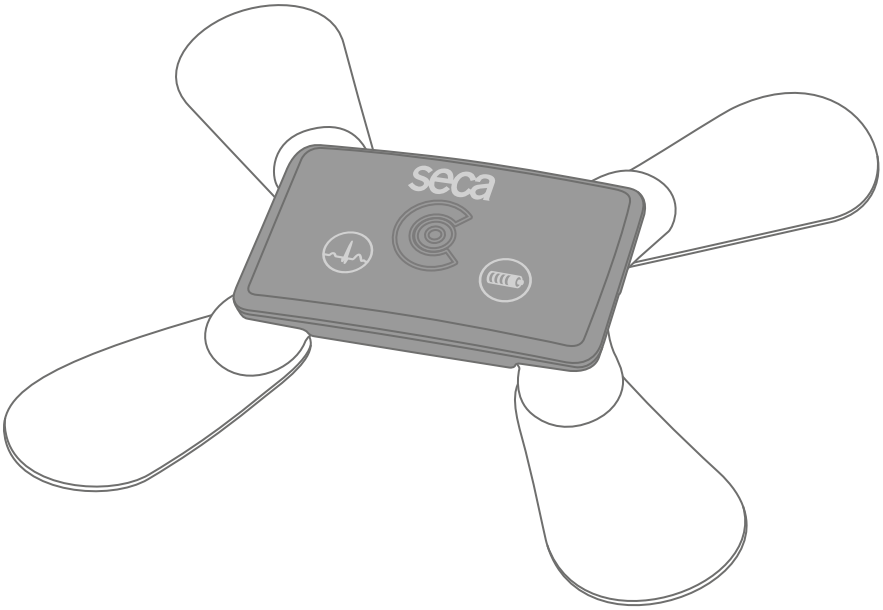
Instructions for Use

Holter with seca guard holter and seca diagnostic 5.9



seca®
Precision for health

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custo diagnostic (medical PC software)

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1 Safety

1.1 General notes

1.1.1 Symbols used in this Operating Manual

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

1.1.2 Laws and regulations applicable to the product

INFORMATION:

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

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

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

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

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

1.1.3 Disclaimer

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

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

1.1.4 Warranty

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

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

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

1.1.5 Support

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

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

1.2 Safety installations and safe working

1.2.1 Putting into operation, setup

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

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

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

1.2.2 Ambient conditions, handling of the devices

Emissions

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

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

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

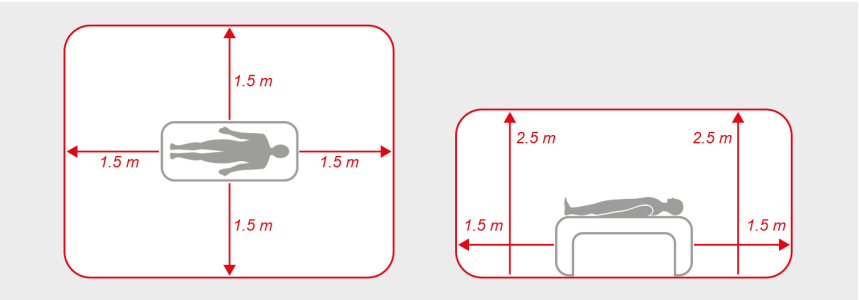


Fig. 1: Safety distances at the patient area

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 Holter

The device is protected against the ingress of dust and splashing water (IP65).

It is not permitted to wear the devices in a swimming pool or in the bath. Do not submerge the devices in liquid.

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

custo wing disposable adhesive electrodes must not be used on infants or small children. Use suitable neonatal or paediatric electrodes.

Disposable adhesive electrodes must be changed daily to avoid skin irritation.

To avoid skin irritation during recordings lasting several days, adhesive electrodes should be attached at a slightly different position when they are changed daily.

In the case of known allergies, e.g. against substances in the adhesive electrodes, the further procedure must be agreed with a doctor before the commencement of recording. If patients experience discomfort during a recording, they must contact their physician.

The custo med Holter systems are perfectly safe for patients with a pacemaker. In Holter systems without pacemaker detection, disturbances in the ECG signal may be incorrectly interpreted as a pacemaker.

Notes on seca diagnostic holter software options

The seca diagnostic function “ANS diagnostics” (balance of the autonomic nervous system) serves as a supporting measure. A correct evaluation of the holter recording must always be preceded.

For an improved informative value, it is advisable to repeat the examination so that a development of the condition can be seen.

1.4 Residual risks holter

DANGER

Risk of strangulation due to neck strap, cable adapter and ECG cable guard.

→ Do not leave infants or small children unattended during recording.

→ Store out of reach of children when not in use.

DANGER

Choking hazard due to small parts

→ Keep small parts away from children.

CAUTION

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

→ Clarify further procedure with the physician before recording.

CAUTION

Skin irritations and skin injuries caused by custo wing electrodes

Applying custo wing electrodes to injured skin areas causes skin irritation and impairs wound healing.

Patients with skin diseases or blood coagulation disorders may suffer skin injuries when custo wing electrodes are removed.

→ custo wing electrodes may only be used on patients with intact skin.

→ In patients with skin diseases or blood coagulation disorders, the responsibility for the use of custo wing electrodes lies with the attending physician.

→ In patients with skin diseases or blood coagulation disorders, the application and removal of the custo wing electrode must be carried out by medical professionals if there is a risk that the patient could injure him/herself when applying or removing the electrodes independently.

→ If skin injuries are likely to occur during removal of the custo wing electrodes, adhesive electrodes should not be used.

CAUTION

Skin reaction due to custo wing electrodes

The use of custo wing electrodes can lead to skin reactions such as burns, redness, itching or small blisters.

→ If symptoms occur, the custo wing electrodes must be removed immediately.

→ In the case of patients with skin diseases or blood clotting disorders, custo wing electrodes must be removed by trained medical staff if there is a risk that the patient could injure themselves when removing the electrodes themselves.

→ If skin injuries are likely to occur during removal of the custo wing electrodes, adhesive electrodes should not be used.

2 Hardware

2.1 Intended use

seca guard holter is a wearable Holter recording device with an internal power supply, and is used to record a 3-channel ECG signal in accordance with Holter standards.

seca guard holter includes pacemaker detection. In addition to the ECG signal, the patient's movement data (walking, running, prone, seated, etc.) is also recorded and later displayed in the seca diagnostic evaluation. The recording time is 24 up to 120 hours. The recording is saved directly in the seca guard holter recording device.

seca guard holter can be used safely on patients with pacemakers.

The ECG recording may be affected by pacemaker pulses.

The system is intended for use by trained specialist staff or physicians in clinics and medical practices. Patients are only allowed to use the recording device after receiving instruction by trained specialist staff. Patients who are not capable of understanding and following the instructions given are not allowed to use the device. This applies in particular to senile patients or patients suffering from dementia.

The system is not suitable for electrocardiographic monitoring of patients as per DIN EN 60601-2-27, e.g. use in intensive care.

The device is not suitable for intracardiac use.

2.1.1 Indications and contraindications

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

Indications for Holter ECG

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

2.1.2 Overview holter software and recorder

Software function	Software edition “standard”
Comparison of evaluations	✓
Analysis (edit templates)	✓
Trend/ECG	✓
Examples	✓
Trend overview	✓
Total ECG	✓
Export as a PDF file	✓
Reduction of the data volume	✓
Movement data	✓
Combined evaluation with ABPM[1)]	screen 300[2)]
multiday evaluation (2/3/5/7 days or unlimited duration)	✓
pacemaker analysis[3)]	–
Event system	–
ST measurement	–
QT measurement	–
HRV	–
AF diagnostics	–
HRT	–
ANS diagnostics[3)]	✓
12-channel recording[3)]	✓

1) Only possible with the specified device.

2) screen 300 is a pure ABPM recorder. If this is applied to the patient at the same time as a seca holter device, the two recordings are displayed as a combined evaluation due to the joint recording period.

3) Optional, suitable device required.

2.2 Symbols on the devices and packaging

seca guard holter, ECG cable guard 4, custo guard base 1/6, custo wing adaptor, custo wing single-use adhesive electrodes

	Manufacturer: custo med GmbH, Maria-Merian-Str. 6, 85521 Ottobrunn, Germany
	Order number/designation
	Serial number
	Unique Device Identifier
	For use with children under 10 kg
	Protection class of electrical equipment (protection against ingress of moisture and dirt)
	CE mark
	CE mark
	Medical device
	Date of manufacture (YYYY-MM, e.g., 2022-01)
	Follow the Operating Manual!
	Observe the Operating Manual
	Safety class classification of medical electrical equipment according to DIN EN 60601-1 (Type BF)
	Separate collection of electrical and electronic equipment, do not dispose with domestic waste.
	Lot designation

	Minimum shelf life, for use until (MM YYYY, e.g. 10 2021)
	Single-use article, do not reuse
	Temperature limit
	Keep dry

2.3 Technical data and system requirements

seca guard holter ECG recording device	
Number of ECG channels	3
Sampling frequency (depending on recording duration)	533 Hz (24 h, high resolution) 400 Hz (24 h, 48 h, 72 h) 100 Hz (5 days, 7 days, unlimited duration)
Resolution	18 bit
3-dB bandwidth ECG amplifier (depending on sampling frequency)	0 Hz – 105 Hz (with a sampling frequency of 533 Hz) 0 Hz – 80 Hz (with a sampling frequency of 400 Hz) 0 Hz – 20 Hz (with a sampling frequency of 100 Hz)
Minimum detection threshold (depending on sampling frequency)	10.46 µV (with a sampling frequency of 533 Hz) 5.51 µV (with a sampling frequency of 400 Hz) 5.51 µV (with a sampling frequency of 100 Hz)
ECG measurement range	+/- 685.7 mV
Radio frequency band	ISM 2.4 GHz
Radio transmission power	10 mW
Radio communication	FHSS Frequency Hopping Spread Spectrum
Radio modulation	GFSK
Radio transmission rate	1Mbit/s
Connection to PC	via custo guard base charging and communication unit (USB) and Bluetooth
Power supply	Lithium polymer battery
Battery runtime[1)]	up to 168 h/7 days
Battery charging time	approx. 2 hours, charging current max. 130 mA
Status display	LED indicators for ECG quality and charging status
Dimensions	approx. 70 * 42 * 12 mm (L * W * H)
Weight	approx. 30 g
Ingress protection level	IP 65
Operating life	approx. 5 years (after this time has elapsed, the recording duration of up to 168 h can no longer be guaranteed)
Operating conditions	Temperature: +5°C ... +45°C Humidity: 10 ... 95 % rH Air pressure: 700 ... 1060 hPa
Transport and storage conditions[2)]	Temperature: -20°C ... +45°C Humidity: 10 ... 95 % rH Air pressure: 700 ... 1060 hPa Only for storage in a medical environment, under consideration of the conditions mentioned here.
Classification	Device with internal power supply, Class IIa, Type BF
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-IEC 60601-1-6, DIN EN 62304, DIN EN 62366-1, DIN EN ISO 10993-1, DIN EN 60601-2-47, DIN EN 60601-1-11, DIN EN ISO 10993-5, DIN EN ISO 10993-10

1) The battery runtime depends on the age of the battery. After 500 or more charge cycles, the battery capacity is at 80% of the initial capacity. Definition of charge cycle: During a charge cycle the entire battery power is recharged; this does not have to occur in a single charging operation, however. For example, you can use a device for several hours on a particular day, use approximately half the capacity, and then fully charge it again. If the same procedure is repeated on the following day, this is equal to only one charging cycle, and not two charging cycles. Therefore, it can take a few days for a charge cycle to be fully completed.

2) For longer storage periods, seca guard holter should be recharged regularly. Recommendation: every 3 months to approx. 60%.

custo guard base charging and communication unit

Model:	1-slot	6-slot
Power supply	5 V	5 V
Max. charging current	130 mA	6 * 130 mA = max. 780 mA
Dimensions (L * W * H)	approx. 80 * 49 * 33 mm	approx. 279 * 80 * 33 mm

ECG cable guard 4

Dimensions, without cables	70 * 50 * 12 mm (L * W * H)
Weight, without neck strap	approx. 35 g
Material	ABS
Cable lengths	approx. 175 mm
Classification	Class I
Operating conditions	Temperature: +5°C ... +45°C Humidity: 10 ... 95 % rH Air pressure: 700 ... 1060 hPa
Transport and storage conditions	Temperature: -20°C ... +45°C Humidity: 10 ... 95 % rH Air pressure: 700 ... 1060 hPa Only for storage in a medical environment, under consideration of the conditions mentioned here.

custo wing single-use adhesive electrodes

Dimensions	max. 61 * 34 mm (L * W)
Height without connection	0.9 mm
Gel type	Hybrid gel
Sensor	silver/silver chloride (Ag/AgCl)
Contact resistance	max. 200 Ohm
Outer adhesive	Acrylic
Environmental data	PVC-free, latex-free
Application duration	24 h moisture resistant at max. 40°C and 95 % humidity
Packaging	Bag of 40 pieces
Operating conditions	Temperature: +5°C ... +45°C Humidity: 10 ... 95 % rH Air pressure: 700 ... 1060 hPa
Transport and storage conditions	Temperature: 0°C ... +40°C Humidity: 10 ... 95 % rH Air pressure: 700 ... 1060 hPa Only for storage in a medical environment, under consideration of the conditions mentioned here.

Technical requirements for the operation of seca diagnostic

seca diagnostic SERVER, hardware and operating system

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

seca diagnostic SERVER, minimum requirements

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

seca diagnostic SERVER, recommendations

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

seca diagnostic CLIENT, hardware and operating system

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

seca diagnostic CLIENT, minimum requirements

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

seca diagnostic CLIENT, recommendations

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

Software requirements for the operation of seca diagnostic

seca diagnostic SERVER

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

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

seca diagnostic CLIENT

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

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

2.4 Shutdown, storage, transport, disposal

Shutdown and storage

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

Transport

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

Disposal

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

Symbols for transport, storage and disposal

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

2.5 Components for the recording

1. seca guard holter, 3-channel holter recording device
2. custo wing adaptor (for single-use adhesive electrodes)
3. custo wing single-use adhesive electrodes for seca guard holter
4. custo guard base 1 charging and communication unit
5. Micro USB cable 2.0 1.5 m
6. Bluetooth LE stick
7. ECG cable guard 4
8. Neck strap for ECG cable guard 4

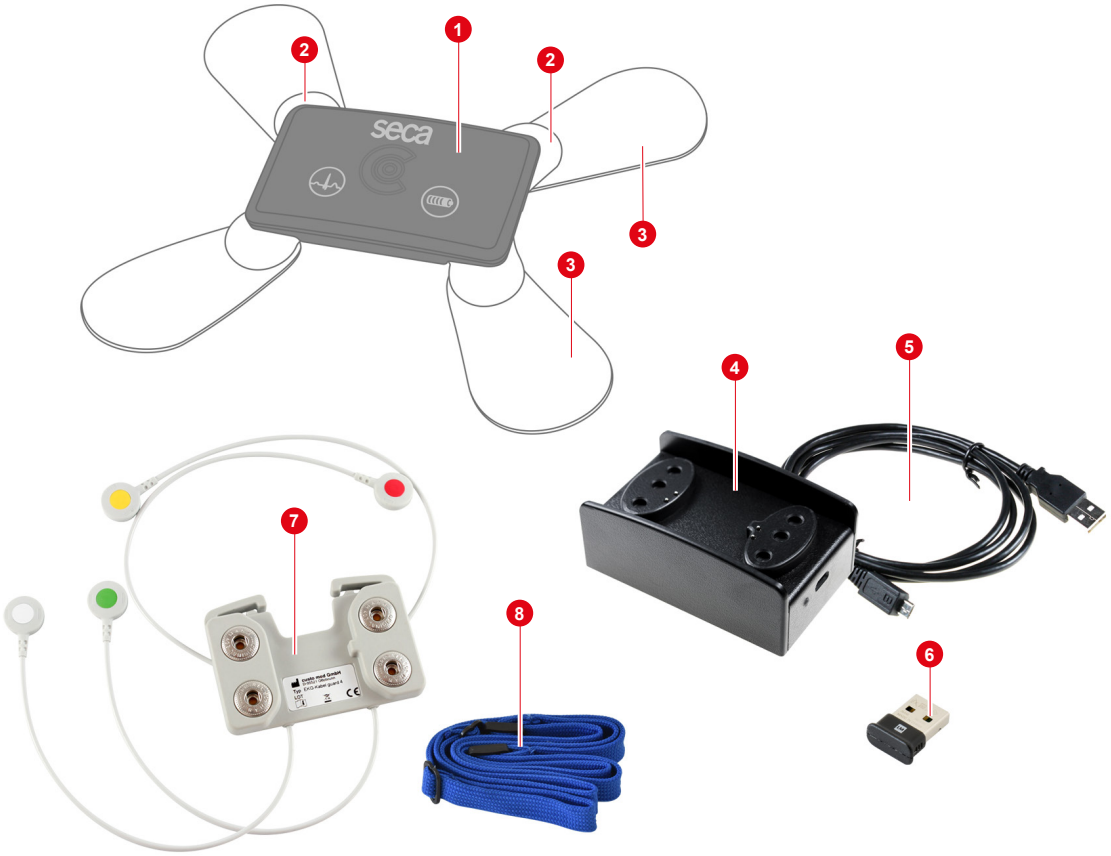


Fig. 2: seca guard holter part designation

2.6 Charging process

IMPORTANT: Charge the seca guard holter before first use!

IMPORTANT: Only place clean, dry seca guard holter devices on the charging and communication unit. Charging damp seca guard holter devices (sweat, disinfectant) will cause oxidation of the electrical contacts.

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

2.6.1 How to work with custo guard base 1

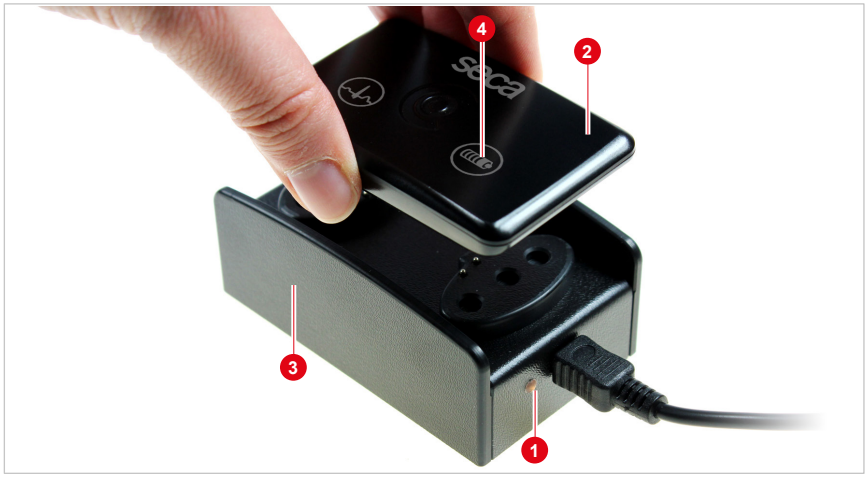


Fig.3: Charging seca guard holter

→ Connect the custo guard base 1 charging and communication unit to the switched-on PC using the micro-USB-cable. Only use the cable supplied!
→ custo guard base 1 is ready for operation when the LED shines orange 1.
→ Place seca guard holter 2 on the custo guard base charging and communication unit 3.
→ The LED next to the “Battery” symbol 4 indicates the charge status of the seca guard holter device.

LED display during charging	
4 LED Battery continuously red	charging
4 LED Battery continuously green	charged for 24 h

For technical reasons, a seca guard holter device displayed as “fully charged” (green LED Battery) can display its status as “Charging” (red LED Battery) again if it is removed and then reinserted into the charger.

Rechargeable battery charging and run time	
Maximum charging time	2 hours

Rechargeable battery charging and run time	
Run time	up to 168 hours

The battery capacity / maximum runtime decreases with time (80 % charge capacity after 500 charging cycles).

2.6.2 How to work with custo guard base 6

custo guard base 6 is a charging and communication unit for six seca guard holter devices. In contrast to custo guard base 1, custo guard base 6 has two connections: USB mini and USB C. The USB-mini-port is used for communication with the PC and for data transfer. The USB-C-port is used for power supply.

IMPORTANT: Make sure that custo guard base 6 is always supplied with power via the USB-C-cable and the supplied power supply unit. Power supply via other power supply units, via the PC or via the USB mini cable will cause problems.

Fig. 4: custo guard base 6 charging and communication unit

Setting up the custo guard base 6 power supply

→ Connect the custo guard base 6 charging and communication unit to the power supply using the USB-C-cable and the supplied power supply unit.
→ custo guard base 6 is ready for operation when the LED on the custo guard base 6 housing lights up orange. The LED is located on the long side of the housing, opposite the USB-C- and USB-mini-port.
→ In this state, seca guard holter devices can be charged.

Setting up the communication connection to the PC

→ Connect the custo guard base 6 charging and communication unit to the PC via the USB-mini-cable.
→ As soon as seca guard holter devices are placed on the custo guard base 6 charging and communication unit, they are available in the seca diagnostic software interface.

Charging several seca guard holter devices and connecting them to the PC

→ Place the seca guard holter devices on the custo guard base 6 charging and communication unit.
→ The devices are charged. Depending on the charging status, the LED next to the battery symbol lights up red or green.
→ The seca guard holter devices are available in seca diagnostic under the examination Holter.
→ Charging and run times *see 2.6.1 How to work with custo guard base 1, p. 27*.

2.6.3 Loading process for unlimited recordings

seca guard holter can be configured in seca diagnostic when starting the device so that the duration of the ECG recording is unlimited.

For recordings with unlimited duration, give the patient a custo guard base charging and communication unit to take home. seca guard holter must be recharged at regular intervals (e.g. daily, during personal hygiene - pauses in the recording are shown with red lines in seca diagnostic).

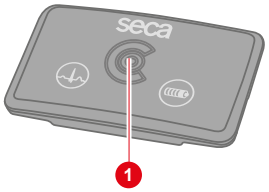
As soon as the battery charge is only sufficient for 8 hours of recording, seca guard holter emits an acoustic warning signal (beep) every 15 minutes. seca guard holter must be recharged within these 8 hours. If seca guard holter is not charged within these 8 hours, the device switches off - however, the device can still be charged within the next 24 hours and recording resumed.

Charging and run times *see 2.6.1 How to work with custo guard base 1, p. 27*.

If more than 24 hours elapse after switching off, recharging and resuming recording is no longer possible (loss of the real-time clock in the device). In this case, the seca guard holter must be read in and restarted at the medical practice.

2.7 Display and control elements

2.7.1 Start and marker key



The seca guard holter recording device has a start and marker function. Both functions are activated by firmly tapping the upper part of the housing 1.

Start function

When prepared accordingly in the seca diagnostic holter software, a holter recording can be started manually, directly on the device. Double-tapping the seca guard holter device 1 starts the recording. Make sure that seca guard holter is correctly applied to the patient, *see 2.9 Attaching the recorder to the patient, p. 33*.

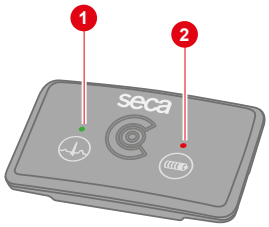
Marker function

Markers can be set during a recording. This is done by tapping the seca guard holter device once 1. Markings can be used to indicate special events during the recording, such as stress, medication intake or similar. In addition, the patient can make a note in the patient diary. Instruct the patient on the correct use of the marker function before recording.

Summary of start and marker key 1

Two firm taps	Starting a recording
One firm tap after starting	Set marker
Both actions are confirmed via a short beep.	

2.7.2 Status display



The seca guard holter recording device has two LED indicator lights displaying recording status and battery power.

The two LEDs are located on the top of the housing and are each marked with a symbol. The “QRS complex” symbol indicates recording status and ECG quality 1. The “Battery” symbol indicates the charging status and battery power 2.

LED display during recording

1 LED QRS complex flashes green	Recording, ECG quality good.
1 LED QRS complex flashes red	Recording, ECG quality poor. Correct the position of the electrodes!
2 LED Battery flashes green	Battery charge sufficient for recording period.
2 LED Battery flashes red	Battery charge low. Charge the device!

LED display in stand-by, without recording

After ten minutes, the battery charge display ends (stand-by mode)

2 LED Battery flashes green	Battery charge is sufficient for 24 hours of recording.
2 LED Battery flashes red	Battery charge is NOT sufficient for 24 h. Charge the device!

LED display during charging

2 LED Battery continuously red	Device is charging.
2 LED Battery continuously green	Charged for 24 h.

2.7.3 Acoustic signals

When starting the seca guard holter device, it emits a beep. This applies for all start options in the seca diagnostic Holter software (Start now, Start later/manually, Automatic start at a specified time). Manual markers set during recording are confirmed via a short beep.

2.8 Procedure of an examination

Prepare the equipment for recording:

- → seca guard holter device (cleaned and fully charged) either with...
- → two pieces of custo wing adaptor and four custo wing electrodes or
- → ECG cable guard 4 and five single-use adhesive electrodes (one to stick the device to the patient's chest, apply the adhesive electrode to the back of the ECG cable guard 4)

Preparing and starting the seca guard holter:

- → Connect the custo guard base charging and communication unit to the PC using the micro USB cable. The device is ready for operation when the LED lights up orange.
- → Place seca guard holter on the charging and communication unit.
- → Start seca diagnostic and open the page Examination, Holter, New Holter. On this screen page, the recording parameters are set and the device can be started with different start options (Start now, Start later, Start at a specified time), *see 3.3.1 Select device for recording, p. 41*.
- → After starting the device, the holter monitoring is displayed, or a confirmation dialogue with information on how to proceed, depending on the configuration.
- → For recording, place the seca guard holter device on the patient, *see 2.9 Attaching the recorder to the patient, p. 33*.
- → If the recording is to be started manually, firmly double-tap the seca guard holter device at the desired start time.
- → Instruct the patient in the correct use of the seca guard holter device, *see 2.10 Patient instructions, handling of the device, p. 36*.

After the recording

- → Take the seca guard holter recording device off of the patient.
- → Clean and disinfect the seca guard holter and the other holter components used on the patient, *see 4 Hygiene, p. 71*.
- → Connect the charging and communication unit to the PC using the micro USB cable. The device is ready for operation when the LED lights up orange.
- → Place seca guard holter on the charging and communication unit.
- → Start seca diagnostic and open the screen page Examination, Holter, Read in recorder, *see 3.5 Read in and display the recording, p. 49*.
- → Fully charge the seca guard holter again, *see 2.6 Charging process, p. 27*.

2.9 Attaching the recorder to the patient

There are various methods of putting the seca guard holter on the patient. A suitable method can be selected for the patient's specific anatomy. Normally, the seca guard holter is put on with the custo wing electrodes. For larger/wider patients, putting the device on with the ECG cable guard 4 is recommended – the cables can reach further. These methods are described in detail on the following pages.

2.9.1 Attaching to patient with custo wing electrodes

→ Apply the two custo wing adaptor connectors to the snap button contacts of the seca guard holter. Press the custo wing adaptor and the seca guard holter together with your forefinger and thumb until the snap button contacts engage 1.
→ Repeat the procedure for the second custo wing adaptor.
→ Prepare the four custo wing electrodes and fasten these to the snap button contacts of the two custo wing adaptor connectors 2.
→ Clean the electrode contact points, the skin must be free of grease and body care products.
→ Remove the protective foils from the custo wing electrodes.
→ Attach seca guard holter to the patient 3.

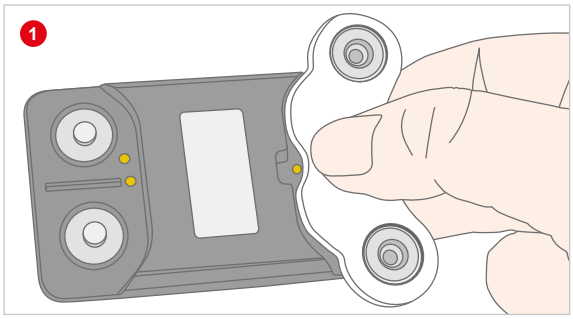


Fig. 5: Attaching the custo wing adaptor

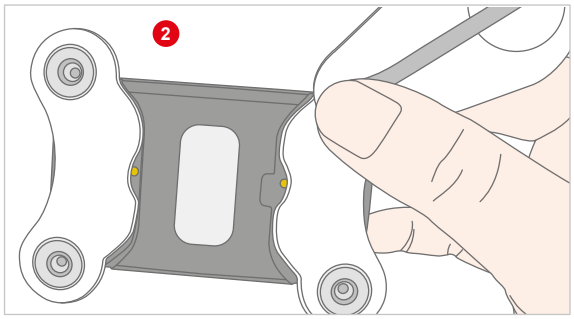


Fig. 6: Attaching the custo wing electrode

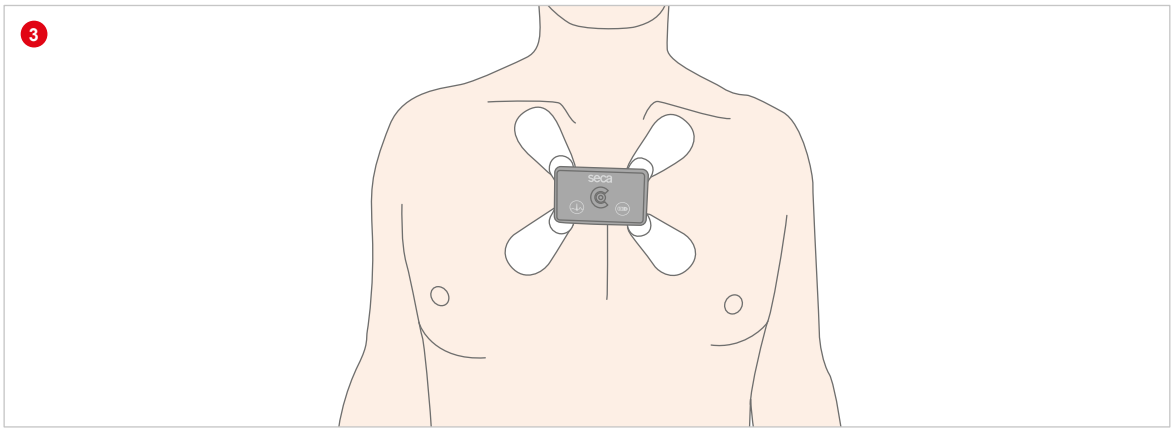


Fig. 7: seca guard holter with custo wing on the patient

2.9.2 Attaching to patient with ECG cable guard 4

For larger/wider patients, putting the device on with the ECG cable guard 4 ❶ is recommended. The cables can reach further. ECG cable guard 4 allows recording of two independent channels.

- → Press the seca guard holter firmly onto the four contact points of the ECG cable guard 4 ❷.
- → Attach the electrodes to the cable ends.
- → Attach (any) additional single-use adhesive electrode to the snap button contact at the rear of the ECG cable guard 4. The electrode serves to stick the ECG cable guard 4 to the patient‘s chest. This reduces movement artefacts and improves the quality of the recording. The electrode has no medical/diagnostic function.
- → Attach the neck strap to the hooks on the ECG cable guard 4.
- → Put the ECG device on the patient and set the neck strap to the desired length.
- → Clean the electrode contact points, the skin must be free of grease and body care products.
- → Remove the protective films from the electrodes.
- → Apply the electrodes to the patient’s chest, see figure ❸.

Fig. 8: ECG cable guard 4

Fig. 9: ECG cable guard 4 with seca guard holter

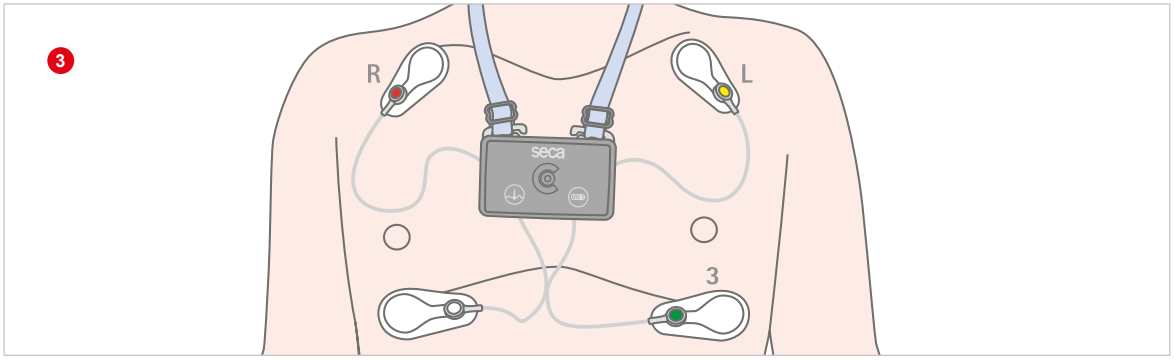


Fig. 10: seca guard holter with ECG cable guard 4 on the patient

2.10 Patient instructions, handling of the device

The recording period selected should be as normal as possible (not a holiday, no out-of-the-ordinary events).

The device must also be worn during the night.

No x-rays may be taken on the day of recording.

The quality of the recording may be affected by other electrical devices (e.g. mobile phones).

The devices must be protected against extreme cold, heat, moisture, dirt and mechanical impact.

No showers, no visits to the swimming pool or sauna.

The patient can set markers during the ECG recording, for example if unwell, stressed or for special occurrences. The reason for a marker can be noted in the patient diary. The marker is set by firmly tapping the front of the housing once (a confirmation beep will follow).

ECG cable guard 4: If any electrodes become detached during recording, they must be reattached. Otherwise, ECG recording is not possible. Patients should contact their physician's practice for assistance in reattaching the electrodes.

DANGER

Risk of strangulation due to neck strap, cable adapter and ECG cable guard.

→ Do not leave infants or small children unattended during recording.

→ Store out of reach of children when not in use.

DANGER

Choking hazard due to small parts

→ Keep small parts away from children.

CAUTION

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

→ Clarify further procedure with the physician before recording.

CAUTION

Skin irritations and skin injuries caused by custo wing electrodes

Applying custo wing electrodes to injured skin areas causes skin irritation and impairs wound healing.

Patients with skin diseases or blood coagulation disorders may suffer skin injuries when custo wing electrodes are removed.

→ custo wing electrodes may only be used on patients with intact skin.

→ In patients with skin diseases or blood coagulation disorders, the responsibility for the use of custo wing electrodes lies with the attending physician.

→ In patients with skin diseases or blood coagulation disorders, the application and removal of the custo wing electrode must be carried out by medical professionals if there is a risk that the patient could injure him/herself when applying or removing the electrodes independently.

→ If skin injuries are likely to occur during removal of the custo wing electrodes, adhesive electrodes should not be used.

CAUTION

Skin reaction due to custo wing electrodes

The use of custo wing electrodes can lead to skin reactions such as burns, redness, itching or small blisters.

→ If symptoms occur, the custo wing electrodes must be removed immediately.

→ In the case of patients with skin diseases or blood clotting disorders, custo wing electrodes must be removed by trained medical staff if there is a risk that the patient could injure themselves when removing the electrodes themselves.

→ If skin injuries are likely to occur during removal of the custo wing electrodes, adhesive electrodes should not be used.

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.

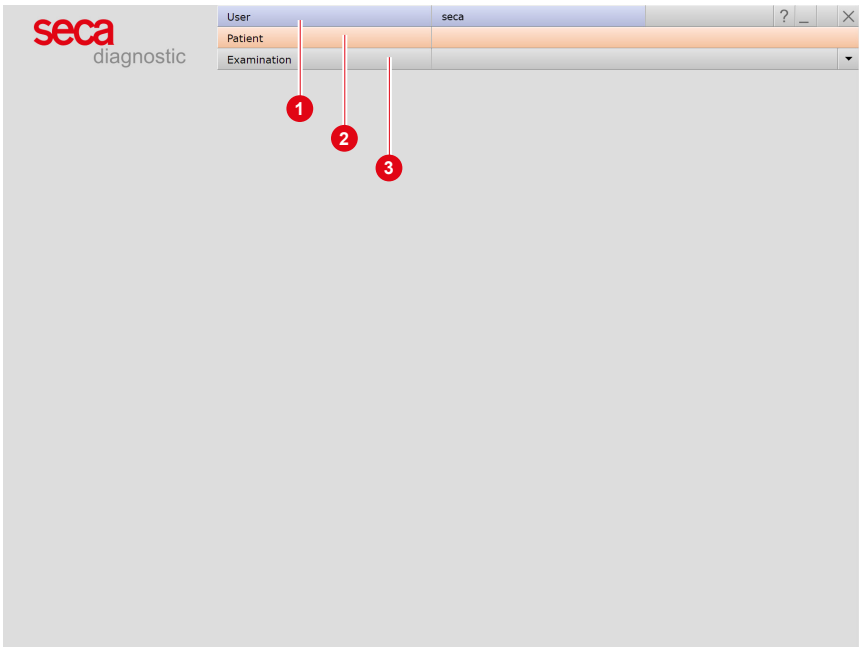


Fig. 11: seca diagnostic main menu

3.2 seca guard holter 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.

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

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

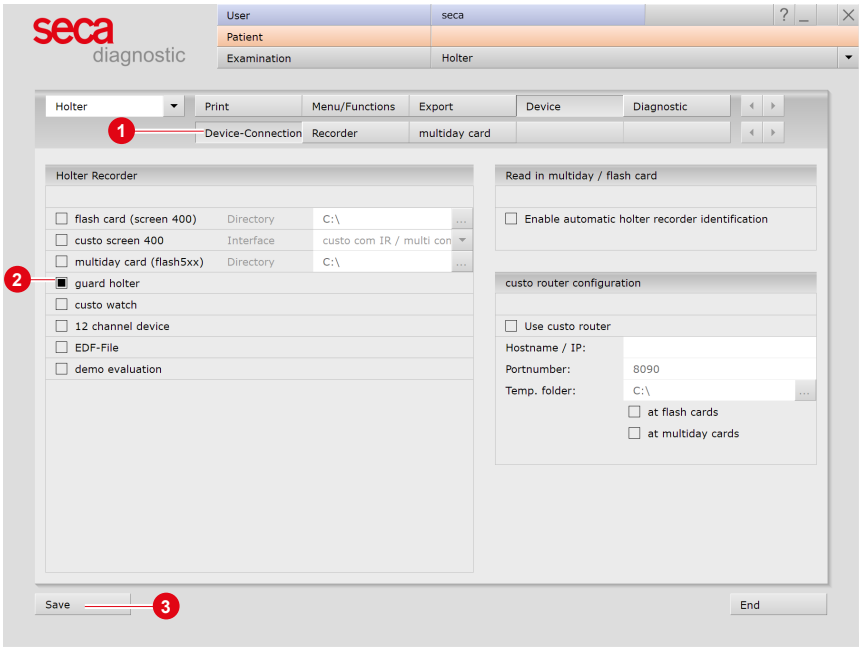


Fig. 12: Device connection in seca diagnostic

Preparing the Bluetooth connection (for monitoring)

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

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

3.3 Performing a holter recording

3.3.1 Select device for 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.

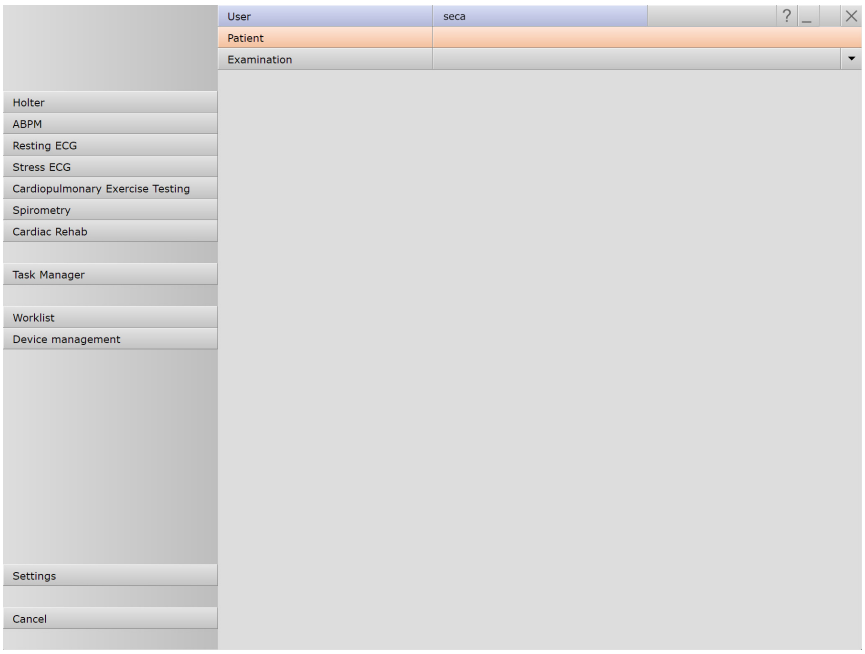


Fig. 13: seca diagnostic examination main menu

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

Selecting the seca guard holter device

- → Ensure that the custo guard base is connected to the PC.
- → Start seca diagnostic and open the screen page: Examination, Holter, New Holter.
- → Select guard holter as the recording device 1.
- → Place the seca guard holter device on the custo guard base.
- → In the right half of the screen, all available seca guard holter devices connected to the PC are displayed in a list 2.
- → In the right half of the window, select the seca guard holter device to be used for recording 3. By clicking on a list entry 3, the corresponding device in the custo guard base flashes briefly (for approx. 30 seconds). The serial number of the selected device is displayed in the left half of the window 4. A seca guard holter device can also be identified by the serial number on the type plate (on the underside of the housing) (comparison of software 4 and type plate).

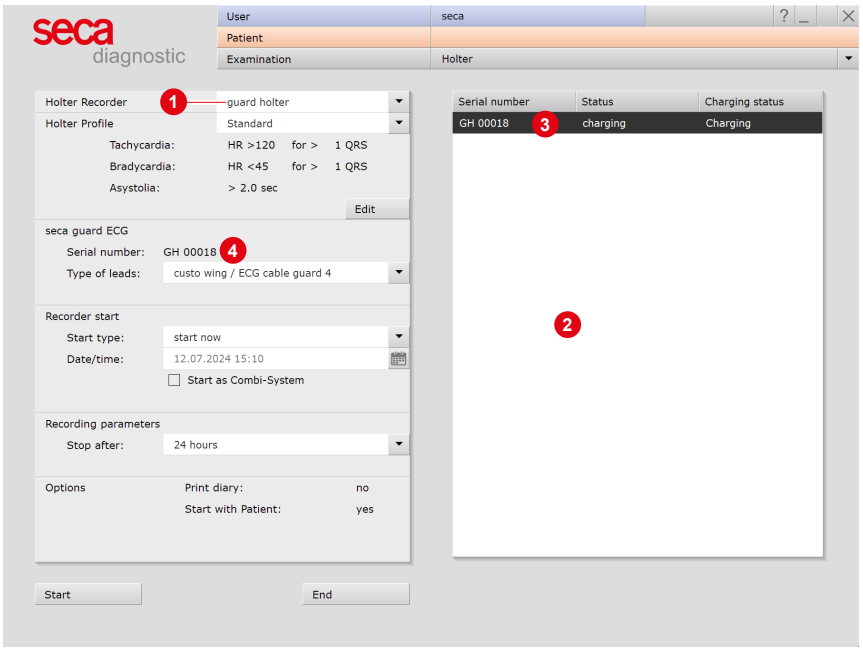


Fig.: 14: Select device for recording

TIP: *The list 2 is configurable. Right-click on the list to open the context menu. Click there on Column selection and select the desired columns for the list view. The Charge status (information on whether the device is sufficiently charged for a 24 h recording) and Charge time (information on how long the device still needs to be charged until the required battery capacity is reached) columns are also suitable for checking the function for a recording. Confirm this selection to adjust the list view.*

3.3.2 Selecting and configuring analysis parameters

→ Select a set of holter parameters, e.g. Standard 1, or create a new set: Edit 2.
→ Edit: Buttons 1 - 5 3 contain additional pages of analysis parameters.
→ The options 4 are to be set as required:
  → Print diary: Printout of the patient diary during the start procedure (for documenting events during recording).
  → Start with patient: Allows selection of a patient when starting the recording. This option is activated by default.

IMPORTANT: When working without selecting a patient, the medical staff must provide a clear and secure assignment of device and patient to ensure that a recording can be assigned to the correct patient when it is later read into seca diagnostic (e.g. labelling, keeping a daily updated list of device numbers and patients).

→ With Save as 5, the changed parameters can be saved under a new name.
→ With Save 6, the current set is overwritten.
→ Close 7 ends the parameter configuration.

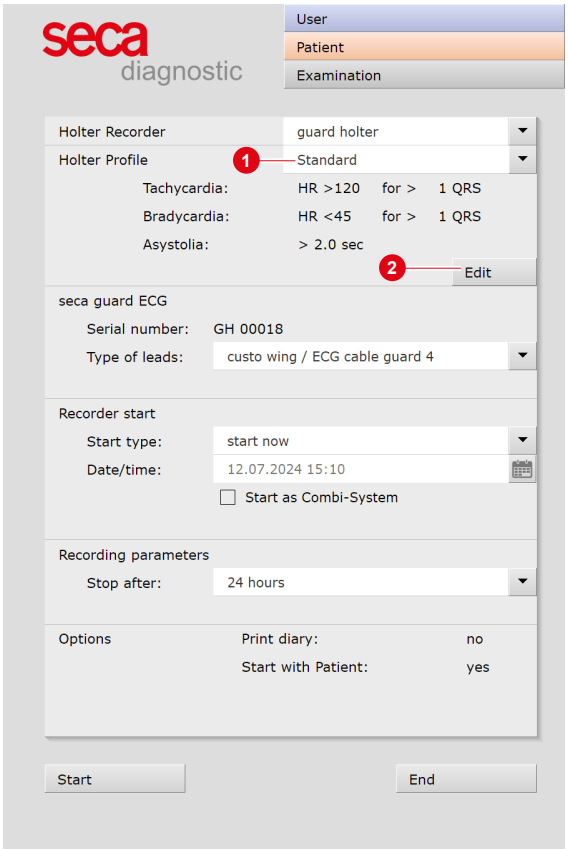


Fig. 15: Call up analysis parameters

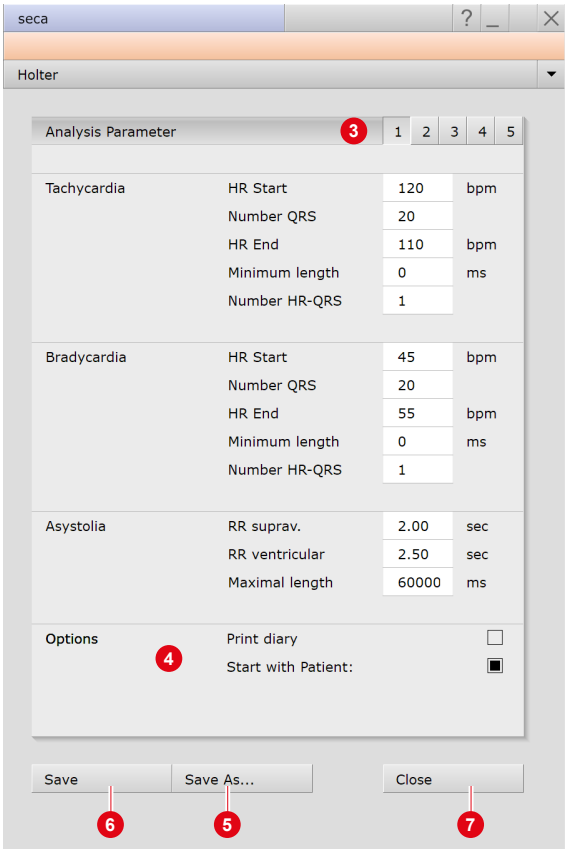


Fig. 16: Configure analysis parameters

3.3.3 Set derivation, start type and duration

→ Depending on the method of application, the ECG derivations[1)] are calculated differently. Specify how seca guard holter is applied to the patient 1:
with custo belt (electrode belt)
with ECG cable guard 3 (adapter for single-use adhesive electrodes)
with custo wing/ECG cable guard 4 (four single-use adhesive electrodes)

→ Set when to start the recording device 2:
Start now
Start later
(manual device start at any time)
Start at date/time
(automatic start at a defined time)

→ If you want to carry out an ABPM recording at the same time as the holter recording, select the “Start as Combi-System” 3 option. After starting the holter recording, the screen for starting the ABPM recording opens automatically. You also need a seca screen 300 device to carry out an ABPM recording.

→ Set the recording duration[2)]:
24 h / 48 h / 72 h / 5 days / 7 days / unlimited 4.

→ Click on the Start button 5.

→ The patient selection screen[3)] appears.

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

2) The selection of recording parameters (recording duration) can be configured individually. The setting is located on the Examination, Holter, Settings, Menu/Functions, Device Start screen. A high resolution (sampling frequency 533 Hz) can also be selected here for 24-hour recordings. Save your input.

3) If the Start with patient option was previously deactivated, the selection of a patient at this point is omitted. The seca guard holter device is prepared for recording without patient data. The medical staff must provide a clear and secure assignment of device and patient to ensure that a recording can be assigned to the correct patient when it is later read into seca diagnostic (e.g. labelling, keeping a daily updated list of device numbers and patients).

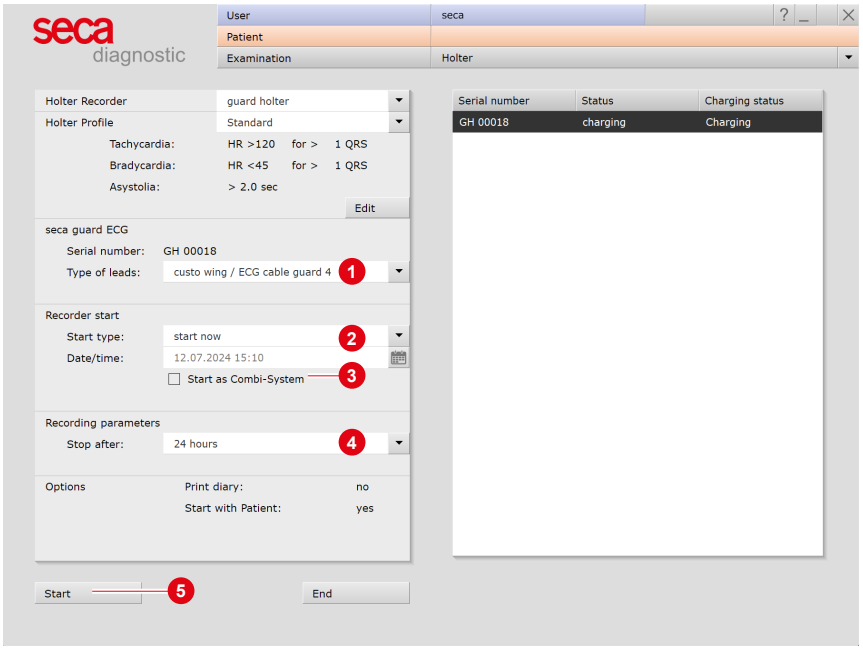


Fig. 17: Type of derivation, start type, recording duration.

IMPORTANT: For recordings with unlimited duration, provide the patient with a custo guard base charging and communication unit to take home. The seca guard holter needs to be recharged at regular intervals (e.g. daily, during personal hygiene - pauses in the recording are shown with red lines in seca diagnostic).
As soon as the battery charge is only sufficient for 8 hours of recording, seca guard holter emits an acoustic warning signal (beep) every 15 minutes. seca guard holter must be recharged within these 8 hours.
If seca guard holter is not charged within these 8 hours, the device switches off - however, the device can still be charged within the next 24 hours and recording resumed.
If more than 24 hours elapse after switching off, recharging and resuming recording is no longer possible (loss of the real-time clock in the device). In this case, seca guard holter must be read in and restarted in the doctor's office.

3.3.4 Selecting a patient for the recording

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.

3.3.5 Transferring the recording parameters to the device

The recording parameters and patient data are then transmitted to the seca guard holter device. Depending on the type of recorder start, the seca guard holter device then provides various visual and acoustic feedback signals.

→ ... after Start now: beep, both LEDs flash quickly, recording is started and monitoring is displayed in seca diagnostic, *see 3.3.6 Monitoring - control electrode system, p. 47*.

→ ... after Start later or Start at date/time: the LED above the battery symbol flashes quickly, a dialogue with information on the recorder start is displayed in seca diagnostic. Confirm the dialogue.

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

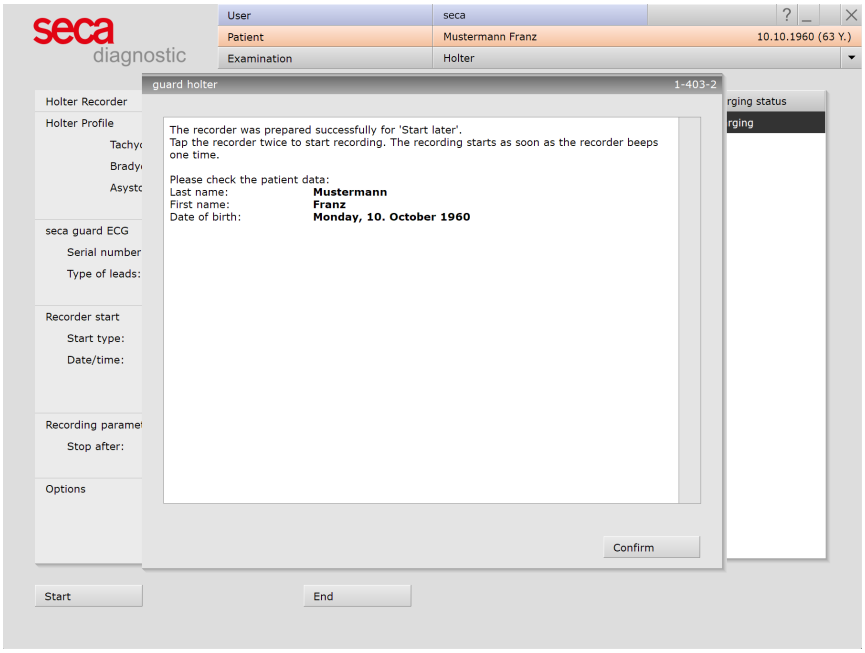
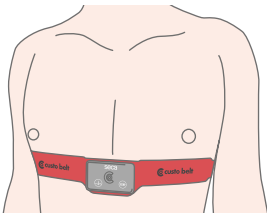
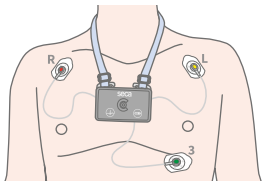


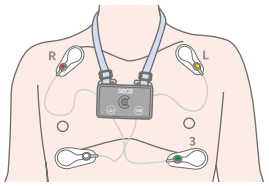
Fig. 18: Dialogue after "Start later" process

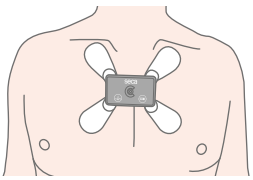
3.3.6 Monitoring - control electrode system

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

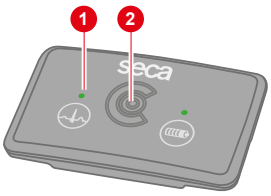








Manual start by double tapping ❷



2) The shortened duration of monitoring for recordings with 120 h, 168 h or unlimited duration serves to extend the battery life of the seca guard holter or to conserve the battery charge in advance.

→ The Monitoring screen either opens automatically after starting (option Start now with patient) or can be called up in all other cases via Examination, Holter, Monitoring.

→ Place the seca guard holter device on the patient, *see 2.9 Attaching the recorder to the patient, p. 33*. When attaching to the patient, the previously selected type of lead must be implemented (custo belt/ECG cable guard/custo wing)[1)]. Otherwise, inaccuracies may occur in the analysis.

→ Check the ECG signal on the screen. Correct the electrode positions, if necessary. If QRS complexes are detected, the ECG LED ❶ of the seca guard holter device lights up green at regular intervals.

→ If the Start later option was selected, start the recording at the desired time by tapping the device twice, centred on the front ❷ or already during Monitoring with the Start recording button. Recording starts after the beep. A quality control of the ECG signal is possible even without monitoring. If the ECG quality is insufficient, the ECG LED ❶ lights up red at regular intervals. Improve the electrode system until the ECG LED ❶ lights up green.

→ If the Start at a specific time option was selected, recording starts automatically at the preset time. Recording starts after the beep.

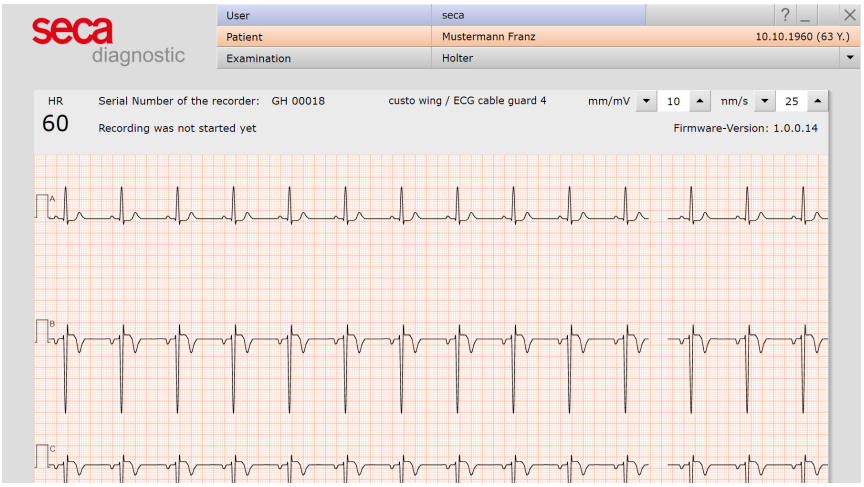


Fig. 19: Monitoring

Duration of monitoring

Start option	Duration of recording	Max. Monitoring duration
start now	24 h, 48h, 72 h	1 h after start
start now	120 h, 168 h, unlimited	15 min after start[2)]
Start later, at specified time	24 h, 48 h, 72 h	1 h before and after start
Start later, at specified time	120 h, 168 h, unlimited	15 min before and after start[2)]

3.4 Work aid “guard holter viewer”

Device-specific information and status display for seca guard holter devices.

- → To receive information from a seca guard holter device, this must be connected to the PC via the custo guard base charging and communication unit.
- → If several seca guard holter devices are connected to the PC (via custo guard base 6), a device is identified by clicking on the list entries in the “guard holter viewer”. The battery LED of the corresponding seca guard holter flashes quickly (for approx. 30 seconds).
- → The columns in the “guard holter viewer” are freely configurable. To display additional or different columns: Right-click in the guard holter viewer, select Column selection in the context menu, select the desired columns, Confirm the selection.
- → The “guard holter viewer” runs in parallel with seca diagnostic as a standalone program. The “guard holter viewer” can be displayed at all times on a second screen, for example.
- → The “guard holter viewer” is opened via Examination, Holter, guard holter viewer. The following information can be displayed in the “guard holter viewer”:
  - → Serial number
  - → Status
  - → Power
  - → Charge status
  - → Charging time
  - → Number of leads
  - → Types of leads
  - → Recording present
  - → Description
  - → Recording start
  - → Start date
  - → Stop date
  - → Recording duration
  - → Task number
  - → Assigned patient
  - → Patient’s date of birth

Applications:

- → Checking the battery capacity and the outstanding charging times.
- → Management and monitoring of several seca guard holter devices, for example in sequential batch processing in larger medical practices or hospitals. Possible questions when working with several seca guard holter devices: Which patient gets which seca guard holter device? Which type of recording has been defined for a seca guard holter device? When and how does the recording start?

3.5 Read in and display the recording

Work steps after the Holter recording

→ Remove the holter recorder and all accessories from the patient (e.g. protective bags, carrying belt, electrodes...).
→ Connect the holter recorder to the PC so that the recording can be read in:
  → clean and dry seca guard holter
  → and place it on the custo guard base.

IMPORTANT: No moisture (sweat, disinfectant) may get on/in the charging and communication units. Charging moist devices leads to oxidation of the electrical contacts.

→ Start seca diagnostic and open the screen page: Examination, Holter, Read in recorder.
→ The “Workflow after download data” dialogue appears ❶. You can analyse and display the recording Now or Later.
Later button ❷: The recording is stored without analysis in the Job Manager. The Job Manager is suitable for reading in several recorders in a short time. To make recordings from the Job Manager available, open the Job Manager via the Examination main menu. Activate the Analysis option and start the process (Start). After the analysis, the recordings can be opened.
Immediately button ❸: The recording is analysed when it is read in and then displayed.
→ When various holter recording devices are used, the “Select Data Source” dialogue appears. Select the appropriate device type.

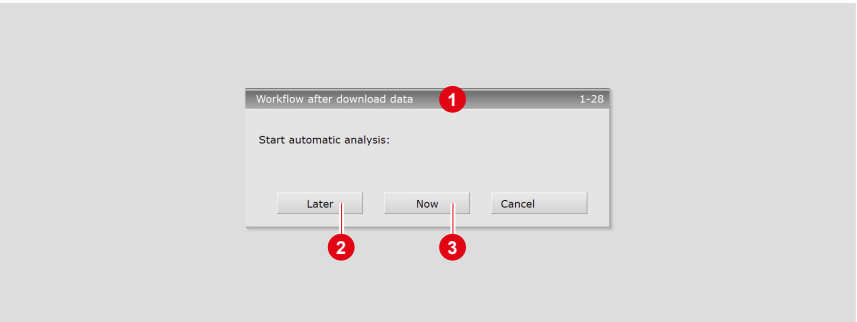
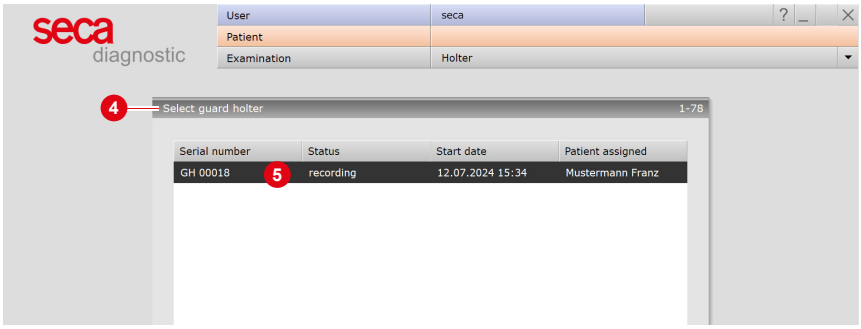


Fig. 20: Read in recording immediately or later

→ If seca guard holter was selected as the device type, a dialogue for selecting the seca guard holter device appears ❹. The seca guard holter devices connected to the PC (USB connection via custo guard base) are displayed in a list ❺. Select the seca guard holter device to be read in by clicking on the corresponding list entry. When the list entry is clicked, the battery LED of the seca guard holter device will flash for approx. 30 seconds (to check and identify the correct seca guard holter device). Confirm the selection.



→ For recordings without patient data: If the holter recording device was started without patient data, the recording must be assigned to a patient at this point.
→ Optional further dialogues: Further dialogues can follow, depending on the device type or software version, for example: “Evaluation Start Time” to check and correct the recording period or “Evaluation Start” to specify whether a recording is read in as a holter or event recorder. With the Event recorder option, only the events in the recording are read in and analysed.
→ The data is read in in seca diagnostic.
→ If the recording is opened after reading, it can be closed via the End button (bottom right).
→ In the End dialogue click on Confirm.
→ For the next examination:
Clean, disinfect, charge devices.

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.

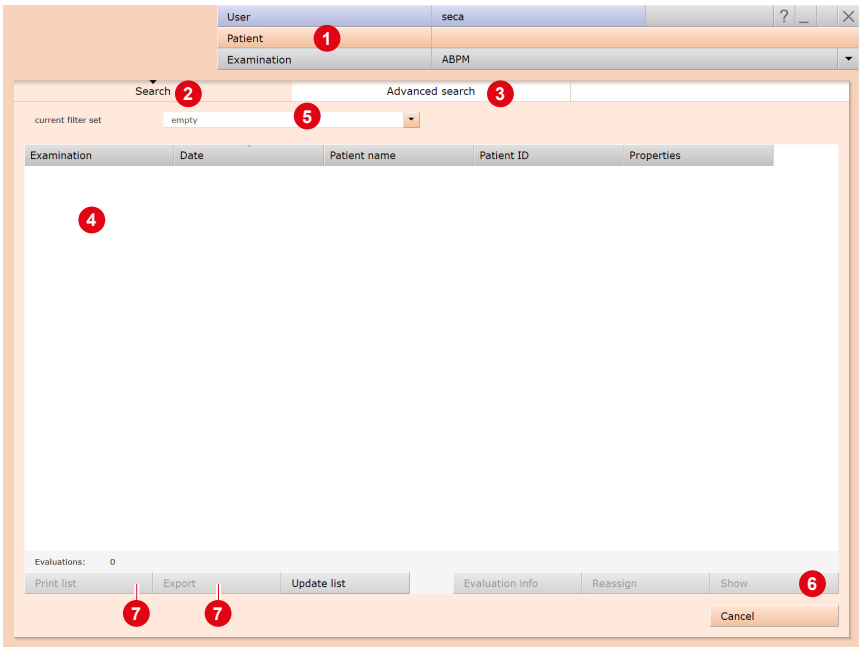


Fig. 21: Evaluation search, search with filter sets

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.

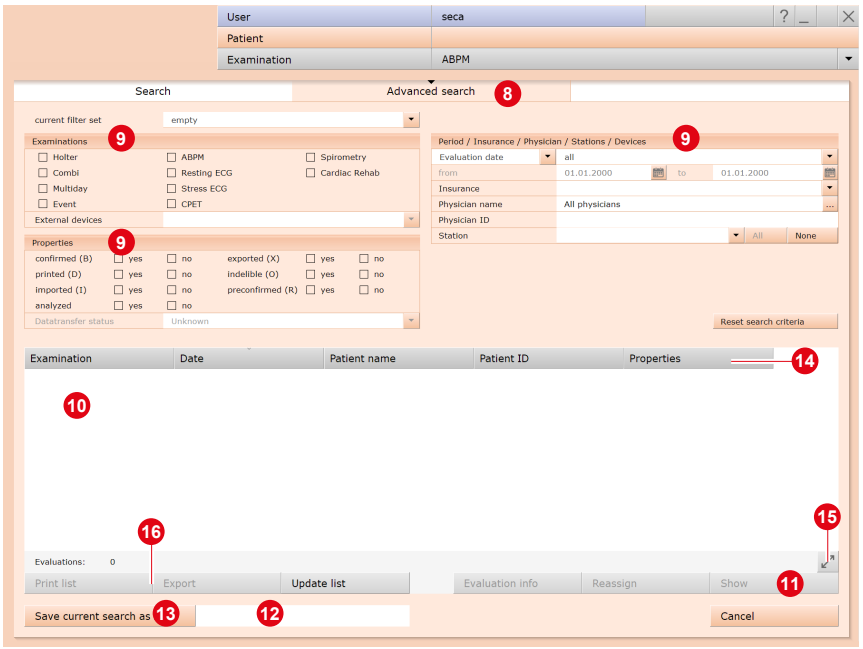


Fig. 22: Evaluation search, extended search

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, Holter.
→ 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.

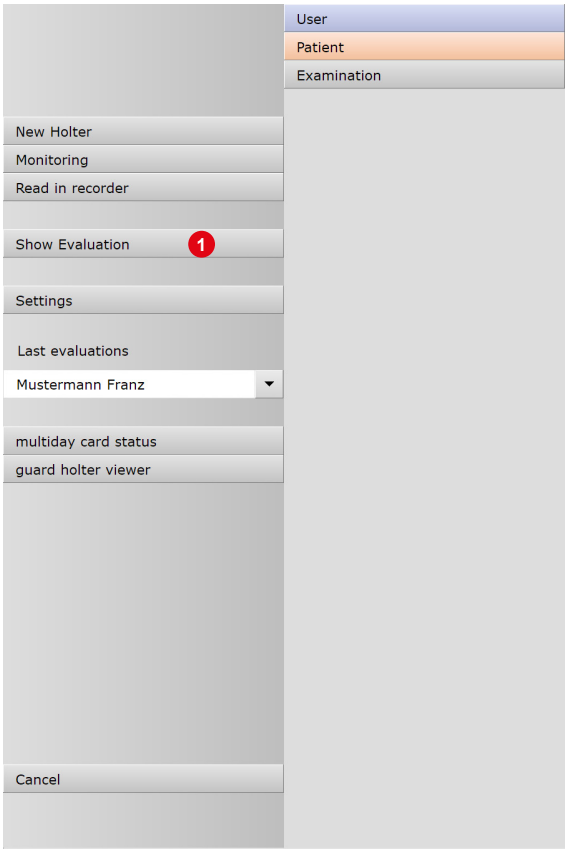


Fig. 23: Holter main menu

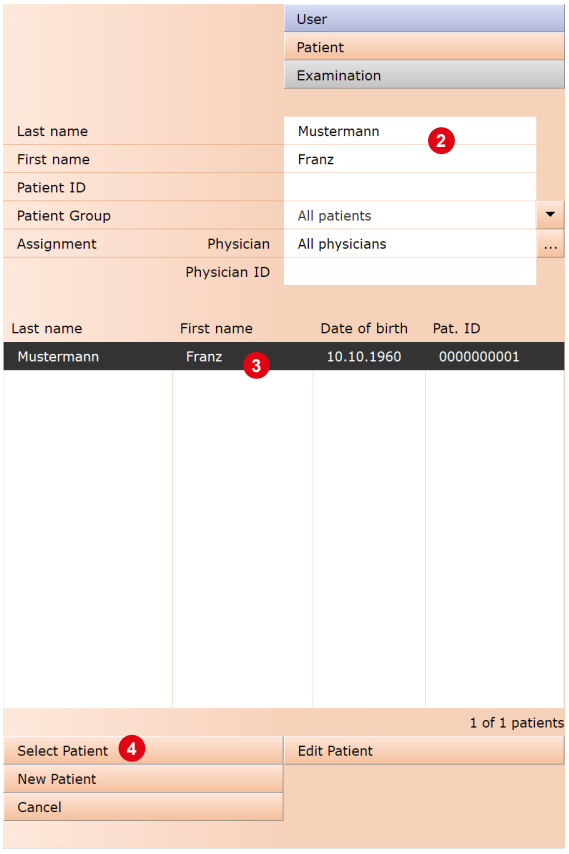


Fig. 24: Select patient

3.7 Evaluation structure

Start screen page "holter overview":

24-hour graph (trend) with a tabular summary of all events.

Further screen pages of the evaluation:

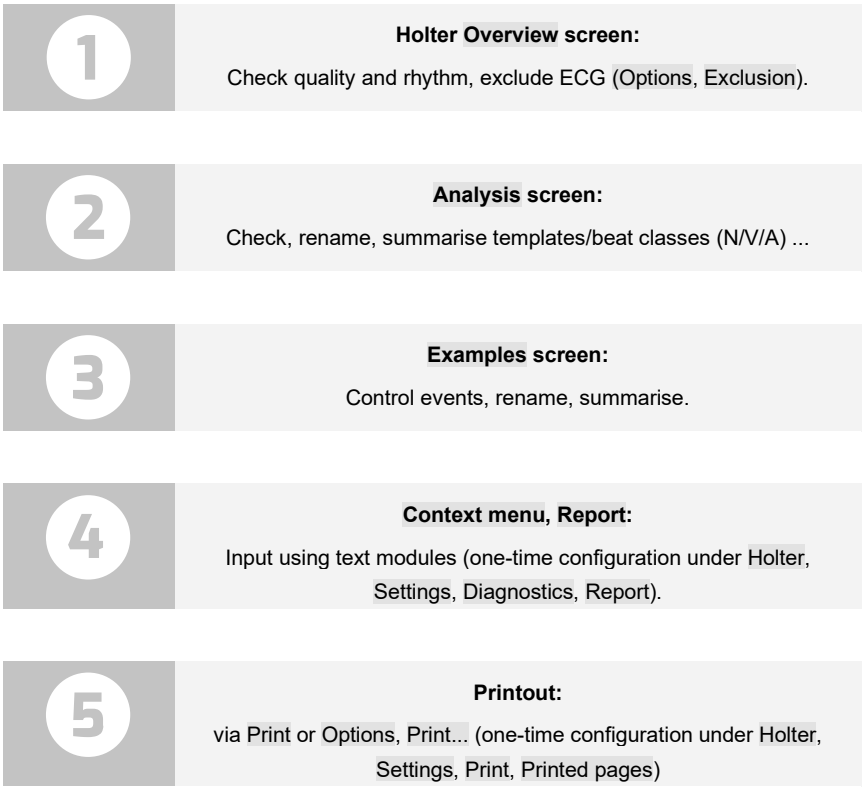
Beat class analysis: representation of all beat classes, divided into Normal, VPB, Artefact and Pacemaker	**Trend & ECG:** 24 h graph and ECG according to the cursor position in the 24 h graph, event-related navigation in the ECG	**ECG examples:** overview with example sections for the VPB classes and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

1) A suitable recorder is required

2) Optional

3.7.1 Workflow for writing the report for an evaluation

Getting to the report in five steps



3.7.2 Context menu

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

The report dialogue is always accessible via the context menu.

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

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

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

3.7.3 Options menu

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

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

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

1) seca diagnostic professional
2) optional

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

3.8 Screens of the evaluation

3.8.1 Holter overview

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

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

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

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

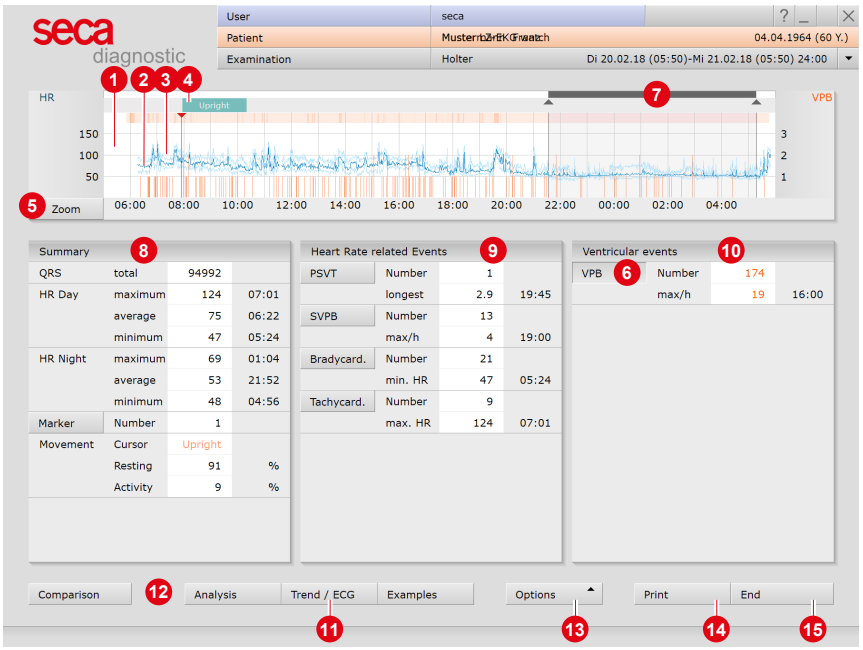


Fig. 25: Holter overview

3.8.2 Analysis

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

Disabled: No compression.

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

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

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

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

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

Fig. 26: Analysis

Beat identification

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

Editing options on the Analysis page

Display and editing levels:

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

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

Selection of several beat classes for further processing:

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

Combine or move several classes

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

Combining or moving single classes

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

Moving single complexes of a beat class

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

Applying changes

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

3.8.3 Trend/ECG

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

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

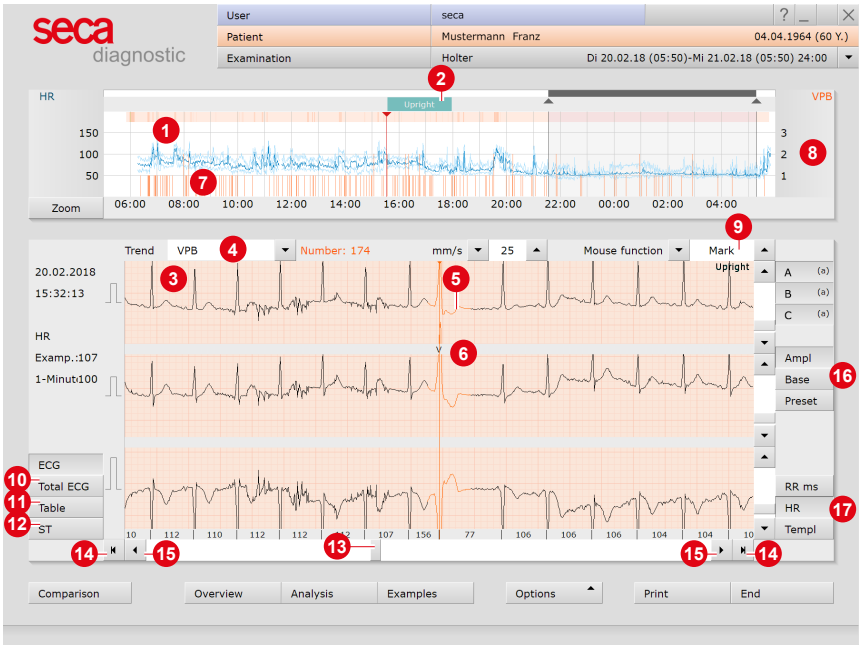


Fig. 27: Trend/ECG

3.8.4 Examples

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

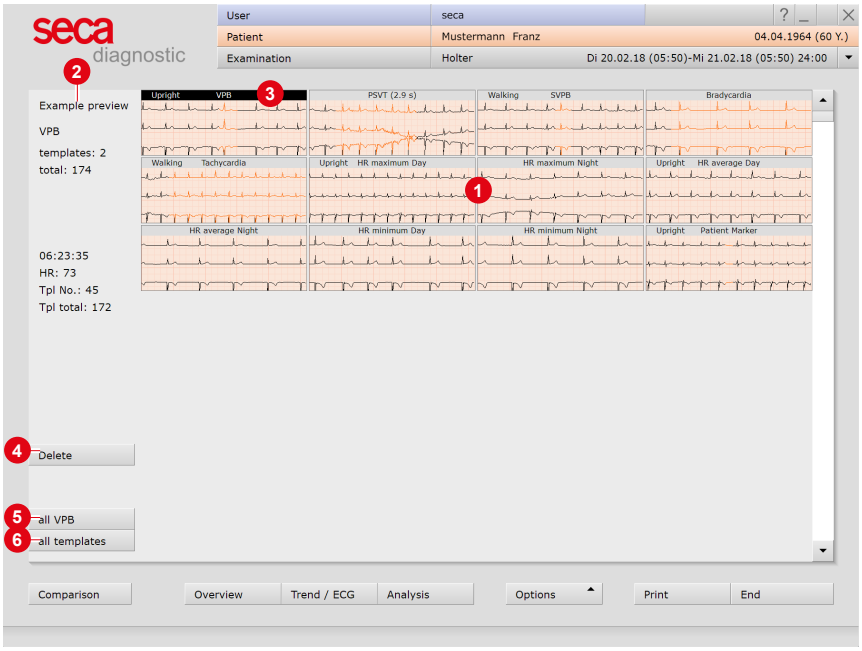


Fig. 28: Example preview

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

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

Considering ECG examples in context

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

Changing the allocation of examples

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

3.8.5 Further standard functions

Comparison

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

Fig. 29: Comparison

Total ECG

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

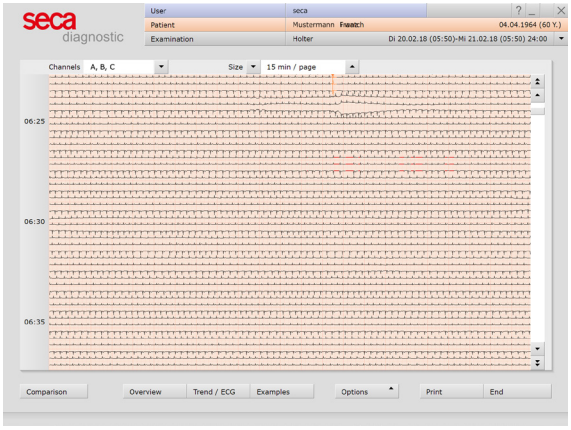


Fig. 30: Total ECG

Trend overview

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

Fig. 31: Trend overview

multiday evaluations

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

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

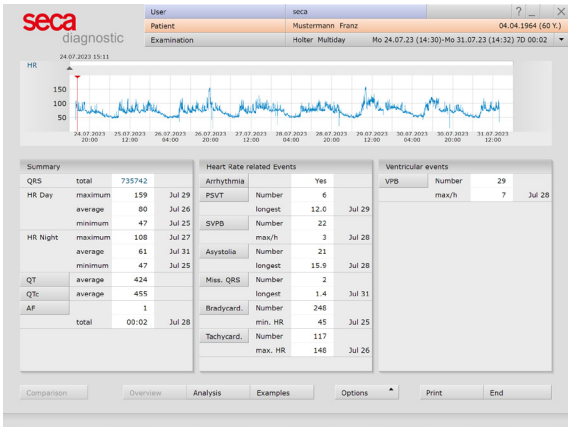


Fig. 32: multiday summary

Holter-ABPM evaluation

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

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

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

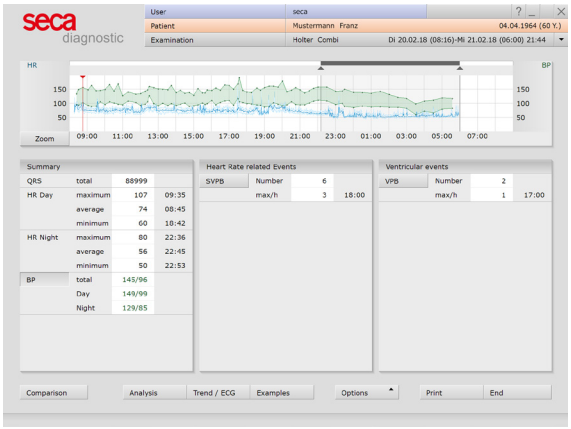


Fig. 33: Holter-ABDM evaluation

3.8.6 Optional functions

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

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

ANS diagnostics (Options menu, ANS diagnostics)

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

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

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

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

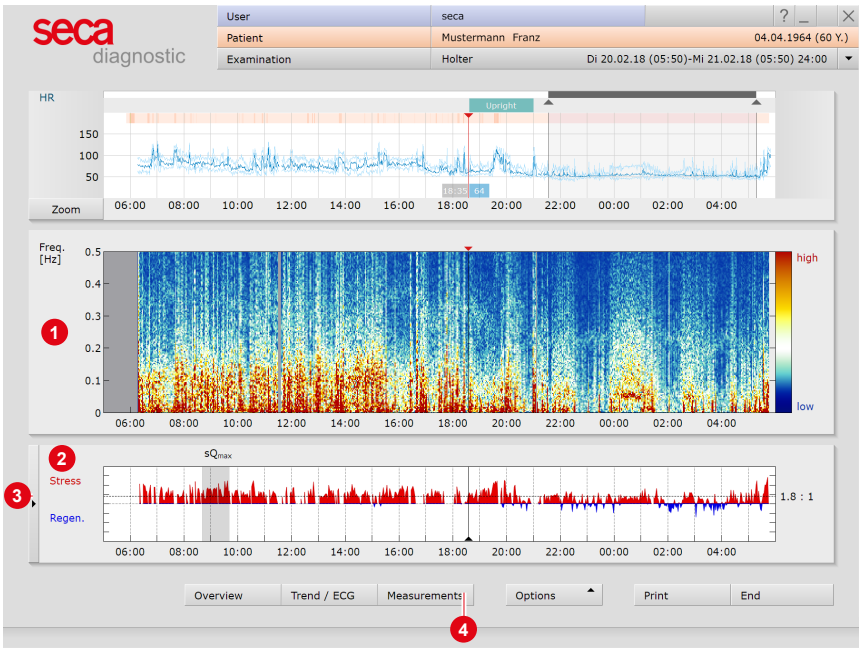


Fig. 34: ANS diagnostics

3.9 Printing the evaluation

Alternative ways to create a printout:

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

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

Options menu, Print... screen

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

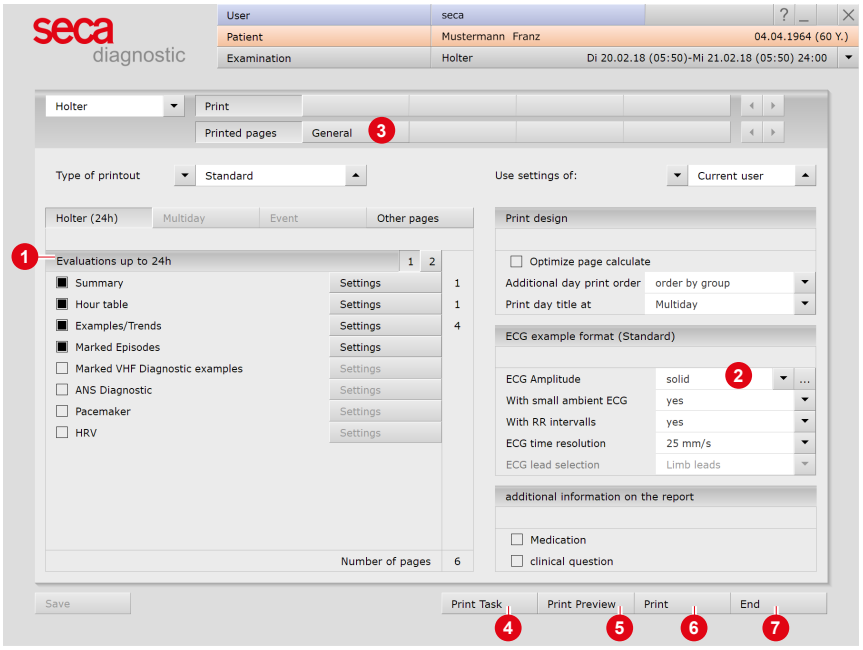


Fig. 35: Print... screen

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

3.10 Confirming the evaluation

Unconfirmed report and report

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

Text modules – an aid for writing reports

On the Examination, Holter, Settings, Diagnostic, Reports screen page, text modules can be created for confirming an evaluation 3. A total of four groups 4 with up to eight text modules 5 can be created. The text modules are called up in the unconfirmed report dialogue via the keyboard (F5 to F12) 6.

A text module can be composed of normal text and variables. Instead of a variable, the actual value from the evaluation is inserted into the report text when using a text module in the report text. The structure of a variable is {VARIABLE}. Via the button Shortcuts for export values 7 you receive a list with all variables. If the text modules are to be displayed in the unconfirmed report dialogue, 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 automatically displayed in each unconfirmed report 10. The text can be changed later in the unconfirmed report dialogue. Save your entries.

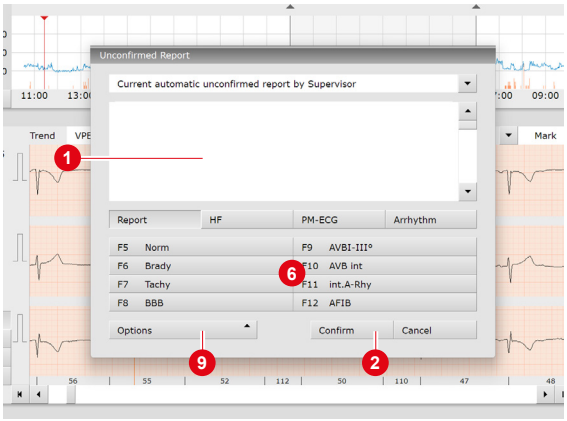


Fig. 36: Unconfirmed report

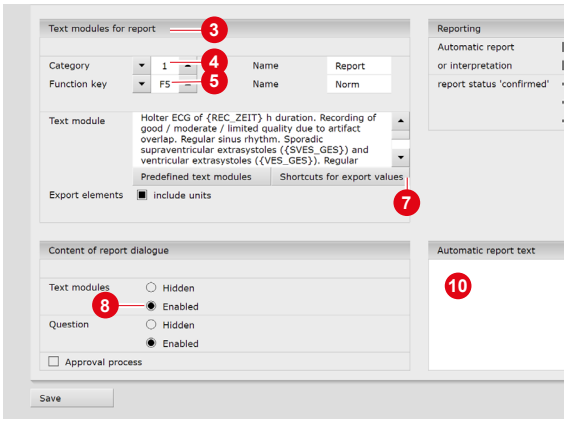


Fig. 37: Text modules

3.11 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.

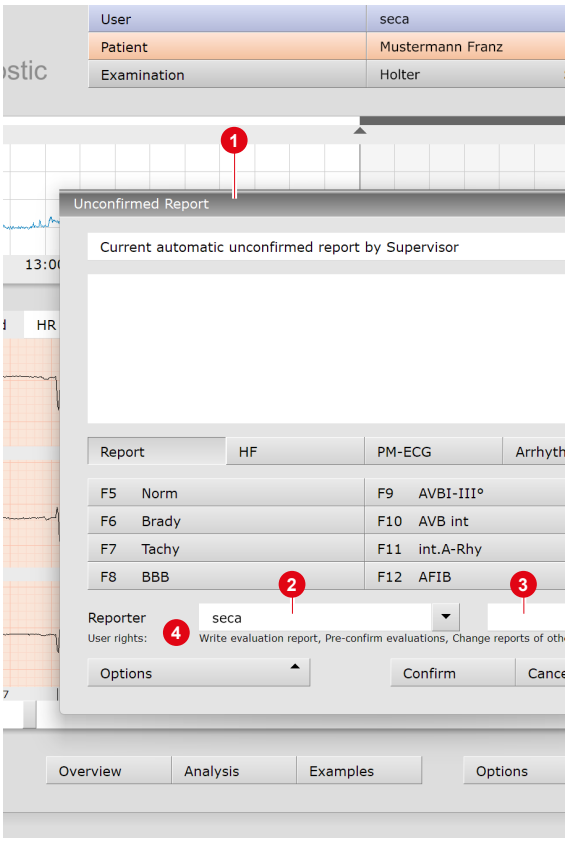


Fig. 38: Unconfirmed report dialogue with approval process

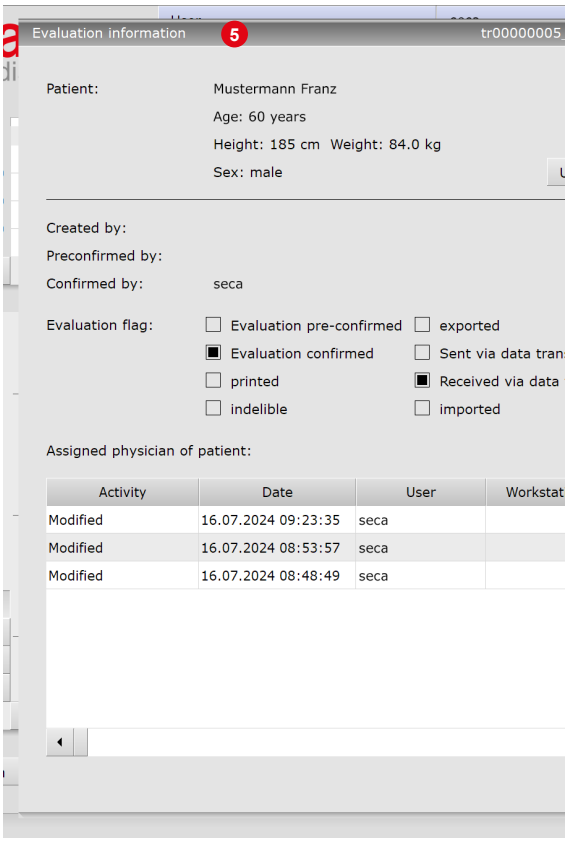


Fig. 39: Evaluation information

3.12 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.

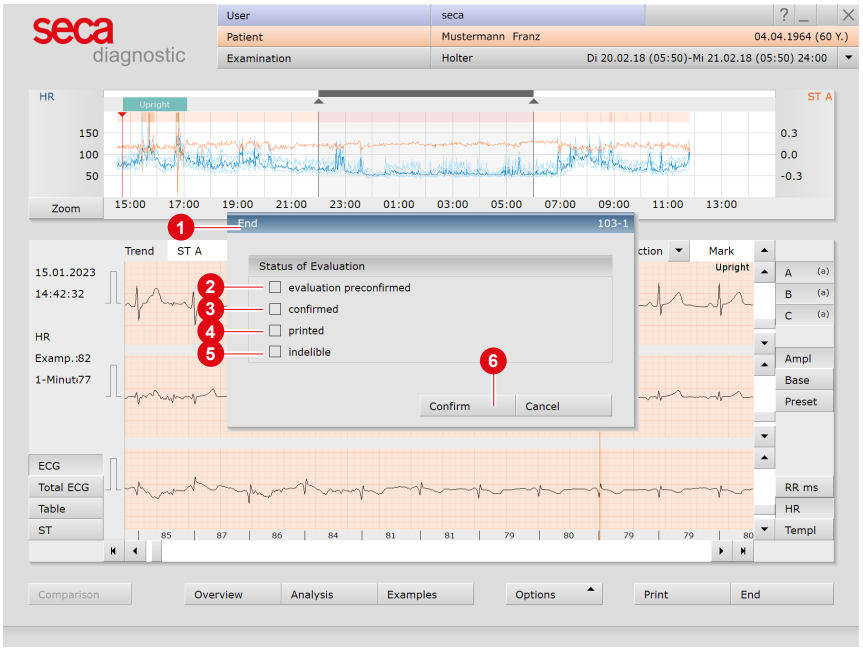


Fig. 40: End dialogue

4 Hygiene

4.1 Important notes

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

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

Contacts must not be soiled or damaged.

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

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

4.2 Hygienic reprocessing

seca guard holter, custo wing adaptor, ECG cable guard 4

→ Reprocessing type: wipe disinfection

IMPORTANT: Do not store moist ECG transmitters in the charging and communication unit. Only place dry devices in the charging and communication unit!

Neck strap (for ECG cable guard 4)

→ Reprocessing type: disinfectant washing in the washing net

custo guard base charging and communication unit

→ Reprocessing type: Wipe down the dry device with a soft, lint-free cloth

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 Calculation methods in the Holter

Beat identification

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

Method for calculating the heart rate

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

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

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

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

Method for determining a heart action break

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

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

5.2 Keyboard navigation and shortcuts

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

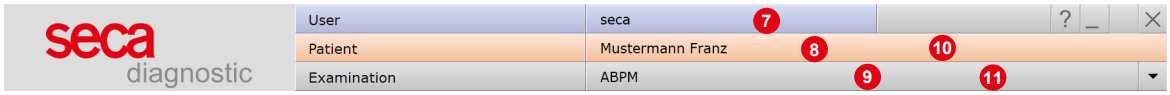
Quick links in the main navigation

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
Shortcuts in screen analysis	
W	Skip normal beats forwards
Shift W	Skip normal beats backwards
Shift D	Skip normal beats forwards in increments of 10
Shift A	Skip normal beats backwards in increments of 10
Shift C	Skip VES/Artefact/Pacemaker forwards in increments of 10
Shift Y	Skip VES/Artefact/Pacemaker backwards in increments of 10
N	Selected beat classes are converted to (N) Normal Beat
V	Selected beat classes are converted to (V) VES
A	Selected beat classes are converted to (A) Artefact
P	Selected beat classes are converted to (P) Pacemaker
Space bar	Pressing the space bar changes the selected beat classes to N / A / V / P
Esc	Current selection is cancelled
Enter	Changes are applied, a new analysis of the ECG is started
Arrow key right	Scroll ECG forwards
Arrow key left	Scroll ECG backwards
F2	Marking dialogue

Shortcuts in the Trend screen	
left/right	Jump to next or previous occurrence of selected event
F2	Marking dialogue
N	With mouse function Change: next beat besides the cursor is changed to normal beat
V	With mouse function Change: The next beat besides the cursor is changed to VES

Shortcuts in the Sample Preview screen	
Arrow keys	Move inside the examples
Itm1	Selection cursor jumps to first example
End	Selection cursor jumps to last example

Shortcuts in the Sample Preview screen	
Page up	scroll up one page
Page down	scroll down one page
Enter	Opens all examples from the selected event
F2	Set marking, pressing again will remove the marking
F3	Deletes all examples of the selected event
Del	Deletes the top (currently displayed) example of the event. If there is no more example of the event, the event will be deleted.

Shortcuts in the Total ECG screen	
Shift arrow up	Scroll ECG up/down by lines
Shift Arrow down	Scroll ECG up/down by lines
Ctrl Arrow up	Scroll ECG up/down by pages
Ctrl Arrow down	Scroll ECG up/down by pages
Arrow up	Scroll ECG up/down for the duration of the key press
Arrow down	Scroll ECG up/down for the duration of the key press
Page up/Page down	ECG automatically scrolls up or down, repeated pressing increases speed. Pressing the “opposite direction” decreases the speed
Blank	Starts/stops automatic scrolling
F2	Marking dialogue

5.3 Manufacturer’s declaration regarding EMC

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

Lead lengths

ECG cable guard 4:	approx. 175 mm

Manufacturer's declaration – electromagnetic emissions

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

Manufacturer’s declaration – electromagnetic immunity

seca guard holter 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	Not applicable
Surges line against line	IEC 61000-4-5	Not applicable
Surges line against earth	IEC 61000-4-5	Not applicable
Conducted disturbances, induced by high-frequency fields	IEC 61000-4-6	Not applicable
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

Recommended protective distances between portable and mobile RF telecommunication devices and seca guard holter

seca guard holter 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 guard holter 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 guard holter 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 guard holter, holter device	10256	1

Description	Accessories	Part no.	Quantity/pc.
Adapter for custo wing electrodes	custo wing adaptor	40008	1 pair
Single-use adhesive electrodes	custo wing	40009	40 pieces
	ECG cable guard 4	10252	1

Description	Complementary parts	Part no.	Quantity/pc.
	Neck strap for ECG cable guard 4	55551	1
	custo guard base 1, 1-device docking station	10123	1
	micro-USB cable 2.0, A plug 1.5 m	16021	1
	custo guard base 6, 6-device docking station	10124	1
	mini-USB cable 2.0, USB A - mini B	16041	1
	USB 3.0 cable, USB C connector	16042	1
	USB universal power supply unit	12223	1
	LM506 Bluetooth 4.0 USB adapter	55050	1
	USB extension cable 1.8m, plug A-socket A	16018	1
	custo clean WA, hygienic bags for seca guard holter with custo wing adaptor	40011	50 pieces
	custo clean CA4, hygienic bags for seca guard holter with ECG cable guard 4	40016	50 pieces

All parts listed here are available separately.

We recommend the following:

- → seca guard holter
- → custo guard base 1
- → micro-USB cable 2.0
- → custo wing adaptor
- → custo wing single-use adhesive electrodes
- → ECG cable guard 4
- → Neck strap for ECG cable guard 4
- → Bluetooth 4.0 USB adapter
- → USB extension cable

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 guard holter (holter 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 guard holter (holter ECG device)
seca diagnostic (medical PC software)

GEB-0220 DK-2307 Version 0012024/08/06

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