0001).
→ Only for Resting ECG: 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.
→ For stress ECG: section for configuring the training device.

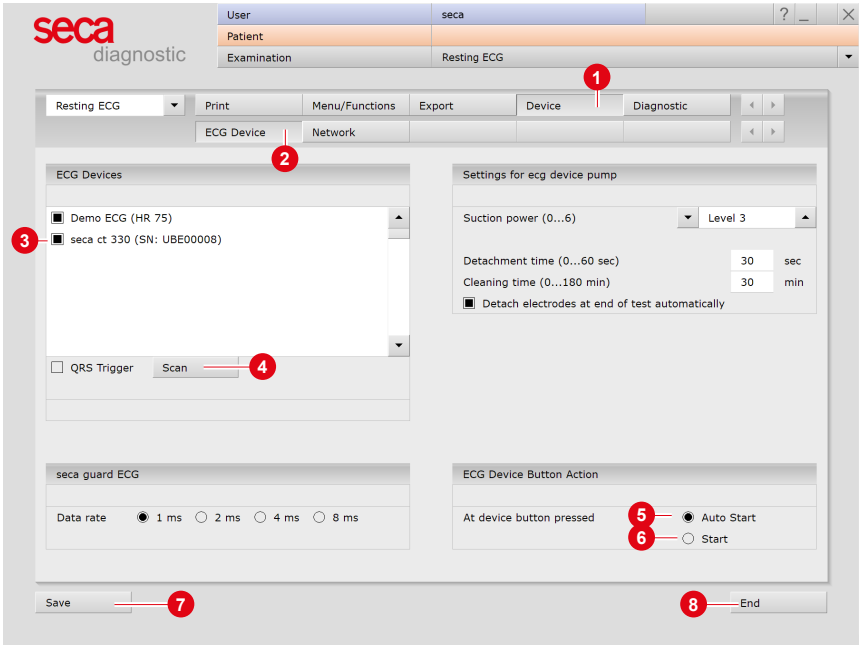


Fig. 10: Configuring the ECG device (USB) for resting ECG

3.2.2 Connecting and configuring seca ct331 (Bluetooth)

To use the USB port, perform the steps for configuring the USB port, *see 3.2.1 Setting up seca ct330 (USB), p. 33*.

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 and stress ECG

→ Start seca diagnostic.
→ Open the screen Examination, Resting ECG or Stress ECG, Settings, Device 1, ECG Device 2.
→ The ECG device is shown in the “ECG devices” section: seca ct331 3.
→ If it is not displayed, click Scan 4 (search process).
→ Select the device: seca ct331 3.
→ A device can be identified by the serial number on the identification plate and in the software interface (e.g., SN: EAS 0001).
→ Only for Resting ECG: 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.
→ For stress ECG: section for configuring the training device.

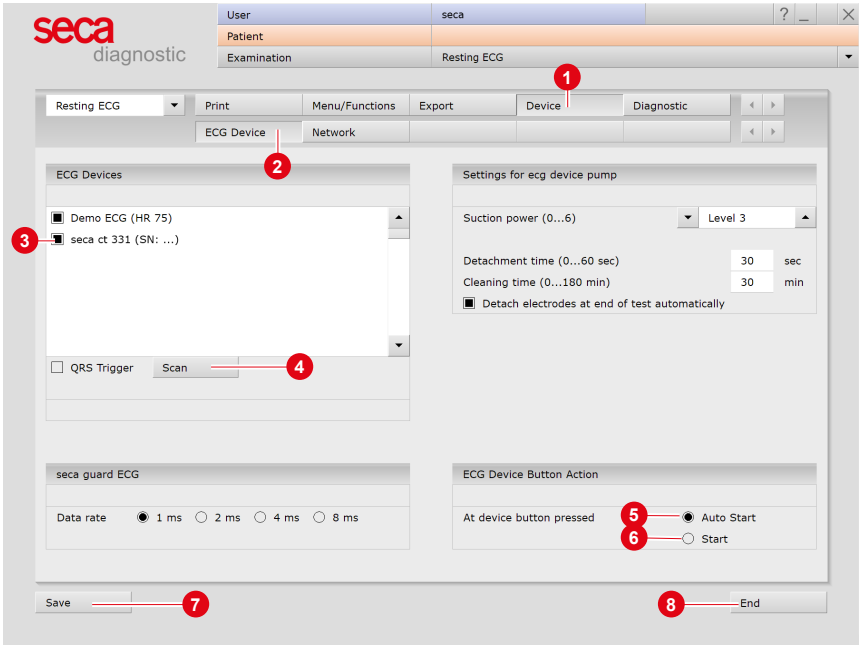


Fig. 11: Configuring the ECG device (BT) for resting ECG

3.2.3 Connecting training devices for stress ECG

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.

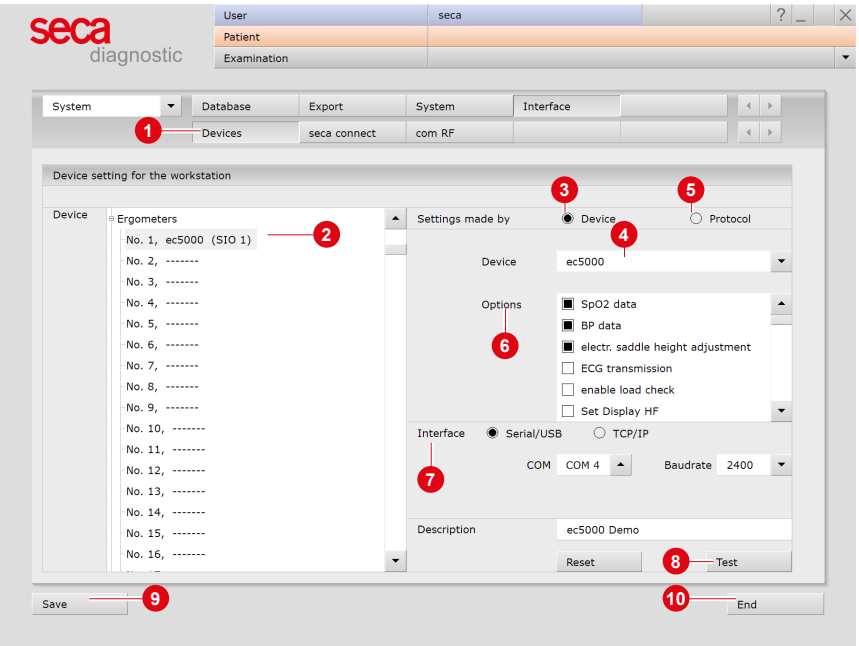


Fig. 12: Connecting training devices with seca diagnostic

3.2.4 Configuring a training device for stress ECG

→ 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.

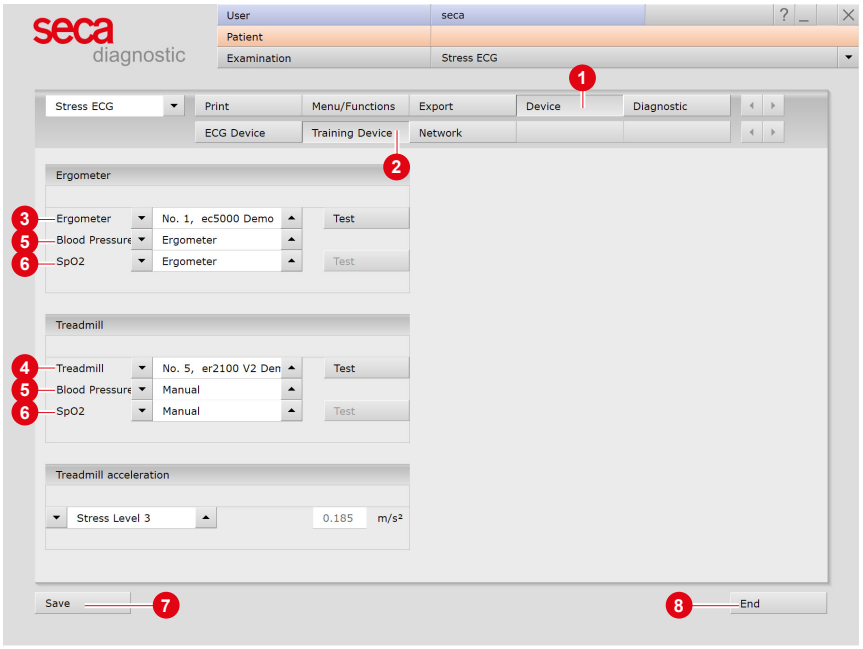


Fig. 13: Configure training devices

3.2.5 Extended ECG settings

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.

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 and stress ECG:

Under Examination, Resting ECG or Stress 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.

Print settings for stress ECG:

On the Examination, Stress ECG, Settings, Print, Printed pages screen, you can specify the contents for different printouts. Select the desired entry in the “Type of printout” list and compose the contents of the printout. Important: This setting is only required if the automatic ECG print pages contains content other 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 screen Examination, Stress ECG, Settings, Diagnostic, Calculation. 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.

3.3 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.

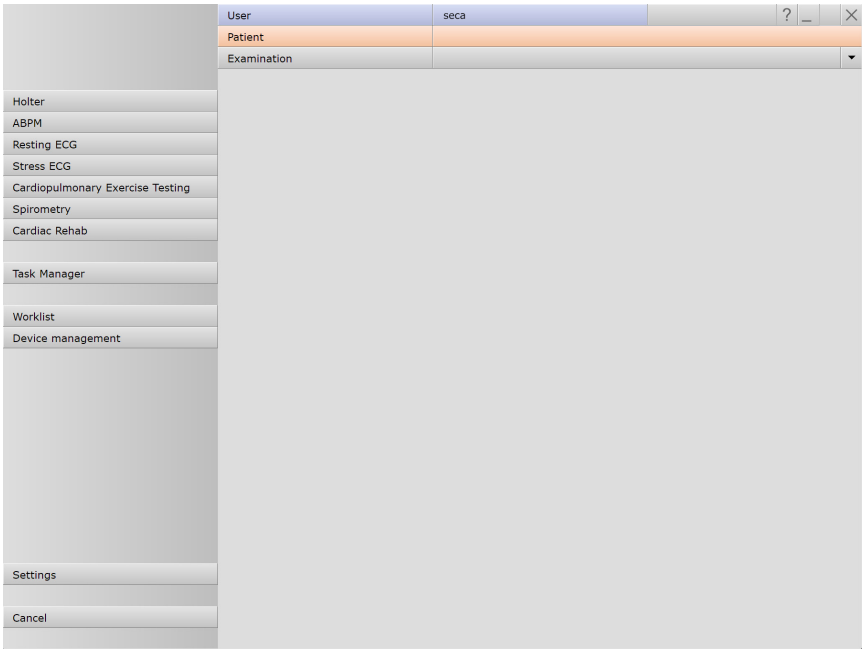


Fig. 14: seca diagnostic examination main menu

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.

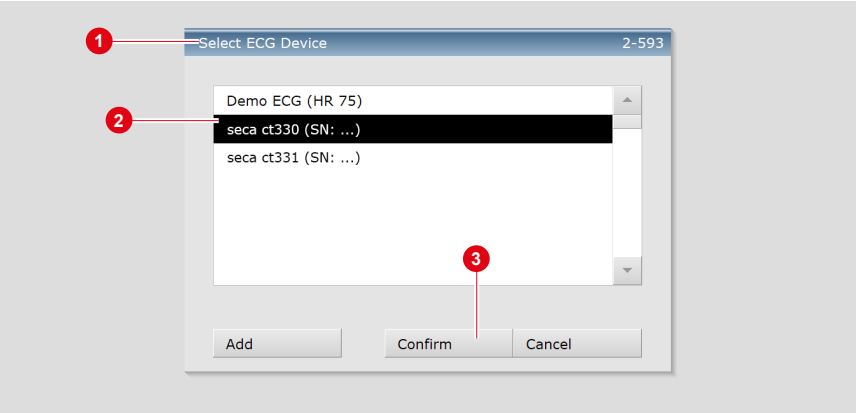


Fig. 15: Select ECG device

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).

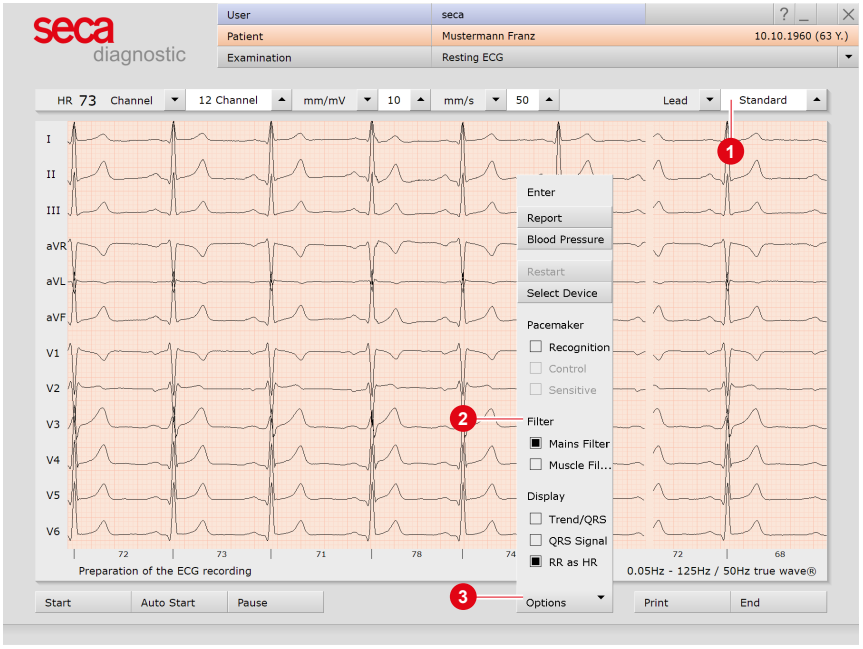


Fig. 16: Monitoring and electrode control, resting ECG

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.

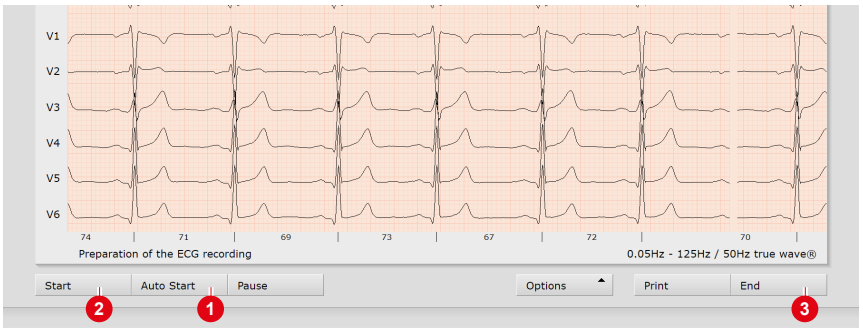


Fig. 17: Start resting ECG recording

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.

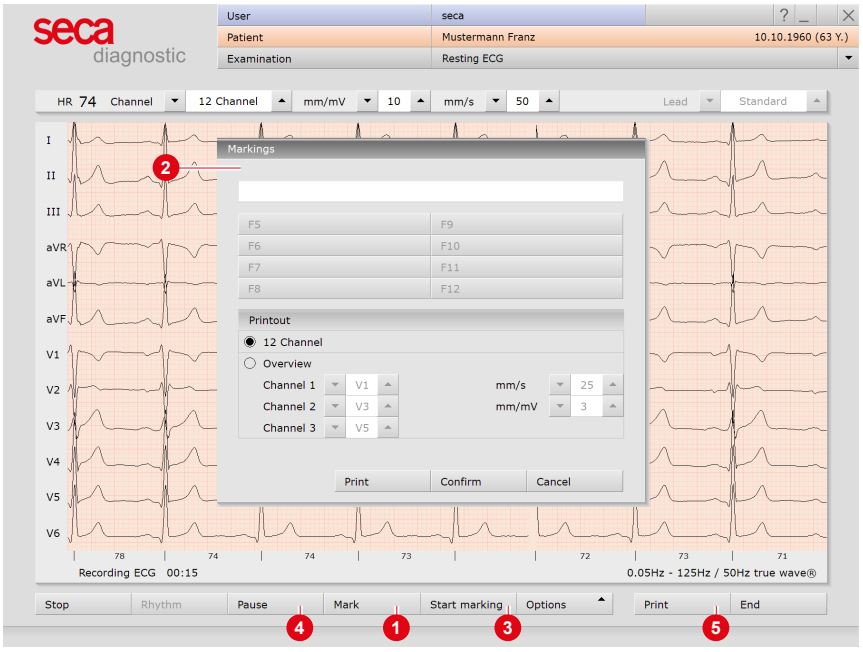


Fig. 18: Resting ECG recording, editing functions

TIP: *Text modules for specifying marked parts*

Application: If a marking is made during recording, the "Markings" dialogue box appears. The marked parts will be automatically specified by pressing the corresponding key (e.g., F5) or a previously configured text module button.

Configuring text modules: Under Examination, Resting ECG, Settings, Menu/Functions, Markings the text modules can be configured for specifying marked parts.

Enter a name for the text module in the "Description" field. This name later appears on the button for calling the text module. In the "Text module" field, enter the text which will later be used to specify the marked parts. Save your input.

3.4 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.

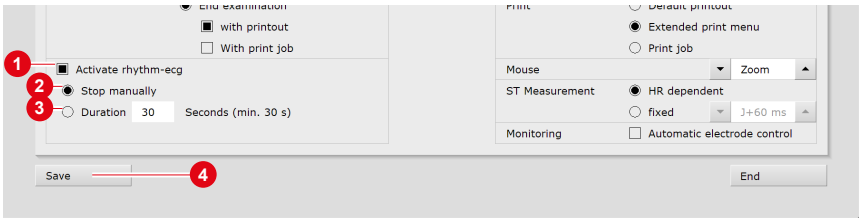


Fig. 19: Rhythm strip settings

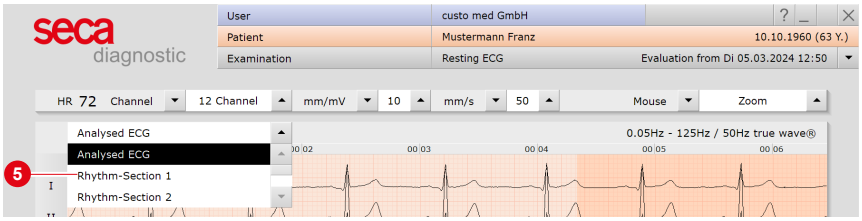


Fig. 20: Resting ECG evaluation with rhythm strips

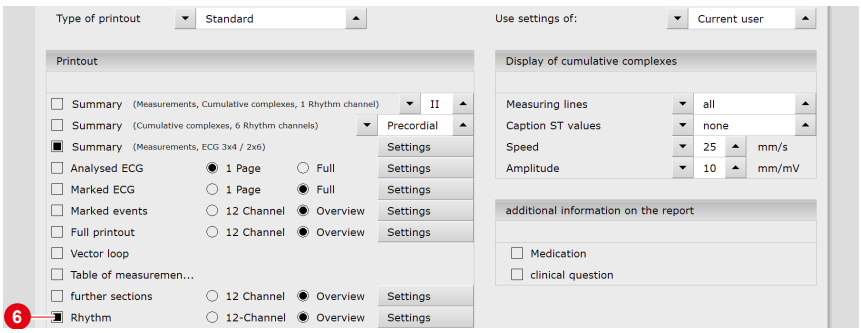


Fig. 21: Rhythm strip printout

3.5 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.

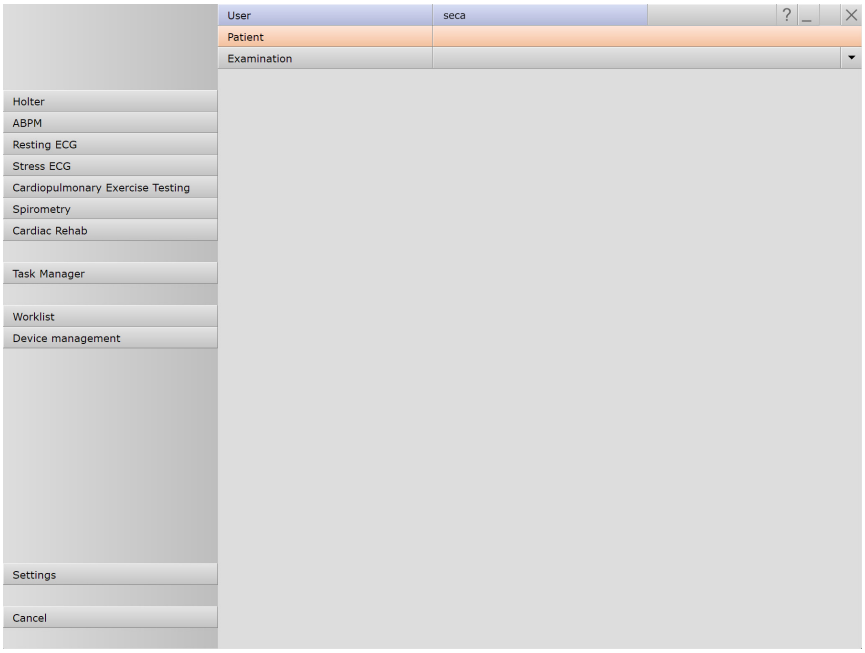


Fig. 22: seca diagnostic examination main menu

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.

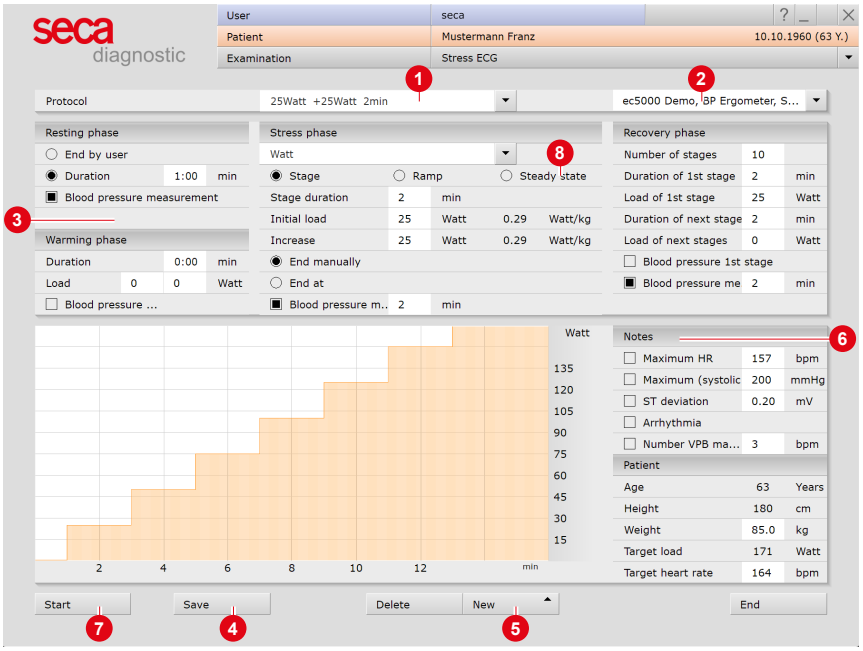


Fig. 23: Profile selection stress ECG

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.

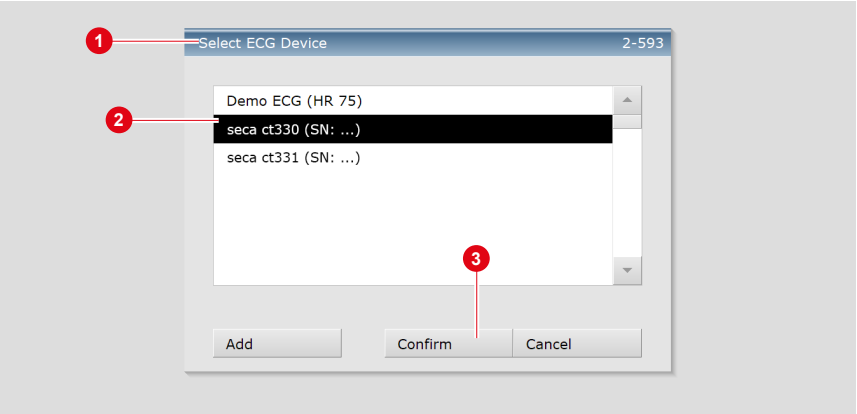


Fig. 24: Select ECG device

Monitoring and electrode control

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

→ Change the type of lead 1 if necessary.
→ If there are red lines on the screen, the contact between the skin and electrode(s) is insufficient. The corresponding electrodes will need to be reattached.
→ Set the required Filters 2 (Options menu 3).

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 stress test ECG with treadmill:

→ Under Options ❸ activate: Mains filter ❹ and Ergo filter ❺. The Ergo filter ❺ is only required if strong movement artifacts are to be expected, e.g., when using a treadmill.
→ ECG display Precordial ❻, 5 mm/mV ❼ and 25 mm/s.
→ Click Start ❽ or Enter to start recording.

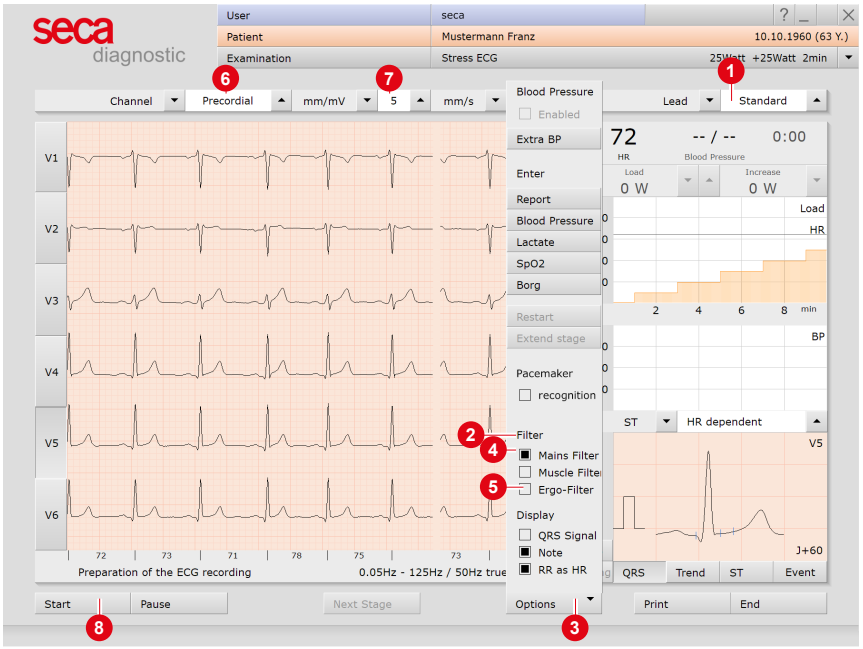


Fig. 25: Monitoring and electrode control stress ECG

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

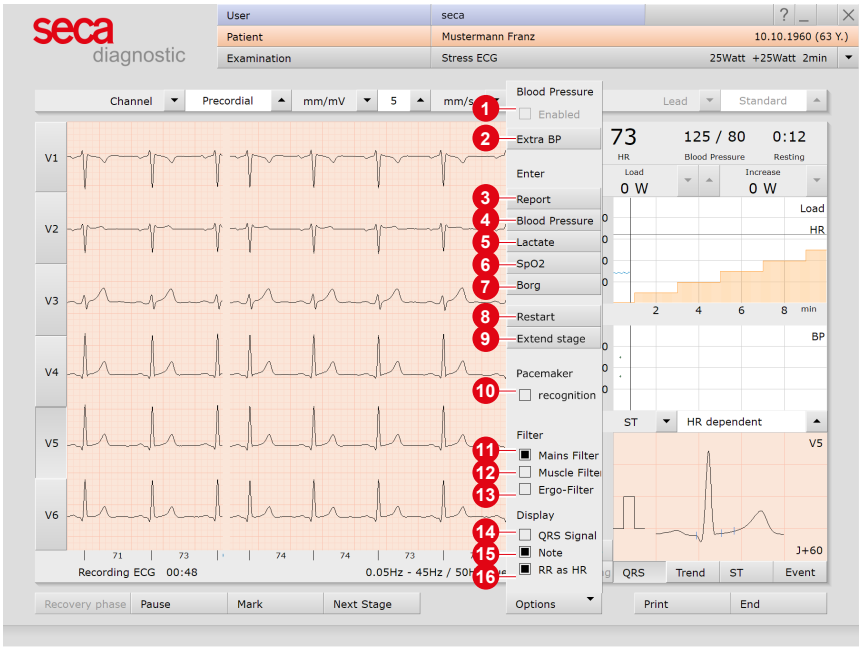


Fig. 26: Options stress ECG, during recording

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.

Tip: Keyboard shortcuts

Change load or speed

Change increase

Change amplitude

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

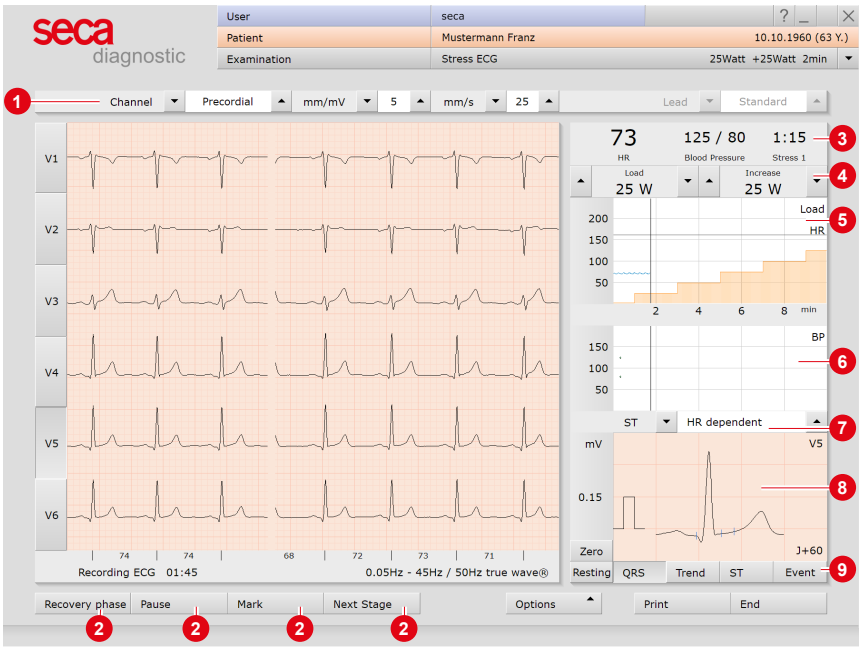


Fig. 27: Stress ECG recording

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).

TIPP: *Text modules for entering the reason for end*

Application: The text modules are called using the keyboard (F5 to F12) in the “Reason for termination” dialogue or by clicking on the corresponding button.

Configuring text modules: Select Examination, Stress ECG, Settings, Diagnostic, Reason for End to configure text modules for entering a reason for end. Enter a name for the text module in the “Description” field. This name will appear on the button for calling the text module in the “Reason for termination” dialogue. In the “Text module” field, enter the text which will later be displayed as the reason for end. Save your input.

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.

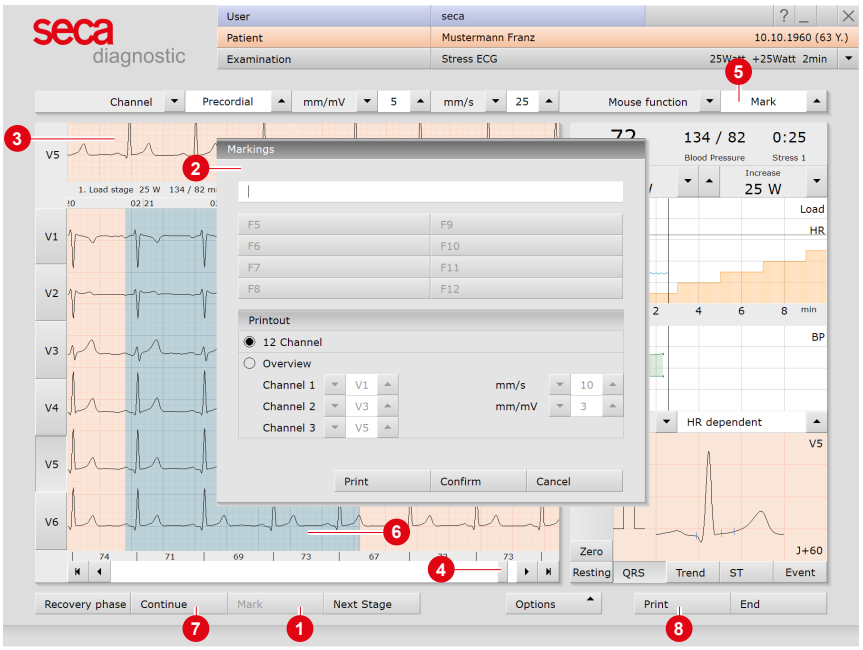


Fig. 28: Stress ECG recording, editing options

TIP: *Text modules for specifying marked parts*

Application: If a marking is made during recording, the "Markings" dialogue box appears. The marked parts will be automatically specified by pressing the corresponding key (e.g., F5) or a previously configured text module button.

Configuring text modules: Under Examination, Stress ECG, Settings, Menu/Functions, Markings the text modules can be configured for specifying marked parts.

Enter a name for the text module in the "Description" field. This name later appears on the button for calling the text module. In the "Text module" field, enter the text which will later be used to specify the marked parts. Save your input.

3.6 Opening evaluations

3.6.1 Opening an evaluation via the evaluation search

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

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

Configuring the list of search results

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

Renaming filter sets, deleting filter sets

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

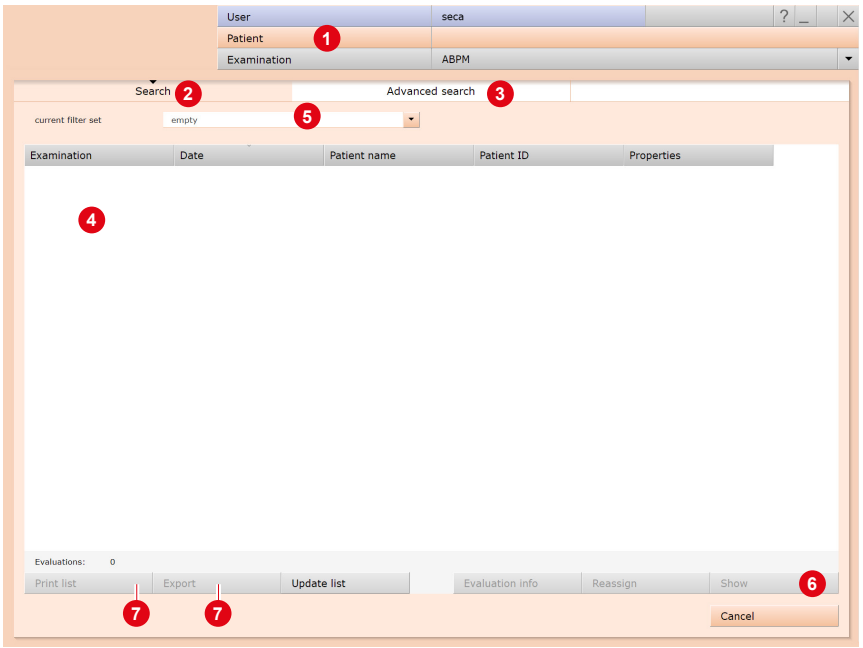


Fig. 29: Evaluation search, search with filter sets

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.

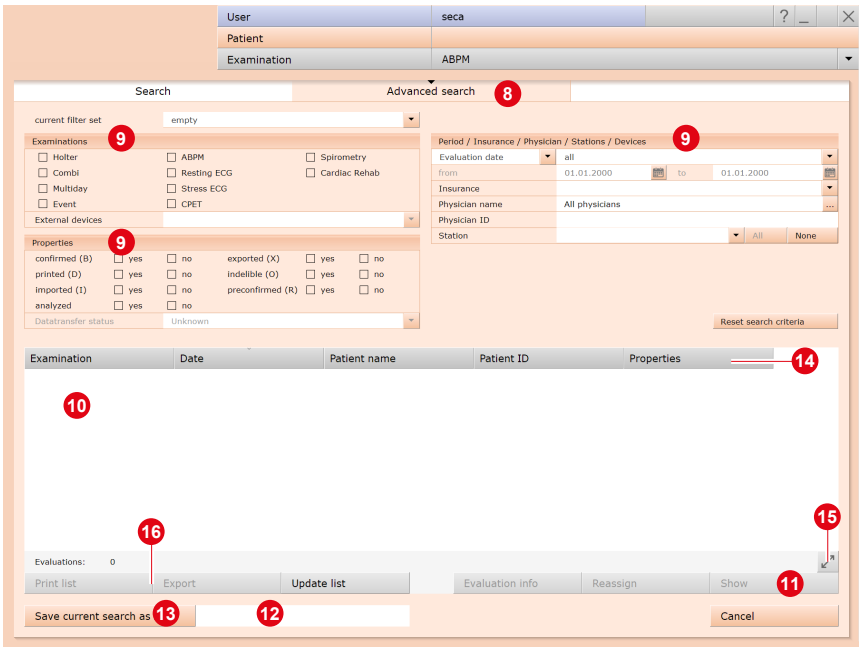


Fig. 30: Evaluation search, extended search

3.6.2 Opening an evaluation via the evaluation menu

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

→ Open the examination main menu via Examination, Resting ECG or Stress ECG.
→ Click on Show evaluation 1.
→ The patient search screen appears. Select the patient whose evaluation you want to open. Enter the name of the patient in the input fields of the search mask 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 evaluations of the patient is displayed. Select the desired evaluation from the list and open it by double-clicking or using the Show evaluation button.

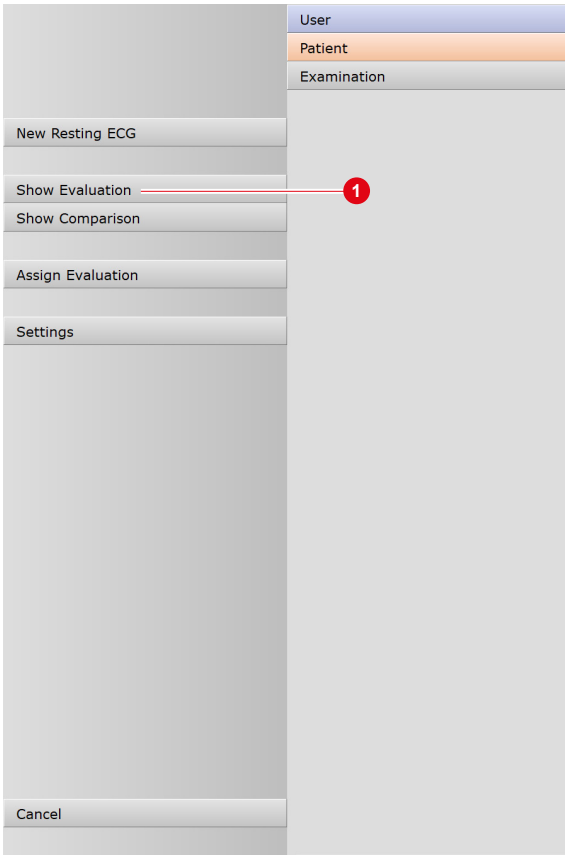


Fig. 31: Resting ECG main menu

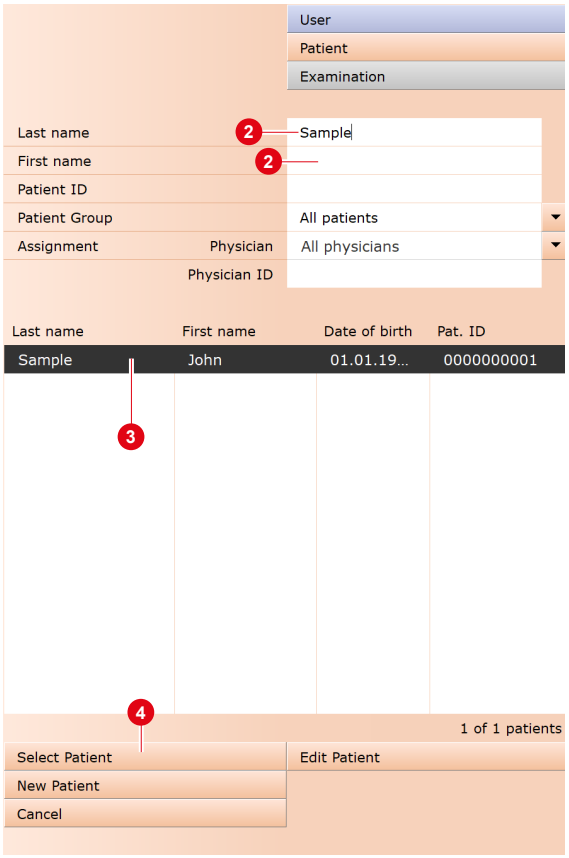


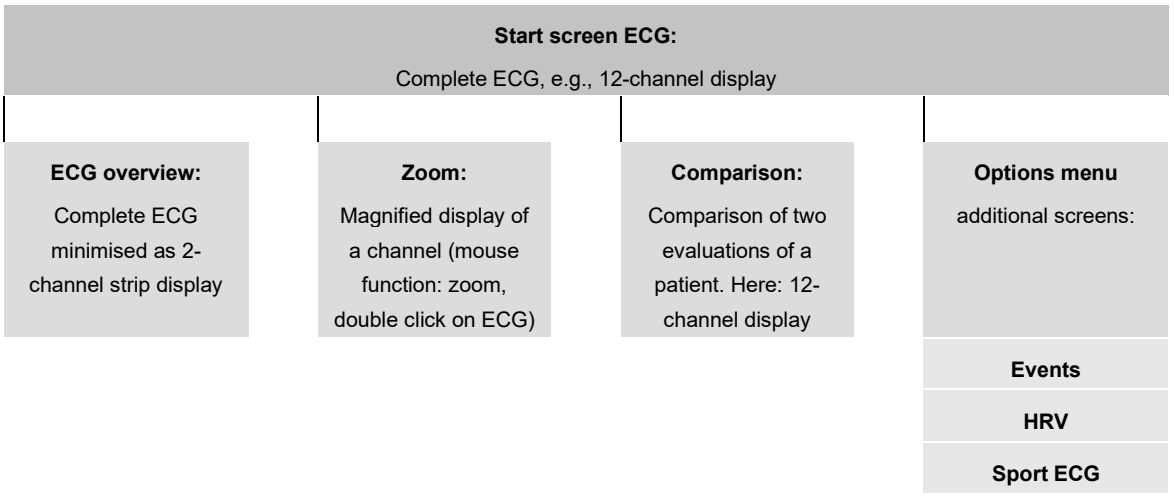
Fig. 32: Select patient

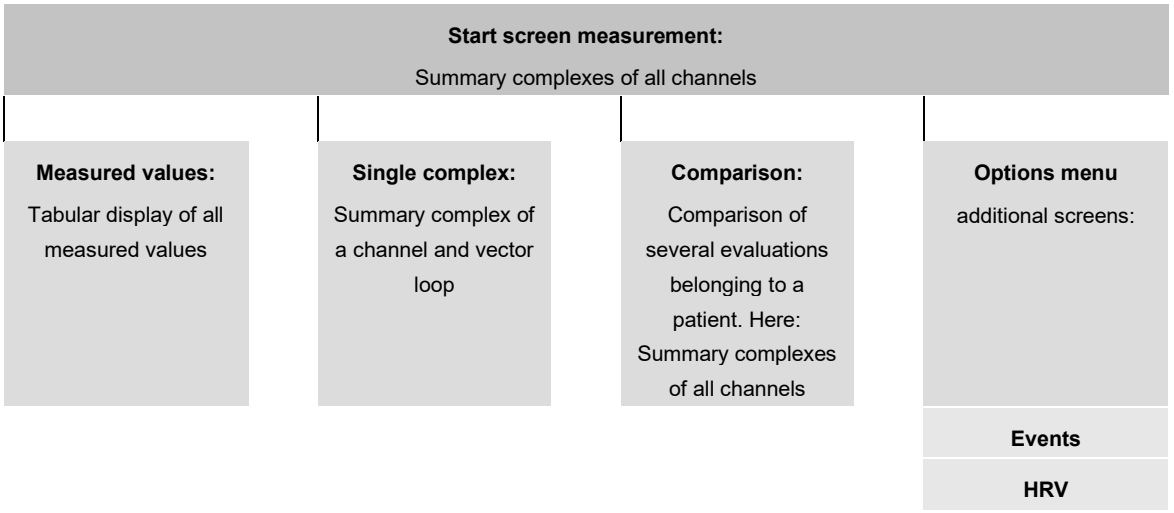
3.7 Resting ECG evaluation

3.7.1 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.





3.7.2 Navigation in the evaluation

At the bottom of the screen there are buttons for opening other evaluation screens. The labelling of the buttons changes as soon as you switch to another evaluation screen. The clicked button always contains the name of the screen from which you came.

Example: You click on the Measurement button ❶ in the evaluation (View: ECG start screen). You arrive at the evaluation screen Measurement and the previously clicked button Measurement ❶ changes to ECG ❷. Clicking on ECG ❷ takes you back to the ECG view.

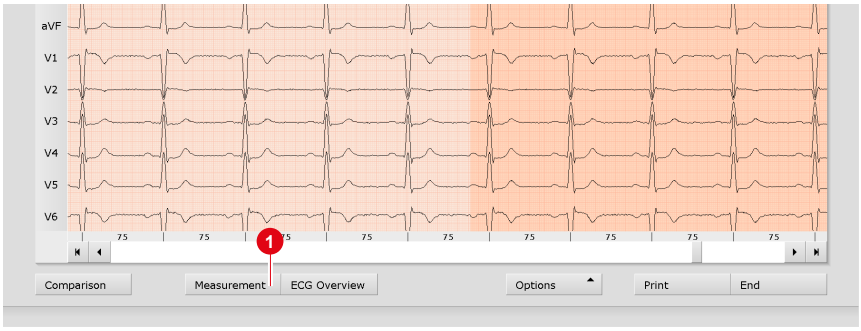


Fig. 33: Evaluation Resting ECG, ECG screen

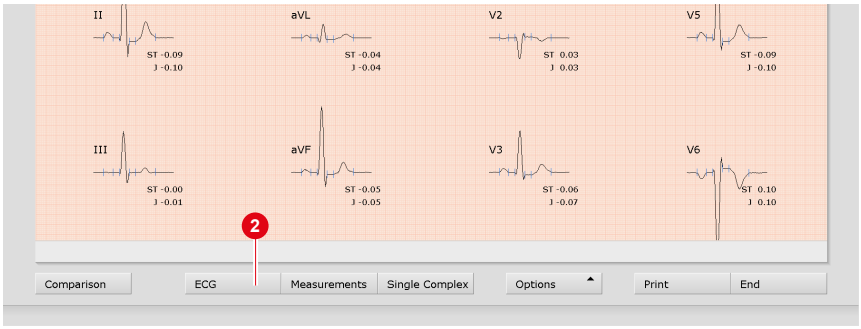


Fig. 34: Evaluation Resting ECG, Measurement screen

3.7.3 Resting ECG evaluation screens

Tip: Keyboard shortcuts

Blood pressure input

F9

Deletes a marking if it was previously selected by mouse click

Delete

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

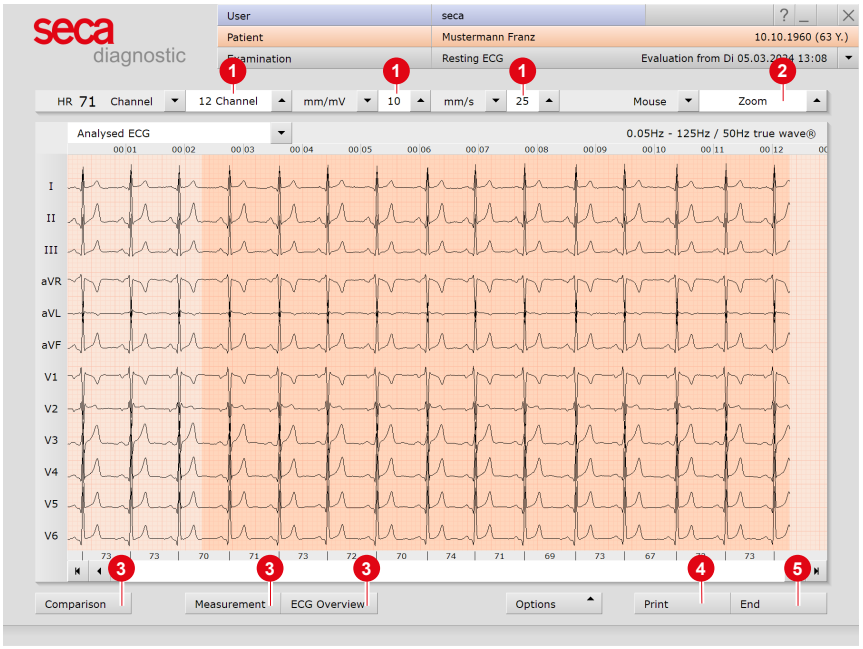


Fig. 35: Evaluation Resting ECG, ECG start screen

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

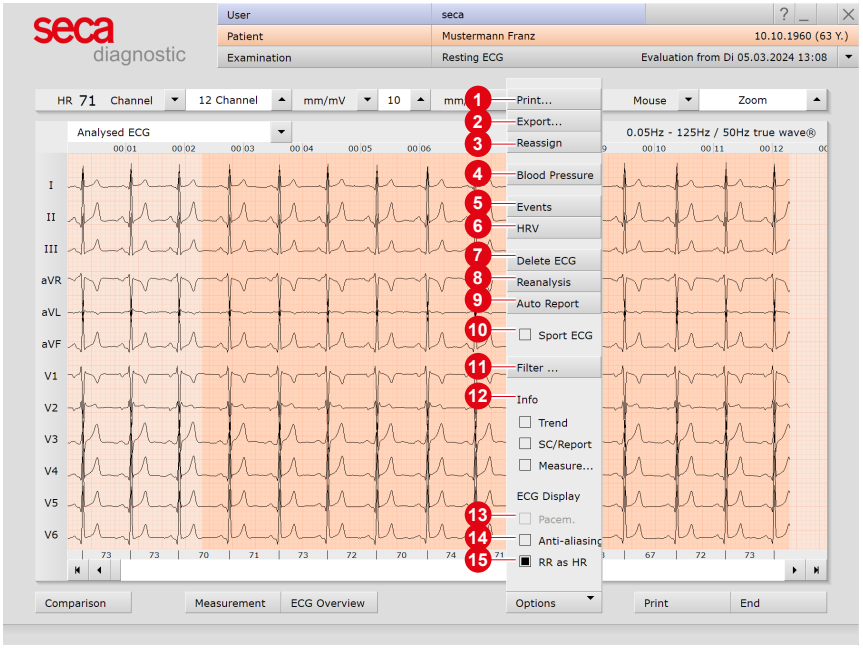


Fig. 36: Resting ECG evaluation, Options menu

3.7.4 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.

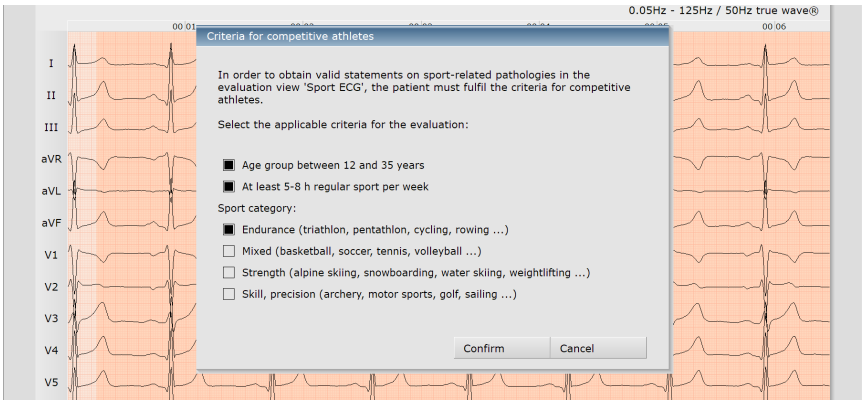


Fig. 37: “Criteria for competitive athletes” dialogue box

Display and control elements in the Sport ECG

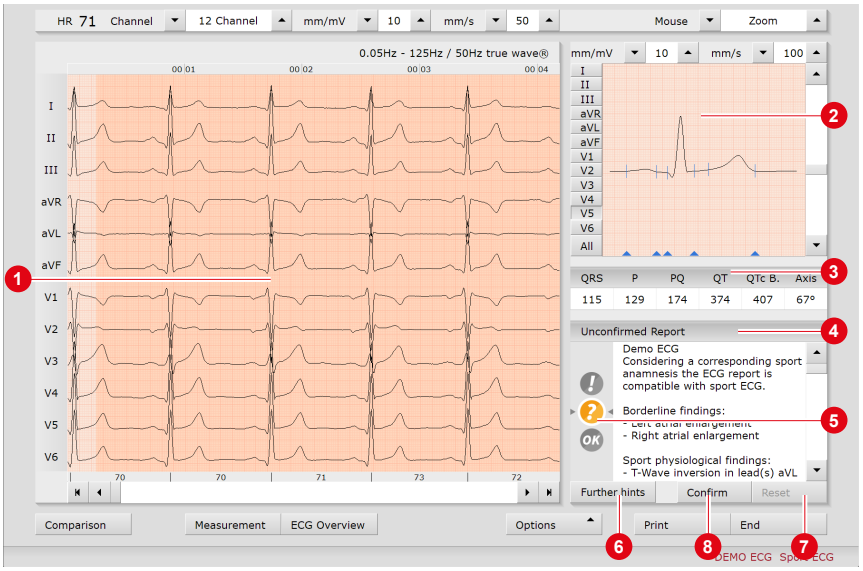


Fig. 38: Sport ECG evaluation view

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

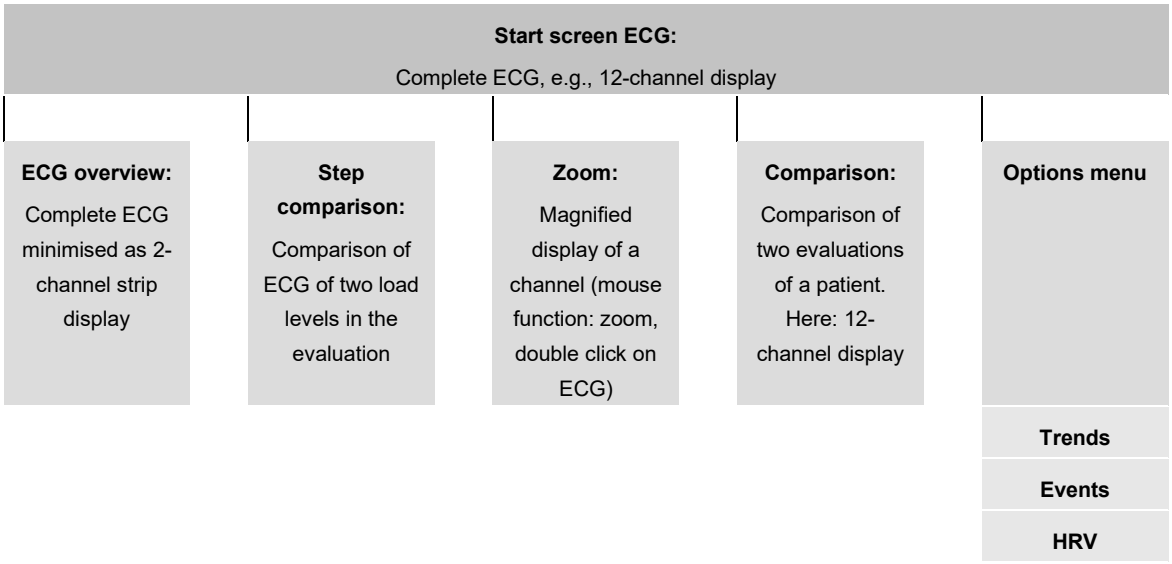
→ Click on Options.
→ Deactivate the Sport ECG option.

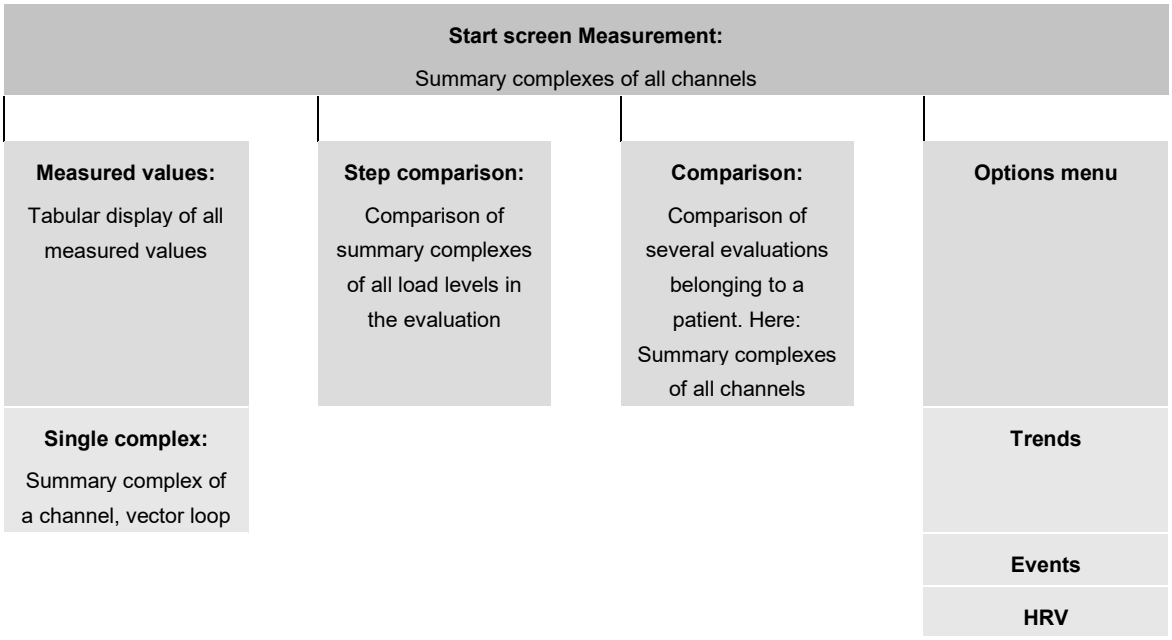
3.8 Stress ECG evaluation

3.8.1 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.





3.8.2 Navigation in the evaluation

At the bottom of the screen there are buttons for opening other evaluation screens. The labelling of the buttons changes as soon as you switch to another evaluation screen. The clicked button always contains the name of the screen from which you came.

Example: You click on the Measurement button ❶ in the evaluation (View: ECG start screen). You arrive at the evaluation screen Measurement and the previously clicked button Measurement ❶ changes to ECG ❷. Clicking on ECG ❷ takes you back to the ECG view.

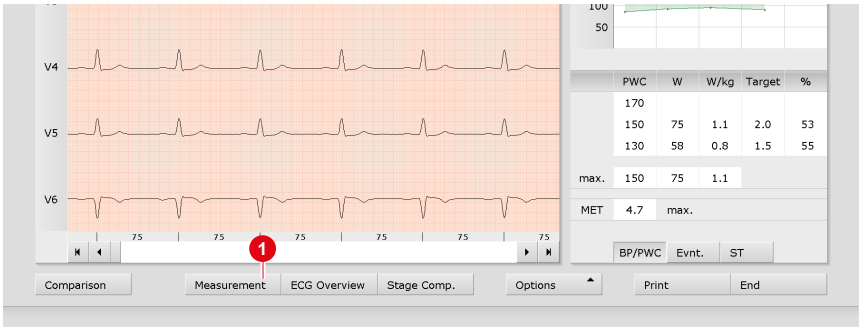


Fig. 39: Evaluation Stress ECG, ECG screen

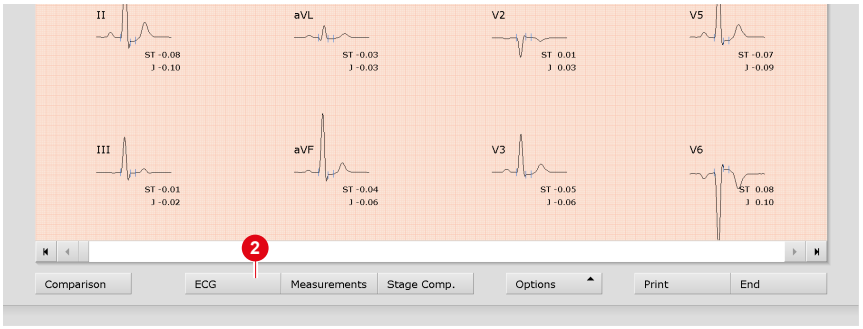


Fig. 40: Evaluation Stress ECG, Measurement screen

3.8.3 Screens of the stress ECG 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. 41: 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. 42: Evaluation of stress ECG, Options menu

3.9 Confirming the evaluation

Unconfirmed report and report

The unconfirmed report is opened by right-clicking on the evaluation interface. Select Report in the context menu. Enter your details in the text field 1. If the Unconfirmed report or interpretation option is selected in the system settings, an unconfirmed automatic system report is already present in the text field. If necessary, older reports can be displayed via the report history (drop-down list above the text input field). Confirm 2 saves your input and the unconfirmed report becomes a (preliminary) report, depending on the current user's report rights. If your (unconfirmed) report is not yet complete and is to be saved without obtaining the status “Evaluation (pre-)confirmed”, reset the report status when ending (End) the evaluation.

Text modules – an aid for writing reports

On the Examination, Resting & Stress ECG, Settings, Diagnostic, Reports screen page, text modules can be created 3. Four groups 4 with up to eight text modules 5 can be created. The text modules are called up in the unconfirmed report via the keyboard (F5 to F12) 6.

A text module can be composed of text and variables. Instead of a variable, the actual value from the evaluation is inserted into the report text when using a text module. The structure of a variable is {VARIABLE}. With Shortcuts for export values 7 you receive a list with all variables. If the text modules are to be displayed in the unconfirmed report dialogue, make sure that the Enabled 8 option is activated. Otherwise, the text modules can be displayed in the unconfirmed report dialogue via Options 9, Texts on. It is also possible to write a text that is displayed in each unconfirmed report 10. The text can be changed in the unconfirmed report. Save your entries.

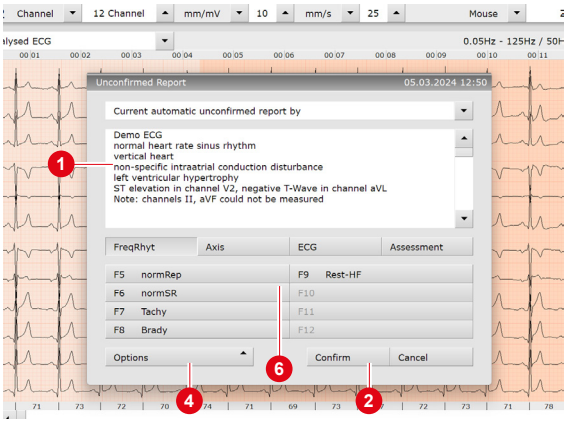


Fig. 43: Unconfirmed report

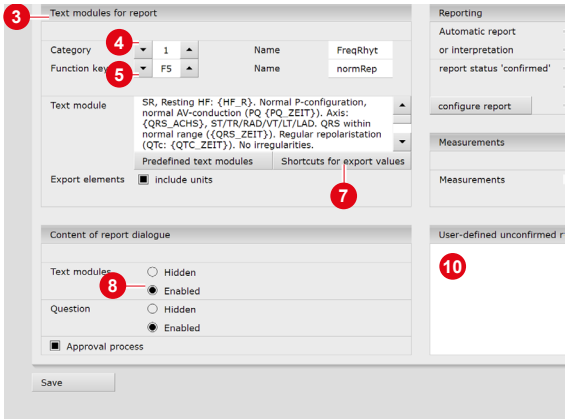


Fig. 44: Text modules

For Stress ECG: Unconfirmed report with Duke Treadmill Score

In order to display the Duke Treadmill Score, some settings are required in seca diagnostic, *see 3.2.5 Extended ECG settings, p. 39*. Information on calculating the Duke Treadmill Score can be found in the appendix, *see 5.1 Values and formulas in the ECG evaluation, p. 80*.

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.

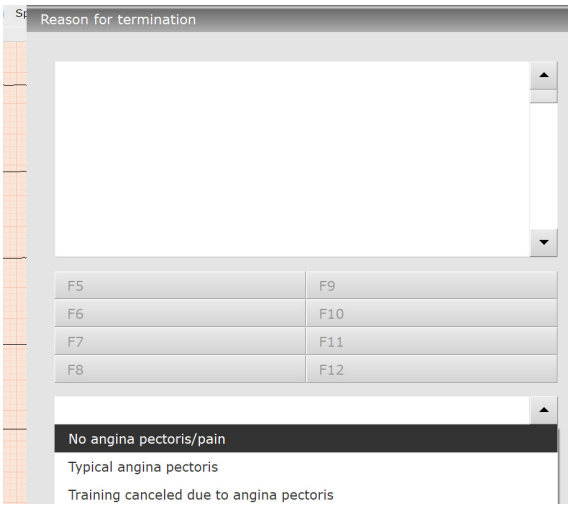


Fig. 45: Specifying the TAI in the “Reason for termination” dialogue

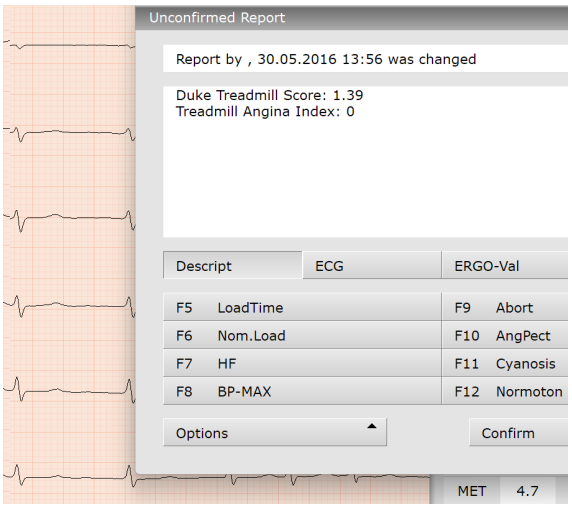


Fig. 46: Unconfirmed report text with the Duke Treadmill Score

3.10 Optional: Reporting with approval process

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

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

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

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

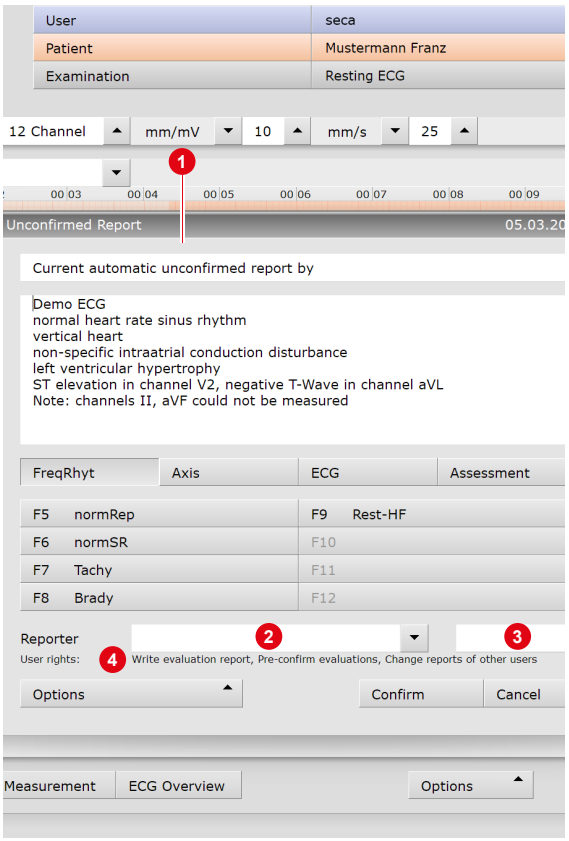


Fig. 47: Unconfirmed report dialogue with approval process

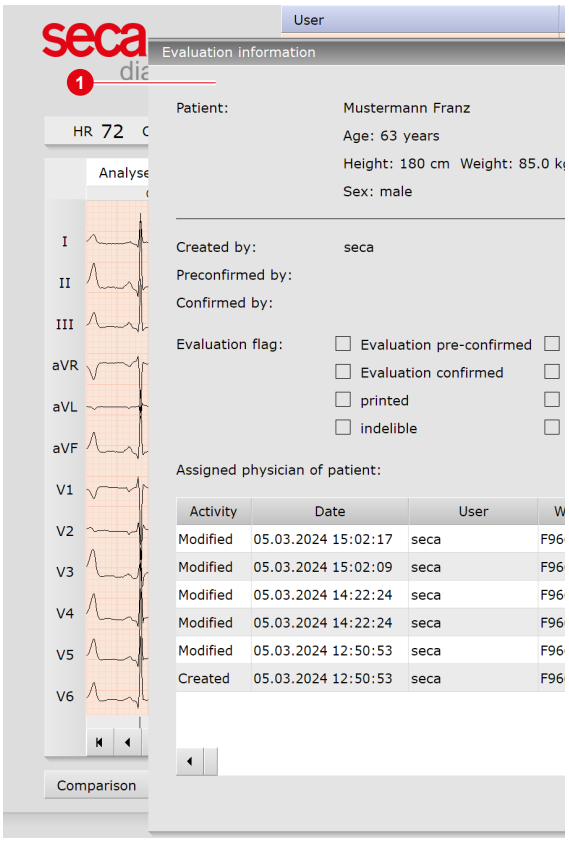


Fig. 48: Evaluation information

3.11 Ending the evaluation

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

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

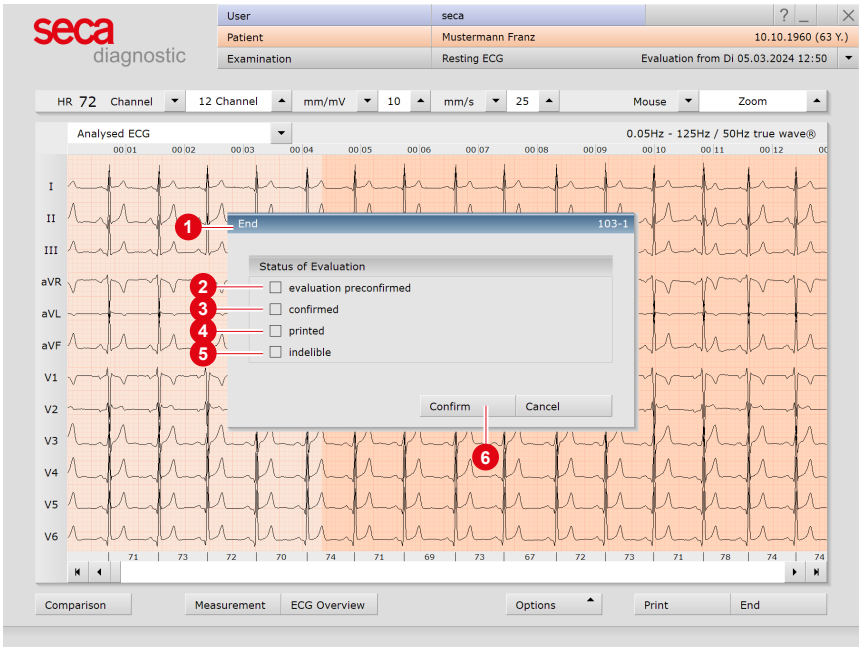


Fig. 49: End dialogue

4 Hygiene

4.1 Important notes

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

Under no circumstances should the device be immersed into liquid or cleaned too wet. Cleaning agents and disinfectants must not be sprayed directly onto or into the device. No moisture may get inside the device (e.g., via interface contacts).

Contacts must not be soiled or damaged.

Clean and disinfect the device after each patient. Make sure that the exterior of the device is always aesthetic and clean.

The device must not be connected to a power source during cleaning and disinfection.

4.2 Hygienic reprocessing

seca ct330/331

→ Reprocessing type: wipe disinfection

Patient cable 10-lead with banana plug

→ Reprocessing type: wipe disinfection

Carrying case and belt

→ Reprocessing type: disinfectant washing in the washing net

4.3 Recommended cleaning agents and disinfectants

Wipe disinfection:

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

Washing with a disinfectant:

- → Eltra 40® Extra (ECOLAB)
- → Observe the manufacturer's instructions!

INFORMATION:

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

	Machine wash at 40°C in a washing net (do not spin)
	Do not treat with harsh chemicals or bleach
	Do not iron
	Do not tumble dry

4.4 Contaminated consumables

Contaminated consumables such as adhesive electrodes (single-use items) are considered as waste with special requirements regarding collection and disposal from an infection prevention perspective. They must be disposed of in a safe and proper manner. Please observe the infection prevention legislation and the legal requirements for the disposal of contaminated consumables.

5 Appendix

5.1 Values and formulas in the ECG evaluation

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, *see 3.2.5 Extended ECG settings, p. 39*.

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

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.

5.2 Keyboard navigation and shortcuts

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

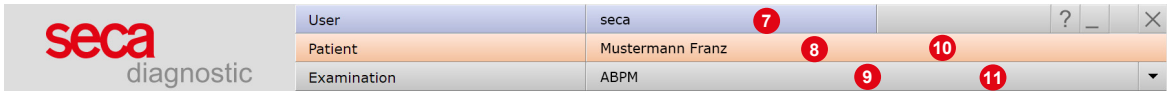
Quick links in the main navigation

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
Resting ECG keyboard shortcuts during the recording	
Enter	Start recording
Esc	End the recording
+	Increase amplitude
-	Decrease amplitude
F9	Input dialogue box blood pressure

Stress test ECG keyboard shortcuts during the recording	
Enter	Start recording
Esc	End the recording
+	Increase amplitude
-	Decrease amplitude
F7	Starts an additional blood pressure measurement
F8	Creates a new load level for steady state profiles
F9	Input dialogue box blood pressure
F10	Input dialogue box lactate
F11	Input dialogue box SPO2
F12	Input dialogue box BORG
Arrow keys right/left	increase/decrease the load rise (bicycle) or the slope (treadmill)
Arrow keys up/down	increase/decrease the load (bicycle) or the speed (treadmill)

5.3 Manufacturer’s declaration regarding EMC

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

Cable lengths of the patient leads and the USB cables

Patient leads:	gray: approx. 1050 mm (R, L, N, F), approx. 700 mm (C1 - C6)

Manufacturer's declaration – electromagnetic emissions

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

Manufacturer’s declaration – electromagnetic immunity

seca ct330/331 meets the test levels specified here.

Phenomenon	EMC standard / test method	IMMUNITY TEST LEVEL
Static electricity discharge (ESD)	IEC 61000-4-2	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radio-frequency electromagnetic fields	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz
Radiofrequency electromagnetic fields in the in the immediate vicinity of wireless communication devices	IEC 61000-4-3	Conforms to the standard, for the immunity test level refer to the table on the next page
Quick transient electric interference factors / bursts	IEC 61000-4-4	± 2 kV 100 kHz Repetition frequency
Surges line against line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges line against earth	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances, induced by high-frequency fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM frequency bands between 0.15 MHz and 80 MHz[1)] 80 % AM at 1 kHz
Power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz
Voltage drops	IEC 61000-4-11	Not applicable
Voltage interruptions	IEC 61000-4-11	Not applicable
Magnetic fields in close proximity	IEC 61000-4-39	Not applicable

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

Recommended protective distances between portable and mobile RF telecommunication devices and seca ct330/331

seca ct330/331 is designed for use in an electromagnetic environment in which the RF transients can be controlled. The user can help avoid electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the device - depending on the power output of the communication device, as indicated below.

Portable RF communication devices (radios) (including their accessories such as antenna cables and external antennas) should not be used within 12 inches (30 cm) of the manufacturer's designated parts and leads of the seca ct330/331 device. Failure to observe this warning can compromise the performance of the device.

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

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

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

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

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

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

5.4 EC Declaration of Conformity

Simplified declaration of conformity

seca ct330/331 complies with the requirements of the Medical Device Regulation (EU) 2017/745 and Directive 2011/65/EU.

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

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

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

5.5 Product components and accessories

Description	Product designation	Part no.	Quantity/pc.
	seca ct330 (USB version)	12054	1
	seca ct331 (Bluetooth version with rechargeable battery)	12056	1

Description	Accessories	Part no.	Quantity/pc.
	Patient cable 10-lead with banana plug	12214	1
	ECG electrodes blue sensor for ECG device with banana plug	40004	60 pieces

Description	Complementary parts	Part no.	Quantity/pc.
	Carrying case incl. belt	12213	1
	USB connection cable A-A, 3 m	12221	1
	USB universal power supply	12212	1
	Bluetooth 4.0 USB adapter	55050	1
	USB extension cable 1.8 m, plug A - socket A	16018	1
	custo clean CR3, hygiene bag for seca ct330/331	40012	50 pieces

All parts listed here are available separately.

5.6 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 cardio 300 (12-channel PC ECG 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 ct330/331 (12-lead PC ECG device)
seca diagnostic (medical PC software)

GEB-0218 DK-2279 Version 002 2024/08/06

seca®
Precision for health