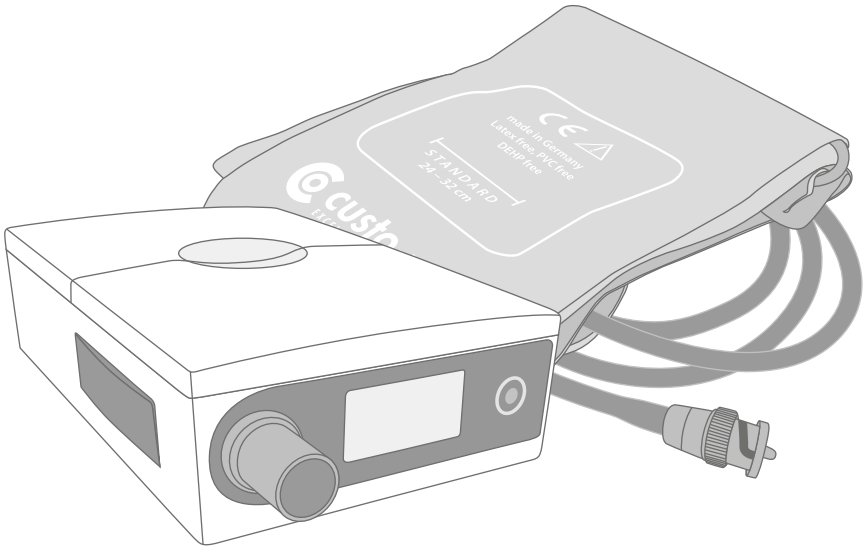
Instructions for Use

ABPM with seca screen 300 and seca diagnostic 5.9



seca
Precision for health

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custo diagnostic (medical PC software)

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seca product names:
seca screen 300 (ABPM device)
seca diagnostic (medical PC software)

seca®
Precision for health

Table of Contents

1 Safety

1.1 General notes

1.1.1 Symbols used in this Operating Manual

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

1.1.2 Laws and regulations applicable to the product

INFORMATION:

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

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

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

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

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

1.1.3 Disclaimer

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

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

1.1.4 Warranty

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

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

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

1.1.5 Support

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

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

1.2 Safety installations and safe working

1.2.1 Putting into operation, setup

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

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

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

1.2.2 Ambient conditions, handling of the devices

Emissions

The seca screen 300 device/system is not suitable for use in rooms or areas with a risk of explosion.

For installation and operation of the seca screen 300 device/system, the EMC (electromagnetic compatibility) instructions in this manual must be observed.

Strong electromagnetic sources in the immediate vicinity of the seca screen 300 device/system may result in recording errors. The seca screen 300 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 screen 300 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

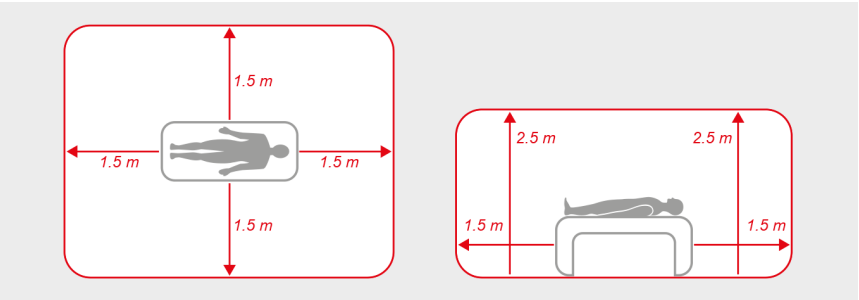


Fig. 1: Safety distances at the patient area

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.

1.2.7 Metrological check (MTK)

With seca screen 300, a metrological check must be performed every two years. Please contact seca.

1.3 Safety instructions for ABPM

The device must be protected from dust and liquids.

Continuous cuff pressure, e.g. exerted by a kinked cuff tube, can cause patient injuries. If the cuff pressure is continuous, the patient should open the cuff's hook and loop fastener and contact his/her medical practice.

In patients with severe blood coagulation disorders, the cuff may cause hematomas. The decision for or against automatic blood pressure measurement should be carefully considered for such patients.

Make sure that the cuff tube does not become crushed or that the cross-section of the cuff tube is not reduced.

The cuff must not be applied to wounds, open or newly operated areas. If the patient suffers from conditions such as arterial occlusive disease or severe blood coagulation disorders, the physician has to decide whether the device should be used or not.

A too loosely applied cuff leads to incorrect measurement results. A cuff that is too tight can lead to vein blockage. It may also cause contusions of the skin and bruising. If the patient is not feeling well, the patient should consult his/her medical practice.

Make sure that the patient does not suffer any long-term adverse effects as a result of the short-term interruption of the blood circulation as required by the measurement method. Such measurements should not be conducted too often.

When conducting blood pressure measurements, the function of additional medical devices which are used in the vicinity of the blood pressure cuff on the patient may be affected.

The following factors can have an effect on the results of a blood pressure measurement: the patient's posture (whether the patient is lying down, standing or sitting), movement, the patient's physical condition, heart rate-related or ventricular events, as well as extreme temperatures and air humidity. Observe the operating conditions and the patient instructions.

The device is not protected against the potential effects of high-frequency (HF) surgical equipment.

The system is not suitable for unsupervised use with unconscious patients.

Never use damaged batteries or rechargeable batteries. If seca screen 300 is not to be used for a prolonged period of time, remove the batteries.

If liquid has been spilled on the device, the batteries or rechargeable batteries must be removed immediately and the device sent to seca for inspection.

1.4 Residual risks ABPM

DANGER

Choking hazard due to small parts

→ Keep small parts away from children.

DANGER

Risk of strangulation due to cuff tube and carrying strap.

→ Do not leave small children unattended during recording.

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

2 Hardware

2.1 Intended use

seca screen 300 is an ABPM recorder with an internal power supply which is used to record and evaluate the blood pressure behaviour of a patient (from age of 10 years on). The recording time can last for up to 72 hours.

The system is perfectly safe for use by patients with a pacemaker.

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 device is not suitable for unsupervised use with unconscious patients

1) Definition according to DIN EN 80601-2-30:2016-02: newborns < 1 month, toddlers < 3 years, children > 3 years.

“pediatric” operating mode for children between 3 and 12 years

seca screen 300 devices with the article number 58025 can be used in “pediatric” mode from seca diagnostic 5.9 onwards. When starting a long-term blood pressure recording, seca diagnostic uses the patient data to check whether the patient is a child between the ages of 3 and 12. If this is the case, seca diagnostic offers the “pediatric” operating mode. With the “pediatric” operating mode, the pediatric cuff (arm circumference 14 - 20 cm) can also be used and the blood pressure cuff is inflated less strongly during recording (max. 200 mmHg).

Blood pressure cuffs suitable for the “pediatric” operating mode: cuff wrap pediatric, cuff wrap small, cuff D-Ring standard. The use of larger blood pressure cuffs is not permitted in “pediatric” operating mode.

INFORMATION:

The “pediatric” (PED) operating mode is intended for use with children[1)]. The “pediatric” (PED) operating mode is NOT suitable for toddlers and newborns (minimum age: 3 years).

IMPORTANT:

Before an examination can be carried out on a child patient, a physician's approval must be obtained and one of the parents must have received detailed instruction by trained specialist staff. The device must not be used for recordings on child patients who are not able to endure the examination.

2.1.1 Indications and contraindications

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

ABPM indications

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

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

Specific indications for ambulatory blood pressure recording:

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

Ambulatory blood pressure contraindications and relative contraindications

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

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

2.1.2 Recorder functions and software options

1) For Holter ABPM recordings, a seca Holter ECG device and seca Holter ECG software are also required, see the operating manuals for Holter ECG.

	seca screen 300	
Recorder functions	**“adult” (ADU) mode ≥ 10 years**	**“pediatric” (PED) mode 3 to ≤ 12 years**
Recording, max. 72 h	✓	✓
Holter ABPM recording, max. 24 h	✓	✓
Software options		
Risk stratification (≥ 16 years)	✓	–
Phenotypes (≥ 18 years)	✓	–

INFORMATION:

seca screen 300 can be operated either in “adult” mode for adults or in “pediatric” mode for children. When starting a recording, seca diagnostic uses the patient data to detect whether the patient is an adult or a child. For children between 3 and 12 years of age, seca diagnostic suggests the “pediatric” operating mode. In all other cases, recording is started in “adult” operating mode.

2.2 Symbols on the devices and packaging

	Manufacturer: custo med GmbH, Maria-Merian-Str. 6, 85521 Ottobrunn, Germany
distributed by seca	Distributor: seca Ltd., 40 Barn Street, Birmingham, West Midlands, B5 5QB, UK
	Date of manufacture (YYYY-MM, e.g., 2022-01)
MD	Medical device
UDI	Unique Device Identifier
SN	Serial number
REF	Order number/designation
CE 0123	CE mark
	Safety class classification of medical electrical equipment according to DIN EN 60601-1 (Type BF)
	The device is suitable for children aged ten and older (not for new-borns and small children).
	The sticker specifies the date when the next metrological check is due. Please contact seca.
	Follow the Operating Manual!
	Observe accompanying documents.
IP22	Protection class of electrical equipment. Protected against solid foreign bodies, 12.5 mm diameter and larger. Protected against dripping water when the enclosure is tilted up to 15°.
	Separate collection of electrical and electronic equipment, do not dispose with domestic waste.

2.3 Technical data and system requirements

1) Meets the requirements of the ESH International Protocol 2010

seca screen 300 during operating mode "adult" (ADU)	
Measurement method	Oscillometric measuring method, automatic zero adjustment
Measurement range	Heart rate 35 - 220 beats / min Systolic blood pressure 70 - 270 mmHg Diastolic blood pressure 40 - 155 mmHg
Measurement accuracy [mmHg][1)]	Mean deviation: SYS -0.5 / DIA -0.1 / MAD --- Standard deviation: SYS 4.5 / DIA 3.3 / MAD ---
Max. number of measurements	500
Max. recording time	72 hours
Duration of one measurement	approx. 30 seconds
Measuring intervals	Adjustable in the software, between 5 and 90 minutes. Standard: every 15 minutes during the day, every 30 minutes at night.
Acoustic signals	The recorder announces measurements during the day phase with a beep. The beep emitted during the day phase can be switched off if required. During the night phase, no acoustic signals are emitted.
Cuff pressure	max. 300 mmHg
Cuff sizes	Cuff D-Ring standard (24 – 32 cm) Cuff D-ring x-large (32 – 40 cm) Cuff D-ring xx-large (38 – 50 cm) Cuff wrap small, child (20 – 24 cm)
Data transmission	Infrared interface with USB port (IrDA standard) Bluetooth Low Energy (BLE) 5.1
Power supply	3 Mignon 1.5 Volt, type AA 3 rechargeable batteries, Ni-MH, 1.2 Volt, min. 1500 mAh
Operating life	Recorder: 5 years Blood pressure cuff: 2 years
Operating conditions	Temperature +10°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
Dimensions	Size approx. 100 * 66 * 26 mm (L * W * H) Weight approx. 159 g (without batteries)
Classification	Device with internal power supply, type BF, class IIa
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, EN 60601-1-6, DIN EN 62304, DIN EN 62366-1, DIN EN ISO 10993-1 DIN EN IEC 80601-2-30, DIN 60601-1-11, ISO 10993-5, DIN EN ISO 10993-10

1) Meets the requirements of the ESH International Protocol 2010

seca screen 300 during operating mode “pediatric” (PED)	
Measurement method	Oscillometric measuring method, automatic zero adjustment
Measurement range	Heart rate 35 - 220 beats / min Systolic blood pressure 50 - 160 mmHg Diastolic blood pressure 30 - 110 mmHg
Measurement accuracy [mmHg][1)]	Mean deviation: SYS -1,4 / DIA -0,7 / MAD --- Standard deviation: SYS 3 / DIA 3,2 / MAD ---
Max. number of measurements	500
Max. recording time	72 hours
Duration of one measurement	approx. 30 seconds
Measuring intervals	Adjustable in the software, between 5 and 90 minutes. Standard: every 15 minutes during the day, every 30 minutes at night.
Acoustic signals	The recorder announces measurements during the day phase with a beep. The beep emitted during the day phase can be switched off if required. During the night phase, no acoustic signals are emitted.
Cuff pressure	max. 200 mmHg
Cuff sizes	Cuff wrap pediatric (14 – 20 cm) Cuff wrap small, child (20 – 24 cm) Cuff D-Ring standard (24 – 32 cm)
Data transmission	Infrared interface with USB port (IrDA standard) Bluetooth Low Energy (BLE) 5.1
Power supply	3 Mignon 1.5 Volt, type AA 3 rechargeable batteries, Ni-MH, 1.2 Volt, min. 1500 mAh
Operating life	Recorder: 5 years Blood pressure cuff: 2 years
Operating conditions	Temperature +10°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
Dimensions	Size approx. 100 * 66 * 26 mm (L * W * H) Weight approx. 159 g (without batteries)
Classification	Device with internal power supply, type BF, class IIa
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, EN 60601-1-6, DIN EN 62304, DIN EN 62366-1, DIN EN ISO 10993-1 DIN EN IEC 80601-2-30, DIN 60601-1-11, ISO 10993-5, DIN EN ISO 10993-10

Technical requirements for the operation of seca diagnostic

seca diagnostic SERVER, hardware and operating system

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

seca diagnostic SERVER, minimum requirements

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

seca diagnostic SERVER, recommendations

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

seca diagnostic CLIENT, hardware and operating system

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

seca diagnostic CLIENT, minimum requirements

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

seca diagnostic CLIENT, recommendations

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

Software requirements for the operation of seca diagnostic

seca diagnostic SERVER

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

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

seca diagnostic CLIENT

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

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

2.4 Shutdown, storage, transport, disposal

Shutdown and storage

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

Transport

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

Disposal

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

Symbols for transport, storage and disposal

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

2.5 Components for the recording

Fig. 2: seca screen 300 designation of parts

1. seca screen 300 ABPM recorder
2. Cuff D-Ring standard, other sizes available
3. Carrying case for the ABPM recorder
4. Carrying belt 127 cm, option 96 cm, 155 cm
5. Batteries (set of 3) Mignon 1.5 Volt, type AA
6. Infrared interface custo com IR or optionally custo multi com (infrared interface with SD card reader)
7. USB extension cable 2.0, type B mini, 2.0 m

TIP: *custo screen protect hygiene set, six washable fleece pads – for more hygiene and comfort when wearing the blood pressure cuff. Worn underneath the cuff with the soft side on the skin.*

Fig. 3: custo screen protect

2.6 Device operation

2.6.1 Inserting the batteries or rechargeable batteries

→ Open the battery compartment as shown.
→ Insert three commercially available batteries.
→ The insertion direction is shown on the drawings in the battery compartment.

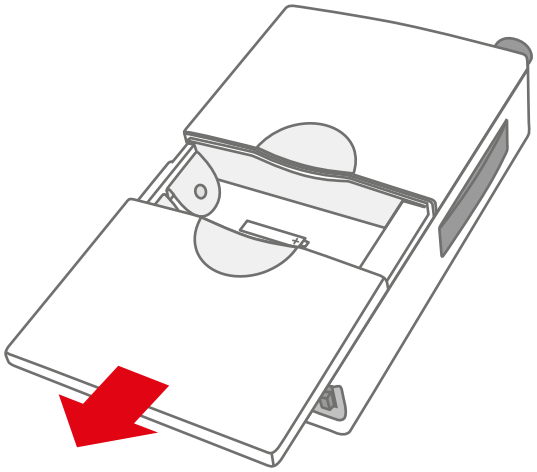


Fig. 4: seca screen 300 Opening the battery compartment

2.6.2 Display and control elements

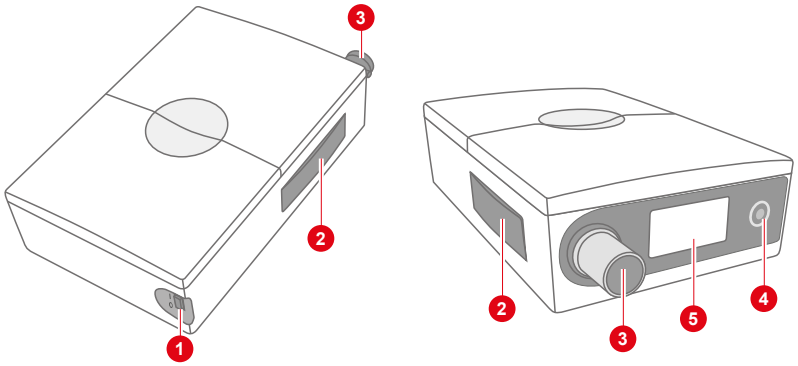


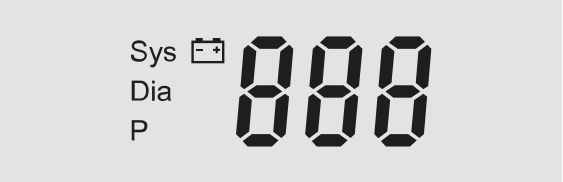
Fig. 5: seca screen 300 display and operating elements

1. On-off switch, I = on, 0 = off
2. Infrared interface (connection to PC)
3. Cuff port (BNC)
4. Function key, for starting and stopping measurements
5. Display, for showing results and messages; blue LED behind the display to indicate the Bluetooth connection

2.6.3 Elements in the display

“adult” (ADU) operating mode, for adults or patients ≥ 10 years.

“pediatric” (PED) operating mode, for children aged 3 to ≤ 12 years.



- → Sys: Systolic blood pressure
- → Dia: Diastolic blood pressure
- → P: Pulse
- → Battery: Lights up if the batteries are weak

If the blood pressure measurement has been carried out successfully systole, diastole and pulse will be displayed three times in succession.

During the data transmission between the recorder and the PC “PC” is shown on the display (the light-emitting diode of the custo com IR infrared interface flashes). When connected via Bluetooth, the display also lights up blue.

In the event of erroneous measurements an error code is shown on the display, e.g. “E06”.

2.6.4 Error codes and causes

Error when reading or writing the time

- → Internal double-layer capacitor (energy storage for the time) discharged
- → Insert batteries, switch device on

Values outside the measurement range

- → Sys: < 70 mmHg > 270 mmHg
- → Dia: < 40 mmHg > 155 mmHg
- → Sys - Dia: < 15 mmHg
- → HR: < 35/min > 220/min
- → Measurement is repeated automatically

Pressure discharge rate outside the given limits

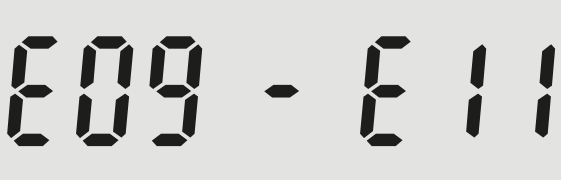
- → Valve leaking or defective
- → Customer service

Disturbed measurement

- → Too many movement artefacts
- → Cuff slipped or not tight enough
- → Attach the cuff carefully and keep the arm steady during the measurement

Battery voltage too low

→ Insert fresh batteries or freshly charged rechargeable batteries into the recorder



Pressure sensors transmit different values

→ Cuff tubing kinked
→ BNC connection dirty
→ One of the pressure sensors is faulty
→ Remove cuff from device, reconnect, repeat procedure
→ If error still occurs, customer service

Pressure increase is too slow

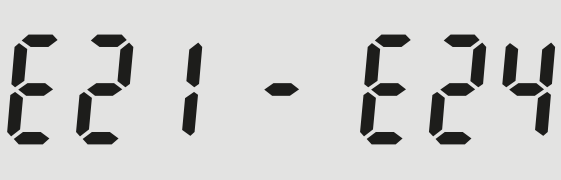
→ Cuff not connected or cuff/valve leaking/defective
→ Connect cuff if necessary
→ Check sleeve (sealing ring)
→ If error still occurs, customer service

Pressure increase is too fast

→ Cuff tube is kinked, valve system is clogged
→ Align the cuff tube
→ If error still occurs, customer service

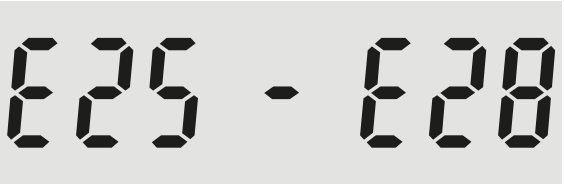
Discharge period is too long

→ Cuff tubing kinked, valve defective
→ Customer service, if several times during a recording



Error when determining diastole

→ Cuff incorrectly fitted
→ Movement artefacts
→ Attach the cuff carefully and keep the arm steady during the measurement



Error when determining systole

→ Cuff incorrectly fitted
→ Movement artefacts
→ Attach the cuff carefully and keep the arm steady during the measurement

In case of an invalid measurement, a repeat measurement is taken after 2 minutes. For errors that are not listed here, switch the device off and on again. Repeat the desired work step. If the error persists, contact seca.

2.7 Procedure of an examination

Prepare the equipment for recording:

- → seca screen 300 with fresh batteries or freshly charged rechargeable batteries
- → Cuff in the appropriate size
- → Optional with custo screen protect fleece pad
- → Carrying bag with belt

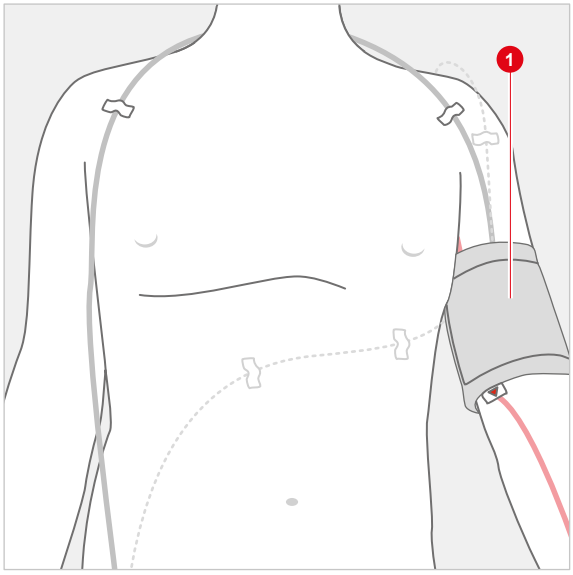
Prepare and start seca screen 300

- → Start seca diagnostic and open the page Examination, ABPM, New ABPM. The recording parameters are set on this screen page, *see 3.3 Performing an ABPM recording, p. 39*.
- → For infrared connection: Place the switched-on recorder in front of the infrared interface.
- → For Bluetooth connection: Switch the seca screen 300 device on.
- → Press Start to transfer the recording parameters to the recorder. Follow the instructions in seca diagnostic.
- → If the patient is a child between 3 and 12 years of age, you can select whether the device should be started in “pediatric” mode (3 to 12 years) or in “adult” mode (10 years and older).
- → Place the recorder on the patient, *see 2.8 Attaching the recorder to the patient, p. 32*.
- → Carry out a sample measurement (press the function key).
- → Instruct the patient how to use the recorder, *see 2.10 For patients: Handling the device, p. 34*.

After the recording

- → Remove the seca screen 300 device from the patient.
- → For infrared connection: Place the switched-on recorder in front of the infrared interface.
- → For Bluetooth connection: Switch the seca screen 300 device on.
- → Start seca diagnostic and open the page Examination, ABPM, Read in recorder, *see 3.4 Downloading the ABPM recorder, p. 43*.
- → After reading in the recording, remove the batteries or rechargeable batteries.
- → Clean and disinfect the device and the other parts attached to the patient (bag, strap), *see 4.2 Hygienic reprocessing, p. 76*.

2.8 Attaching the recorder to the patient



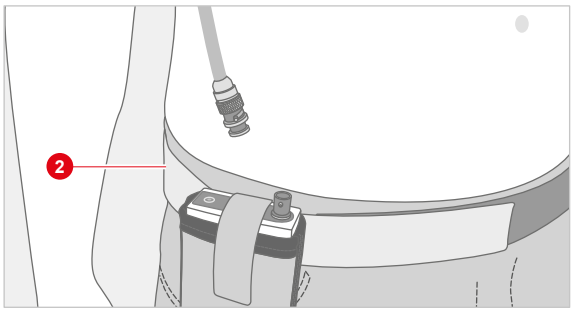
Attaching the blood pressure cuff 1

Make sure to select the correct cuff size for the patient. Each cuff contains information for which arm circumference it is suited, e.g., 24 – 32 cm.

Attach the cuff to the left upper arm, two to three centimetres above the crook of the arm. Apply the cuff in such a way that the marking is situated on the brachial artery. The cuff must not be attached too firmly. It should still be possible to fit approximately two fingers between the arm and the cuff.

Lay the cuff tube from the left shoulder over the right shoulder to the right hip. There the recorder will be placed later.

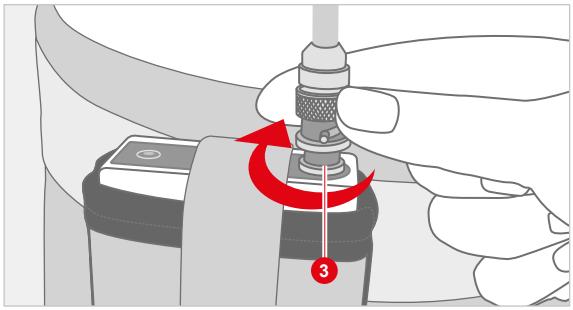
Fix the cuff and the tube to the patient's body. This serves to avoid erroneous measurements due to incorrect positioning of the cuff or tube. Use professional fixing aids with a low level of adhesive residues.



Attaching the belt and the carrying case 2

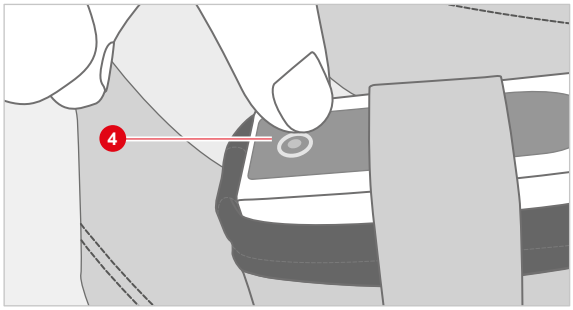
Attach the carrying case to the carrying belt. Put the carrying belt on the patient. The case should be positioned on the patient's right hip.

Put the switched-on recorder into the carrying case and close it with the hook and loop fastener.



Connecting the cuff 3

Connect the cuff tube to the recorder as shown.



Sample measurement 4

Press the function key in order to carry out a sample measurement. Take care that the patient keeps still during the measurement. In the event of an erroneous measurement, improve the fitting of the cuff and the tube. If the sample measurement is successful, patient and recorder are ready for recording.

2.9 For patients: Removing and putting on the device

IMPORTANT: The ABPM recorder must be taken off if you plan to shower or bathe during an ABPM recording lasting several days. Do not get the device wet.

Removing the recorder for showering or bathing

- → If present, remove the adhesive strips securing the cuff tubing.
- → Open the Velcro fastener of the blood pressure cuff.
- → Take off the blood pressure cuff.
- → Open the Velcro fastener of the carrying belt.
- → Remove the carrying belt together with the neoprene bag and recorder.
- → Store the device in a safe and dry place.
- → While the recorder and cuff are off, erroneous measurements will occur. Do not switch off the recorder. Allow the recording to continue.
- → If you keep a recording diary, make a note that the recorder was put down for a short time.

Putting on the recorder after showering or bathing

- → Put the carrying belt on. The carrying belt is put on so that the recorder is on the front right side of your hip.
- → Pass the cuff tube over your abdomen, to your right shoulder, around your neck from behind to your left shoulder.
- → Put your left arm through the blood pressure cuff.
- → Place the blood pressure cuff two finger widths above the crook of your arm.
- → First align the blood pressure cuff so that the red arrow labelled “ARTERIA” is centred above the crook of the arm.
- → Then pull the red arrow with the label “ARTERIA” one finger width to the right, towards the inside of the upper arm.
- → Close the Velcro closure of the blood pressure cuff. Make sure the red arrow “ARTERIA” is oriented correctly.
- → Two fingers should still fit between the cuff and the upper arm. However, the cuff must fit tightly enough to prevent it from slipping during recording.
- → In order to fix the tube of the blood pressure cuff again a tight-fitting undershirt or T-shirt can be worn.

2.10 For patients: Handling the device

Handling of the recorder

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

The switched-on recorder and the cuff must also be worn during the night.

No x-rays may be taken on the day of recording. Sources of interference, such as stimulation current devices, are to be avoided.

Each measurement is announced with a beep (unless this function is deactivated in seca diagnostic). With default settings, measurements are taken every 15 minutes during the day and every 30 minutes at night.

The recorder must be protected against extreme cold, heat, moisture, dirt and mechanical impact. No showers, no visits to the swimming pool or sauna.

The recorder must be protected against moisture and splashing water. Immersion in liquids is prohibited. The recorder must not be used in a shower, bathtub, sauna or similar damp areas.

The patient is not allowed to remove the batteries or rechargeable batteries or modify the device in any way.

Avoiding invalid measurements

The patient must keep still during the measurement.

The cuff tube must not be kinked.

A repeat measurement is automatically performed two minutes after an invalid measurement. If several measurements are invalid (especially E6, E21-24 and E25-28), it should be checked if the cuff is still positioned correctly. The marker should be located on the brachial artery and the cuff should be positioned on the arm so that approximately two fingers fit between the cuff and the arm. Other causes of erroneous measurements, *see 2.6.4 Error codes and causes, p. 28*.

Discomfort during the recording

If the patient experiences discomfort during a recording, e.g. caused by a too high cuff pressure, the patient must contact his/her physician. The patient can stop the measurements at any time by pressing the function key or by opening the cuff's hook and loop fastener. Pregnant women should consider their individual physical endurance and contact their physician, if necessary.

DANGER

Choking hazard due to small parts

→ Keep small parts away from children.

DANGER

Risk of strangulation due to cuff tube and carrying strap.

→ Do not leave small children unattended during recording.

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

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.

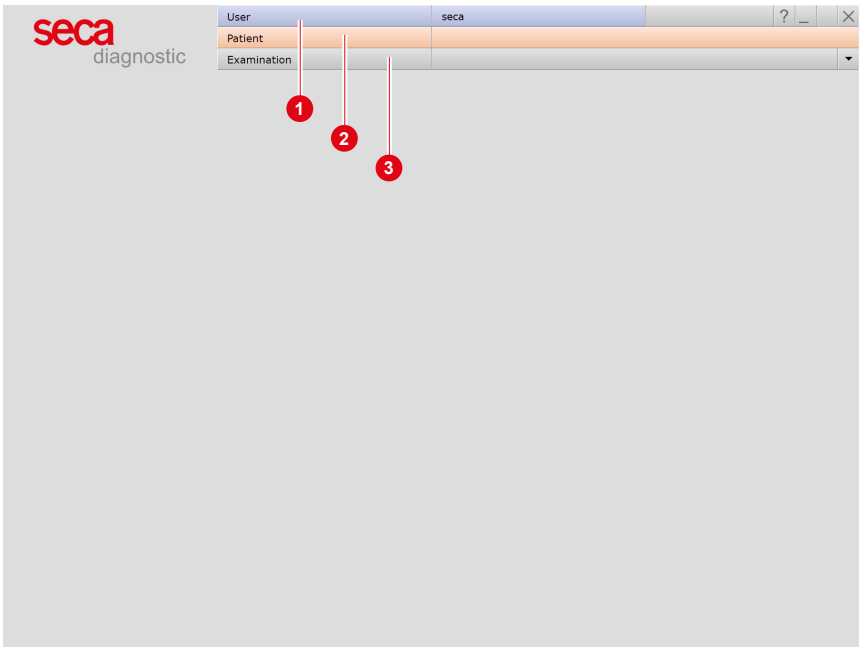


Fig. 6: seca diagnostic main menu

3.2 seca screen 300 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.

Setting up the infrared connection

- → Connect the custo com IR / multi com infrared interface to the PC. The device drivers are installed automatically.
- → Start seca diagnostic.
- → In seca diagnostic, open the page Examination, ABPM, Settings, Device 1, Device connection 2.
- → If the previously connected infrared interface is not displayed in the list, click on Scan 3.
- → Select the infrared interface, e.g. custo com IR COM3 4.
- → Click Save to accept your entries.
- → The infrared interface is ready for operation. seca screen 300 can be connected to the PC via the infrared interface.

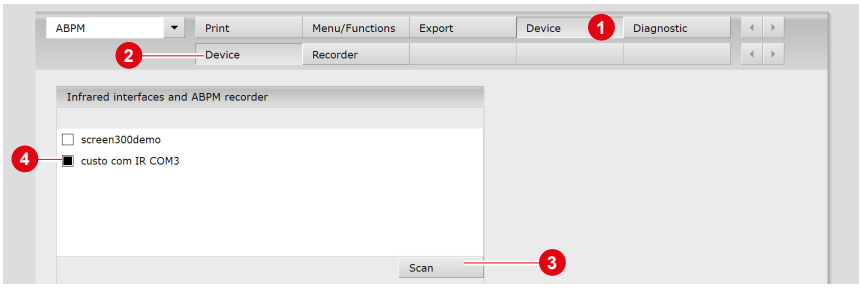


Fig. 7: Selecting a device connection

Setting up the Bluetooth connection

→ Start seca diagnostic.
→ In seca diagnostic, open the page Examination, ABPM, Settings, Device 1, Device connection 2.
→ Switch the seca screen 300 device on (the switch is set to I).
→ Click on Scan in seca diagnostic 3.
→ The device is displayed with the product name, serial number and the note “(Not configured)” 4.
→ Click on Configure Bluetooth Devices 5.
→ In the “Configure BTLE Devices” dialogue box, select the seca screen 300 device that should be connected to the PC via Bluetooth 6.
→ Click on Start 7.
→ Check whether seca screen 300 is switched on.
→ Press the function key of the seca screen 300 device until the message “Configuration successful...” appears in seca diagnostic.
→ Confirm 8 the process.
→ The display lights up blue and shows the message “PC”. seca screen 300 is now connected to the PC and seca diagnostic via Bluetooth.
→ Select the device by activating the corresponding checkbox in the list 9.
→ Click on Save to apply your settings.

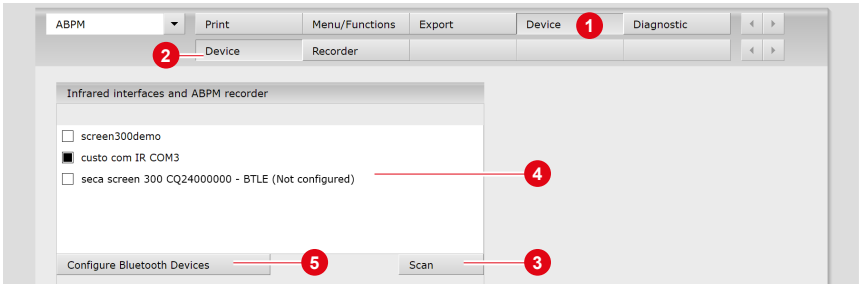


Fig. 8: Searching for Bluetooth devices

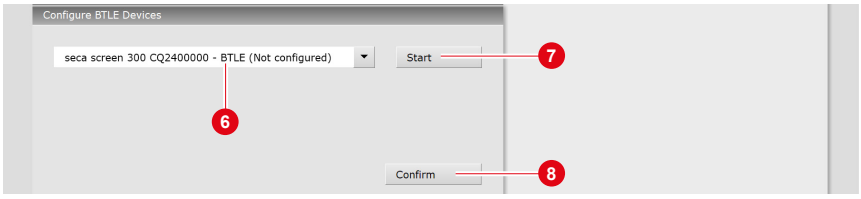


Fig. 9: Configuring the Bluetooth connection

Fig. 10: Selecting a Bluetooth device

3.3 Performing an ABPM recording

Procedure with SystmOne or EMIS Health connection

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

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

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

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

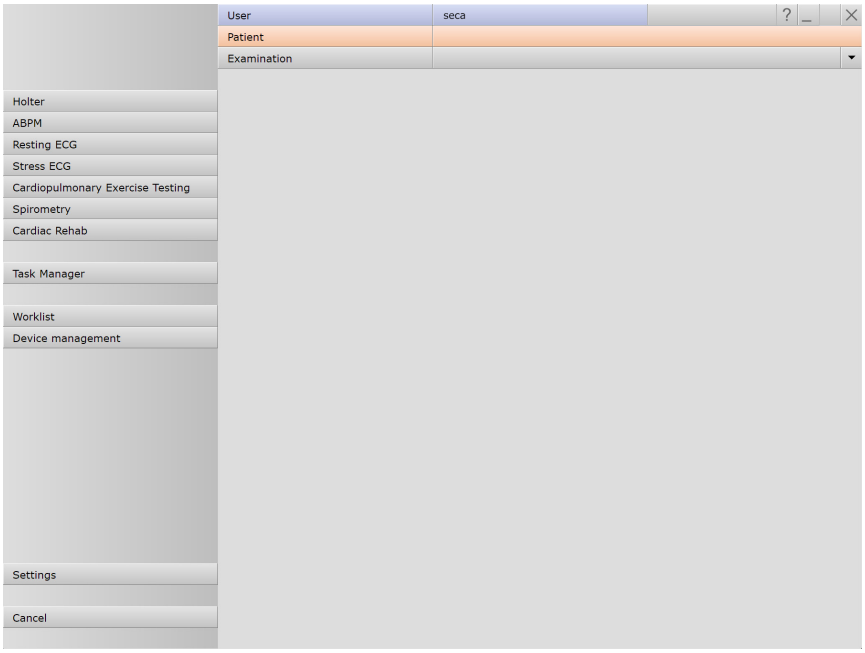


Fig. 11: seca diagnostic examination main menu

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

Program start, calling the ABPM

→ If you want to start the seca screen 300 device via the infrared interface: Make sure that the infrared interface is connected to the PC and ready for operation.
→ Start seca diagnostic and log in.
→ Click on Examination ❶, ABPM ❷, New ABPM ❸.

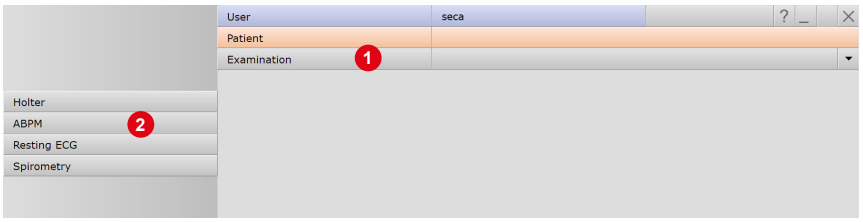


Fig. 12: Main menu Examinations

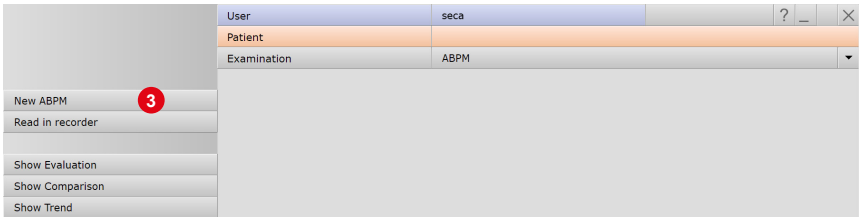


Fig. 13: Main menu ABPM

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

Selecting a patient

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

Creating a new patient

→ If the patient does not yet exist in your database:
Click on New Patient.
→ Enter the patient data. The fields marked with an asterisk are mandatory.
→ Save the data.
→ The patient is entered into the database.
→ After the patient has been selected, the screen for configuring the start parameters is opened.

Setting the start parameters

- → Recorder seca screen (custo screen ...) 1.
- → Set the start parameters for the blood pressure measurements: select previously saved start parameters, such as Standard 2 or create new start parameters. Information on the selected start parameters is displayed below the selection fields 3.
- → Click on Edit 4, to change the selected start parameters. Day, night and additional phases can be set in the right part of the screen 5.
- → In the Repeat measurement area 6, you can select whether a repeat measurement should be performed if the limit values are exceeded or not reached.
- → The options are to be set as required.
  - → Beep 7: A signal is emitted before each measurement so that the patient can prepare himself/herself accordingly.
  - → Display results 8: SYS, DIA, HR are shown on the recorder display after each measurement.
  - → Print diary 9: After clicking on Start, a patient diary will be printed.
- → By selecting Save As 10, start parameters with changed settings can be saved under a new name and made available for further recordings.
- → Save 11 overwrites the original parameters.
- → Optional: Risk stratification 12 (seca diagnostic professional)
- → The recorder can be started.

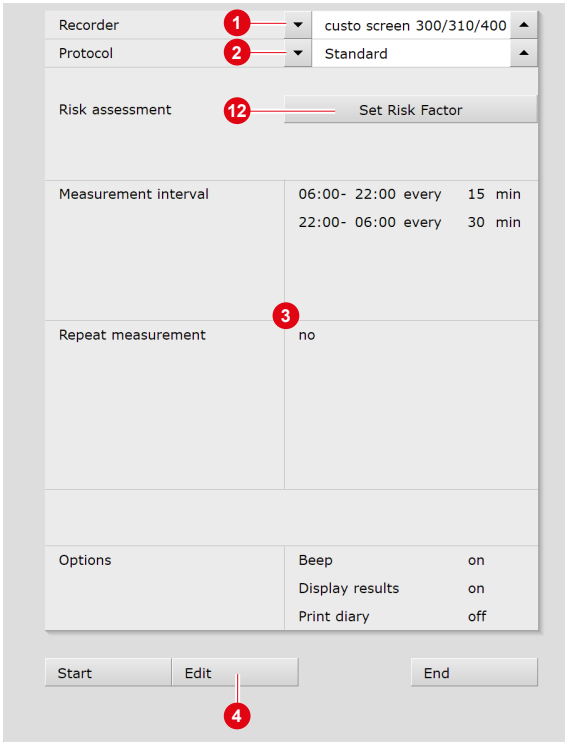


Fig. 14: Recording device and start parameters

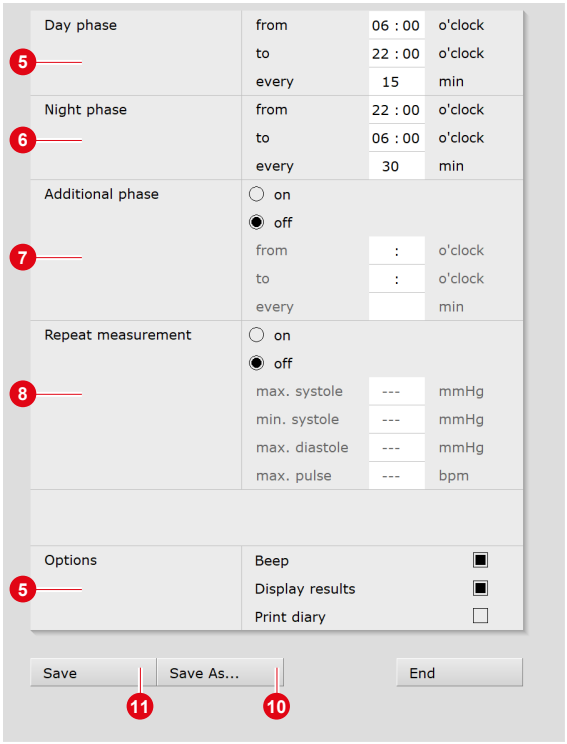


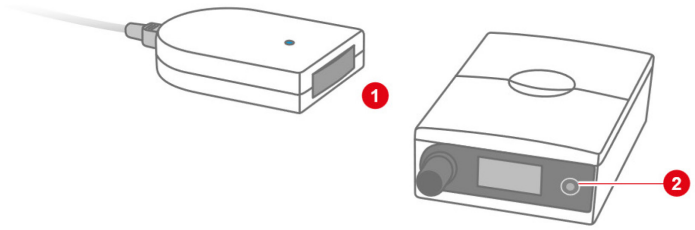
Fig. 15: Changing start parameters

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

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

Data transfer, starting the recording

- → For infrared connection: Place the switched-on recorder in front of the custo com IR / multi com interface so that the two infrared interfaces are opposite each other (approx. 10 – 20 cm) 1.
- → For Bluetooth connection: Switch seca screen 300 on.
- → In seca diagnostic, click on Start (bottom left).
- → Confirm the data in the “Patient data entry” dialogue.
- → In the “Select device” dialogue, select which device is to be used for data transfer. Confirm the selection.
- → For infrared connection: If more than 55 seconds elapse between switching on the recorder and clicking on Start, data transmission is no longer possible as the recorder is in sleep mode. To activate the recorder, press function key 2.
- → If “PC” appears on the display of the recorder, the device is in data transfer mode. When connected via Bluetooth, the display also lights up blue.
- → If the patient is a child between 3 and 12 years of age, you can select whether the device should be started in “pediatric” mode (3 to 12 years) or in “adult” mode (10 years and older)[1)]. Confirm the selection.
- → The data is transferred to the device 3.
- → Attach the recorder to the patient.
- → Carry out a sample measurement (press the function key).
- → Instruct patients on how to use the recorder.
- → The patient and the recorder are ready for recording.



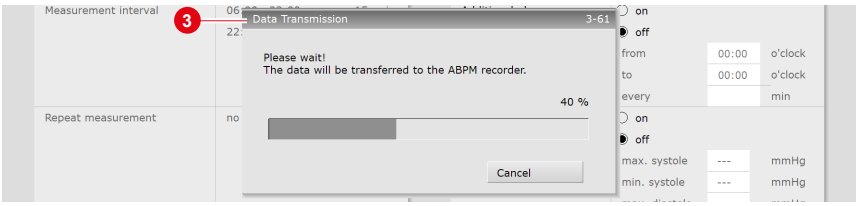


Fig. 16: Data transmission during start

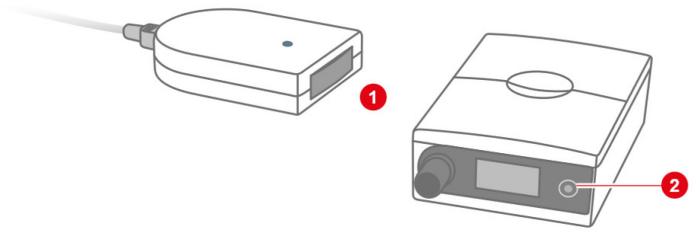
3.4 Downloading the ABPM recorder

Remove the recorder from the patient:

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

Reading in a recording via the infrared connection

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



Reading in a recording via the Bluetooth connection

→ Start seca diagnostic and log in.
→ Switch seca screen 300 on, click on Examination, ABPM, Read in recorder.
→ If more than one interface has been configured for data transfer: In the “Select device” dialogue, select which device is to be used for data transfer. Confirm the selection.
→ The dialogue box for data transfer is displayed.
→ If “PC” appears on the display of the recorder, the device is in data transfer mode. When connected via Bluetooth, the display also lights up blue.
→ The recording is downloaded and displayed as an evaluation.

Evaluation overview, incoming control and printout

→ After reading in the data, the evaluation overview is displayed automatically. The standard overview contains the heart rate trend ❶ and blood pressure trend ❷ as well as a table with the most important measured values ❸.

→ If additional software options are used, further evaluation views are possible: e.g. risk stratification or phenotypes.

→ The red cursor ❹ can be used to select specific points in the trends. The measured values at the cursor position are displayed in the “Current” ❺ area.

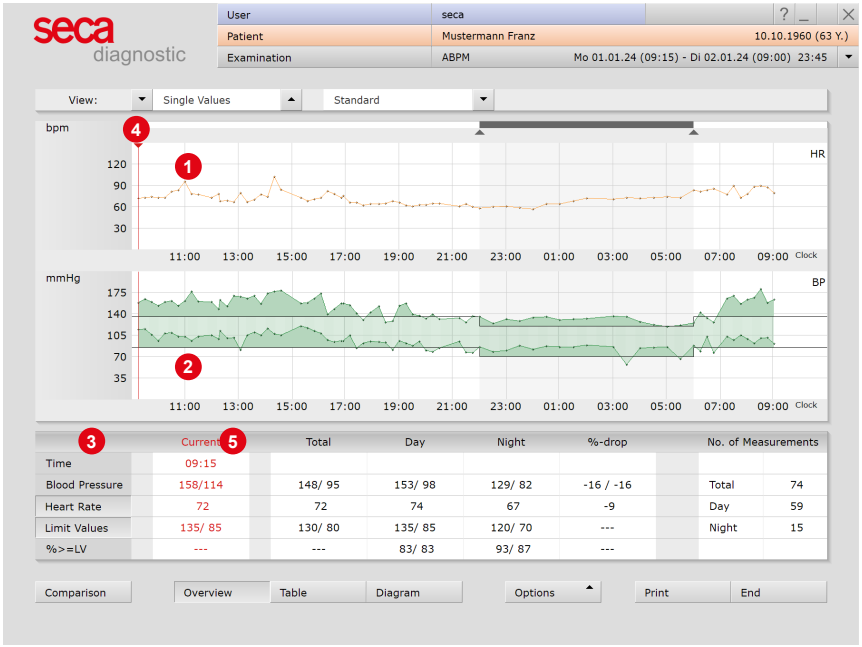


Fig. 17: Overview, Standard

Checking the quality of the recording

Open the detailed measured values table by clicking on Table ❶. The percentage of successfully performed and thus valid measurements is shown there ❷. To check the causes of faulty measurements, click on Options ❸, Erroneous meas. ❹. The error codes for the invalid measurements are displayed on this screen page.

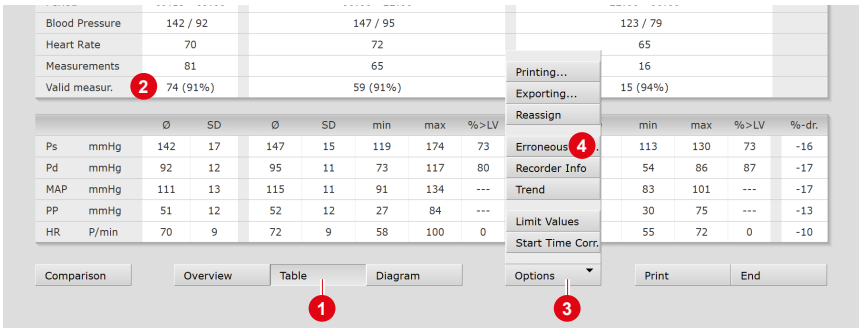


Fig. 18: Checking valid measurements and erroneous measurements

Printing the evaluation

Click on Print to print the evaluation according to the system settings. The print settings for ABPM evaluations are located on the screen page Examination, ABPM, Settings, Print, Printed pages. If the open evaluation is not to be printed according to the system settings, the contents of the print pages for the current printout can be changed. To do this, open the print menu in the evaluation via Options, Printing.... Changes in the print menu of the evaluation are not transferred to the system settings and only apply to the current printout.

Ending the evaluation

The End button (bottom right) closes the evaluation. Confirm the End dialogue box to exit the evaluation.

Preparation for the next examination

Clean and disinfect the recorder and accessories, *see 4.2 Hygienic reprocessing, p. 76*. Remove the batteries or rechargeable batteries from the recorder. Fully charge the rechargeable batteries.

3.5 Opening evaluations

3.5.1 Opening an evaluation via the evaluation search

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

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

Configuring the list of search results

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

Renaming filter sets, deleting filter sets

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

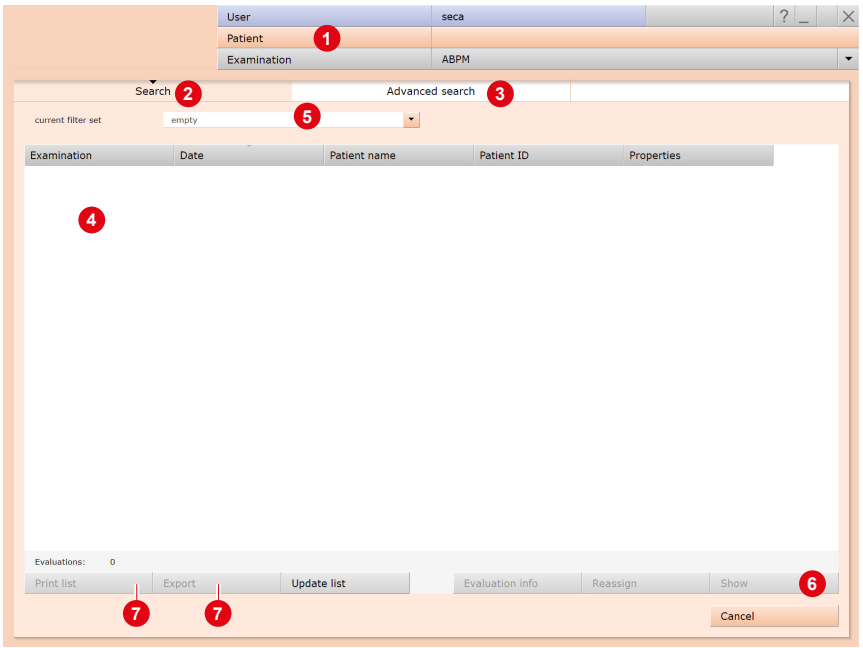


Fig. 19: Evaluation search, search with filter sets

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.

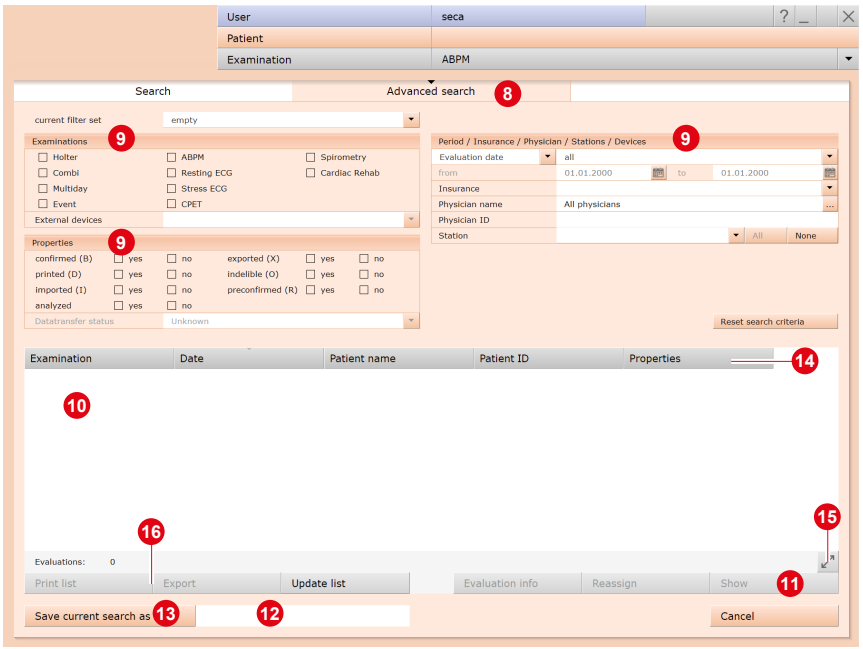


Fig. 20: Evaluation search, extended search

3.5.2 Opening an evaluation via the evaluation menu

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

→ Open the examination main menu via Examination, ABPM.
→ Click on Show evaluation 1.
→ The patient search screen appears. Select the patient whose evaluation you would like to open. Enter the name of the patient in the input fields of the search screen 2.
→ Select the patient from the list below the input fields 3 and confirm the selection with the Select patient button 4 or by double-clicking on the name.
→ A list with all of the patient's evaluations is then displayed. Select the desired evaluation from the list and open it with a double-click or via the Show Evaluation button.

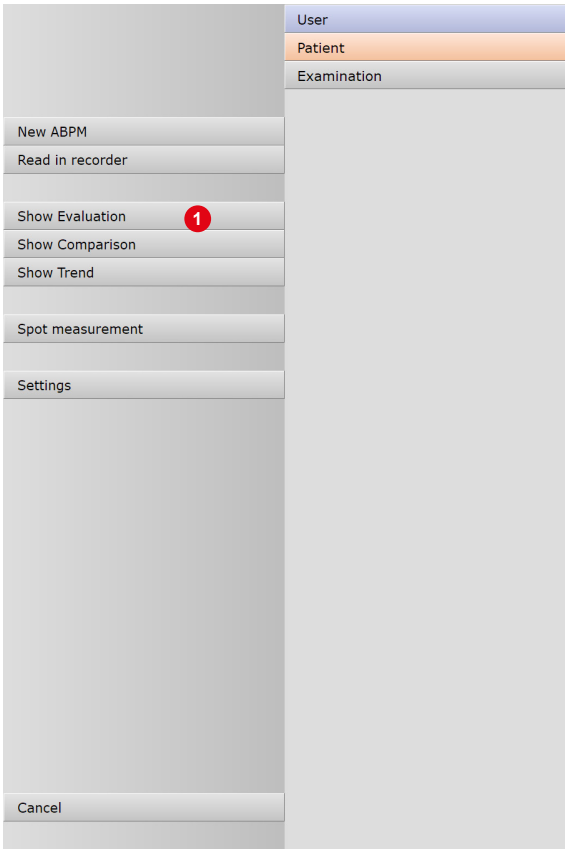


Fig. 21: ABPM main menu

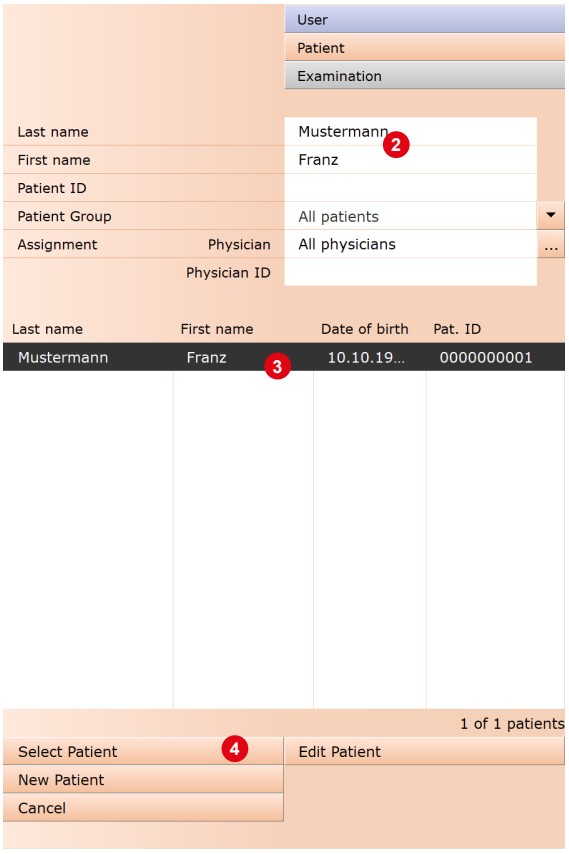


Fig. 22: Select patient

3.6 Evaluation structure

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

Start screen "Overview, Standard"

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

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

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

Erroneous measurements:

List of all erroneous measurements with error codes.

Recorder information:

Recording parameters, battery trend of the recorder

Trend:

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

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

3.7 Navigation in the evaluation

The buttons for opening the various evaluation screens are located at the bottom of the screen. The button for the screen that is currently opened is pressed. This enables you to see at a glance on which screen you are 1.

The display of the page content can be changed in the View area 2. On the Overview screen, for example, you can switch between Hourly values and Single values 3. Single values 3 means that the results of all measurements are displayed in the blood pressure and HF trend. If the Hourly values option is selected, only the hourly average is displayed for each hour (advantage: better overview due to smoother measurement curve).

In the second menu of the View area 4, the contents of the Overview screen can be changed. Depending on the software options and the system configuration, different displays are possible for the overview:

- → Standard: basic overview of an ABPM evaluation, available for all operating modes (ADU/PED).
- → Risk stratification: optional software function, included in seca diagnostic professional, for use from 16 years of age to determine the 10-year risk of severe cardiovascular disease.
- → Phenotypes: optional software function, included in seca diagnostic professional, suitable for use on patients aged 18 and over. Provides information about the cause of a patient's pathological blood pressure behaviour.

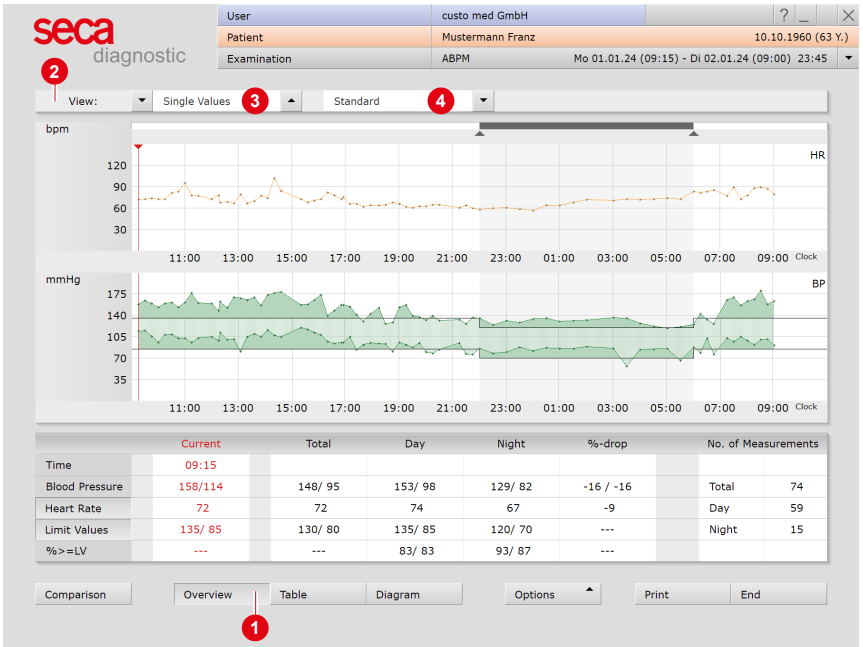


Fig. 23: Overview, Standard

3.8 Screens of the evaluation

3.8.1 Overview “Standard”

Fig. 24: Overview, Standard

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

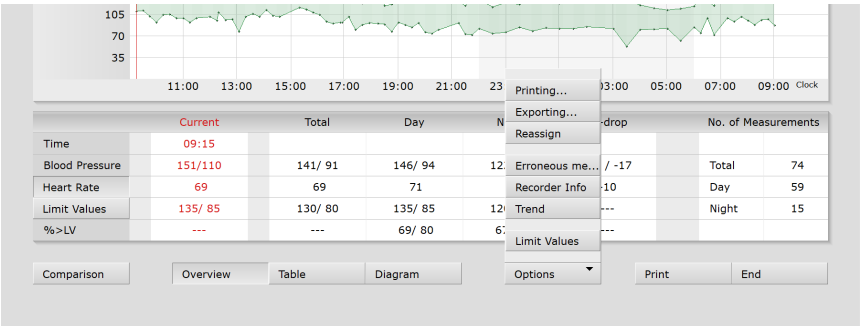


Fig. 25: Options menu

Options menu

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

3.8.2 Evaluation screen “Table”

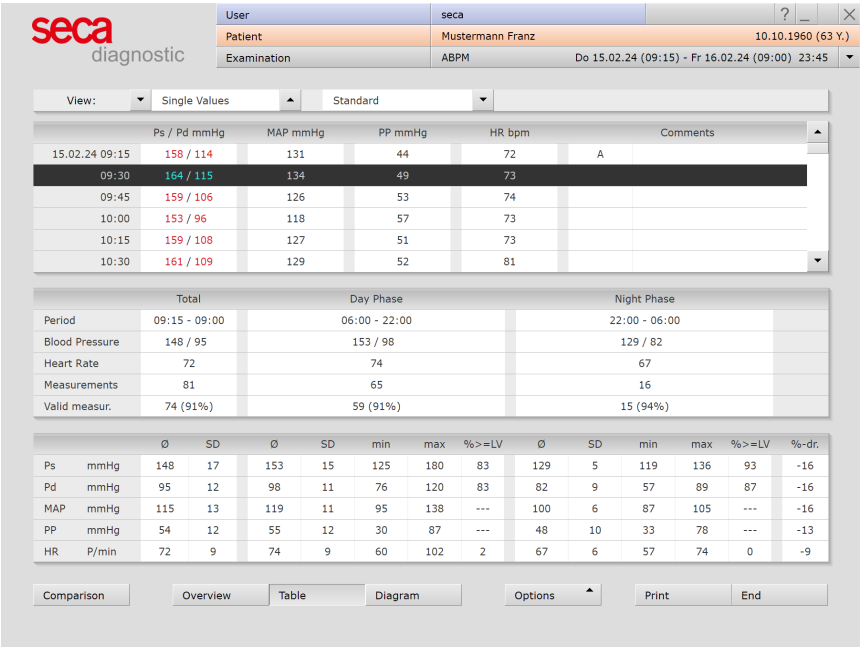


Fig. 26: Measured value table Standard

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

Transfer patient diary to the software

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

Delete measurements

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

Abbreviations in the third table:

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

3.8.3 Evaluation screen “Diagram”

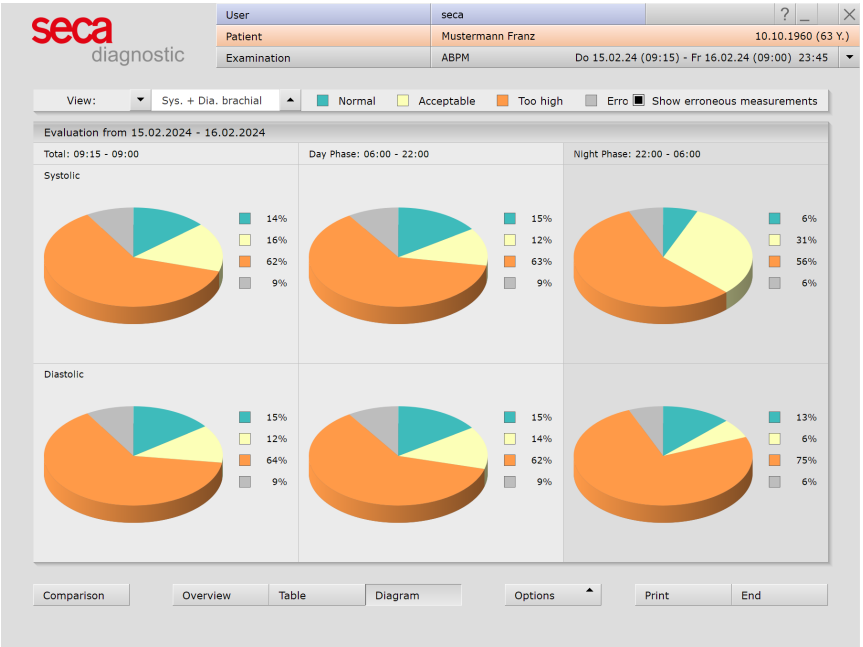


Fig. 27: Diagrams

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

Definition of the limit values (default setting)

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

Change limit values

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

3.8.4 Evaluation screen “Comparison”

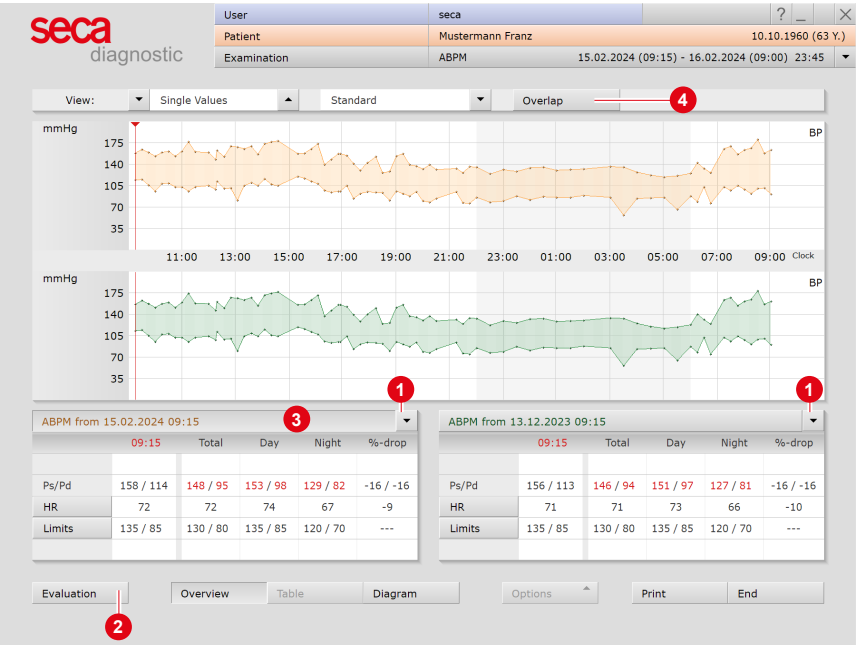


Fig. 28: Comparison

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

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

3.8.5 Evaluation screen “Trend”

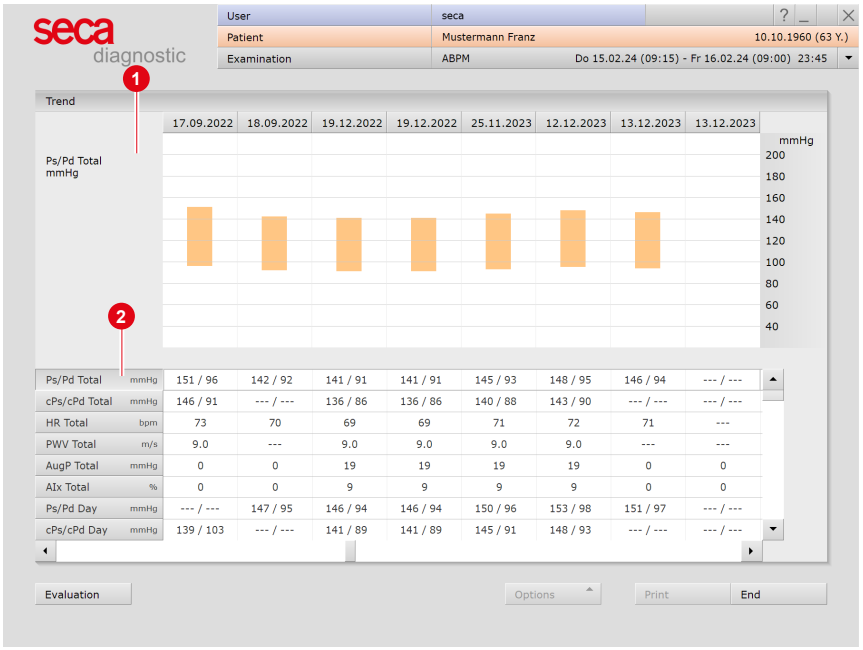


Fig. 29: Trend

To be opened via Options, Trend. Long-term trend displaying all blood pressure evaluations for a patient. The selected value, e.g. Ps/Pd total 1, is graphically displayed for all evaluations 2. In this way, the development of the individual values can be viewed at a glance.

Abbreviations in the table:

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

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

3.8.6 Dialogue “Automatic report”

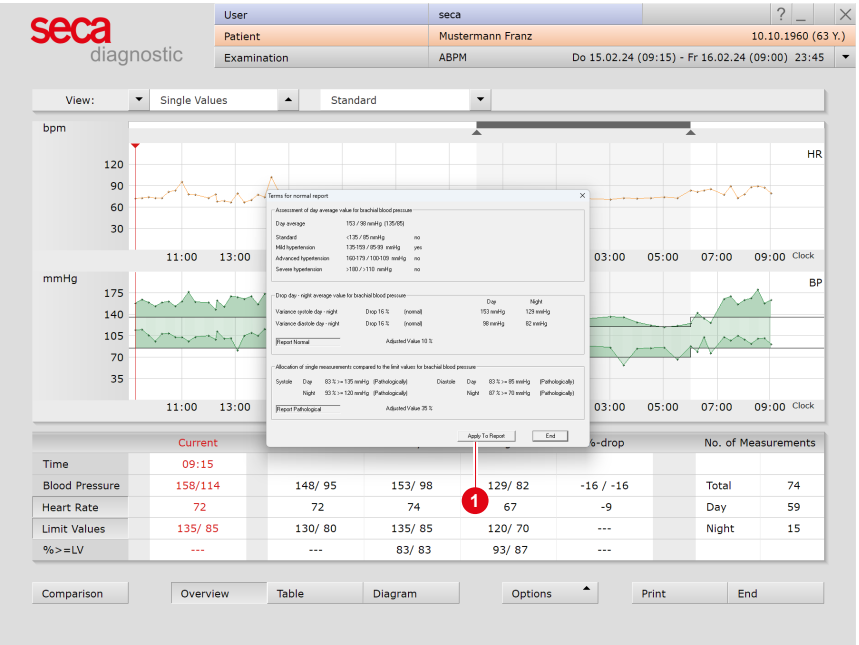


Fig. 30: Automatic report

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

INFORMATION:

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

3.9 Printing the evaluation

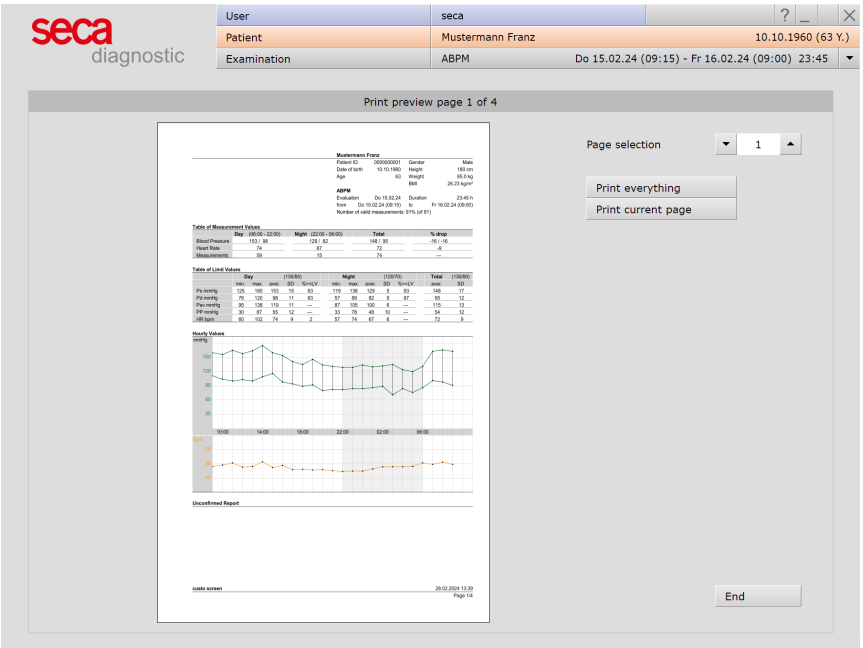


Fig. 31: Print preview

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

3.10 Confirming the evaluation

Unconfirmed report and report

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

Text modules – an aid for writing reports

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

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

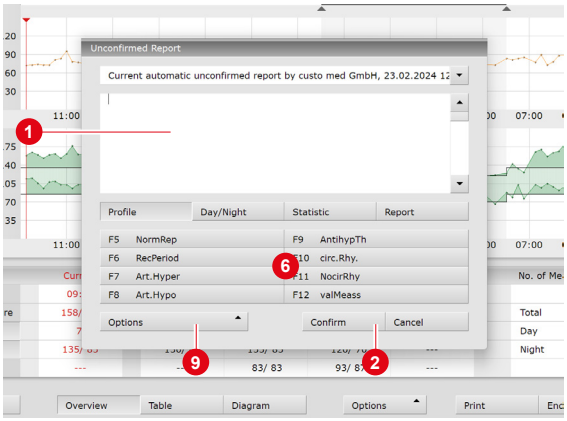


Fig. 32: Unconfirmed report

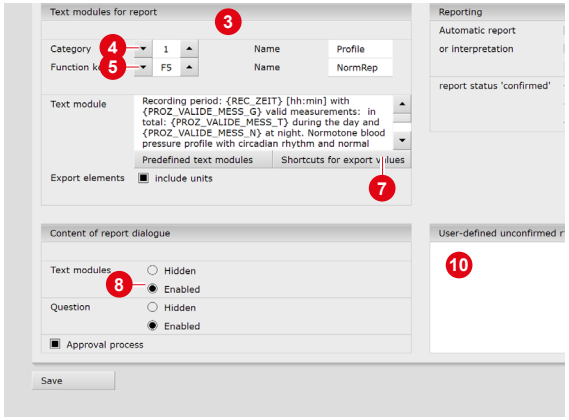


Fig. 33: Text modules

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.

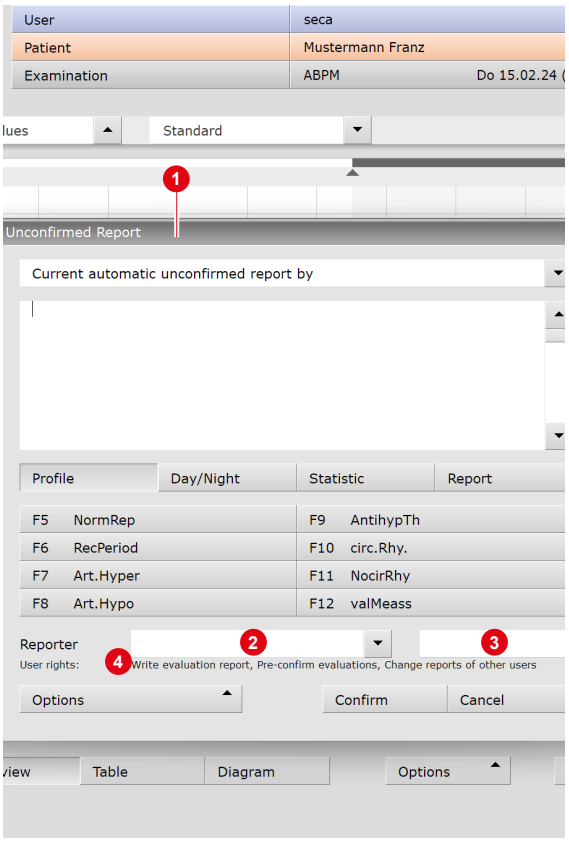


Fig. 34: Unconfirmed report dialogue with approval process

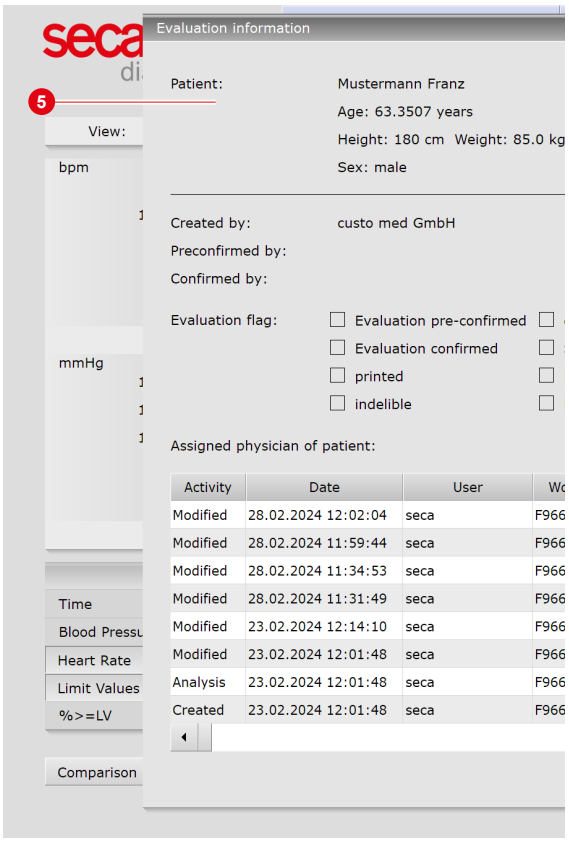


Fig. 35: Evaluation information

3.12 Ending the evaluation

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

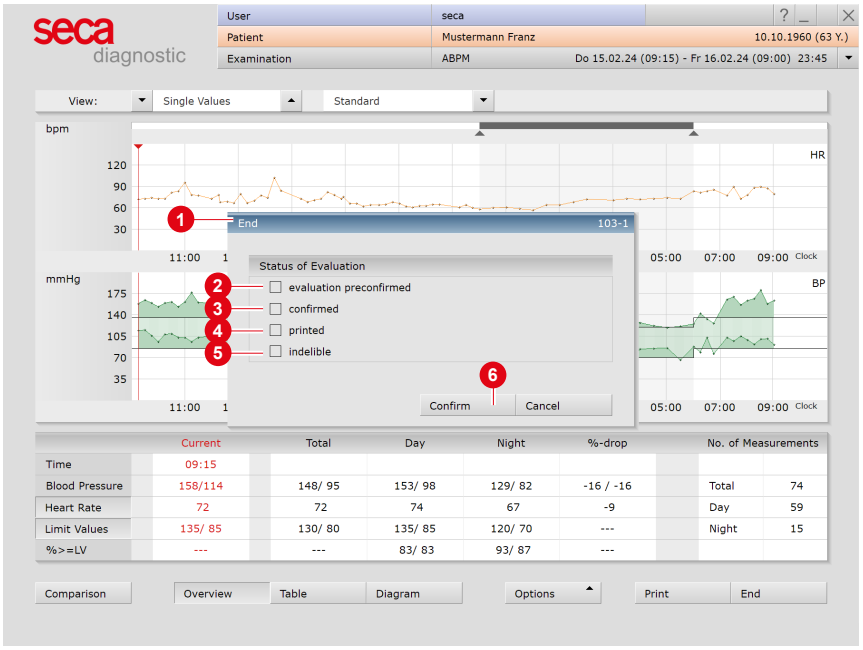


Fig. 36: End dialogue

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.

3.13 Evaluation with phenotypes

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

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

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

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

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

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

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

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

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

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

3.13.1 Accessing haemodynamic phenotypes

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

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

“Phenotypes” overview

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

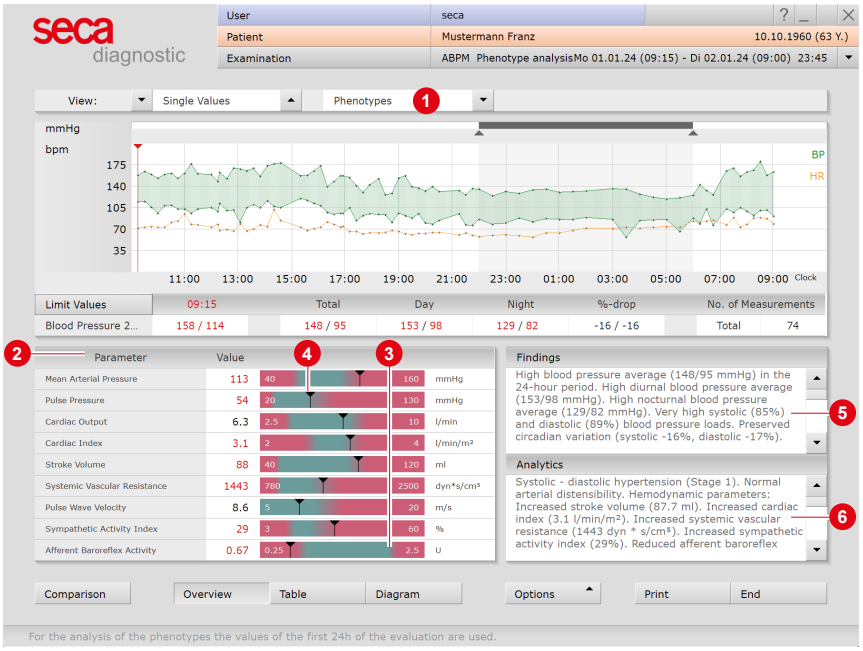


Fig. 37: Overview, phenotypes

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

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

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

3.13.2 Expression of the haemodynamic parameters

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

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

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

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

3.13.3 Description of the phenotypes

Cardiogenic phenotype

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

Neurogenic phenotype

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

Vasoconstriction phenotype

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

Volumetric phenotype

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

Arterial stiffness phenotype

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

3.14 Risk stratification

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

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

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

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

3.14.1 Configuring workflows

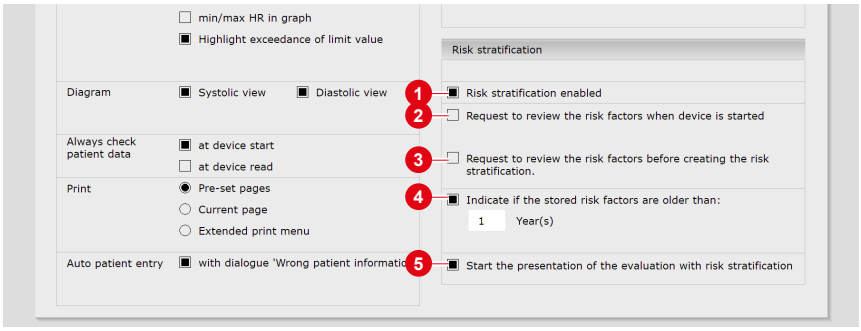


Fig. 38: Settings for risk stratification

→ Start seca diagnostic and open the screen page Examination, ABPM, Settings, Menu/Functions, Workflow.
→ ❶ Enable or disable risk stratification. If the option is not selected, seca diagnostic will not perform risk stratification.
→ ❷ If this option is selected, the dialogue for entering the risk factors opens automatically when starting the recorder. If the option is not selected, the input dialogue can be opened via Set Risk Factors.
→ ❸ If this option is selected, a prompt to check the previously set risk factors appears in the evaluation before risk stratification is performed. If the option is not selected, risk stratification is performed automatically without any prompt to check the risk factors.
→ ❹ If this option is selected, a prompt to check the existing risk factors appears if these are older than the set time period (e.g., 1 year). This is to ensure that the existing risk factors also correspond to the acute condition of the patient during follow-up examinations. If no check is performed when starting the recorder, the prompt appears again in the evaluation before the risk assessment is created.
→ ❺ If this option is selected, risk stratification is automatically displayed in the overview when opening an evaluation. If the option is deactivated, the standard view without risk stratification is displayed. Risk stratification can be opened manually.
→ Click on Save (bottom left) to apply your settings.

3.14.2 Defining evaluation guidelines

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

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

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

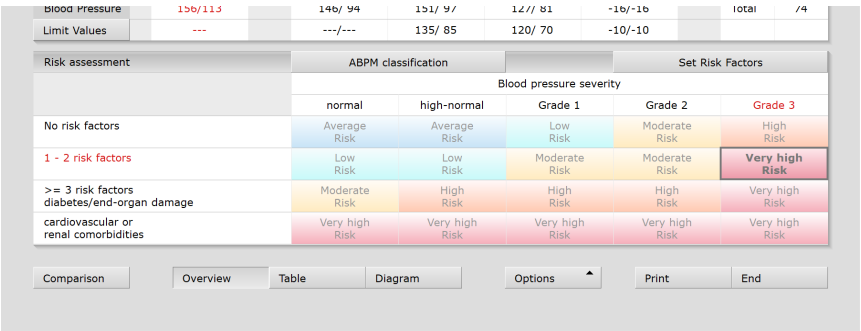


Fig. 39: Risk stratification according to DHL.

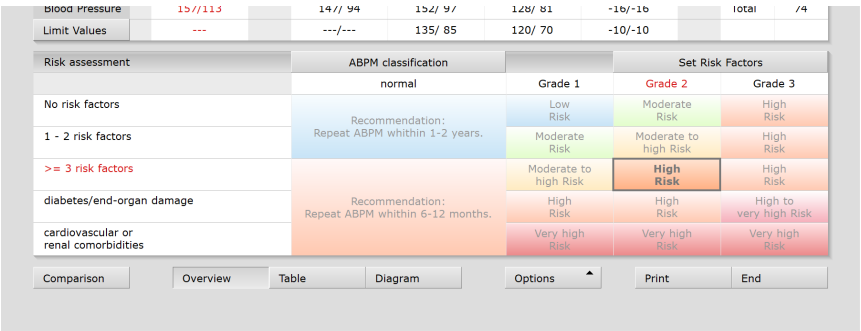


Fig. 40: Risk stratification according to international criteria

3.14.3 Print settings for risk stratification

The contents of the ABPM print pages are defined under Examination, ABPM, Settings, Print, Printed pages in seca diagnostic. To print the results of risk stratification, select the Summary with risk stratification option (= physician's printout) 2. In addition, the Summary standard 1 without risk stratification can be printed. With the Patient printout risk stratification option 3, the results are summarized in a simplified form for the patient on an A4 page. Click on Save (bottom left) to apply your settings.

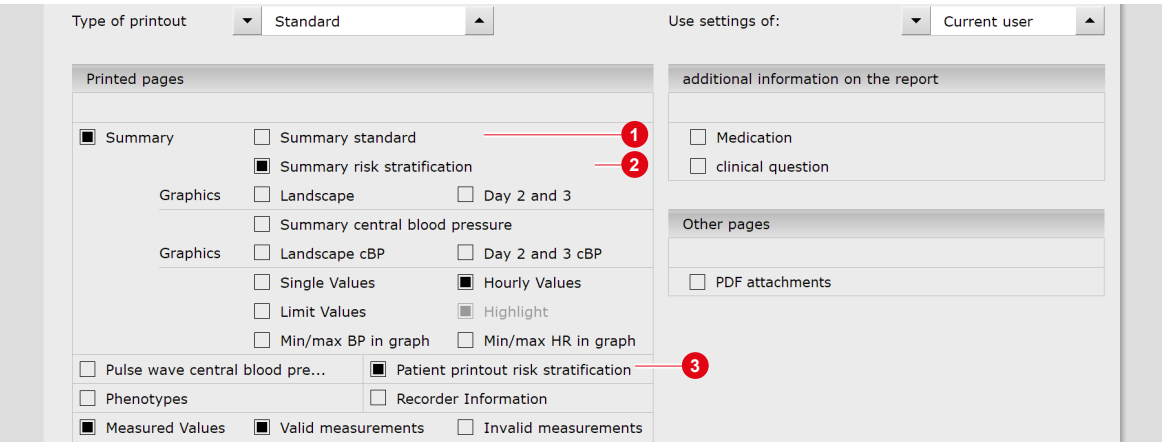


Fig. 41: Settings for the printout

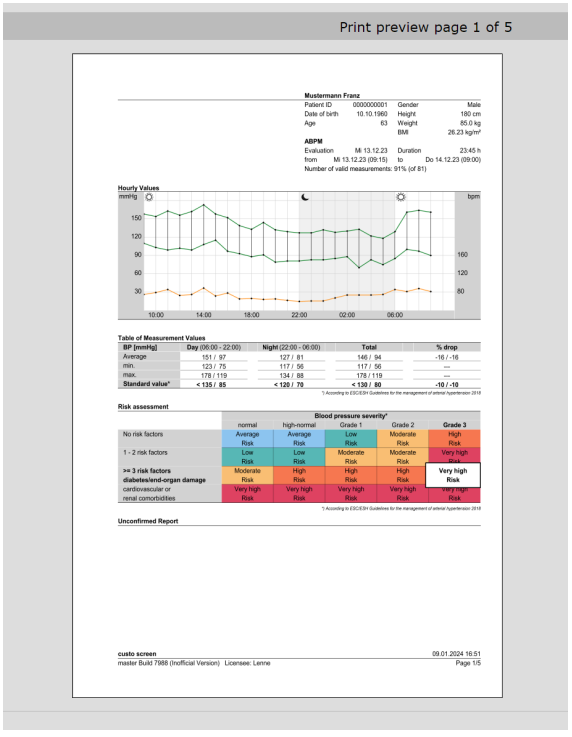


Fig. 42: Print preview of physician's printout with risk stratification

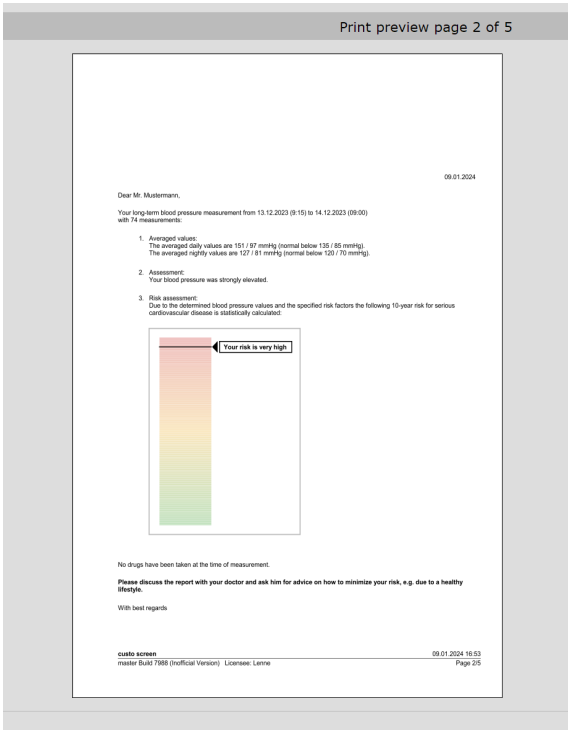


Fig. 43: Print preview of patient's printout with risk stratification

3.14.4 Recorder start with risk stratification

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

The start procedure for a recording with risk stratification corresponds to the standard procedure, *see 3.3 Performing an ABPM recording, p. 39*. In addition, the patient's cardiovascular risk factors must be entered.

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

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

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

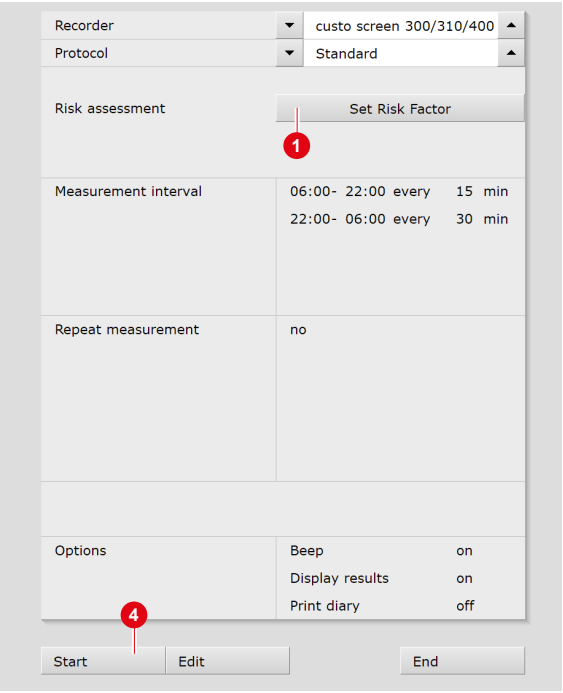


Fig. 44: Start parameters, set risk factors

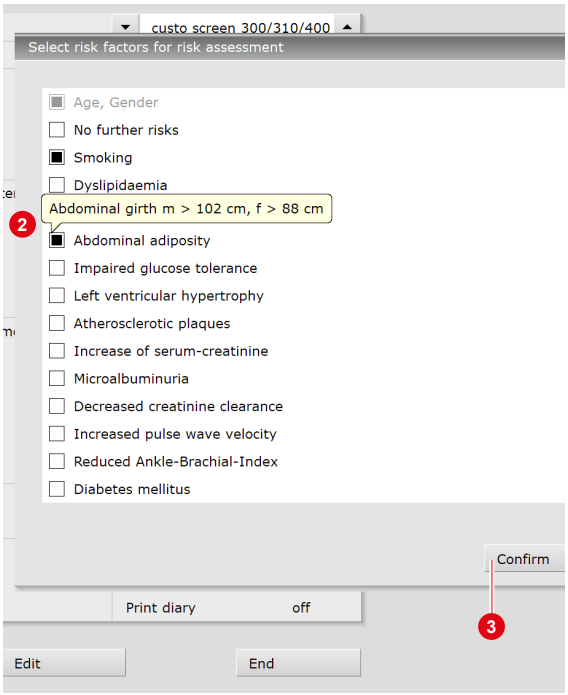


Fig. 45: Select risk factors

3.14.5 Downloading an evaluation with risk stratification

The download procedure corresponds to the standard procedure, *see 3.4 Downloading the ABPM recorder, p. 43*. After the download the evaluation overview is displayed. This contains, in addition to the standard contents, the risk stratification with indication of the 10-year risk of severe cardiovascular disease. The risk stratification is only displayed if the risk factors were set when starting the recorder. Otherwise, you will be prompted to enter them.

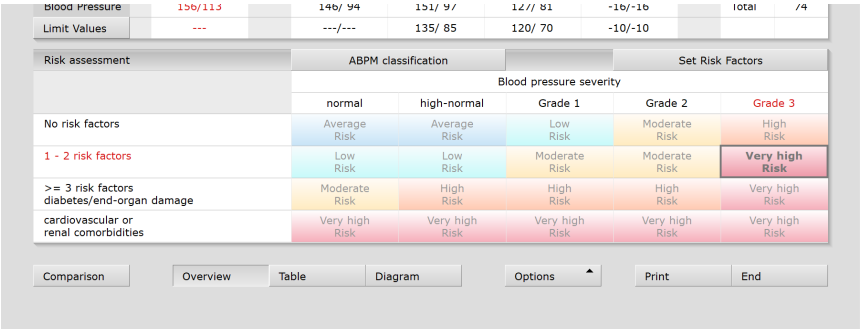


Fig. 46: Evaluation with risk stratification

3.14.6 Evaluation overview with risk stratification

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

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

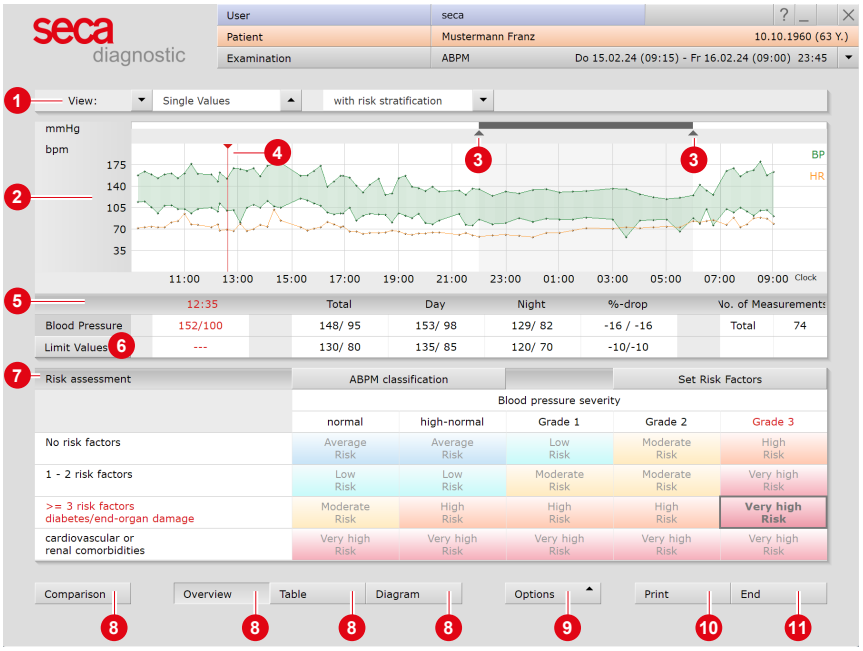


Fig. 47: Evaluation with risk stratification

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

3.14.7 If the risk stratification is not displayed...

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

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

Entering or checking the risk factors

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

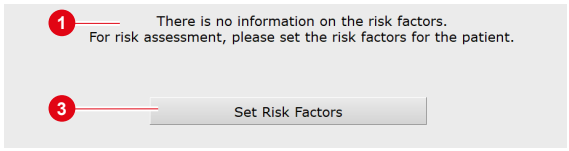


Fig. 48: No risk factors entered

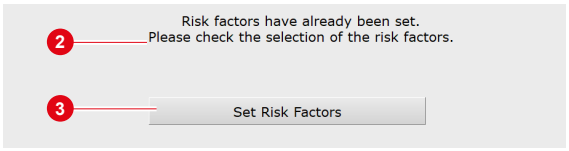


Fig. 49: Check existing risk factors

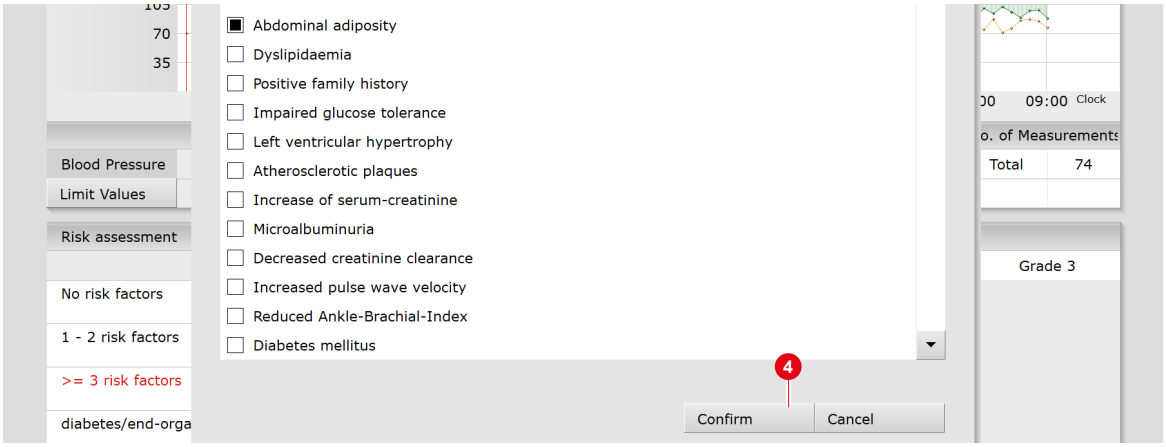


Fig. 50: Confirm risk factors

3.14.8 Unconfirmed report with risk stratification

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

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

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

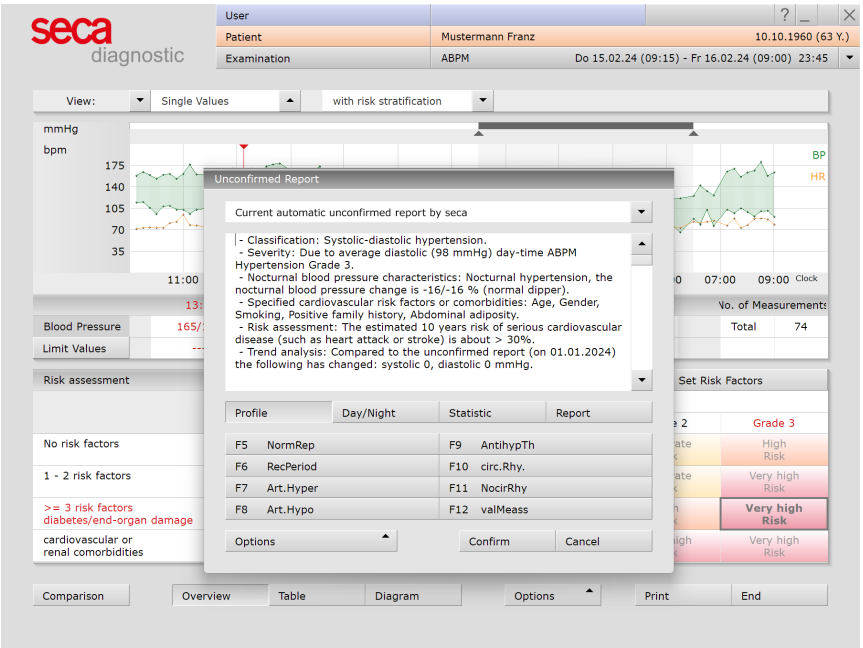


Fig. 51: Unconfirmed report with risk stratification

3.14.9 Definition of the blood pressure severity grades

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

Classification of blood pressure ranges according to DHL

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

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

Classification of blood pressure ranges according to international guidelines

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

4 Hygiene

4.1 Important notes

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

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

Contacts must not be soiled or damaged.

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

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

4.2 Hygienic reprocessing

seca screen 300

→ Reprocessing type: wipe disinfection

Carrying case and belt

→ Reprocessing type: disinfectant washing in the washing net

Blood pressure cuff

IMPORTANT: Never autoclave.

The cuff tube, especially the BNC connector, must never be immersed in liquids.

INFORMATION: Observe the information on the instruction leaflet provided with the blood pressure cuff.

→ Reprocessing type: wipe disinfection

Cleaning and disinfection of the blood pressure cuff:

→ Wipe the cuff with a damp cloth.
→ If necessary, remove the bladder and wash the cuff cover with soap or disinfectant solution.
→ After disinfection, rinse the cuff under clear water and allow to air dry.

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!

Additional agents for blood pressure cuff disinfection:

- → Cidex, Sporicidin, Microzide, 70% isoprophy alcohol, ethanol 70%, buraton liquid.
- → 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 Limit values for adults

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

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

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

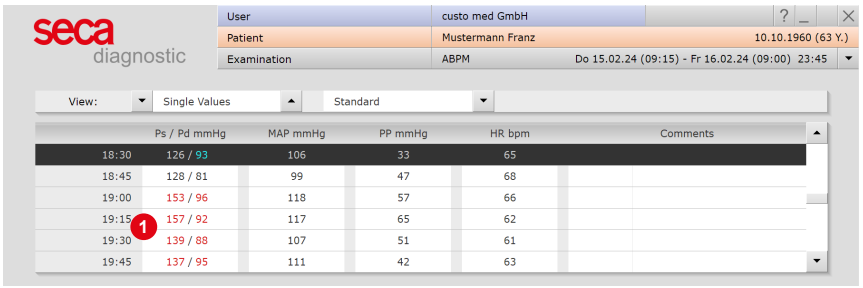


Fig. 52: Exceeded limit values in the table

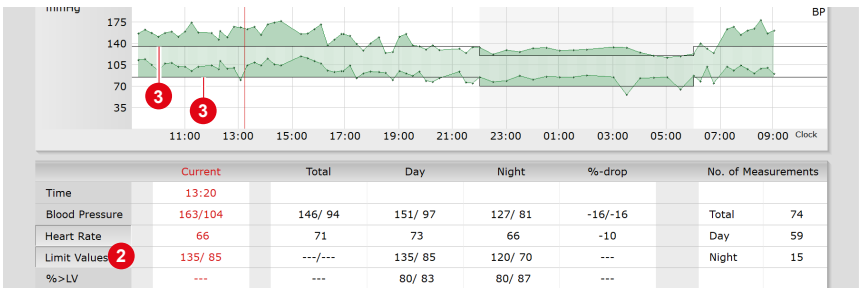


Fig. 53: Limit Values button in the overview

5.2 Limit values for children and adolescents

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

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

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

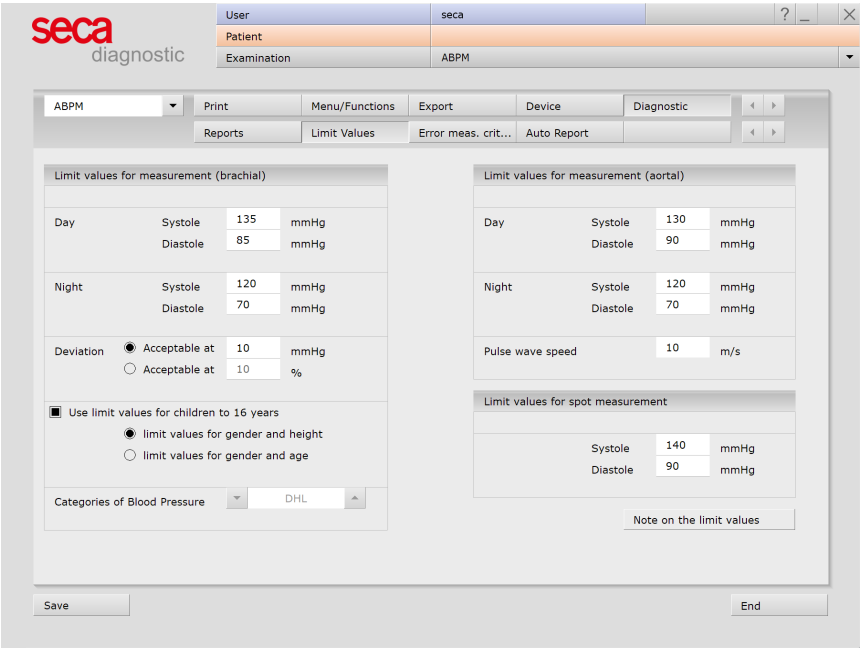


Fig. 54: Limit values for children and adolescents

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

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

Definition of hypertension in automatic findings

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

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

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

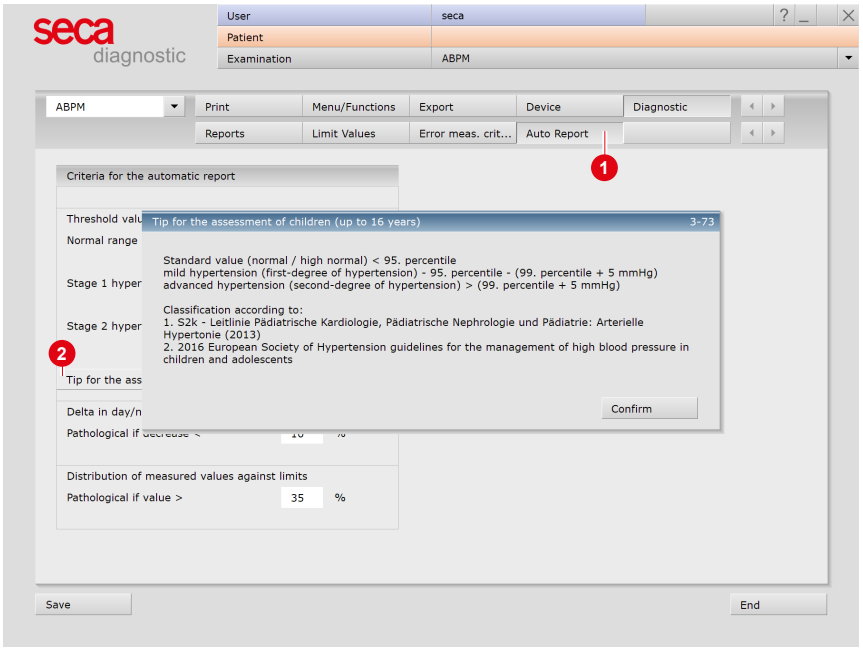


Fig. 55: Note for the assessment of children up to 16 years of age

Table 1:

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

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

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

Table 2:

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

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

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

5.3 Abbreviations in the evaluation

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

Phenotype analysis values and abbreviations

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

5.4 Keyboard navigation and shortcuts

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

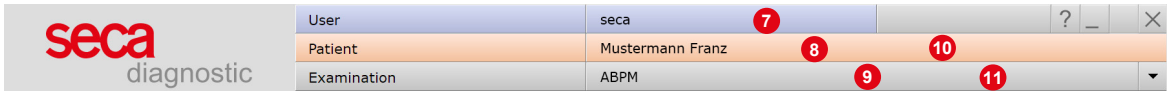
Quick links in the main navigation

Left click

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

Right click

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



Left click

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

Right click

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

Keyboard navigation

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

Keyboard shortcuts

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

Generally valid keyboard shortcuts in an open evaluation	
Ctrl N	Unconfirmed report input dialogue
Ctrl K	Medication input dialogue
Ctrl T	Call trend
Ctrl D	Call print dialogue
Ctrl O	Call options menu

5.5 Manufacturer’s declaration regarding EMC

Electromagnetic compatibility according to DIN EN 60601-1-2:2016-05

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 screen 300 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

Recommended protective distances between portable and mobile RF telecommunication devices and seca screen 300

seca screen 300 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 screen 300 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.

5.6 EC Declaration of Conformity

Simplified declaration of conformity

seca screen 300 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.

5.7 Product components and accessories

Description	Product designation	Part no.	Quantity/pc.
	seca screen 300 recorder	58025	1

Description	Accessories	Part no.	Quantity/pc.
	Cuff Wrap pediatric	23078	1
	Cuff Wrap small, child	23071	1
	Cuff D-Ring standard	23070	1
	Cuff D-Ring x-large	23072	1
	Cuff D-Ring xx-large	23073	1

Description	Complementary parts	Part no.	Quantity/pc.
	Carrying belt, length 127 cm	20011	1
	Carrying belt, length 155 cm	20012	1
	Belt for children, length 96 cm	20015	1
	Carrying case for seca screen	23060	1
	Batteries AA LR6 Mignon 1.5 Volt	20032[1)]	3
	USB connection cable	16020	1
	custo com IR infrared interface	25058	1
	custo multi com infrared interface with SD card reader	12171	1
	LM506 Bluetooth 4.0 USB adapter	55050	1
	custo screen protect hygiene set: six fleece pads for custo med blood pressure cuffs in the sizes standard, XL, XXL and a wash bag	23077	1
	custo clean SC, hygiene bag for seca screen	40015	50 pieces

1) These are IT accessories or consumables with changing article numbers.

5.8 List of Figures

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Email: info@customed.de
Internet: www.customed.de

custo med product names:
custo screen 300 (ABPM device)
custo diagnostic (medical PC software)

Distribution:

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seca product names:
seca screen 300 (ABPM device)
seca diagnostic (medical PC software)

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