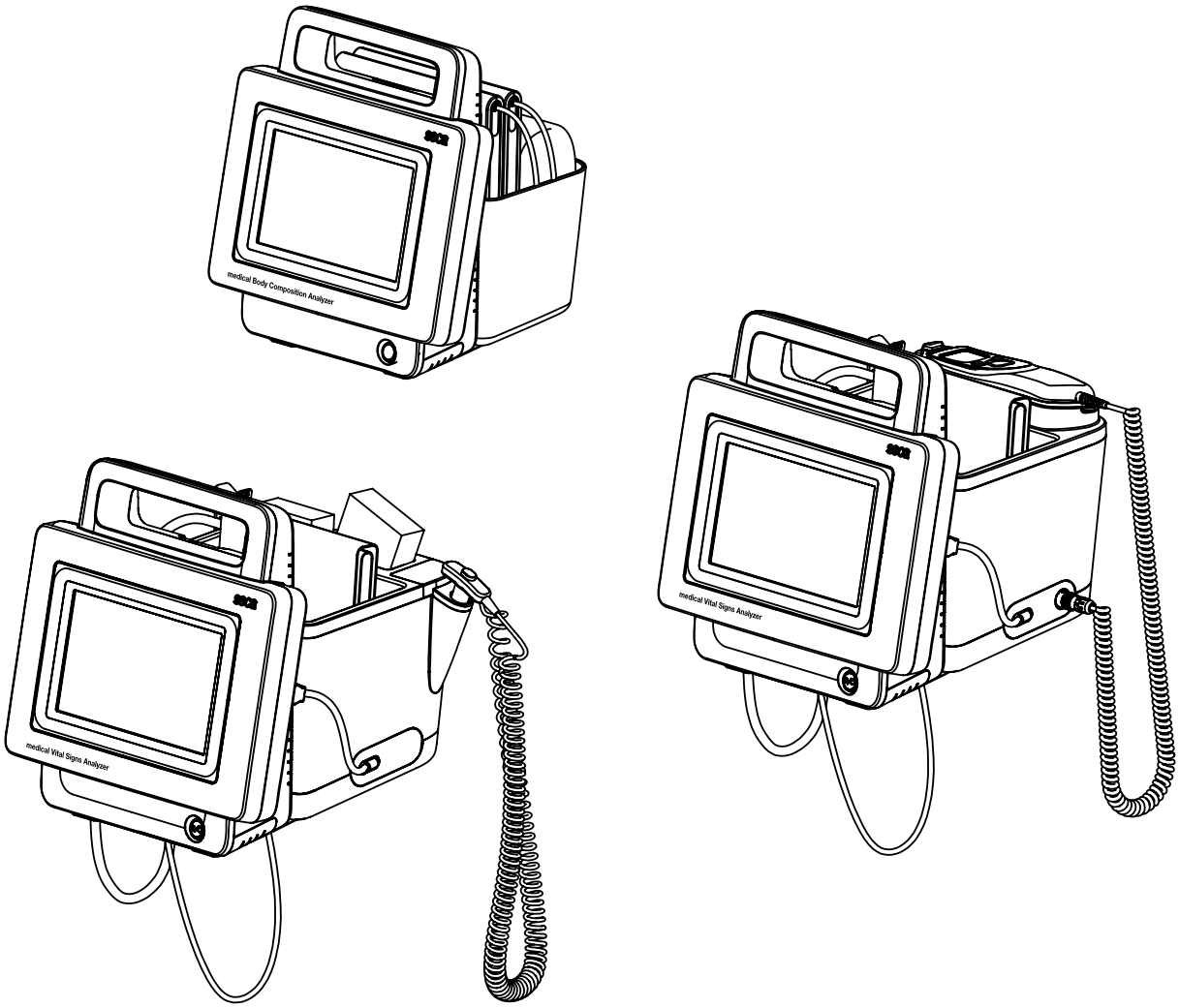
# seca 535/525

## Instructions for use

Software version 1.0
from Build 930




seca®
Precision for health

# CONTENTS

# INSTRUCTIONS FOR USE FOR SECA 535/SECA 525




Software version: 1.0 from Build 930
Article number of this document: 17-10-05-353-002d_02-2019 B


**NOTE**
This document describes the maximal equipment of the **seca mVSA 535**/**seca mBCA 525** product family: measurement of blood pressure, temperature, oxygen saturation and bioimpedance. Depending on the actual equipment of your device, some of this information may not be relevant to your device. Pay attention to the information in this document which is relevant to your device.

# 1. DEVICE DESCRIPTION



## 1.1 Intended use seca 535

The medical Vital Signs Analyzer **seca mVSA 535** is mainly used in inpatient facilities (hospitals, medical practices and care facilities) in accordance with national regulations.

The medical Vital Signs Analyzer **seca mVSA 535** is used for non-invasive, discontinuous determination of arterial blood pressure and/or non-invasive determination of oxygen saturation of arterial hemoglobin and/or determination of body temperature and pulse rate and determination of weight and height.

With the inclusion of the “bioimpedance analysis” function, the medical device is also used to record bioelectric impedance measurements and to calculate automatically parameters such as fat-free mass (FFM) which can be derived from these measurements. The results are displayed in graphical form and assist the attending physician with the following medical issues:

- Determining energy expenditure and energy reserves as a basis for nutritional advice
- Assessing metabolic activity and the success of a training program, e.g. within the framework of rehabilitation or physiotherapy
- Determining a patient's fluids status


17-10-05-353-002d_02-2019 B

The medical Vital Signs Analyzer **seca mVSA 535** is intended for use in children 3 years and older and adults. The “Bioimpedance analysis” function is **not** intended for use on children.

## 1.2 Intended use seca 525

The medical Body Composition Analyzer **seca mBCA 525** is mainly used in inpatient facilities (hospitals, medical practices and care facilities) in accordance with national regulations.

The medical Body Composition Analyzer **seca mBCA 525** records weight, height and bioelectric impedance measurements and automatically calculates parameters such as fat-free mass (FFM) which can be derived from these measurements. The results are displayed in graphical form and assist the attending physician with the following medical issues:

- Determining energy expenditure and energy reserves as a basis for nutritional advice
- Assessing metabolic activity and the success of a training program, e.g. within the framework of rehabilitation or physiotherapy
- Determining a patient's fluids status

The device is **not** intended for use on children.

## 1.3 Description of function

➔ Device components
➔ Power supply
➔ Bioimpedance measurement
➔ Vital signs measurement
➔ Alarms
➔ Record weight and height
➔ Administration of seca user accounts
➔ Administration of seca patient files
➔ Analysis of measured results
➔ Data transmission and network functions
➔ Compatibility

### Device components

The device consists of a monitor and a SmartBucket (**seca mVSA 535**) or a monitor and a storage compartment (**seca mBCA 525**).

The monitor is for administering patient and user data and for preparing and analyzing measurements. The monitor is equipped with a touchscreen display.

The SmartBucket (**seca mVSA 535** only) includes the measuring equipment for recording vital signs and storage facilities for the measuring accessories.

The storage compartment (**seca mBCA 525** only) is for storing the measuring mat (bioimpedance measurement).

In the maximal configuration, the vital signs blood pressure, body temperature, pulse rate and oxygen saturation can be recorded and bioimpedance measurements performed. Your version of the device may have a more limited functional scope.

### Power supply

The monitor is powered by a connection to the power supply. The monitor has a lithium-ion rechargeable battery to provide a mobile power supply.

The SmartBucket is supplied with power over a USB connection from the monitor.

17-10-05-353-002d_02-2019 B

The measuring mat is powered by a lithium-ion rechargeable battery. The rechargeable battery is charged by an inductive charging interface in the magnetic catch of the monitor.

**Bioimpedance measurement**

The bioimpedance measurement is performed with a measuring mat developed by seca.

The bioimpedance measurement is carried out with the patient lying down, using the 8-point method. The 4-point method (measuring the right half of the body) is likewise possible. The low alternating current is provided and impedance is measured by the electrode cables of the measuring mat. The electrode cables are connected to two pairs of electrodes for each half of the body. The electrodes are affixed to the patient's hands and feet.

**Vital signs measurement**

Blood pressure is measured non-invasively with seca measuring equipment and seca blood pressure cuffs.

Temperature is measured with COVIDIEN™ measuring equipment and, depending on the device version, as an oral/axillary (blue temperature probe), rectal (red temperature probe) or in-ear thermometer procedure.

Depending on the device version, oxygen saturation is measured with Masimo SET® or with seca measuring equipment and with the corresponding $SpO_2$ sensors and patient cables.

Depending on device version, pulse rate is determined using either oxygen saturation or blood pressure.

**Alarms**

The device is intended for discontinuous measurement of vital signs, so it does **not** have an alarm function.

**Record weight and height**

Scales and stadiometers from the **seca 360° wireless** system can transmit measured results to the device wirelessly. Alternatively, the patient's weight and height can be recorded manually.

**Administration of seca user accounts**

User accounts can be set up and administered directly on the device. The user accounts for the device can be synchronized automatically with the user accounts of the **seca analytics 115** PC software. This allows access to both the device and the PC software with the same user account.

**Administration of seca patient files**

Measured results are administered in seca patient files. seca patient files can be created directly on the device. With administrator rights, seca patient files can be edited directly on the device.

The device can be configured so that the seca patient files of the device are automatically synchronized with the seca patient files of the **seca analytics 115** PC software.

seca patient files and seca patient databases contain exclusively data necessary for working with seca products or which were determined using seca products.

The export and import functions of the **seca analytics 115** PC software can be used for exchanging data with practice and hospital information systems.

**Analysis of measured results**

Bioimpedance measurements are analyzed in graphical form based on scientifically-validated formulas. In-house studies by seca generated predictive formulas for determining the parameters total body water (TBW), extracellular water (ECW), fat-free mass (FFM) and skeletal muscle mass (SMM) for arms, legs, torso and the whole body. Further studies generated normal ranges for the following parameters: Bioelectric impedance vector analysis (BIVA), mass indices (FMI, FFMI), phase angle(φ), fat mass (FM) and skeletal muscle mass (SMM).

17-10-05-353-002d_02-2019 B

Measured results for the vital signs blood pressure (NIBP), temperature (TEMP), pulse rate (PR) and oxygen saturation ($SpO_2$) are displayed in graphical form.

**Data transmission and network functions**

The device can be incorporated in a PC network via a LAN interface or via WiFi. The device can thus communicate with the databases of **seca analytics 115** PC software and use the **seca directprint** function of the **seca analytics 115** PC software.

Monitor and measuring mat communicate with each other via a WiFi direct connection or via an infrared interface.

The monitor and the measuring mat communicate with one another via WiFi. If WiFi is unavailable, the infrared interface in the magnetic catch of the monitor is used.

Measured results for the parameters blood pressure, body temperature, pulse rate and oxygen saturation are transmitted from the SmartBucket to the monitor over a USB connection.

Scales and stadiometers from the **seca 360° wireless** system can transmit measured results to the device wirelessly.

**Compatibility**

This device (software version 1.0, Build 930 or higher) is only compatible with version 1.4 (Build 800 or higher) of the PC software **seca analytics 115**. There is no downward compatibility with older versions of the **seca analytics 115**.

medical Body Composition Analyzer **seca mBCA 525** from serial number 10000000090505 can be retrofitted by the user with the SmartBucket **seca mVSA 526** to measure vital signs.

## 1.4 User qualification

➔ Administration/network connection

➔ Measuring mode

**Administration/network connection**

The device may only be set up and incorporated in a network by experienced administrators or hospital technicians.

**Measuring mode**

The device and the **seca analytics 115** PC software may only be operated by persons with sufficient specialist expertise.

Basic knowledge for measuring vital parameters is **not** the subject of this manual.

## 1.5 Contraindications

The device is **not** intended for permanent monitoring of patients.

The device is **not** intended for patient monitoring during transport (for example, in ambulances or helicopters) or a transfer within an institution.

The device is **not** intended for operation in the vicinity of an MRT device or in a pressurized chamber.

The $SpO_2$ measuring function of the device is **not** intended for monitoring apneas, detecting arrhythmias or for use during defibrillation or electrocauterization.

This device is not suitable for persons with the following characteristics:

- Cramps
- Tremors

17-10-05-353-002d_02-2019 B

This device is **not** suitable for individuals who are connected to electronic life-support systems, for example, artificial heart/lung.

Bioimpedance measurements may **not** be performed on individuals exhibiting the following characteristics:

- electronic implants, e.g. cardiac pacemakers
- active prostheses

Bioimpedance measurements may **not** be performed on persons who are connected to one of the following devices:

- electronic life-support systems, e.g. artificial heart, artificial lung
- portable electronic medical devices, e.g. ECG devices or infusion pumps

Impedance measurements may only be performed on persons exhibiting the following characteristics after discussion with the attending physician:

- cardiac arrhythmias
- pregnancy

17-10-05-353-002d_02-2019 B

# 2. SAFETY PRECAUTIONS

➔ Safety precautions in these Instructions for Use

➔ Basic safety precautions

## 2.1 Safety precautions in these Instructions for Use

**DANGER!**
Used to identify an extremely hazardous situation. If you fail to take note of this information, serious irreversible or fatal injuries will occur.

**WARNING!**
Used to identify an extremely hazardous situation. If you fail to take note of this information, serious irreversible or fatal injuries may result.

**CAUTION!**
Used to identify a hazardous situation. If you fail to take note of this information, minor to moderate injuries may result.

**NOTICE!**
Used to identify possible incorrect usage of the device. If you fail to take note of this information, you may damage the device, or the measured results may be incorrect.

**NOTE**
Includes additional information about use of the device.

## 2.2 Basic safety precautions

➔ Handling the device

➔ Handling a wheeled stand

➔ Prevent electric shock

➔ Prevent injuries and infections

➔ Prevent device damage

➔ Handling measured results

➔ Handling packaging material

➔ Handling batteries and rechargeable batteries

### Handling the device

- Please take note of the information in these instructions for use.
- Keep the instructions for use in a safe place. The instructions for use are a component of the device and must be available at all times.

**DANGER!**
**Risk of explosion**
Do not use the device in an environment in which one of the following gases has accumulated:

- oxygen
- flammable anesthetics
- other flammable substances/air mixtures

17-10-05-353-002d_02-2019 B

**CAUTION!**
**Patient hazard, damage to device**

- Additional devices which are connected to electrical medical devices must provide evidence of compliance with the relevant IEC or ISO standards (e.g. IEC 60950 for data-processing devices). Furthermore, all configurations must comply with the requirements of standards for medical systems (see IEC 60601-1-1 or Section 16 of the 3rd edition of IEC 60601-1 respectively). Anyone connecting additional devices to electrical medical devices is considered a system configurer and is therefore responsible for ensuring that the system complies with the requirements of standards for systems. Your attention is drawn to the fact that local laws take precedence over the above-mentioned requirements of standards. In the event of any queries, please contact your local specialist dealer or Technical Service.
- Please have servicing and measuring technology checks performed every two years.
- Technical modifications may not be made to the device. The device does not contain any parts for servicing by the user. Only have servicing and repairs performed by an authorized seca Service partner. You can find service partners in your area at www.seca.com or by sending an e-mail to service@seca.com.
- Only use original seca accessories and spare parts, otherwise seca will not grant any warranty.

**CAUTION!**
**Patient hazard, malfunction**

- Keep other electrical medical devices, e.g. high-frequency surgical devices, a minimum distance of approx. 1 meter away to prevent incorrect measurements or wireless transmission interference.
- Keep HF devices such as cell phones a minimum distance of approx. 1 meter away to prevent incorrect measurements or wireless transmission interference.
- The actual transmission output of HF equipment may require minimum distances of more than 1 meter. Details can be found at www.seca.com.

## Handling a wheeled stand

**WARNING!**
**Injury from falling, damage to device**

- When transporting the device on a wheeled stand, make sure that all cables and tubes are stowed properly directly on the machine or in the basket of the stand.

**CAUTION!**
**Damage to device**

- Do not pull on cables and tubes to move the equipment or wheeled stand.
- Do not move the wheeled stand when the power cord of the device is plugged into an electrical outlet.

17-10-05-353-002d_02-2019 B

## Prevent electric shock

**WARNING!**
**Electric shock**

- Set up devices which can be operated with the electricity supply so that the power supply socket is within easy reach and the power supply can be disconnected quickly.
- Ensure that your local power supply matches the details on the device.
- Connect this device only to a power supply with a protective earth facility.
- Do not connect the device to a power supply network if there is any uncertainty about whether the protective earth is functioning. In this case, use the device exclusively in rechargeable battery mode.
- Do not connect the device to sockets that are switched by an on/off switch or a dimmer.
- Never touch the power supply cable with wet hands.
- Do not use extension cables or power strips.
- Make sure that cables are not pinched or damaged by sharp edges.
- Make sure that cables do not come into contact with hot objects.
- Do not operate the device at an altitude of more than 3000 m above sea level.

## Prevent injuries and infections

**WARNING!**
**Injury from falls**

- Ensure that the device is positioned firmly and level.
- Route connecting cables (if present) in such a way that neither user nor patient can trip over them.

**WARNING!**
**Risk of infection**

- Before and after every measurement, wash your hands to reduce the risk of cross-contamination and nosocomial infections.
- Hygienically reprocess the scale regularly as described in the respective section in this document.
- Make sure that the patient has no infectious diseases.
- Make sure that the patient has no open wounds or infectious skin alterations, which may come into contact with the device.

17-10-05-353-002d_02-2019 B

## Prevent device damage

**NOTICE!**

**Damage to device**

- Ensure that no liquids enter the device. They can damage the electronics.
- Switch off the device (if option is provided) before you take the power supply connector out of the power supply socket.
- If you are not going to use the device for an extended period, disconnect the power supply connector from the power supply socket and remove the rechargeable battery (if present and removable). Only then is the device de-energized.
- Make sure not to drop the device.
- Do not expose the device to any impacts or vibrations.
- Perform function controls regularly as described in the relevant section in this document. Do not operate the device if it is damaged or not working properly.
- Ensure that the air openings of the device (if present) are not covered.
- Ensure that there is no heat source in the immediate vicinity. Do not expose to direct sunlight. The excessive temperature could damage the electronics.
- Avoid rapid temperature fluctuations. When the device is transported so that a temperature difference of more than 20 °C occurs, it must stay turned off for at least 2 hours before it can be turned on again. Otherwise, condensation water will form which can damage the electronics.
- Use the device only in the ambient conditions outlined in "Intended use".
- Store the device only in the storage conditions outlined in "Intended use".
- Use only disinfectants free of chlorine and alcohol which are explicitly suitable for acrylic sheet and other sensitive surfaces (active ingredient: quaternary ammonium compounds, for example).
- Do not use aggressive or abrasive cleaning agents.
- Do not use organic solvents (e.g. white spirit or petroleum spirit).
- Use disinfectants containing 70% isopropyl alcohol for vital signs measurement accessories only.

## Handling measured results

**CAUTION!**

**Patient hazard**

In order to avoid misinterpretations, test results for medical use must be displayed and used in SI units (weight: kilogrammes, length: metres) only. Some devices offer the ability to display test results in other units. This is only an additional function.

- Use the results exclusively in SI units.
- The use of measurement results in non-SI units is the sole responsibility of the user.

**NOTICE!**

**Inconsistent measuring results**

- Before you electronically save measurement values determined using this device and use them further (e.g. in seca PC software or in an EMR system), make sure that the measurement values are plausible.
- If measurement values are transmitted to seca PC software or an EMR system, make sure prior to further use that the measurement values are plausible and are assigned to the correct patient.

17-10-05-353-002d_02-2019 B

**NOTICE**

**Results not comparable to other devices**

Results of bioelectric impedance measurements are not interchangeable with measurements obtained from different manufacturers' devices. Follow-up measurements not performed on a seca device may lead to inconsistent data and to misinterpreted measured results.

- Ensure that follow-up measurements are also performed on a seca device.

**NOTE**

For an overview of the parameters which can be determined with this device, see section "Technical data\Analysis parameters". If necessary, you can print out this overview and give it to your patients (printout from device not possible).

## Handling packaging material

**WARNING!**

**Risk of suffocation**

Packaging material made of plastic foil (bags) is a choking hazard.

- Keep packaging material out of reach of children.
- In the event that the original packing material may not be available anymore, only use plastic bags with security holes in order to reduce the risk of suffocation. Use recyclable materials if possible.

**NOTE**

Keep the original packing material for future use (e.g. returning for servicing).

## Handling batteries and rechargeable batteries

**WARNING!**

**Personal injury as a result of improper handling**

Batteries and rechargeable batteries contain harmful substances which may explode if not handled properly.

- Do not try to recharge batteries.
- Do not expose (rechargeable) batteries to heat.
- Do not burn (rechargeable) batteries.
- If acid is leaking out, avoid contact with the skin, eyes and mucous membranes. Rinse affected areas with plenty of clean water and seek medical help at once.

**NOTICE!**

**Damage to device and malfunctions with improper handling**

- Only use the type of (rechargeable) battery specified in this document.
- When replacing (rechargeable) batteries, always replace a complete set at a time.
- Do not short-circuit (rechargeable) batteries.
- If you do not use the device for a long period of time, remove the batteries (incl. rechargeable batteries). This prevents acid from leaking into the device.
- If acid leaked into the device, discontinue use. Have the device checked by an authorised seca Service partner and repaired if necessary.

17-10-05-353-002d_02-2019 B

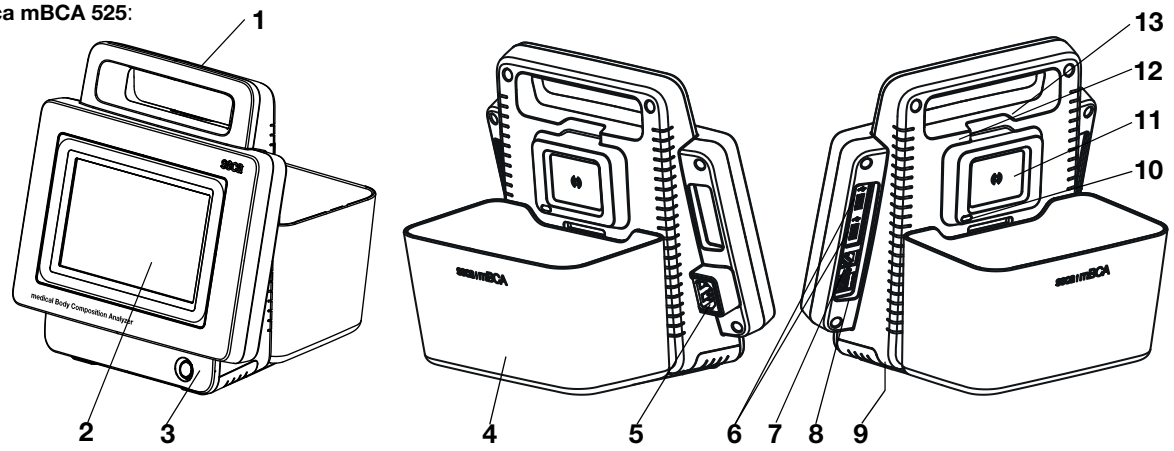
# 3. DEVICE OVERVIEW



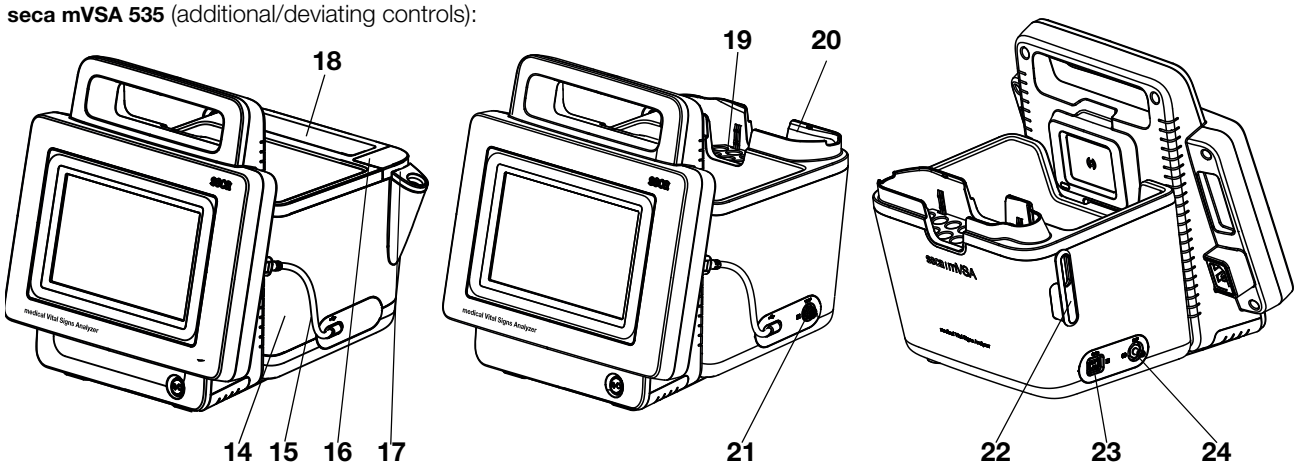
## 3.1 Monitor controls for seca 535/seca 525

**NOTE**
This section shows product versions. The functional scope of your device may deviate from this.

**seca mBCA 525**:




**seca mVSA 535** (additional/deviating controls):



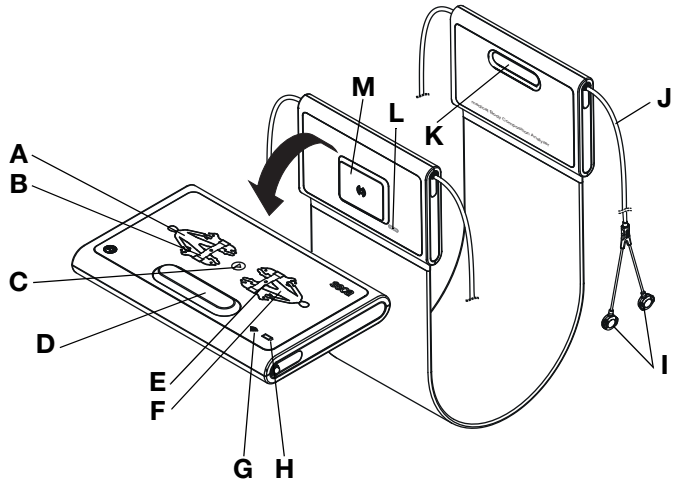

| No. | Control | Function |
|---|---|---|
| **1** | Handle | Transporting the device |
| **2** | Touchscreen display | Central control/display element |

17-10-05-353-002d_02-2019 B

| No. | Control | Function |
|---|---|---|
| **3** | ON/OFF button with LED | LED white: Device on |
| | | LED green: Device on standby |
| | | LED off: Device off |
| **4** | Storage compartment (**seca mBCA 525** only) | Transporting/storing the measuring mat (bioimpedance analysis) |
| | | Data transmission: Monitor/measuring mat |
| | | For charging measuring mat rechargeable battery |
| **5** | Power supply socket | For connecting the power supply cable |
| **6** | USB port, 2 pcs | For transmitting data via a USB memory stick |
| | | Transmit data between monitor and SmartBucket |
| | | Supply SmartBucket with power |
| | | Connect a scanner |
| **7** | ISIS port | Advance feature for future system upgrade (currently no function) |
| **8** | LAN port | Integrate device in a PC network, use with **seca analytics 115** PC software |
| **9** | Rechargeable battery compartment | To take lithium-ion rechargeable battery supplied |
| **10** | Infrared interface | Automatic data transmission: Monitor/measuring mat (alternative if no WiFi available) |
| **11** | Inductive charging interface with magnetic catch | For charging measuring mat rechargeable battery |
| **12** | Internal **seca 360°** wireless module | For connecting scales and stadiometers from the **seca 360° wireless** system |
| **13** | Internal WiFi module | Integrate device in a PC network, use with **seca analytics 115** PC software<br>For automatic transmission of data, monitor/measuring mat |
| **14** | SmartBucket (**seca mVSA 535** only) | Transporting/storing measuring equipment (bioimpedance analysis, vital signs) |
| | | For storing consumables |
| | | Data transmission: Monitor/measuring mat |
| | | For charging measuring mat rechargeable battery |
| **15** | Connecting cable with USB connector | Power supply and data transmission between monitor and SmartBucket |
| **16** | Connection for temperature measurement | For COVIDIEN™ FILAC™ 3000 temperature probes<br>• Blue: Oral/axillary measurement<br>• Red: Rectal measurement |
| **17** | Probe holder | For COVIDIEN™ FILAC™ 3000 temperature probes<br>• Blue: Oral/axillary measurement<br>• Red: Rectal measurement |
| **18** | Storage compartment for probe covers | Capacity: 2 packs for COVIDIEN™ FILAC™ 3000 |
| **19** | Removable magazine holder for probe covers | Capacity: 2 magazines for in-ear thermometers COVIDIEN™ GENIUS®2 |
| **20** | Thermometer compartment | For COVIDIEN™ GENIUS®2 in-ear thermometer |
| **21** | Connection for temperature measurement | For COVIDIEN™ GENIUS®2 in-ear thermometer |
| **22** | Holder | For $SpO_2$ sensor |
| **23** | Connection for $SpO_2$ measurement | Depending on version, to fit:<br>• Masimo SET® patient cables and sensors (no illustration)<br>• seca patient cables and sensors (shown in illustration) |
| **24** | Connection for blood pressure measurement | For seca blood pressure cuffs |

17-10-05-353-002d_02-2019 B

## 3.2 Measuring mat controls (bioimpedance analysis)

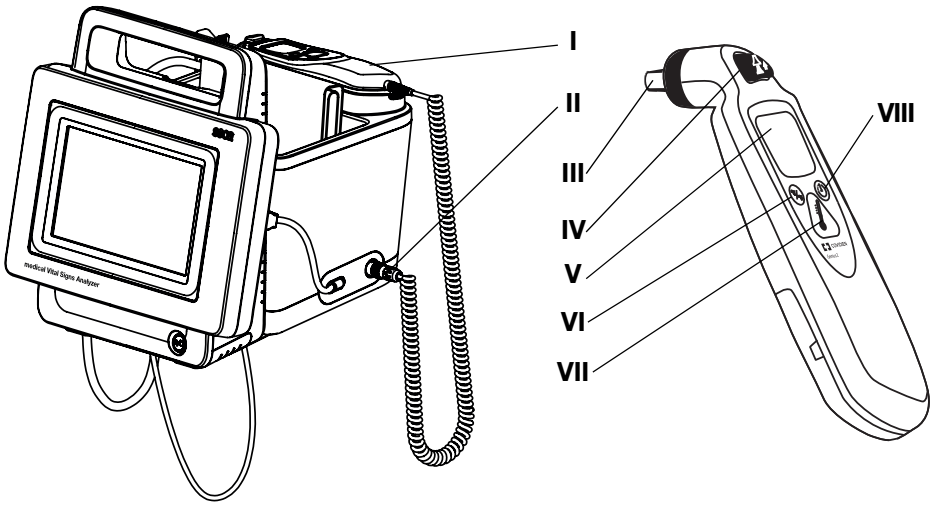



| No. | Control | Function |
|---|---|---|
| **A** | LEDs, electrodes on left | LED green: Electrode contact good |
| | | LED green, flashing: Measurement in progress |
| | | LED red: Electrode contact poor |
| **B** | Button with LED, patient position left | Enter patient position |
| | | LED green: seca patient file loaded, patient position selected |
| | | LED green, flashing: Measurement stopped |
| | | LED red: No seca patient file loaded |
| **C** | Start button | Start measurement |
| **D, K** | Magnetic catch | For folding up measuring mat for transport/storage |
| **E** | Button with LED, patient position right | Enter patient position |
| | | LED green: seca patient file loaded, patient position selected |
| | | LED green, flashing: Measurement stopped |
| | | LED red: No seca patient file loaded |
| **F** | LEDs, electrodes on right | LED green: Electrode contact good |
| | | LED green, flashing: Measurement in progress |
| | | LED red: Electrode contact poor |
| **G** | LED, WiFi | LED green: WiFi connection to monitor OK |
| | | LED green, flashing: WiFi connection being set up |
| | | LED red: No WiFi connection to monitor |
| | | LED off: WiFi deactivated |
| **H** | LED, charging status | LED green: Rechargeable battery full |
| | | LED green, flashing: Rechargeable battery almost discharged, charge as soon as possible |
| | | LED red: Rechargeable battery discharged |
| **I** | Electrode connections | For connecting to electrodes |
| **J** | Electrode cables | For transmitting signals from electrodes to the measuring mat |
| **L** | Infrared interface | Automatic data transmission: Monitor/measuring mat<br>Alternative if no WiFi available |
| **M** | Inductive charging interface with magnetic catch | For charging measuring mat rechargeable battery |

17-10-05-353-002d_02-2019 B

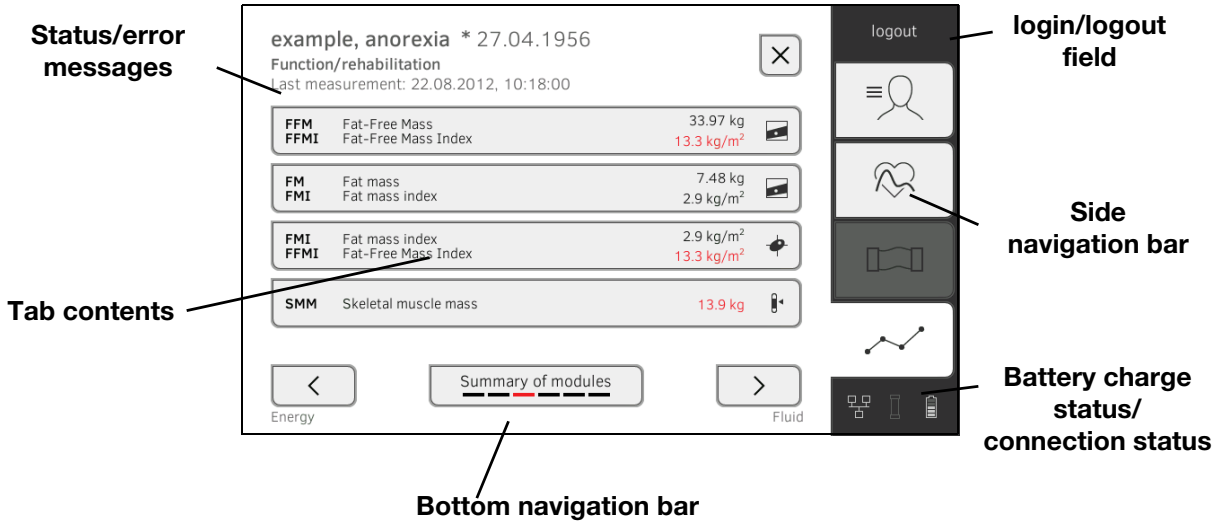
## 3.3 In-ear thermometer controls

**NOTE**
The illustration shows one equipment example. The actual functional scope of your device may deviate from this.



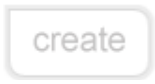

| No. | Control | Function |
|---|---|---|
| **I** | Thermometer | COVIDIEN™ GENIUS®2 In-ear thermometer |
| **II** | Connection for temperature measurement | For COVIDIEN™ GENIUS®2 in-ear thermometer |
| **III** | Measuring head | Measuring temperature in ear |
| **IV** | “Discard” button | For discarding probe cover |
| **V** | In-ear thermometer display | Serves as a secondary display. seca mVSA display takes priority |
| **VI** | “Switch unit” button | Switch between °C and °F |
| **VII** | “Measure” button | Press button to start measurement |
| **VIII** | “Pulse timer” button | Not relevant for seca mVSAs Pulse rate is determined automatically by the seca mVSA |

## 3.4 Fields in the touchscreen display




17-10-05-353-002d_02-2019 B

## 3.5 Login/navigation: Buttons and symbols in the touchscreen display

| Button/symbol | Meaning |
|---|---|
|  | **patient** tab |
|  | **vital signs** tabFor system upgrade, currently no function |
|  | **bia** tab |
|  | **analysis** tab |
|  | Open Instructions for Use |
|  | Instructions for Use: Return to section summary |
|  | Enter text or numbers |
|  | No input or input faulty |
|  | Select user account |
|  | Enter password |
|  | • Navigation: Confirm entry<br>• Measuring: Save measuring procedure |
|  | Process running |
|  | Button available |
|  | Button pressed |
|  | Button not available |
|  | Navigate left/right |
|  | Navigate up/down |

17-10-05-353-002d_02-2019 B

| Button/symbol | Meaning |
|---|---|
|  | One or more items from list selected/not selected |
|  | Alternative from list selected/not selected |
|  | • Back to previous screen<br>• Vital signs: Measurement is stored anonymously<br>• Administrator menu: Changes are accepted |
| **Logout** | Log off/switch user |

## 3.6 Operating state: Symbols

➔ Operating state: Symbols in the touchscreen display

➔ Operating state: Symbols on the measuring mat

### Operating state: Symbols in the touchscreen display

| Symbol | Operating state |
|---|---|
|  | Monitor:<br>Controls permanently on: Rechargeable battery charging status (%)<br>Controls flashing: Rechargeable battery charging |
|  | Measuring mat:<br>Controls permanently on: Rechargeable battery charging status (%)<br>Controls flashing: Rechargeable battery charging |
|  | Monitor:<br>Controls permanently on: Rechargeable battery full<br>Controls flashing consecutively: Rechargeable battery charging |
|  | Monitor: Rechargeable battery discharged |
|  | Measuring mat:<br>Controls permanently on: Rechargeable battery full<br>Controls flashing consecutively: Rechargeable battery charging |
|  | Measuring mat: Rechargeable battery discharged |
|  | LAN available |
|  | WiFi available |
|  | Measuring mat detected |

17-10-05-353-002d_02-2019 B

| Symbol | Operating state |
|---|---|
|  | Measuring mat not detected |
|  | Popup window:<br>Information for the user |
|  | Popup window:<br>Error message |
|  | Popup window:<br>Setting option for the user |
|  | Error message during vital signs measurement |

**Operating state: Symbols on the measuring mat**

| Symbol | Operating state |
|---|---|
|  | LED green: Rechargeable battery full<br>Green, flashing: Charge rechargeable battery as soon as possible |
|  | LED red: Rechargeable battery discharged |
|  | LED green: WiFi available<br>Green, flashing: WiFi connection being set up |
|  | LED red: WiFi not available<br>LED off: WiFi deactivated |

## 3.7 Measuring mode: Buttons and symbols


➔ “patient” tab
➔ “vital signs” tab
➔ “bia” tab
➔ Measuring mat
➔ “analysis” tab

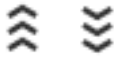

### “patient” tab

| Button/symbol | Meaning |
|---|---|
|  | Search for seca patient file |
|  | Switch sorting direction |
|  | Enter weight |
|  | Enter height |
|  | Enter waist circumference |
|  | Enter Physical Activity Level (PAL) |

17-10-05-353-002d_02-2019 B

| Button/symbol | Meaning |
|---|---|
|  | Adopt **seca 360° wireless** value |
|  | Adopt value from previous measurement |
|  | Close seca patient file, changes will not be saved |

**“vital signs” tab**

| Button/symbol | Meaning |
|---|---|
| **NIBP** | Blood pressure measured non-invasively |
|  | Start blood pressure measurement |
|  | Blood pressure measurement in progress |
| **SYS/DIA** | Blood pressure:<br>Systolic/diastolic pressure in mmHg |
| **MAD** | Blood pressure:<br>Mean arterial pressure in mmHg |
|  | Blood pressure:<br>Upward measurement, downward measurement |
|  | Blood pressure:<br>Single measurement, multiple measurement |
| **TEMP** | Temperature in °C |
|  | Temperature measurement mode:<br>Predictive, direct |
|  | temperature probe<br>COVIDIEN™ FILAC™ 3000<br>Measuring position: Oral, axillary, rectal |
|  | COVIDIEN™ GENIUS®2 in-ear thermometer<br>Measuring position: Oral |
| **PR** | Pulse rate in bpm |
|  | Measuring range for pulse rate:<br>Default, extended |
| **$SpO_2$** | Oxygen saturation in % |
| **PI** | Devices with Masimo SET® measuring equipment:<br>Perfusion index, information on the quality of perfusion (min: 0.02 %, max: 20 %) |

17-10-05-353-002d_02-2019 B

| Button/symbol | Meaning |
|---|---|
|  | Devices with Masimo SET® measuring equipment, oxygen saturation measuring mode:<br>Normal, APOD, maximum |
|  | Devices with seca measuring equipment, oxygen saturation measuring mode:<br>Stable, default, sensitive |
|  | Save measuring procedure |
|  | Discard measurement |
|  | Display list of all vital sign measurements |

**“bia” tab**

| Button/symbol | Meaning |
|---|---|
|  | Enter patient position |
|  | Start measurement |
|  | Measurement in progress |
|  | Permanently on: Electrode OK<br>Flashing: Measurement in progress |
|  | Electrode not OK |
|  | Measurement successful |
|  | Write comment |
|  | Save measuring procedure |
|  | Discard measurement |

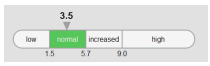
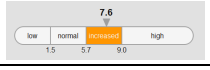
**Measuring mat**

| Button/symbol | Meaning |
|---|---|
|  | Enter patient position<br>LED green: seca patient file loaded, patient position selected<br>LED green, flashing: Measurement stopped<br>LED red: No seca patient file loaded |

17-10-05-353-002d_02-2019 B

| Button/symbol | Meaning |
|---|---|
|  | Start measurement |
|  | Electrode LEDs:<br>LED green: Electrode OK<br>LED green, flashing: Measurement in progress |
|  | Electrode LEDs:<br>LED red: Electrode not OK |

## “analysis” tab

| Button/symbol | Meaning |
|---|---|
|  | View history |
|  | Print results report (**seca directprint**: Function of **seca analytics 115**PC software) |
|  | Position indicator for analysis modules,<br>Here: second module of 5 |
|  | Position indicator for analysis parameters,<br>Here: second analysis parameter of 4 |
|  | Detail view available for analysis parameter:<br>Bar chart |
|  | Detail view available for analysis parameter:<br>Percentile curve |
|  | Detail view available for analysis parameter:<br>Tolerance ellipse |
|  | Parameter-dependent symbols, red: Value outside normal range |
|  | Parameter-dependent symbols, gray: Value within normal range |
|  | Text red: Value outside normal range |
|  | Text black: Value within normal range |
|  | Green: Value within normal range |
|  | Orange: Value elevated |
|  | Red: Value outside normal range |
|  | Male |
|  | Female |

17-10-05-353-002d_02-2019 B

## 3.8 Markings on the device and on the type plate

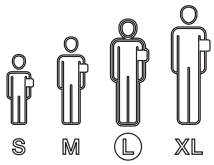
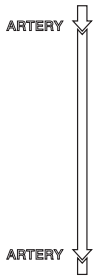
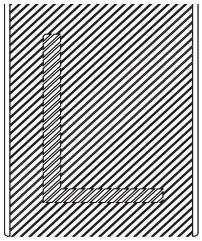
| Text/symbol | Meaning |
|---|---|
|  | Name and address of manufacturer, date of manufacture |
|  | Model number |
|  | Serial number, consecutive |
| **ProdID** | Product identification number, consecutive |
| **Mat.No.** | Variant number |
|  | Follow Instructions for Use |
|  | Do not use device on individuals with cardiac pacemakers or implanted defibrillators |
|  | Medical electrical device, type BF |
|  | Medical electrical device, type BF (defibrillation-protected) |
|  | No alarm function |
| **Li-ion** | Lithium-ion rechargeable battery |
|  | Device complies with EC directives<br>• **0123**: appointed office for medical devices |
|  | Symbol of the US Federal Communications Commission (FCC) |
| FCC ID | Device license number from the Federal Communications Commission (FCC) |
| IC | Device license number from Industry Canada |
|  | The device meets the regulatory requirements of INMETRO/ANVISA certification |
|  | The device meets the requirements of the Agência Nacional de Telecomunicações [National Telecommunications Agency (ANATEL), Brazil]. Details of the wireless device license:<br>- HHHHH: license number of device<br>- AA: year of license<br>- FFFFF: identification number of the manufacturer |
|  | The device meets the regulatory requirements of GOST R certification (Russia) |
|  | License number of the Chinese Pharmaceutical Association (CPA) |

17-10-05-353-002d_02-2019 B

| Text/symbol | Meaning |
|---|---|
|  | The device meets the regulatory requirements on wireless equipment in Japan. License number: VORL.202WW09118012 |
| **xxx-yyy V ~**<br>**min xx-yy Hz**<br>**xx A** | Type plate for power supply socket:<br>• Permitted supply voltage<br>• Permitted power supply frequency<br>• Power consumption |
|  | ON/OFF key |
|  | Inductive charging interface |
|  | LAN interface |
|  | USB interface |
| **NIBP** | Connection of blood pressure cuff |
| **TEMP** | Connection of temperature sensor |
| **$SpO_2$** | Connection of $SpO_2$ sensor |
|  | Do not dispose of device with household waste |

17-10-05-353-002d_02-2019 B

## 3.9 Markings on the blood pressure cuff

| Text/symbol | Meaning |
|---|---|
|  | Follow instructions for use |
|  | Cuff size (here: L) |
|  | Cuff suitable for specified arm size |
|  | Artery position: These arrows must be on the brachial or femoral artery when blood pressure cuff is put on. |
|  | Cuff end: These markings must be within the adjustment range when closing the blood pressure cuff. |
|  | Adjustment range: The marking “Cuff end” must be in this range when closing the blood pressure cuff. This area also contains the cuff size (here: L). |
|  | Latex-free |
|  | The blood pressure cuff complies with EU directives |

17-10-05-353-002d_02-2019 B

## 3.10 Markings on the packaging

| | |
|---|---|
|  | Protect from moisture |
|  | Arrows indicate top of product<br>Transport and store in an upright position |
|  | Fragile<br>Do not throw or drop |
|  | Permitted min. and max. temperature for transport and storage |
|  | Permitted min. and max. moisture for transport and storage |
|  | Not sterile |
|  | Do not reuse |
|  | Open packaging here |
|  | Packaging material can be disposed of through recycling programs |

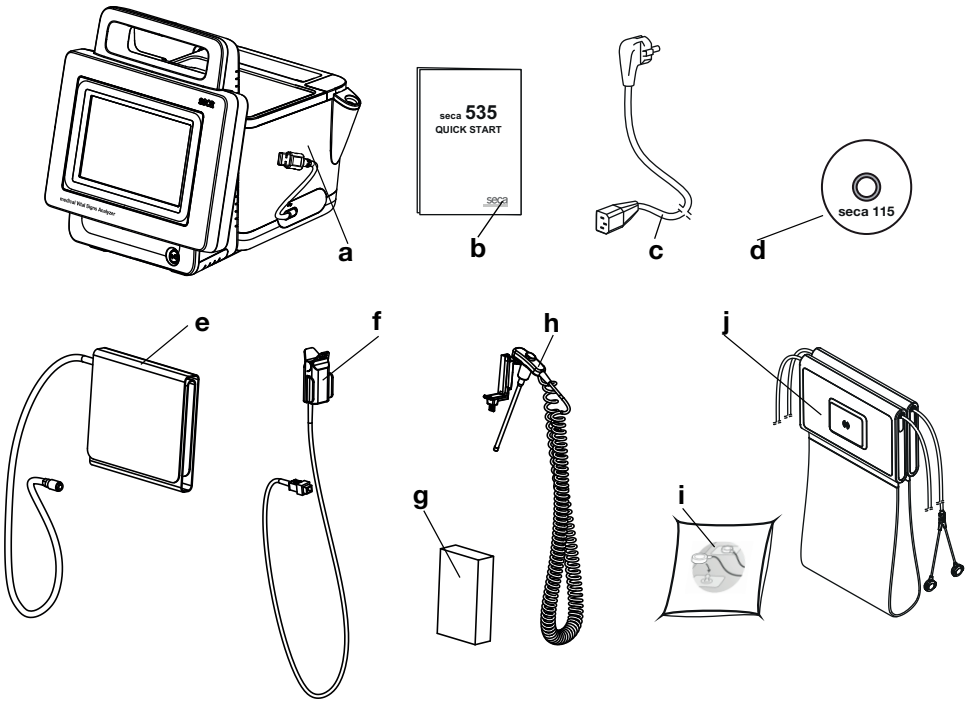
17-10-05-353-002d_02-2019 B

# 4. START UP DEVICE



## 4.1 Scope of delivery

**NOTE**
This section shows version 535-3110-001 by way of an example. The scope of delivery of your device may deviate from this. An overview of versions can be found at www.seca.com




| No. | Standard scope of delivery | Pcs. |
|---|---|---|
| **a** | Monitor to suit the version ordered | 1 |
| **b** | "Quick Start" brief instructions, printed | 1 |
| **c** | Power supply cable (country-specific) | 1-3 |
| **-** | Accessories to suit the version ordered (for details of version shown, see below) | - |

| No. | Accessory for the version shown | Pcs. |
|---|---|---|
| **d** | DVD with **seca analytics 115** PC software and license for one permanent workstation | 1 |
| **e** | seca Blood pressure cuff, size L | 1 |
| **f** | • $SpO_2$ sensor (Masimo SET® or seca)<br>• Patient cable (Masimo SET® or seca), or as illustration | 1<br>1 |
| **g** | COVIDIEN™ FILAC™ 3000 probe covers (pack of 20) | 1 |
| **h** | COVIDIEN™ FILAC™ 3000 temperature probe | 1 |

17-10-05-353-002d_02-2019 B

| No. | Accessory for the version shown | Pcs. |
|---|---|---|
| i | Push-button electrodes for affixing to patient (pack of 100) | 1 |
| j | Measuring mat with rechargeable battery and electrode cables | 1 |

## 4.2 Set up device


➔ Connect SmartBucket

➔ Connect blood pressure cuff

➔ Connect temperature probe

➔ Connect in-ear thermometer

➔ Connect $SpO_2$ sensor

➔ Suspend measuring mat in magnetic catch


**NOTE**

This section shows how to assemble all of the measurement accessories available for this device. The actual scope of delivery of your device may be less than this.

**NOTICE!**

**Device damage, malfunction**

Excessive use of force may damage tubes and cables.

- Only take hold of tubes at the tube coupling when attaching measuring accessories to the device or removing them from it.
- Only take hold of cables at the connectors when attaching measuring accessories to the device or removing them from it.
- Use only measuring accessories which have no externally visible damage.

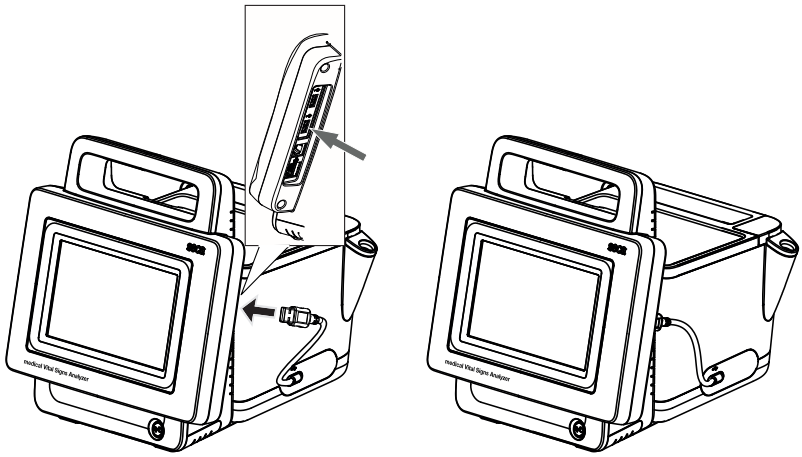
### Connect SmartBucket

**NOTICE!**

**Malfunction**

The SmartBucket needs one of the USB interfaces for communication and power supply. If the USB connection is removed, no vital data can be measured.

- Always keep the SmartBucket connected to the USB interface.
- Only connect accessories, for example, a USB memory stick, to the other USB interface.

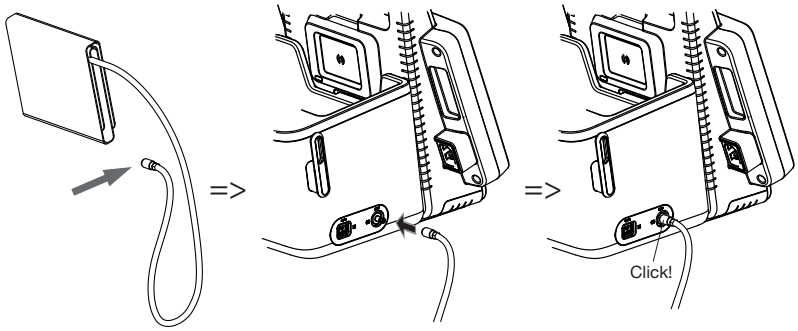


- Connect the USB cable of the SmartBucket to a free USB port of the monitor.

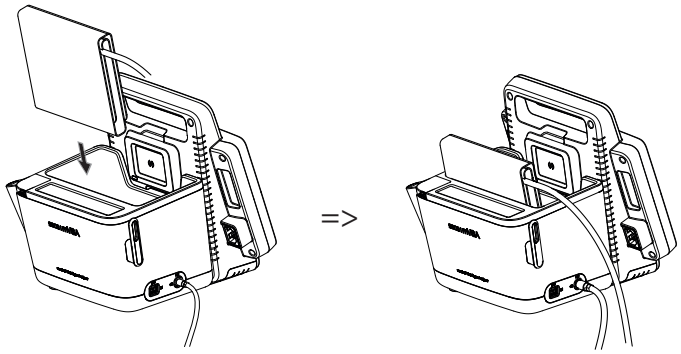
17-10-05-353-002d_02-2019 B

## Connect blood pressure cuff

1. Connect the tube coupling for the blood pressure cuff to the compressed air connection of the device until you hear the tube coupling engage.

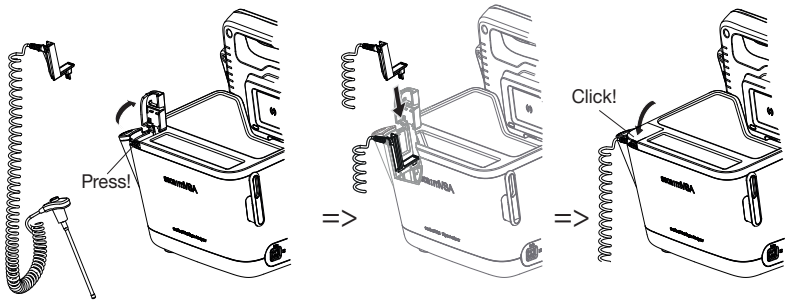



2. Stow the blood pressure cuff in the SmartBucketas shown in the illustration below.

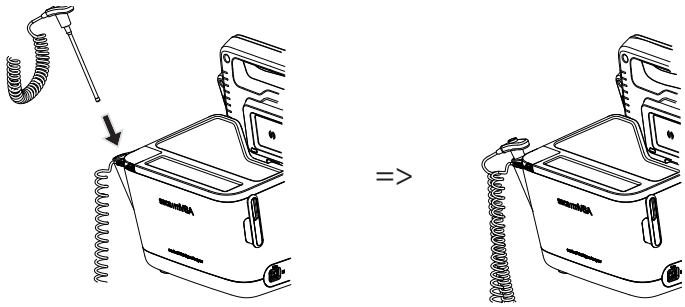



## Connect temperature probe

1. Open the cover cap of the connection compartment.
2. Insert the connector for the temperature probe completely in the probe connection as shown in the illustration below.
3. Close the cover cap of the connection compartment.




4. Push the temperature probe completely into the probe holder as shown in the illustration below.




17-10-05-353-002d_02-2019 B

**ATTENTION**

**Device damage, malfunction**

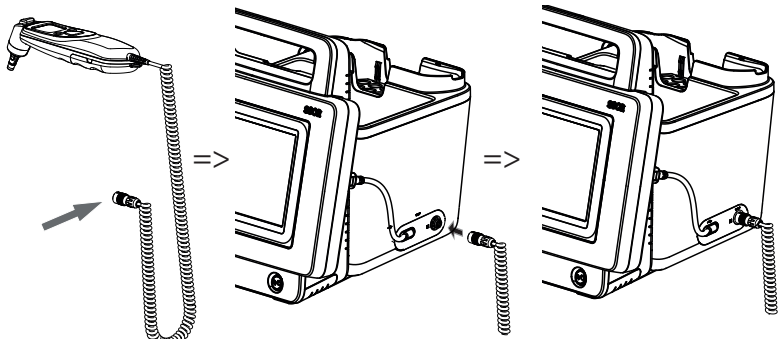
The temperature probe can only be pushed right into the probe holder if it does not have a probe cover on.

- ► Ensure that there is no probe cover on the temperature probe.

**NOTE**

The storage compartment on the probe connection provides space for two packs of probe covers.

## Connect in-ear thermometer

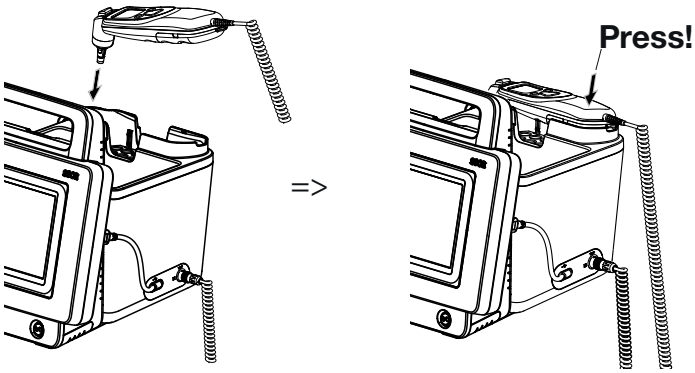


1. Put the connector for the in-ear thermometer in the socket on the Smart-Bucket until you feel the connector engage.

**NOTE**

The magazine holder in the thermometer compartment provides space for two probe cover magazines.

2. Place the in-ear thermometer in the thermometer compartment as shown in the illustration below.




## Connect $SpO_2$ sensor

**NOTICE!**

**Device damage, malfunction**

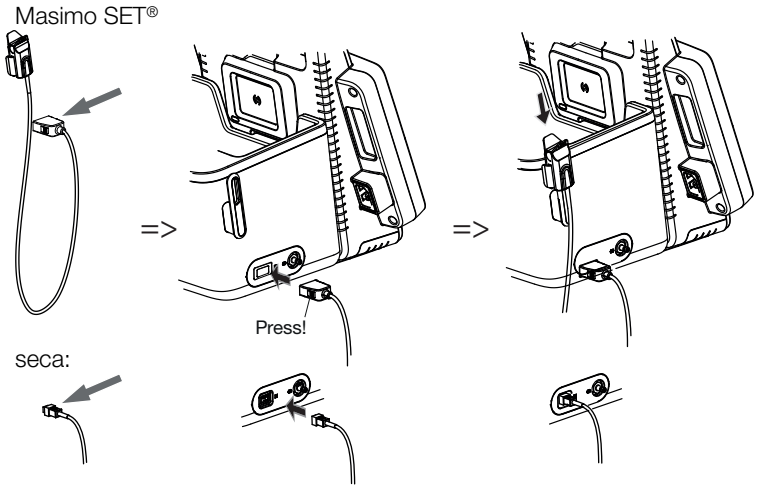
The $SpO_2$ sensor must be compatible with the $SpO_2$ measuring equipment (Masimo SET® or seca) fitted.

- ► Ensure that the $SpO_2$ sensor is compatible with the $SpO_2$ measuring equipment fitted in your device ➔ Optional accessories and spare parts.
- ► Follow the user documentation from the sensor manufacturer.

1. If necessary, connect a patient cable to the $SpO_2$ sensor as described in the user documentation from the sensor manufacturer.

17-10-05-353-002d_02-2019 B

2. Put the connector for the $SpO_2$ sensor/the patient cable in the socket on the SmartBucket until you feel the connector engage.



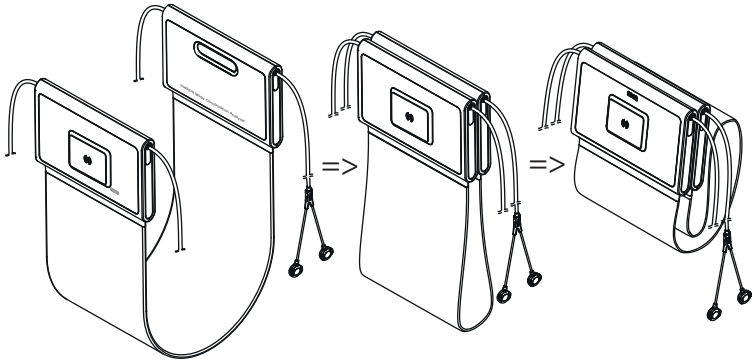

**NOTE**
The holder above the $SpO_2$ connection is for storing the $SpO_2$ sensor.

## Suspend measuring mat in magnetic catch

**NOTICE!**
**Malfunction**
The measuring mat rechargeable battery is only charged via the inductive charging interface of the monitor.

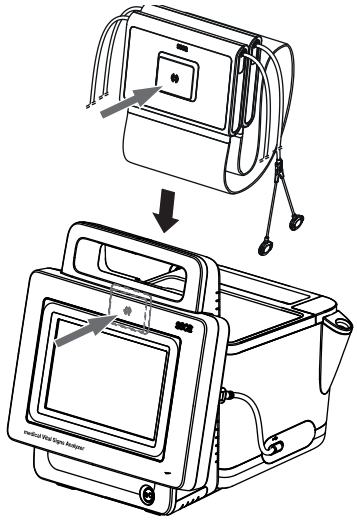
- Ensure that the inductive charging interface is not covered by other measuring accessories such as a blood pressure cuff, for example.
- After each measurement, suspend the measuring mat back in the magnetic catch. This ensures that the measuring mat rechargeable battery is always adequately charged.

1. Fold up the measuring mat as shown in the illustration below.

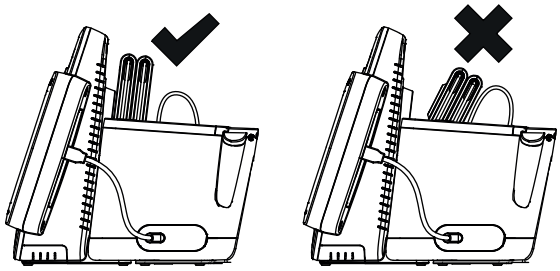



17-10-05-353-002d_02-2019 B

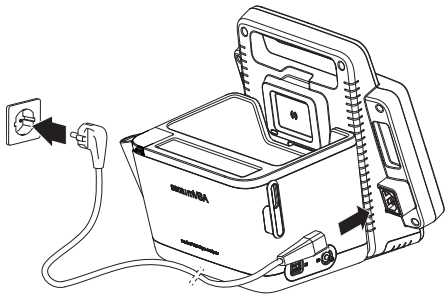
2. Suspend the measuring mat in the magnetic catch as shown in the illustration below.



3. Ensure that the measuring mat is correctly located in the magnetic catch of the monitor.



## 4.3 Establish power supply



1. Plug the device connector of the power supply cable into the connecting socket of the device.
2. Plug the power supply connector into a power supply socket.

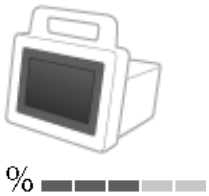
17-10-05-353-002d_02-2019 B

## 4.4 Charge rechargeable batteries

Before starting up the device for the first time, the rechargeable batteries for the monitor and the measuring mat - if there is a measuring mat - must be fully charged.

1. Ensure that the measuring mat is correctly suspended in the magnetic catch of the monitor ➔ Suspend measuring mat in magnetic catch.
2. Connect the device to the power supply ➔ Establish power supply.

3. Press the ON/OFF button of the monitor.
   The LED of the ON/OFF button is white.
   The charging process starts.
   The current charging status is displayed for approx. 15 seconds:


   After approx. 5 minutes, the device switches to standby.
   The screen goes dark.
   The ON/OFF button LED flashes green.
   When the rechargeable batteries are fully charged, the device switches off automatically.
   The LED of the ON/OFF button goes out.

**NOTE**
Leave the device connected to the power supply for approx. 4 hours when starting it up for the first time. This ensures that the rechargeable batteries for the monitor and the measuring mat are fully charged.

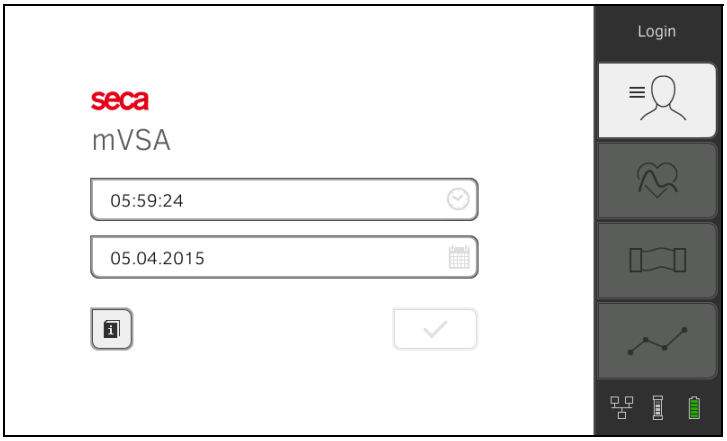
## 4.5 Set date and time

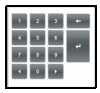
When you start up the device for the first time, you first need to set date and time.

1. Ensure that the measuring mat - if there is a measuring mat - is correctly suspended in the magnetic catch of the monitor ➔ Suspend measuring mat in magnetic catch.
2. Connect the device to the power supply.

17-10-05-353-002d_02-2019 B

3. Press the ON/OFF button of the monitor.
   The LED of the button is white.
   The initial start screen appears.




4. Enter the current date:
   a) Press input field 
   b) Enter the current date using the keypad 
   c) Confirm your entry by pressing the  button
5. Enter the current time:
   a) Press input field 
   b) Enter the current time using the keypad 
   c) Confirm your entry by pressing the  button
6. Press the  button.
7. Continue operating the device - you have the following options:

- Leave device switched on, charge rechargeable batteries (recommended): ➔ Charge rechargeable batteries
- Perform measurements using the power supply: ➔ Operation
- Configure device using the power supply: ➔ For administrators: Configure seca 535/seca 525

## 4.6 Configure the device

The device can only be configured by users with administrator rights. Further information is available here: ➔ For administrators: Configure seca 535/ seca 525.

17-10-05-353-002d_02-2019 B

# 5. OPERATION



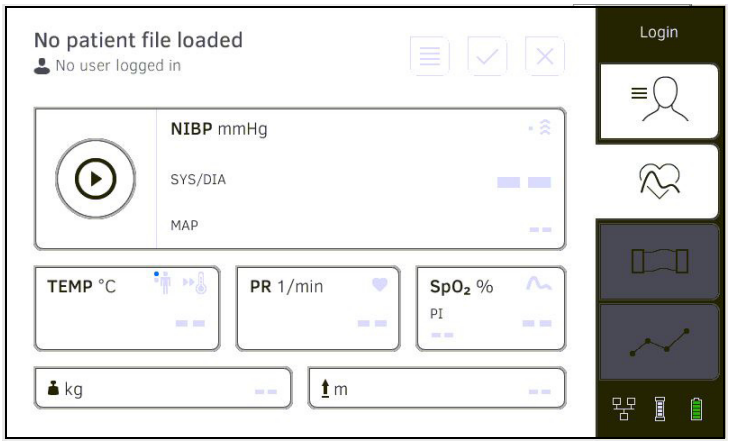
## 5.1 Switch system on/off



### Switch on

1. Ensure that the measuring mat - if there is a measuring mat - is correctly suspended in the magnetic catch of the monitor ➔ Suspend measuring mat in magnetic catch.

2. Press the ON/OFF button of the monitor.
   The LED of the ON/OFF button is white.
   The internal PC boots up. This takes several seconds.




   The **vital signs** tab is displayed.
   The measuring mat - if there is one - switches on automatically.
   You have the following options:

   - Measure vital signs (without patient identification) ➔ Measure vital signs
   - Use full functional scope: Log on ➔ Log in

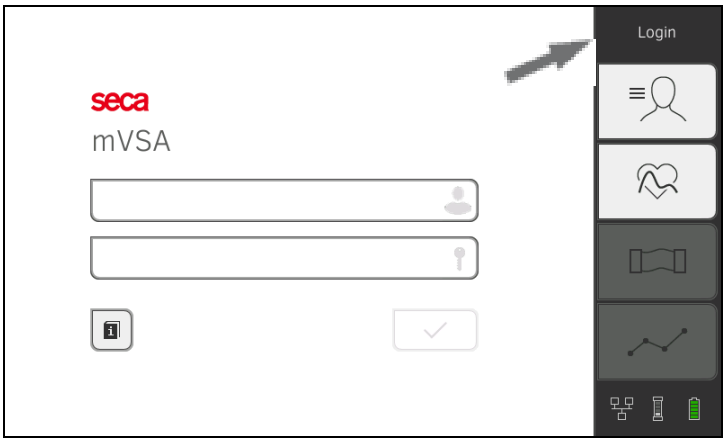
17-10-05-353-002d_02-2019 B

## Log in

You have to log in to the device for the steps below.

- Assign vital signs measurement to a seca patient file
- Perform a bioimpedance measurement
- Analyze measured results
- Administer the system

1. Press the **Login** button.



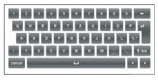

The login window is displayed.

2. Press the input field  .
The list of user accounts is displayed.
The following user accounts are available when you first start up the device:
   - Administrator: admin
   - User: demouser1, demouser2

   **NOTE**
   “demouser1” and “demouser2” are example user accounts for training purposes. If you log in as demouser, you can select example patient files, view existing measured results and perform training measurements.

3. Press your user account.
Your user account is displayed in the input field.

4. Press the input field .

5. Enter your password using the keypad  (admin: “1357”, demouser1: “1234”, demouser2: no password).

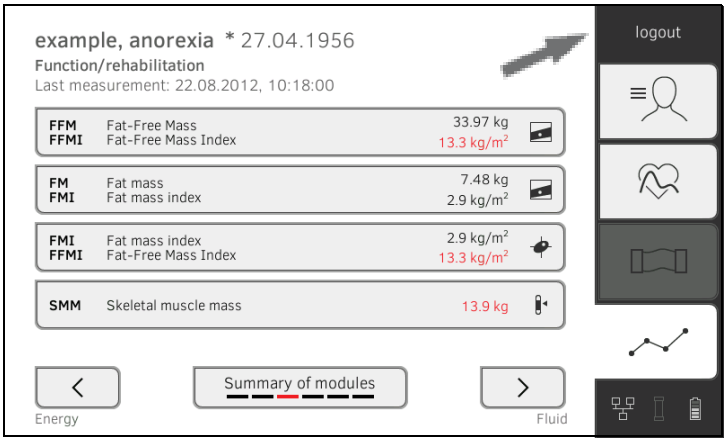
   **NOTICE!**
   **Unauthorized data access**
   Failure to change the initial admin password may lead to unauthorized access to patient data or device settings.

6. Continue depending on your login.
   - ► Logged in as a user: The **patient** tab is displayed. Continue with ➔ Prepare seca patient file
   - ► Logged in as administrator: The administrator area is displayed. Continue with ➔ For administrators: Configure seca 535/seca 525

17-10-05-353-002d_02-2019 B

## Log out/switch user

► Press the **logout** button.




You will be logged out.
The login window is displayed.
Another user can log in ➔ Log in.

## Save energy

The device provides three energy-saving modes which are activated automatically after 5, 10 and 20 minutes if no entries are made:

After 5 minutes, the device switches to standby:

- The LED of the ON/OFF button is green.
- The touchscreen display goes dark.
- All entries are retained.
- The measuring mat remains switched on.

After you switch back on, you have to log in again. Operation can be continued.

After 10 minutes, the device goes to sleep:

- The LED of the ON/OFF button goes out.
- Data which have not been saved are lost.
- The measuring mat - if there is one - switches off.

After you switch back on, you have to log in again. Entries have to be made again.

After 20 minutes, the device behaves as follows:

- Power supply operation:
  - The charging process for the rechargeable batteries for the device and the measuring mat - if there is one - starts automatically.
  - The device remains asleep.
- Rechargeable battery operation:
  - The internal PC shuts down.
  - The device switches off.

## Switch the monitor to standby

► Briefly press the ON/OFF button of the monitor.
The LED of the ON/OFF button is green.
The touchscreen display goes dark.
The monitor is on standby ➔ Save energy.

17-10-05-353-002d_02-2019 B

### Switch off

**WARNING!**
**Electric shock**
The monitor cannot be de-energized by pressing the ON/OFF button.

- ► Always remove the power supply connector and remove the re-chargeable battery (if present and intended for technical purposes) if the device needs to be de-energized, e.g. for the hygiene treatment.

1. Ensure that the measuring mat - if there is a measuring mat - is correctly suspended in the magnetic catch of the monitor ➔ Suspend measuring mat in magnetic catch.
2. Keep the ON/OFF button of the monitor pressed until the touchscreen display and the LED of the ON/OFF button go out.
   The device is switched off.
   The measuring mat switches off automatically.

## 5.2 Prepare seca patient file

➔ Introduction

➔ Call up seca patient file

➔ Create seca patient file

➔ Enter basic parameters

### Introduction

Before every bioimpedance measurement, ➔ Measure bioimpedance you have to prepare a seca patient file in the **patient** tab. The prepared seca patient file is transmitted to the measuring mat.

For vital signs measurement ➔ Measure vital signs, you do not initially need to prepare a patient file. After the measurement you can decide whether you want to assign the measured results to a patient file.

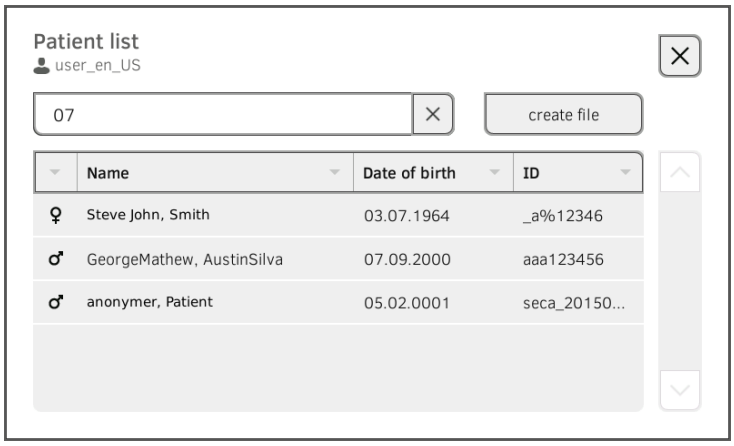

Preparation of the seca patient file includes the following items:

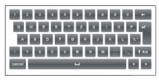
- Call up or create seca patient file ➔ Call up seca patient file or ➔ Create seca patient file
- enter weight, height, waist circumference and Physical Activity Level ➔ Enter basic parameters

17-10-05-353-002d_02-2019 B

## Call up seca patient file

1. Press the **patient** tab.
2. Press the **open patient list** button.




3. Select a seca patient file:
   - ► Desired entry not visible: Continue at Step 4.
   - ► Desired entry visible: Continue at Step 5.
4. Search for the desired seca patient file in the list:
   a) Press input field 
   b) Enter patient name or patient ID using the keypad 
   c) Confirm your entry by pressing the  button

   A hit list is displayed.
5. Press the desired entry.
   The selected seca patient file appears in the **Patient information** dialog field.
6. Press the **confirm** button.
   The seca patient file is opened.
7. Enter the basic parameters ➔ Enter basic parameters.

## Create seca patient file

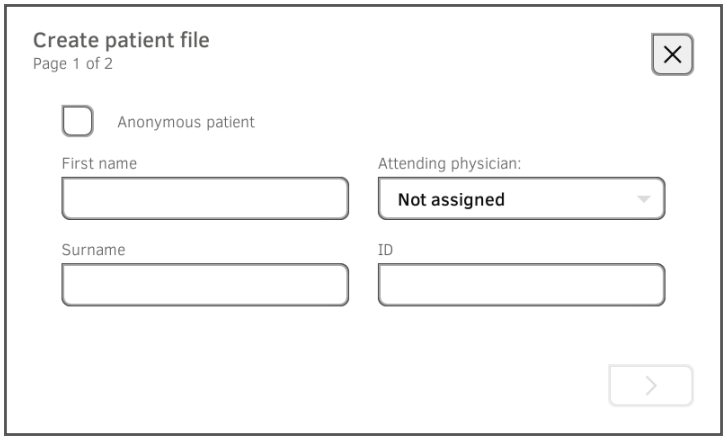
**NOTICE!**
**Inconsistent measured results**
If you create seca patient files several times, this can lead to incorrect assignment of measured results and falsify the analysis.

- ► If there is no seca patient file on the device for the current patient, check whether there is already a seca patient file in the **seca analytics 115** PC software.
- ► If there is a seca patient file for the current patient in the **seca analytics 115** PC software, ask your administrator to synchronize the data of the device and the PC software.
- ► Only create a new seca patient file directly on the device if you are sure that there is no seca patient file for the current patient in the **seca analytics 115** PC software.

1. Ensure that the measuring mat - if there is a measuring mat - is correctly suspended in the magnetic catch of the monitor ➔ Suspend measuring mat in magnetic catch.
2. Press the **patient** tab.

17-10-05-353-002d_02-2019 B

3. Press the **create patient file** button.

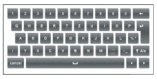



**NOTICE!**
**Restricted function**
If you press the **Anonymous patient** field, the first input screen is skipped and an anonymous patient file is created. It is not possible to display **any** measured value graphs (histories) in anonymous patient files.

- Always fill in **both** input screens in order to be able to show measured value graphs (histories).

4. Enter the first name and surname of the patient:

a) Press input field 

b) Enter text using the keypad 

c) Confirm your entry by pressing the  button

**NOTICE!**
**Unauthorized data access**
Failure to enter an attending physician makes patient data accessible to all physicians who have been granted access to this device.

- Enter the attending physician to prevent unauthorized access. If an attending physician is not yet assigned upon measurement make sure to add this entry as soon as possible.

5. Enter the attending physician (optional):

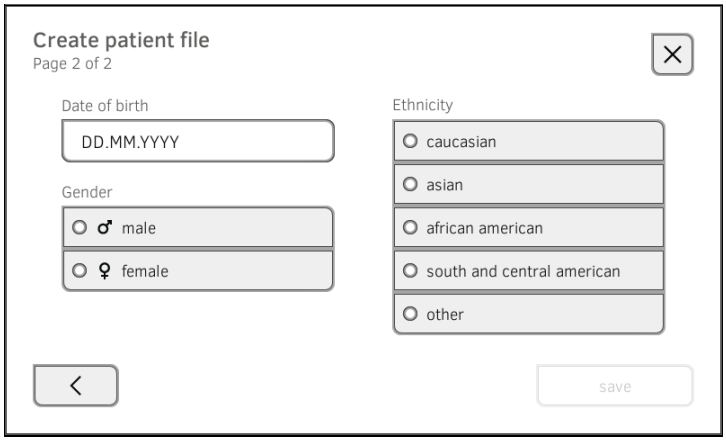
a) Press input field 

b) Press the attending physician in the dropdown menu

**NOTE**
You only need to assign a patient ID if this has to follow a specific structure in your institution. If you leave the **ID** input field empty, the device will automatically assign an ID when the data are saved.

17-10-05-353-002d_02-2019 B

6. Press the  button.




7. Enter the date of birth:
   a) Press input field 
   b) Enter dates using the keypad  .
   c) Confirm your entry by pressing the  button
8. Press the appropriate gender.
9. Press the appropriate ethnicity.
10. Press the **save** button.
    The seca patient file has been created and is displayed.

    **NOTE**
    If you realize that patient data need changing, contact your administrator.
11. Enter the basic parameters ➔ Enter basic parameters.

## Enter basic parameters

After you have called up a seca patient file ➔ Call up seca patient file or created a new one ➔ Create seca patient file, you must enter basic parameters so that the device can analyze the measurement correctly.


17-10-05-353-002d_02-2019 B

You can enter the values for basic parameters manually or take them from other sources:

• = possible, - = not possible

| Button | Meaning | Enter manually | seca 360° Adopt value | Re-use old value |
|---|---|---|---|---|
|  | Weight | • | • | • |
|  | Height | • | • | • |
|  | Waist circumf. | • | - | • |
|  | Physical Activity Level (PAL) | • | - | • |

**NOTE**
If you are unsure whether the device is set up for receiving measurement results from devices from the **seca 360° wireless** system, contact your administrator. Follow the Instructions for Use for the **seca 360° wireless** device that is used.

1. Ensure that the measuring mat - if there is a measuring mat - is correctly suspended in the magnetic catch of the monitor ➔ Suspend measuring mat in magnetic catch.
2. Press a basic parameter.
   You have the following options for entering the value:
   - Enter value using the keypad 
   - **seca 360° wireless** Confirm the value using the  button
   - Adopt the value from the previous measurement using the  button
3. Confirm the entry with the  button.
4. Repeat steps 2. and 3. for the remaining basic parameters.
5. Press the  button.
   The seca patient file is prepared and is displayed.
6. Press the **bia** tab.
   The seca patient file is transmitted to the measuring mat.
   You can start with the measurement ➔ Measure bioimpedance.

17-10-05-353-002d_02-2019 B

## 5.3 Measure bioimpedance


➔ Performing a measurement (with WiFi direct connection to the measuring mat)

➔ Performing a measurement (without WiFi direct connection to the measuring mat)

➔ Connecting the measuring mat

➔ Cancel a measurement procedure


**WARNING!**
**Hazard to patient, malfunction, damage to device**

- Set up the device so that it cannot fall on patients.
- Route the cables and tubes of the measurement accessory so that the patient cannot become entangled or be strangled.
- The device has **no** alarm function. Never leave the patient unobserved during a measurement.
- Always connect only one individual patient to the device for each measurement procedure.

Observe the points below in order to obtain meaningful and comparable bioimpedance measurements.

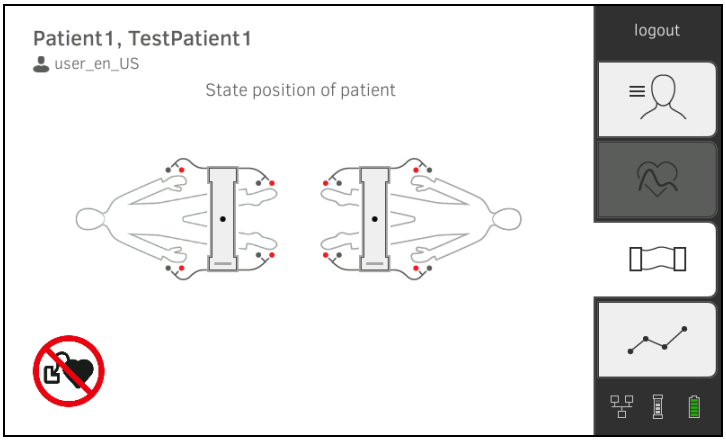
- Amount of time patient should lie **before** each measurement: Approx. 10 minutes
- If possible, arrange follow-up measurements at the same time of day

### Performing a measurement (with WiFi direct connection to the measuring mat)

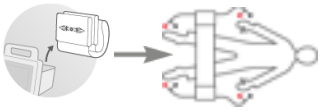
If a direct WiFi connection is **active** between the monitor and the measuring mat, the measuring mat and the monitor communicate continuously. Therefore, some operating steps can be performed on both the monitor and the measuring mat.

**NOTE**
If you are unsure whether the WiFi direct connection between the monitor and the mat is active, contact your administrator.

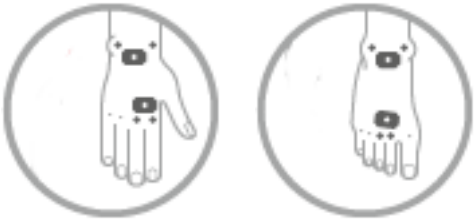
1. Switch on the system ➔ Switch system on/off.
2. Prepare the seca patient file ➔ Prepare seca patient file.
   The seca patient file is transmitted to the measuring mat.
3. Press the **bia** tab.
4. Wait until the position keys on the monitor are active.



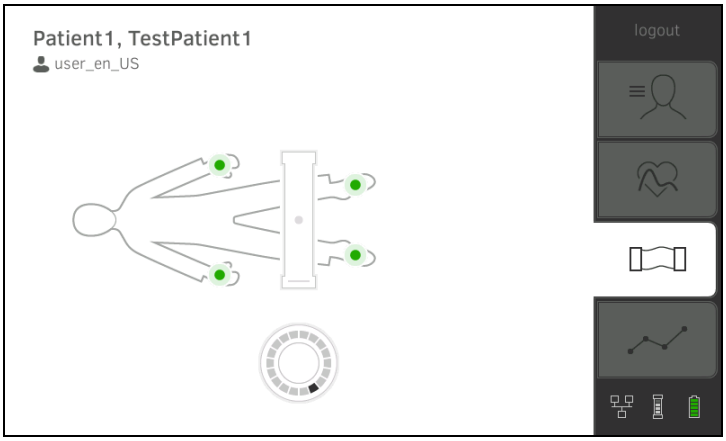

17-10-05-353-002d_02-2019 B



5. Attach the electrodes to all extremities as shown.



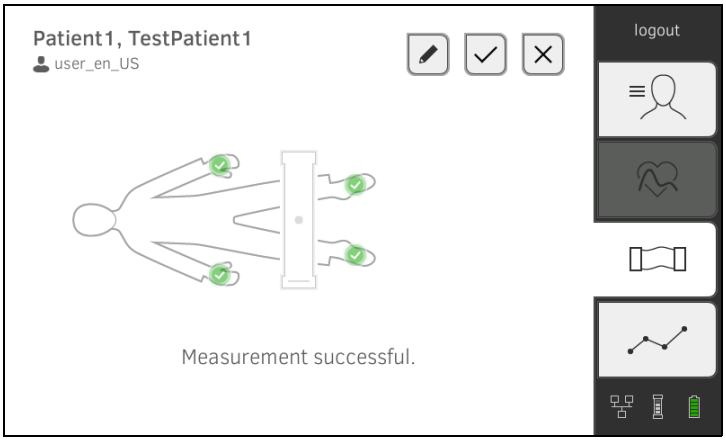
6. Take the measuring mat out of the magnetic catch on the monitor.
7. Connect the measuring mat to the electrodes ➜ Connecting the measuring mat.
8. Perform the following steps on the monitor or on the measuring mat:
   a) Enter patient position: press the relevant position key
   b) Start the measurement procedure: Press  button
9. Watch the measurement progress on the monitor:




| Monitor | | | |
|---|---|---|---|
| **Measurement progress** | | **Electrode symbol** | **Progress symbol** |
| 1. | Electrodes being tested |  |  |
| 2. | Measurement in progress<br>Measured results are stored on the measuring mat |  |  |
| 3. | Measured result are transmitted to the monitor |  |  |
| 4. | Measurement end: Measured results were transferred to the monitor |  | Off |

17-10-05-353-002d_02-2019 B

The measurement procedure is completed when the message **Measurement successful** appears.




You have the following options to continue:

- Press  button: Add comments.
- Press  button: Save measurement
- Press **analysis** tab ➔ Analyze measurement.
- Press **vital signs** tab: ➔ Measure vital signs
- Press  button: Discard measurement

10. Remove the electrode cables from the electrodes.
11. Remove the electrodes from the patient.

## Performing a measurement (without WiFi direct connection to the measuring mat)

If **no** WiFi direct connection is **active** between the monitor and measuring mat, some operating steps can only be carried out at the measuring mat. Measuring mat and monitor communicate via an infrared connection. The measuring mat must be attached in the magnetic catch of the monitor before and after a measurement so that data can be transferred.

**NOTE:**
If you are unsure whether the WiFi direct connection between the monitor and the mat is active, contact your administrator.

1. Switch on the system ➔ Switch system on/off.
2. Ensure that the measuring mat is correctly suspended in the magnetic catch of the monitor ➔ Suspend measuring mat in magnetic catch.

The  symbol is displayed on the monitor.

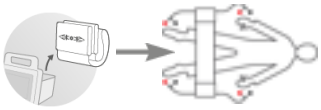
3. Prepare the seca patient file ➔ Prepare seca patient file.
The seca patient file is transmitted to the measuring mat.

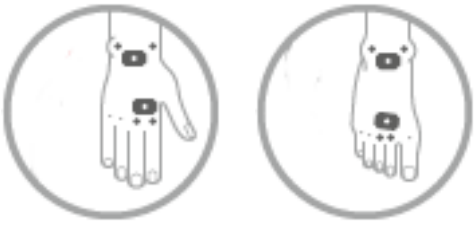
17-10-05-353-002d_02-2019 B

4. Press the **bia** tab.


**NOTE**
If you tap the operating steps on the screen, additional information will be displayed to assist you with the bioimpedance measurement.

5. Attach the electrodes to all extremities as shown.



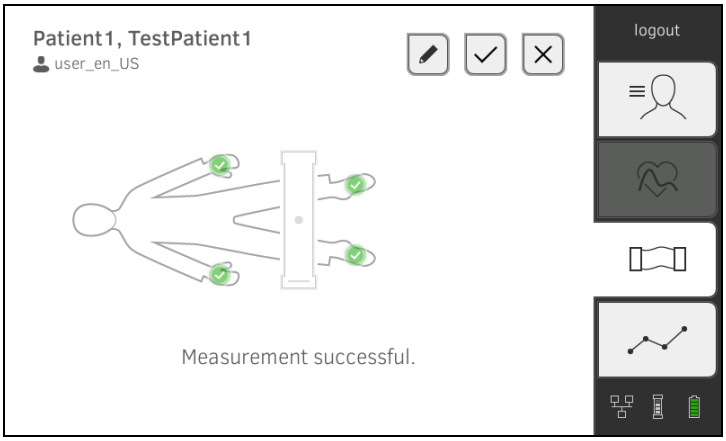


6. Take the measuring mat out of the magnetic catch.
7. Connect the measuring mat to the electrodes ➔ Connecting the measuring mat.
8. Use the keyboard of the measuring mat for the following steps:
   a) Enter patient position: press the relevant position key
   b) Start the measurement procedure: Press button
9. Observe the measuring progress on the measuring mat:

| Measuring mat | | | |
|---|---|---|---|
| **Measurement progress** | | **Electrodes** | **Patient position** |
| 1. | • Patient position is given<br>• Electrodes being tested | On | On |
| 2. | • Measurement in progress<br>• Measured results are stored on the measuring mat | Flashing | On |
| 3. | Measurement end: Measurement results are stored on the measuring mat, waiting for transmission to the monitor | Off | Flashing |

17-10-05-353-002d_02-2019 B

10. Remove the electrode cables from the electrodes.
11. Remove the electrodes from the patient.
12. Suspend the measuring mat in the storage compartment of the monitor
    ➔ Suspend measuring mat in magnetic catch.
    The updated seca patient file is transmitted to the monitor.
    The measurement procedure is completed when the message **Measurement successful** appears.



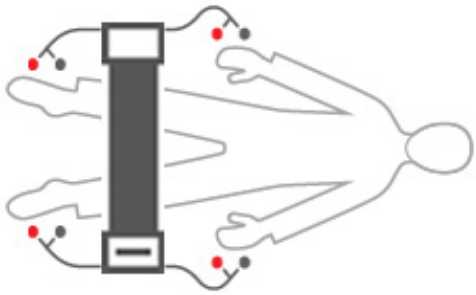

You have the following options to continue:

- Press  button: Add comments
- Press  button: Save measurement
- Press **analysis** tab ➔ Analyze measurement
- Press **vital signs** tab: ➔ Measure vital signs
- Press  button: Discard measurement

## Connecting the measuring mat

The device is intended for bioimpedance measurements using the 8-point method (measurement of the whole body) with the patient in a lying position. Measurement by the 4-point method (right half of the body) is likewise possible.

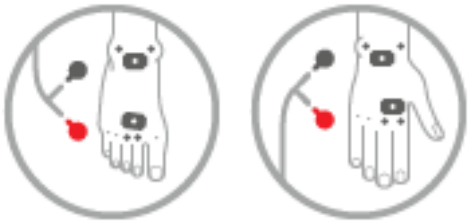
1. Lay the measuring mat on the patient's knees.
   - The side with the writing on it should be facing upwards
   - The key should be facing the user



**NOTE**
If you want to measure with the 4-point method, connect the electrode cables on the key of the measuring mat to the hand and foot electrodes of the right half of the body.

17-10-05-353-002d_02-2019 B

2. Connect the measuring mat to the electrodes.
   - Arrange the electrode cables so that they do not cross over one another
   - Set push-button adapter on electrodes (black: proximal, red: distal)



3. Ask the patient to perform the following during the measurement:
   - Spread arms and legs away from the body
   - Lie still
4. Continue with the measurement as described in the relevant section.
   - Step 8. of the measurement with active WiFi direct connection
   - Step 8. of the measurement without active WiFi direct connection

**Cancel a measurement procedure**

You can cancel the measurement procedure at any time.

1. Press the **logout** button.
   The measurement procedure will be discarded.
2. Log in again ➔ Log in.

## 5.4 Measure vital signs

➔ Introduction

➔ Measure blood pressure

➔ Measure temperature orally/axillary (COVIDIEN™ FILAC™ 3000, blue)

➔ Measure temperature rectally (COVIDIEN™ FILAC™ 3000 red)

➔ Measuring temperature in the ear (COVIDIEN™ GENIUS®2)

➔ Read off pulse rate

➔ Measure oxygen saturation ($SpO_2$)

➔ Display weight and height

➔ Stop a measurement procedure

➔ Assigning anonymous measurement procedure to a seca patient file

➔ Display “Measurements vital signs” list

**WARNING!**
**Hazard to patient, malfunction, damage to device**

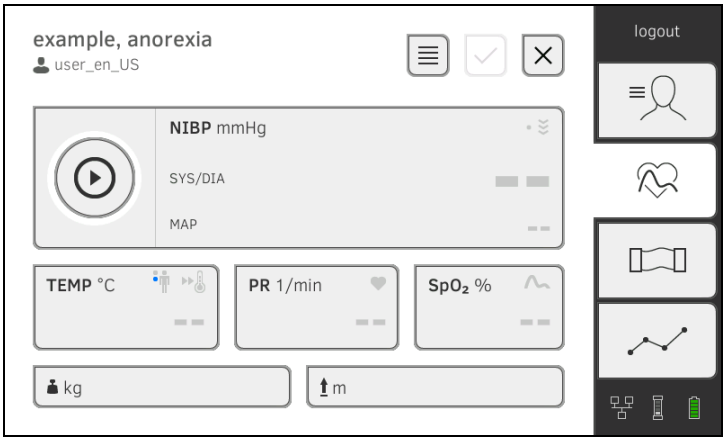
- Set up the device so that it cannot fall on patients.
- Route the cables and tubes of the measurement accessory so that the patient cannot become entangled or be strangled.
- The device has **no** alarm function. Never leave the patient unobserved during a measurement.
- Always connect only one individual patient to the device for each measurement procedure.

17-10-05-353-002d_02-2019 B

## Introduction

The "Vital sign measurement" function is available directly after switching on the device in order to be able to carry out measurements without patient identification (anonymous measurements) and without logging in.

If you want to assign the measurement process to a patient record, we recommend opening or creating a patient record **before** the measurement ➔ Call up seca patient file ➔ Create seca patient file. This applies in particular when repeat measurements are likely for a patient.




You can measure individual or multiple vital parameters in a single measurement. The measurement starts automatically after attaching the measuring equipment to the patient (exception: blood pressure measurement and temperature measurement in the ear). The pulse rate is determined, depending on the device configuration, via oxygen saturation or blood pressure.

## Measure blood pressure

➔ Start blood pressure measurement

➔ Modify presets

**WARNING!**
**Hazard to patient**

- Do not use luer lock adapter on the blood pressure measurement tubes. The use of luer lock adapters can lead to accidental connection of the blood pressure tubes to intravenous lines and thus lead to an infusion of air into the bloodstream of the patient.
- The decision to use this device with pregnant or preclamptic patients is the responsibility of the user.
- The device has **no** alarm function. Never leave the patient unobserved during a measurement.
- Frequent measurements may lead to perfusion disorders and consequently to severe harm to the patient.
- Route the compressed air tube so that it cannot kink. A kinked compressed air tube leads to sustained cuff pressure. This may lead to perfusion disorders and consequently to severe harm to the patient.
- Do not place the blood pressure cuff over open wounds. This may lead to further harm to the patient.
- Do not apply any external pressure onto the blood pressure measurement tubes or onto the blood pressure cuff.
- For patients with moderate to severe cardiac arrhythmias, inaccurate measurements may result with the blood pressure measurement.
- The following factors may affect the measurement result:
  - Measuring location (e.g. altitude)
  - Patient position (standing, sitting, lying)

17-10-05-353-002d_02-2019 B

- Physiological state of the patient (e.g. exertion, movement, shaking, shivering)
- Patient's age
- Arteriosclerosis
- Poor perfusion
- Diabetes
- Kidney disease

► If the measurements seem implausible, check and evaluate the vital signs of the patient using alternative means. Then check the measurement function of the device with the help of the section "What to do if...".

**WARNING!**
**Patient hazard, incorrect measurement**

► Do not place the blood pressure cuff on the arm on the side on which a mastectomy has been performed.

► Apply the blood pressure cuffs so that the blood circulation of the patient is not compromised.

► Do not apply the blood pressure cuffs on spots that have weak circulation or on extremities on which intravenous routes lie.

► High cuff pressures may be unpleasant for sensitive patients. Keep the patient's general condition under observation during the measurement.

**WARNING!**
**Incorrect measurement**

► Inflating the blood pressure cuff may lead to occasional malfunctions of other medical electrical devices used on the same limb.

► Use only blood pressure cuffs from seca.

► Before every measurement, ensure that the blood pressure measurement tubes and connections are free of damage and airtight.

► Ensure that the arm on which the blood pressure cuff is attached does not move during the measurement.

► Ensure that the blood pressure cuff is applied according to the printed mark "Artery".

**CAUTION!**
**Incorrect measurement**
If the blood pressure cuff is too mall, the measured blood pressure values will be too high. If the blood pressure cuff is too large, the measured blood pressure values will be too small.

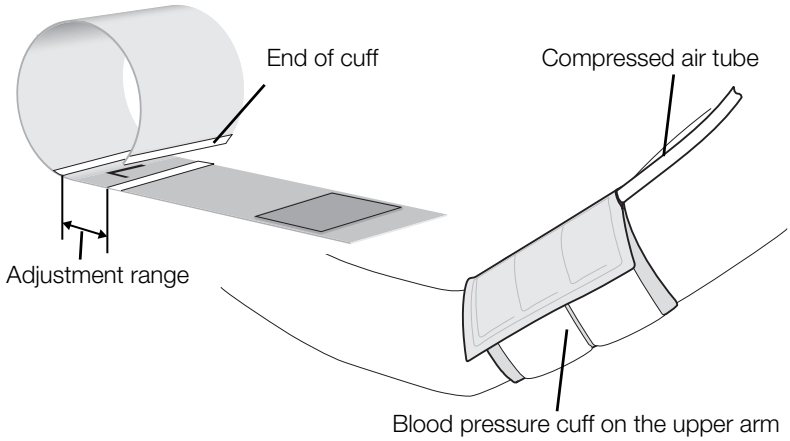
► Always use a blood pressure cuff that is the correct size.

**Start blood pressure measurement**

1. Ensure that the patient adopts the following position:
   - Sitting comfortably
   - Legs not crossed
   - Feet flat on the floor
   - Back and arm supported

17-10-05-353-002d_02-2019 B

2. Apply the blood pressure cuff to the patient's non-dominant arm as shown in the illustration below.
   a) Note the labeling on the blood pressure cuff ➔ Markings on the blood pressure cuff
   b) Use correct size of blood pressure cuff: End of cuff inside the adjustment range when put on
   c) Position blood pressure cuff at the level of the right atrium
   d) Ensure correct fit of the blood pressure cuff
   e) Route compressed air tube so that it cannot kink.




**NOTE:**
Get the patient to sit quietly for 5 minutes before recording measured values. The patient should remain relaxed and not talk during the measurement.

3. Press the  button on the monitor.
Blood pressure measurement starts:


Current cuff pressure is displayed.
The symbols for measurement procedure and measuring mode (in this case: Single measurement, upward measurement) flash.
The measurement is automatically stopped as soon as valid blood pressure values are recorded.


The values for systolic/diastolic blood pressure **SYS/DIA** and mean arterial pressure **MAP** are displayed.
You have the following options to continue:

- Measure further vital signs ➔ Measure vital signs
- Measure bioimpedance ➔ Measure bioimpedance
- Stop measurement procedure ➔ Stop a measurement procedure.

17-10-05-353-002d_02-2019 B

**NOTE**

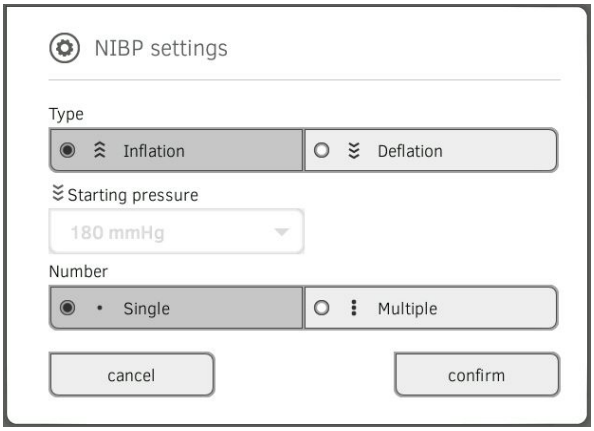
- Using the Start button, you can cancel and restart blood pressure measurement at any time.
- If an upward measurement does not deliver a measured value, the device automatically switches to a downward measurement.
- If necessary, the device reinflates several times during the downward measurement (reinflation: increasing cuff pressure by approx. 50 mmHg and releasing it in increments). If no measured value is delivered even after reinflating several times, the process is canceled and an error message is issued.

### Modify presets

**NOTE**

Your settings apply only to the current measurement procedure. If you stop the measurement procedure ➔ Stop a measurement procedure, the presets defined by the administrator become active again.

1. Ensure that the blood pressure cuff is not applied.
2. Press the **NIBP** field.
   The **NIBP settings** dialog window opens.
   The presets are displayed.




3. Press the desired measurement method.
   - Upward measurement (inflation), continue with Step 5.
   - Downward measurement (deflation), continue with Step 4.
4. If necessary, modify the starting pressure.
5. Press the desired number of measurements.
   - Single measurement
   - Multiple measurement
6. Press the **confirm** button.
   The dialog window closes.
   Changed settings are used for the current measurement.
7. Start the blood pressure measurement as described in the section entitled ➔ Start blood pressure measurement.

17-10-05-353-002d_02-2019 B

## Measure temperature orally/axillary (COVIDIEN™ FILAC™ 3000, blue)

➔ Start an oral/axillary temperature measurement

➔ Modify presets

**WARNING!**
**Patient hazard, incorrect measurement**

- The decision to use this device with children, pregnant or lactating patients is the responsibility of the user.
- Before every measurement, ensure that the measurement mode and the measuring method have been correctly selected.
- For each temperature measurement, use a new probe cover to reduce the risk of cross-contamination, nosocomial infections and inplausible measurements.
- Only use probe covers that are approved for the thermometer being used.
- Always use the probe cover directly with the thermometer from the cover box on the device.
- Ensure that the probe covers engage correctly on the thermometer.
- Probe covers are only intended for an individual measurement, they are not reusable and not sterile. Do not disinfect or sterilize the probe covers. Dispose of the according to national regulations and the regulations of your institute.
- Only use properly functioning thermometers. If you find damage, do not use the thermometer. Use a suitable replacement.
- When not in use, store the thermometer in the corresponding holder on the machine.
- If the measurements seem implausible, check and evaluate the vital signs of the patient using alternative means. Then check the measurement function of the device with the help of the section "What to do if...".

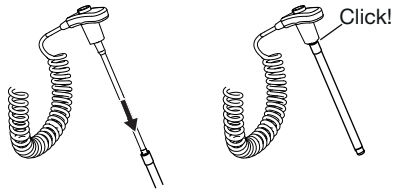
**WARNING!**
**Patient hazard, incorrect measurement**

- Ensure that in “Direct” measuring mode, oral temperature measurements do not last longer than 3 minutes and axillary measurements do not last longer than 5 minutes.
- Only perform oral/axillary measurement with devices that are equipped with a blue temperature probe and a blue probe holder.
- For devices with COVIDIEN™ FILAC™ 3000 measurement equipment, only use COVIDIEN™ temperature probes and probe covers.
- For axillary temperature measurements, ensure that the temperature probe, with probe cover, makes direct contact with the skin of the patient and does not come into contact with clothing or other objects.

17-10-05-353-002d_02-2019 B

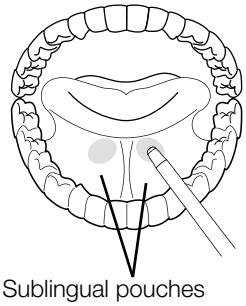
**Start an oral/axillary temperature measurement**

1. Remove the temperature probe (blue) from the probe holder (blue).
2. Pick up a probe cover:



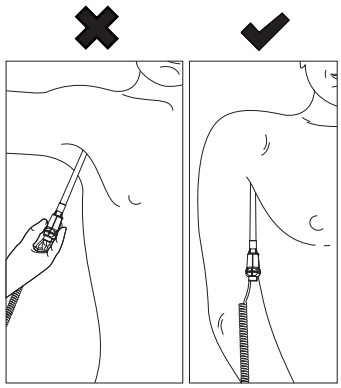

   a) Insert the probe in a probe cover in the pack
   b) Allow the probe cover to engage audibly with the probe
   c) Remove probe and probe cover from the pack
   d) Ensure that the probe cover is undamaged
3. Position the temperature probe as shown in the illustration:

Oral measurement:



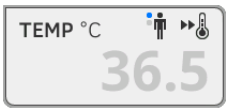
Sublingual pouches

Axillary measurement:

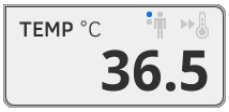


Measurement starts automatically.

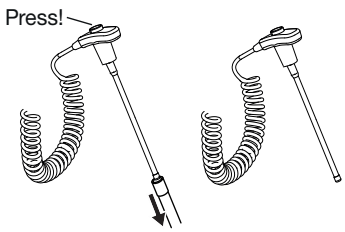
The measured value and the symbol for the measuring procedure (in this case predictive) flash until a valid measured value is obtained.




The temperature value is displayed until you stop the measurement procedure ➔ Stop a measurement procedure.



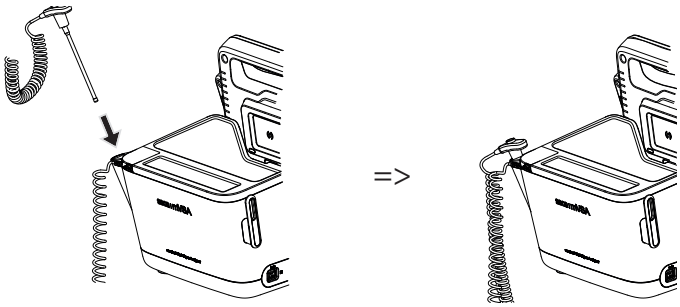

4. Discard the probe cover and dispose of it in line with your institution's policy.




17-10-05-353-002d_02-2019 B

**NOTE**
You can then only perform a further temperature measurement if you discard the probe cover and push the temperature probe completely back into the probe holder.

5. Push the temperature probe completely into the probe holder.



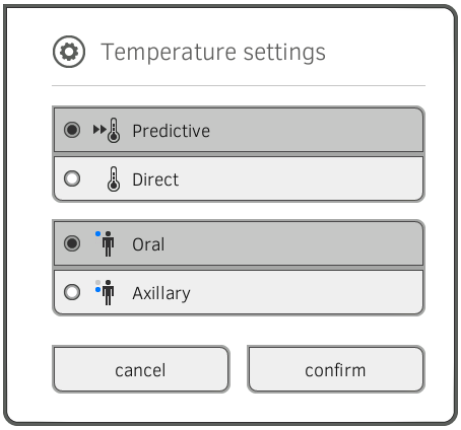
You have the following options to continue:

- Measure further vital signs ➔ Measure vital signs
- Measure bioimpedance ➔ Measure bioimpedance
- Stop measurement procedure ➔ Stop a measurement procedure.

**Modify presets**

**NOTE**
These settings apply to the current measurement procedure. If you stop the measurement procedure ➔ Stop a measurement procedure, the presets defined by the administrator are then active again.

1. Ensure that the temperature probe is pushed completely into the probe holder.
2. Press the **TEMP** field
   The **TEMP settings** dialog window opens.
   The presets are displayed.




3. Press the desired measurement method.
   - Predictive
   - Direct
4. Press the desired measuring position.
   - Oral
   - Axillary
5. Press the **confirm** button.
   The dialog window closes.
   Changed settings are used for the current measurement.
6. Perform a temperature measurement as described in the section entitled ➔ Start an oral/axillary temperature measurement.

17-10-05-353-002d_02-2019 B

## Measure temperature rectally (COVIDIEN™ FILAC™ 3000 red)

➔ Start a rectal temperature measurement

➔ Modify presets

**WARNING!**
**Patient hazard, incorrect measurement**

- The decision to use this device with children, pregnant or lactating patients is the responsibility of the user.
- Before every measurement, ensure that the measurement mode and the measuring method have been correctly selected.
- For each temperature measurement, use a new probe cover to reduce the risk of cross-contamination, nosocomial infections and inplausible measurements.
- Only use probe covers that are approved for the thermometer being used.
- Always use the probe cover directly with the thermometer from the cover box on the device.
- Ensure that the probe covers engage correctly on the thermometer.
- Probe covers are only intended for an individual measurement, they are not reusable and not sterile. Do not disinfect or sterilize the probe covers. Dispose of the according to national regulations and the regulations of your institute.
- Only use properly functioning thermometers. If you find damage, do not use the thermometer. Use a suitable replacement.
- When not in use, store the thermometer in the corresponding holder on the machine.
- If the measurements seem implausible, check and evaluate the vital signs of the patient using alternative means. Then check the measurement function of the device with the help of the section "What to do if...".

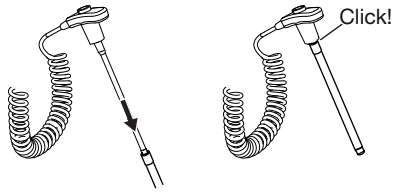
**WARNING!**
**Patient hazard, incorrect measurement**

- Ensure that rectal temperature measurements in “Direct” measuring mode do not last longer than 5 minutes.
- Only perform rectal measurement with devices that are equipped with a red temperature probe and a red probe holder.
- For devices with COVIDIEN™ FILAC™ 3000 measurement equipment, only use COVIDIEN™ temperature probes and probe covers.
- For rectal temperature measurement use some lubricant on the temperature probe. Too much lubricant can distort the measurement result.
- For rectal temperature measurements, do not insert the temperature probes deeper than about 19 mm (3/4 inch) for adults and about 13 mm (1/2 inch) for children.

17-10-05-353-002d_02-2019 B

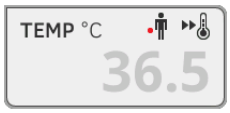
**Start a rectal temperature measurement**

1. Remove the temperature probe (red) from the probe holder (red).
2. Pick up a probe cover:

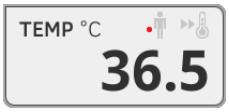



   a) Insert the probe in a probe cover in the pack
   b) Allow the probe cover to engage audibly with the probe
   c) Remove probe and probe cover from the pack
   d) Ensure that the probe cover is undamaged
3. Apply a little lubricant.
4. Guide the temperature probe into the patient's rectum:
   - For adults: 12 - 19 mm
   - For children: 6 - 13 mm

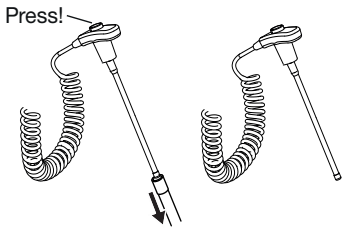
   The measurement starts automatically.
   The symbol for the measurement procedure (in this case: Predictive) flashes until a valid measured value is obtained.




   The temperature value is displayed until you stop the measurement procedure ➔ Stop a measurement procedure.




5. Discard the probe cover and dispose of it in line with your institution's policy.

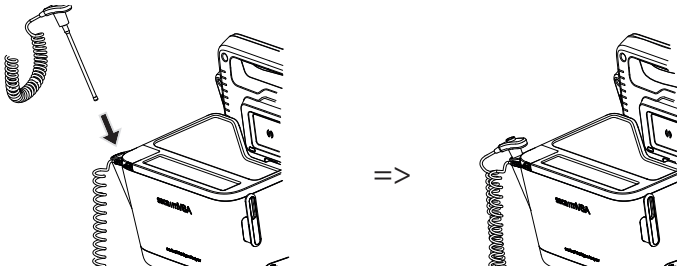



**NOTE**

- You can then only perform a further temperature measurement if you discard the probe cover and push the temperature probe completely back into the probe holder.

17-10-05-353-002d_02-2019 B

6. Push the temperature probe completely into the probe holder.



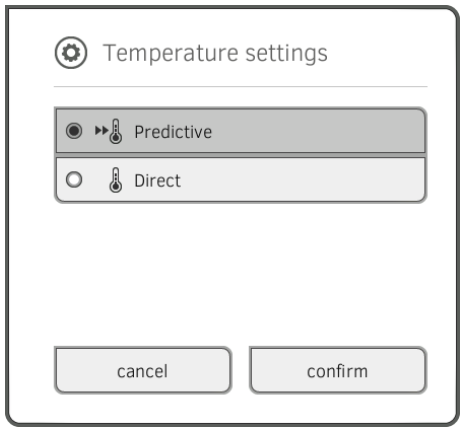
You have the following options to continue:

- Measure further vital signs ➔ Measure vital signs
- Measure bioimpedance ➔ Measure bioimpedance
- Stop measurement procedure ➔ Stop a measurement procedure.

**Modify presets**

**NOTE**
Your settings apply to the current measurement procedure. If you stop the measurement procedure ➔ Stop a measurement procedure, the presets defined by the administrator become active again.

1. Ensure that the temperature probe is pushed completely into the probe holder.
2. Press the **TEMP** field
   The **TEMP settings** dialog window opens.
   The presets are displayed.




3. Press the desired measurement method.
   - Predictive
   - Direct
4. Press the **confirm** button.
   The dialog window closes.
   The modified settings are adopted.
5. Start the temperature measurement as described in the section entitled ➔ Start a rectal temperature measurement.

17-10-05-353-002d_02-2019 B

## Measuring temperature in the ear (COVIDIEN™ GENIUS®2)

**WARNING!**
**Patient hazard, incorrect measurement**

- The decision to use this device with children, pregnant or lactating patients is the responsibility of the user.
- Before every measurement, ensure that the measurement mode and the measuring method have been correctly selected.
- For each temperature measurement, use a new probe cover to reduce the risk of cross-contamination, nosocomial infections and inplausible measurements.
- Only use probe covers that are approved for the thermometer being used.
- Always use the probe cover directly with the thermometer from the cover box on the device.
- Ensure that the probe covers engage correctly on the thermometer.
- Probe covers are only intended for an individual measurement, they are not reusable and not sterile. Do not disinfect or sterilize the probe covers. Dispose of the according to national regulations and the regulations of your institute.
- Only use properly functioning thermometers. If you find damage, do not use the thermometer. Use a suitable replacement.
- When not in use, store the thermometer in the corresponding holder on the machine.
- If the measurements seem implausible, check and evaluate the vital signs of the patient using alternative means. Then check the measurement function of the device with the help of the section "What to do if...".

**WARNING!**
**Patient hazard, incorrect measurement**

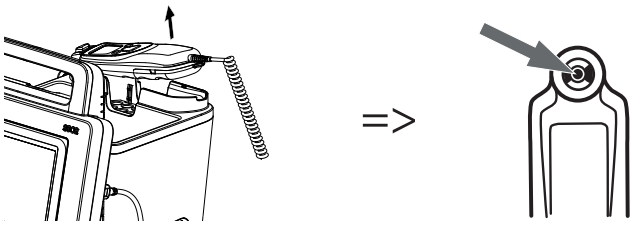
- Do not use the in-ear thermometer if the patient's auditory canal is blocked with blood, cerebrospinal fluid or other discharge.
- Do not use the in-ear thermometer if the patient's auditory canal is blocked with wax or a foreign body.
- If the patient has been fitted with grommets, do not resume measuring temperature in the ear for at least a week after the operation.
- Only use probe covers intended for your in-ear thermometer.

**CAUTION!**
**Incorrect measurement**

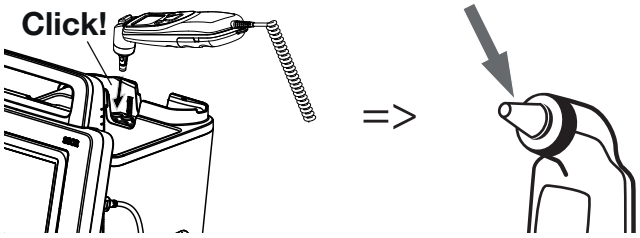
- Ensure that the measuring window of the ear thermometer is clean, dry and undamaged. Contamination, for example fingerprints, ear wax or dust will impair the transparency of the measuring window with the result that low values will be measured.
- Severe scarring of the eardrum may falsify the measurement, resulting in values which are too low being measured.
- Patients who wear removable hearing aids should remove them from the ear at least 10 minutes before the measurement.
- Ear drops or other medications applied to the ear can falsify the measured results. If possible, take the measurement on the other, non-treated ear.
- Temperature measurements on the left or right ear can lead to different results. Always perform follow-up measurements on the same ear.
- Wait at least two minutes before performing a follow-up measurement on the same ear.

17-10-05-353-002d_02-2019 B

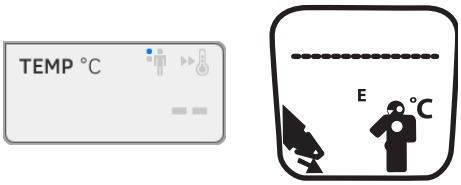
1. Take the in-ear thermometer out of the SmartBucket.
2. Make sure that the lens of the measuring head is clean.



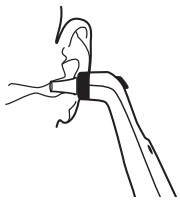
3. Press the  button to switch on the in-ear thermometer.
4. Pick up a probe cover:
   a) Push the measuring head firmly into a probe cover in the magazine
   b) Ensure that the probe cover engages audibly with the measuring head.
   c) Remove the probe cover and thermometer from the magazine.
   d) Ensure that the probe cover is undamaged.




The system is ready to measure when the monitor and the display of the in-ear thermometer display dashes, the current measuring position and the thermometer icon as shown in the illustration below.




5. Introduce the measuring head into the patient's auditory canal as shown in the illustration.



17-10-05-353-002d_02-2019 B

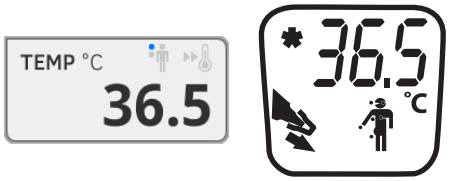
6. Measure the patient's temperature:

   a) Press the  button on the in-ear thermometer

   b) Wait until you hear a triple acoustic signal

   c) Take the measuring head out of the patient's ear

   The monitor displays the temperature value.
   The in-ear thermometer display likewise displays the temperature value and the "Discard probe cover" symbol.

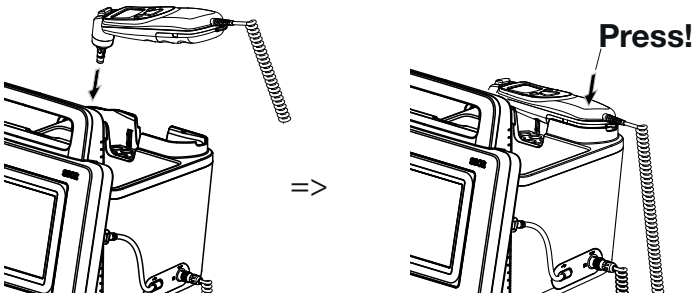



   The temperature value is displayed on the monitor until you stop the measurement procedure ➜ Stop a measurement procedure.

   **NOTE**
   The monitor always displays measured values in the unit set on the monitor. If required, the values sent by the in-ear thermometer are converted automatically.

7. Press the  key to discard the probe cover.

8. Dispose of the probe cover in line with your institution's policy.
9. Press the in-ear thermometer into the SmartBucket holder until you feel it engage.




   You have the following options to continue:

   - Measure further vital signs ➜ Measure vital signs
   - Measure bioimpedance ➜ Measure bioimpedance
   - Stop measurement procedure ➜ Stop a measurement procedure.

17-10-05-353-002d_02-2019 B

## Read off pulse rate

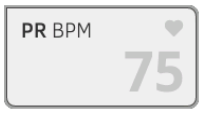
➔ Interrogate pulse rate source

➔ Modify presets (seca measuring equipment only)

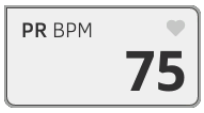
**WARNING!**
**Patient hazard, incorrect measurement**
A pulse rate determined on the basis of blood pressure or oxygen saturation is susceptible to artifacts.

- To obtain an exact value, determine pulse rate by means of ECG or palpation.

Depending on device configuration, pulse rate is determined on the basis of blood pressure or oxygen saturation.




Pulse rate is displayed until you stop the measurement procedure ➔ Stop a measurement procedure.



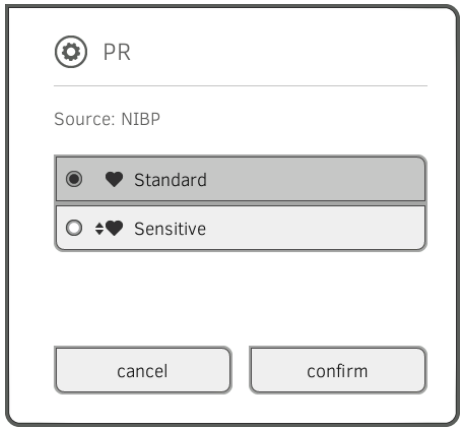

### Interrogate pulse rate source

1. Press the **PR** field.
   The **PR settings** dialog window opens.
   The source of the pulse rate (NIBP or $SpO_2$) is displayed.
2. Press the **confirm** button.
   The dialog window closes.

### Modify presets (seca measuring equipment only)

**NOTE**
These settings apply to the current measurement procedure. If you stop the measurement procedure➔ Stop a measurement procedure, the presets defined by the administrator are then active again.

1. Ensure that neither the blood pressure cuff nor the $SpO_2$ sensor are applied.
2. Press the **PR** field.
   The **PR settings** dialog window opens.
   The presets are displayed (in this case: Default)




17-10-05-353-002d_02-2019 B

3. Press the desired measuring mode.

| seca measuring equipment | | |
|---|---|---|
| **Mode** | **Measuring range** | **Motion tolerance** |
| Default | 0 - 240 bpm | High |
| Sensitive | 20 - 300 bpm | Low |

4. Press the **confirm** button.
   The dialog window closes.
   Changed settings are used for the current measurement.
5. Start a blood pressure or an $SpO_2$ measurement as described in the sections entitled ➔ Start blood pressure measurement and ➔ Start an $SpO_2$ measurement.

17-10-05-353-002d_02-2019 B

## Measure oxygen saturation ($SpO_2$)

➔ Start an $SpO_2$ measurement

➔ Modify presets

**WARNING!**
**Patient hazard, incorrect measurement**

- The device has **no** alarm function. Never leave the patient unobserved during a measurement.
- The pulse oximeter is not an apnea monitoring device.
- The pulse oximeter must not be used to analyze arrhythmia.
- Incorrectly-applied sensors may lead to injuries at the point of application. Follow the Instructions for Use from the sensor manufacturer.
- Apply the blood pressure cuff and $SpO_2$ sensor to different extremities to avoid falsifying measured results.
- Apply the intravenous pressure catheter and $SpO_2$ sensor to different extremities to avoid falsifying measured results.
- Red and infrared light at fixed wavelengths is used for $SpO_2$ measurement. These wavelengths can affect other optical applications. Information about the wavelengths used can be found in the Instructions for Use for the sensor used.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the pulse oximeter or accessories in any position that might cause it to fall on the patient.
- Do not start or operate the pulse oximeter unless the setup was verified to be correct.
- Do not use the pulse oximeter during magnetic resonance imaging (MRI) or in an MRI environment.
- Do not use the pulse oximeter if it appears or is suspected to be damaged.
- Explosion hazard: Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
- To protect against injury, follow the directions below:
  - Avoid placing the device on surfaces with visible liquid spills.
  - Do not soak or immerse the device in liquids.
  - Do not attempt to sterilize the device.
  - Use cleaning solutions only as instructed in this operator's manual.
  - Do not attempt to clean the device while monitoring a patient.
- To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.
- If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning. Follow the section entitled "What do I do if ...?".
- Inaccurate $SpO_2$ readings may be caused by the following conditions:
  - Improper sensor application and placement
  - Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal $SpO_2$. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
  - Elevated levels of bilirubin
  - Elevated levels of dyshemoglobin

17-10-05-353-002d_02-2019 B

- Vasospastic disease, such as Raynaud's, and peripheral vascular disease
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Hypocapnic or hypercapnic conditions
- Severe anemia
- Very low arterial perfusion
- Extreme motion artifact
- Abnormal venous pulsation or venous constriction
- Severe vasoconstriction or hypothermia
- Arterial catheters and intra-aortic balloon
- Intravascular dyes, such as indocyanine green or methylene blue
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
- Skin color disorders

► Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.

► The pulse oximeter should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

► $SpO_2$ is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

► Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximeter for servicing if necessary.

**WARNING!**
**Patient hazard, damage to device**

► For devices equipped with Masimo SET® $SpO_2$ measurement equipment, only use Masimo sensors and patient cables.

► For devices equipped with seca $SpO_2$ measurement equipment, only use seca sensors and patient cables.

17-10-05-353-002d_02-2019 B

**CAUTION!**
**Patient hazard, incorrect measurement**

- Do not use damaged sensors or damaged patient cables, for example with exposed optics.
- Do not place the pulse oximeter where the controls can be changed by the patient.
- Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.
- When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- Do not place the pulse oximeter on electrical equipment that may affect the device, preventing it from working properly.
- If $SpO_2$ values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
- If the Low Perfusion or Low Signal Qualitiy message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
- Change the application site or replace the sensor and/or patient cable when a "Replace sensor" and/or "Replace patient cable", or a persistent poor signal quality message (such as "Low SIQ") is displayed on the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.
- Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
- Do not submerge the pulse oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.
- Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximeter.
- Replace the cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.

**NOTE:**

- A functional tester cannot be used to assess the accuracy of the pulse oximeter.

17-10-05-353-002d_02-2019 B

- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse oximeter to obtain vital sign readings.
- When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.
- Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
- Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/ measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).
- Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.

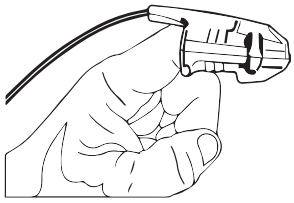
### Start an $SpO_2$ measurement

► Apply the $SpO_2$ sensor according to the Instructions for Use from the sensor manufacturer.

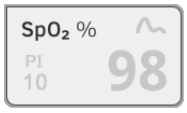
a) Ensure that the $SpO_2$ sensor is the correct size.

b) Prepare measuring point (e.g. remove jewelry or nail varnish)

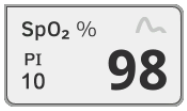
c) Position the $SpO_2$ sensor on the measurement point (in this case, Softclip sensor)



Measurement starts automatically.




The symbol for the measurement method flashes (in this case: Normal) until a valid measured value is obtained.




The $SpO_2$ value is displayed.

You have the following options to continue:

► Measure further vital signs ➔ Measure vital signs

► Measure bioimpedance ➔ Measure bioimpedance

► Stop measurement procedure ➔ Stop a measurement procedure.

**NOTE**

If your device is equipped with Masimo SET® measuring equipment, perfusion index (PI) is displayed in addition to oxygen saturation. This helps you assess perfusion at the measurement point and to find a better measurement point if necessary.

17-10-05-353-002d_02-2019 B

### Modify presets

**NOTE**
These settings apply to the current measurement procedure. If you stop the measurement procedure ➔ Stop a measurement procedure, the presets defined by the administrator become active again.

1. Ensure that no $SpO_2$ sensor has been applied to the patient.
2. Press the **$SpO_2$** field.
   The **$SpO_2$ settings** dialog window opens.
   The presets are displayed (in this case: Masimo SET®-pulse oximetry.


3. Press the desired sensitivity:

| **Masimo SET® $SpO_2$ module** | |
|---|---|
| **Mode** | **Indication** |
| Normal | • Normal perfusion<br>• Mild perfusion disorders |
| Adaptive Probe Off Detection (APOD) | Vigorous patient movements |
| Maximum | • Poor perfusion<br>• Severely disrupted signal, for example due to indoor lighting or direct sunlight |

| **seca $SpO_2$ module** | |
|---|---|
| **Mode** | **Motion tolerance** |
| Stable | High |
| Normal | Normal |
| Sensitive | Low |

4. Press the **confirm** button.
   The dialog window closes.
   The changed settings are used for the current measurement.
5. Start the $SpO_2$ measurement as described in the section entitled ➔ Start an $SpO_2$ measurement.

## Display weight and height

➔ Receive weight and height from seca 360° wireless device

➔ Adopt weight and height from seca patient file

In the **vital signs** tab, you can have a patient's weight and height displayed. You have the following options:

17-10-05-353-002d_02-2019 B

**NOTE**
The fields “Weight” and “Height” appear in the **vital signs** tab if the **seca 360° wireless** module of the mVSA is activated. The module can be activated/deactivated with administrator rights ➔ For administrators: Configure seca 535/seca 525.

### Receive weight and height from seca 360° wireless device

1. Measure the patient as described in the Instructions for Use for the **seca 360° wireless** device.

2. Transmit the measured values as described in the Instructions for Use for the **seca 360° wireless** device.
   The values received appear in the **vital signs** tab of the mVSA.


### Adopt weight and height from seca patient file

1. Open a secapatient file or create a new one ➔ Call up seca patient file, ➔ Create seca patient file.
2. Enter the values for weight and height in the seca patient file ➔ Enter basic parameters.


3. Press the **vital signs** tab on the mVSA.
   Weight and height are displayed.


17-10-05-353-002d_02-2019 B

## Stop a measurement procedure

You have to stop the current measurement procedure before you can start a new measurement procedure. You have the following options:

- Save measuring procedure: Press  button
- Assign anonymous measurement to a seca patient file: ➔ Assigning anonymous measurement procedure to a seca patient file
- Discard measurement procedure: Press  button (anonymous measurements are added to list **Measurements vital signs**)

## Assigning anonymous measurement procedure to a seca patient file

To assign an anonymous measurement to a patient record, proceed as follows:

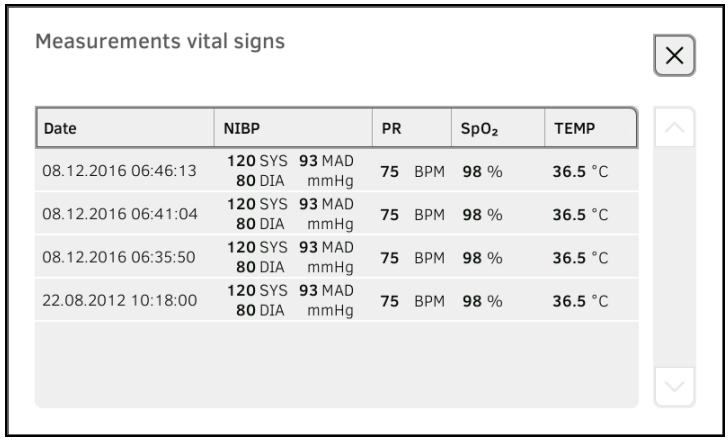
1. Press the **patient** tab.
2. Select an action:
   - Press **open patient list** button
   - Press **create patient file** button
3. Continue according to your login status:
   - Not logged in: Log in ➔ Log in.
   - Logged in: Continue with Step 4.
4. Proceed according to your selection in step 2.
   - ➔ Call up seca patient file
   - ➔ Create seca patient file
5. Confirm the message **Assign measurement?**.
   The measurement procedure is assigned to the patient file
6. Press  button
   The measurement procedure is saved.

## Display “Measurements vital signs” list

The **Measurements vital signs** list contains the last 12 vital signs measurements correctly completed ➔ Stop a measurement procedure. You can call up the list to enter measured results in a paper file manually, for example.

Measurement procedures that have not been assigned to any seca patient file (anonymous measurement procedures) are also shown in this list.

1. In the **vital signs** tab, press the  button.
   The **Measurements vital signs** list is displayed.




2. Use the scroll bar to see all the measurements.

17-10-05-353-002d_02-2019 B

3. To close the list, press the  button.

## 5.5 Analyze measurement

➔ View analysis

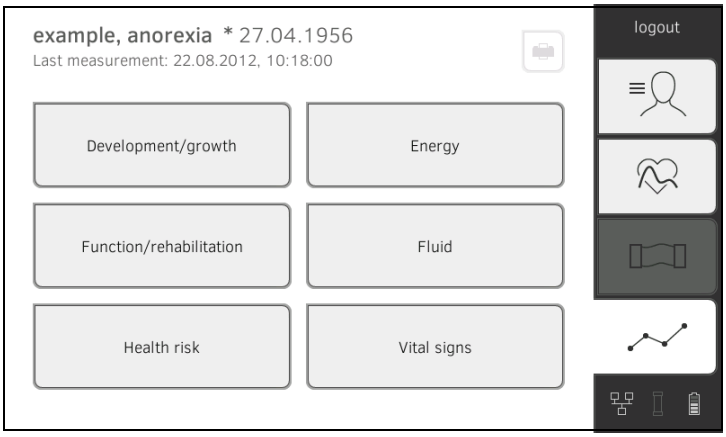
➔ View the history of an analysis parameter

**NOTE**
In order to be able to view analyses, you must assign the current measurement to a seca patient file ➔ Assigning anonymous measurement procedure to a seca patient file or call up a seca patient file ➔ Call up seca patient file.

### View analysis

The device determines a series of analysis parameters and groups these in analysis modules.

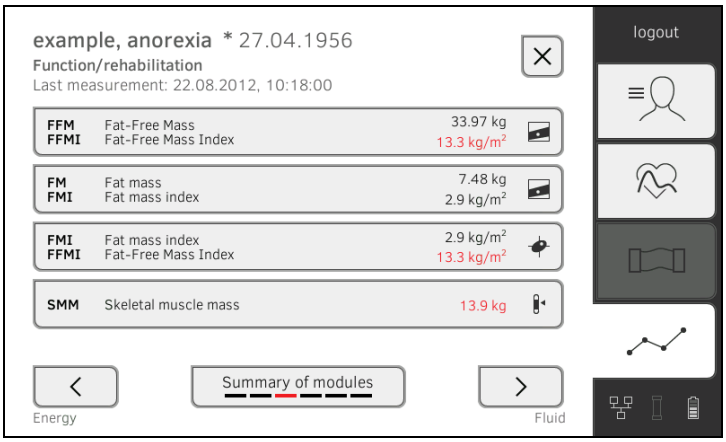
1. Press the **analysis** tab.
   The module summary is displayed.




   You have the following navigation options:

   - Press the  button: Print a results report (**seca directprint**: Function of **seca analytics 115**PC software)
   - View an analysis module: Continue with Step 2.

2. Press an analysis module.
   The summary of parameters is displayed, in this case: **Function/ rehabilitation**.

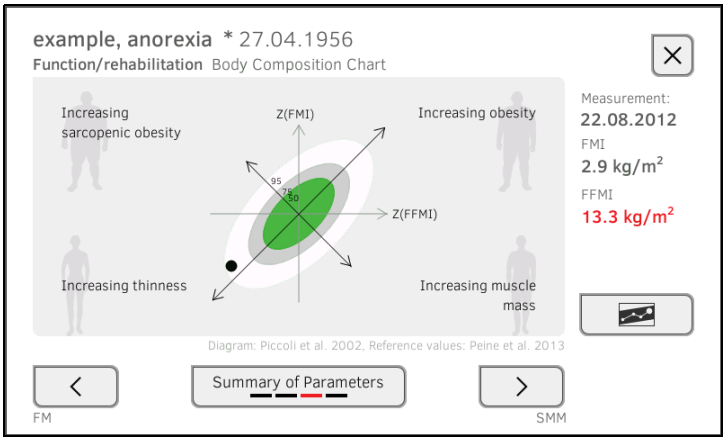



17-10-05-353-002d_02-2019 B

You have the following navigation options:

- Press  buttons: View other analysis modules
- Press  button: Return to module summary
- To view details of an analysis parameter: Continue with Step 3.

3. Press an analysis parameter.
The detail view is displayed, in this case: **Body Composition Chart**.




You have the following navigation options:

- Press the  button to view the history of this analysis parameter ➔ View the history of an analysis parameter
- Press the  buttons: View other analysis parameters
- Press the  button: Return to parameter summary

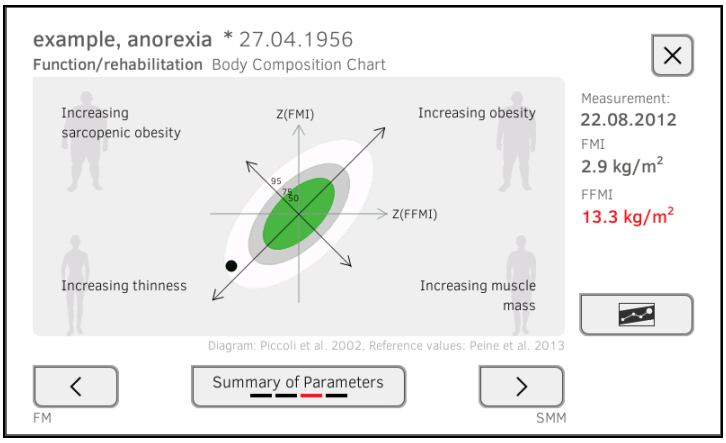
**NOTE**
This section is restricted to navigation in the **analysis** tab. For details about analysis parameters and modules, see the section entitled ➔ Bioimpedance measurement.

17-10-05-353-002d_02-2019 B

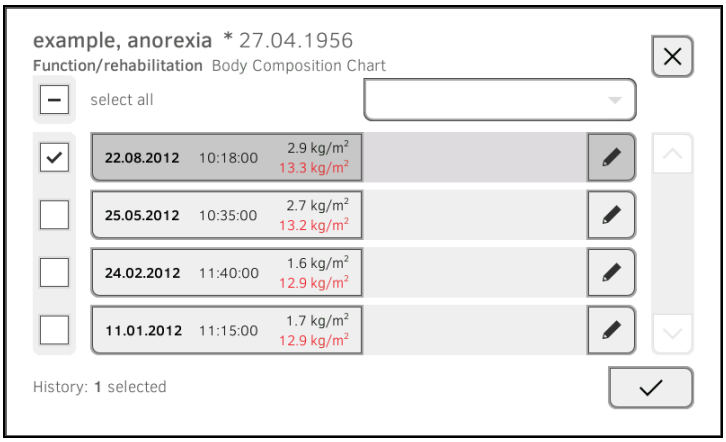
## View the history of an analysis parameter

After every measurement, you can view the history of an analysis parameter in the **analysis** tab. A maximum of five measurements can be selected. The latest measurement is selected automatically.

1. In the **analysis** tab, select an analysis parameter ➔ Analyze measurement.




2. Press the  button.
All measurements for the current patient are displayed.
The latest measurement is selected automatically.




You have the following navigation options:

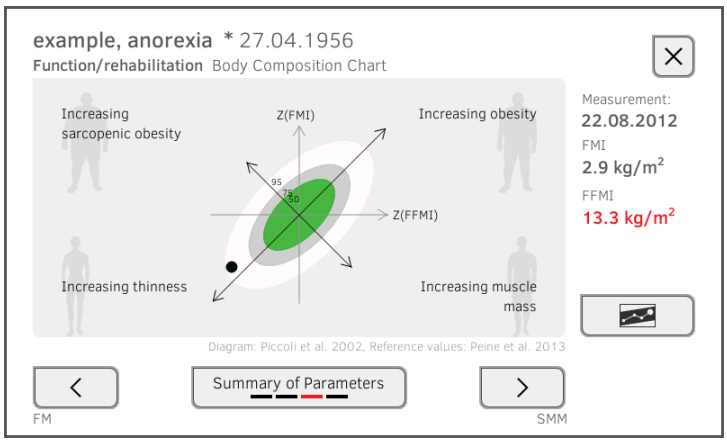
- Press the checkboxes  : Select values for history: Continue with Step 3.
- Press the  button: Add a comment
- Press the  button: Return to the analysis of the current measurement

**NOTE**
Just a single comment can be added to each measured result. Existing comments will be overwritten.

17-10-05-353-002d_02-2019 B

3. Press the checkboxes  for all the values you want to look at in the history.

4. Press the  button.
The history will be displayed.




# 6. HYGIENE TREATMENT

➔ Cleaning

➔ Disinfecting

➔ Sterilizing

➔ Remove/fit probe holder (versions with temperature probe)

➔ Remove/fit magazine holder (versions with in-ear thermometer)

**WARNING!**
**Electric shock**
The device is not de-energized when the on/off key is pressed and the display goes out. Use of fluids on the device may cause electric shock.

- Ensure that the device is switched off before performing any hygiene treatment.
- Disconnect the power supply connector before performing any hygiene treatment.
- Before each hygiene treatment, take the rechargeable battery out of the device (if present and removable).
- Ensure that no fluids penetrate the device.

**NOTICE!**
**Damage to device**
Inappropriate detergents and disinfectants may damage the sensitive surfaces of the device.

- Use only disinfectants free of chlorine and alcohol which are explicitly suitable for acrylic sheet and other sensitive surfaces (active ingredient: quaternary ammonium compounds, for example).
- Do not use caustic or abrasive detergents.
- Do not use organic solvents (e.g. white spirit or petroleum spirit).
- Use disinfectants containing 70% isopropyl alcohol for vital signs measurement accessories only.

17-10-05-353-002d_02-2019 B

## 6.1 Cleaning

► Clean the device and its accessories as described in the table.

| Component (depending on version) | Interval | Cleaning |
|---|---|---|
| Monitor with **seca mBCA 525** storage compartment<br>Monitor with SmartBucket<br>**seca mVSA 535** | As required | 1. Remove all the measuring accessories (measuring devices and consumables) from the device Depending on version:<br>➔ Remove probe holder<br>➔ Remove magazine holder<br>2. Moisten a soft cloth with a soap solution<br>3. Wipe over all surfaces<br>4. Allow to air-dry for approx. 30 minutes |
| Measuring mat and electrode cables | As required | 1. Moisten a soft cloth with a mild soap solution<br>2. Clean measuring mat and electrode cables<br>3. Allow to air-dry for approx. 30 minutes |
| Blood pressure cuff and compressed air tube | As required | 1. Moisten a soft cloth with a mild soap solution<br>2. Clean blood pressure cuff and compressed air tube<br>3. Rinse thoroughly with water<br>4. Allow to dry at room temperature |
| Temperature probe (red/blue) with cable | As required | 1. Discard probe cover and dispose of it<br>2. Moisten a soft cloth with a mild soap solution<br>3. Clean temperature probe<br>4. Shake out temperature probe so that no liquid remains in it<br>5. Allow to air-dry for approx. 30 minutes |
| Probe holder (red/blue) | As required | 1. ➔ Remove probe holder<br>2. Moisten a cotton bud with a mild soap solution<br>3. Wipe over all the surfaces of the probe holder |
| In-ear thermometer with cable | As required | 1. Do **not** discard probe cover<br>2. Moisten a soft cloth with a mild soap solution<br>3. Wipe over in-ear thermometer and cable<br>4. Allow to air-dry for approx. 30 minutes<br>5. Discard probe cover |
| Magazine holder for probe covers (in-ear thermometer) | As required | 1. ➔ Remove magazine holder<br>2. Moisten a soft cloth or cotton bud with a mild soap solution<br>3. Wipe over the surfaces of the magazine holder<br>4. Allow to air-dry for approx. 30 minutes |
| $SpO_2$ sensor with cable | Follow the manufacturer's Instructions for Use | |
| Patient cable for $SpO_2$ sensor | Follow the manufacturer's Instructions for Use | |

17-10-05-353-002d_02-2019 B

## 6.2 Disinfecting

1. Follow the instructions on the disinfectant.
2. Disinfect device and accessories as indicated in the table below.

| Component (depending on equipment) | Interval | Disinfecting |
|---|---|---|
| Monitor with **seca mBCA 525** storage compartment<br>Monitor with SmartBucket<br>**seca mVSA 535** | As required | 1. Remove all the measuring accessories (measuring devices and consumables) from the device (Depending on version:<br>➔ Remove probe holder<br>➔ Remove magazine holder<br>2. Moisten a soft cloth with disinfectant (active ingredient: quaternary ammonium compounds)<br>3. Wipe over all surfaces<br>4. Allow to air-dry for approx. 30 minutes |
| Measuring mat and electrode cables | **Before** and **after** a measure-ment | 1. Moisten a soft cloth with disinfectant (active ingredient: quaternary ammonium compounds)<br>2. Wipe over measuring mat and electrode cables<br>3. Allow to air-dry for approx. 30 minutes |
| Blood pressure cuff and compressed air tube | **Before** and **after** a measure-ment | 1. Moisten a soft cloth with disinfectant (active ingredient: 70% isopropyl alcohol)<br>2. Wipe over cuff and compressed air tube<br>3. Rinse thoroughly with water<br>4. Allow to air-dry for approx. 15 hours |
| Temperature probes (red/blue) with cable | **Before** and **after** a measure-ment | 1. Discard probe cover and dispose of it<br>2. Moisten a soft cloth with disinfectant (active ingredient: 70% isopropyl alcohol)<br>3. Wipe over temperature probe<br>4. Shake out temperature probe so that no liquid remains in it<br>5. Allow to air-dry for approx. 30 minutes |
| Probe holder (red/blue) | As required | 1. ➔ Remove probe holder<br>2. Moisten a cotton bud with disinfectant (active ingredi-ent: 70% isopropyl alcohol)<br>3. Wipe over the inner surfaces of the probe holder<br>4. Allow to air-dry for approx. 30 minutes |
| In-ear thermometer with cable | **Before** and **after** a measure-ment | 1. Discard probe cover and dispose of it<br>2. Moisten a soft cloth with disinfectant (active ingredient: 70% isopropyl alcohol)<br>3. Wipe over in-ear thermometer and cable<br>4. Wipe over probe tip, ensuring that all foreign particles are removed.<br>5. Wipe probe tip dry with lint-free cloth (e.g. spectacles cleaning cloth)<br>6. Allow to air-dry for approx. 30 minutes |
| Magazine holder for probe covers (in-ear thermometer) | As required | 1. ➔ Remove magazine holder<br>2. Moisten a cotton bud with disinfectant (active ingredi-ent: quaternary ammonium compounds<br>3. Wipe over surfaces<br>4. Allow to air-dry for approx. 30 minutes |
| $SpO_2$ sensor with cable | Follow the manufacturer's Instructions for Use | |
| Patient cable for $SpO_2$ sensor | Follow the manufacturer's Instructions for Use | |

17-10-05-353-002d_02-2019 B

## 6.3 Sterilizing

The device and accessories may not be sterilized.

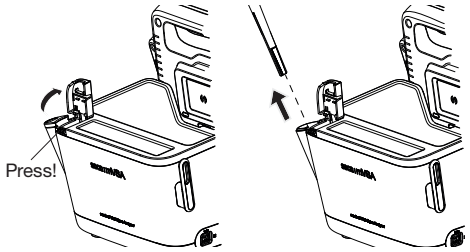
## 6.4 Remove/fit probe holder (versions with temperature probe)

**WARNING!**
**Hazard to patient**
The color of the probe holder indicates whether a device is intended for oral/axillary or rectal temperature measurement. This distinction can no longer be made once the probe holder has been removed. Confusing the probe holders can lead to cross-contamination.

- ► Ensure that the probe holder is fitted back in the device from which it was removed following a hygiene treatment.

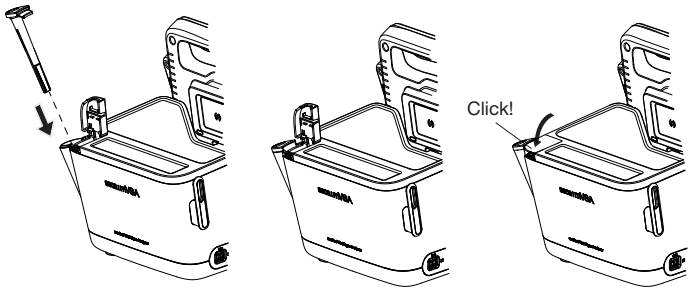
**Remove probe holder**

1. Open the covering cap.
2. Remove the probe holder.




**Fit probe holder**

1. Insert the probe holder in the SmartBucket as shown in the illustration below.

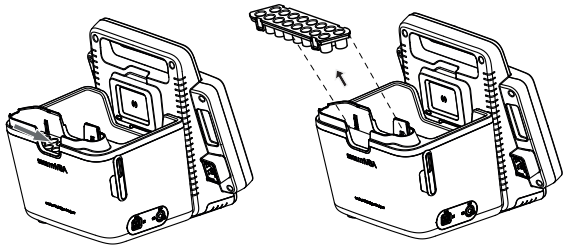



2. Close the cover cap until you hear it engage.

## 6.5 Remove/fit magazine holder (versions with in-ear thermometer)

**Remove magazine holder**

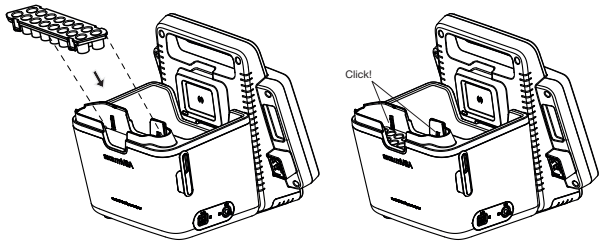
1. Lift the magazine holder with a finger until the magazine holder comes out of its catch.
2. Remove the magazine holder.



17-10-05-353-002d_02-2019 B

### Fit magazine holder

1. Insert the magazine holder in the SmartBucket as shown in the illustration below.
2. Push down the magazine holder until you feel it engage.




## 7. FUNCTION CHECK

► Perform a function check prior to each use.

A complete function check includes:

- visual inspection for mechanical damage
- checking the alignment of the device
- visual and function check of the display elements
- function check of all the controls shown in the section entitled “Overview”
- function check of optional accessories

If you notice any faults or deviations during the function check, first try to resolve the error with the aid of the section entitled “What do I do if ...” in this document.

**CAUTION!**
**Personal injury**
If you notice any faults or deviations during the function check which cannot be resolved with the aid of the section entitled “What do I do if ...” in this document, you may not use the device.

► Have the device repaired by seca Service or by an authorized service partner.

► Follow the section entitled “Servicing” in this document.

## 8. MAINTENANCE

The measuring technology of this device must be checked every two years. We recommend servicing the whole device as part of this check.

**NOTICE!**
**Incorrect measurements as a result of poor servicing**

► Have servicing and repairs carried out exclusively by seca Service or by an authorized service partner.

► You can find service partners in your area at www.seca.com or by sending an e-mail to service@seca.com.

17-10-05-353-002d_02-2019 B

# 9. WHAT DO I DO IF ...?



## 9.1 Monitor

| Problem | Cause | Remedy |
|---|---|---|
| **Monitor cannot be switched on** | No power supply | Provide power supply |
| | Rechargeable battery discharged | Provide power supply and charge rechargeable battery |
| | Rechargeable battery faulty | Replace rechargeable battery |
| **Touchscreen display remains dark** | Device on standby | • Touch the touchscreen display<br>• Press the ON/OFF button |
| | Device not switched on | Switch on the device |
| | No power supply | Check whether power is being supplied |
| | Touchscreen display faulty | Inform seca Service |
| **Touchscreen display not reacting** | Device in undefined state following implausible input | • Switch off the device (press and hold the ON/OFF button for approx. 15 seconds)<br>• Switch the device back on |
| **Image on touchscreen display faulty** | Touchscreen display faulty | Inform seca Service |
| **Password not accepted** | Password overwritten on last synchronization with **seca analytics 115** PC software | • Use new password<br>• If new password not known, contact administrator |
| **The vital signs tab is not active on an mVSA** | USB connecting cable of the SmartBucket not connected to the monitor | • Connect the USB connecting cable of the SmartBucket to the monitor<br>• Restart the device |
| | SmartBucket not activated | Administrator:<br>Activate SmartBucket: ➔ Administer system components in the Administrator menu |
| **The vital signs tab is not active on an mBCA** | The **vital signs** tab is only displayed on a seca mVSA | Retrofit SmartBucket ➔ Optional accessories and spare parts<br>Note the serial number of your mBCA |
| **The fields “Weight” and “Height” are not displayed in the vital signs tab** | **seca 360° wireless** module of the mVSA not activated | Administrator:<br>**seca 360° wireless** Activate module of the mVSA: ➔ Set up peripherals in the Administrator menu |

17-10-05-353-002d_02-2019 B

| Problem | Cause | Remedy |
|---|---|---|
| **bia tab not active** | No seca patient file prepared | Prepare seca patient file ➔ Prepare seca patient file |
| | Measuring mat not activated | Administrator:<br>Activate measuring mat: ➔ Administer system components in the Administrator menu |
| | No measuring mat present | Administrator, if desired:<br>• Retrofit measuring mat<br>• Activate measuring mat: ➔ Administer system components in the Administrator menu |

## 9.2 Measuring mat

| Problem | Cause | Remedy |
|---|---|---|
| **Measuring mat cannot be switched on** | Rechargeable battery discharged | Suspend measuring mat in storage compartment of monitor and charge rechargeable battery |
| | Measuring mat faulty | Replace measuring mat |
| **“Charging state” LED is red** | Rechargeable battery discharged | Suspend measuring mat in storage compartment of monitor and charge rechargeable battery |
| | Rechargeable battery faulty | Replace measuring mat |
| | Inductive charging interface of monitor covered, e.g. by other measuring accessories | Suspend the measuring mat in the magnetic catch first, then stow other measuring accessories |
| | Inductive charging interface faulty | Inform seca Service |
| **“WiFi” LED is red** | No WiFi connection to monitor | Administrator:<br>Check settings for WiFi connection and correct if necessary |
| | WiFi module of measuring mat faulty | Replace measuring mat |
| **One or more “Electrode contact” LEDs is red** | Electrode cables not connected to electrodes | Ensure that all electrode cables are engaged in the push-buttons of the electrodes |
| | Electrodes faulty | Replace electrodes |
| | Electrode cables or measuring mat faulty | Replace measuring mat |
| **One or more LEDs on the measuring mat not on** | Measuring mat faulty | Replace measuring mat |
| **seca patient files cannot be transmitted to the measuring mat** | No WiFi connection | • Suspend the measuring mat in the storage compartment of the device<br>• Call up seca patient file again, data will be transmitted via the infrared interface |
| | Infrared interface faulty | Inform seca Service |

17-10-05-353-002d_02-2019 B

| Problem | Cause | Remedy |
|---|---|---|
| **No WiFi connection** | WiFi function of device is deactivated | Administrator:<br>Activate WiFi |
| | Distance between measuring mat and monitor is too big | • Reduce distance<br>• Perform offline measurement |
| | Distance between monitor and WiFi router is too big | • Reduce distance<br>• Transmit measured results to **seca analytics 115** PC software via LAN |
| | WiFi not available in your institution | • Perform offline measurement<br>• Transmit measured results to **seca analytics 115** PC software via LAN |

## 9.3 Bioimpedance measurement

| Problem | Cause | Remedy |
|---|---|---|
| **Results of bioimpedance measurement deviate significantly from expected results** | Patient position set on device does not match actual patient position | Ensure that the patient position set on the device and the actual position match |
| | Patient moved during the measurement | Request the patient not to move during the measurement and repeat the measurement |
| | The patient's arms or legs are not spread away from the body | Ask the patient to spread arms and legs away from the body |
| | Electrode cables incorrectly assigned | Ensure that the electrode cables are connected to the correct electrodes to suit patient position |
| | Electrodes faulty | Replace electrodes |
| | Electrode cables or measuring mat faulty | Replace measuring mat |
| | Incorrect seca patient file called up | Transmit measurement to **seca analytics 115** and assign to the correct seca patient file there |
| **Some analysis modules are not shown in the “analysis” tab** | List of analysis modules which can be displayed has been restricted by administrator | Administrator: Modify the analysis modules which can be displayed |
| **Value of an analysis parameter is shown in red** | Value outside the normal range determined for the analysis parameter | • Repeat the measurement to rule out measurement error<br>• If the value remains outside the normal range on a repeat measurement, take the value into account as the examination continues |

17-10-05-353-002d_02-2019 B

## 9.4 Vital signs measurement


➔ General

➔ Blood pressure measurement

➔ COVIDIEN™ FILAC™ 3000 temperature measurement

➔ COVIDIEN™ GENIUS®2 temperature measurement

➔ $SpO_2$ measurement


### General

| Problem | Cause | Remedy |
|---|---|---|
| **vital signs tab is not displayed** | USB connecting cable of the SmartBucket not connected to the monitor | • Connect the USB connecting cable of the SmartBucket to the monitor<br>• Restart the device |
| | SmartBucket not activated | Administrator:<br>Activate SmartBucket: ➔ Administer system components in the Administrator menu |
| **The fields "Weight" and "Height" are not displayed in the vital signs tab** | **seca 360° wireless** module of the mVSA not activated | Administrator:<br>Activate the **seca 360° wireless** module of the mVSA: ➔ Set up peripherals in the Administrator menu |
| **seca mVSA 535 is being operated on a wheeled stand: Measured results for vital signs are implausible** | • Original seca USB connecting cable not being used<br>• USB extension cable also in use | • Use original seca USB connecting cable (in scope of supply for wheeled stand)<br>• Do not use a USB extension cable |

### Blood pressure measurement

| Problem | Cause | Remedy |
|---|---|---|
| **Implausible measured results** | Excessive patient movement | • Ask the patient to move as little as possible |
| | Incorrect blood pressure cuff used | • Use correct size of blood pressure cuff<br>• Only use seca blood pressure cuffs |
| | Blood pressure cuff not applied correctly | Correctly apply blood pressure cuff, see Instructions for Use for blood pressure cuff |
| | Blood pressure cuff applied to an extremity to which there is intravenous access | Apply blood pressure cuff to a different extremity |
| **Insufficient cuff pressure** | Incorrect blood pressure cuff used | • Use correct size of blood pressure cuff<br>• Only use seca blood pressure cuffs |
| | Blood pressure cuff or compressed air tube leaking | Dispose of blood pressure cuff, use replacement |
| | Pump in device faulty | Do not continue using device and have it repaired by seca Service |

17-10-05-353-002d_02-2019 B

### COVIDIEN™ FILAC™ 3000 temperature measurement

| Problem | Cause | Remedy |
|---|---|---|
| **No temperature measurement possible** | Temperature module of the SmartBucket not activated | Activate temperature module (administrator rights required):<br>➔ Retrofit SmartBucket (seca 525 only) |
| **Implausible measured results, temperature measurement unsuccessful** | Special patient condition, such as hypothermia | • Assess patient vital signs using alternative means<br>• Switch from predictive measurement mode to direct mode |
| | Rectal measurement performed with blue temperature probe | Only perform rectal measurement with red temperature probe |
| | Oral/axillary measurement performed with red temperature probe | Only perform oral/axillary measurement with blue temperature probe |
| | Patient activity before oral temperature measurement:<br>• Physical exertion<br>• Eating/drinking<br>• Brushing teeth<br>• Smoking | Only perform oral temperature measurement about 20 minutes after any of these activities |
| | Set measuring position does not match actual measuring position | • Select measuring position according to the probe in use<br>• Set correct measuring position on device |
| | No probe cover used | • Desinfect probe/ear thermometer<br>➔ Disinfecting<br>• Use probe cover |
| | Temperature probe faulty | Dispose of temperature probe, use replacement |
| **Temperature probe cannot be pushed completely into the probe holder** | Probe cover not discarded | • Carefully withdraw temperature probe and probe cover from the probe holder<br>• Discard probe cover<br>• Push the temperature probe into the probe cover |

### COVIDIEN™ GENIUS®2 temperature measurement

| Problem | Cause | Remedy |
|---|---|---|
|  | Patient temperature exceeds measuring range of in-ear thermometer | Assess patient vital signs using alternative means |
|  | Patient temperature undershoots measuring range of in-ear thermometer | |
|  | Ambient temperature exceeds permitted range | • Modify ambient temperature<br>• Perform measurement at a location with an ambient temperature within the permitted range |
|  | Ambient temperature undershoots permitted range | |

17-10-05-353-002d_02-2019 B

| Problem | Cause | Remedy |
|---|---|---|
| **Measurement does not start** | No probe cover used | • Desinfect probe/ear thermometer<br>➔ Disinfecting<br>• Use probe cover |
| | Probe cover not properly located on measuring head | Ensure that probe cover engages audibly with the measuring head |
| | Probe cover damaged | Dispose of damaged probe cover, use new one |
| | Temperature module of the SmartBucket not activated | Activate temperature module (administrator rights required):<br>➔ Retrofit in-ear thermometer (seca 535 only) |
| **Measured result unexpectedly high** | Probe cover damaged | Dispose of damaged probe cover and use new one |
| **Measured result unexpectedly low** | Lens of measuring head blocked<br>Opening in probe cover blocked | • Clean measuring head<br>• Dispose of probe cover, use new one |
| | Patient's auditory canal blocked | Clean auditory canal |
| **Implausible measured results** | Probe cover damaged | Dispose of damaged probe cover and use new one |
| | Measuring position on in-ear thermometer in wrong place | Correct setting on in-ear thermometer (see Operating Instructions for in-ear thermometer) |
| | Ear thermometer faulty | Dispose of in-ear thermometer, use replacement |
| **Different temperature units on monitor and display** | Setting of unit on monitor and on in-ear thermometer is not synchronized automatically. If necessary, the monitor converts measured results automatically. | • Press the °C/°F button on the in-ear thermometer<br>• Change units on the monitor (administrator rights required). |

## $SpO_2$ measurement

| Problem | Cause | Remedy |
|---|---|---|
| **Implausible measured results** | Intra aortic balloon pump affecting pulse rate | Check pulse rate using ECG |
| | Sensor damp | • Dry sensor<br>• Use dry sensor |
| | Sensor not applied correctly | Apply sensor correctly, see Instructions for Use for sensor |
| | Strong ambient light | Cover application site with opaque material |
| | Electromagnetic interference | • Switch off devices in proximity, isolate interfering device<br>• Align interfering device differently or set up in a different location<br>• Increase the distance between it and the interfering device |
| | Poor perfusion | • Assess patient vital signs using alternative means<br>• Apply blood pressure cuff to location with better perfusion |
| **Measurement not possible** | Masimo SET® only:<br>Sensor service life expired | Use new Masimo SET® sensor. |
| | Sensor or patient cable defective | Dispose of sensor or patient cable, use spare part |

17-10-05-353-002d_02-2019 B

| Problem | Cause | Remedy |
|---|---|---|
| **Pulse is not found or is lost** | Sensor too rigid | • Use suitable size of sensor<br>• Apply sensor to a different finger |
| | Strong ambient light | Cover application site with opaque material |
| | Poor perfusion | • Assess patient vital signs using alternative means<br>• Apply sensor to a location with better perfusion |

## 9.5 Data connection

| Problem | Cause | Remedy |
|---|---|---|
| **Data transmission cannot be set up between device and seca analytics 115** | Software versions not compatible | Use a compatible version of the **seca analytics 115**: 1.4 Build 800 or higher |
| **seca patient file not found when searching for a patient on the device** | No seca patient file set up yet | Create seca patient file ➔ Create seca patient file |
| | seca patient file is not assigned to the user in the **seca analytics 115** | Check whether the seca patient file can be assigned to the user in the **seca analytics 115** |
| | Windows firewall port-blocking is active, required ports are blocked | Administrator:<br>Release the ports required |
| **No access to seca patient database of the seca analytics 115 PC software** | No network connection set up between the device and the PC on which the **seca analytics 115** PC software is installed | Administrator:<br>➔ Setting up LAN connection to the network (stationary operation)<br>➔ Set up WiFi connection (mobile operation)<br>➔ Setting up a data connection to the seca analytics 115 PC software |
| | The PC on which the **seca analytics 115** PC software is installed is not switched on | Switch on PC |
| | Automatic synchronization is deactivated on the device | Administrator:<br>➔ Activate automatic synchronization |
| **The fields “Weight” and “Height” are not shown in the display** | **seca 360°** wireless module of the device not activated | Administrator:<br>➔ Set up seca 360° wireless network |
| **Neither weight nor height values are shown in the display** | **seca 360°** wireless module of the scale/stadiometer not activated | Administrator:<br>➔ Set up seca 360° wireless network |
| | No **seca 360°** wireless connection set up | |
| | No **seca 360°** wireless module included in scale/stadiometer | Enter measured values manually:<br>➔ Enter basic parameters |

17-10-05-353-002d_02-2019 B

## 9.6 Print

| Problem | Cause | Remedy |
|---|---|---|
| **Print function not available** | Software versions not compatible | Use a compatible version of the **seca analytics 115** PC software: 1.4 Build 800 or higher |
| **Results report not being printed** | PC printer not switched on | Switch on PC printer |
| | The PC on which the **seca analytics 115** PC software is installed is not switched on | Switch on PC |
| | No network connection set up between device and **seca analytics 115** PC software | Administrator: Set up LAN connection |
| | No connection set up between **seca analytics 115** PC software and PC printer | Administrator: Set up connection between **seca analytics 115** PC software and PC printer |

# 10. TECHNICAL DATA


➔ Monitor
➔ Measuring mat
➔ Bioimpedance measurement
➔ Vital signs measurement
➔ Analysis parameters
➔ Analysis modules
➔ seca 360° wireless system


## 10.1 Monitor

| Dimensions, weights | |
|---|---|
| **Monitor with storage compartment (seca mBCA 525)** | |
| Dimensions (**seca mBCA 525**)<br>• Depth<br>• Width<br>• Height | <br>230 mm<br>252 mm<br>262 mm |
| Weight (**seca mBCA 525**) | approx. 2 kg |
| **Monitor with SmartBucket (seca mVSA 535)** | |
| Dimensions, empty (**seca mVSA 535** for temperature probe)<br>• Depth<br>• Width<br>• Height | <br>278 mm<br>254 mm<br>262 mm |
| Dimensions, empty (**seca mVSA 535** for in-ear thermometer)<br>• Depth<br>• Width<br>• Height | <br>278 mm<br>252 mm<br>262 mm |
| Weight (**seca mVSA 535**) | approx. 3 kg |
| **Further technical data (all models)** | |
| Ambient conditions, operation<br>• Temperature (with COVIDIEN™ FILAC™ 3000)<br>• Temperature (with COVIDIEN™ GENIUS®2)<br>• Air pressure<br>• Humidity | <br>+10 °C to +40 °C (50 °F to 104 °F)<br>+16 °C to +33 °C (60.8 °F to 91.4 °F)<br>700 hPa - 1060 hPa<br>30 % - 80 %, no condensation |
| Ambient conditions, storage<br>• Temperature<br>• Air pressure<br>• Humidity | <br>-10 °C to +55 °C (14 °F to 131 °F)<br>700 hPa - 1060 hPa<br>15 % - 95 %, no condensation |

17-10-05-353-002d_02-2019 B

| | |
|---|---|
| Ambient conditions, transport<br>• Temperature<br>• Air pressure<br>• Humidity | <br>-10 °C to +55 °C (14 °F to 131 °F)<br>700 hPa - 1060 hPa<br>15 % - 95 %, no condensation |
| Setup location, maximum altitude above mean sea level | 3000 m |
| Display type | 7" touchscreen display |
| Power supply for monitor, input<br>• Type<br>• Supply voltage<br>• Supply frequency<br>• Current consumption | <br>Internal power supply unit, IEC 60320 C13<br>100 V ~ - 240 V ~<br>50 Hz - 60 Hz<br>0.85 A |
| Mobile power supply<br>Voltage<br>Capacity<br>Range (**seca mVSA 535**: full brightness, new battery pack) | Lithium-ion battery<br>11.25 V<br>2950 mAh<br>approx. 5 h |
| Power consumption<br>• Standby (touchscreen display off, ON/OFF button green)<br>• In operation (ON/OFF button white)<br>• Operation (battery charging, monitor and measuring mat, on/off button illuminated white) | <br>< 5 W<br>< 9 W<br>< 35 W |
| Medical device in accordance with Directive 93/42/EEC | Class IIa |
| EN 60601-1:<br>Insulated device, protection class: | <br>I |
| Type of protection **seca mBCA 525** | IP20 |
| Type of protection **seca mVSA 535** | IP21 |
| Duty cycle | Continuous duty |
| Interfaces | **seca 360° wireless**<br>2 x USB 2.0 (max 500 mA)<br>LAN: Ethernet (10/100 Base-T)<br>WiFi<br>Infrared<br>Inductive charging of rechargeable battery for measuring mat |
| Compatible printer | Microsoft® Windows®-compatible printer via **seca analytics 115** PC software |

17-10-05-353-002d_02-2019 B

## 10.2 Measuring mat

| Measuring mat | |
|---|---|
| Dimensions<br>• Depth<br>• Width<br>• Height | <br>783 mm<br>170 mm<br>20 mm |
| Net weight | approx. 1 kg |
| Ambient conditions, operation<br>• Temperature<br>• Air pressure<br>• Humidity | <br>+10 °C to +40 °C (50 °F to 104 °F)<br>700 hPa - 1060 hPa<br>30 % - 80 %, no condensation |
| Ambient conditions, storage<br>• Temperature<br>• Air pressure<br>• Humidity | <br>-10 °C bis +60 °C (14 °F bis 140 °F)<br>700 hPa - 1060 hPa<br>15 % - 95 %, no condensation |
| Ambient conditions, transport<br>• Temperature<br>• Air pressure<br>• Humidity | <br>-10 °C bis +60 °C (14 °F bis 140 °F)<br>700 hPa - 1060 hPa<br>0 % - 95 %, no condensation |
| Setup location, maximum altitude above mean sea level | 3000 m |
| Power supply<br>Range (measurements) | Lithium-ion battery<br>approx. 5 h |
| Medical device in accordance with Directive 93/42/EEC | Class IIa |
| EN 60601-1: Medical electrical device, type BF |  |
| Type of protection | IP44 |
| Duty cycle | Continuous duty |

## 10.3 Bioimpedance measurement

➔ Measuring method

➔ Clinical studies

➔ Accuracy of predictive formulas

### Measuring method

| Measuring method | |
|---|---|
| Measuring method | 8-point bioimpedance measurement<br>4-point bioimpedance measurement<br>(measure right half of body) |
| Measuring frequencies | 1; 2; 5; 10; 20; 50; 100; 200; 500 kHz |
| Measured values | Impedance (Z), resistance (R),<br>reactance ($X_c$), phase angle (φ) |
| Phase angle measuring range | 0° to 20° |
| Impedance measuring range | 10 Ω to 1000 Ω |
| Measuring segments | Right arm, left arm, right leg, left leg,<br>right half of body, torso |
| Measuring current | 100 µA (+20 %, -50 %) |
| Measuring time | max. 30 s |
| Accuracy<br>(8-point bioimpedance measurement, frequencies 5 kHz and 50 kHz<br>Segments: Right half of body, left half of body)<br>• Impedance (at phase angle 0°)<br>• Phase angle (at phase angle 0°, impedance 200 Ω to 1000 Ω) | <br><br><br>±5 Ω<br>0.5° |

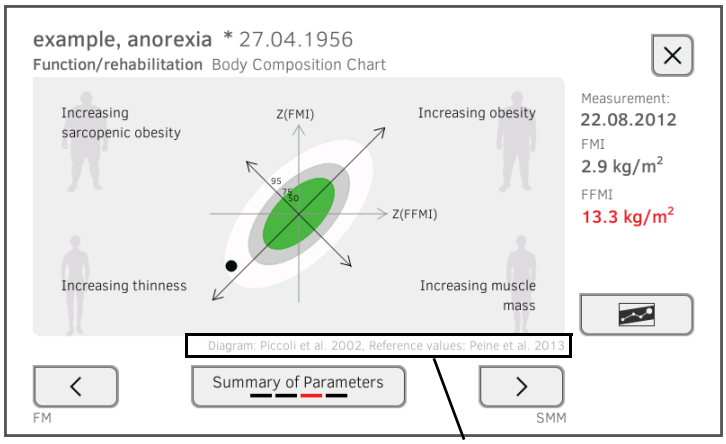
17-10-05-353-002d_02-2019 B

## Clinical studies

Clinical studies form the scientific basis for analyzing body composition using the mVSA **seca mVSA 535** and the mBCA **seca mBCA 525**. The study results are integrated in the device software in the form of reference values.

For some analysis parameters, the reference used depends on the patient's ethnicity. The device automatically uses ethnicity-dependent references to suit the corresponding entry in the seca patient file ➜ Prepare seca patient file.

The study used is quoted on screen for each analysis parameter.




Details about the clinical studies can be found on our website, www.seca.com.

## Accuracy of predictive formulas

| Standard deviation (SEE) for predictive formulas in this device[a] | | | | | |
|---|---|---|---|---|---|
| **Ethnicity:** | **Caucasian** | **Afro-American** | **Asian** | **South and Central American** | **Other** |
| **Parameter** | **SEE** | **SEE** | **SEE** | **SEE** | **SEE** |
| FFM | 2.50 kg | 2.21 kg | 2.54 kg | 2.62 kg | 2.49 kg |
| TBW | 2.0 l | 1.8 l | 1.4 l | 1.4 l | 1.7 l |
| ECW | 1.1 l | 0.9 l | 0.9 l | 0.7 l | 0.9 l |
| SMM left arm | 0.19 kg | 0.28 kg | 0.19 kg | 0.16 kg | 0.21 kg |
| SMM right arm | 0.22 kg | 0.30 kg | 0.21 kg | 0.17 kg | 0.23 kg |
| SMM left leg | 0.81 kg | 0.71 kg | 0.81 kg | 0.83 kg | 0.79 kg |
| SMM right leg | 0.68 kg | 0.66 kg | 0.76 kg | 0.71 kg | 0.70 kg |
| SMM total | 1.8 kg | 2.0 kg | 1.7 kg | 1.7 kg | 1.8 kg |
| VAT | 0.5 l | 0.6 l | 0.6 l | 1.2 l | 0.8 l |

a. In the USA, a study was conducted on 130 healthy adults of different ethnicities. The aim of the study was to validate the parameters determined using seca formulas against clinically established reference methods. The results of this comparative study are shown in the table above. The table shows the standard deviation (SEE) for the parameters determined using seca's in-house formulas by ethnicity.

17-10-05-353-002d_02-2019 B

## 10.4 Vital signs measurement

➔ Blood pressure measurement
➔ Temperature measurement COVIDIEN™ FILAC™ 3000
➔ $SpO_2$ measurement Masimo SET®
➔ seca $SpO_2$ measurement

### Blood pressure measurement

| seca blood pressure module | |
|---|---|
| Measuring method | Oscillometric measurement<br>Switch between upward/downward measurement<br>Switch between single/ multiple measurement (3 measurements) |
| Initial cuff pressure, downward measurement<br><br>Maximum cuff pressure | Adjustable: 80 mmHg - 280 mmHg<br>(260 mmHg cannot be set)<br>300 mmHg |
| Measuring range for blood pressure<br>Upward measurement (inflation):<br>• Systolic BP<br>• Diastolic BP<br>• Mean arterial pressure<br>Downward measurement (deflation):<br>• Systolic BP<br>• Diastolic BP<br>• Mean arterial pressure<br>Accuracy (under laboratory conditions, verified with CuffLink patient simulator from Fluke) | <br><br>77 mmHg - 200 mmHg<br>45 mmHg - 190 mmHg<br>56 mmHg - 193 mmHg<br><br>25 mmHg - 280 mmHg<br>10 mmHg - 220 mmHg<br>15 mmHg - 260 mmHg<br>max. ± 3 mmHg / 3 %,<br>The larger value in each case applies |
| Measuring range for blood pressure:<br>• Systolic BP<br>• Diastolic BP<br>• Mean arterial pressure | <br>25 mmHg - 280 mmHg<br>10 mmHg - 220 mmHg<br>15 mmHg - 260 mmHg |
| Measuring accuracy for blood pressure (determined by measuring module manufacturer in clinical trial according to DIN EN ISO 81060)<br>Upward measurement (inflation):<br>• Mean deviation of systolic BP<br>• Standard deviation of systolic BP<br>• Mean deviation of diastolic BP<br>• Standard deviation of diastolic BP<br>Downward measurement (deflation):<br>• Mean deviation of systolic BP<br>• Standard deviation of systolic BP<br>• Mean deviation of diastolic BP<br>• Standard deviation of diastolic BP | <br><br><br>0,94 mmHg<br>3,84 mmHg<br>0,57 mmHg<br>3,17 mmHg<br><br>0,39 mmHg<br>2,57 mmHg<br>0,43 mmHg<br>1,73 mmHg |
| Pressure transducer:<br>• Accuracy<br>• Resolution | <br>±1 mmHg<br>1 mmHg |
| • Leakage rate<br>• Limit value for pressure<br>• Switch off and release pressure at (first fault) | < 3 mmHg/min<br>300 mmHg<br>> 330 mmHg |
| Measuring time for blood pressure:<br>• Normal<br>• Maximum (adults) | <br>15 - 20 s<br>90 s |

17-10-05-353-002d_02-2019 B

| seca blood pressure module | |
|---|---|
| Pulse rate:<br>• Measuring range for upward measurement (inflation)<br>• Measuring range for downward measurement (deflation)<br>• Accuracy (under laboratory conditions, verified with CuffLink patient simulator from Fluke) | <br>45 $min^{-1}$ - 200 $min^{-1}$<br>30 $min^{-1}$ - 240 $min^{-1}$<br>max. ± 3 $min^{-1}$ / 3 %,<br>The larger value in each case applies |
| Medical electrical device, type BF (defibrillation-protected) |  |
| Type of protection | IP20 |

## Temperature measurement COVIDIEN™ FILAC™ 3000

**General technical data**

| COVIDIEN™ FILAC™ 3000 temperature module | |
|---|---|
| Measurement modes | Direct, predictive |
| Measuring position:<br>Blue Probes<br>Red Probes | <br>oral, axillary<br>rectal |
| Measuring range<br>• Direct mode<br>• Predictive mode | <br>30 °C - 43 °C (86 °F - 109,4 °F)<br>35,5 °C - 42 °C (95,9 °F - 107,6 °F) |
| Measuring time (following application at measuring position)<br>Direct:<br>• All measuring positions<br>Predictive:<br>• Oral, no fever<br>• Oral, fever<br>• Axillary<br>• Rectal | <br><br>60 - 120 sec<br><br>3 - 5 sec<br>8 - 10 sec<br>8 - 12 sec<br>10 - 14 sec |
| Switchover time from predictive mode to direct mode<br>• Measuring position not detected (following removal from probe cover)<br>• No stable temperature value obtained (following application) | <br>60 sec<br>70 sec |
| Accuracy (water bath):<br>• Direct mode<br>• Predictive mode | <br>± 0,1 °C ( ± 0,2 °F)<br>± 0,1 °C (± 0,2 °F) |
| EN 60601-1: Medical electrical device, type BF |  |
| Type of protection against ingress of liquids | IPX0 |

| Clinical accuracy[a] [b] | | | |
|---|---|---|---|
| **Measurement site:** | **Oral** | **Axillary** | **Rectal** |
| $\overline{d}$ (age group I) | -0.44 | -0.01 | 0.09 |
| $L_A$ (age group I) | 1.01 | 0.86 | 0.99 |
| $\overline{d}$ (age group II) | -0.21 | -0.04 | 0.12 |
| $L_A$ (age group II) | 0.75 | 0.65 | 0.67 |
| $\sigma_r$ | 0.34 | 0.28 | 0.28 |

a. The clinical accuracy of the COVIDIEN™ FILAC™ 3000 was determined in a clinical study in accordance with EN 80601-2-56. Clinical bias $\overline{d}$ and limits of agreement $L_A$ are quoted for the age group and measurement site in question. Clinical repeatability $\sigma_r$ is independent of age. The reference body sites of the reference thermometer used in the clinical study correspond to the measurement sites quoted.

b. The age of the subjects in age group I is between 3 and 4 years. The age of the subjects in age group II is 5 and above.

17-10-05-353-002d_02-2019 B

## Temperature measurement COVIDIEN™ GENIUS®2

| COVIDIEN™ GENIUS®2 in-ear thermometer | |
|---|---|
| Measuring method | Direct mode |
| Measuring range (in-ear) | 33 °C - 42 °C (91,4 °F - 107,6 °F) |
| Measuring time | Less than 2 sec |
| Resolution | 0,1 °C; 0,1 °F |
| Accuracy<br>• Ambient temperature: 25 °C (77 °F)<br>Target temperature: 36,7 °C - 38,9 °C (98,1 °F - 102 °F)<br>• Ambient temperature: 16 °C - 33 °C (60,8 °F - 91,4 °F)<br>Target temperature: 33 °C - 42 °C (91,4 °F - 107,6 °F) | <br><br>± 0,1 °C (± 0,2°F)<br><br>± 0,2 °C (± 0,4°F) |
| EN 60601-1: Medical electrical device, type BF |  |
| Type of protection against ingress of liquids | IPX0 |

## $SpO_2$ measurement Masimo SET®

| Masimo SET® $SpO_2$ module[a b c d e f g] | |
|---|---|
| Measurement<br>Measuring method | Functional oxygen saturation<br>Spectrophotometry (red/infrared) |
| LED wavelength:<br>Red<br>Infrared<br>Maximum light output<br>This information may be of particular interest to clinicians | <br>660 nm<br>905 nm<br>15 mW |
| Measuring time:<br>• Device switched on, sensor not applied<br>• Device switched off, sensor applied | <br>≤ 12 sec<br>≤ 8 sec |
| Measuring range:<br>• $SpO_2$<br>• Pulse rate<br>• Perfusion Index | <br>0 % - 100 %<br>25 $min^{-1}$ - 240 $min^{-1}$<br>0,02 % - 20 % |
| Measuring accuracy:<br>• Measuring range<br>• $SpO_2$ (no patient movement)<br><br>• $SpO_2$ (patient movement)<br><br>• Pulse rate (no patient movement)<br>• Pulse rate (patient movement) | <br>70 % - 100 %<br>70% - 100% ± 2 digits<br>0% - 69% not specified<br>70% - 100% ± 3 digits<br>0% - 69% not specified<br>25 $min^{-1}$ - 240 $min^{-1}$ ± 3 digits<br>25 $min^{-1}$ - 240 $min^{-1}$ ± 5 digits |
| Low perfusion performance<br>• Pulse amplitude<br>• Transmission<br>• Oxygen saturation ($SpO_2$)<br>• Pulse frequency | <br>> 0.02%<br>> 5%<br>± 2 digits<br>± 3 digits |
| Resolution:<br>• Oxygen saturation ($SpO_2$)<br>• Pulse rate | <br>1 %<br>1 $min^{-1}$ |
| EN 60601-1: Medical electrical device, type BF |  |

a. The Masimo SET technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

17-10-05-353-002d_02-2019 B

b. The Masimo SET technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation, which encompasses 68% of the population.

c. The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2™ simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

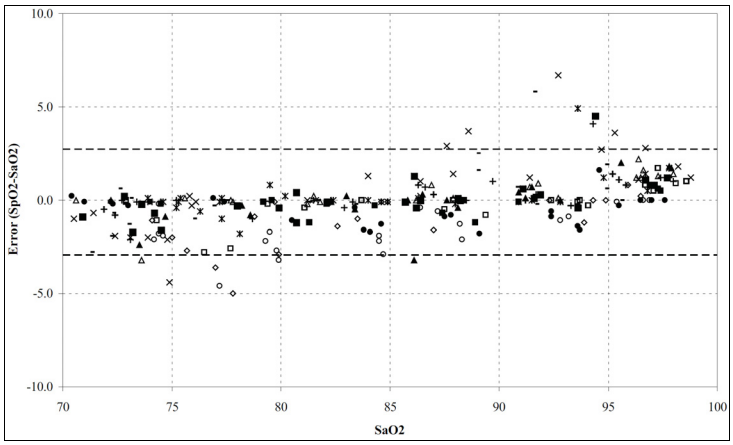
d. The Masimo SET Technology with Masimo Neo sensors has been validated for neonatal motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 1% has been added to the results to account for the effects of fetal hemoglobin present in neonates.

e. The Masimo SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25 -240 $min^{-1}$ in bench top testing against a Biotek Index 2™ simulator. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

f. See sensor directions for use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.

g. Sensor accuracy specified when used with Masimo technology using a Masimo patient cable for LNOP sensors, RD SET sensors, the LNCS sensors, or the M-LNCS sensors. Numbers represent Arms (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of ± Arms compared to the reference value. Unless otherwise noted, SpO2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 $min^{-1}$.

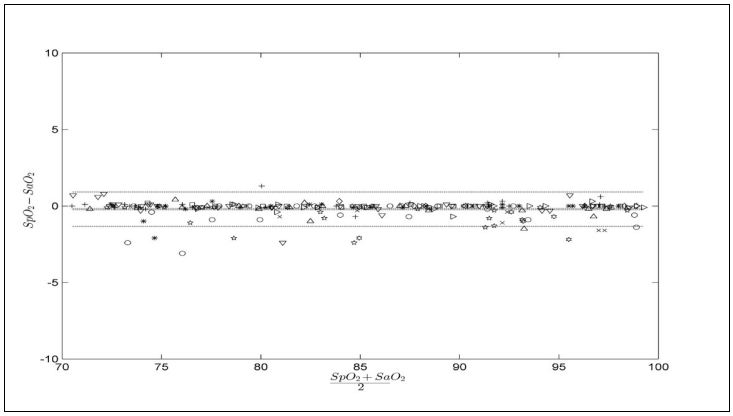
**Accuracy of Masimo SET® adults/children**




| Measured values | |
|---|---|
| **Measuring range** | **$A_{RMS}$** |
| 90-100% | 1.64% |
| 80-90% | 1.07% |
| 70-80% | 1.55% |
| **Total value** | |
| 70-100% | ± 2% |

17-10-05-353-002d_02-2019 B

### Accuracy of Masimo SET® DCI/DCIP sensors




| Measured values | |
|---|---|
| **Measuring range** | **$A_{RMS}$** |
| 90-100% | 0.60% |
| 80-90% | 0.54% |
| 70-80% | 0.67% |
| **Total value** | |
| 70-100% | 2% |

### Masimo Patent Information

Masimo Patents: www.masimo.com/patents.htm

### No Implied License Statement

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

### seca $SpO_2$ measurement

| seca $SpO_2$ module[a] [b] | |
|---|---|
| Measurement<br>Measuring method | Functional oxygen saturation<br>Spectrophotometry (red/infrared) |
| LED wavelength:<br>Red<br>Infrared<br>Maximum light output<br>This information may be of particular interest to clinicians | <br>660 nm<br>905 nm<br>5 mW |
| Measuring range:<br>• $SpO_2$<br>• Pulse frequency (default)<br>• Pulse frequency (enhanced) | <br>0 % - 100 %<br>30 $min^{-1}$ - 240 $min^{-1}$<br>20 $min^{-1}$ - 300 $min^{-1}$ |
| Measuring accuracy:<br>• $SpO_2$ (no patient movement)<br><br><br>• $SpO_2$ (patient movement)<br><br>• Pulse rate (no patient movement)<br>• Pulse rate (patient movement) | <br>60% - 70% ± 3 $A_{rms}$<br>60% - 100% ± 2 $A_{rms}$<br><60% not specified<br>70% - 100% ± 3 $A_{rms}$[c]<br><70% not specified<br>≤ 2 $min^{-1}$<br>- |

17-10-05-353-002d_02-2019 B

| seca $SpO_2$ module[a] [b] | |
|---|---|
| Resolution:<br>• Oxygen saturation ($SpO_2$)<br>• Pulse rate | 1 %<br>1 $min^{-1}$ |
| EN 60601-1: Medical electrical device, type BF |  |

a. Validated by clinical tests, where the measured values of the sensors were compared with those of the arterial co-oximetry in healthy adult subjects over the specified functional oxygen saturation range.

b. As inherent to their functional principle, pulse oximetry measurements are statistically distributed; therefore only about two-thirds of the measurement data are expected to fall within $\pm A_{rms}$ (Accuracy root mean square) of the value measured by a co-oximeter.

c. Tested with all motion patterns Fluke Index II oximeter tester.

## 10.5 Analysis parameters

**NOTE**
These Instructions for Use describe the maximal available functional scope of the device. The actual functional scope of your device may be less than this.

| Analysis parameter | Display | Analysis module |
|---|---|---|
| Bioimpedance vector analysis (BIVA) | • Normal range display of R and $X_c$ in co-ordinate system in relation to height<br>• 50 %, 75 %, 95 % percentiles in the form of tolerance ellipses | Fluid<br>Health risk |
| Body mass index (BMI) | • Absolute in $kg/m^2$<br>• Graph of WHO reference values | Development/growth |
| Extracellular water (ECW) | Absolute in l | Fluid |
| Fat-free mass (FFM) | Absolute in kg | Function/rehabilitation |
| Fat mass (FM) | • Absolute in kg<br>• Relative to weight in %<br>• Normal range display | Energy<br>Function/rehabilitation |
| Total energy expenditure (TEE) | Absolute in MJ/d or kcal/d | Energy |
| Total body water (TBW) | Absolute in l | Fluid |
| Weight (W) | Absolute in kg | Development/growth |
| Height (H) | Absolute in m | Development/growth |
| Extracellular water (ECW)/total body water (TBW) | Relative in % | Fluid (international) |
| Energy stored in the body ($E_{body}$) | Absolute in MJ or kcal | Energy |
| Body composition chart (BCC):<br>Mass indices<br>Fat-free mass index (FFMI)<br>Fat mass index (FMI) | • Absolute in $kg/m^2$<br>• Normal range display<br>• 50 %, 75 %, 95 % percentiles in the form of tolerance ellipses | Function/rehabilitation<br>Health risk |
| Phase angle (φ) | • Absolute in degrees<br>• Normal range display | Health risk |
| Reactance ($X_c$) | Absolute in ohms | Fluid<br>Health risk |
| Resistance (R) | Absolute in ohms | Fluid<br>Health risk |
| Resting energy expenditure (REE) | Absolute in MJ/d or kcal/d | Energy |
| Skeletal muscle mass (SMM) | • Absolute in kg<br>• Normal range display | Function/rehabilitation |
| Visceral adipose tissue (VAT) | Absolute in l | Health risk |
| Blood pressure, non-invasive (NIBP) | Absolute in mmHg | Vital signs |
| Body temperature (TEMP) | Absolute in °C | Vital signs |
| Pulse rate: (PR) | Absolute in bpm (based on NIBP or $SpO_2$) | Vital signs |

17-10-05-353-002d_02-2019 B

| Analysis parameter | Display | Analysis module |
|---|---|---|
| Oxygen saturation ($SpO_2$) | Relative in % | Vital signs |

## 10.6 Analysis modules

**NOTE**
These Instructions for Use describe the maximal available functional scope of the device. The actual functional scope of your device may be less than this.

| Analysis module | Description | Analysis parameter |
|---|---|---|
| Development/growth | Supports the monitoring of weight changes | • Weight<br>• Height<br>• Body mass index (BMI) |
| Energy | • Determination of energy expenditure and energy reserves<br>• Required: Weight, height, PAL | • Fat mass (FM)<br>• Energy stored in the body ($E_{body}$)<br>• Resting energy expenditure (REE)<br>• Total energy expenditure (TEE) |
| Function/rehabilitation | • Determining fitness level<br>• Assessing the success of a training program<br>• Required: Weight, height | • Fat-free mass (FFM)<br>• Fat mass (FM)<br>• Body composition chart (BCC)<br>• Skeletal muscle mass (SMM) |
| Fluid | • Determination of fluid status<br>• Required: Weight, height | • Total body water (TBW)<br>• Extracellular water (ECW)<br>• ECW/TBW [%]<br>• Bioimpedance vector analysis (BIVA) |
| Health risk | • Summary of body composition<br>• Estimate of health risk<br>• Required: Weight, height, waist circumference | • Phase angle (φ)<br>• Visceral adipose tissue (VAT)<br>• Bioimpedance vector analysis (BIVA)<br>• Body composition chart (BCC) |
| Vital signs | Overview of vital signs to support a diagnosis | • Blood pressure (NIBP)<br>• Body temperature (TEMP)<br>• Pulse rate: (PR)<br>• Oxygen saturation ($SpO_2$) |

## 10.7 seca 360° wireless system

| seca 360° wireless | |
|---|---|
| Maximum number of wireless groups | 3 |
| Maximum configuration per wireless group | 1 baby scale<br>1 measuring station (or 1 personal scale and 1 stadiometer)<br>1mVSA/1mBCA<br>1 PC with **seca 360° wireless USB adapter 456** and **seca analytics 115** PC software |
| Number of channels per wireless group | 3 |
| Type of channel assignment | Automatic (recommended)<br>Manual |
| Channel numbers | 0 - 99 |
| Minimum spacing of channel numbers | 30 |
| • Frequency band<br>• Transmission power<br>• Maximum range | 2.433 GHz - 2.480 GHz<br>< 10 mW<br>10 m |

17-10-05-353-002d_02-2019 B

# 11. OPTIONAL ACCESSORIES AND SPARE PARTS

| Optional accessories and spare parts | Article number |
|---|---|
| SmartBucket **seca mVSA 526**<br>(mBCA **seca mBCA 525** compatible from serial number 10000000090505) | Version overview at<br>www.seca.com |
| Bioimpedance measurement:<br>**seca mBCA 531** measuring mat | <br>531-20-00-001 |
| Blood pressure measurement:<br>• Cuff, size S<br>• Cuff, size M<br>• Cuff, size L<br>• Cuff, size XL<br>• Extension for compressed air tube | <br>490-0001-001<br>490-0002-001<br>490-0003-001<br>490-0004-001<br>490-0005-001 |
| Masimo SET® $SpO_2$ measurement:<br>Masimo RD SET® Series sensors and patient cables<br>**Not compatible:** Sensors for neonates | Obtainable directly<br>from the manufacturer,<br>see www.masimo.com |
| seca $SpO_2$ measurement:<br>• Finger Clip SF7500 (adults)<br>• Soft sensor SC7500 (adults)<br>• Soft sensor SCM7500 (children)<br>• Patient cable XT6500 | <br>490-0006-001<br>490-0007-001<br>490-0008-001<br>490-0012-001 |
| Temperature measurement:<br>• COVIDIEN™ FILAC™ 3000 blue for oral/axillary measurement<br>• COVIDIEN™ FILAC™ 3000 red for rectal measurement<br>• COVIDIEN™ GENIUS®2 in-ear thermometer | <br>68-90-00-044-009<br>68-90-00-045-009<br>490-0014-001 |
| Push-button electrodes for affixing to patient;<br>pack of 100 | 68-90-00-043-009 |
| Probe covers for COVIDIEN™ FILAC™ 3000;<br>100 packs, pack of 20 probe covers | 490-0015-001 |
| Probe covers for COVIDIEN™ GENIUS®2;<br>22 packs, pack of 6 magazines (16 probe covers per magazine) | 490-0016-001 |
| PC software<br>• **seca analytics 115** | Application-specific license packages<br>Details at www.seca.com |
| **seca 475** wheeled stand for **seca mBCA 525**<br>Bracket for SmartBucket (retrofit for 475-00-00-009)<br>**seca 475** wheeled stand for **seca mVSA 535** | 475-00-00-009<br>490-0017-009<br>475-05-35-009 |
| seca carry case **seca 432** | 432-00-00-009 |

# 12. COMPATIBLE SECA MEASURING DEVICES

| **seca 360° wireless Measuring device** | Article number |
|---|---|
| Measuring stations<br>• **seca 287**/**seca 286**<br>• **seca 285**/**seca 284** | For country-specific versions,<br>details at www.seca.com |
| Stadiometers<br>• **seca 274**<br>• **seca 264** | |
| Personal scales<br>• **seca 704**/**seca 703** | |
| Multifunctional and platform scales<br>• **seca 635**/**seca 634**<br>• **seca 645**/**seca 644**<br>• **seca 657**/**seca 656**<br>• **seca 665**/**seca 664**<br>• **seca 677**/**seca 676**<br>• **seca 685**/**seca 684** | |

17-10-05-353-002d_02-2019 B

# 13. DISPOSAL

➔ Measuring mat and device
➔ Batteries and rechargeable batteries
➔ Consumables

## 13.1 Measuring mat and device

Do not dispose of the device with household waste. The device must be disposed of properly as electronic waste. Comply with the national provisions applicable in your country. For further information contact our service department at:

**service@seca.com**

## 13.2 Batteries and rechargeable batteries

Spent (rechargeable) batteries should not be discarded with household waste, regardless of whether they contain harmful substances or not. As a consumer you are obliged by law to dispose of (rechargeable) batteries via the collection points set up by the municipal authorities or the retail sector. Only discard (rechargeable) batteries when fully discharged.

## 13.3 Consumables

Do not dispose single-use items such as probe covers with household waste. Comply with facility requirements and the national provisions applicable in your country.

# 14. WARRANTY

We offer a two-year warranty from the date of delivery for defects attributable to faulty material or poor workmanship. This excludes all moveable parts such as (rechargeable) batteries, cables, power supply units, etc. Defects which are covered by the warranty shall be rectified free of charge for customers on production of the sales receipt. No further claims can be accepted. The costs of shipment in both directions shall be borne by the customer where the device is not located at the customer's premises. In the event of any damage during shipment warranty claims can only be asserted where the complete original packaging was used for shipment and the scales were secured inside in the same manner as in the original packaging. You should therefore keep all packaging.

The warranty shall become null and void where the device is opened by persons not expressly authorised to do so by seca.

In the event of a warranty issue, please contact your local seca office or the dealer from whom you ordered the product.

Details on the warranty for measurement accessories, such as blood pressure cuffs, $SpO_2$ sensors or thermometers, for example, can be found at www.seca.com.

17-10-05-353-002d_02-2019 B

# 15. DECLARATIONS OF CONFORMITY

➔ For Europe

➔ For USA and Canada

## 15.1 For Europe

CE

seca gmbh & co. kg hereby declares that the product meets the terms of the applicable European directives. The unabridged declaration of conformity can be found at: www.seca.com.

## 15.2 For USA and Canada

seca 535
seca 525
seca 360 wireless Module Monitor:
FCC ID: X6T172A01
IC: 8898A-172A01
WiFi Module Monitor:
FCC QOQWF111
IC 5123A-BGTWF111

WiFi Module Measuring Mat:
FCC QOQWF121
IC 5123A-BGTWF121

This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada. Operation is subject to the following two conditions. (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

**NOTE**
This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

**NOTE**
Changes or modifications made to this equipment not expressly approved by seca may void the FCC authorization to operate this equipment.

**NOTE**
Radiofrequency radiation exposure Information:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance of 1 m between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

17-10-05-353-002d_02-2019 B

# FOR ADMINISTRATORS: CONFIGURE SECA 535/SECA 525



**NOTE**
This document describes the maximal equipment of the **seca 535**/ **seca 525** product family: measurement of blood pressure, temperature, oxygen saturation and bioimpedance. Depending on the actual equipment of your device, some of this information may not be relevant to your device. Pay attention to the information in this document which is relevant to your device.

**NOTE**
- This part of the user documentation contains information about configuring the device for measuring operation and for integration in a PC network.
- Integrating this device into a PC network containing further devices may create previously unknown risks to patient, user and third part. The responsibility to identify, analyse, evaluate and control these risks lays with the operator.
- The functions described in this part of the user documentation are accessible only to users with administrator rights.
- Follow the information in the Instructions for Use ➔ Instructions for Use for seca 535/seca 525.

# 1. PREPARE CONFIGURATION



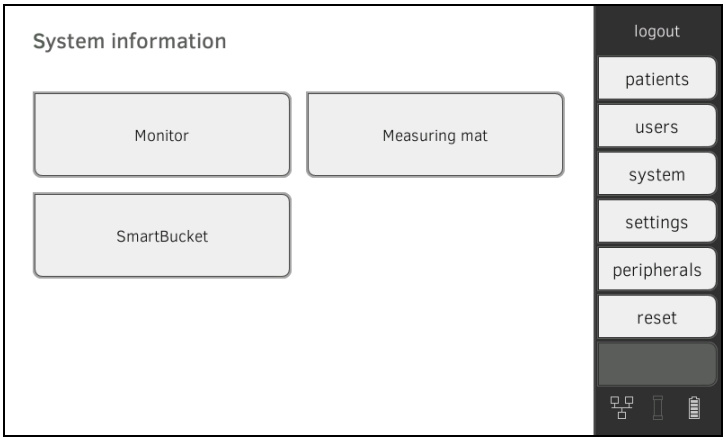
## 1.1 Log in

**NOTICE!**
**Unauthorized data access**
Failure to change the initial admin password may lead to unauthorized access to patient data or device settings.
► Change admin password directly after first log in.
**Notice!**
**Faulty configuration**
During configuration, data are transmitted to the measuring mat via the infrared interface. The infrared interface is located in the magnetic catch of the monitor.
► Ensure that the measuring mat is correctly suspended in the magnetic catch of the monitor throughout the entire configuration process ➔ Suspend measuring mat in magnetic catch.

1. Switch on the device.
   The measuring mat switches on automatically.

17-10-05-353-002d_02-2019 B

2. Log on as the administrator (default user account: “admin”; password “1357”) ➔ Log in.
   The administrator area is displayed.




## 1.2 Configuration options

➔ Network functions

➔ User role model

### Network functions

• = possible, - = not possible

| Function | LAN | WiFi | seca 360° | Infrared |
|---|---|---|---|---|
| Transmit weight to monitor | - | - | • | - |
| Transmit height to monitor | - | - | • | - |
| Communication between monitor and measuring mat | - | • | - | • |
| **seca directprint** Use (function of the **seca analytics 115** PC software) | • | • | - | - |
| Synchronize seca patient files and user accounts with the **seca analytics 115** PC software | • | • | - | - |

### User role model

• = possible, - = not possible

| Function | Administrator | User |
|---|---|---|
| Create seca patient files | • | • |
| Call up seca patient files | - | • |
| Enter basic parameters (weight, height, waist circumference, PAL) | - | • |
| Edit seca patient files | • | - |
| Delete seca patient files | • | - |
| Restore seca patient files | • | - |
| Perform measurements | - | • |
| View examination results | - | • |
| Print examination results | - | • |
| Analysis parameters: Add comments | - | • |
| Administer patient database | • | - |
| Administer user database | • | - |
| Modify basic settings (e.g. time, date) | • | - |
| Modify units for measured values | • | - |

17-10-05-353-002d_02-2019 B

| Function | Administrator | User |
|---|---|---|
| Modify analysis parameters which can be displayed | • | - |
| Set up network connections | • | - |
| Configure automatic database synchronization | • | - |
| Configure automatic export | • | - |
| Import data from USB memory stick | • | - |
| Restore factory settings | • | - |
| Reset user interface | • | - |
| Export data to USB memory stick | • | - |

# 2. ADMINISTER PATIENT FILES

➔ Create a seca patient file

➔ Edit a seca patient file

➔ Delete a seca patient file

➔ Restore a seca patient file

**NOTICE!**

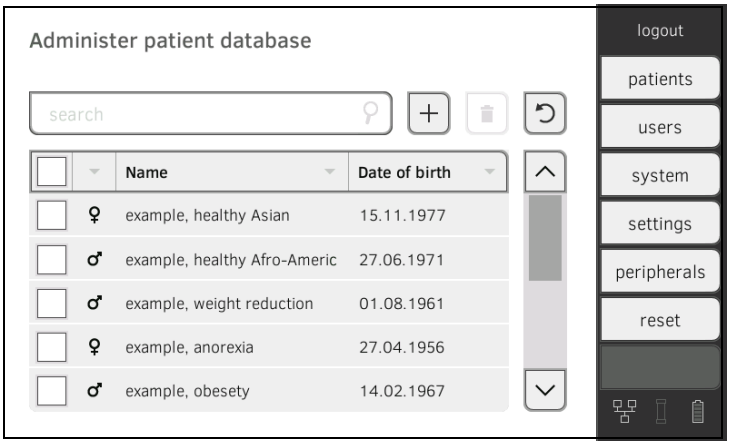
**Inconsistent measured results**

If you create seca patient files several times, this can lead to incorrect assignment of measured results and falsify the analysis.

- If there is no seca patient file on the device for a patient, check whether there is already a seca patient file in the **seca analytics 115** PC software.
- If a seca patient file for this patient exists in the **seca analytics 115** PC software, check the synchronization settings ➔ Activate automatic synchronization.
- Only create a new seca patient file directly on the device if you are sure that there is no seca patient file for the patient in the **seca analytics 115** PC software.

## 2.1 Create a seca patient file

1. Press the **patients** tab.




2. Press the  button.
3. Create a seca patient file as described in the relevant section of the Instructions for Use ➔ Create seca patient file.

17-10-05-353-002d_02-2019 B

## 2.2 Edit a seca patient file

1. Call up a seca patient file as described in the relevant section of the Instructions for Use ➔ Edit a seca patient file.
2. Edit the seca patient file.
3. Press the **save** button.
   The changes will be saved.

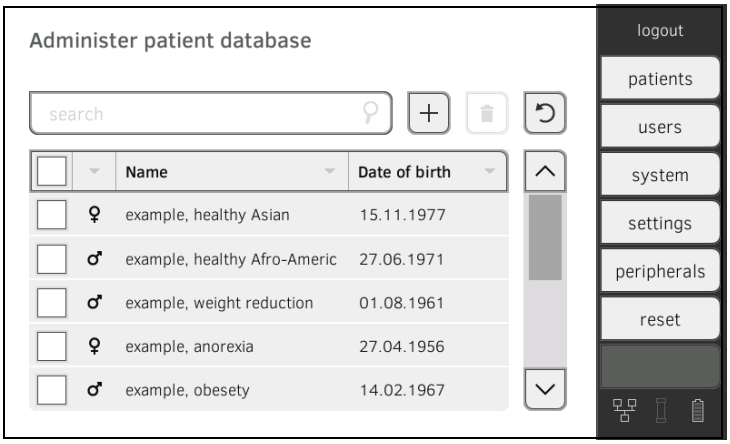
## 2.3 Delete a seca patient file

If you use this function, patient files will be deleted from the patient list of the device, but will be retained in the patient database of the device ➔ Restore a seca patient file.

To delete patient files from the patient database of the device, you must reset the device to the factory settings ➔ Reset device. With this process all patient files are deleted from the device.

**NOTICE!**
**Unintentional synchronization of data**
If your device is synchronized with an external patient database, patient data may be accidentally transferred to the device.
- ► Configure your external patient database so that only patient files which are required on the device are transferred.

1. Press the **patients** tab.

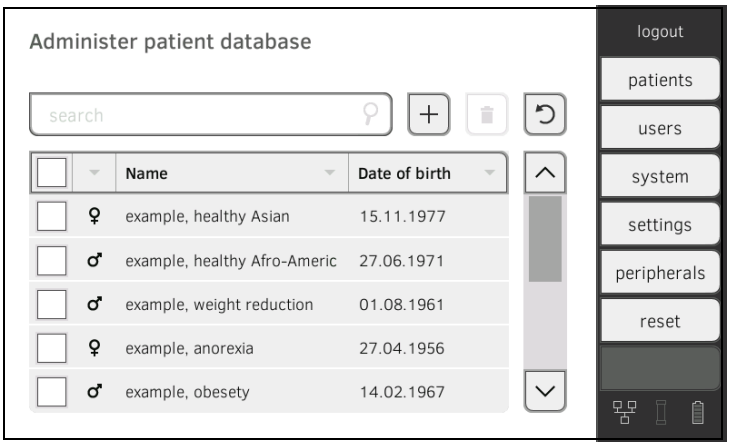



2. Press the checkboxes  of all seca patient files you would like to delete.
3. Press the  button.
   The marked seca patient files will be deleted.

17-10-05-353-002d_02-2019 B

## 2.4 Restore a seca patient file

1. Press the **patients** tab.




2. Press the  button.
   A list of deleted seca patient files is displayed.
3. Press the checkboxes  of all seca patient files you would like to restore.
4. Press the **restore** button.
   The marked seca patient files will be moved to the patient list and be available for measuring operation again.

# 3. ADMINISTER USER ACCOUNTS

➔ Set up a user account

➔ Edit a user account

➔ Delete a user account

## 3.1 Set up a user account

**NOTICE!**

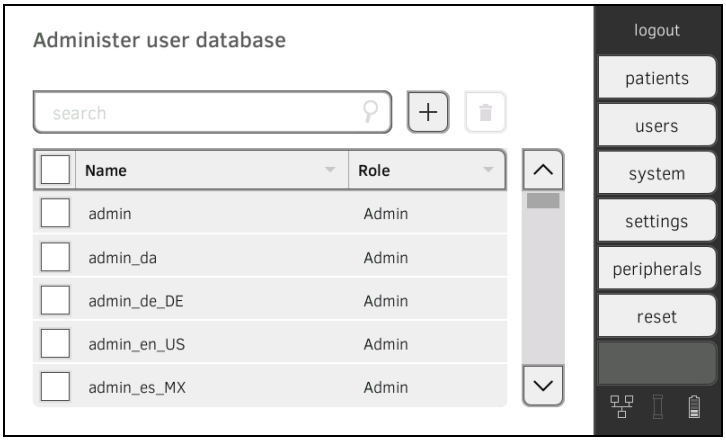
**Inconsistent measured results**

If you create user accounts several times, this can lead to incorrect assignment of measured results and falsify the analysis.

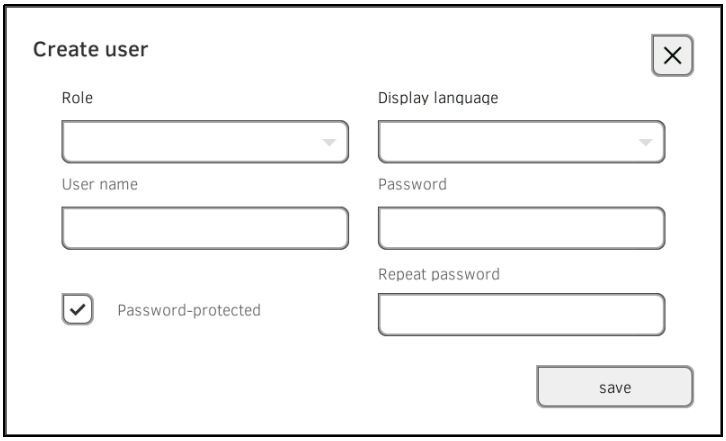
- If there is no user account for a user on the device, check whether there is already a user account in the **seca analytics 115** PC software.
- If a user account for the user exists in the **seca analytics 115** PC software, check the synchronization settings on the device to allow you to adopt the user account from the **seca analytics 115** PC software ➔ Activate automatic synchronization.
- Only create a new user account directly on the device if you are sure that there is no user account for this user in the **seca analytics 115** PC software.

17-10-05-353-002d_02-2019 B

1. Press the **users** tab.




2. Press the  button.




3. Enter the requested user data by pressing the relevant input field:
   - Specify role
   - Select display language
   - Assign user name

   **NOTE**
   The “display language” is specified for each user individually. If no user is logged in, the user interface is displayed in the “system language”
   ➔ Make regional settings.
4. Enter a password.
5. Repeat the password.
6. Let the user know his or her password.
7. Ensure that the **Password-protected** field is activated (default).
8. Press the **save** button.
   The user account is set up.
   The user account can be synchronized with the **seca analytics 115** PC software.

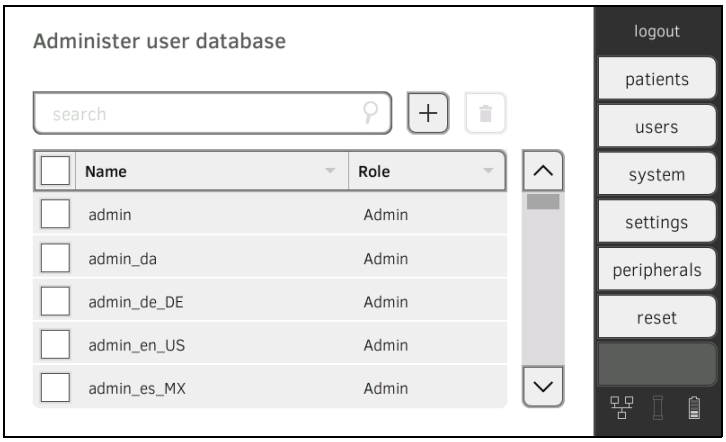
   **NOTE**
   - To protect patient data, we recommend always assigning a password to user accounts. User accounts without password protection should only be set up for special applications (e.g. configuring interfaces to practice or hospital information systems). seca service will be pleased to assist if you have any questions relating to “interface configuration”.

17-10-05-353-002d_02-2019 B

- Specification of the **Assistance** or **Doctor** roles is relevant for use of the user account in the **seca analytics 115** PC software. Details on this can be found in the Administrator Manual for the PC software.

## 3.2 Edit a user account

1. Press the **users** tab.




   You have the following navigation options:
   - ► Desired entry visible: Continue at Step 3.
   - ► Desired entry not visible: Continue at Step 2.
2. Search for the desired user account in the list:
   a) Press input field  .
   b) Enter the user name using the keypad  .

   A hit list is displayed.
3. Press the desired entry.
   The selected user account is displayed.
4. Edit the user account to the extent necessary.

**NOTE**

- If automatic synchronization is activated, changes which you make to user accounts are automatically adopted into the **seca analytics 115** PC software ➔ Activate automatic synchronization.
- The user name cannot be changed. If you want to change the user name, first set up a user account with the new user name and then delete the original user account ➔ Delete a user account.

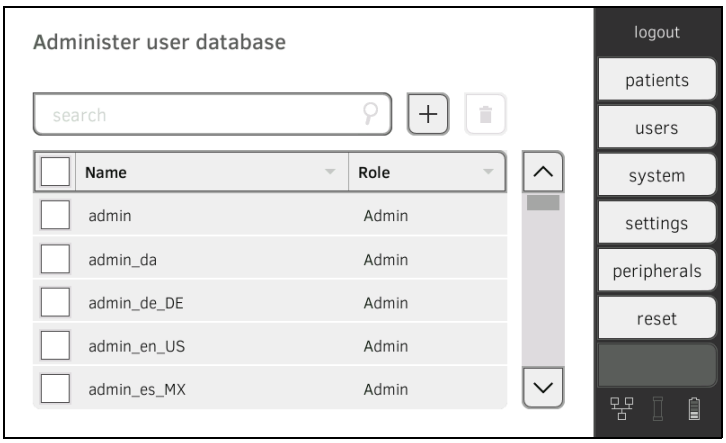
17-10-05-353-002d_02-2019 B

## 3.3 Delete a user account

**NOTICE!**
**Loss of data**
In contrast to seca patient files, it is **not** possible to restore deleted user accounts.

- ► Ensure that user accounts you would like to delete really are no longer required.

1. Press the **users** tab.




2. Press the checkboxes  of all user accounts you would like to delete.
3. Press the  button.
4. Confirm that you wish to proceed.
   The marked user accounts will be deleted.

17-10-05-353-002d_02-2019 B

# 4. MAKE SETTINGS FOR MEASURING OPERATION

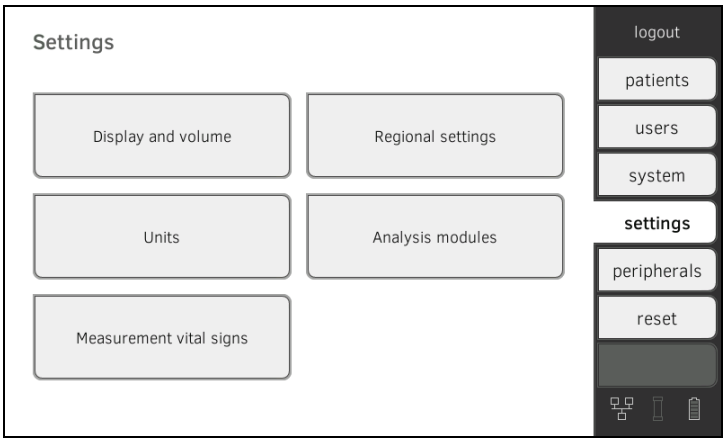


## 4.1 Make regional settings

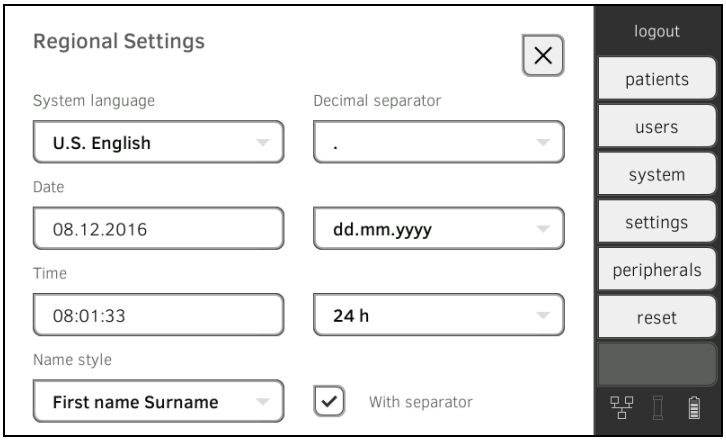
**CAUTION!**
**Loss of data, misinterpretation of measurements**
Incorrect settings for date and time may lead to measurements being misinterpreted.

- Stand-alone operation: Make sure to set correct date and time on the device.
- Network operation: Make sure to set correct date and time in the seca PC Software as the device uses the settings made there.

1. Press the **settings** tab.




2. Press the **Regional settings** button.




17-10-05-353-002d_02-2019 B

3. Specify the regional settings by pressing the relevant input field.
   - ► Select system language
   - ► Select decimal separator
   - ► Enter date
   - ► Select date format
   - ► Enter time
   - ► Select time format
   - ► Select naming convention
   - ► Activate/deactivate name separator.

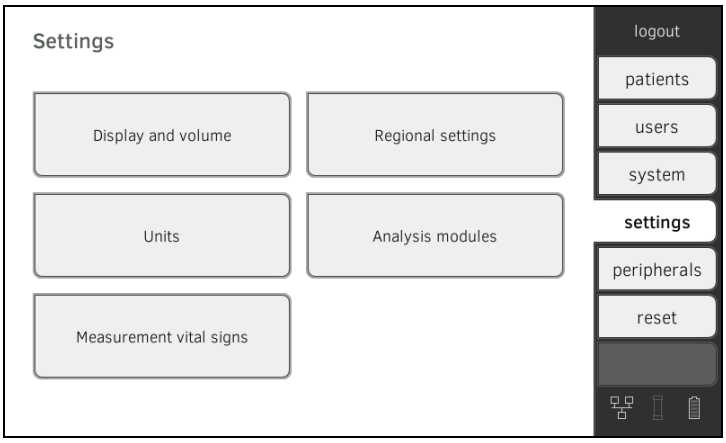
   The settings will be transmitted to the measuring mat automatically.

**NOTE**

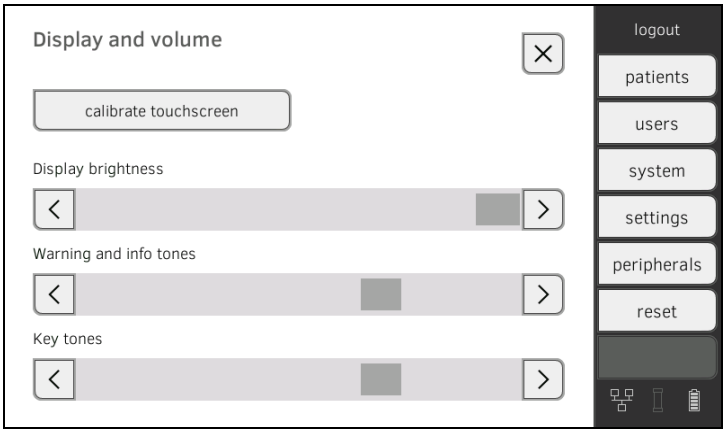
- In the “system language”, the user interface is shown if no user is logged on to the device. If a user is logged in, the user interface is displayed in the individual “display language” ➔ Set up a user account.
- Settings you make in this tab are active directly. You do not need to save or confirm them.

## 4.2 Set display brightness and volume

1. Press the **settings** tab.




2. Press the **Display and volume** button.



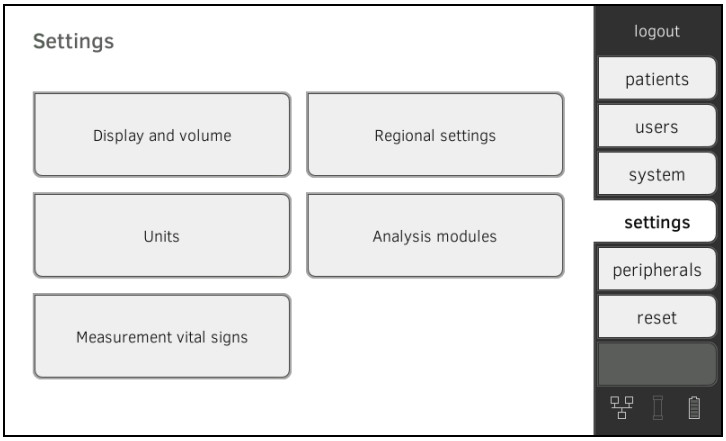

17-10-05-353-002d_02-2019 B

3. Press the  buttons as appropriate.
   - Set display brightness
   - Set volume for warning and information sounds
   - Set volume for button sounds

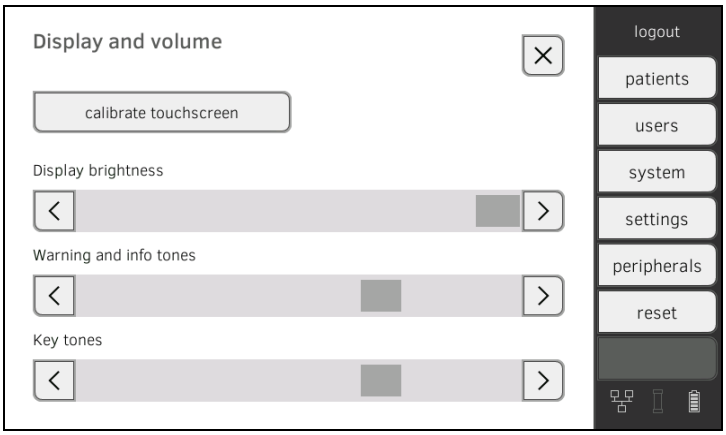
   **NOTE**
   Amended settings can immediately be seen/heard each time a button is pressed.
4. Press the **confirm** button.
   The settings will be saved.

## 4.3 Calibrate touchscreen display

1. Press the **settings** tab.



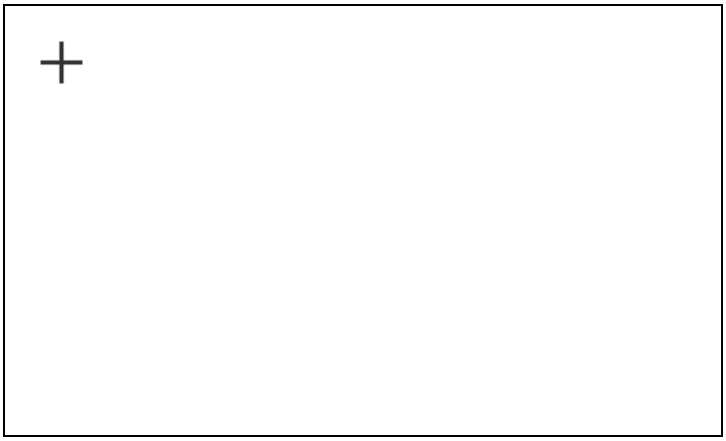

2. Press the **Display and volume** button.




3. Press the **calibrate touchscreen** button.

17-10-05-353-002d_02-2019 B

4. Confirm that you wish to proceed.
   The calibration display appears.



5. Press the + symbol.
   The symbol changes position.

6. Press the + symbol again.
   The symbol changes its position again.
7. Repeat Step 6., until you get a request to confirm calibration.
8. Confirm calibration.
   The touchscreen display is calibrated.

**NOTE**
If calibration is not confirmed, the procedure re-starts after a few seconds.

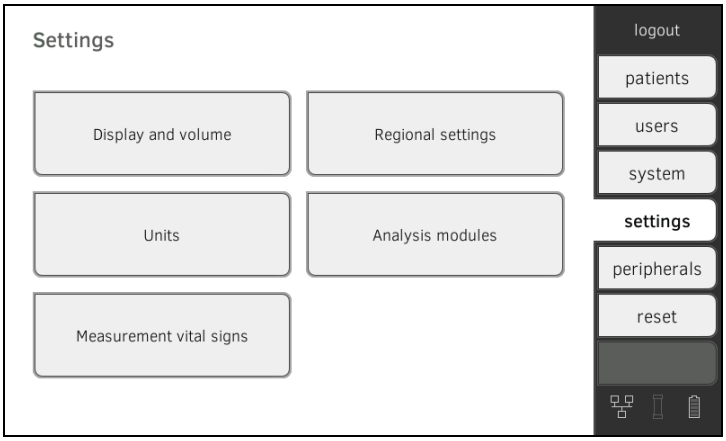
## 4.4 Set units of measurement

**CAUTION!**
**Patient hazard**
In order to avoid misinterpretations, test results for medical use must be displayed and used in SI units (weight: kilogrammes, length: metres) only. Some devices offer the ability to display test results in other units. This is only an additional function.

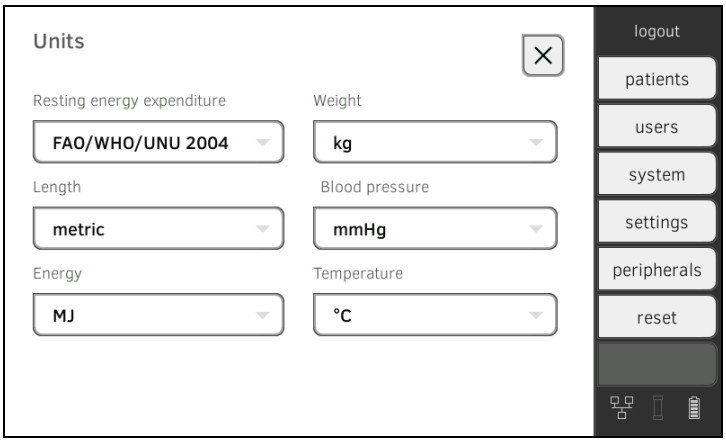
- Use the results exclusively in SI units.
- The use of measurement results in non-SI units is the sole responsibility of the user.

17-10-05-353-002d_02-2019 B

1. Press the **settings** tab.




2. Press the **units** button.



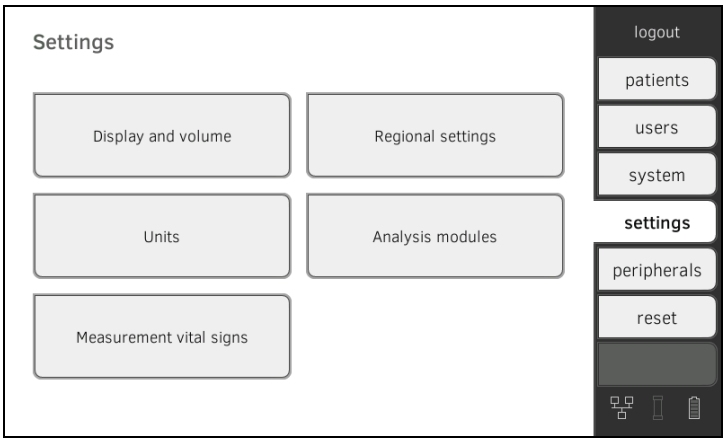

3. Make the desired settings.
   - Reference for resting energy expenditure
   - Unit for energy
   - Unit for weight
   - Unit for height
   - Unit for temperature
   - Unit for blood pressure

**NOTE**
Settings you make in this tab are active directly. You do not need to save or confirm them.

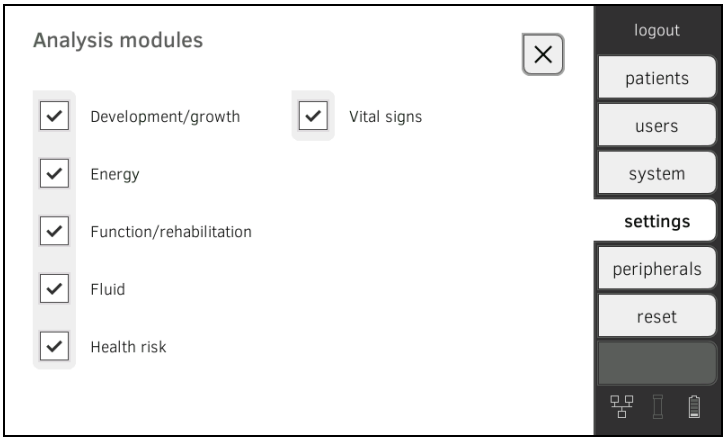
17-10-05-353-002d_02-2019 B

## 4.5 Deactivate analysis modules

1. Press the **settings** tab.




2. Press the **analysis modules** button.




All analysis modules are activated at the factory.

3. Press the checkboxes  of all analysis modules you would like to deactivate.
The deactivated analysis modules are no longer displayed in the analysis ➔ Analyze measurement.

4. To reactivate analysis modules, press the checkboxes  of the deactivated analysis modules again.
The reactivated analysis modules will be displayed in the analysis ➔ Analyze measurement again.

**NOTE**

- If the analysis modules **Energy** and **Health risk** are deactivated, the basic parameters **Waist circumference** and **Physical Activity Level** will not be interrogated ➔ Prepare seca patient file.
- Settings you make in this tab are active directly. You do not need to save or confirm them.

17-10-05-353-002d_02-2019 B

## 4.6 Make presets for vital signs measurement

➔ Presets for blood pressure

➔ Presets for pulse rate (seca measuring equipment only)

➔ Presets for $SpO_2$

➔ Presets for temperature (COVIDIEN™ FILAC™ 3000 only)

➔ Select color mode for “Vital signs” tab

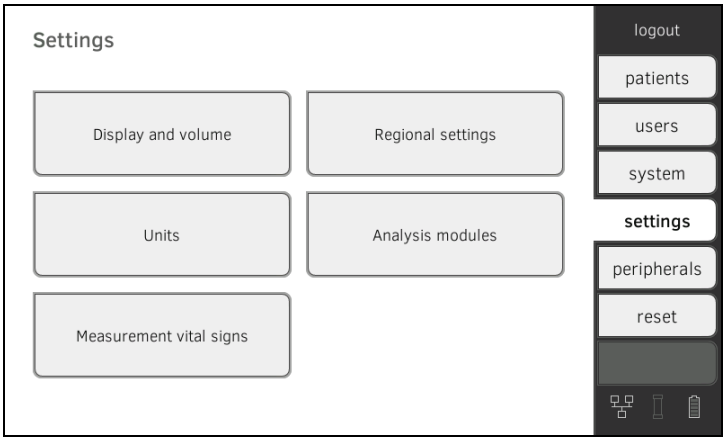
In the **settings** tab, you can set up your institution’s preferred settings for blood pressure, temperature and $SpO_2$ measurements.

The user can modify the settings during a measurement procedure ➔ Measure vital signs. The presets will be active again after the end of the measurement procedure.

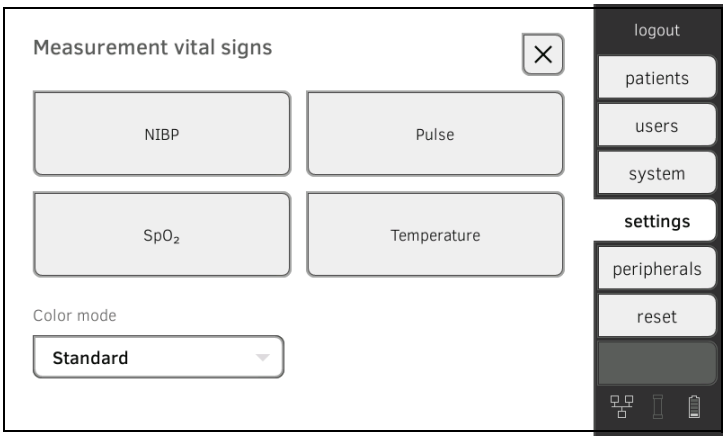
For the **vital signs** tab, you can select a color mode to enable the device to be read perfectly whatever the illumination conditions. This function is not available for other tabs. This setting cannot be changed during a measurement procedure.

### Presets for blood pressure

1. Press the **settings** tab.

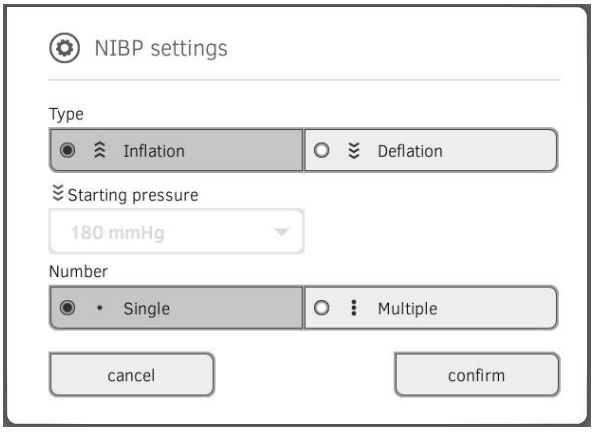



2. Press the **Measurement vital signs** button.




17-10-05-353-002d_02-2019 B

3. Press the **NIBP** button.
   The presets are displayed.

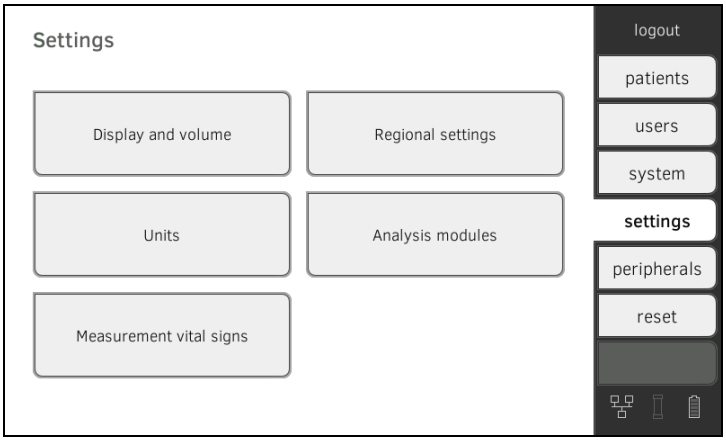



4. Press the desired measurement method.
   - Upward measurement, continued with Step 6.
   - Downward measurement, continued with Step 5.
5. If necessary, modify the starting pressure.
6. Press the desired number of measurements.
   - Single measurement
   - Multiple measurement
7. Press the **confirm** button.
   The dialog window closes.
   The modified settings are adopted.

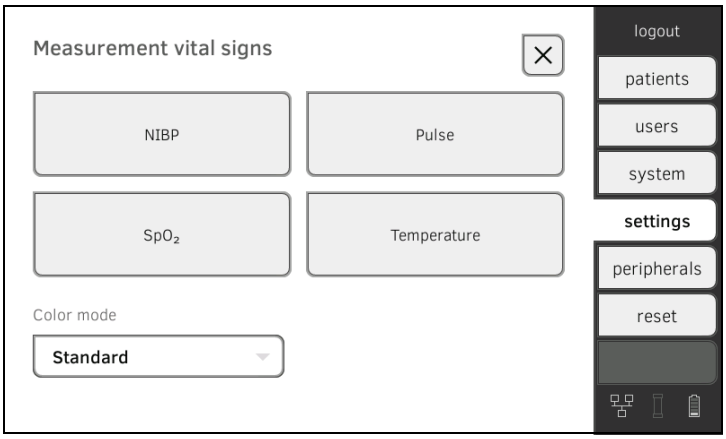
17-10-05-353-002d_02-2019 B

**Presets for pulse rate (seca measuring equipment only)**

1. Press the **settings** tab.




2. Press the **Measurement vital signs** button.




3. Press the **PR** button.


4. Press the desired measuring mode (seca measuring equipment only):

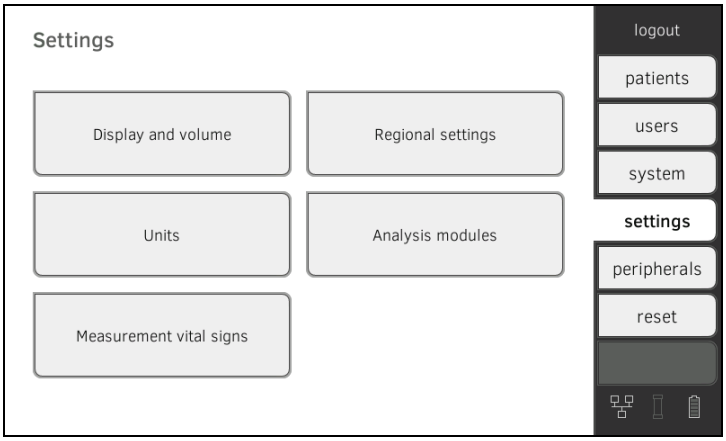
| seca measuring equipment | | |
|---|---|---|
| **Mode** | **Measuring range** | **Motion tolerance** |
| Default | 0 - 240 bpm | High |
| Sensitive | 20 - 300 bpm | Low |

5. Press the **confirm** button.
   The dialog window closes.
   The modified settings are adopted.

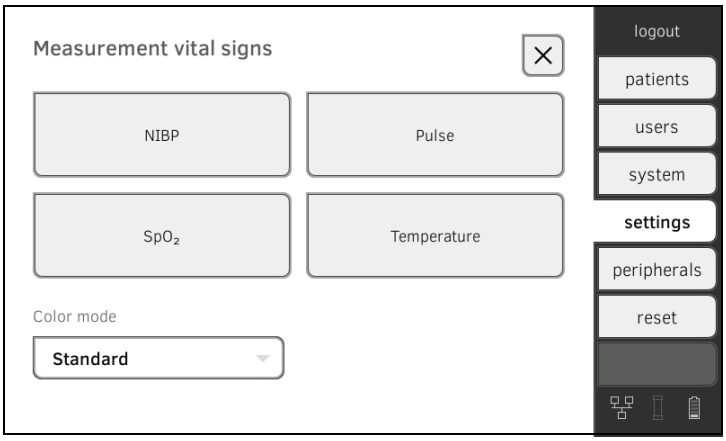
17-10-05-353-002d_02-2019 B

## Presets for $SpO_2$

1. Press the **settings** tab.




2. Press the **Measurement vital signs** button.




3. Press the **$SpO_2$** button.

   The presets are displayed (in this case: Masimo SET®-pulse oximetry:


4. Press the desired sensitivity:

17-10-05-353-002d_02-2019 B

**NOTE:**
The „Maximum“ setting (Masimo SET®-pulse oximetry) is not available as a preset. Select this setting for each session directly ➔ Measure oxygen saturation ($SpO_2$).

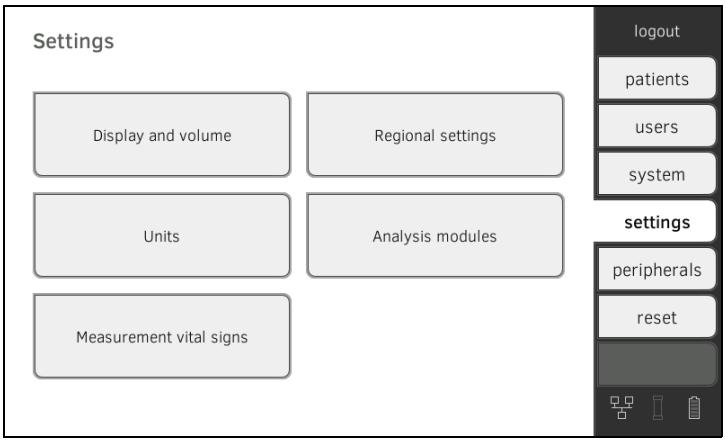
| Masimo SET® $SpO_2$ module | |
|---|---|
| **Mode** | **Indication** |
| Normal | • Normal perfusion<br>• Mild perfusion disorders |
| Adaptive Probe Off Detection (APOD) | Vigorous patient movements |
| Maximum | • Poor perfusion<br>• Severely disrupted signal, for example due to indoor lighting or direct sunlight |

| seca $SpO_2$ module | |
|---|---|
| **Mode** | **Motion tolerance** |
| Stable | High |
| Normal | Normal |
| Sensitive | Low |

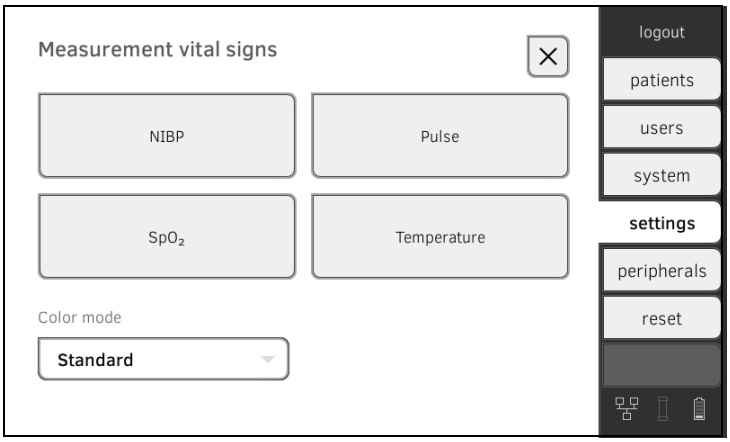
5. Press the **confirm** button.
   The dialog window closes.
   The modified settings are adopted.

## Presets for temperature (COVIDIEN™ FILAC™ 3000 only)

1. Press the **settings** tab.



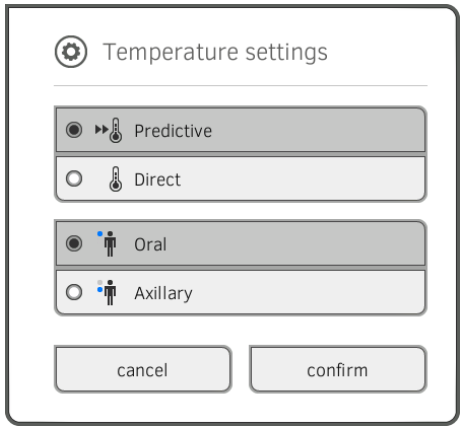

2. Press the **Measurement vital signs** button.




3. Ensure that the temperature probe is pushed completely into the probe holder.

17-10-05-353-002d_02-2019 B

4. Press the **TEMP** field.
   The presets are displayed (in this case: COVIDIEN™ FILAC™ 3000 blue):

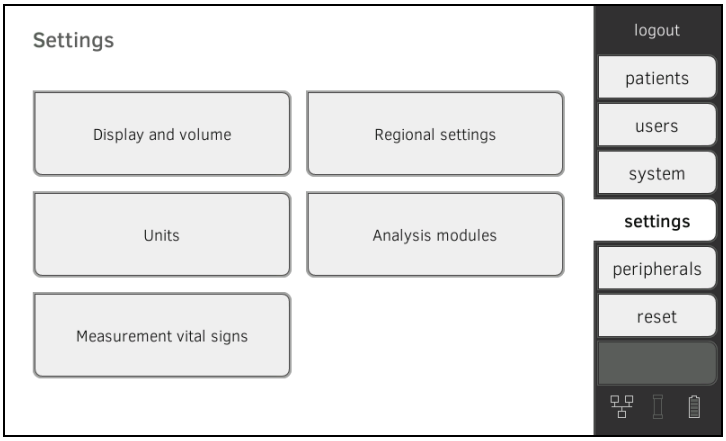



5. Press the desired measurement method.
   - Predictive
   - Direct
6. Press the desired measuring position (COVIDIEN™ FILAC™ 3000 blue only):
   - Oral
   - Axillary
7. Press the **confirm** button.
   The dialog window closes.
   The modified settings are adopted.

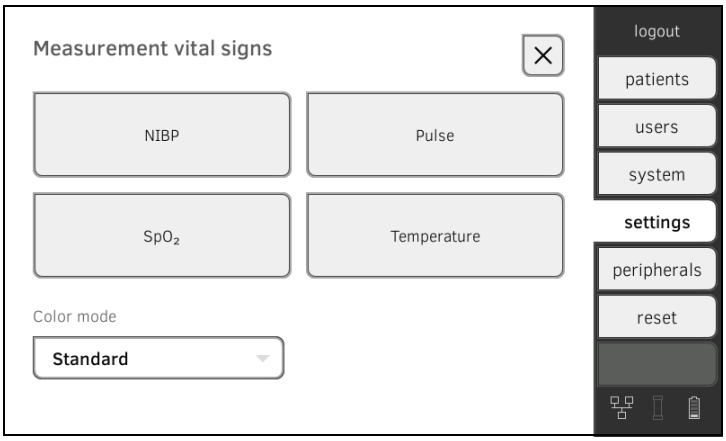
17-10-05-353-002d_02-2019 B

### Select color mode for “Vital signs” tab

1. Press the **settings** tab.




2. Press the **Measurement vital signs** button.




3. Press the **Color mode** input field.
4. Select a color mode.
   - **Default**
   - **Color, day**
   - **Color, night**
5. Log off.
6. Press the **vital signs** tab.
   The **vital signs** tab is displayed in the selected color mode.

17-10-05-353-002d_02-2019 B

# 5. SET UP PERIPHERALS



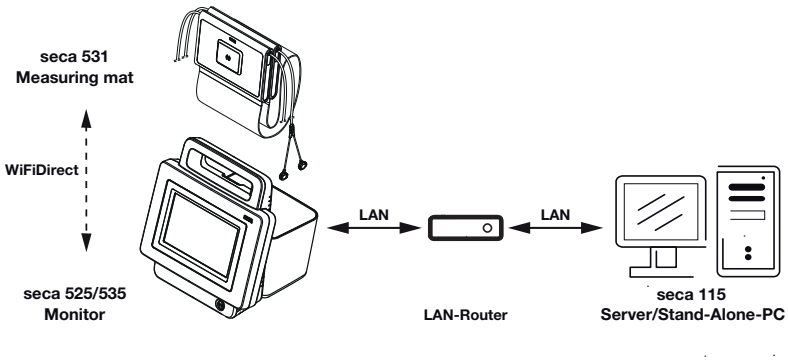
## 5.1 Setting up LAN connection to the network (stationary operation)



### Introduction

For stationary use, for example, in a treatment room in your practice, you can connect the monitor to your LAN network to exchange data using the PC software **seca analytics 115**.

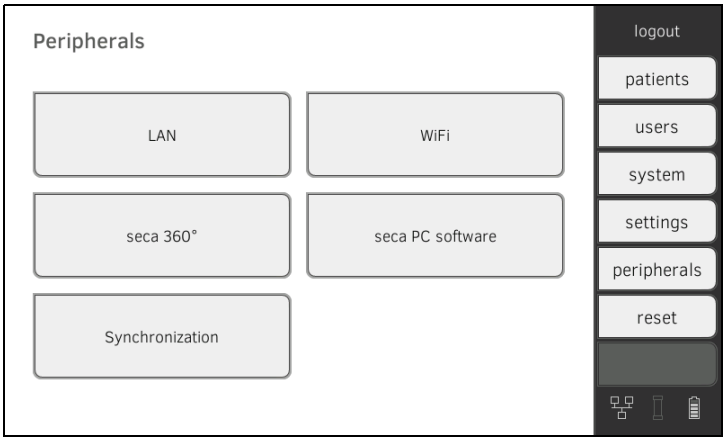
A requirement is that the PC software **seca analytics 115** is installed on a server or stand-alone PC and the network configuration (UDP or DHCP) is known.




If you connect the device to your network via LAN cable, the measuring mat, if present, can communicate with the monitor via the factory-activated **WiFi direct** connection. This allows data to be exchanged even when the measuring mat is not hung in the magnetic catch of the monitor.

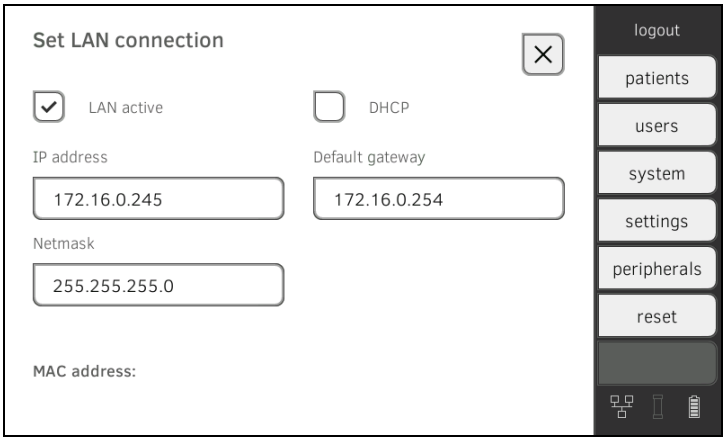
### Activating the LAN connection

1. Press the **peripherals** tab.

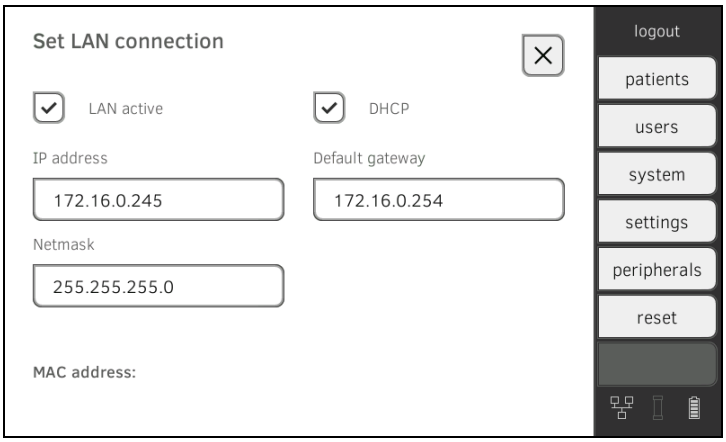



17-10-05-353-002d_02-2019 B

2. Press the **LAN** button.

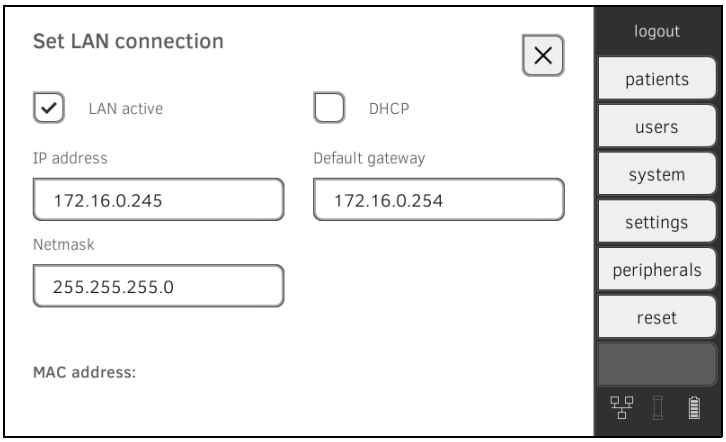



3. Press the **LAN active** checkbox.
   The LAN function is activated.
4. Make the setting applicable to your network.
   - To set up connection manually, continue at Step 5.
   - To set up connection on automated basis: Press **DHCP** button and continue with ➔ Setting up a data connection to the seca analytics 115 PC software




17-10-05-353-002d_02-2019 B

5. Make the settings relevant to your network.
   - Enter the IP address of the monitor (last three digits must be different from the PC address)
   - Enter netmask (must match the netmask of the PC)
   - Enter default gateway (if available)




The  symbol is displayed on the monitor.
The LAN connection is set up.

**NOTE**
Settings you make in this tab are active directly. You do not need to save or confirm them.

6. Continue based on your device variant.
   - Measuring mat present: continue with step 7.
   - No measuring mat present: continue with step 10.
7. Ensure that the measuring mat is correctly suspended in the magnetic catch of the monitor.
8. In the **peripherals** tab, press the **WiFi** button.
9. In the drop-down menu **WiFi Mode**, tap on the desired mode:
   - **WiFi direct**: The monitor and the measuring mat communicate with one another via a direct WiFi connection
   - **WiFi off**: The monitor and the measuring mat communicate with one another via an infrared interface


17-10-05-353-002d_02-2019 B

**NOTE**

- If the setting **WiFi off** is selected, the measuring mat must be mounted in the magnetic catch of the monitor before and after each measurement so that data can be exchanged via the infrared interface.
- If the device is integrated in a LAN network, the **WiFi client** mode is not available.

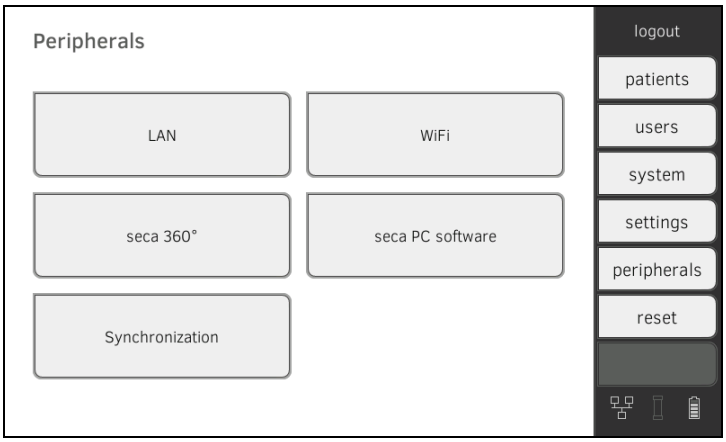
10. Connect the device with the PC software **seca analytics 115** ➔ Setting up a data connection to the seca analytics 115 PC software.

**NOTE**

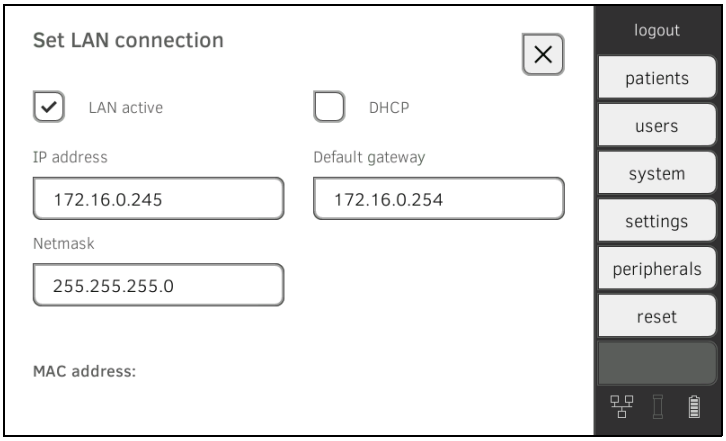
Settings you make in this tab are active directly. You do not need to save or confirm them.

## Deactivate LAN connection

1. Press the **peripherals** tab.




2. Press the **LAN** button.




3. Press the **LAN active** checkbox.
   The LAN function is deactivated.
   The connection data are deleted.
4. To reactivate the LAN function, proceed as outlined below.
   a) Press the **LAN active** checkbox
   b) ➔ Activating the LAN connection

17-10-05-353-002d_02-2019 B

## 5.2 Set up WiFi connection (mobile operation)


➔ Introduction

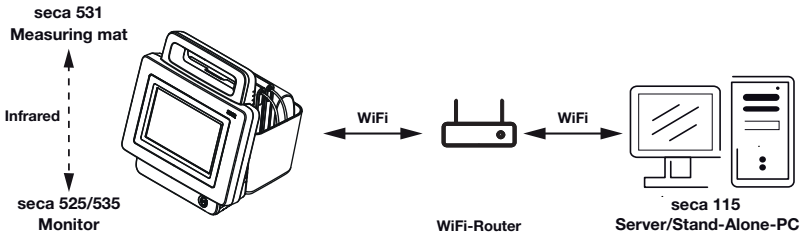
➔ Activating the WiFi connection

➔ Deactivate WiFi


### Introduction

For mobile use, for example, on the ward of a hospital, you can integrate the device into your network as a WiFi client to exchange data with the PC software **seca analytics 115**.

A requirement is that the PC software **seca analytics 115** is installed on a server or stand-alone PC and the access data for your WiFi network is known.



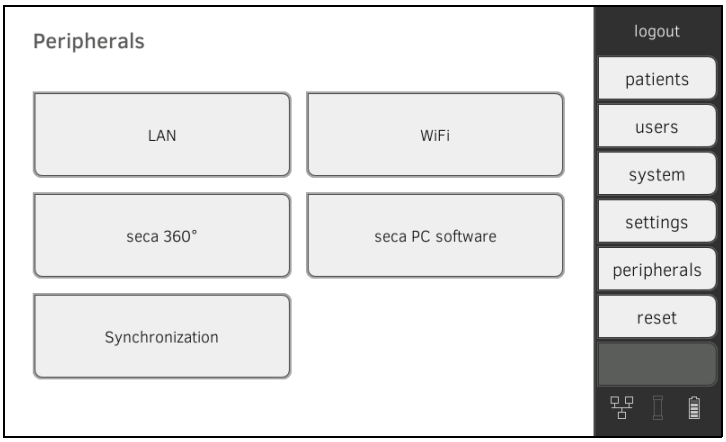

If you connect the device to your network as a WiFi client, the measuring mat, if present, can only communicate with the monitor via the infrared interface.

**NOTICE!**
**Malfunction**
The measuring mat and the monitor can communicate via the infrared interface only when the measuring mat is suspended in the magnetic catch of the monitor.

- Ensure that the measuring mat is suspended in the magnetic catch of the monitor before and after each measurement.

### Activating the WiFi connection

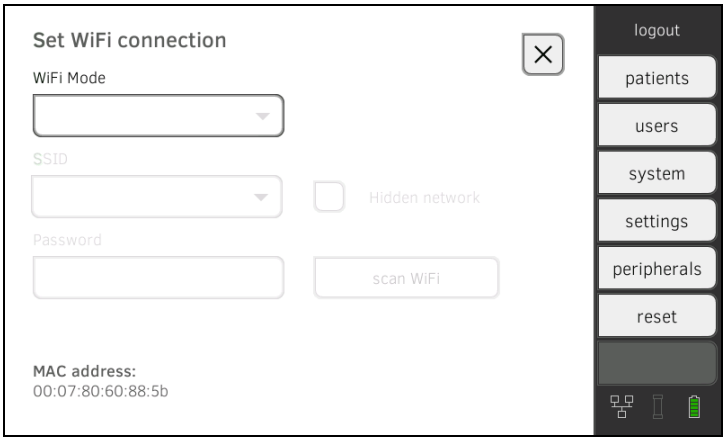
1. Ensure that the measuring mat is correctly suspended in the magnetic catch of the monitor.
2. Press the **peripherals** tab.




3. Make sure that the LAN connection to the network is **not** active ➔ Deactivate LAN connection.

17-10-05-353-002d_02-2019 B

4. Press the **WiFi** button.




5. In the drop-down menu **WiFi Mode**, select the setting **WiFi client**.
6. Make the setting applicable to your WiFi network.
   - Visible network: Press the **scan WiFi** button.
   - Hidden network: Press **Hidden Network** button
7. Enter the SSID for your network.
   - Visible network: Select SSID from drop-down menu
   - Hidden network: Enter SSID manually
8. Enter the password for your network.
   The settings will be transmitted to the measuring mat.

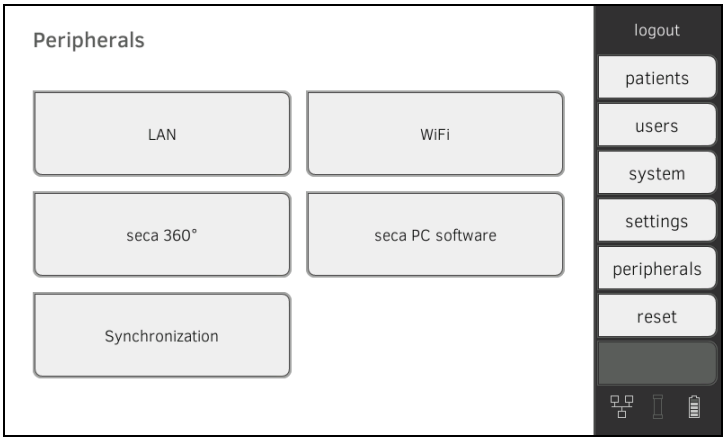
   The symbols  and  are displayed on the monitor.
   The device is connected to your network via WiFi.

   **NOTE**
   Settings you make in this tab are active directly. You do not need to save or confirm them.
9. Connect the device with the PC software **seca analytics 115**.
   - ➔ Setting up a data connection to the seca analytics 115 PC software.

17-10-05-353-002d_02-2019 B

## Deactivate WiFi

1. Press the **peripherals** tab.




2. Press the **WiFi** button.


3. Press the **WiFi active** checkbox.
   The WiFi function is deactivated.
   The connection data are deleted.

17-10-05-353-002d_02-2019 B

## 5.3 Setting up a data connection to the seca analytics 115 PC software

➔ Introduction

➔ Connecting the device automatically (UDP)

➔ Manually connecting the device (TCP)

### Introduction

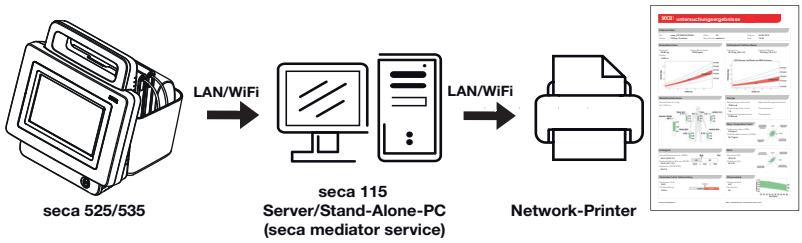
If you connect the device with the PC software **seca analytics 115**, the following functions are available.

- Synchronize patient and user data automatically ➔ Activate automatic synchronization.
- **seca directprint**: Issue results reports directly from the device on a network printer ➔ View analysis.

A requirement is that the device is connected to the LAN or WiFi network of your institution.

➔ Setting up LAN connection to the network (stationary operation)

➔ Set up WiFi connection (mobile operation)

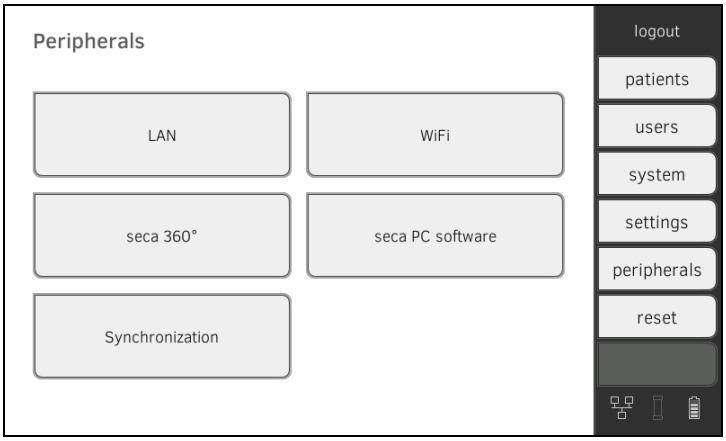



**NOTE**

- You specify the network printer for the **seca directprint** function directly in the **seca analytics 115** PC software.
- You should also follow the Administrator Manual for the **seca analytics 115** PC software.

### Connecting the device automatically (UDP)

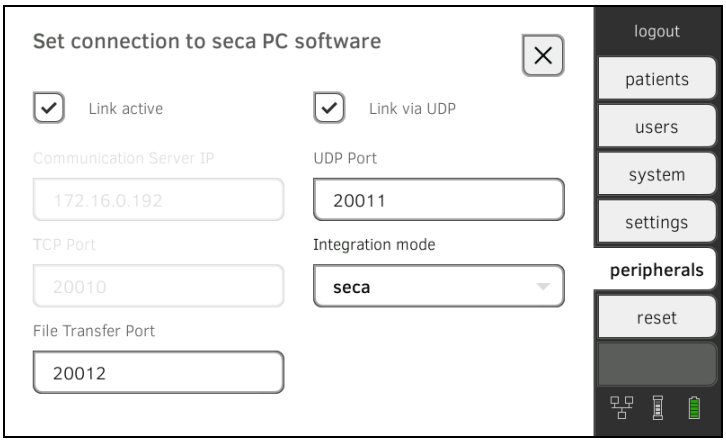
1. Press the **peripherals** tab.




2. Press the **seca PC software** button.
   The dialog window **Set connection to seca PC software** is opened.

17-10-05-353-002d_02-2019 B

3. Press the **Link active** checkbox.
4. Press the **Link via UDP** checkbox.
   The recommended presets are displayed.



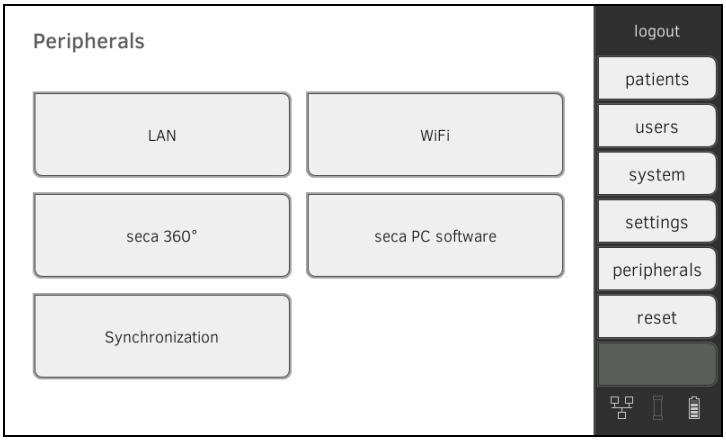

5. Adapt the default settings if necessary.
6. Make sure these settings match those in the PC software **seca analytics 115** (menu: Extras\Settings\Synchronization).
7. Ensure that in the drop-down menu **Integration mode** the mode **seca** is selected.

**NOTE**

- Settings you make in this tab are active directly. You do not need to save or confirm them
- The drop-down menu **Integration mode** is intended for integration of the device into a hospital information system (HIS). Contact seca Service if you want to integrate the device into your HIS.

## Manually connecting the device (TCP)

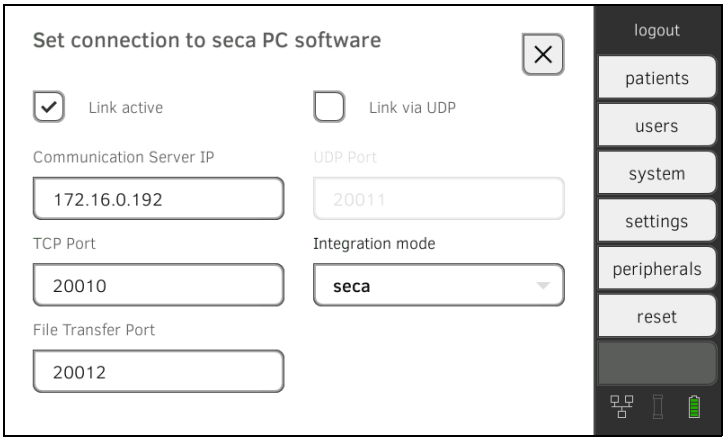
1. Press the **peripherals** tab.




2. Press the **seca PC software** button.
   The dialog window **Set connection to seca PC software** is opened.

17-10-05-353-002d_02-2019 B

3. Press the **Link active** checkbox.
   The recommended presets are displayed.




4. Adapt the default settings if necessary.
5. Make sure that the checkbox **Connect via UDP** is deactivated.
6. In the **Communication Server IP** line, enter the appropriate IP address.

| Configuration | IP address |
|---|---|
| **seca analytics 115** PC software as client/server solution | The IP address of the PC on which the **seca analytics 115** PC software was installed with the options **Server** or **Complete** |
| **seca analytics 115** PC software as a standalone solution | IP address of the PC workstation |

7. In the **TCP Port** line, enter the value of the PC selected under 6., default: 20010.
8. Ensure that in the drop-down menu **Integration mode** the mode **seca** is selected.

**NOTE**

- Settings you make in this tab are active directly. You do not need to save or confirm them
- The drop-down menu **Integration mode** is intended for integration of the device into a hospital information system (HIS). Contact seca Service if you want to integrate the device into your HIS.

## 5.4 Synchronization and backup

➔ Activate automatic synchronization
➔ Set up automatic export
➔ Export patient and user data manually
➔ Restore patient and user data manually

### Activate automatic synchronization

If you are using the device in combination with the **seca analytics 115** PC software, you should activate automatic synchronization. The following data are then synchronized as soon as they are changed either on the device or in the PC software:

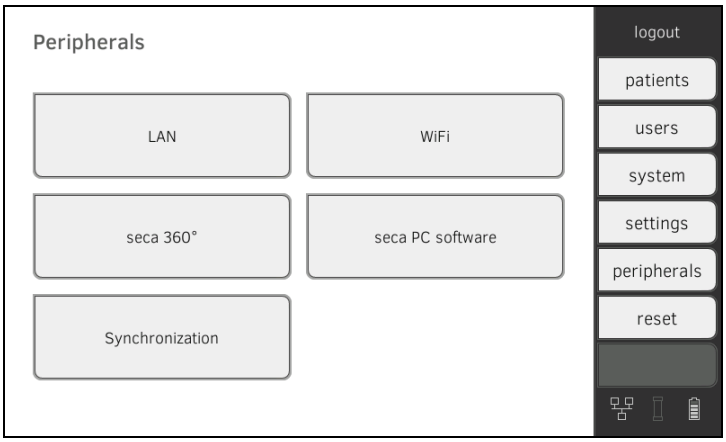
- seca patient files
- User accounts and passwords
- Automatic export settings

17-10-05-353-002d_02-2019 B

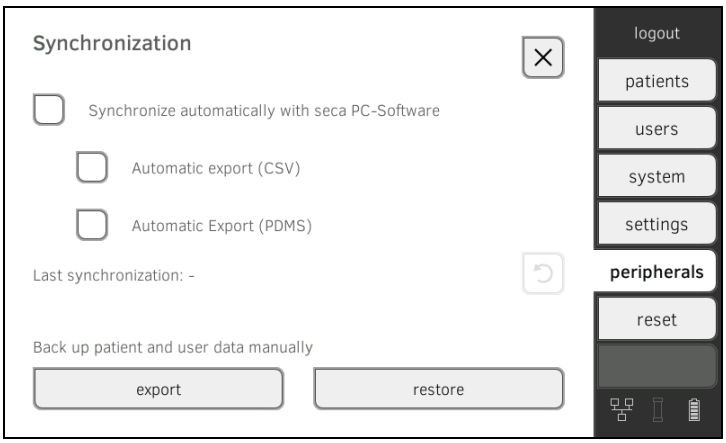
**NOTICE!**
**Malfunction**
In order to be able to use automatic synchronization, a connection to the PC software must be set up ➔ Setting up a data connection to the seca analytics 115 PC software.

► Ensure that the connection to the PC software is set up before you activate automatic synchronization.

1. Press the **peripherals** tab.




2. Press the **Synchronization** button.




3. Press the **Synchronize automatically with seca PC software** checkbox.
Automatic synchronization is activated.

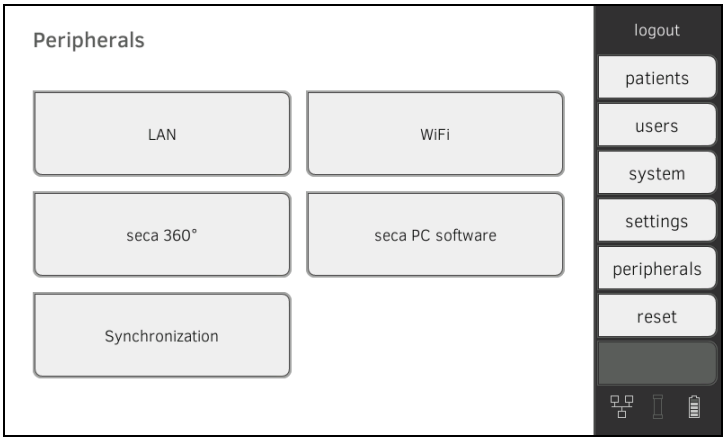
**NOTE**
- The data are synchronized as soon as they are changed either on the device or in the PC software. No further settings are required.
- In the event of conflicts during synchronization, the data of the **seca analytics 115** PC software take priority. The data of the device will be overwritten.

17-10-05-353-002d_02-2019 B

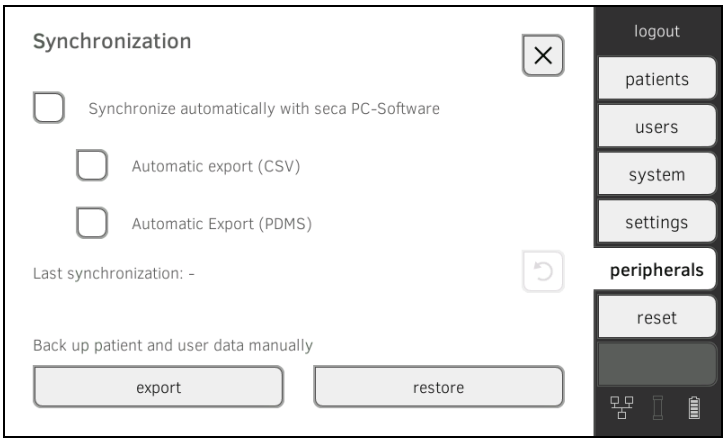
## Set up automatic export

This function allows you to transmit measured results to a practice or hospital information system automatically. The export takes place as soon as data are generated or amended on the device. To be able to use this function, an interface to the **seca analytics 115** PC software must be set up in your practice or hospital information system.

1. Establish which data format your practice or hospital information system accepts.
2. Press the **peripherals** tab.




3. Press the **Synchronization** button.




4. Ensure that the **Synchronize automatically with seca PC software** checkbox is activated.
5. Press the desired export format.
   - **Automatic export CSV**
   - **Automatic export PDMS**
6. Set up an interface to the **seca analytics 115** PC software in your practice or hospital information system.

**NOTE**

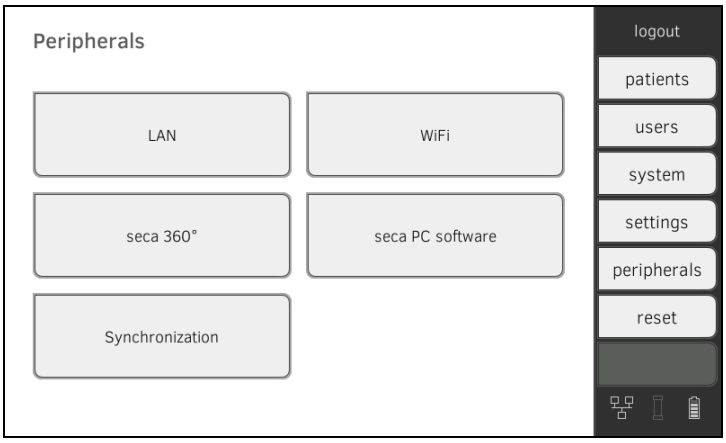
- Settings you make in this dialog window are transmitted to the **seca analytics 115** PC software ➔ Activate automatic synchronization.
- Note the user documentation for the practice or hospital information system used.
- seca service will be pleased to assist if you have any questions relating to “interface configuration”.

17-10-05-353-002d_02-2019 B

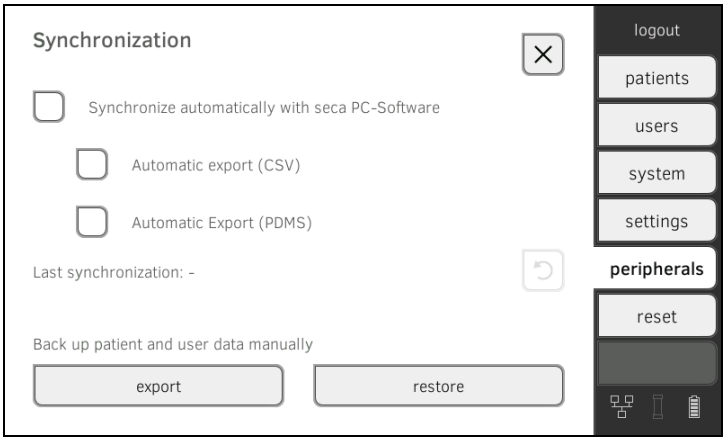
## Export patient and user data manually

This function allows you to export seca patient files and user accounts in order to create a backup copy, for example.

1. Press the **peripherals** tab.




2. Press the **Synchronization** button.




3. Connect a USB memory stick to the monitor.
4. Press the **export** button.
   The data are exported to the USB memory stick.
5. Archive the data in line with your institution's policy.

## Restore patient and user data manually

This function allows you to restore externally backed-up seca patient files and user accounts.

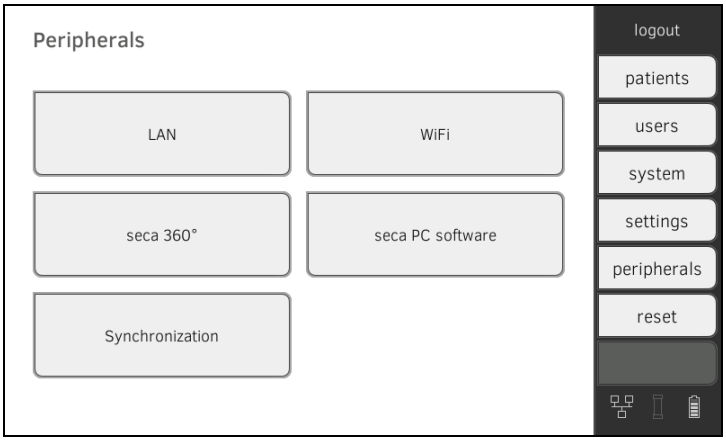
**NOTICE!**
**Loss of data**
When you restore externally backed-up data, the current data on the device will be overwritten.

- Export seca patient files and user accounts manually **before** restoring older data manually (operate without **seca analytics 115** PC software).
- **Before** restoring manually, ensure that all the data on the device have been synchronized with the **seca analytics 115** PC software (operate with **seca analytics 115** PC software).

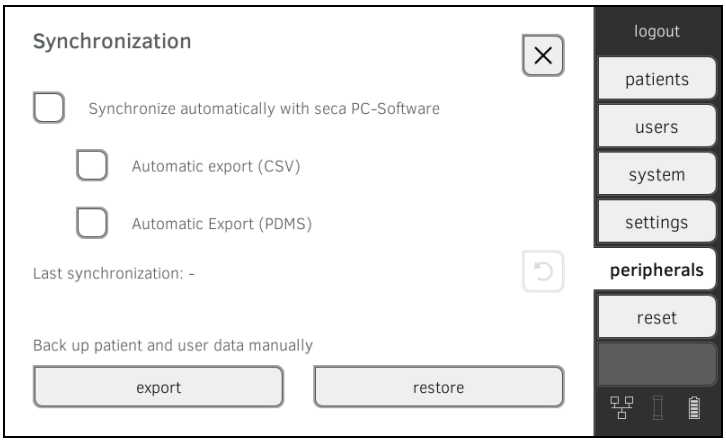
1. Load the archived seca patient files and user accounts onto a USB memory stick.

17-10-05-353-002d_02-2019 B

2. Press the **peripherals** tab.




3. Press the **Synchronization** button.




4. Connect the USB memory stick to the monitor.
5. Press the **restore** button.
   The data will be imported.

17-10-05-353-002d_02-2019 B

## 5.5 Set up seca 360° wireless network

➔ Activate/deactivate seca 360° wireless module

➔ Set up a seca 360° wireless connection

### Introduction

If you use devices from the **seca 360° wireless** system in your institution, e.g. a measuring station, you can link them to the mVSA/mBCA. You can transmit the parameters height and weight directly to the mVSA/mBCA and adopt them in a seca patient file.

In the mVSA, the values also appear in the **vital signs** tab

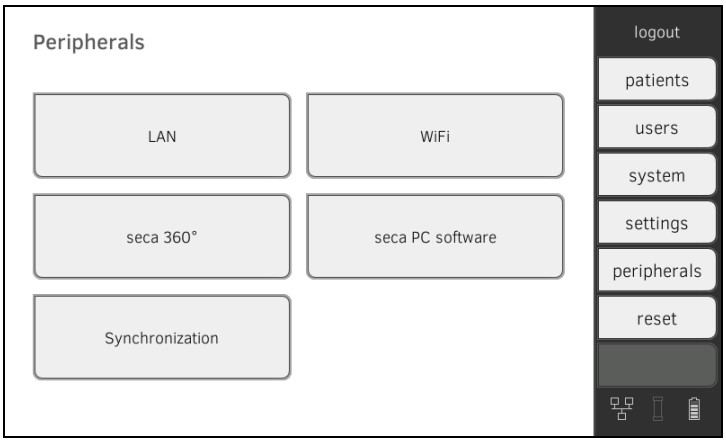
In order to be able to communicate with devices from the **seca 360° wireless** system, the **seca 360° wireless** module of the mVSA/mBCA must be activated and a wireless group set up.

**NOTE**

- The device can only receive data, not send them via the **seca 360° wireless** link.
- The fields “Weight” and “Height” only appear in the **vital signs** tab if the **seca 360° wireless** module is activated.
- You should also follow the Instructions for Use for the **seca 360° wireless** system devices being used.

### Activate/deactivate seca 360° wireless module

1. Press the **peripherals** tab.



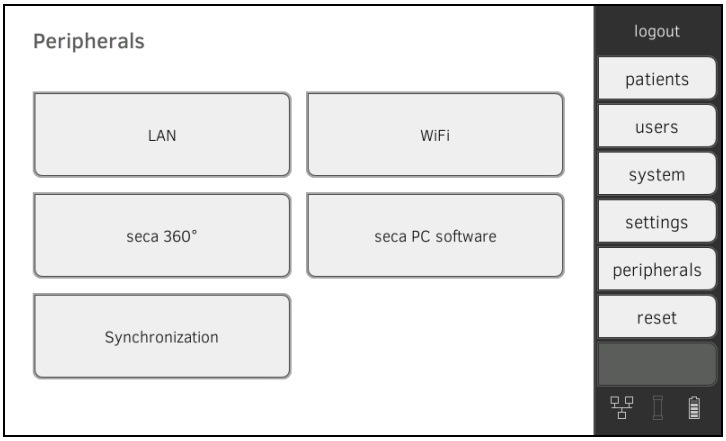

17-10-05-353-002d_02-2019 B

2. Press the **seca 360°** button.


3. Press the **Send/receive on** checkbox.
   The **seca 360° wireless** module is activated.
4. To deactivate the **seca 360° wireless** module, press the **Send/receive on** checkbox again.

### Set up a seca 360° wireless connection

1. Ensure that the **seca 360° wireless** modules of the mVSA/mBCA and of all the devices you want to connect to the mVSA/mBCA are activated.
2. Switch off all the devices you want to connect to the mVSA/mBCA.
3. Press the **peripherals** tab.




4. Press the **seca 360°** button.


5. Press the **set up** button.

17-10-05-353-002d_02-2019 B

6. Press one of the three wireless groups.
   The device searches for **seca 360° wireless** devices which are switched on.
   The device will suggest three wireless channels.

   **NOTICE!**
   **Incorrect device assignment**
   Only one example of a device category (e.g. personal scale or stadiometer) can be integrated in each wireless group.
   - ► Take note of the Technical Data in the section of the Instructions for Use entitled ➔ seca 360° wireless system.

   **NOTICE!**
   **Data transmission interference**
   The proposed channel numbers can be edited. This function is intended purely for special reception situations. Devices may be assigned to the wrong wireless groups or unreliable wireless connections may arise.
   - ► Only change the channel numbers if the proposed channel numbers do not result in a reliable wireless connection.
   - ► Ensure that the new channel numbers are not being used for other wireless groups.
   - ► Ensure that the channel numbers are at least 30 apart from one another.

7. Switch on all **seca 360° wireless** devices you wish to incorporate in the wireless group.
   When devices are detected, a beep will be heard.
   Detected devices will be displayed on the monitor.
8. Press the **finish** button once all **seca 360° wireless** devices have been detected.

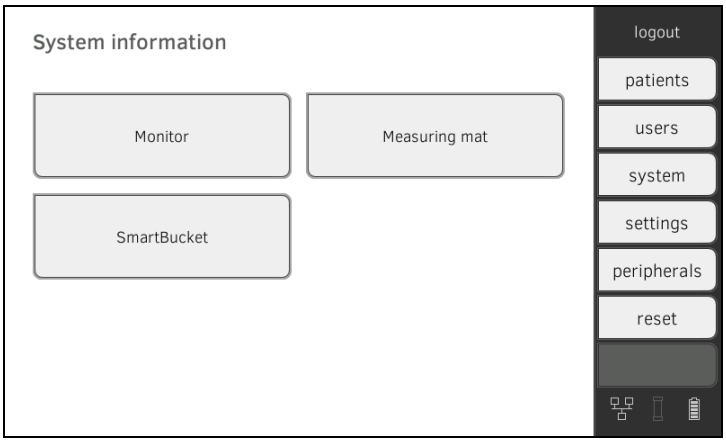
17-10-05-353-002d_02-2019 B

# 6. ADMINISTER SYSTEM COMPONENTS



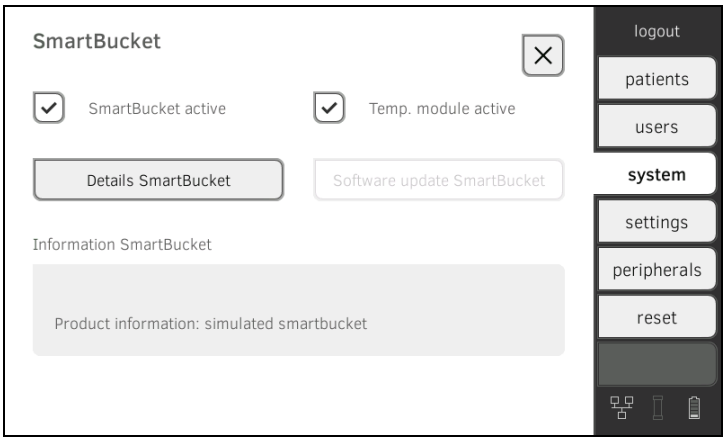
## View system information

1. Press the **system** tab.




2. Select a system component.

   The system information for the selected system component is displayed (in this case, **SmartBucket**).




   You have the following options:

   - View details
   - Perform software update (not for **SmartBucket**) ➔ Update monitor software, ➔ Update the measuring mat software

17-10-05-353-002d_02-2019 B

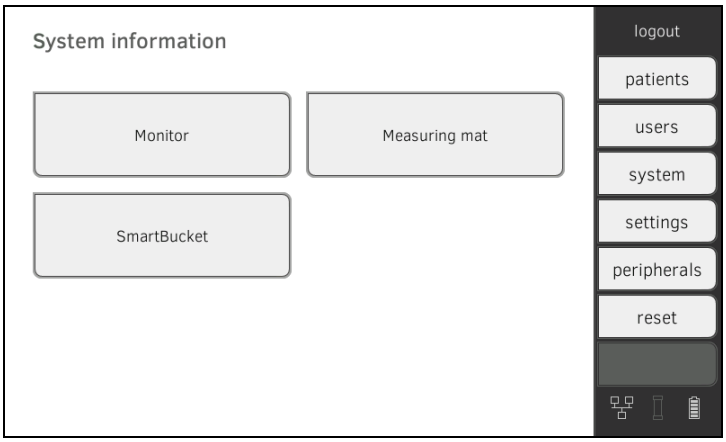
## Update monitor software

This function allows you to update the software of the device. Current software packages can be found at www.seca.com.

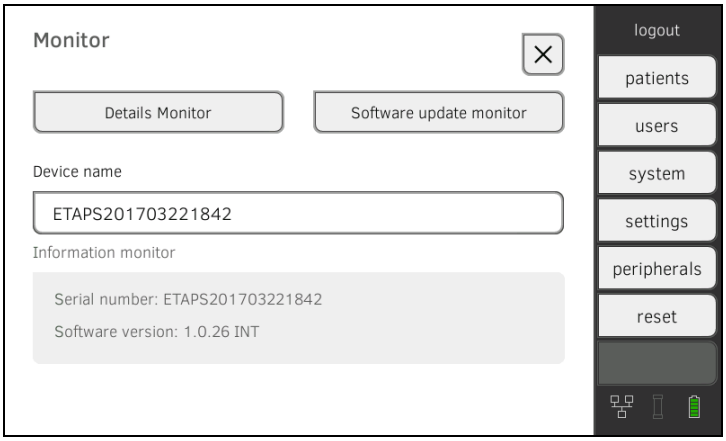
**NOTICE!**
**Loss of data**
The device will be reset to factory settings. seca patient files and user accounts will be deleted.

- Export seca patient files and user accounts manually **before** updating the software (operate without **seca analytics 115** PC software).
- **Before** updating the software, ensure that all the data on the device have been synchronized with the **seca analytics 115** PC software (operate with **seca analytics 115** PC software).

1. Press the **system** tab.




2. Press the **Monitor** button.




3. Press the **Software update monitor** button.
4. Select the source for the software update.
   - USB memory stick: Continue with Step 5.
   - Network: Continue with Step 6.
5. Connect the USB memory stick to the monitor.
   The software package is automatically transmitted to the device.
   Following successful transmission, the **start software update** button is active.
6. Press the **start software update** button.
   The software package will be installed.

17-10-05-353-002d_02-2019 B

**NOTE**
The software package for the monitor also contains data for the measuring mat. If this data is more current than the software on the measuring mat, the corresponding message will appear on screen. Then proceed as described in the section entitled ➔ Update the measuring mat software.

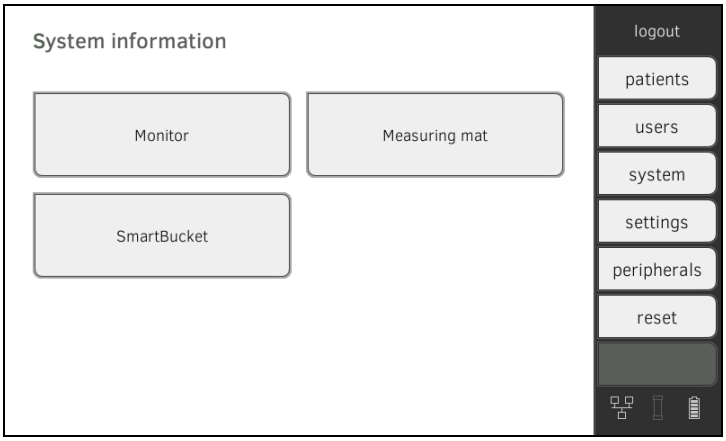
## Update the measuring mat software

In the following cases, it may be necessary to update the software of the measuring mat:

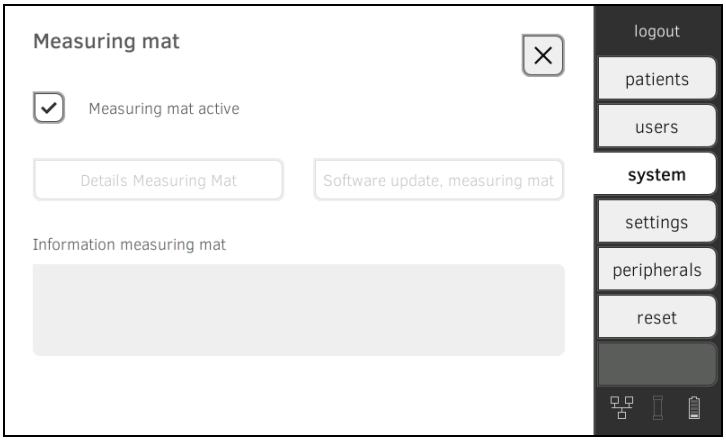
- Monitor software has been updated (**seca 535**, **seca 525**)
  ➔ Update monitor software
- System has had a measuring mat added (**seca 535**)
  ➔ Retrofit measuring mat (seca 535 only)
- Measuring mat has been replaced with a new one (**seca 535**, **seca 525**)

If the measuring mat software is out of date, the corresponding message will appear on the monitor. In this case, proceed as outlined below.

1. Press the **system** tab.




2. Press the **Measuring mat** button.



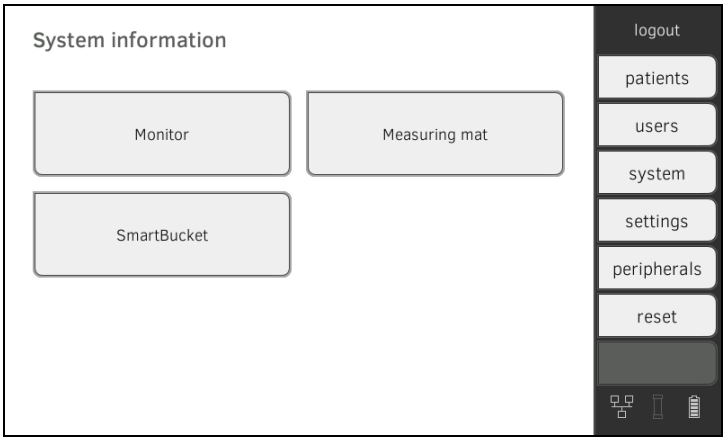

3. Press the **software update measuring mat** button.
4. Follow the on-screen instructions.
5. Press the **start software update** button.
   The software update will be installed.

17-10-05-353-002d_02-2019 B

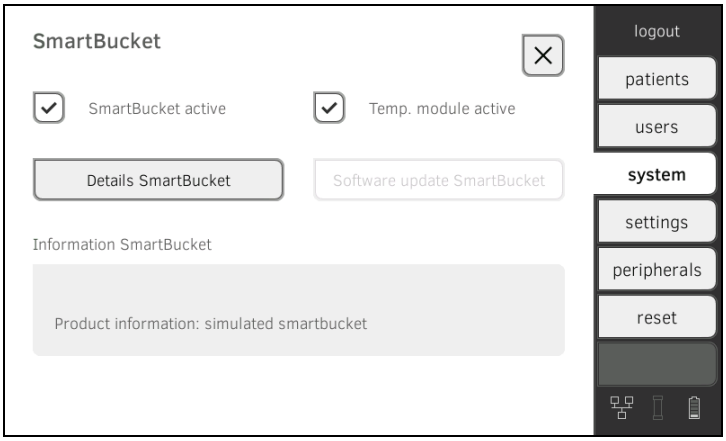
## Retrofit SmartBucket (seca 525 only)

medical Body Composition Analyzer **seca 525** from serial number 10000000090505 can be retrofitted with the SmartBucket **seca 526** to measure vital signs ➔ Optional accessories and spare parts.

1. Retrofit the SmartBucket as described in the relevant assembly instructions.
2. Activate the SmartBucket in the device:
   a) Press the **system** tab.




   b) Press the **SmartBucket** button
   c) Activate the **SmartBucket active** checkbox
   d) If SmartBucket contains a temperature module: Activate the **Temp. module active** checkbox.



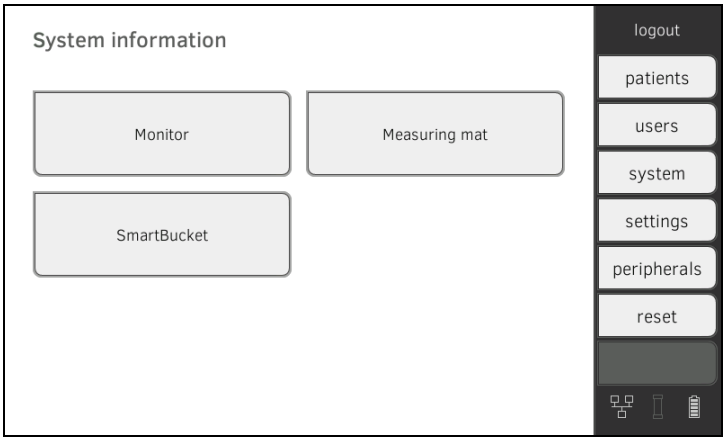

3. Follow the on-screen instructions.

17-10-05-353-002d_02-2019 B

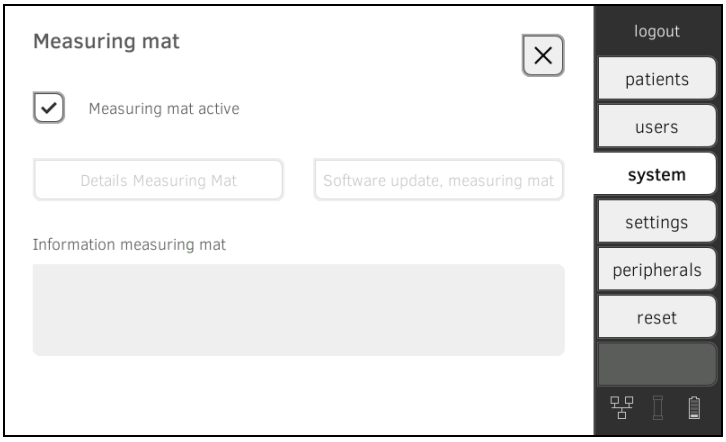
## Retrofit measuring mat (seca 535 only)

medical Vital Signs Analyzer **seca 535** can be retrofitted with the **seca 531** measuring mat to perform bioimpedance measurements ➔ Optional accessories and spare parts.

1. Retrofit the measuring mat as described in the relevant assembly instructions.
2. Activate the measuring mat in the device.
   a) Press the **system** tab.




   b) Press the **Measuring mat** button
   c) Activate the **Measuring mat active** checkbox.



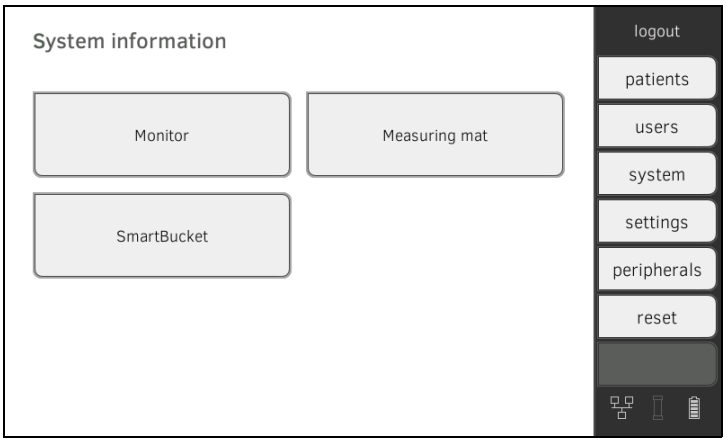

3. Follow the on-screen instructions.

17-10-05-353-002d_02-2019 B

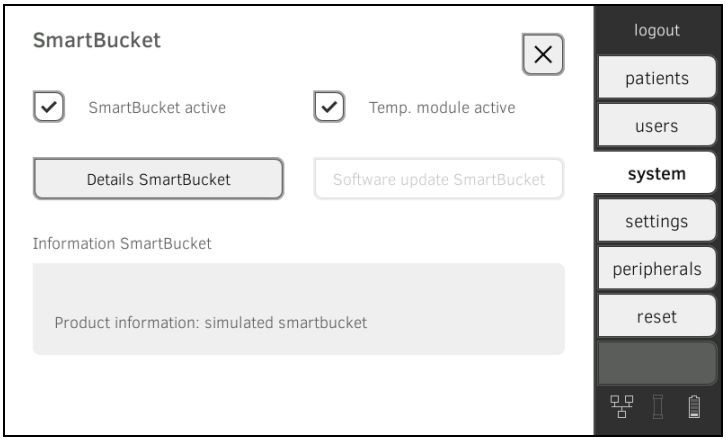
## Retrofit in-ear thermometer (seca 535 only)

medical Vital Signs Analyzer **seca 535** without temperature measurement can be retrofitted with the COVIDIEN™ GENIUS®2 in-ear thermometer➔ Optional accessories and spare parts.

1. Connect the in-ear thermometer as described in the section entitled ➔ Connect in-ear thermometer.
2. Activate the temperature module in the device.
   a) Press the **system** tab.




   b) Press the **SmartBucket** button
   c) Activate the **Temp. module active** checkbox




3. Follow the on-screen instructions.

17-10-05-353-002d_02-2019 B

# 7. FACTORY SETTINGS



## 7.1 Summary of factory settings

In the **reset** tab, you can reset the device to the following factory settings:

| Function | Setting |
|---|---|
| Administrator password | 1357 |
| Display language | English |
| Date format:<br>International | <br>dd.mm.yyyy |
| Time format:<br>International | <br>24 h |
| Naming convention:<br>International | <br>First name, surname |
| Name separator | Period |
| Display brightness | 100 % |
| Volume for warning and information sounds<br>Volume for button sounds | <br>70 %<br>70 % |
| Weight:<br>International | <br>kg |
| Height:<br>International | <br>m |
| Blood pressure:<br>Unit:<br>Presets | <br>mmHg<br>Upward, single measurement |
| Temperature:<br>Unit<br>COVIDIEN™ FILAC™ 3000<br>Blue<br>Red | <br>°C<br><br>Oral, predictive measurement<br>Predictive measurement |
| Pulse rate:<br>Unit<br>Preset (seca measuring equipment only) | <br>$min^{-1}$<br><br>Standard |
| Oxygen saturation:<br>Unit:<br>Mode: | <br>%<br>Normal |
| Decimal separator:<br>International | <br>Period |
| Energy: | MJ |
| Reference resting energy expenditure: | FAO/WHO/UNU |
| LAN<br>Connection data: | On<br>None |

17-10-05-353-002d_02-2019 B

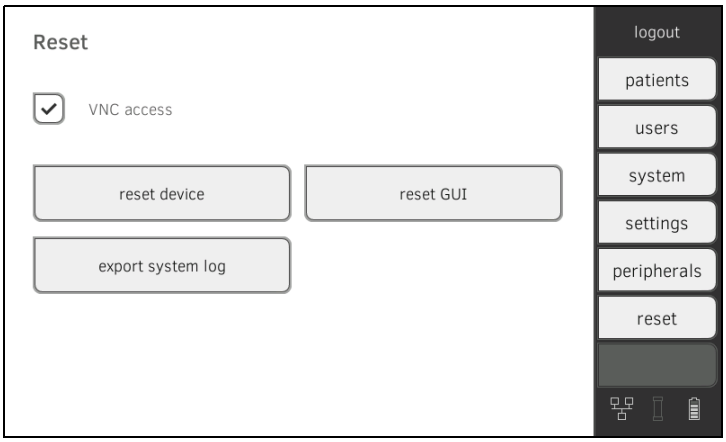
| Function | Setting |
|---|---|
| WiFi client (device <-> network):<br>Connection data<br><br>WiFi direct (device <-> measuring mat) | <br>Off<br>None<br><br>On |
| Device name | None |
| Integration mode | seca |
| seca 360° wireless:<br>Connection data: | Off<br>None |
| seca PC software:<br>UDP<br>Communication server IP:<br>TCP port:<br>UDP port:<br>File transfer port: | Off<br>Off<br>None<br>20010<br>20011<br>20012 |
| Active analysis modules | All |

## 7.2 Reset device

Use the **reset device** function to reset the device to ➔ Factory settings; seca patient files and user accounts are deleted from the device with this process.

**NOTE**
If seca patient files and user accounts are to be retained, proceed as described in the section entitled ➔ Reset user interface.

1. Press the **reset** tab.




2. Ensure that seca patient files and user accounts have been exported or synchronized using the **seca analytics 115** PC software.
3. Press the **reset device** button.
   seca patient files and user accounts will be deleted.
   The device will be reset to ➔ Factory settings.

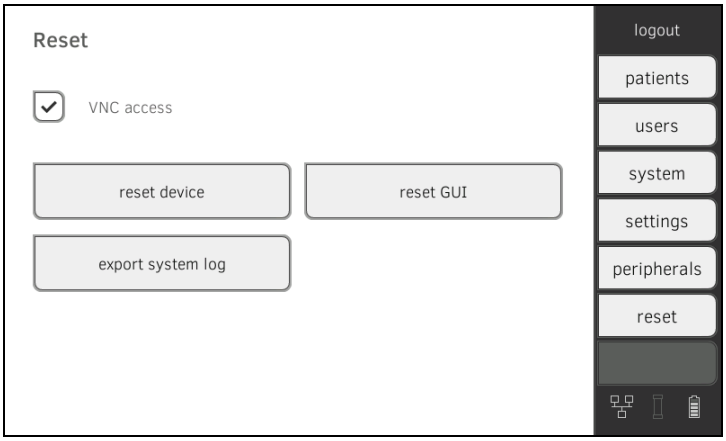
## 7.3 Reset user interface

Use the **reset GUI** function to reset the user interface (GUI = Graphical User Interface) of the device to ➔ Factory settings; seca patient files and user accounts are retained with this process.

**NOTE**
If all seca patient files and user accounts are to be deleted from the device, proceed as described in the section entitled ➔ Reset device.

17-10-05-353-002d_02-2019 B

1. Press the **reset** tab.

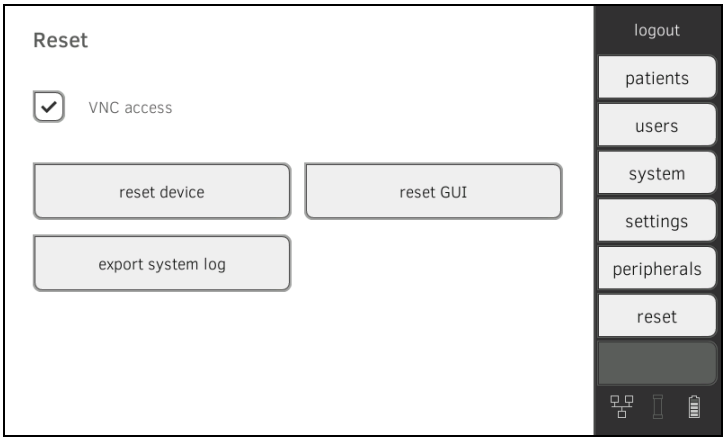



2. Press the **reset GUI** button.
   The user interface will be reset to ➔ Factory settings.
   seca patient files and user accounts will be retained.

## 7.4 Export system log

This function allows you to export the system log and make it available to seca Service for support purposes, for example.

1. Press the **reset** tab.




2. Press the **export system log** button.
3. Select the export destination:
   - USB memory stick: Continue with Step 4.
   - Network: Continue with Step 5.
4. Connect a USB memory stick to the monitor.
5. Press the **export system log** button.
   The system log will be exported.

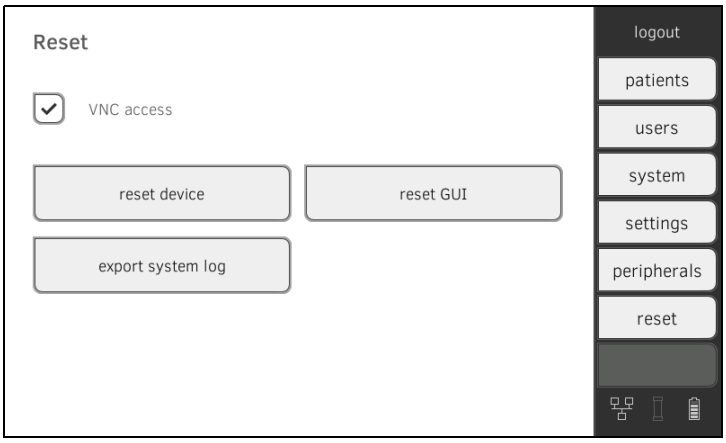
**NOTE**
If you have selected “Network” as the export destination, the system log in the installation directory of the **seca analytics 115** PC software (server or standalone PC) will be exported to the “Program-Data\seca\LogExports” folder.

17-10-05-353-002d_02-2019 B

## 7.5 Release VNC access

With a VNC connection, you can reproduce the user interface of the device on a PC screen and remotely control the device from the PC. The requirement is that a VNC viewer is installed on the PC.

1. Press the **reset** tab.




2. Press the **VNC access** checkbox.
3. Restart the device.
   The VNC service of the device will be started.
4. Set up the VNC connection using the VNC viewer of your PC.

17-10-05-353-002d_02-2019 B

# Medical Measuring Systems and Scales since 1840

seca gmbh & co. kg
Hammer Steindamm 3–25
22089 Hamburg · Germany

Telephone +49 40 20 00 00 0
Fax +49 40 20 00 00 50

info@seca.com

seca operates worldwide with headquarters in Germany and branches in:

seca france

seca united kingdom

seca north america

seca schweiz

seca zhong guo

seca nihon

seca mexico

seca austria

seca polska

seca middle east

seca brasil

seca suomi

seca américa latina

seca asia pacific

seca danmark

seca benelux

seca lietuva

and with exclusive partners in more than 110 countries.

All contact data at seca.com

17-10-05-353-002d_02-2019 B