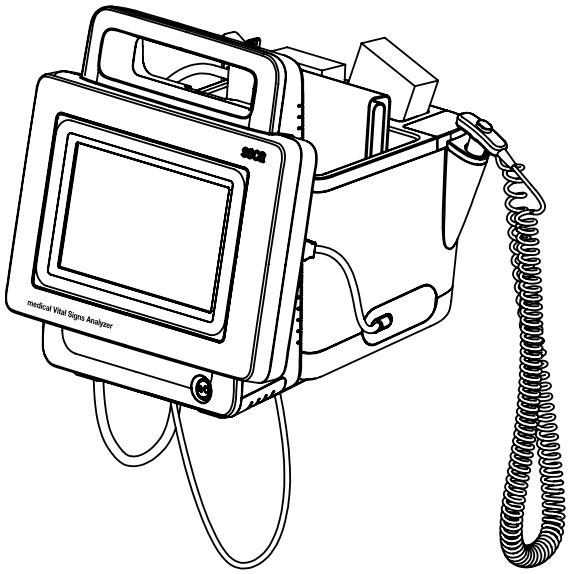
seca
Precision for health

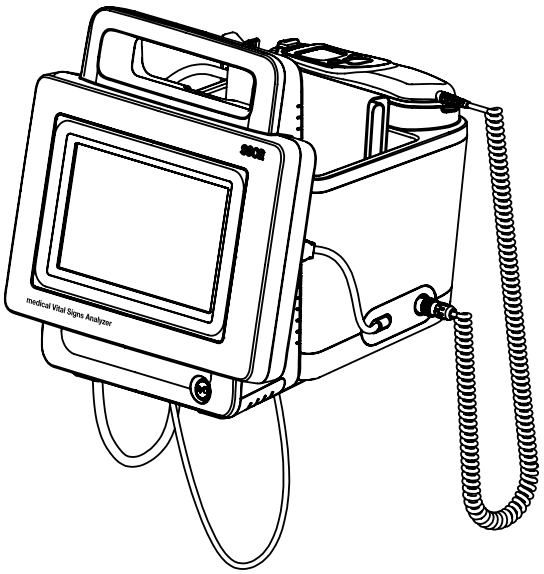
seca mVSA 535

Instructions for Use

Software version 2.1 from Build 1522

Art. no.: 17-10-05-395-002b_2022_09B





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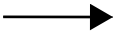
INSTRUCTIONS FOR USE FOR seca mVSA 535

Software version: 2.1 from Build 1522
Article number of this document: 17-10-05-395-002b_2022-09B

1. ABOUT THIS DOCUMENT

NOTE

This document describes the maximal equipment of the **seca mVSA 535** 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.

	Display conventions
Symbol	**Description**
►	Handling instruction
1. 2.	Handling instructions which have to be performed in the specified sequence
a) b)	Steps of a handling instruction which have to be performed in the specified sequence
• •	First level of a list
– –	Second level of a list
	Indicates points on the device or on device components which require particular attention
	Indicates areas on the display which require particular attention
	Indicates directions in overview graphics
	Correct handling method Correct handling result
	Incorrect handling method Incorrect handling result

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2. DESCRIPTION OF DEVICE

2.1 Intended use for seca mVSA 535

The medical Vital Signs Analyzer **seca mVSA 535** is 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.

The medical Vital Signs Analyzer **seca mVSA 535** is intended for use in children 3 years and older and adults.

2.2 Restrictions on use of seca mVSA 535

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

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

The device is **not** intended for operation in the vicinity of an MRI 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 individuals who are connected to electronic life-support systems, for example artificial heart-lung machine.

2.3 Functional description

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Device components

The **seca mVSA 535** consists of a monitor and a SmartBucket.

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

The SmartBucket includes the measuring equipment for recording vital signs and storage facilities for the measuring accessories.

In the maximum configuration, the vital signs blood pressure, body temperature, pulse rate and oxygen saturation can be recorded. 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 via a USB connection from the monitor.

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.

Alternatively, a patient's vital signs can be entered manually.

Alarms

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

Weight and height

Scales and measuring rods with an internal interface module or a **seca 452** external interface module can transmit measured results to the device via LAN or WiFi.

Alternatively, the patient's weight and height can be recorded manually.

User IDs of EMR systems

If the device is connected to an EMR system via the **seca connect 103** software, the user IDs of the EMR system can be used for measurements. Local user accounts on the device are required for administration and service tasks.

seca patient files

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

In stand-alone mode, measured results are managed in seca patient files. seca patient files can be set up, edited, exported and deleted directly on the device.

Patient data from EMR systems

Depending on the EMR system in question, patient data from EMR systems can be used by means of a connection to the **seca connect 103** software.

Measured results

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

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Data transmission and network functions

The device can be integrated into a network via a LAN interface or via WiFi in order to use the following functions:

- Connection of the device to the **seca connect 103** software available as an option: Using the user and patient data of an EMR system and submitting measured results to the EMR system
- **seca 360° proximity** connection: Receiving weight and height from scales and measuring rods with an internal interface module or a **seca 452** external interface module

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

Compatibility

seca connect 103 software

This device (software version 2.1, Build 1522 or higher) is only compatible with version 3.2 or higher of the **seca connect 103** software. There is no downward compatibility with older versions of the **seca connect 103** software.

Internal interface module/seca 452 interface module

This device (software version 2.1, Build 1522 or higher) is only compatible with interface modules on which firmware version R1.3 Build 79 or higher is installed.

2.4 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 may only be used by persons with sufficient expertise.

Basic knowledge required for measuring vital parameters is **not** the subject of these instructions for use.

Connecting the device to an EMR system affects the measuring sequence and operation of the device: ➔ Operation when connected to an EMR system. People operating the device must be informed about these effects.

2.5 Contraindications

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

- Cramps
- Tremors

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3. SAFETY PRECAUTIONS

➔ Safety precautions in these instructions for use

➔ Basic safety precautions

3.1 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.

3.2 Basic safety precautions

➔ Handling the device

➔ Handling a wheeled stand

➔ Handling a wall bracket

➔ Preventing electric shock

➔ Prevent injuries and infections

➔ Preventing damage to device

➔ 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.
- In the interest of patient safety, you and your patients are obliged to report serious events that occur in connection with this product to the manufacturer and the authority responsible in your country.
- Do not leave the device unsupervised.

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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

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 edition 3.1 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.

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Handling a wall bracket

WARNING!
Injury from falling objects, damage to device

- The wall bracket and the adapter plate must only be fitted by adequately qualified individuals (e.g. specialist dealers, hospital technicians or seca Service).
- The wall bracket and the adapter plate must be fitted in line with the relevant assembly instructions.
- Do not mount the wall bracket immediately above beds, couches or seating.
- Ensure that the monitor adapter plate is correctly inserted and locked in the wall bracket.

Preventing 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 device 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.

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Preventing damage to device

NOTICE!

Damage to device

- If liquids have penetrated the device, the device may not be operational for a short period. Allow the device to dry for an extended period (e.g. overnight), before starting it up again.
- Switch off the device 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.
- Ensure that there is no heat source in the immediate vicinity. Do not expose to direct sunlight. The excessive temperature could damage the electronics.
- Ensure that the air openings of the device (if present) are not covered.
- 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.
- 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 intended ambient conditions.
- Store the device only in the intended storage conditions.
- 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 including the active ingredient 70 % isopropanol only for measuring accessories for measuring vital signs.

Handling measured results

CAUTION!

Patient hazard

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

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

NOTICE!

Inconsistent measuring results

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

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NOTE
For an overview of the parameters which can be determined using this device, see the section entitled “Technical data\analysis parameters”. If necessary, you can print out this overview and give it to your patients (print-out from the 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 (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.

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4. DEVICE OVERVIEW

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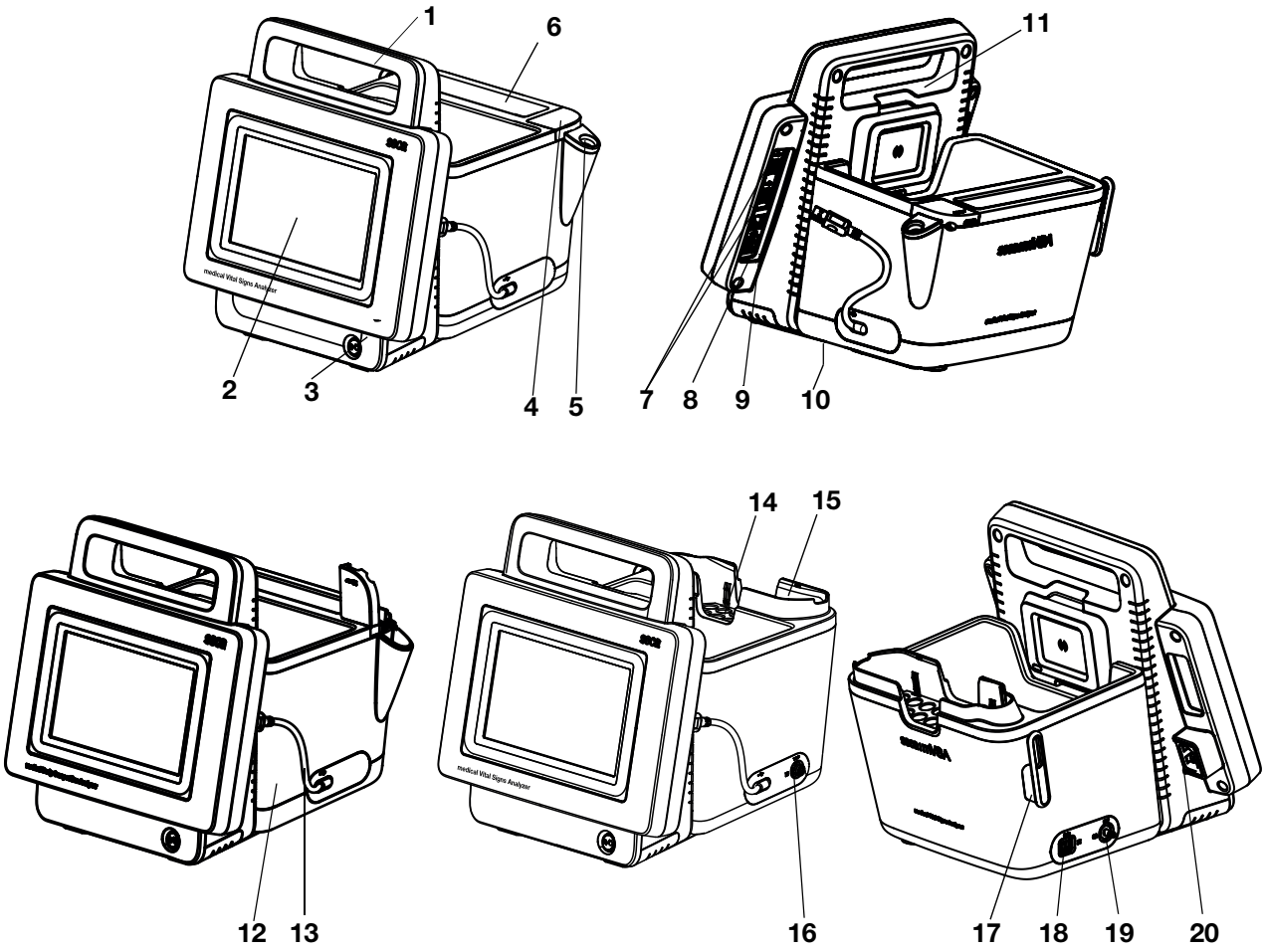
4.1 Monitor controls for seca mVSA 535

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



No.	Controls	Function
1	Handle	Transporting the device
2	Touchscreen display	Central control/display element
3	ON/OFF key with LED	LED white: Device on
		LED green: Device on standby
		LED off: Device off
4	Connection for temperature measurement	For COVIDIEN™ FILAC™ 3000 temperature probes • Blue: Oral/axillary measurement • Red: Rectal measurement
5	Probe holder	For COVIDIEN™ FILAC™ 3000 temperature probes • Blue: Oral/axillary measurement • Red: Rectal measurement
6	Storage compartment for probe covers	Capacity: 2 packs for COVIDIEN™ FILAC™ 3000
7	USB interface, 2 pcs	For transmitting data via a USB memory stick
		For transmitting data between monitor and SmartBucket
		For supplying SmartBucket with power
		Connecting the scanner
8	ISIS interface	Advance feature for future system upgrade (currently no function)

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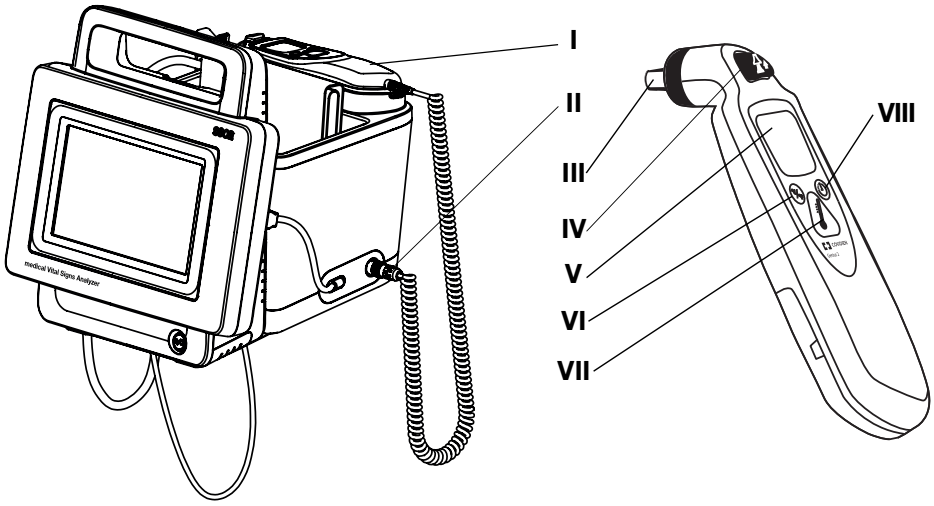
No.	Controls	Function
9	LAN interface	Integrating the device in a network (using the **seca connect 103** software for connection to an EMR system)
10	Rechargeable battery compartment	To take lithium-ion rechargeable battery supplied
11	Internal WiFi module	Integrating the device in a network (using the **seca connect 103** software for connection to an EMR system)
12	SmartBucket	Transporting/storing the metrology equipment
		For storing consumables
13	Connecting cable with USB connector	For power supply and data transmission between monitor and SmartBucket
14	Sensor holder	For SpO_2 sensor
18	Connection for SpO_2 measurement	• Masimo SET® patient cables and sensors (no illustration) • seca patient cables and sensors (shown in illustration)
19	Connection for blood pressure measurement	For seca blood pressure cuffs
20	Power supply connection socket	For connecting the power supply cable
21	Removable magazine holder for probe covers	Capacity: 2 magazines for COVIDIEN™ GENIUS®3
19	Thermometer compartment	For COVIDIEN™ GENIUS®3 in-ear thermometer
20	Connection for temperature measurement	For COVIDIEN™ GENIUS®3 in-ear thermometer

4.2 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®3 in-ear thermometer
II	Connection for temperature measurement	For COVIDIEN™ GENIUS®3 in-ear thermometer
III	Measuring head	For measuring temperature in ear
IV	Discard key	For discarding probe cover
V	In-ear thermometer display	Serves as a secondary display. **seca mVSA 535** display takes priority
VI	Switch unit key	Switch between °C and °F
VII	Measure key	Press key to start measurement
VIII	Pulse timer key	Not relevant for **seca mVSA 535**. Pulse rate is determined automatically by the **seca mVSA 535**

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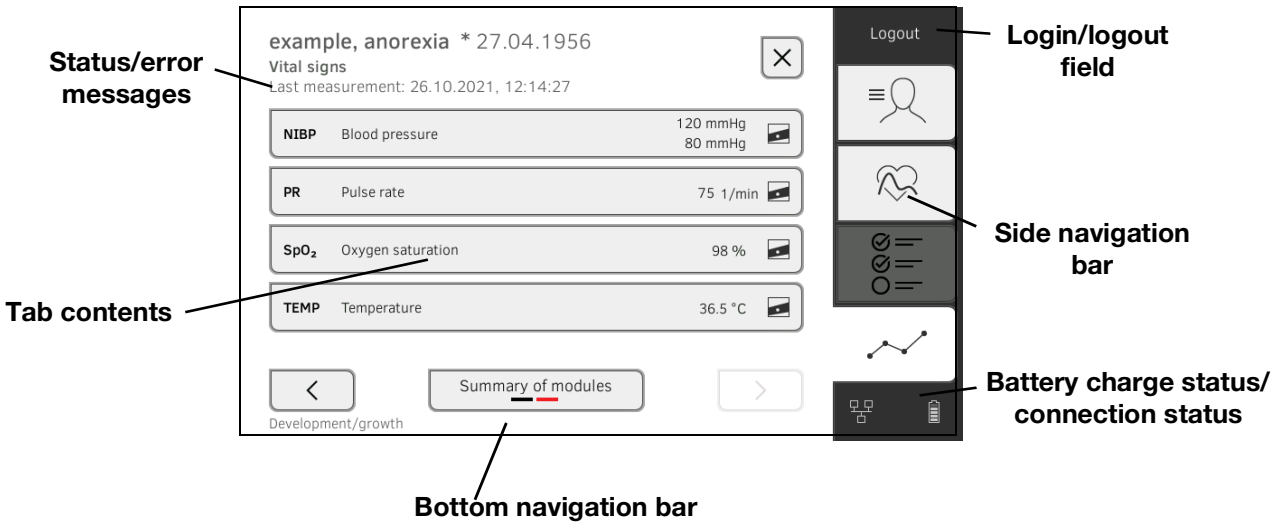
4.3 Fields in the touchscreen display



4.4 Login/navigation: Keys and symbols in the touchscreen display

Key/symbol	Meaning
	Patient tab
	Vital signs tab
	Clinical observations 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

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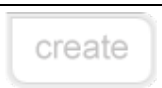
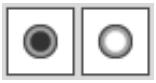
Key/symbol	Meaning
	Enter password
	• Navigation: Confirm entry • Measuring: Save measurement
	Process running
	Key available
	Key pressed
	Key not available
	Navigate to the left/right
	Navigate up/down
	One or more items from list selected/not selected
	Alternative from list selected/not selected
	Return to previous screen
Login	Log in user
Logout	Log out/switch user

4.5 Operating state: Symbols

Operating state: Symbols in the touchscreen display

Symbol	Operating state
	Monitor: Controls permanently on: Rechargeable battery charge status (%) Controls flashing: Rechargeable battery charging
	Monitor: Controls permanently on: Rechargeable battery full Controls flashing consecutively: Rechargeable battery charging
	Monitor: Rechargeable battery discharged

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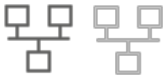
Symbol	Operating state
	LAN connection set up: on/off
	WiFi connection set up: on/off
	**seca connect 103** ()EMR: connection active
	**seca connect 103** (EMR): connection interrupted
	Pop-up window: Information for the user
	Pop-up window: Error message
	Pop-up window: Setting option for the user
	Error message during vital signs measurement

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4.6 Measuring: Keys and symbols

➔ Patient tab

➔ Vital signs tab

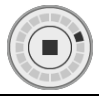
➔ Clinical observations tab

➔ Analysis tab

Patient tab

Key/symbol	Meaning
	Search for seca patient file
	Switch sorting direction
	Edit seca patient file
	Export seca patient file
	Delete seca patient file
	Adopt value from previous measurement
	Close seca patient file, changes will not be saved

Vital signs tab

Key/symbol	Meaning
NIBP	Blood pressure measured non-invasively
	Start blood pressure measurement
	Blood pressure measurement in progress
1.~~117/77~~ 2.116/63 3.123/80	Blood pressure: Multiple measurement: First measurement will be discarded
	Blood pressure: Multiple measurement: Waiting time until next part-measurement running
SYS/DIA	Blood pressure: Systolic/diastolic pressure

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Key/symbol	Meaning
MAP	Blood pressure: Mean arterial pressure
	Blood pressure: Upward measurement, downward measurement
	Blood pressure: Single measurement, multiple measurement
TEMP	Temperature
	Temperature measuring mode: Predictive, direct
	Manual measured value input
	COVIDIEN™ FILAC™ 3000 temperature probe Measuring position: Oral, axillary, rectal
	COVIDIEN™ GENIUS®3 in-ear thermometer Measuring position: in-ear
PR	Pulse rate
	Measuring range for pulse rate: Default, extended
SpO_2	Oxygen saturation in %
PI	Devices with Masimo SET® measuring equipment: Perfusion index, information on the quality of perfusion (min: 0.02 %, max: 20 %)
	Devices with Masimo SET® measuring equipment, oxygen saturation measuring mode: Normal, APOD, maximum
	Devices with seca measuring equipment, oxygen saturation measuring mode: Stable, default, sensitive
	Write comment
	Call up list of unsubmitted measurements
	Adopt value from previous measurement
	Save measurement
	Discard measurement

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Clinical observations tab

Key/symbol	Meaning
	Position indicator for pages, here: Page 1 of 2
	Adopt observations
	Delete observations
	Yellow marking: Mandatory field

Analysis tab

Key/symbol	Meaning
	View history
	Position indicator for analysis modules, here: second module of 5
	Position indicator for analysis parameters, here: second analysis parameter of 4
	Detail view available for analysis parameter: Percentile curve
	Blue marking: Mean value

4.7 Unsubmitted measurements list: Symbols

Key/symbol	Meaning
	Clinical observations
	Weight (W)
	Height (H)
	Body mass index (BMI)
	Pulse rate (PR)
	Blood pressure (NIBP)
	Oxygen saturation (SpO_2)
	Temperature (Temp)

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Key/symbol	Meaning
Average (NIBP)	Blue marking: Mean value
FN2222225852 FN2222225852	Yellow marking (when connected to EMR system): Unconfirmed offline measurement

4.8 Markings on the device and on the type plate

Text/symbol	Meaning
	Name and address of manufacturer, date of manufacture
REF	Model number
SN	Serial number, consecutive
ProdID	Product identification number, consecutive
Mat.No.	Variant number
	Follow Instructions for Use
	Medical electrical device, type BF
	Medical electrical device, type BF (defibrillation-protected)
	Insulated device in accordance with IEC 60601-1: Protection class II
	Device with functional grounding in accordance with IEC 60601-1: The third wire of the power supply connecting cable is the functional ground
	No alarm function
IP21	Type of protection in accordance with IEC 60529: • Protection against ingress of solid foreign bodies with a diameter of over 12.5 mm • Protection against access with fingers • Protection against drips
IP22	Type of protection in accordance with DIN EN 60 529: • Protection against ingress of solid foreign bodies with a diameter of over 12.5 mm • Protection against access with fingers • Protection against dripping water when the housing is tilted up to 15°
Li-ion	Lithium-ion rechargeable battery
CE 0123	Device complies with EC directives • **0123**: appointed office for medical devices

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Text/symbol	Meaning
UK CA	Product complies with the applicable regulations of the United Kingdom Authorized person and importer: seca Ltd 40 Barn Street Birmingham B5 5QB United Kingdom
FC	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
xxx-yyy V ~ **min xx-yy Hz** **xx A**	Type plate for power supply socket: • Permitted supply voltage • Permitted power supply frequency • 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

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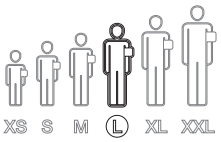
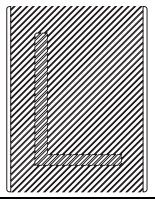
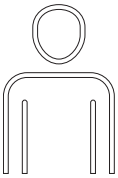
4.9 Markings on the blood pressure cuff

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).
	This side facing the patient
	Latex-free
	Name and address of manufacturer
	Date of manufacture
	Name and address of distributor
	Model number
	Lot number
	The blood pressure cuff complies with EU directives

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4.10 Markings on the packaging

Text/symbol	Meaning
	Protect from moisture
	Arrows indicate top of product Transport and store in an upright position
	Fragile Do not throw or drop
	Permitted min. and max. temperature for transport and storage
	Permitted min. and max. humidity for transport and storage
	Open packaging here
	Packaging material can be disposed of through recycling programs

4.11 Other symbols

Depending on device version, the symbols below may be applied to accessories and consumables and their packaging.

Text/symbol	Meaning
	Not sterile
	Do not reuse
	Small parts present a danger of suffocation if swallowed.
	Keep out of sunlight
	Only use indoors
	Non-ionizing radiation
	DEHP-free
	Latex-free
	Not resistant to magnetic resonance
	Do not use if packaging damaged
	Lot number
	Person with authority in the EU

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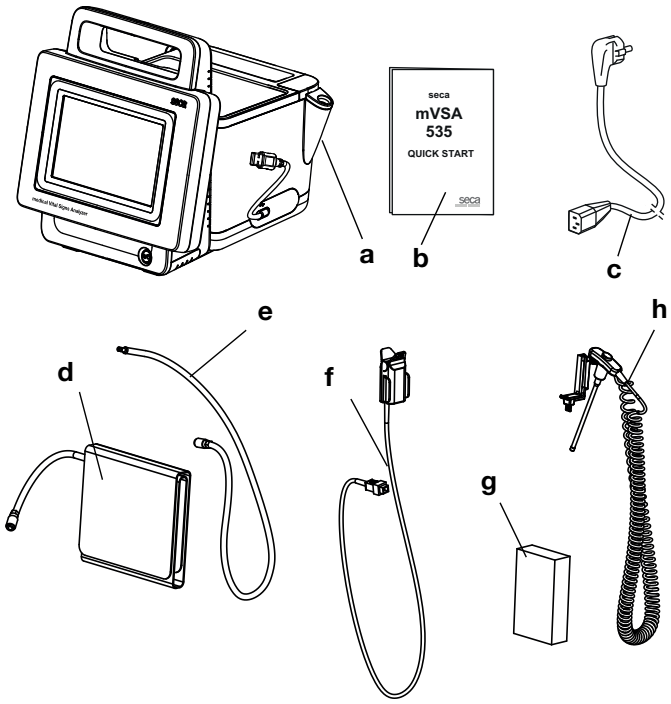
5. STARTING UP THE DEVICE

5.1 Scope of delivery

NOTE
This section shows version 535-1110-001 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	-

No.	Accessory for the version shown	Pcs.
d	seca blood pressure cuff, size M	1
e	Extension for compressed air tube (1.3 m)	1
f	• SpO_2 sensor (Masimo SET® or seca) • Patient cable (Masimo SET® or seca), not illustrated	1 1
g	COVIDIEN™ FILAC™ 3000 probe covers (pack of 20 pcs)	1
h	COVIDIEN™ FILAC™ 3000 temperature probe	1

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5.2 Setting up device

➔ Connecting the SmartBucket

➔ Connecting the blood pressure cuff

➔ Connecting the temperature probe

➔ Connecting the in-ear thermometer

➔ Connecting the seca SpO_2 sensor

➔ Connecting the Masimo SET® SpO_2 sensor

NOTE

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

NOTICE!

Damage to device, malfunction

Excessive use of force may damage tubes and cables.

- In order to connect measuring accessories to the device or remove them from it, take hold of tubes only by the tube coupling.
- In order to connect measuring accessories to the device or remove them from it, take hold of cables only by the connectors.
- Use only measuring accessories which have no externally visible damage.

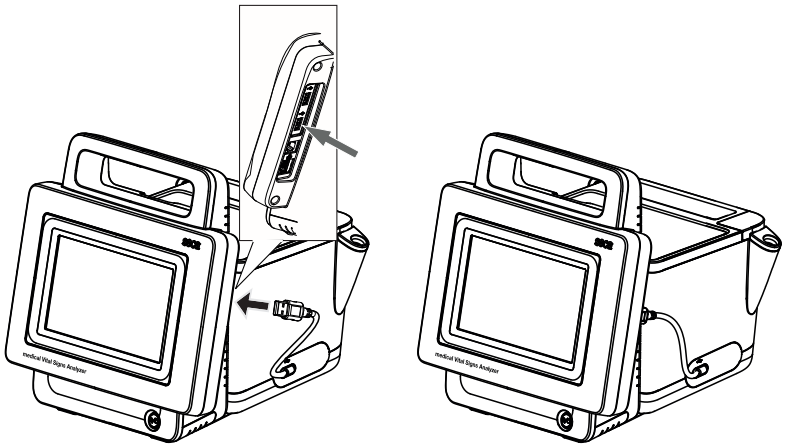
Connecting the SmartBucket

NOTICE!

Malfunction

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

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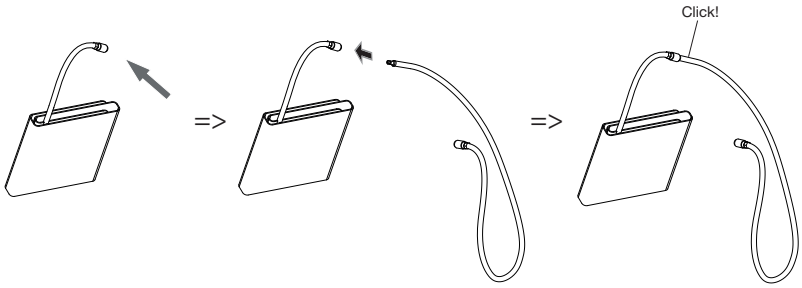
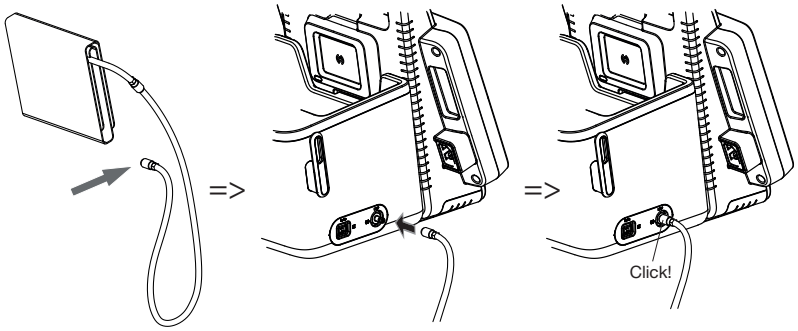
Connecting the blood pressure cuff

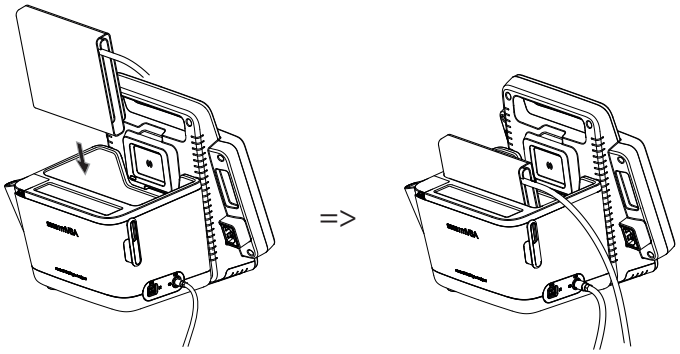
1. Variant-dependent: Connect the tube coupling for the blood pressure cuff to the connector of the extension tube until you hear the tube coupling engage.



2. Connect the tube coupling for the extension tube to the compressed air connection of the device until you hear the tube coupling engage.

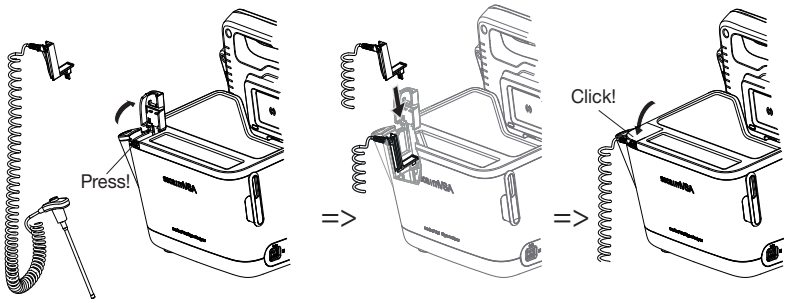


3. Stow the blood pressure cuff in the SmartBucketas shown in the illustration below.



Connecting the temperature probe

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



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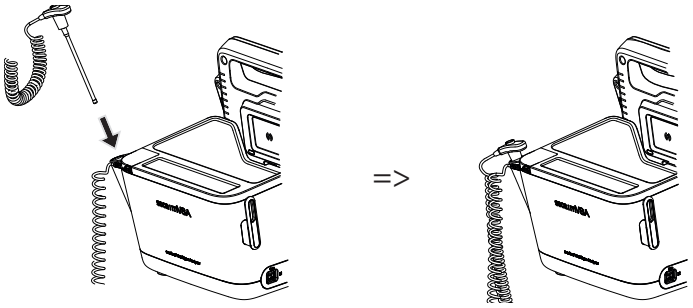
4. Push the temperature probe into the probe holder completely as shown in the illustration below.



NOTICE!

Damage to device, malfunction

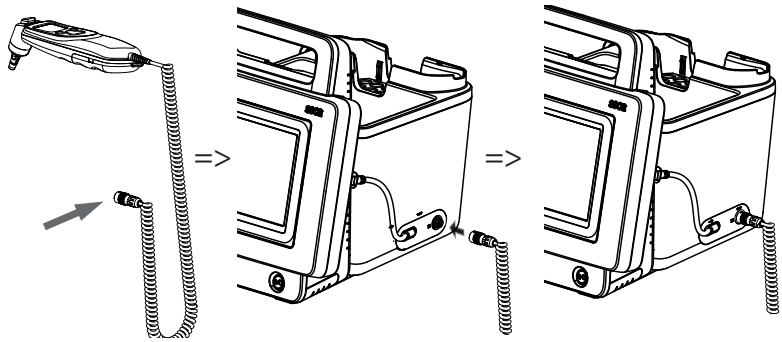
The temperature probe can only be pushed right into the probe holder if it does not have a probe cover on.

► 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.

Connecting the in-ear thermometer

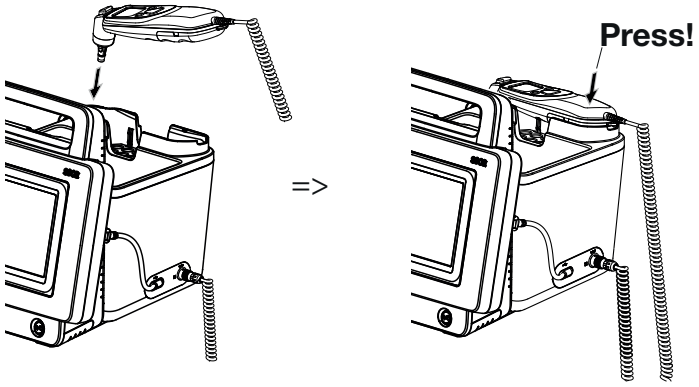


1. Put the connector for the in-ear thermometer in the socket on the SmartBucket until you feel the connector engage.

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.



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Connecting the seca SpO_2 sensor

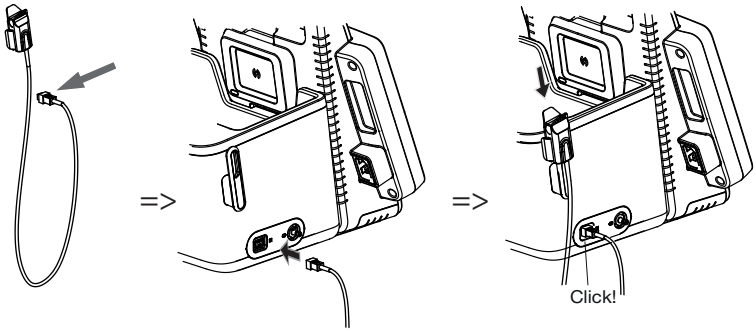
NOTICE!

Damage to device, malfunction

The SpO_2 sensor must be compatible with the seca SpO_2 measuring equipment 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.
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.

Connecting the Masimo SET® SpO_2 sensor

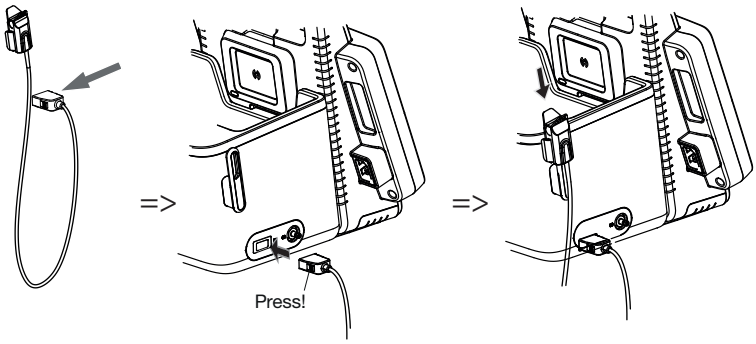
NOTICE!

Damage to device, malfunction

The SpO_2 sensor must be compatible with the SpO_2 measuring equipment 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.
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.

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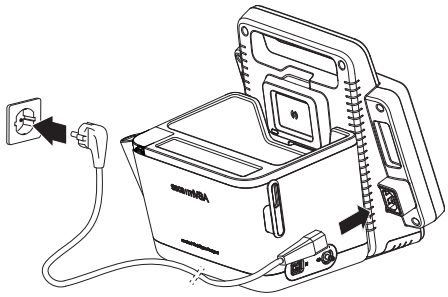
5.3 Establishing a power supply



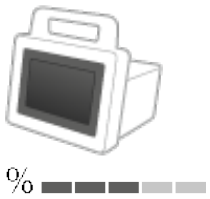
1. Plug the device connector of the power supply cable into the connecting socket of the device.
2. Plug the power supply connector into a power supply socket.

5.4 Charging rechargeable battery

Before starting up the device for the first time, the rechargeable battery for the monitor must be fully charged.

1. Connect the device to the power supply ➔ Establishing a power supply.
2. Press the ON/OFF key of the monitor.
   The LED of the ON/OFF key is white.
   The charging process starts.
   Current charge status is displayed for approx. 15 seconds:

   After approx. 5 minutes, the device switches to standby.



   The screen goes off.
   The LED of the ON/OFF key flashes green.
   When the rechargeable batteries are fully charged, the device switches off.
   The LED of the ON/OFF key goes off.

5.5 Setting the date and time

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

1. Connect the device to the power supply.

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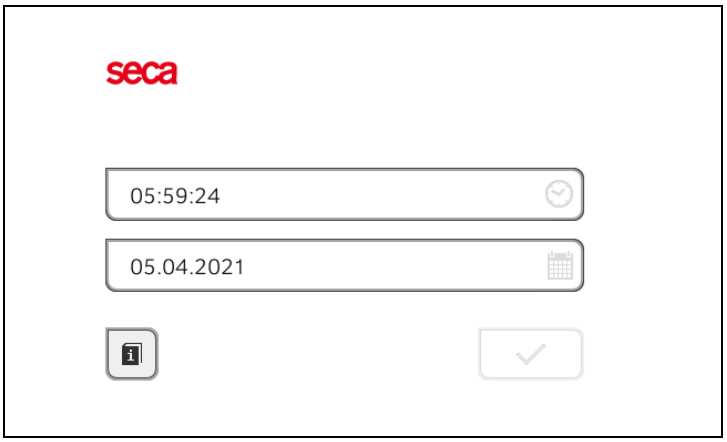
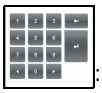
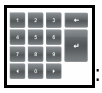
2. Press the ON/OFF key of the monitor.
   The LED of the key is white.
   The initial start screen appears.



3. Enter the current date:
   a) Press the input field
   b) Use the keypad  : Enter current date
   c) Press the  key: Confirm entry
4. Enter the current time:
   a) Press the input field
   b) Use the keypad  : Enter current time
   c) Press the  key: Confirm entry
5. Press the  key.
6. Continue operating the device – you have the following options:
   - Leave device switched on (recommended): ➔ Charging rechargeable battery
   - Perform measurements using the power supply: ➔ Operation
   - Configure device using the power supply: ➔ For administrators: Configuring seca mVSA 535

5.6 Initial login

The following user accounts are available on the device initially:

- admin: Configure and manage device
- user: Perform and manage measurements
- service: For authorized service technicians

On initial login, these user accounts must be activated and configured.

Further information is available here: ➔ For administrators: Configuring seca mVSA 535\ ➔ User accounts

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5.7 Configuration options

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

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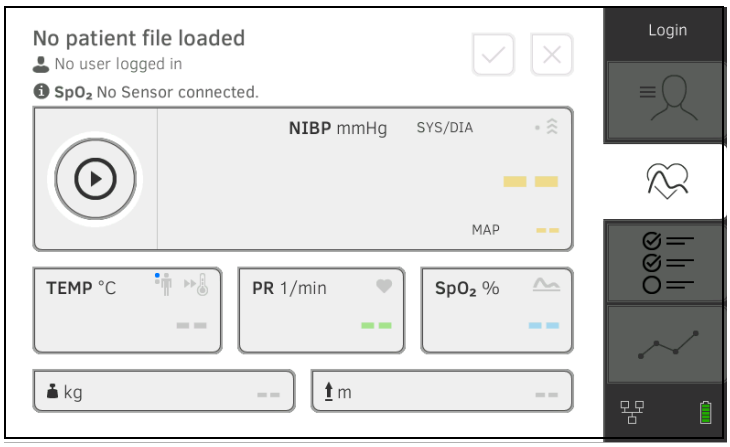
6. OPERATION

6.1 Switching the system on/off

Switching on

1. Press the ON/OFF key of the monitor.
   The LED of the ON/OFF key is white.
   The device starts up. This takes a few seconds.



The Vital signs tab is displayed.
You have the following options:

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

Logging in

You must log in to the device if you want to do one of the following:

- Assign vital signs measurement to a seca patient file
- Analyze measured results
- Manage the system

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1. Press the **Login** key.
   The login window is displayed:

2. Press the input field.
   The list of user accounts is displayed.

   NOTE
   In stand-alone operation, a user account is available for measuring mode ➔ Initial login. No further user accounts can be set up for this area.

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

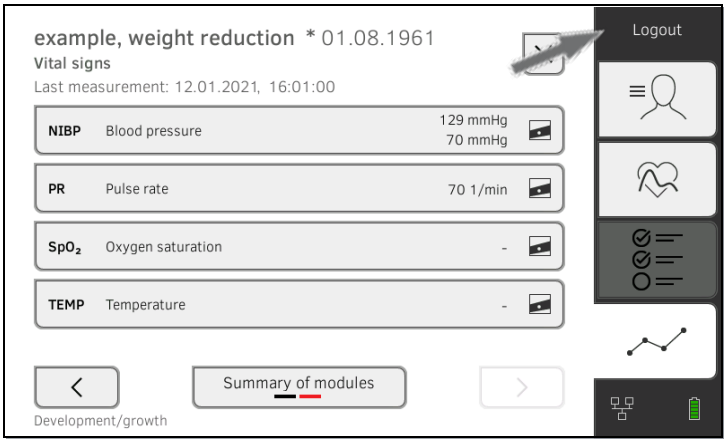
4. Press the input field.

5. Enter your password using the keypad  .
   The Patient tab is displayed.

6. Continue with ➔ Managing seca patient files.

Logging out/switching user

► Press the **Logout** key.



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

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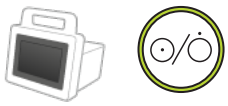
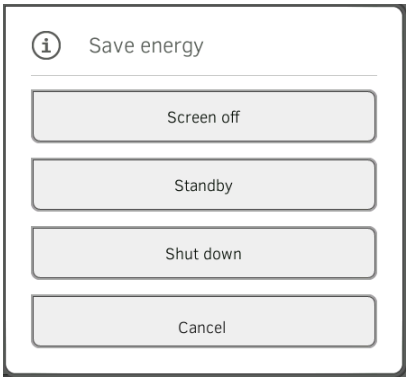
Saving power/switching off



1. Briefly press the ON/OFF key of the monitor.
2. The **Save energy** dialog window appears.



3. Select an option in accordance with the table:

NOTE
The device automatically switches to standby/shuts down if it is not used for an extended period (phased by idle time)

Idle time key	Device behavior	To remove setting
Screen off	• Display switches off • The LED of the ON/OFF key is white. • Entries are retained • User remains logged in • Patient file remains active • Measurements continue to run	Press screen
Standby **10 minutes**	• Display switches off. • The LED of the ON/OFF key is green • Data which have not been saved are lost • User is logged out • Patient file is deactivated	Press screen
Shut down **20 minutes**	• Power supply operation: - When the charging process is complete: Device shuts down and switches off • Rechargeable battery operation: - Device shuts down - The device switches off	Press the ON/OFF key

NOTE
If rechargeable battery charge status undershoots a preset limit value [%], the device shuts down and switches off. It behaves in this way regardless of the option you select in the **Save energy** dialog. The limit value for rechargeable battery charge status is specified by your administrator: ➔ Power management.

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6.2 Managing seca patient files

➔ Creating a seca patient file

➔ Calling up a seca patient file

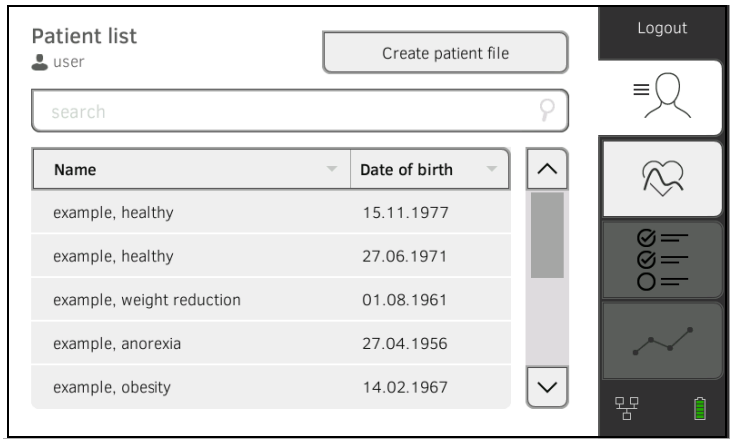
➔ Editing a seca patient file

➔ Exporting a seca patient file

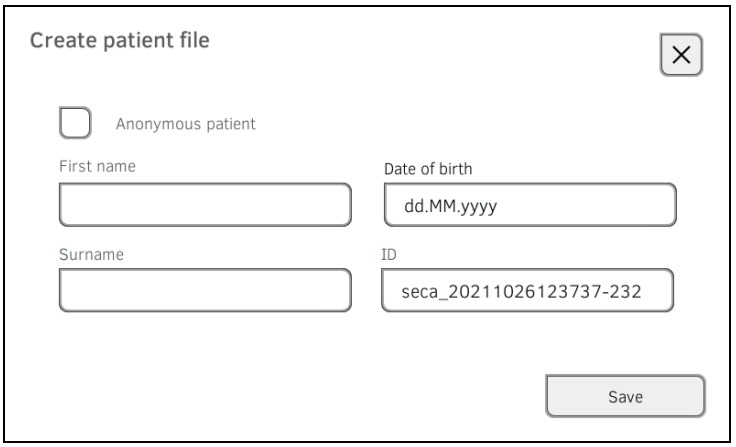
➔ Deleting a seca patient file

Creating a seca patient file

1. Log in ➔ Logging in.
2. Press the Patient tab.
   The patient list is displayed.



3. Press the **Create patient file** key.



4. Select the option **Anonymous patient** if desired.

NOTE
For an anonymous patient, the name is not displayed on the Vital signs and Analysis tabs. Name and measured results are never displayed together.

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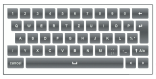
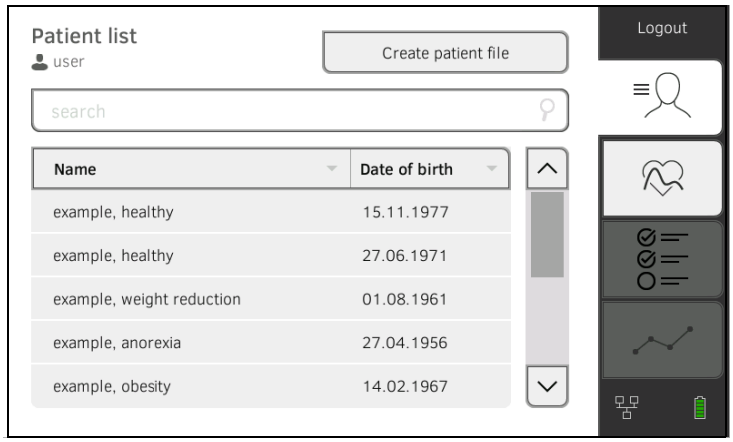
5. Enter the first name and surname of the patient:
   a) Press the  input field
   b) Use the keypad  : Enter text
   c) Press the  key: Confirm entry
6. Enter the date of birth:
   a) Press the  input field
   b) Use the keypad  : Enter date
   c) Press the  key: Confirm entry
7. Enter a patient ID:
   a) Press the  input field
   b) Delete an automatically-generated ID
   c) Enter patient ID

   NOTE
   You only need to assign a specific patient ID if a specific structure is provided for this in your institution. If you do not edit the **ID** input field, the device saves the automatically-generated patient ID.
8. Press the **Save** key.
   The seca patient file has been created and is displayed.



You have the following options for continuing:

- Measure vital signs: ➔ Measuring vital signs
- Measure vital signs: ➔ Entering vital signs manually

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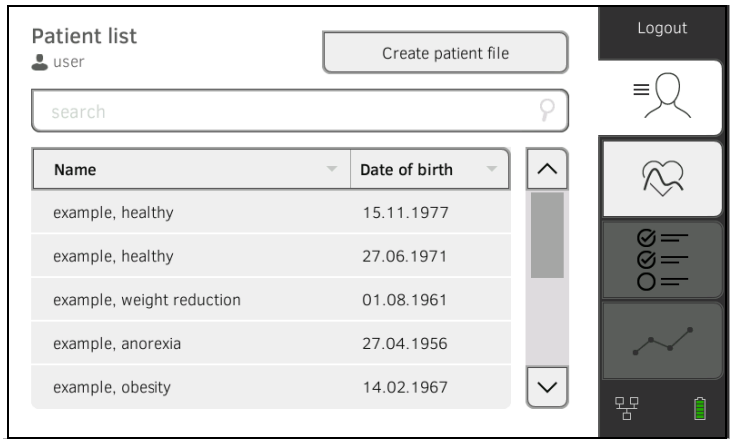
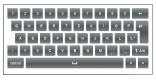
Calling up a seca patient file

1. Log in ➔ Logging in.
2. Press the Patient tab.
   The patient list is displayed.



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 the  input field
   b) Use the keypad  : Patient name or ID
   c) Press the  key: Confirm entry
   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** key.
   The seca patient file is opened.
   You have the following options for continuing:
   - Measure vital signs: ➔ Measuring vital signs

Editing a seca patient file

1. Call up a seca patient file ➔ Calling up a seca patient file.
2. Press the  key.
3. Edit the entries.
4. Press the **Save** key.
   The changes are saved.

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Exporting a seca patient file

1. Connect a USB memory stick to the monitor.
2. Call up a seca patient file ➔ Calling up a seca patient file.
3. Press the  key.
   A confirmation dialog opens.
4. Press the **Confirm** key.
   The patient file is exported to the USB memory stick.

Deleting a seca patient file

1. Call up a seca patient file ➔ Calling up a seca patient file.
2. Press the  key.
   A confirmation dialog opens.
3. Press the **Delete** key.
   The patient file is deleted.

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6.3 Measuring vital signs

Introduction

The Vital signs measurement function is available after the device is switched on. You can perform measurements without login and without patient identification.

If you want to assign the measurement to a patient file, we recommend calling up ➜ Calling up a seca patient file or creating ➜ Creating a seca patient file a patient file **before** the measurement. This applies in particular when repeat measurements for a patient are likely.

You can measure one or more vital signs in one measurement procedure. Measurement starts automatically after the measuring accessories have been attached to the patient (exception: blood pressure measurement and in-ear temperature measurement). Depending on device configuration, pulse rate is determined using either oxygen saturation or blood pressure.

Alternatively, a patient's vital signs can also be entered manually ➜ Entering vital signs manually.

Weight and height can be recorded by compatible seca measuring devices or entered manually: ➜ Adding weight and height.

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Measuring blood pressure

➔ Preparing the blood pressure measurement

➔ Starting a single measurement

➔ Performing a multiple measurement

➔ Modifying 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)
  - 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 "Troubleshooting".

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.

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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!
Patient hazard
If maximum pressure for an upward measurement is set too high, this may cause a hematoma in the patient.

- Select a value suitable for the patient as the maximum pressure (example: A patient with an estimated blood pressure of 120/80 mmHg should be measured using a maximum pressure of 160 mmHg).

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.

Preparing the 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

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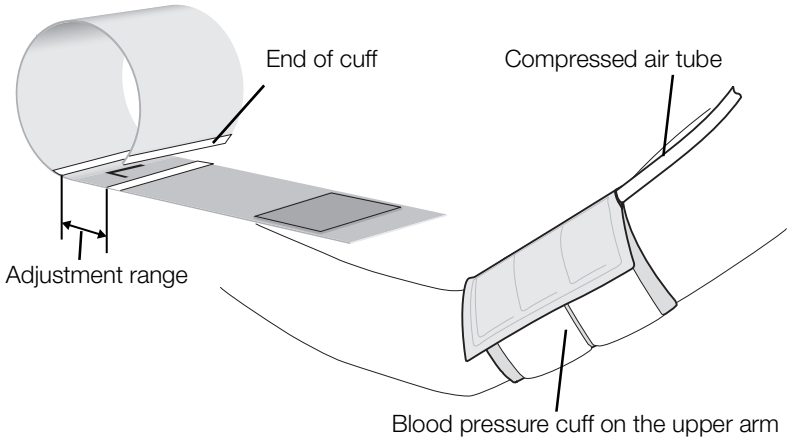
2. Apply the blood pressure cuff to the patient's non-dominant arm as shown in the illustration below:
   a) Note the labeling on the blood pressure cuff ➔ Markings on the blood pressure cuff
   b) Use correct size of blood pressure cuff: End of cuff inside the adjustment range when put on
   c) Position the 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.

You have the following options for continuing:

- ➔ Starting a single measurement
- ➔ Performing a multiple measurement

NOTE
Your administrator will specify whether Single measurement or Multiple measurement is available when the device starts up. You can modify this and other presets for the current measurement: ➔ Modifying presets. After this, the settings specified by the administrator will be active again.

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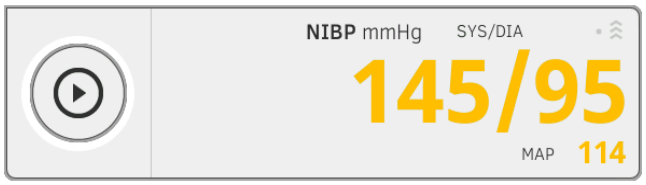
Starting a single measurement

► Press the  key on the monitor.
Blood pressure measurement starts:

Current cuff pressure is displayed.
The symbols for measurement method and measuring mode flash (here: Single measurement, upward measurement).
Measurement stops automatically as soon as valid blood pressure values are detected.



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

- ► Measure more vital signs ➔ Measuring vital signs
- ► Stop the measurement ➔ Stopping a measurement

NOTE

- Using the Start key, you can cancel and restart a blood pressure measurement at any time.
- If upward measurement fails to deliver a measured value, the device automatically switches to downward measurement. If necessary, the device re-pumps several times during the downward measurement (re-pumping: Increasing cuff pressure by approx. 50 mmHg followed by incremental releasing of that pressure). If no measured value is delivered even after several re-pumping steps, the procedure is canceled.

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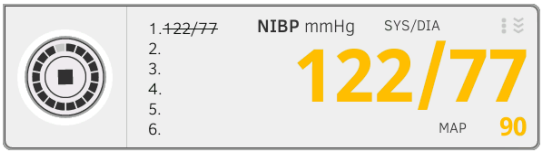
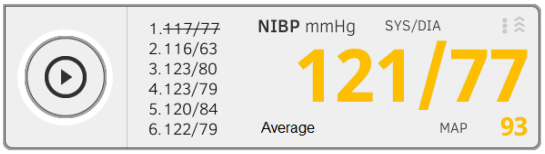
Performing a multiple measurement

1. Press the  key on the monitor.
   The first part-measurement starts (here: 6 part-measurements).

   Current cuff pressure is displayed.
   The symbols for measurement method and measuring mode flash (here: Upward measurement).
   The part-measurement stops automatically as soon as valid blood pressure values are detected.

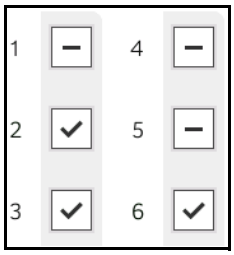


   The values for systolic/diastolic blood pressure **SYS/DIA** and mean arterial pressure **MAP** are displayed.
   The waiting time until the next part-measurement starts.
   The next part-measurement starts automatically.
   Once all part-measurements are present, mean blood pressure (mean value) is displayed.



   Disregarded part-measurements are displayed struck through (here: Measurement 1).

2. Edit the list of part-measurements to be taken into account:
   - ► Press the list of part-measurements
   - ► Put a tick against the part-measurements to be used for calculating the mean (example:)



   - ► Click **Confirm**

   Average blood pressure is displayed.
   You have the following options for continuing:
   - ► Measure more vital signs ➔ Measuring vital signs
   - ► Stop the measurement ➔ Stopping a measurement

   NOTE
   • Use the Start key to interrupt and continue the mean measurement or to cancel and re-start it.

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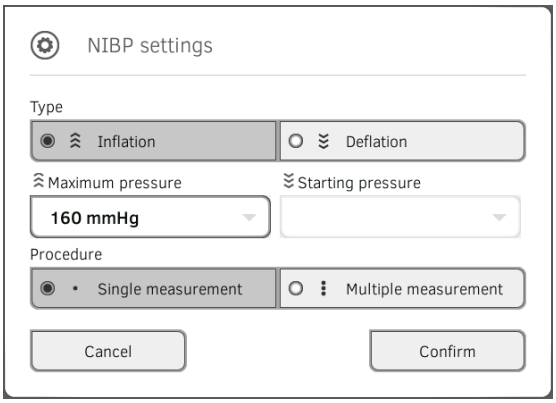
- If upward measurement does not deliver a measured value, the device automatically switches to downward measurement.
- If necessary, the device re-pumps several times during the downward measurement (re-pumping: Increasing cuff pressure by approx. 50 mmHg followed by incremental releasing of that pressure). If no measured value is delivered even after several re-pumping steps, the procedure is canceled.

Modifying presets

NOTE
Your settings apply only to the current measurement procedure. If you stop the measurement ➔ Stopping a measurement, 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: Adapt maximum pressure if necessary
   - ► Downward measurement: Adapt starting pressure if necessary
4. Press the desired measuring sequence.
   - ► Single measurement
   - ► Multiple measurement or – if a measuring profile has been configured for the multiple measurement – name of the measuring profile

NOTE
If you have questions about configuring the multiple measurement, contact your administrator.

5. Press the **Confirm** key.
   The dialog window closes.
   Changed settings are adopted for the current measurement.
6. Start the blood pressure measurement as described in the section entitled ➔ Preparing the blood pressure measurement.

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Measuring temperature, oral/ axillary (COVIDIEN™ FILAC™ 3000, blue)

➔ Starting an oral/axillary temperature measurement

➔ Modifying 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 "Troubleshooting".

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.

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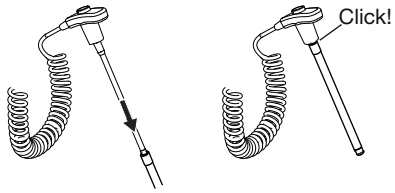
Starting an oral/axillary temperature measurement

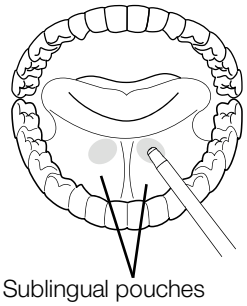
1. Remove the temperature probe (blue) from the probe holder (blue).
2. Pick up a probe cover:



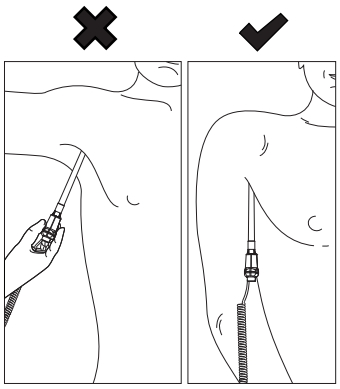
   a) Insert the probe in a probe cover in the pack
   b) Allow the probe cover to engage audibly with the probe
   c) Remove probe and probe cover from the pack
   d) Ensure that the probe cover is undamaged

3. Position the temperature probe as shown in the illustration:

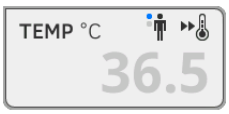
Oral measurement:



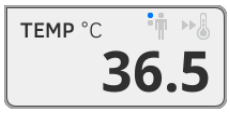
Axillary measurement:



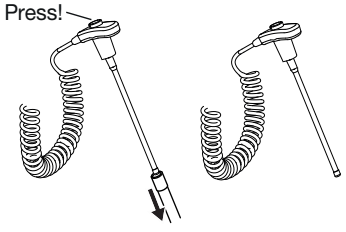
Measurement starts automatically.
The measured value and the symbol for the measurement method (here: Predictive) flash until a valid measured value is obtained.



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



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



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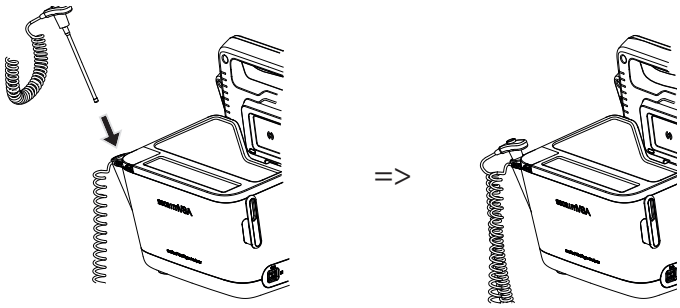
NOTE
You can only perform a further temperature measurement if you discard the probe cover and push the temperature probe back into the probe holder completely.

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



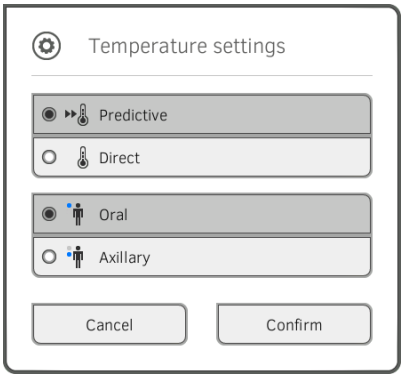
You have the following options for continuing:

- Measure further vital signs ➔ Measuring vital signs
- Stop the measurement ➔ Stopping a measurement

Modifying presets

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

1. Ensure that the temperature probe is pushed into the probe holder completely.
2. Press the **TEMP** field.
   The **Temperature 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** key.
   The dialog window closes.
   Changed settings are adopted for the current measurement.
6. Perform a temperature measurement as described in the section entitled ➔ Starting an oral/axillary temperature measurement.

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Measuring temperature, rectal (COVIDIEN™ FILAC™ 3000 red)

➔ Starting a rectal temperature measurement

➔ Modifying 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 "Troubleshooting".

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.

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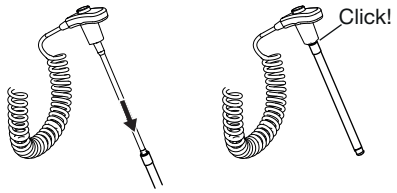
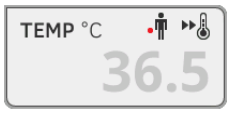
Starting a rectal temperature measurement

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

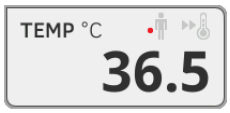


   a) Insert the probe in a probe cover in the pack
   b) Allow the probe cover to engage audibly with the probe
   c) Remove probe and probe cover from the pack
   d) Ensure that the probe cover is undamaged
3. Apply a little lubricant.
4. Guide the temperature probe into the patient's rectum:
   - For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

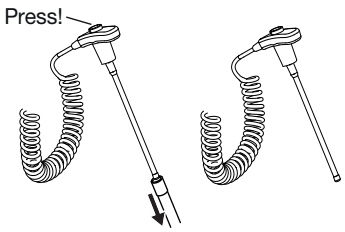
   Measurement starts automatically.
   The symbol for the measurement method (here: Predictive) flashes until a valid measured value is obtained.



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



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



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

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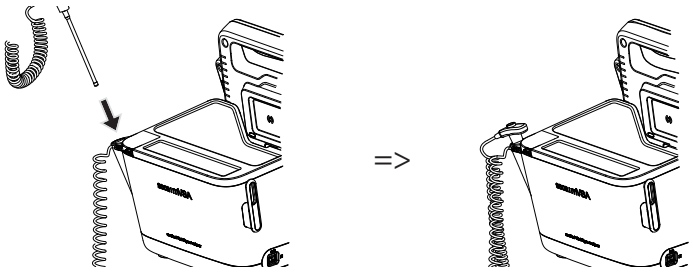
6. Push the temperature probe into the probe holder completely.



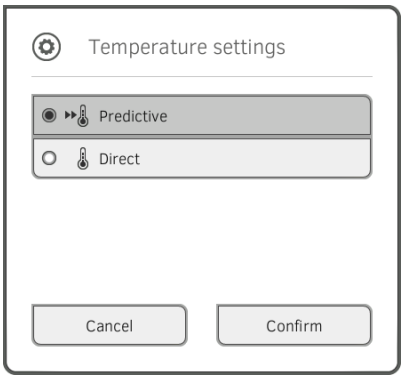
You have the following options for continuing:

- Measure further vital signs ➔ Measuring vital signs
- Stop the measurement ➔ Stopping a measurement

Modifying presets

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

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



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

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Measuring in-ear temperature (COVIDIEN™ GENIUS®3)

DANGER!
Patient hazard

- Choking on probe covers can lead to serious injury.

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 "Troubleshooting".

WARNING!
Patient hazard, incorrect measurement

- If the thermometer is not placed in the auditory canal correctly, this may lead to permanent injury.
- 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.
- Grommets or tympanostomy tubes have no negative impact on measuring accuracy. To prevent problems for the patient, do not resume in-ear temperature measurement any sooner than one week after an operation.
- Only use probe covers intended for your in-ear thermometer. Other probe covers may falsify the measuring results.
- Ensure that the probe tip seals the auditory canal. If this is not the case, measuring results will be falsified.
- Severe scarring of the eardrum may falsify the measurement, resulting in values which are too low being measured.

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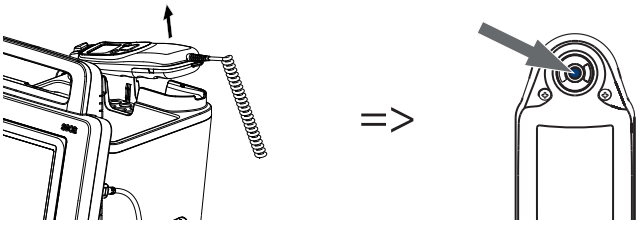
CAUTION!
Incorrect measurement

- Once there is a probe cover on the thermometer, do not point the probe tip at objects which generate heat – such as hands, computers or windows. This will lead to falsified measuring results.
- Use a new probe cover for every temperature measurement. The surface of the probe cover must be smooth, with no holes, cracks or creases.
- Using the thermometer without a probe cover will lead to falsified measuring results.
- 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.
- Patients who wear removable hearing aids should remove them from the ear at least 10 minutes before the measurement. Implants do not generally have any effect on in-ear temperature.
- At low outdoor temperatures, the patient should wait at room temperature for a while before the measurement so as not to falsify the measuring results.
- If the thermometer has been stored outside the ambient temperature range quoted in the “Technical data” section, wait at least 30 minutes before using it until the thermometer has adapted to room temperature.
- Ear drops or other medications applied to the ear can falsify the measuring 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.

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  key to switch on the in-ear thermometer.

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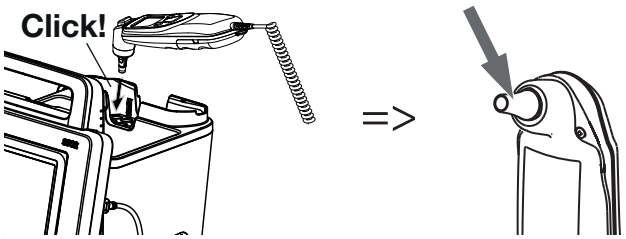
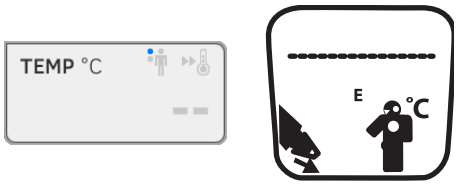
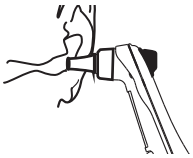
4. Pick up a probe cover:
   a) Push the measuring head firmly into a probe cover in the magazine
   b) Ensure that the probe cover engages audibly with the measuring head
   c) Remove the probe cover and thermometer from the magazine
   d) Ensure that the probe cover is undamaged



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

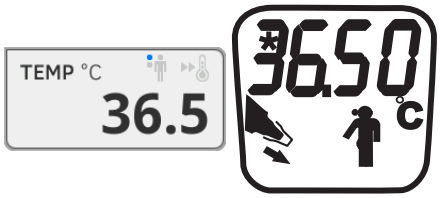


5. Introduce the measuring head into the patient's auditory canal as shown in the illustration.



6. Measure the patient's temperature:
   a) Press the  key 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 shows the temperature value and the Discard probe cover symbol.



The temperature value is displayed on the monitor until you stop the measurement ➔ Stopping a measurement.

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

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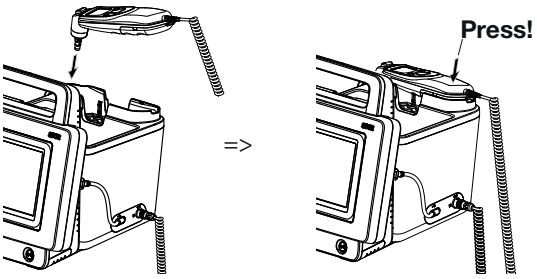
7. Press the  key to discard the probe cover.

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 for continuing:

- Measure further vital signs ➔ Measuring vital signs
- Stop the measurement ➔ Stopping a measurement

Reading off pulse rate

➔ Interrogating pulse rate source

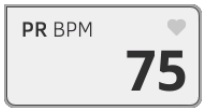
➔ Modifying presets (seca measuring equipment only)

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 ➔ Stopping a measurement.



Interrogating 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** key.
   The dialog window closes.

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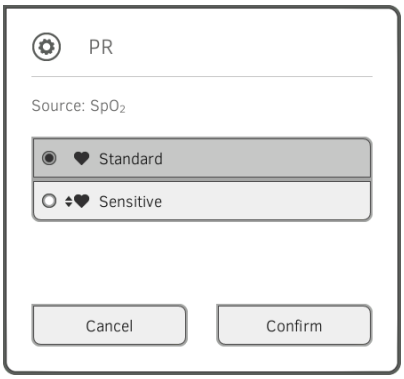
Modifying presets (seca measuring equipment only)

NOTE
These settings apply to the current measurement procedure. If you stop the measurement ➔ Stopping a measurement, the presets defined by the administrator become 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 preset is displayed (here: Default).



3. Press the desired measuring mode:

seca measuring equipment		
Mode	**Measuring range**	**Motion tolerance**
Default	0 - 240 min^{-1}	High
Sensitive	20 - 300 min^{-1}	Low

4. Press the **Confirm** key.
   The dialog window closes.
   Changed settings are adopted for the current measurement.
5. Start a blood pressure measurement or an SpO_2 measurement as described in the sections entitled ➔ Preparing the blood pressure measurement and ➔ Starting an SpO_2 measurement.

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Measuring oxygen saturation (SpO_2)

➔ Starting an SpO_2 measurement

➔ Modifying 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 measuring results.
- Apply the intravenous pressure catheter and SpO_2 sensor to different extremities to avoid falsifying measuring 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 instructions for use.
  - 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 "Troubleshooting".
- 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

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- 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.

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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.

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- 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.

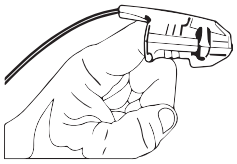
Starting an SpO_2 measurement

► Apply the SpO_2 sensor according to the sensor manufacturer's instructions for use.

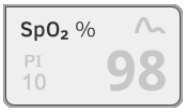
a) Ensure that the SpO_2 sensor is the correct size

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

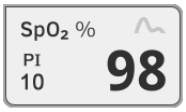
c) Apply the SpO_2 sensor to the measurement point (here: Soft clip sensor)



Measurement starts automatically.



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



The SpO_2 value is displayed.

You have the following options for continuing:

► Measure more vital signs ➔ Measuring vital signs

► Stop the measurement ➔ Stopping a measurement

NOTE

If your device is equipped with Masimo SET® pulse oximetry, 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.

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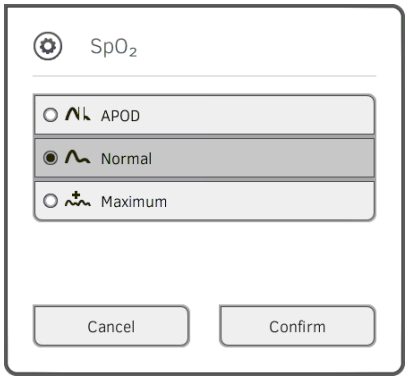
Modifying presets

NOTE
Your settings apply to the current measurement procedure. If you stop the measurement ➔ Stopping a measurement, 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 (here: Masimo SET® pulse oximetry).



3. Press the desired sensitivity:

Masimo SET® SpO_2 module	
Mode	**Indication**
Normal	• Normal perfusion • Mild perfusion disorders
Adaptive Probe Off Detection (APOD)	Vigorous patient movements
Maximum	• Poor perfusion • 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** key.
   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 ➔ Starting an SpO_2 measurement.

Weight and height

The device provides several options for adding the parameters weight and height. Your administrator specifies which of the options you can use. Further information is available here: ➔ Adding weight and height.

Adding a comment

In stand-alone mode, you have the option of adding a comment to every measurement.

1. Press the  key.
2. Enter the comment.
3. ➔ Stopping a measurement

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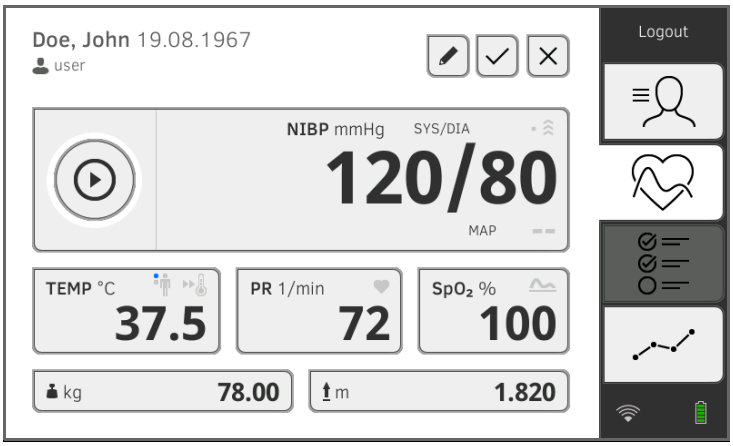
Stopping a measurement

- Stop the current measurement before you start a new one.



You have the following options:

- Press the  key: Save measurement
- Assign anonymous measurement to a seca patient file: ➔ Assigning anonymous measurement to a seca patient file
- Press the  key: Discard measurement

Assigning anonymous measurement to a seca patient file

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

1. Log in ➔ Logging in.
2. Press the Patient tab.
   You have the following options for continuing
   - ➔ Calling up a seca patient file
   - ➔ Creating a seca patient file
3. Confirm the **Assign measurement?** message.
   The measurement is assigned to the patient file.
4. Press the  key.
   The measurement is saved.

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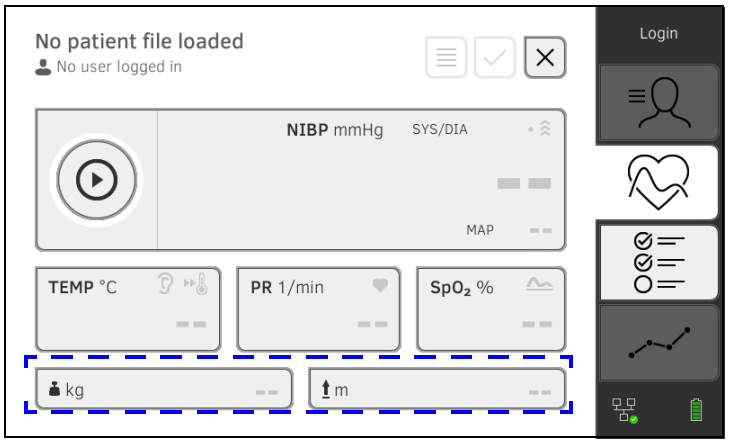
6.4 Adding weight and height

➔ Receiving weight and height (seca 360° proximity)

➔ Entering weight and height manually

You can add the parameters weight  and height  in the Patient tab:



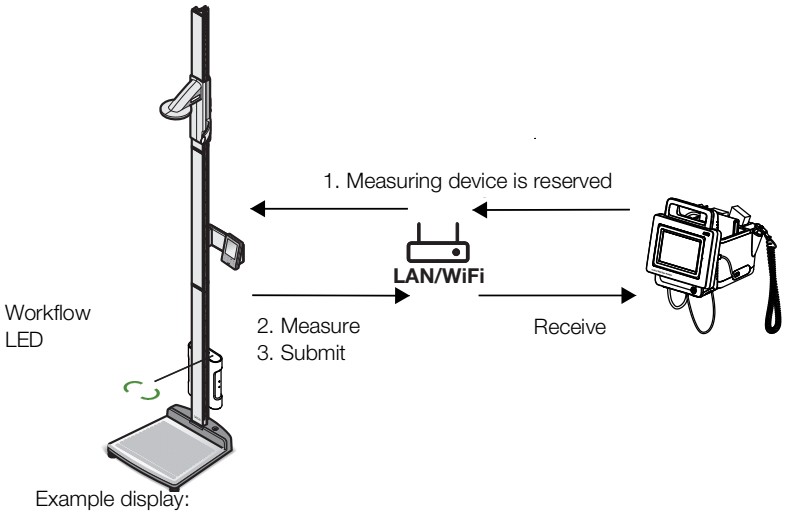
Your administrator can set up the device so that weight and height can be received by compatible seca measuring devices:

- ➔ Receiving weight and height (seca 360° proximity)

You can also enter weight and height manually: ➔ Entering weight and height manually.

Receiving weight and height (seca 360° proximity)

If a corresponding network connection is set up, weight and height can be submitted from a seca measuring device via LAN or WiFi.



Example display:
seca 285 measuring station with **seca 452** interface module and **seca mVSA 535**

1. If you have not yet done so, call up a patient file: ➔ Calling up a seca patient file.
   The measuring device preset by your administrator is reserved automatically.
   The Workflow LED on the preset measuring device is green.

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2. Measure the patient as described in the instructions for use for the measuring device.
3. Submit the measured values as described in the instructions for use for the measuring device.
   The values appear on **seca mVSA 535** in the Weight and Height fields (here: Vital signs tab):

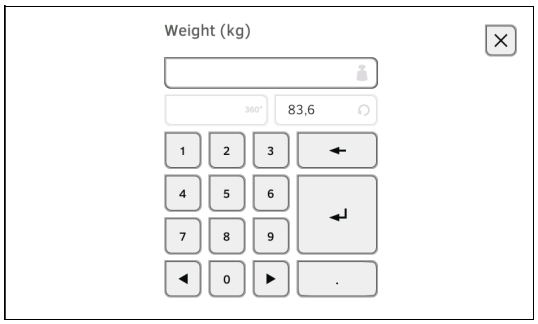
You have the following options for continuing:

- Measure more vital signs ➔ Measuring vital signs
- Stop the measurement ➔ Stopping a measurement

Entering weight and height manually

You can enter weight and height manually or adopt the values from the previous measurement.

1. Press the Patient tab.
2. If you have not yet done so, select a patient file.
3. Press the Vital signs tab.
4. Press the Weight or Height field.
   A numerical keypad appears (here: Weight):



You have the following options for entering a value:

- Use the keypad  : Enter current value
- Press the  key: Adopt the value from the previous measurement of patient

5. Press the  key.
   The values appear in the Weight and Height fields:

Vital signs tab

You have the following options for continuing:

- Measure more vital signs ➔ Measuring vital signs
- Stop the measurement ➔ Stopping a measurement

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6.5 Entering vital signs manually

➔ Entering blood pressure manually

➔ Entering temperature manually

➔ Entering pulse rate manually

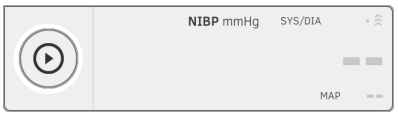
➔ Entering oxygen saturation manually

Entering blood pressure manually

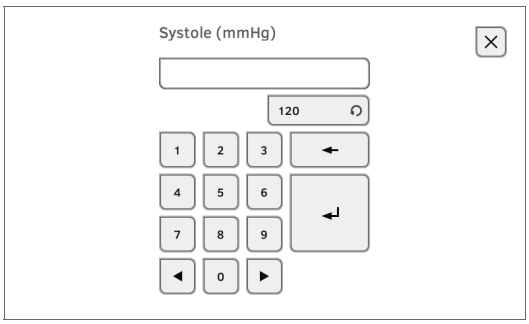
NOTE

- Follow the safety precautions in the instructions for use for your blood pressure measuring device.

1. Measure blood pressure as described in the instructions for use for your blood pressure measuring device.
2. Call up a patient file ➔ Calling up a seca patient file.
3. In the Vital signs tab, keep the **NIBP** field depressed for at least three seconds:

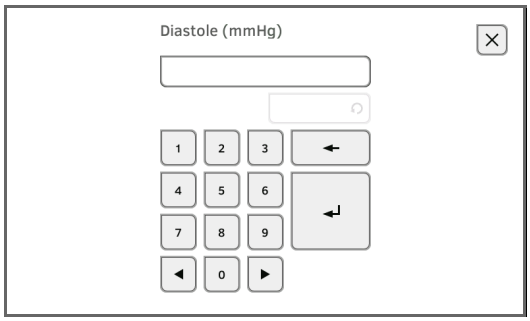


A numerical keypad for inputting systolic BP appears:



4. Enter the measured value for systolic BP:
   a) Enter the value
   b) Press the  key: Confirm entry

A numerical keypad for inputting diastolic BP appears.



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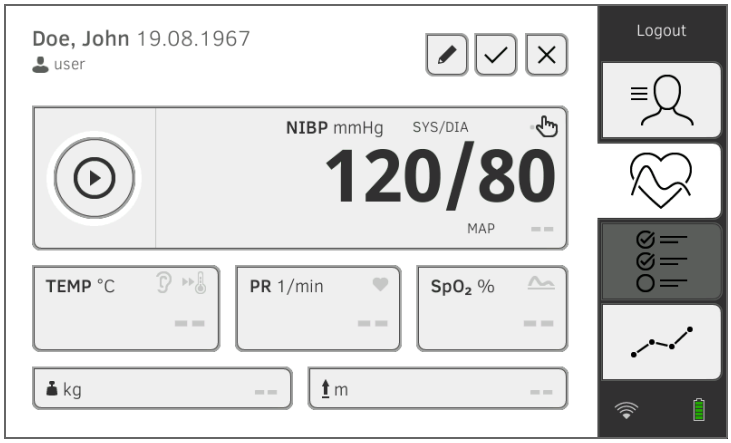
5. Enter the measured value for diastolic BP:
   a) Enter the value
   b) Press the  key: Confirm entry

The values entered appear in the **NIBP** field of the Vital signs tab.
The symbol for manual input of measured values is displayed above the measured value.



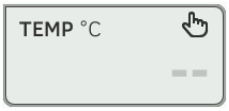
You have the following options for continuing:

- Measure more vital signs ➔ Measuring vital signs
- Enter more vital signs manually ➔ Entering vital signs manually
- Stop the measurement ➔ Stopping a measurement

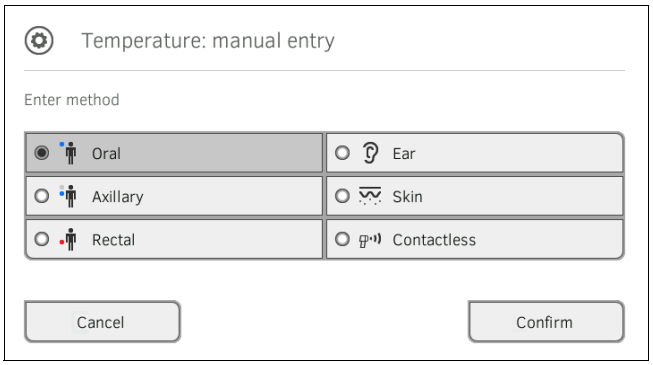
Entering temperature manually

NOTE
Follow the safety precautions in the instructions for use for your thermometer.

1. Measure body temperature as described in the instructions for use for your thermometer.
2. Call up a patient file ➔ Calling up a seca patient file.
3. In the Vital signs tab, keep the **TEMP** field depressed for at least three seconds:



The **Temperature: manual entry** dialog window is displayed:



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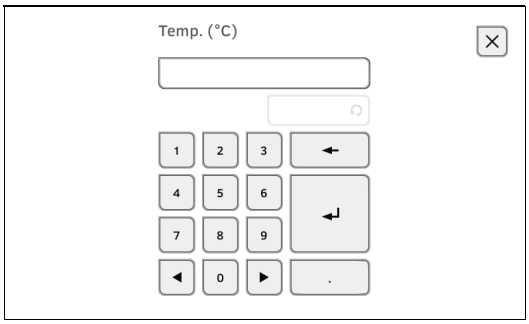
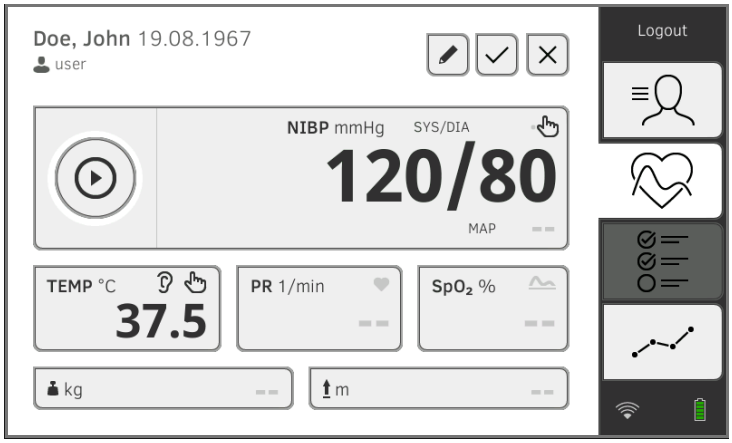
4. State the measuring method:
   a) Press the appropriate key
   b) Press the **Confirm** key

   A numerical keypad appears:



5. Enter body temperature:
   a) Enter the value
   b) Press the  key: Confirm entry

   The value entered appears in the **TEMP** field of the Vital signs tab. The symbol for manual input of measured values is displayed above the measured value.



You have the following options for continuing:

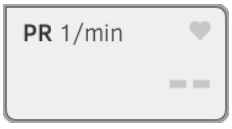
- Measure more vital signs ➔ Measuring vital signs
- Enter more vital signs manually ➔ Entering vital signs manually
- Stop the measurement ➔ Stopping a measurement

Entering pulse rate manually

NOTE

- Follow the safety precautions in the instructions for use for your pulse rate measuring device.

1. Measure pulse rate as described in the instructions for use for your pulse rate measuring device.
2. Call up a patient file ➔ Calling up a seca patient file.
3. In the Vital signs tab, keep the **PR** field depressed for at least three seconds:



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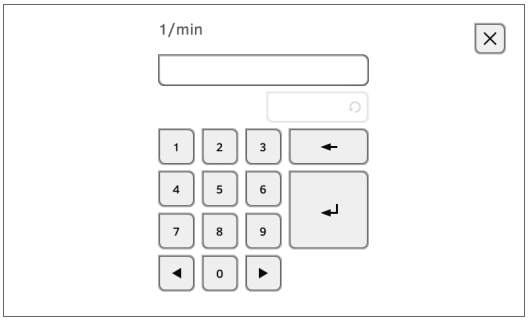
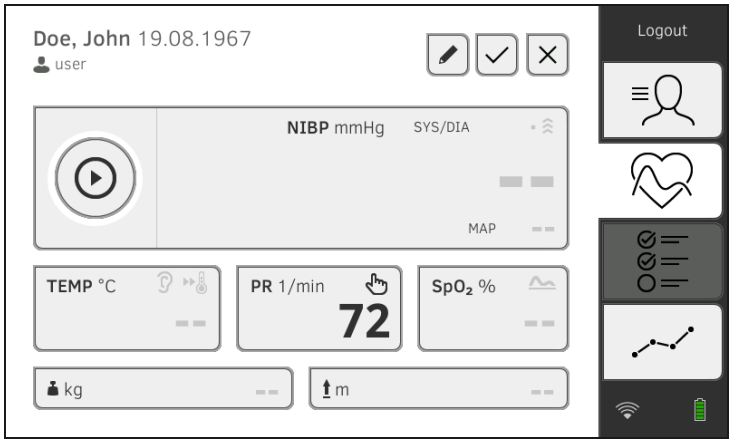
4. A numerical keypad appears:



5. Enter the pulse rate:
   a) Enter the value
   b) Press the  key: Confirm entry

The value entered appears in the **PR** field of the Vital signs tab.
The symbol for manual input of measured values is displayed above the measured value.



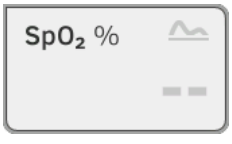
You have the following options for continuing:

- Measure more vital signs ➔ Measuring vital signs
- Enter more vital signs manually ➔ Entering vital signs manually
- Stop the measurement ➔ Stopping a measurement

Entering oxygen saturation manually

NOTE
Follow the safety precautions in the instructions for use for your oxygen saturation measuring device.

1. Measure oxygen saturation as described in the instructions for use for your oxygen saturation measuring device.
2. Call up a patient file ➔ Calling up a seca patient file.
3. In the Vital signs tab, keep the **SpO_2** field depressed for at least three seconds:



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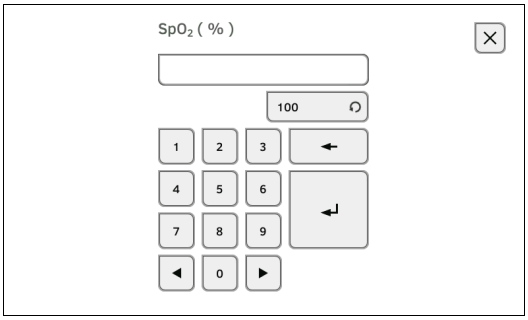
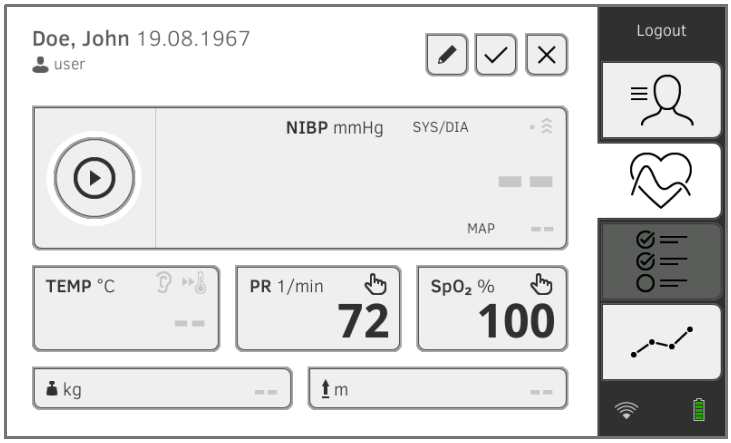
4. A numerical keypad appears:



5. Enter the oxygen saturation:
   a) Enter the value
   b) Press the  key: Confirm entry

The value entered appears in the **SpO$_2$** field of the Vital signs tab.
The symbol for manual input of measured values is displayed above the measured value.



You have the following options for continuing:

- Measure more vital signs ➔ Measuring vital signs
- Enter more vital signs manually ➔ Entering vital signs manually
- Stop the measurement ➔ Stopping a measurement

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6.6 Analyzing measurement

➔ Viewing current measured results

➔ Analyzing vital signs (history)

NOTE

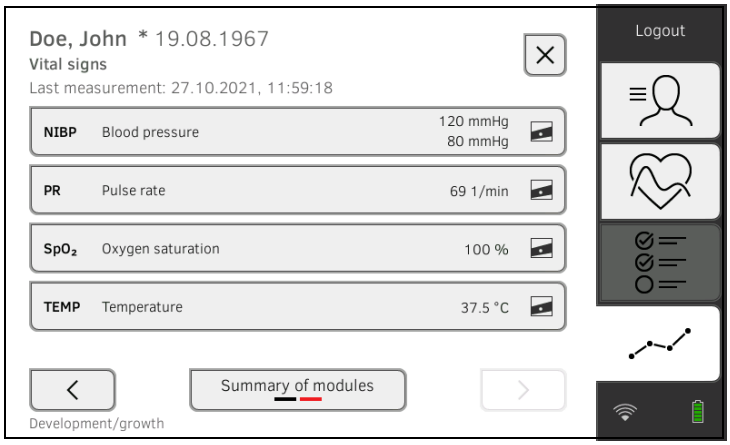
- In order to be able to view analyses, you must assign the current measurement to a seca patient file ➔ Stopping a measurement or call up a seca patient file ➔ Calling up a seca patient file.
- This section is restricted to navigation in the Analysis tab. For details about analysis parameters and modules, see the sections entitled ➔ Analysis parameters and ➔ Analysis modules.

Viewing current measured results

In order to view a summary of the current measured results, proceed as follows:

1. Press the Analysis tab.
   The module overview is displayed.

2. Press an analysis module.
   A parameter overview of the current measured results is displayed:



You have the following options for continuing:

- Press the  keys: View more analysis modules
- Press the  key: Return to the previous view

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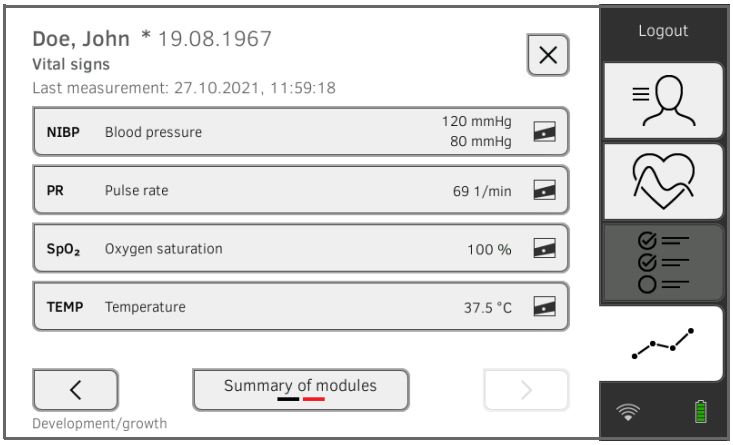
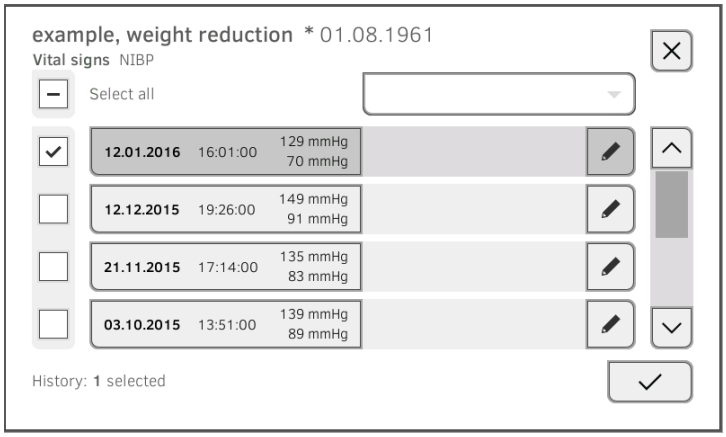
Analyzing vital signs (history)

To view the history of an analysis parameter, proceed as follows:

1. Call up a parameter overview ➔ Viewing current measured results.



2. Press the parameter whose history you wish to view.
   All measurements for the selected analysis parameter are displayed.
   The latest measurement is selected automatically:



   You have the following navigation options:

   - Press the drop-down menu: Filter measured results by period. Then continue at step 5.
   - To select values for the history individually: continue at step 4.
   - Press the  key: Add a comment
   - Press the  key: Return to the previous view

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

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

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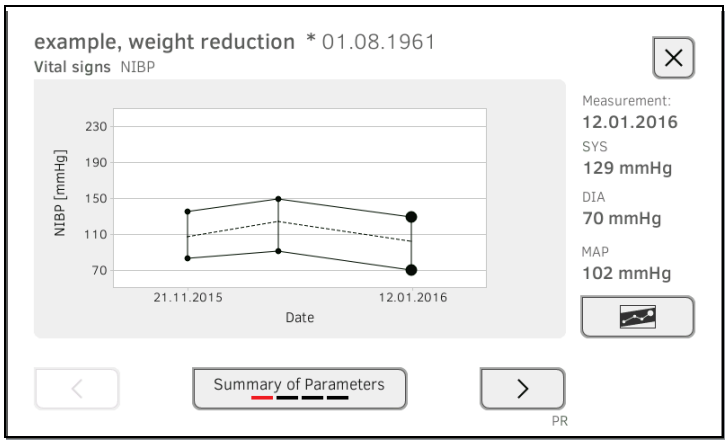
4. Press the  key.
The history is displayed (in this case three measurements)



You have the following navigation options:

- Press the  key: Select other values for history
- Press the  keys: View more analysis parameters
- Press the  key: Return to the previous view

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7. OPERATION WHEN CONNECTED TO AN EMR SYSTEM

Your administrator can set up the device so that it communicates with your EMR system. In this case, the following additional functions are available:

- Log in with EMR system user ID
- Call up EMR system patient data on the device
- Submit measured results to the EMR system
- Record clinical observations

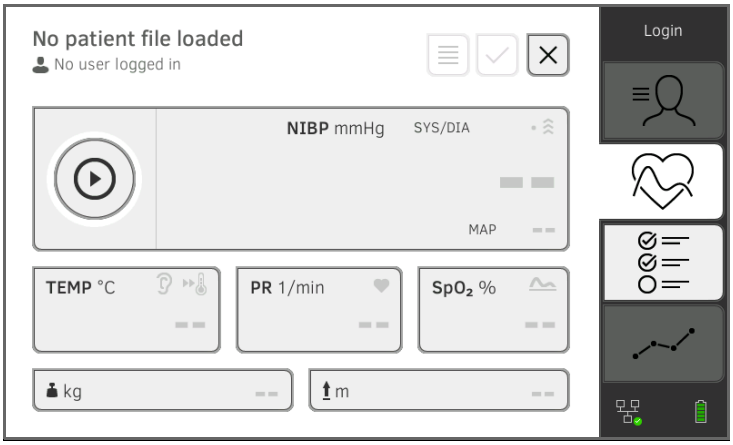
NOTICE!
Faulty operation, implausible measured results

► Connection of the device to your EMR system is based on the technical and regulatory situation in your institution. In the individual case, this may lead to the device behaving differently to the way described in these instructions for use. If you have any questions, contact your administrator.

7.1 Switching on the device

NOTE
To prevent faulty input, we recommend entering IDs with the aid of a barcode scanner; information about compatible barcode scanners can be found here: ➔ Optional accessories and spare parts.

1. Ensure that a barcode scanner is connected to the free USB interface of the device.
2. Press the ON/OFF key of the monitor.
   The LED of the ON/OFF key is white.
3. Wait until the Vital signs tab is displayed:



You have the following options for continuing:

► ➔ Measuring with an active connection to an EMR system

► ➔ Measuring with an interrupted connection to an EMR system

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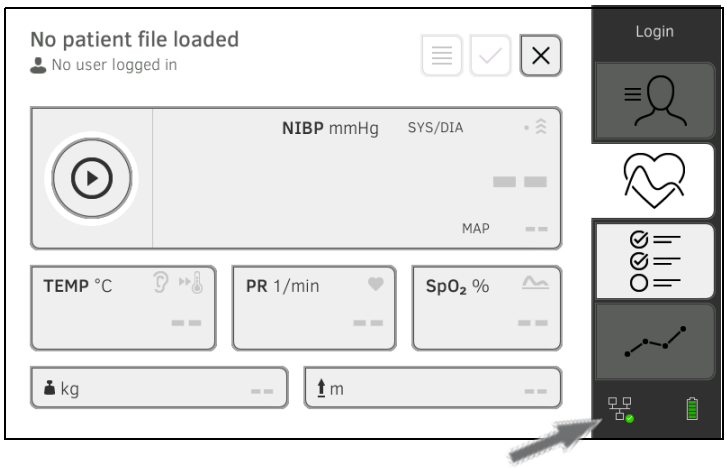
7.2 Measuring

➔ Measuring with an active connection to an EMR system
➔ Measuring with an interrupted connection to an EMR system

Measuring with an active connection to an EMR system

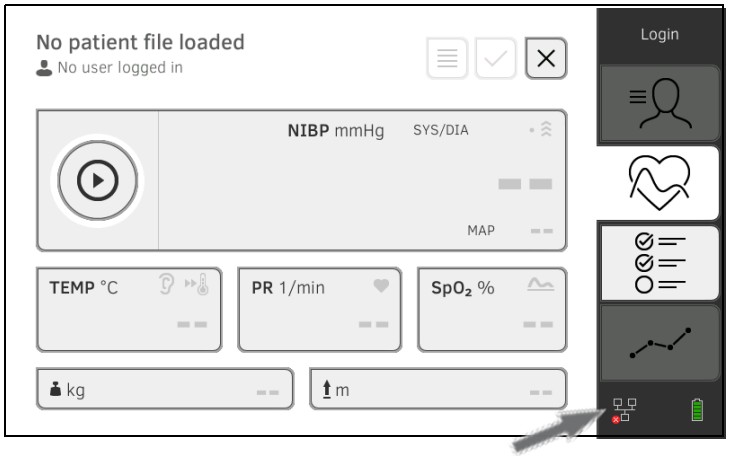


If the device has an active connection to the EMR system, proceed as described in the following sections:

1. ➔ Scanning EMR system user ID (recommended)
2. ➔ Scanning patient ID
3. ➔ Measuring vital signs
4. ➔ Adding weight and height
5. ➔ Saving measurements in the EMR system

Measuring with an interrupted connection to an EMR system

The device provides the option of performing measurements with an interrupted connection to the EMR system. The measurements are temporarily saved on the device and can be submitted as soon as the connection to the EMR system is active again.



To perform a measurement with an interrupted connection to an EMR system, proceed as follows:

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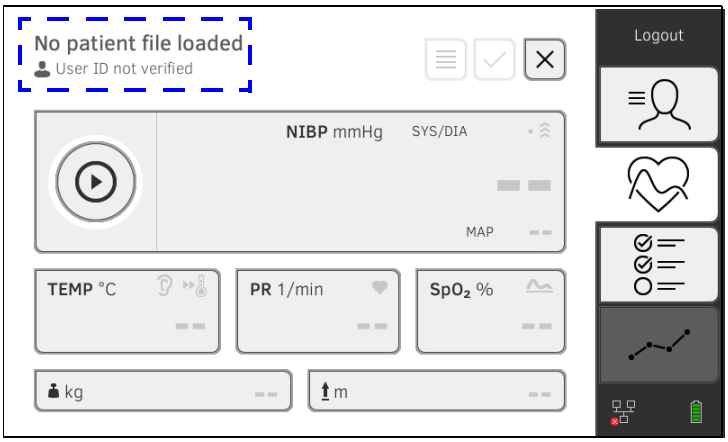
1. Log yourself in:
   a) Scan EMR system user ID
   b) Confirm status message

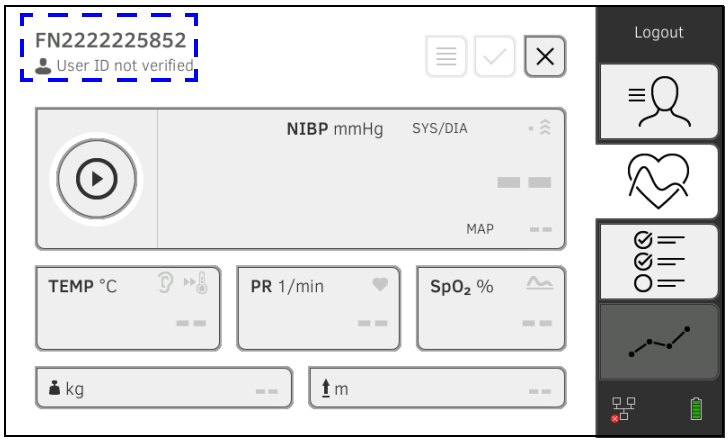
   The **User ID not verfied** message appears:



   NOTE
   If you are not sure if this function is enabled, contact your administrator.

2. Call up a patient file:
   a) Scan patient ID
   b) Confirm status message

   The patient ID is displayed:



3. Perform the measurement as described in the following sections:
   - ➔ Measuring vital signs
   - ➔ Adding weight and height
   - ➔ Stopping a measurement

   The measurement is saved in the **Unsubmitted measurements** list.
4. Log in again when the connection to the EMR system is active again.
5. Proceed as described in this section: ➔ Using the Unsubmitted measurements list.

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7.3 Logging in with EMR system user ID

If the device is connected to your EMR system, you must log in to the device using your EMR system user ID. You have the following options:

➔ Scanning EMR system user ID (recommended)

➔ Entering EMR system user ID manually

Scanning EMR system user ID (recommended)

1. Scan your EMR system user ID.

   Your EMR system user ID is displayed in the input field.
2. Enter your EMR system password.
   The Vital signs tab is displayed.
   You can call up patient data from the EMR system ➔ Calling up patient data from the EMR system.

Entering EMR system user ID manually

1. Press the **Login** key.

   The login window is displayed.
2. Enter your EMR system user ID.

   Your EMR system user ID is displayed in the input field.
3. Enter your EMR system password.
   The Patient tab is displayed.
   You can call up patient data from the EMR system ➔ Calling up patient data from the EMR system.

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7.4 Calling up patient data from the EMR system

➔ Searching for patient by name

➔ Scanning patient ID

➔ Manually entering patient ID

To call up patient data from the EMR system, you can search for patients by name or use the patient ID.

The two search functions (patient name and patient ID) are not available simultaneously. This is set in the **seca connect 103** software. For more information, contact your administrator ➔ Information about user and patient data.

Searching for patient by name

1. Log in ➔ Logging in with EMR system user ID.
2. Press the Patient tab.
   The patient list is displayed:

3. Search for the desired patient:

   a) Press the input field 

   b) Use the keypad  : Enter the patient's name

NOTE

- A help text in the input field indicates the sequence in which surname and first name are to be entered. This setting is specified by your administrator ➔ Making regional settings.
- The additional input of first name or surname in second place (depending on administrator setting) is optional. Refine your search if necessary by also entering first name or surname.
- If you enter both surname and first name, there must be a space between surname and first name. There must not be a space within the surname or within the first name.

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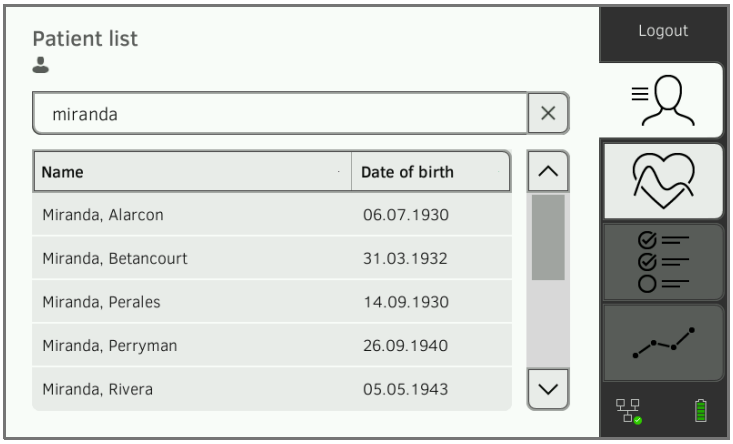
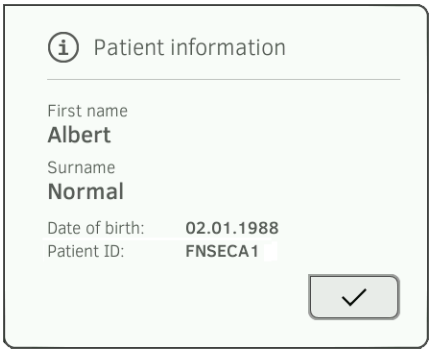
- Enter at least the first letter of the name. Refine your search if necessary by entering more letters or the whole name.

c) Press the  key: Confirm entry

A hit list is displayed (example):



4. Use the scroll bar if necessary to display more patient data.
5. Select a patient:
   - ► Desired entry not visible: Repeat step 3. and step 4.
   - ► Desired entry visible: Continue at step 6.
6. Press the desired entry.
   The patient data are shown in the **Patient information** dialog window.



7. Ensure that the patient data displayed are correct.
8. Press the  key.
   The patient data are transmitted to the device and displayed in the Vital signs tab.

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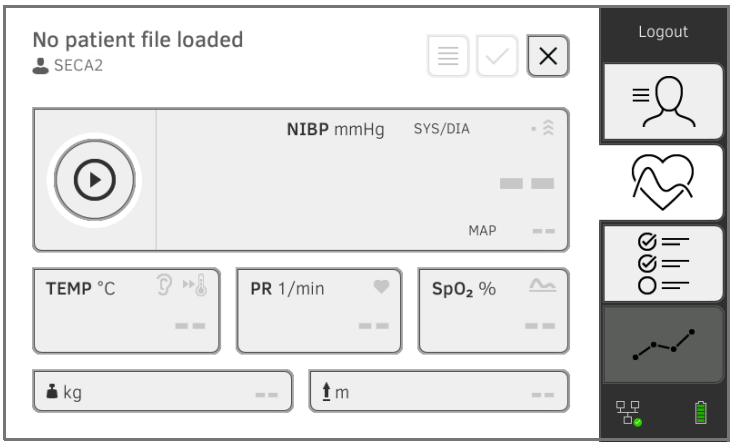
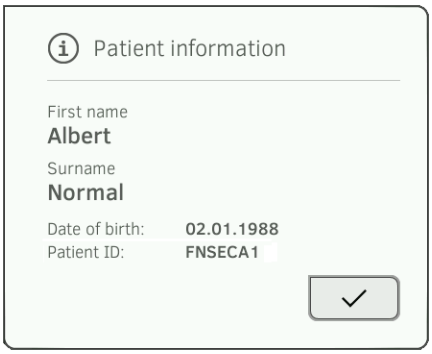
Scanning patient ID

If you logged in from the Vital signs tab using a scanner (➔ Logging in with EMR system user ID), the Vital signs tab continues to be shown after login:



1. Scan the patient ID.
   The patient data are shown in the **Patient information** dialog window.



2. Ensure that the patient data displayed are correct.
3. Press the  key.
   The patient data are transmitted to the device and displayed in the Vital signs tab.

Manually entering patient ID

NOTE
We recommend scanning the patient ID (➔ Scanning patient ID).

If you logged in using a keypad (➔ Entering EMR system user ID manually), the Patient tab is shown after login:

1. Press the **Find patient file** key.

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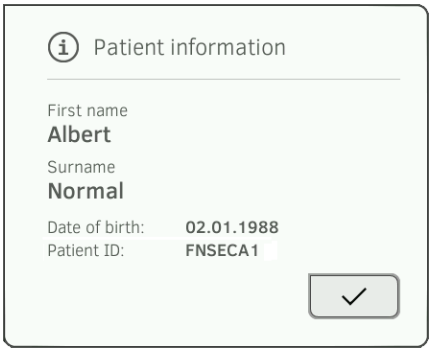
2. Enter patient ID using the keypad  .
   The patient data are shown in the **Patient information** dialog window.



3. Ensure that the patient data displayed are correct.
4. Press the  key.
   The patient data are transmitted to the device and displayed in the Vital signs tab.

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7.5 Saving measurements in the EMR system

➔ Submitting the measurement directly to the EMR system

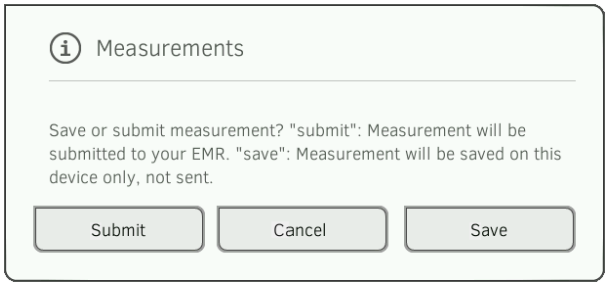
➔ Saving measurement temporarily and submitting it later

➔ Using the Unsubmitted measurements list

Submitting the measurement directly to the EMR system

To submit a measurement directly to the EMR system, proceed as follows:

1. In the Vital signs tab, press the  key.
2. In the dialog window, press the **Submit** key:

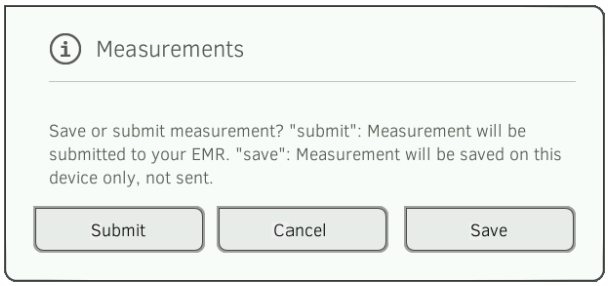


The measurement is submitted to the EMR system and assigned to the EMR system patient file.
The measurement procedure is complete.
The patient data are removed from the display.

Saving measurement temporarily and submitting it later

You can temporarily save a measurement on the device, for example to have the measured results assessed by a third party. The measurement can then be submitted to the EMR system. This ensures that only plausible measured results are saved in the EMR system.

1. In the Vital signs tab, press the  key.
2. In the dialog window, press the **Save** key:



The measurement is assigned to the patient ID and saved temporarily on the device.
The measurement procedure is complete.
The measurement can be assessed in the Unsubmitted measurements list and submitted to the EMR system ➔ Using the Unsubmitted measurements list.

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Using the Unsubmitted measurements list

➔ Confirming offline measurement (EMR system connection)

➔ Viewing details

➔ Submitting the measurement

➔ Deleting a measurement

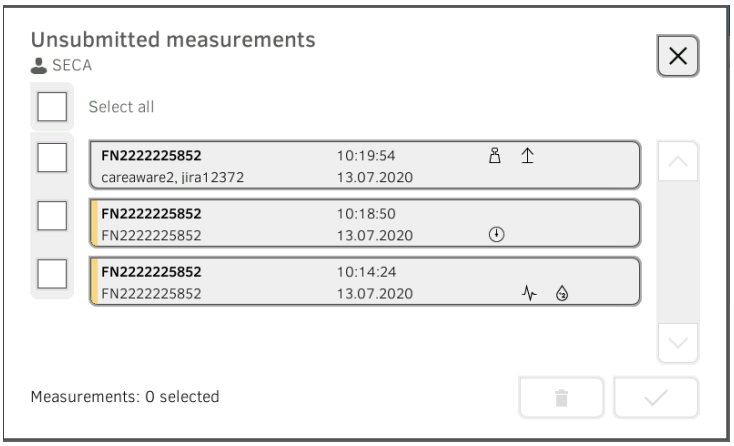
In the **Unsubmitted measurements** list, you can view and assess the details of a measurement before submitting the measurement to the EMR system. The list is available in the Patient and Vital signs tabs:

A measurement appears in the list under the following conditions:

- In the **Measurements** dialog window, press the **Save** key ➔ Saving measurement temporarily and submitting it later.
- The measurement cannot be submitted because the connection to the EMR system is interrupted.

To open the **Unsubmitted measurements** list, proceed as follows:

1. Log in ➔ Scanning EMR system user ID (recommended).
2. Ensure that the Patient and Vital signs tabs are active.
3. Press the  key.
   The **Unsubmitted measurements** list is displayed:



NOTE
Measurements marked yellow (offline measurement) contain unconfirmed patient data - because the connection to the EMR system was interrupted, for example.

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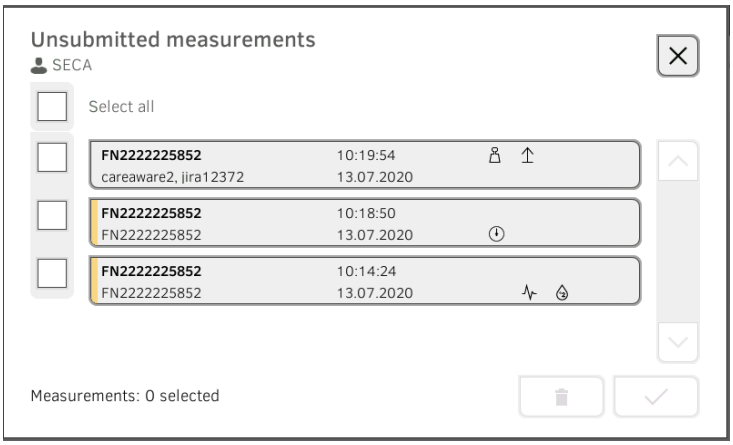
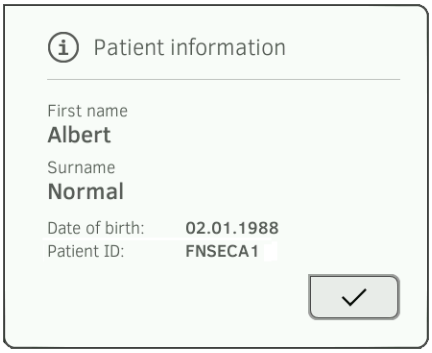
Confirming offline measurement (EMR system connection)

Measurements marked yellow (offline measurement) contain unconfirmed patient data - because the connection to the EMR system was interrupted during patient/user identification, for example. These measurements have to be confirmed before you can view details or submit the measurement to your EMR system.

1. Ensure that the connection to the EMR system is active.
2. Press an offline measurement (marked yellow).



The patient data are displayed in the **Patient information** dialog window:



3. Ensure that the patient data displayed are correct.
4. Press the  key.
   The measurement is confirmed.
   The yellow marking is no longer displayed in the **Unsubmitted measurements** list.
   The details of the measurement are displayed ➔ Viewing details.

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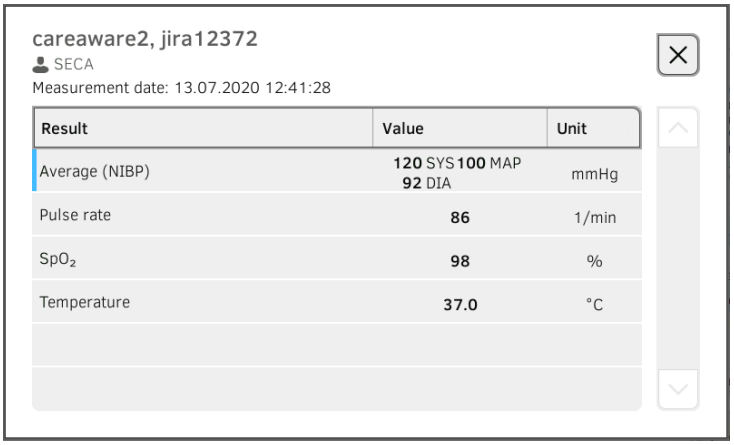
Viewing details

1. Press a measurement.
   The details of the measurement are displayed:

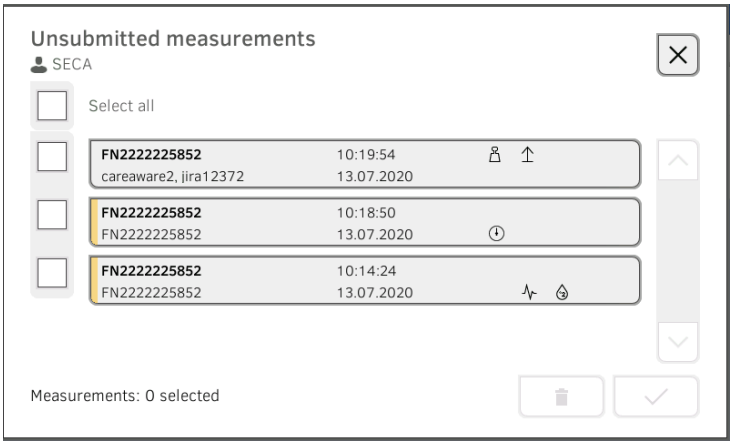


NOTE
Measurements marked blue contain mean values. If you press the measurement, you can view the individual results.

2. Press the  key to close Detail view.

Submitting the measurement

1. Ensure that the connection to the EMR system is active:
2. Press the checkboxes  of the measurements to be submitted:



3. Press the  key.
   The measurements are submitted to the EMR system.
   The measurements are deleted from the list.

NOTE

- Only confirmed measurements are submitted ➔ Confirming offline measurement (EMR system connection).
- In the EMR system, measurements from the **Unsubmitted measurements** list are assigned to the user who submitted them, not to the user who performed them.

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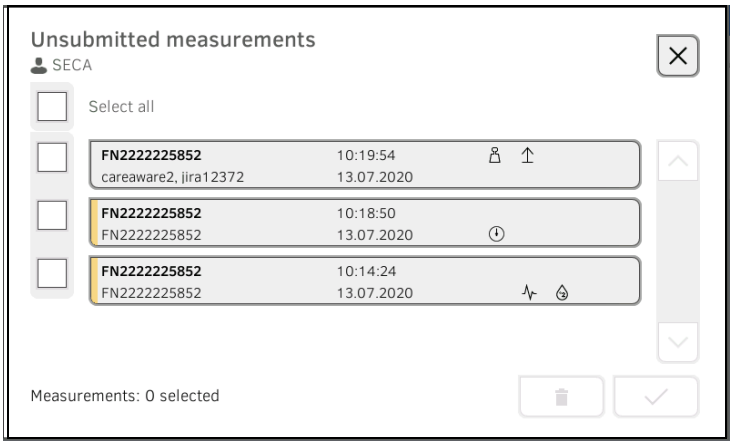
Deleting a measurement

1. Press the checkboxes  of the measurements to be deleted:



2. Press the  key.
   The selected measurements are deleted.

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7.6 Recording clinical observations

➔ Introduction

➔ Entering/amending clinical observations

Introduction

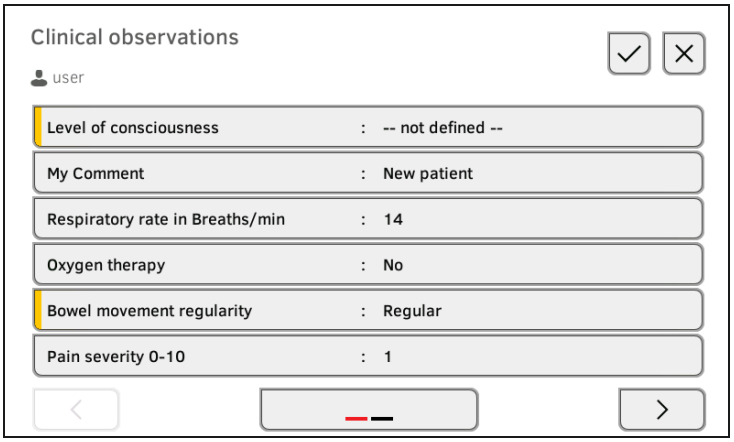
The device provides the option of recording clinical observations. The options for inputting clinical observations are configured in line with the specifications of your institution.

NOTE
If there is no configuration on the device or if you want to change the configuration of the clinical observations, contact your administrator.

You can enter clinical observations without login and without patient identification. We recommend calling up a patient file ➔ Calling up a seca patient file **before** making your entry. Clinical observations can be submitted to the EMR system together with other vital signs in the Vital signs tab.

Entering/amending clinical observations

1. Press the Clinical observations tab.
   The list of parameters is displayed (example for a configuration):



2. Press the  keys to navigate on the pages and to view other parameters.

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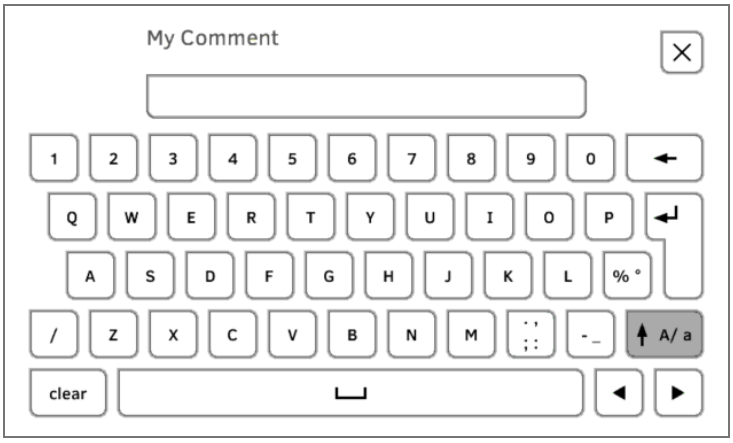
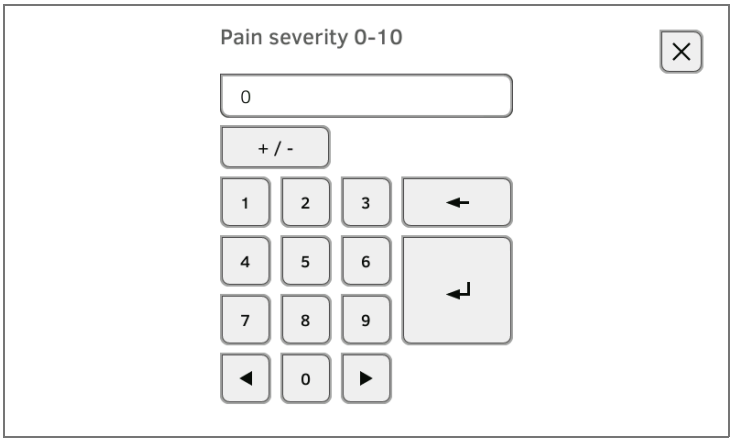
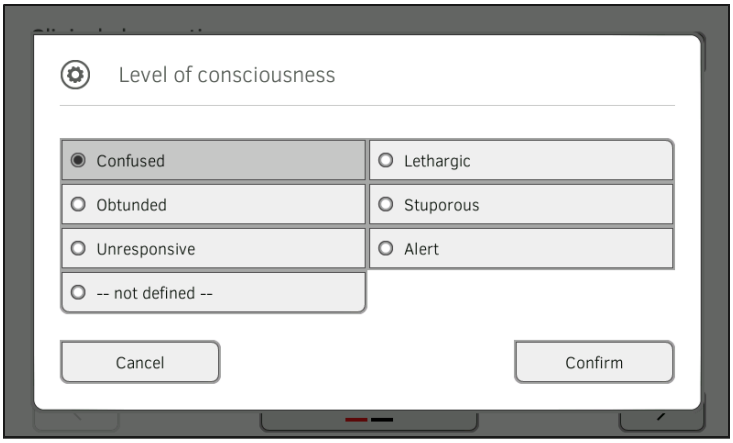
3. Press the parameter for which you would like to enter or amend an observation.
   You have the following options for input depending on configuration:
   - Enter free text (example):



   - Enter a numerical value (example):



   - Select a value from the option field (example):



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4. Enter the observation.
   You have the following options for continuing:
   - Enter more observations ➔ Recording clinical observations
   - Press the  key: Adopt observations
   - Press the  key: Delete observations
   - Submit all observations to the EMR system: ➔ Saving measurements in the EMR system

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8. HYGIENE TREATMENT

➔ Cleaning

➔ Disinfecting

➔ Sterilizing

➔ Removing/fitting probe holder (devices with temperature probe)

➔ Removing/fitting the magazine holder (devices 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 including the active ingredient 70 % isopropanol only for measuring accessories for measuring vital signs.

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8.1 Cleaning

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

Component (depending on version)	Interval	Cleaning
seca mVSA 535: Monitor with SmartBucket	As required	1. Remove all the measuring accessories (measuring devices and consumables) from the device (depending on version) • ➔ Removing the probe holder • ➔ Removing the magazine holder 2. Moisten a soft cloth with a soap solution 3. Wipe over all surfaces 4. 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 2. Clean blood pressure cuff and compressed air tube 3. Rinse thoroughly with water 4. Allow to dry at room temperature
Temperature probe (red/blue) with cable	As required	1. Discard probe cover and dispose of it 2. Moisten a soft cloth with a mild soap solution 3. Clean temperature probe 4. Shake out temperature probe so that no liquid remains in it 5. Allow to air-dry for approx. 30 minutes
Probe holder (red/blue)	As required	1. ➔ Removing the probe holder 2. Moisten a cotton bud with a mild soap solution 3. Wipe over all the surfaces of the probe holder
In-ear thermometer	After every use	In-ear thermometer and cable: 1. Do **not** discard probe cover 2. Moisten a soft cloth with a mild soap solution: Ratio of water to soap solution: 20:1, temperature: Max. 55 °C (130 °F) 3. Wring out the cloth so that no excess liquid can penetrate the in-ear thermometer 4. Wipe over in-ear thermometer and cable 5. Dry the in-ear thermometer and cable using a lint-free cloth 6. Discard probe cover
	As required	Measuring head and lens: 1. Carefully remove all foreign particles using a cloth moistened with alcohol (70 % isopropanol) 2. Wipe dry the lens at the tip of the measuring head with a lint-free cloth (e.g. spectacle-cleaning cloth) 3. Make sure that the lens at the tip of the measuring head does not have any fingerprints or marks on it 4. Allow the in-ear thermometer to air-dry completely
Magazine holder for probe covers (in-ear thermometer)	As required	1. ➔ Removing the magazine holder 2. Moisten a soft cloth or cotton bud with a mild soap solution 3. Wipe over the surfaces of the magazine holder 4. Allow the magazine holder to air-dry completely
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	

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8.2 Disinfecting

1. Follow the instructions for use for the disinfectant.
2. Disinfect the device and its accessories as described in the table:

Component (depending on equipment)	Interval	Disinfecting
seca mVSA 535: Monitor with SmartBucket	As required	1. Remove all the measuring accessories (measuring devices and consumables) from the device (depending on version): • ➔ Removing the probe holder • ➔ Removing the magazine holder 2. Moisten a soft cloth with disinfectant (active ingredient: quaternary ammonium compounds) 3. Wipe over all surfaces 4. Allow to air-dry for approx. 30 minutes
Blood pressure cuff and compressed air tube	As required	1. Moisten a soft cloth with disinfectant (active ingredient: 70 % isopropanol) 2. Wipe over cuff and compressed air tube 3. Rinse thoroughly with water 4. Allow to dry at room temperature
Temperature probes (red/blue) with cable	As required	1. Discard probe cover and dispose of it 2. Moisten a soft cloth with disinfectant (active ingredient: 70 % isopropanol) 3. Wipe over temperature probe 4. Shake out temperature probe so that no liquid remains in it 5. Allow to air-dry for approx. 30 minutes
Probe holder (red/blue)	As required	1. ➔ Removing the probe holder 2. Moisten a cotton bud with disinfectant (active ingredient: 70 % isopropanol) 3. Wipe over the inside of the probe holder 4. Allow to air-dry for approx. 30 minutes
In-ear thermometer, cable, measuring head and lens	As required	1. Discard probe cover and dispose of it 2. Wipe over in-ear thermometer several times with a cloth moistened with alcohol (70 % isopropanol) so that all surfaces are visibly moist for at least one minute 3. Make sure that the lens at the tip of the measuring head does not have any fingerprints or marks on it 4. Allow the in-ear thermometer to air-dry completely
Magazine holder for probe covers (in-ear thermometer)	As required	1. ➔ Removing the magazine holder 2. Moisten a cotton bud with disinfectant (active ingredient: quaternary ammonium compounds) 3. Wipe over surfaces 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	

8.3 Sterilizing

This device may not be sterilised.

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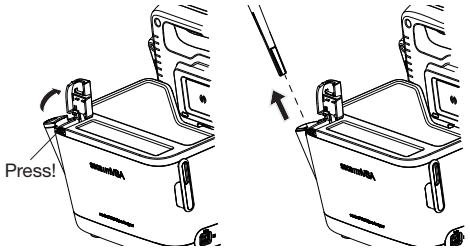
8.4 Removing/fitting probe holder (devices with temperature probe)

WARNING!
Patient hazard
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.

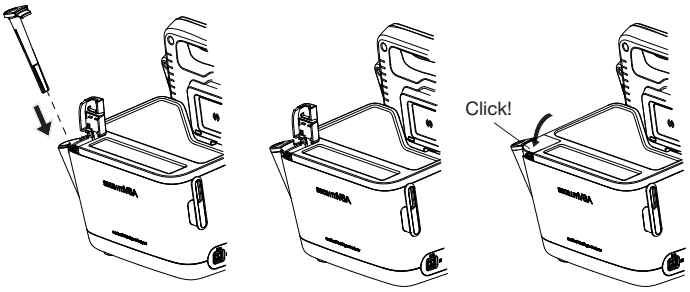
Removing the probe holder

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



Fitting the 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.

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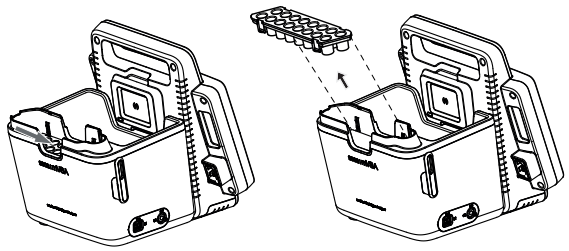
8.5 Removing/fitting the magazine holder (devices with in-ear thermometer)

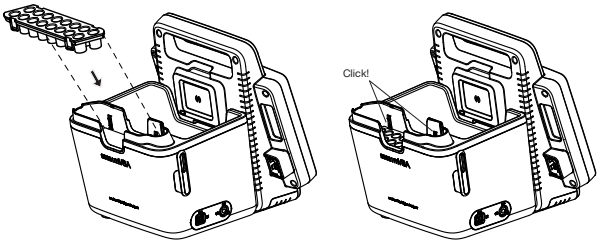
Removing the magazine holder

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



Fitting the magazine holder

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



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9. FUNCTION CHECK

9.1 Device

► 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 “Troubleshooting” 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 “Troubleshooting” 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.

9.2 COVIDIEN™ GENIUS®3 in-ear thermometer

For the COVIDIEN™ GENIUS®3 in-ear thermometer, the manufacturer CardinalHealth™ recommends a function check if one of the following situations applies:

- In-ear thermometer was not used in accordance with purpose
- In-ear thermometer was dropped
- In-ear thermometer was stored below -25 °C or above +55 °C

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10. SERVICING

10.1 Device

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.

10.2 COVIDIEN™ GENIUS®3 in-ear thermometer

For the COVIDIEN™ GENIUS®3 in-ear thermometer, the manufacturer CardinalHealth™ recommends performing calibration regularly every 25 weeks. The COVIDIEN™ Genius Checker/Calibrator is required for calibration. If you do not have a COVIDIEN™ Genius Checker/Calibrator available, get in touch with your contact at CardinalHealth™.

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11. TROUBLESHOOTING

11.1 Monitor

Fault	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 off	Device on standby	• Touch the touchscreen display • Press the ON/OFF key
	Device not switched on	Switch on 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 key for approx. 15 seconds) • Switch the device back on
Image on touchscreen display faulty	Touchscreen display faulty	Inform seca Service
Password not accepted	Following a backup, the old passwords are valid again	• Use the old password
		Administrator: • If you no longer know the old password, assign a new password • Have the administrator password reset by seca Service
Vital signs tab not active	USB connecting cable of the SmartBucket not connected to the monitor	• Connect the USB connecting cable of the SmartBucket to the monitor • Restart the device
Patient and user data cannot be restored manually	USB stick contains several backup copies	Ensure that there is only one folder on the USB stick with the designation **<ddMMyyyy_hhmm>_seca_monitor_backup** (if necessary, rename other folders)
	Backup copy on the USB stick has been renamed	Ensure that backup copies are saved in the folder with the designation **<ddMMyyyy_hhmm>_seca_monitor_backup** (if necessary, rename folders)

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11.2 Vital signs measurement

➔ General

➔ Blood pressure measurement

➔ COVIDIEN™ FILAC™ 3000 temperature measurement

➔ COVIDIEN™ GENIUS®3 temperature measurement

➔ SpO_2 measurement

General

Fault	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 • Restart the device
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 • USB extension cable also in use	• Use original seca USB connecting cable (in scope of delivery for the wheeled stand) • Do not use a USB extension cable
Manual vital signs input not possible	Measured values outside permitted range	Observe permitted range, technical data: ➔ Manual input of vital signs

Blood pressure measurement

Fault	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 • Only use seca blood pressure cuffs
	Blood pressure cuff not applied correctly	Apply blood pressure cuff correctly, 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 • 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
No option to select Multiple measurement in the NIBP settings dialog window	Administrator has configured a measuring profile. The name of the measuring profile is displayed	Not a malfunction • Press the name of the measuring profile • ➔ Performing a multiple measurement.
Blood pressure values do not appear in the EMR system	Multiple measurement was performed	For current measurement: • ➔ Modifying presets and ➔ Starting a single measurement Administrator: • Specify Individual measurement as preset ➔ Presets for blood pressure

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COVIDIEN™ FILAC™ 3000 temperature measurement

Fault	Cause	Remedy
No temperature measurement possible	Temperature module of the SmartBucket not activated	Administrator: Activate temperature module: **System\SmartBucket** tab
Implausible measured results, temperature measurement unsuccessful	Special patient condition, such as hypothermia	• Assess patient vital signs using alternative means • 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: • Physical exertion • Eating/drinking • Brushing teeth • 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 to suit the probe used • Set correct measuring position on device
	No probe cover used	• Disinfect the temperature probe ➔ Disinfecting • 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 • Discard probe cover • Push the temperature probe into the probe cover

COVIDIEN™ GENIUS®3 temperature measurement

Fault	Cause	Remedy
No temperature measurement possible	Temperature module of the SmartBucket not activated	Administrator: Activate temperature module: **System\SmartBucket** tab
	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	

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Fault	Cause	Remedy
	Ambient temperature exceeds permitted range	• Modify ambient temperature • Perform measurement at a location with an ambient temperature within the permitted range
	Ambient temperature undershoots permitted range	
Measurement does not start	No probe cover used	• Disinfect the in-ear thermometer ➔ Disinfecting • 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
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 • Opening in probe cover blocked	• Clean measuring head • 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 instructions for use for in-ear thermometer)
	In-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 key on the in-ear thermometer • Change units on the monitor (administrator rights required)
	Internal memory: Checksum error	• Put on a new probe cover and repeat measurement. • If the error occurs again, contact seca Service
	Thermometer no longer calibrated	• Do not continue using device • Contact seca Service

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SpO_2 measurement

Fault	Cause	Remedy
Implausible measured results	Intra-aortic balloon pump affecting pulse rate	Check pulse rate using ECG
	Sensor damp	• Dry sensor • 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 • Align interfering device differently or set up in a different location • Increase the distance between this device and the interfering device
	Poor perfusion	• Assess patient vital signs using alternative means • Apply blood pressure cuff to location with better perfusion
Measurement not possible	Masimo SET® only: Sensor service life expired	Use new Masimo SET® sensor.
	Sensor or patient cable defective	Dispose of sensor or patient cable, use spare part
Measurement not possible	Sensor or patient cable defective	Dispose of sensor or patient cable, use spare part
Pulse is not found or is lost	Sensor too rigid	• Use suitable size of sensor • Apply sensor to a different finger
	Strong ambient light	Cover application site with opaque material
	Poor perfusion	• Assess patient vital signs using alternative means • Apply sensor to a location with better perfusion

11.3 Network connection

Fault	Cause	Remedy
No WiFi connection	WiFi function of device is deactivated	Administrator: Activate WiFi
	Distance between monitor and WiFi router is too big	• Reduce distance • Transmit measured results to **seca connect 103** software via LAN
	WiFi not available in your institution	Transmit measured results to **seca connect 103** software via LAN
No network connection	Firewall: ports required are not enabled	Administrator: Enable required ports in firewall ➔ Monitor interfaces and network ports
	Firewall/gateway configuration does not permit use of LAN and WiFi in parallel	Administrator: Deactivate one of the two transmission options on the device.

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11.4 EMR system connection via seca connect 103 software

For more information on using the **seca connect 103** software, see the **seca 103/452** system instructions for use.

Fault	Cause	Remedy
Data transmission cannot be set up between device and seca connect 103	Software versions not compatible	Administrator: Use a compatible version of the **seca connect 103** software ➔ Compatibility
Unable to find user ID	No connection to the server	Administrator: Check server connection
	User ID not recognized by the server	Ensure that user ID is valid
Unable to find patient ID	No connection to the server	Administrator: Check server connection
	Patient ID not recognized by the server	Ensure that patient ID is valid
Unable to scan IDs	Scanner not connected correctly	Ensure that the USB stick is correctly located in the USB interface
	Barcode scanner incompatible	Use compatible barcode scanner
	Scanner defective	Replace scanner
There is no request for a password following input of the EMR user ID. The Vital signs tab is displayed immediately	Not a malfunction: The device connection to the EMR system has been configured so that no password needs to be entered.	Administrator: Modify configuration in the **seca connect 103** software if necessary. Contact seca Service.
Unable to find EMR system patient data	No patient file available in the EMR system	Create patient file in the EMR system
	Error scanning patient ID	Scan patient ID again
	No network connection to the EMR system	Administrator: Check the network connection and set up again if necessary
Login using EMR system user ID not possible	EMR system connection interrupted, device set up so that no measurements are possible	Administrator: Modify configuration in the **seca connect 103** software if necessary. Contact seca Service.
Blood pressure values do not appear in the EMR system	Multiple measurement was performed	For current measurement: • ➔ Modifying presets and ➔ Starting a single measurement Administrator: • Specify Individual measurement as preset ➔ Presets for blood pressure
Not possible to submit measured results to the EMR system	Network cable not plugged in correctly	Check whether the network cable is connected correctly and that the connectors are firm in their sockets
	Network cable defective	Replace network cable
	Device outside WiFi range	Bring device into WiFi range
	No network connection to the EMR system	Administrator: Check the network connection and set up again if necessary
	Network connection interrupted	If network connection active ➔ Using the Unsubmitted measurements list

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11.5 Clinical observations

Fault	Cause	Remedy
Impossible to update configuration file	Saved clinical observations not sent to the EMR system	➔ Submitting the measurement
	User or administrator logged in to the device	Log out of the device ➔ Logging out/ switching user
Impossible to delete configuration file	Saved clinical observations not sent to the EMR system	➔ Submitting the measurement
Clinical observations tab not active	Clinical observations function not available in stand-alone operation	Administrator: • Check whether stand-alone operation or connection to an EMR system is desired • If necessary, set up a connection to an EMR system
	Configuration file invalid	Administrator: Note error message in **System** tab in the **Data management** area

11.6 seca 360°proximity connection

Fault	Cause	Remedy
Weight or height values do not appear in the display	No **seca 360° proximity** connection set up	Administrator: ➔ Setting up a seca 360° proximity connection
	Network connection interrupted	• LAN: Ensure that the network cable is correctly plugged in and is not damaged • WiFi: Reduce distance from router
	seca scale/measuring rod incorrectly configured	Administrator: Configure seca scale/ measuring rod as follows: • Scan user ID: Required • Scan patient ID: Required • Confirmation of measurement on seca measuring device: Required • Port used: Port configured for communication with the **seca connect 103** software (default: 22020) ➔ Setting up a connection to the seca connect 103 software • Follow **seca 103/452** system instructions for use
	No measurement has yet been performed using the seca scale/ measuring rod	Perform measurement as described in the instructions for use for the seca scale/seca measuring rod
	seca scale/measuring rod has not submitted a value	Submit value as described in the instructions for use for the seca scale/seca measuring rod
An error message appears in the Weight or Height field	An error occurred on the seca scale/ measuring rod	• Note error message on the display of the seca scale/seca measuring rod • Eliminate error as described in the instructions for use for the seca scale/ seca measuring rod. • Follow **seca 103/452** system instructions for use • If you are unable to eliminate the error, contact seca Service.

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12. TECHNICAL DATA

12.1 Monitor

Dimensions, weights	
Monitor with SmartBucket (seca mVSA 535)	
Dimensions, empty (**seca mVSA 535** for temperature probe) • Depth • Width • Height	 278 mm 254 mm 262 mm
Dimensions, empty (**seca mVSA 535** for in-ear thermometer) • Depth • Width • Height	 278 mm 252 mm 262 mm
Net weight (**seca mVSA 535**)	approx. 3 kg

Further technical data (all models)	
Ambient conditions, operation • Temperature (with COVIDIEN™ FILAC™ 3000) • Temperature (with COVIDIEN™ GENIUS®3) • Air pressure • Humidity	 +10 °C to +40 °C (50 °F to 104 °F) +16 °C to +33 °C (60,8 °F to 91,4 °F) 700 hPa - 1060 hPa 20 % - 80 %, no condensation
Ambient conditions, storage • Temperature • Air pressure • Humidity	 -10 °C to +55 °C (14 °F to 131 °F) 700 hPa - 1060 hPa 15 % - 95 %, no condensation
Ambient conditions, transport • Temperature • Air pressure • Humidity	 -10 °C to +55 °C (14 °F to 131 °F) 700 hPa - 1060 hPa 15 % - 95 %, no condensation
Setup location, maximum altitude above MSL	3000 m
Display type	7" touchscreen display
Power supply for monitor, input • Type • Power supply voltage • Power supply frequency • Current consumption	 Internal power supply unit, IEC 60320 C13 100 V ~ - 240 V ~ 50 Hz - 60 Hz 0,85 A
Mobile power supply Voltage Capacity Range (:: full brightness, new rechargeable battery)	Lithium-ion battery 11,25 V 2950 mAh approx. 5 h
Power consumption • Standby (touchscreen display off, ON/OFF key green) • In operation (ON/OFF key white) • Operation (charging rechargeable battery for monitor ON/OFF key is white)	 < 5 W < 9 W < 35 W
Medical device in accordance with Richtlinie 93/42/EWG	Class IIa

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Further technical data (all models)	
IEC 60601-1: Insulated device, protection class: **seca mVSA 535**	II
Type of protection **seca mVSA 535**	IP21
Duty cycle	Continious duty
Interfaces	2 x USB 2.0 (max 500 mA) LAN: Ethernet (10/100 Base-T) WiFi: 2.4 GHz (WPA, WPA2 PSK, WPA2 Enterprise PEAP RADIUS, EAP-TLS)

12.2 Monitor interfaces and network ports

Interfaces and network ports

Interfaces	Protocol	Data transmission rate	Factory setting
WiFi:	IEEE 802.11 b/g/n	Up to 72.2 Mbps	Off
LAN:	IEEE 802.3u	100 Mbit/s	On
Connect port:	Proprietary	n/a	22020
USB (2 ports):	USB 2.0	480 Mbit/s per port	On

Recommended WiFi settings

This table contains settings for optimal WiFi performance.

Settings	Recommended settings	Consequences in the event of different settings
Authentication/ encryption	• WPA2 Personal • WPA2 Enterprise (EAP-TLS, PEAP RADIUS)	No network connection, other encryption methods not supported
Frequency band	• Single band 2.4 MHz • IEEE 802.11 b/g/n	–
Data transmission rate	Up to 72.2 Mbps	–
Network configuration	DHCP	Manual network configuration required if connection is to be made to **seca connect 103** software or via **seca 360° proximity**
Firewall/ ports to be opened	Connect port: 22020	No connection to **seca connect 103** software
Separate VLAN	No special requirements	–
QoS	No special requirements	–
VoiP	No special requirements	–
WiFi multimedia	No special requirements	–
Network latency	No special requirements	–
IT support	No special requirements	–
Redundant power supply	No special requirements	–

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12.3 Vital signs measurement

➔ Blood pressure measurement

➔ COVIDIEN™ FILAC™ 3000 temperature measurement

➔ COVIDIEN™ GENIUS®3 temperature measurement

➔ Masimo SET® SpO_2 measurement

➔ seca SpO_2 measurement

➔ Manual input of vital signs

Blood pressure measurement

seca blood pressure module	
Measuring method	• Oscillometric • Possible to switch between upward and downward measurement • Single measurement • Multiple measurement can be configured: Max. 6 measurements in max. 30 minutes
Maximum pressure, upward measurement Initial cuff pressure, downward measurement Maximum cuff pressure	Can be set: 80 mmHg - 280 mmHg (260 mmHg cannot be set) Can be set: 80 mmHg - 280 mmHg (260 mmHg cannot be set) 300 mmHg
Measuring range for blood pressure Upward measurement: • Systolic BP • Diastolic BP • Mean arterial pressure Downward measurement: • Systolic BP • Diastolic BP • Mean arterial pressure	 77 mmHg - 200 mmHg 45 mmHg - 190 mmHg 56 mmHg - 193 mmHg 25 mmHg - 280 mmHg 10 mmHg - 220 mmHg 15 mmHg - 260 mmHg
Accuracy (under laboratory conditions, verified with CuffLink patient simulator from Fluke)	max. ± 3 mmHg / 2 %, the larger value in each case applies
Measuring accuracy for blood pressure (determined by the manufacturer of the measuring module in clinical trial in accordance with DIN EN ISO 81060) Upward measurement: • Mean deviation of systolic BP • Standard deviation of systolic BP • Mean deviation of diastolic BP • Standard deviation of diastolic BP Downward measurement: • Mean deviation of systolic BP • Standard deviation of systolic BP • Mean deviation of diastolic BP • Standard deviation of diastolic BP	 0,36 mmHg 4,27 mmHg -0,12 mmHg 3,78 mmHg 0,10 mmHg 3,24 mmHg -0,20 mmHg 2,95 mmHg
Pressure transducer: • Accuracy • Resolution	 ±1 mmHg 1 mmHg
• Leakage rate • Limit value for pressure • Switch off and release pressure in the event of (a first fault)	< 3 mmHg/min 300 mmHg > 330 mmHg
Measuring time for blood pressure: • Normal • Maximum (adults)	 15 - 20 s 90 s

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seca blood pressure module	
Pulse rate: • Measuring range for upward measurement • Measuring range for downward measurement • Accuracy (under laboratory conditions, verified with CuffLink patient simulator from Fluke)	 45 min^{-1} - 200 min^{-1} 30 min^{-1} - 240 min^{-1} max. ± 3 min^{-1} / 3 %, the larger value in each case applies
IEC 60601-1: Medical electrical device, type BF (defibrillation-protected)	

COVIDIEN™ FILAC™ 3000 temperature measurement

COVIDIEN™ FILAC™ 3000 temperature module	
Measurement modes	Direct, predictive
Measuring position: Blue probes Red probes	 Oral, axillary Rectal
Measuring range • Direct mode • Predictive mode	 30 °C - 43 °C (86 °F - 109,4 °F) 35,5 °C - 42 °C (95,9 °F - 107,6 °F)
Measuring time (following application at measuring position) Direct: • All measuring positions Predictive: • Oral, no fever • Oral, fever • Axillary • Rectal	 60 - 120 sec 3 - 5 sec 8 - 10 sec 8 - 12 sec 10 - 14 sec
Switchover time from predictive mode to direct mode • Measuring position not detected (following removal from probe cover) • No stable temperature value obtained (following application)	 60 sec 70 sec
Accuracy (water bath): • Direct mode • Predictive mode	 ± 0,1 °C (± 0,2 °F) ± 0,1 °C (± 0,2 °F)
IEC 60601-1: Medical electrical device, type BF	
Type of protection against ingress of liquids	IP21

Clinical accuracy[a] [b]			
Measuring position:	**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
σ_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 measuring position in question. Clinical repeatability σ_r is independent of age. The reference body sites of the reference thermometer used in the clinical study correspond to the measuring positions quoted.

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

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COVIDIEN™ GENIUS®3 temperature measurement

COVIDIEN™ GENIUS®3 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 • Ambient temperature: 16 °C - 33 °C (60,8 °F - 91,4 °F) Target temperature: 33 °C - 42 °C (91,4 °F - 107,6 °F)	± 0,3 °C (± 0,5 °F)
IEC 60601-1: Medical electrical device, type BF	
Type of protection against ingress of liquids	IP22

Masimo SET® SpO_2 measurement General technical data

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

a. The accuracy of the Masimo SET® technology with Masimo sensors was validated with no movement in human blood studies with induced hypoxia on healthy adult male and female volunteers with light to dark skin pigmentation in the range from 70 - 100 % for SpO_2 compared to a laboratory CO oximeter and ECG monitor. This fluctuation corresponds to ± 1 standard deviation. Plus or minus one standard deviation covers 68 % of the population.

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b. The accuracy of the Masimo SET® technology with Masimo sensors was validated with movement in human blood studies with induced hypoxia on healthy adult male and female volunteers with light to dark skin pigmentation, 2 to 4 Hz rubbing and tapping movements being performed at an amplitude of 1 to 2 cm and a non-repetitive movement being performed at 1 to 5 Hz at an amplitude of 2 to 3 cm in the range from 70 - 100 % for SpO_2 compared to a laboratory CO oximeter and ECG monitor. This fluctuation corresponds to ± 1 standard deviation and thus covers 68 % of the population.

c. The accuracy of the Masimo SET® technology in the case of poor perfusion was validated on the test bench compared to a Biotek Index 2™ simulator and the Masimo simulator with signal strengths of over 0.02 % and a transmission of over 5 % for saturations in the range from 70 to 100 %. This fluctuation corresponds to ± 1 standard deviation. Plus or minus one standard deviation covers 68 % of the population.

d. The accuracy of the pulse rate of the Masimo SET® technology with Masimo sensors was validated on the test bench for the range 25 - 240 min^{-1} compared to a Biotek Index 2™ simulator. This fluctuation corresponds to ± 1 standard deviation. Plus or minus one standard deviation covers 68 % of the population.

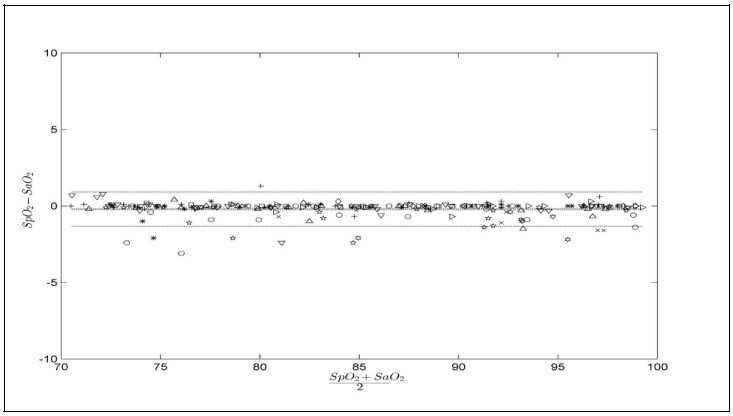
e. The precise data can be found in the directions for use (DFU) for the sensors. Unless otherwise stated, the measuring position for reusable sensors should be changed at least every 4 hours and for adhesive sensors, at least every 8 hours.

f. The sensor accuracy quoted applies in conjunction with the Masimo technology with a Masimo patient cable used for LNOP sensors, RD SET sensors, the LNCS sensors or the M-LNCS sensors. The numbers stand for ARMS (accuracy root mean square). Because pulse oximeter measurements are statistically distributed measuring procedures, only about two-thirds of the measurements are expected to be in a range of ± Arms compared to the reference value. Unless stated otherwise, accuracy for SpO_2 of 70 % to 100 % is quoted. The accuracy of pulse rate is quoted from 25 to 240 min-1.

g. The Masimo sensor types M-LNCS, LNOP, RD SET and LNCS exhibit identical optical and electrical properties. They differ in terms of type of attachment (self-adhesive/non-self-adhesive/hook-and-loop cuff), cable length, position of optical components (top or underside of sensor depending on the orientation with the cable), type/size of adhesion point and type of connector (LNOP: modular 8-pin connector; RD: modular 15-pin connector; LNCS: 9-pin, cable-based; M-LNCS: 15-pin, cable-based). All the information about sensor accuracy and instructions on using sensors are included in the instructions for use for the sensors.

h. Digit: Numerical value by which the last place of a value displayed can deviate from the actual measured value; used to state the accuracy of a measuring device (example: displayed SpO_2 value 70 %, accuracy ± 2 digits; actual value is between 68 % and 72 %).

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

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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 Measuring method	Functional oxygen saturation Spectrophotometry (red/infrared)
LED wavelength: Red Infrared Maximum light output This information may be of particular interest to clinicians	 660 nm 900 nm 5 mW
Measuring range: • SpO_2 • Pulse rate (default) • Pulse rate (enhanced)	 0 % - 100 % 30 min^{-1} - 240 min^{-1} 20 min^{-1} - 300 min^{-1}
Measuring accuracy: • SpO_2 (no patient movement) • SpO_2 (patient movement) • Pulse rate (no patient movement) • Pulse rate (patient movement)	 60% - 70% ± 3 A_{rms} 60% - 100% ± 2 A_{rms} <60% not specified 70% - 100% ± 3 A_{rms}[c] <70% not specified ≤ 2 min^{-1} -
Resolution: • Oxygen saturation (SpO_2) • Pulse rate	 1 % 1 min^{-1}
IEC 60601-1: Medical electrical device, type BF	

a. Validated by clinical tests in which the sensor values measured were compared to those of the arterial CO oximetry of healthy adults over the specified range of functional oxygen saturation.

b. As the measurements of pulse oximeters are statistically distributed, only approximately two-thirds of these measurements will probably fall in the range from ± A_{RMS} (accuracy root mean square) of the value measured by CO oximeters.

c. Tested with a Fluke Index II Oximeter Tester (all movement patterns).

Manual input of vital signs

Measuring ranges for manual input of vital signs	
Measuring range for blood pressure • Systolic BP • Diastolic BP	 25 mmHg - 280 mmHg 10 mmHg - 220 mmHg
Pulse rate	25 min^{-1} - 240 min^{-1}
Temperature	32 °C - 44 °C (89,6 °F - 111,2 °F)
SpO_2	0 % - 100 %

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12.4 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
Body mass index (BMI)	Absolute in kg/m^2	Development/growth
Weight (W)	Absolute in kg	Development/growth
Height (H)	Absolute in m	Development/growth
Blood pressure, non-invasive (NIBP)	Absolute in mmHg	Vital signs
Body temperature (TEMP)	Absolute in °C	Vital signs
Pulse rate (PR)	Absolute in min^{-1} (based on NIBP or SpO_2)	Vital signs
Oxygen saturation (SpO_2)	Relative in %	Vital signs

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12.5 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 • Height • Body mass index (BMI)
Vital signs	Overview of vital signs to support a diagnosis	• Blood pressure (NIBP) • Body temperature (TEMP) • Pulse rate (PR) • Oxygen saturation (SpO_2)

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12.6 Standards and directives

This device complies with the following standards and directives:

- IEC 60601-1 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance)
- IEC 60601-1-2 (Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests)
- ISO 80601-2-56 (Medical Electrical Equipment - Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement.)
- IEC 80601-2-30 (Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers)
- ISO 80601-2-61 (Medical Electrical Equipment - Part 2-61: Particular Requirements For Basic Safety And Essential Performance Of Pulse Oximeter Equipment)

13. OPTIONAL ACCESSORIES AND SPARE PARTS

Optional accessories and spare parts	Article number
SmartBucket	Version overview at www.seca.com
Blood pressure measurement: • Cuff, size XS • Cuff, size S • Cuff, size M • Cuff, size L • Cuff, size XL • Cuff, size XXL • Extension for compressed air tube (1.3 m) • Extension for compressed air tube (3.0 m) • Cuff, size S • Cuff, size XL • Extension for compressed air tube	 490-0024-001 490-0025-001 490-0026-001 490-0027-001 490-0028-001 490-0029-001 490-0033-001 490-0034-001 490-0001-001 490-0004-001 490-0005-001
Masimo SET® SpO_2 measurement: Sensors and patient cables from the Masimo RD SET® product line **Not compatible:** Sensors for neonates	Obtainable directly from the manufacturer, see www.masimo.com
seca SpO_2 measurement: • Finger Clip SF7500 (adults) • Soft Sensor SC7500 (adults) • Soft Sensor SCM7500 (children) • Patient cable XT6500	 490-0006-001 490-0007-001 490-0008-001 490-0012-001
Temperature measurement: • COVIDIEN™ FILAC™ 3000 blue for oral/axillary measurement • COVIDIEN™ FILAC™ 3000 red for rectal measurement • COVIDIEN™ GENIUS®3 in-ear thermometer	 68-90-00-044-009 68-90-00-045-009 68-90-00-143-009
Probe covers for COVIDIEN™ FILAC™ 3000; 100 packs, pack of 20 probe covers	490-0015-001
Probe covers for COVIDIEN™ GENIUS®3; 22 packs, pack of 6 magazines (16 probe covers per magazine)	490-0016-001
Software: **seca connect 103**	For details of application-specific licence packages go to www.seca.com
seca 475 wheeled stand for **seca mVSA 535**	475-05-35-009
seca 432 carry case	432-00-00-009

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Optional accessories and spare parts	Article number
Accessory kit for wall bracket for **seca mVSA 535**	490-0017-001
Scanner (medical device): • Honeywell Xenon 1900H (2D) • Datalogic Gryphon I (GD4430 HC (2D))	Cannot be ordered through seca

14. COMPATIBLE SECA PRODUCTS

Product	seca 360° proximity	Article number
Measuring stations		
seca 285/**seca 284** **seca 287**/**seca 286**	Yes, with accessories [a]	For details of country-specific versions, go to www.seca.com
seca 787 **seca 797**	Yes, with accessories [a.] Yes	
Multifunctional scales		
seca 651 **seca 650**	Yes	For details of country-specific versions, go to www.seca.com
seca 655 **seca 654**	Yes	
seca 635 **seca 634**	Yes, with accessories [a.]	
seca 645 **seca 644**		
seca 657 **seca 656**		
seca 665 **seca 664**		
seca 677 **seca 676**		
seca 675 **seca 674**		
seca 685 **seca 684**		
Column scales		
seca 704 **seca 703**[b]	Yes, with accessories [a.]	For details of country-specific versions, go to www.seca.com
Chair scales[b.]		
seca 954 (1309007) **seca 954** (1309377)	Yes, with accessories [a.]	For details of country-specific versions, go to www.seca.com
seca 959 (7021002) **seca 959** (7021092)		
seca 963		

a.**seca 452** external interface module (firmware version R1.3 Build 79 or higher) required
b.**seca 452** external interface module can only be retrofitted by authorized service technicians

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15. DISPOSAL

➔ Device
➔ Batteries and rechargeable batteries
➔ Consumables

15.1 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

15.2 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.

15.3 Consumables

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

16. 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 device was 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 measuring accessories, such as blood pressure cuffs, SpO_2 sensors or thermometers, can be found at www.seca.com.

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17. DECLARATION OF CONFORMITY

CE 0123

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.

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FOR ADMINISTRATORS: CONFIGURING seca mVSA 535

NOTE
This document describes the maximal equipment of the **seca mVSA 535** 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 mode and for integrating it in a network.
- Integrating this device in a network containing other devices may lead to previously unknown risks to patients, operators or third parties. It is the responsibility of the operating company to determine, analyze, rate, and manage these risks.
- 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 mVSA 535.

1. PREPARING CONFIGURATION

1.1 Administrator login

1. Switch on the device.
2. Log in as the administrator:
   - ► Initial login: ➔ Activating initial user accounts
   - ► Routine login: continue at step 3.

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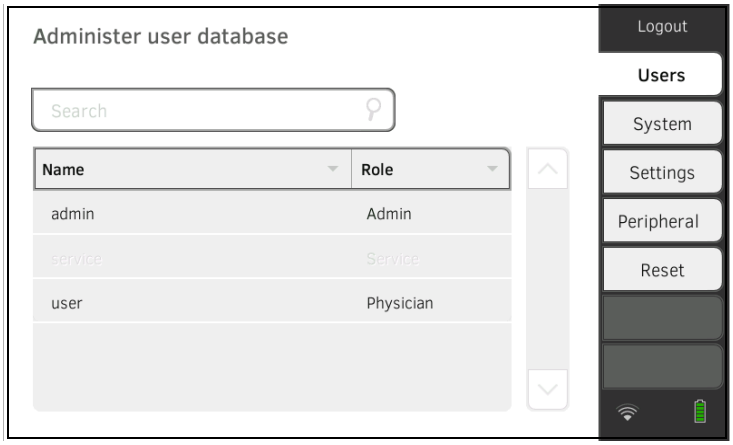
3. Press the **Login** key.

The login window is displayed.

4. Press the input field.
The list of user accounts is displayed.
5. Press your user account.
Your user account is displayed in the input field.

6. Press the input field.

7. Enter your password using the keypad  .
The administrator area is displayed.



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1.2 Configuration options

➔ Network functions
➔ Overview of access rights

Network functions

• = possible, **-** = not possible

Function	LAN	WiFi
Receiving patient weight from scale/ measuring rod	•[a]	•[a.]
Receiving patient height from measuring rod/ measuring station	•[a.]	•[a.]
Connecting to the EMR system via the **seca connect 103** software	•	•

a. **seca 360° proximity** connection: Available for seca measuring devices with an internal interface module or **seca 452** external interface module (firmware version R1.3 Build 79 or higher)

Overview of access rights

• = possible, **-** = not possible

Function	Administrator	User
Creating seca patient files	-	•
Calling up seca patient files	-	•
Entering basic parameters (weight, height)	-	•
Editing seca patient files	-	•
Deleting seca patient files	-	•
Exporting a seca patient file	-	•
Performing measurements	-	•
Viewing examination results	-	•
Analysis parameters: Adding comments	-	•
Managing the patient database	-	•
Managing the user database	•	-
Modifying default settings (e.g. time, date)	•	-
Modifying units for measured values	•	-
Modifying analysis parameters which can be displayed	•	-
Setting up network connections	•	-
Importing backup from USB memory stick	•	-
Restoring factory settings	•	-
Resetting the user interface	•	-
Exporting backup to USB memory stick	•	-
Updating the monitor software	•	-

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2. USER ACCOUNTS

➔ Activating initial user accounts
➔ Working with user accounts

2.1 Activating initial user accounts

The following user accounts are available on the device initially:

- admin: (Configure and manage device)
- user: (Perform and manage measurements).

The user accounts have to be activated in order to be able to use the device:

- ➔ Changing the password for the “admin” user account
- ➔ Assigning a password to the “user” user account

Changing the password for the “admin” user account

1. Press the **Login** key.
   The login window is displayed.

2. Press the input field.
   The list of user accounts is displayed.
3. Press the “admin” user account.
   The account is displayed in the input field.
4. Press the input field.
5. Enter the initial administrator password “1357”.
   You are prompted to change the password.
6. Enter a new administrator password.

   NOTICE!
   Data access by unauthorized persons
   An insecure password may allow unauthorized persons to access patient data or device settings.
   ► Select a password which satisfies your institution's security requirements.
7. Enter the password again.
   The login window is displayed.
8. Activate the “user” user account ➔ Assigning a password to the “user” user account.

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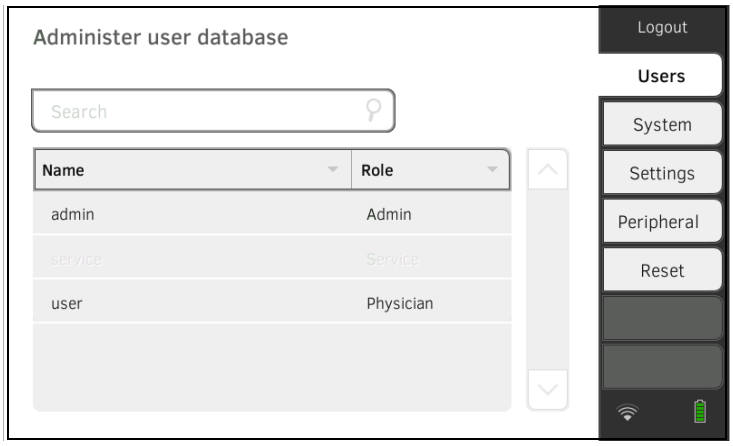
Assigning a password to the “user” user account

1. Log in using the “admin” user account.
2. Press the **Users** tab.



3. Select the “user” user account.
4. Enter a password.

NOTICE!
Data access by unauthorized persons
An insecure password may allow unauthorized persons to access patient data or device settings.
- ► Select a password which satisfies your institution's security requirements.

5. Enter the password again.
6. Press the **Save** key.
   The password has been saved.
   The “user” user account can be used.
7. Configure the device as required for your specific situation ➔ For administrators: Configuring seca mVSA 535.

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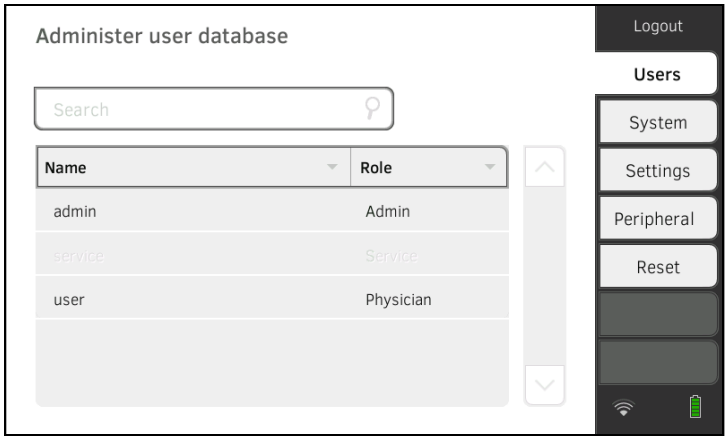
2.2 Working with user accounts

Editing user accounts

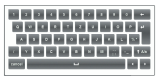
NOTE
In stand-alone operation, only the initial user accounts are available ➔ Initial login. Further user accounts can only be set up if there is a connection to an EMR system.

To edit a user account, proceed as follows:

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 the  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. Change the user data to the extent required by pressing the relevant input field:
   - ► Changing a password
   - ► Changing user name (“user” user account only)
   - ► Select display language

   NOTICE!
   Data access by unauthorized persons
   An insecure password may allow unauthorized persons to access patient data or device settings.
   - ► Select a password which satisfies your institution's security requirements.
   - ► Use the user accounts without password protection only for special applications (e.g. configuring interfaces with EMR systems). seca Service will be pleased to assist if you have any questions relating to interface configuration.

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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
➔ Making regional settings.

5. Ensure that the **Password protected** field is activated (default setting).
6. Press the **Save** key.
   The changes will be saved.

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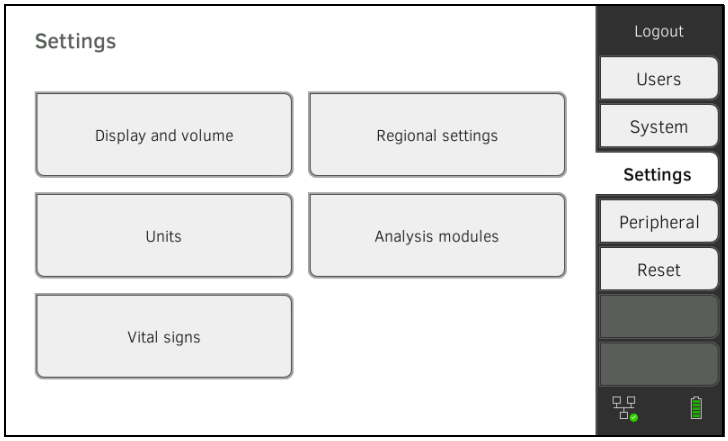
3. MAKING SETTINGS FOR MEASURING MODE

3.1 Making regional settings

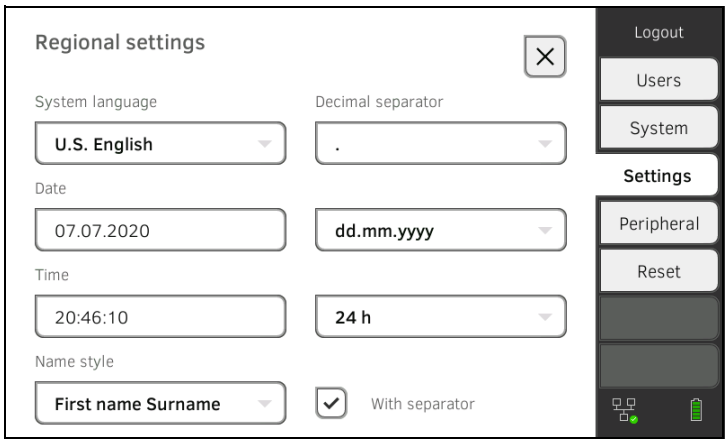
CAUTION!
Loss of data, misinterpretation of measurements
Incorrect settings for date and time may lead to misinterpretation of measurements.

- Stand-alone operation: Ensure that the date and time information on the device is correct.
- Network operation: Ensure that the date and time information in the seca software is correct. These settings are adopted by the device.

1. Press the **Settings** tab.



2. Press the **Regional settings** key.



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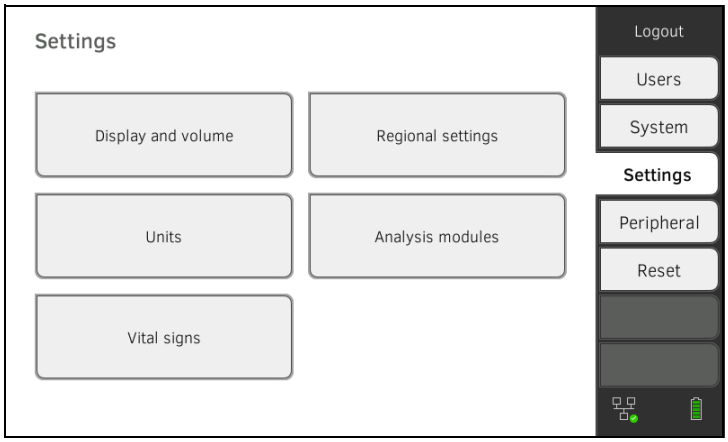
3. Specify the regional settings by pressing the relevant input field:
   - ► Select system language
   - ► Select decimal separator
   - ► Enter date
   - ► Select date format
   - ► Enter time
   - ► Select time format
   - ► Select naming convention
   - ► Activate/deactivate name hyphen

NOTE

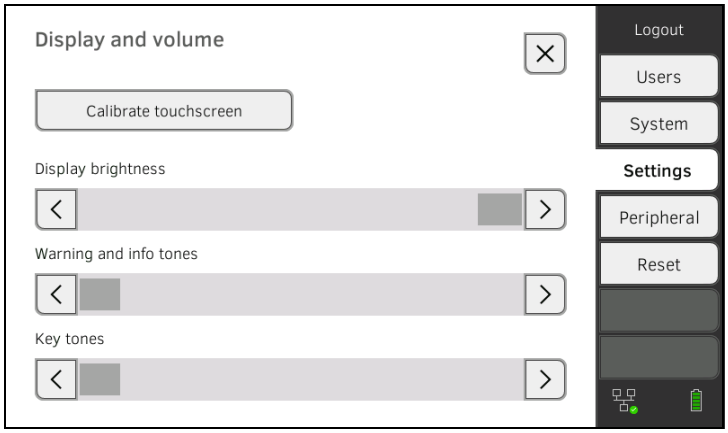
- The user interface is shown in the system language if no user is logged in to the device. If a user is logged in, the user interface is displayed in the individual display language ➔ User accounts.
- Amendments in the Naming convention area affect the search for patient data ➔ Searching for patient by name. You specify here whether the surname or the first name is to be entered first in the search.
- Settings you make in this tab are active directly. You do not need to save or confirm them.

3.2 Setting display brightness and volume

1. Press the **Settings** tab.



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



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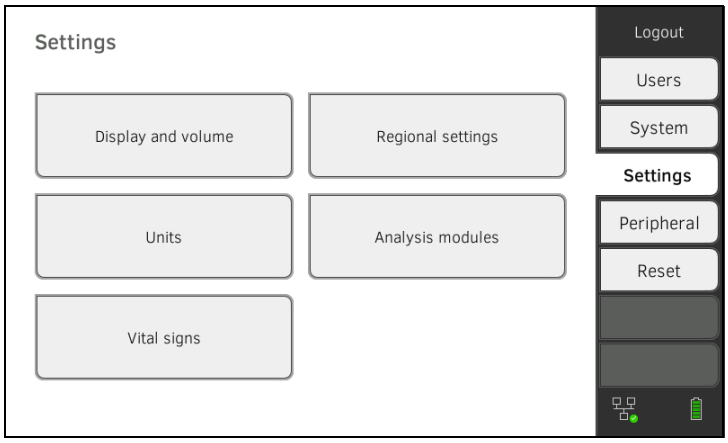
3. Press the  keys as appropriate:
   - Set display brightness
   - Set volume for warning and information sounds
   - Set volume for key sounds

   NOTE
   Amended settings can immediately be seen/heard each time a key is pressed. You do not need to save or confirm them.

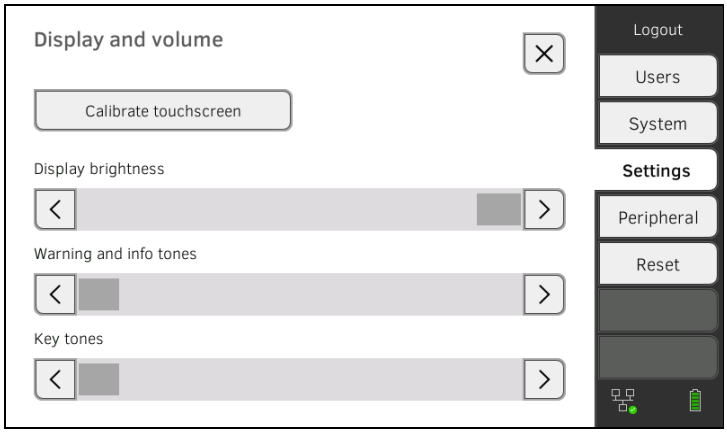
3.3 Calibrating the touchscreen display

NOTE
We recommend using a stylus (touchpen) for calibration.

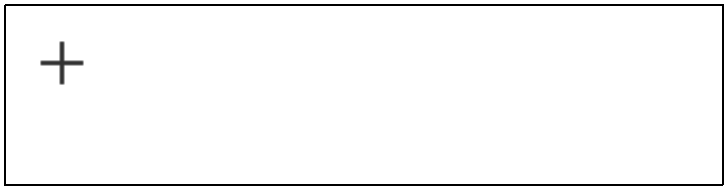
1. Press the **Settings** tab.



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



3. Press the **Calibrate touchscreen** key.
4. Confirm that you wish to proceed.
   The calibration display appears:



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5. Press the  symbol with a stylus.
   The symbol changes position.

6. Press the  symbol with a stylus 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.

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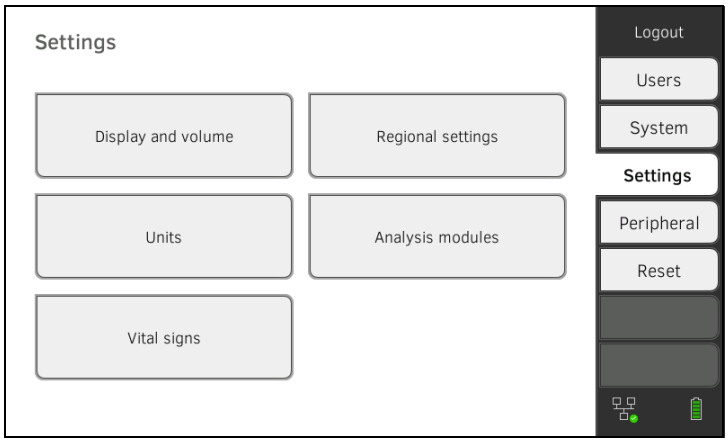
3.4 Setting units of measurement

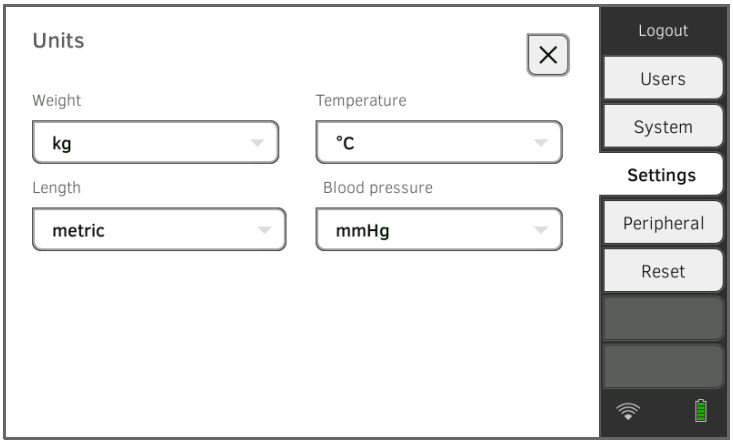
CAUTION!
Patient hazard
In order to avoid misinterpretations, measuring results for medical use must be displayed and used in SI units (weight: kilogrammes, length: metres) only. Some devices offer the ability to display measuring results in other units. This is only an additional function.

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

1. Press the **Settings** tab.



2. Press the **Units** key.



3. Make the desired settings:
   - 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.

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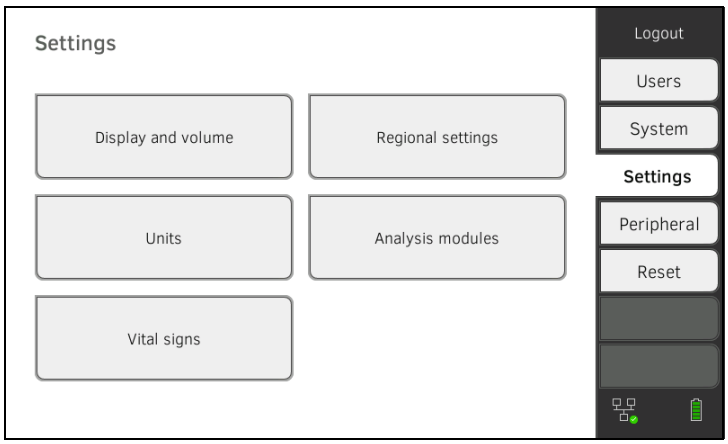
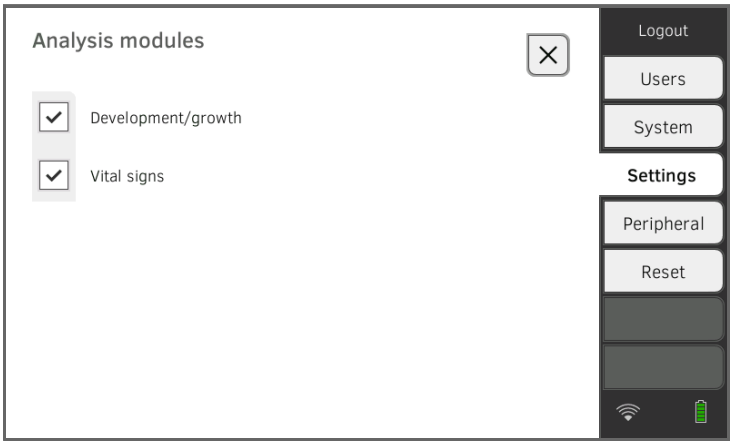
3.5 Deactivating analysis modules

1. Press the **Settings** tab.



2. Press the **Analysis modules** key.



All analysis modules are activated at the factory.

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

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

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

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3.6 Making 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)

➔ Selecting color mode for Vital signs tab

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

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

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.

Presets for blood pressure

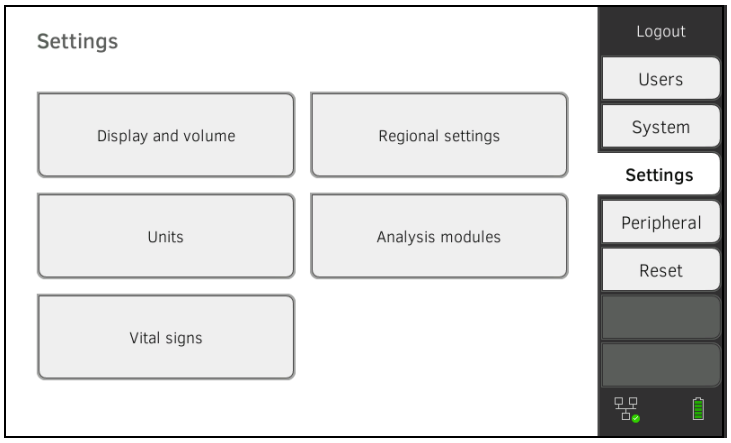
➔ Making general settings

➔ Configuring multiple measurement

NOTE
This is where to specify default settings which the user can modify for the respective current measurement procedure. The settings from the default settings then become active again.

Making general settings

1. Press the **Settings** tab.



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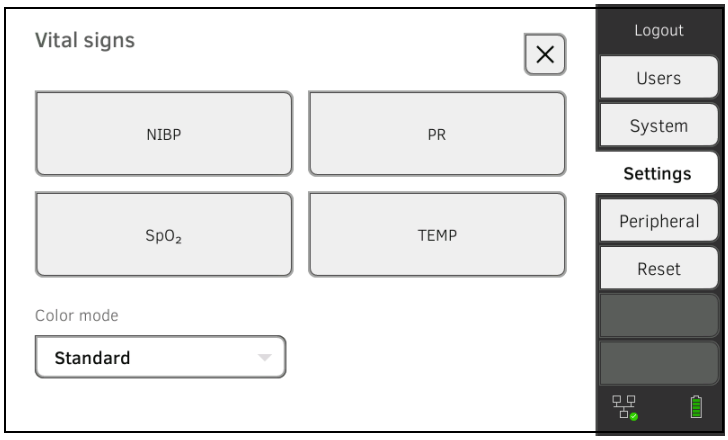
2. Press the **Vital signs** key.



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

4. Press the desired measurement method.
   - Upward measurement: Adapt maximum pressure if necessary
   - Downward measurement: Adapt starting pressure if necessary
5. Press the desired measuring sequence.
   - Single measurement
   - Multiple measurement ➔ Configuring multiple measurement
6. Press the **Confirm** key.
   The dialog window closes.
   The modified settings are adopted.

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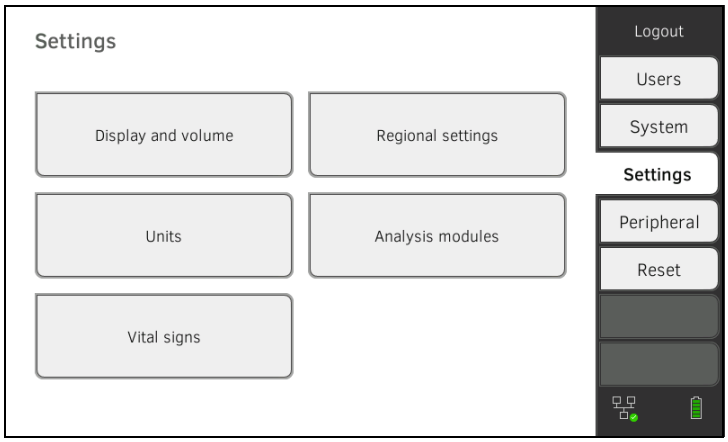
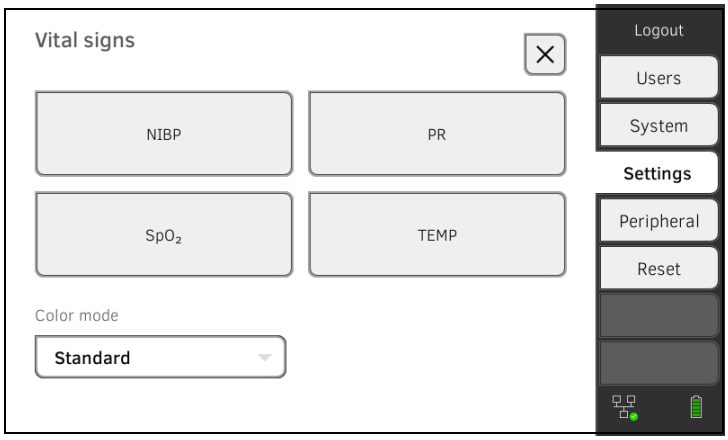
Configuring multiple measurement

NOTE
Settings you make here can**not** be changed by the user.

1. Press the **Settings** tab.



2. Press the **Vital signs** key.



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

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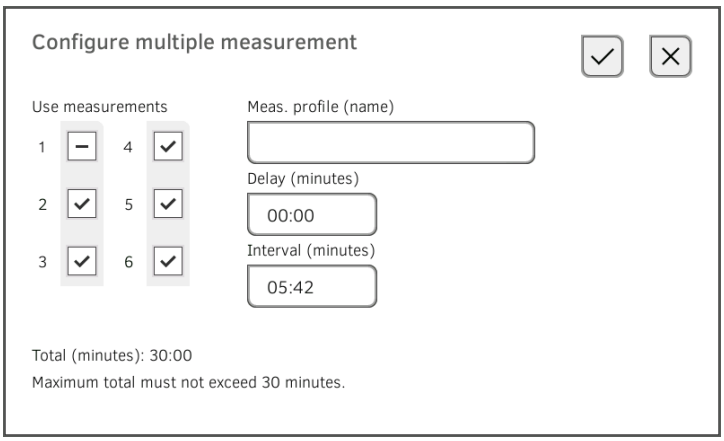
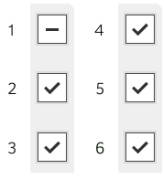
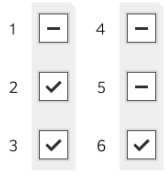
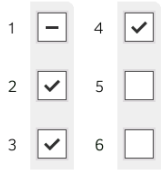
4. Press the  key.
   The **Configure multiple measurement** dialog window appears:



5. Specify the number of part-measurements:
   - Maximum six part-measurements
   - Deactivated part measurements at the start and during the measuring sequence are performed but not used to form the mean value
   - Deactivated part-measurements at the end of the measuring sequence are not completed: The running time of the measurement is reduced.

Example	Measuring sequence
	Factory setting: 6 part-measurements Part-measurement 1 is discarded
	Example: 6 part-measurements Part-measurements 1, 4 and 5 are discarded
	Example: 4 part-measurements • Part-measurement 1 is discarded • Part-measurements 5 and 6 are not performed

6. Specify a start delay (waiting time before part-measurement 1):
   - Format: mm:ss
   - Min: 00:00, Max:10:00
7. Specify the interval (waiting time between part-measurements)
   - Format: mm:ss
   - Min: 01:35, max: 14:15 minutes

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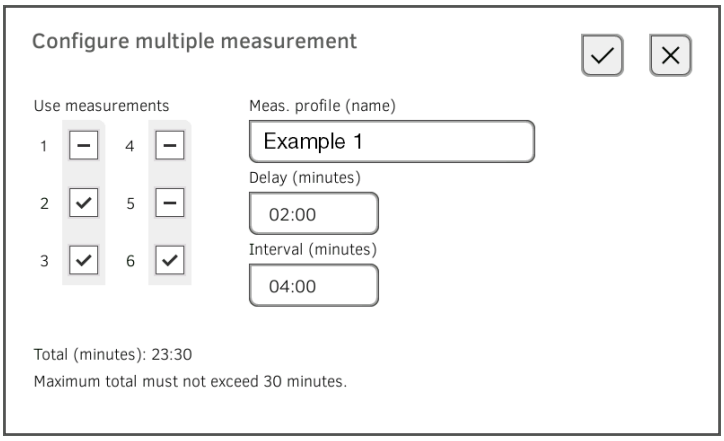
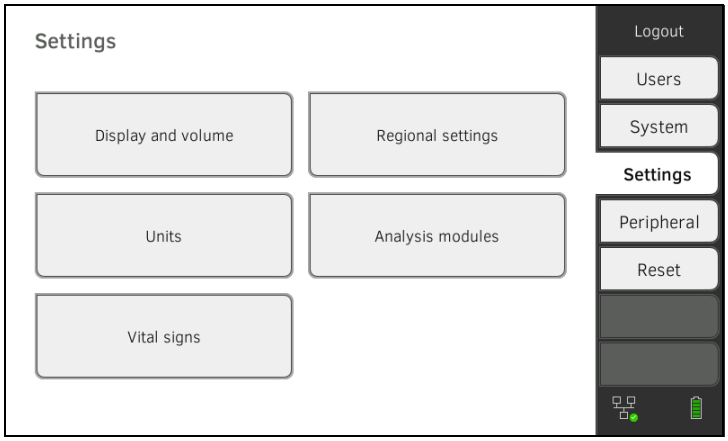
8. Assign a name to the measuring profile.



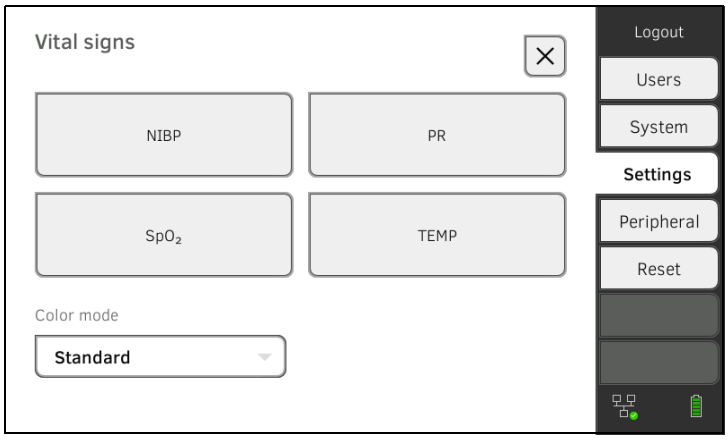
9. Press the  key.
The measuring profile is saved.
The name of the measuring profile appears in the **NIBP settings** dialog window instead of the text **Multiple measurement**.

Presets for pulse rate (seca measuring equipment only)

1. Press the **Settings** tab.



2. Press the **Vital signs** key.



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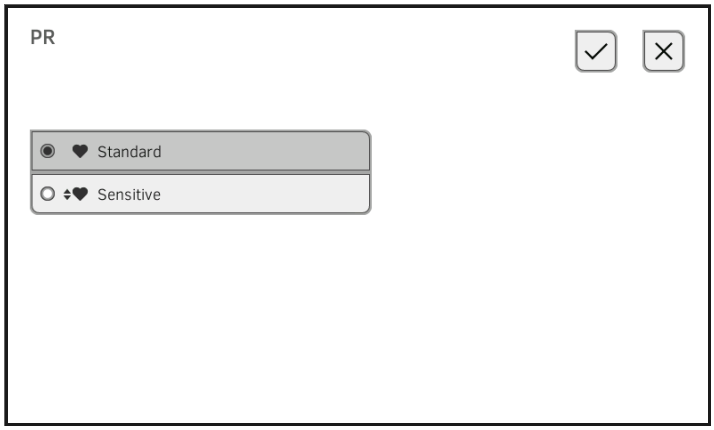
3. Press the **PR** key.



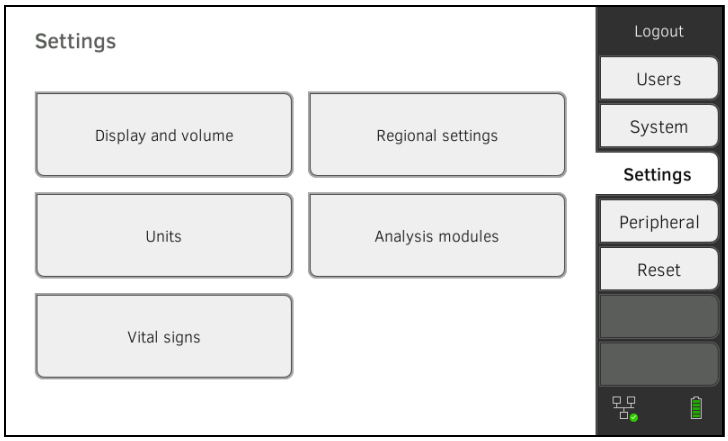
4. Press the desired measuring mode (seca measuring equipment only):

seca measuring equipment		
Mode	**Measuring range**	**Motion tolerance**
Default	0 - 240 min^{-1}	High
Sensitive	20 - 300 min^{-1}	Low

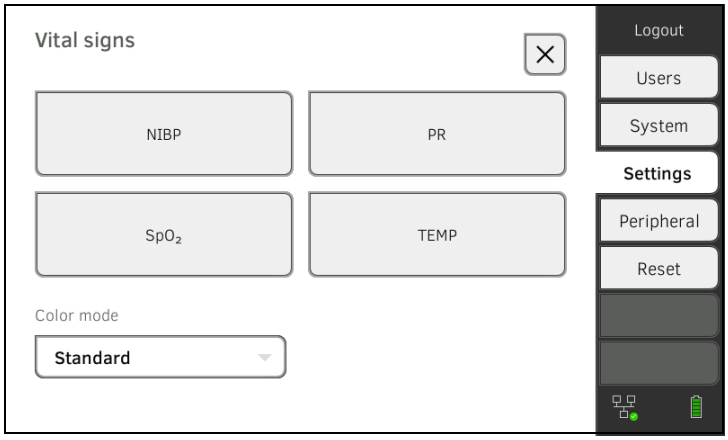
5. Press the **Confirm** key.
   The dialog window closes.
   The modified settings are adopted.

Presets for SpO_2

1. Press the **Settings** tab.



2. Press the **Vital signs** key.



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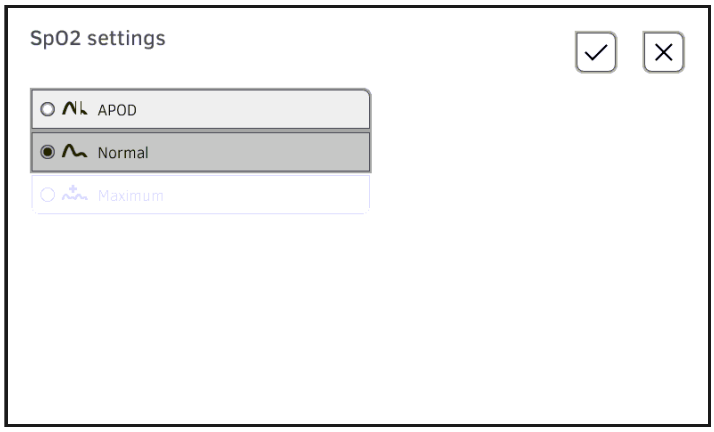
3. Press the **SpO_2** key.

   The presets are displayed (here: Masimo SET® pulse oximetry):



4. Press the desired sensitivity:

   NOTE
   The Maximum setting (Masimo SET® pulse oximetry) is not available as a preset. Select this setting for each measurement directly
   ➔ Measuring oxygen saturation (SpO_2).

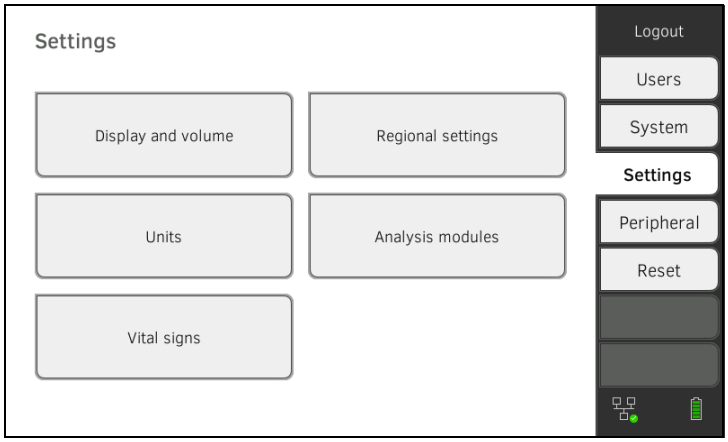
Masimo SET® SpO_2 module	
Mode	**Indication**
Normal	• Normal perfusion • Mild perfusion disorders
Adaptive Probe Off Detection (APOD)	Vigorous patient movements
Maximum	• Poor perfusion • Severely disrupted signal, for example due to indoor lighting or direct sunlight

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

5. Press the **Confirm** key.
   The dialog window closes.
   The modified settings are adopted.

Presets for temperature (COVIDIEN™ FILAC™ 3000 only)

1. Press the **Settings** tab.



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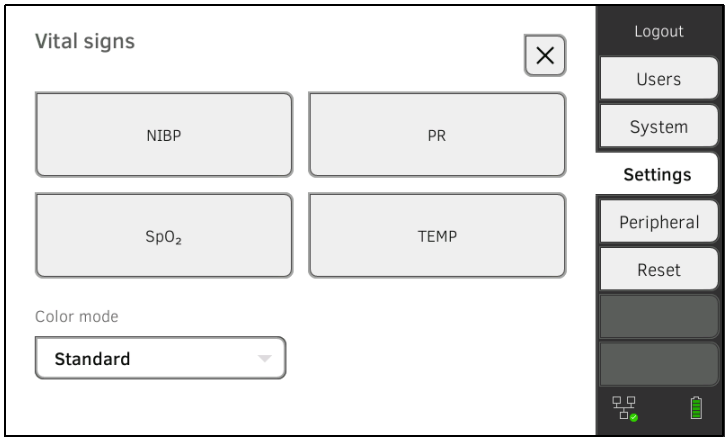
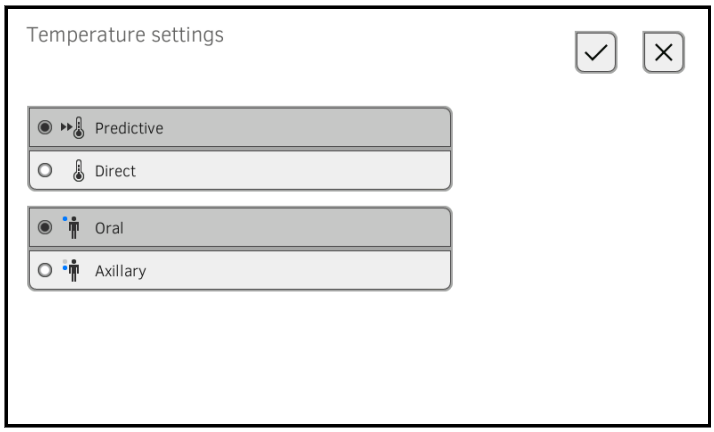
2. Press the **Vital signs** key.



3. Ensure that the temperature probe is pushed into the probe holder completely.
4. Press the **TEMP** field.
   The presets are displayed (here: 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** key.
   The dialog window closes.
   The modified settings are adopted.

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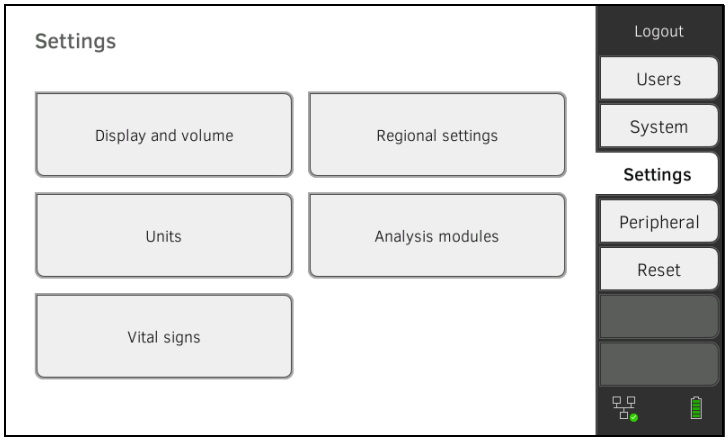
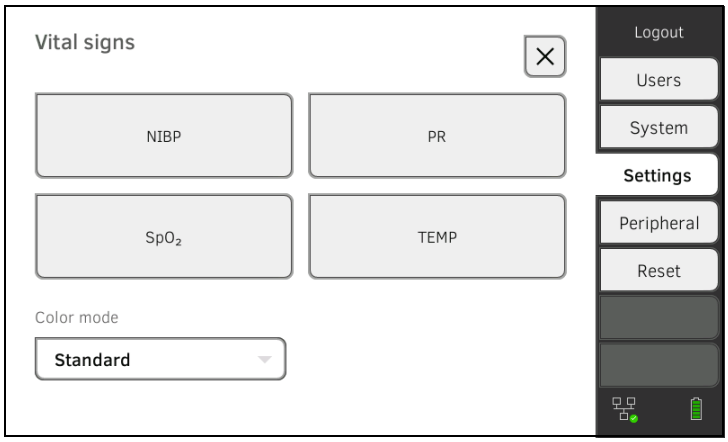
Selecting color mode for Vital signs tab

1. Press the **Settings** tab.



2. Press the **Vital signs** key.



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

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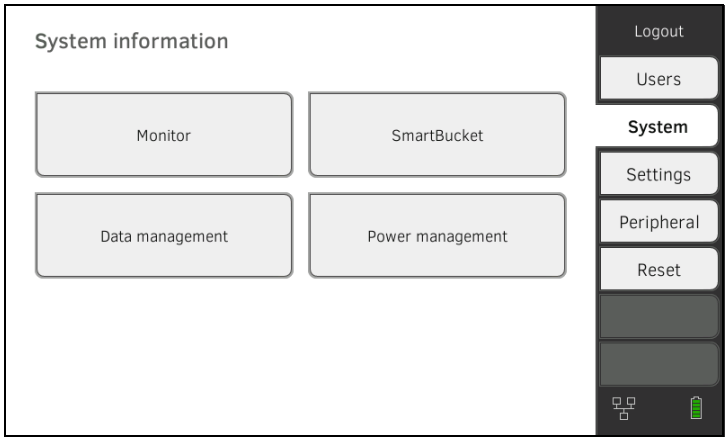
4. MANAGING SYSTEM COMPONENTS

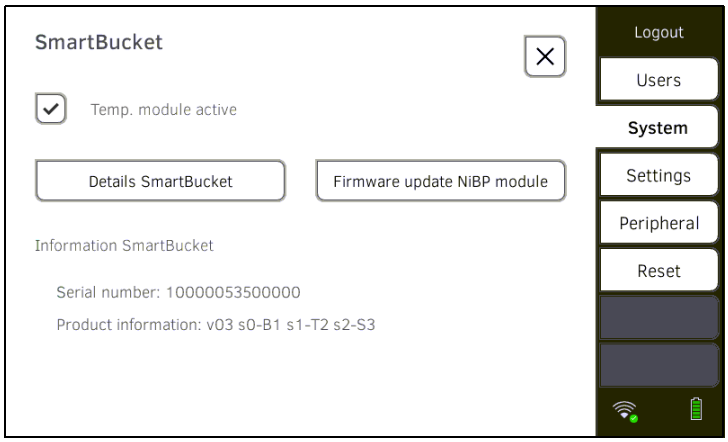
4.1 Viewing system information

1. Press the **System** tab.



2. Select a system component.

   The system information for the selected system component is displayed (here: **SmartBucket**).



   You have the following options:

   - View details
   - Perform firmware update
   - Perform software update (not for **SmartBucket**) ➔ Updating the monitor software

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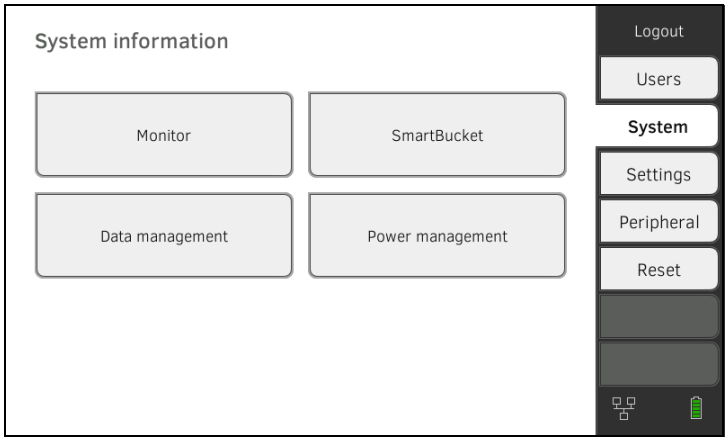
4.2 Updating the monitor software

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

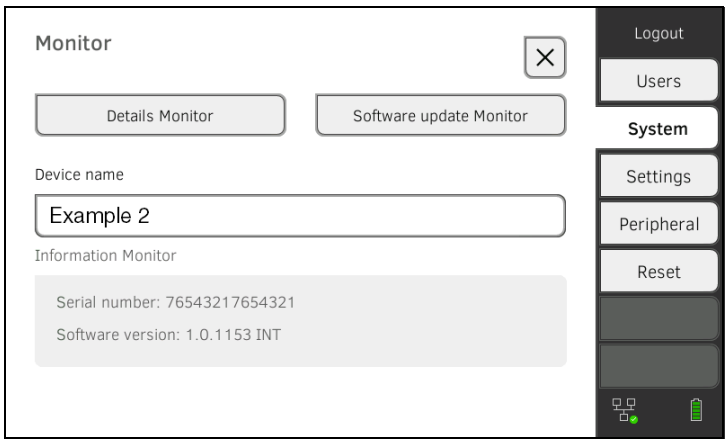
NOTICE!
Data loss

- Export seca patient files and user accounts manually **before** updating the software.

1. Press the **System** tab.



2. Press the **Monitor** key.



3. Press the **Software update Monitor** key.
4. Connect the USB memory stick to the monitor.
   The software package is automatically transmitted to the device.
   Following successful transmission, the **Start software update** key is active.
5. Press the **Start software update** key.
   The software package will be installed.
   Following successful installation, the device restarts automatically.

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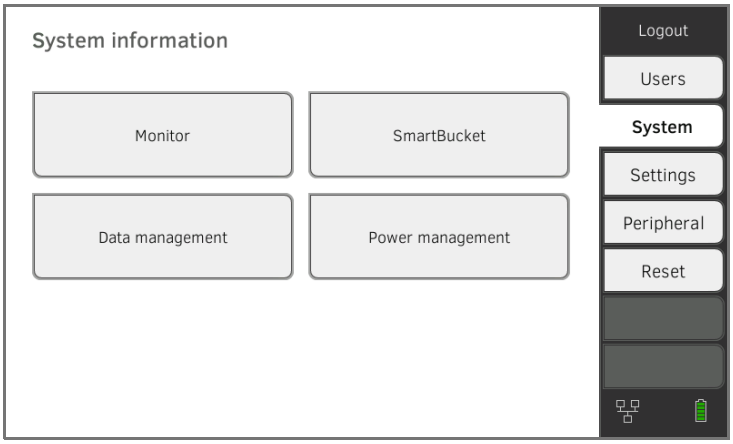
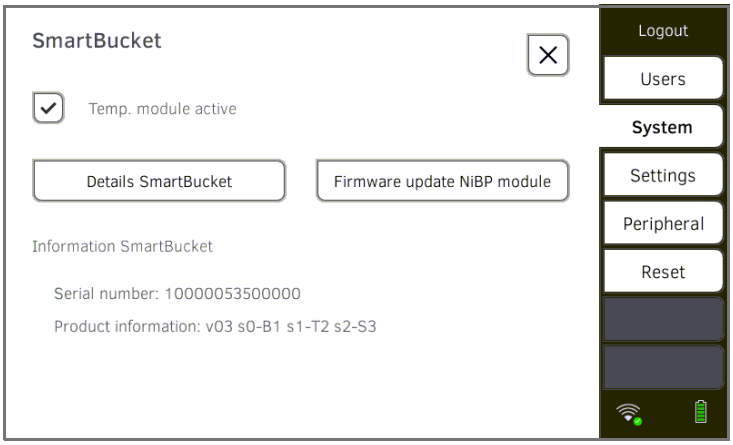
4.3 Updating the firmware of the blood pressure module

This function allows you to update the firmware of the blood pressure module. Current firmware packages are automatically announced in the GUI of the device. The firmware package is available for installation on the device after the monitor software has been updated (from software version 2.1)
➔ Updating the monitor software.

1. Press the **System** tab.



2. Press the **SmartBucket** button.
   If there is a firmware update for the blood pressure module, the **Firmware update NiBP module** button can be clicked.



3. Press the **Firmware update NiBP module** button.
   A confirmation dialog is displayed.

   NOTICE!
   Damage to device
   The device must remain connected to the power cord throughout the entire update process.
   - ► Connect the device to a power cord. Do not disconnect the device from the power cord throughout the entire update process.

4. Press the **Confirm** key.
   The firmware package will be installed.
   Following successful installation, the device restarts.

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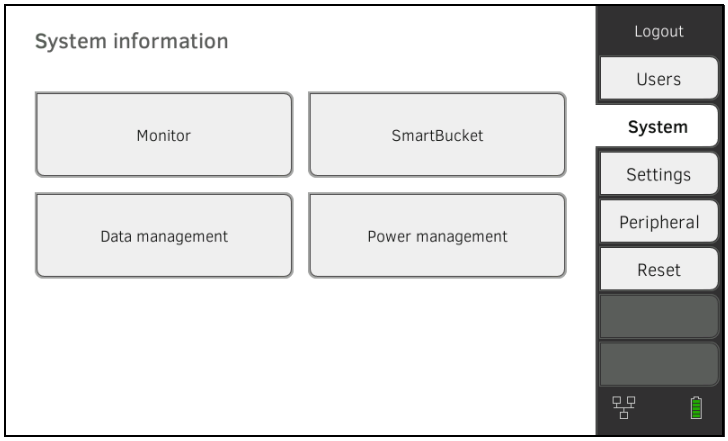
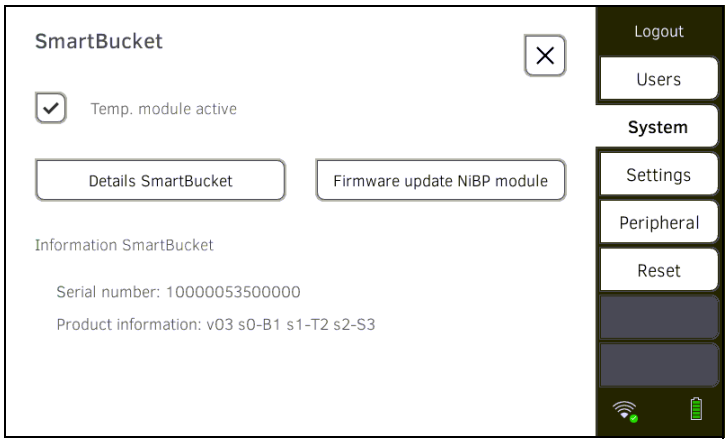
4.4 Retrofitting the in-ear thermometer

seca mVSA 535 without temperature measurement can be retrofitted with the COVIDIEN™ GENIUS®3 in-ear thermometer ➔ Optional accessories and spare parts.

1. Connect the in-ear thermometer as described in the section entitled ➔ Connecting the in-ear thermometer.
2. Activate the temperature module in the device:
   a) Press the **System** tab



   b) Press the **SmartBucket** key
   c) Activate the **Temp. module active** checkbox



3. Follow the on-screen instructions.

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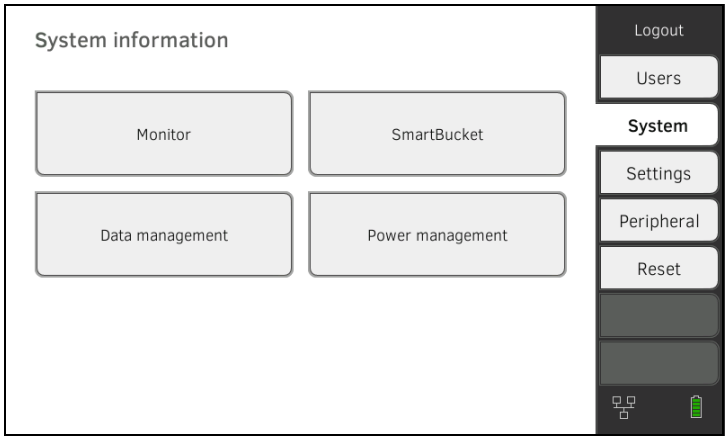
4.5 Data export and backup

➜ Exporting patient and user data manually
➜ Restoring patient and user data manually

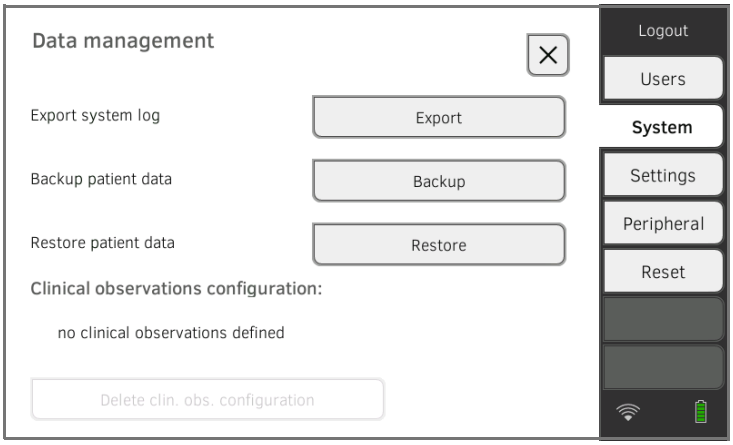
Exporting patient and user data manually

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

1. Press the **System** tab.



2. Press the **Data management** key.



3. Connect a USB memory stick to the monitor.
4. Press the **Backup (Backup)** key.
5. Enter a password to encrypt the data.

NOTICE!
Data access by unauthorized persons
An insecure password may allow unauthorized persons to access patient data.
- Select a password which satisfies your institution's security requirements.

6. Enter the password again to confirm it.
   The data are exported to the USB memory stick.
7. Archive the data in line with your institution's policy.

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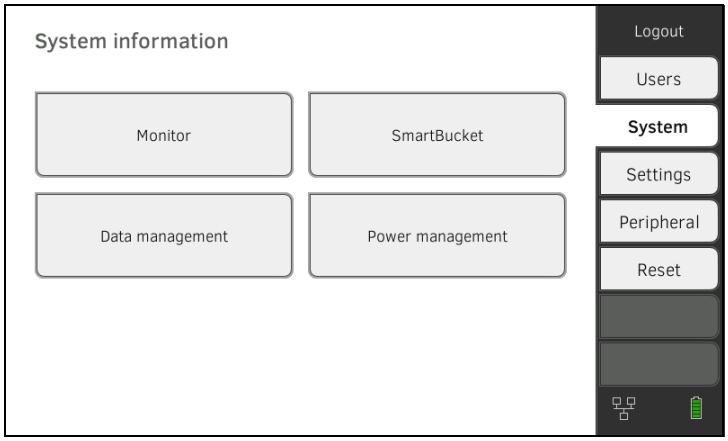
Restoring patient and user data manually

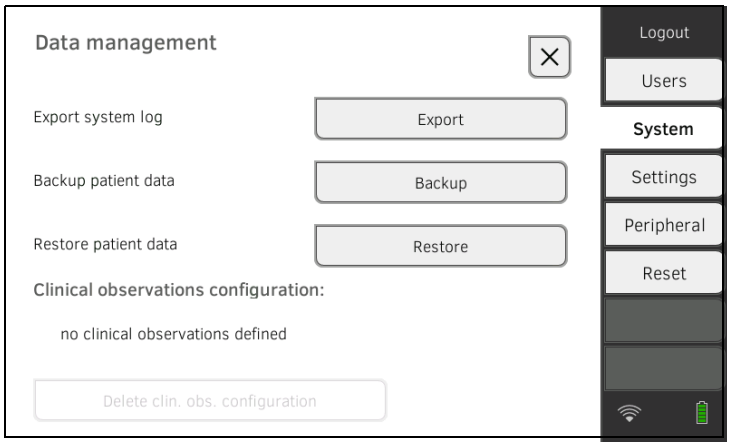
This function allows you to restore externally backed-up seca patient files and user accounts.

NOTICE!
Data loss
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.

1. Load the archived seca patient files and user accounts onto a USB memory stick.
2. Press the **System** tab.



3. Press the **Data management** key.



4. Connect the USB memory stick to the monitor.
5. Press the **Restore** key.
6. Enter the password you assigned on export to decrypt the data. The data are imported.

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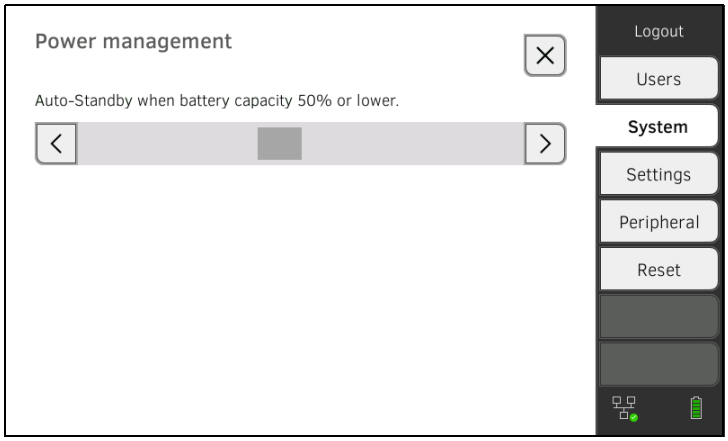
4.6 Power management

You can specify from which battery charge status (in %) the device shuts down and switches off.

1. Press the **System** tab.
2. Press the **Power management** key.
   The current setting is displayed (default setting: 50 %).



3. Set the desired battery charge status from which the device is to shut down and switch off.

   - Press the < key to switch off the device at a lower battery charge status (minimum: 10 %).
   - Press > to switch off the device at a higher battery charge status (maximum: 100 %).

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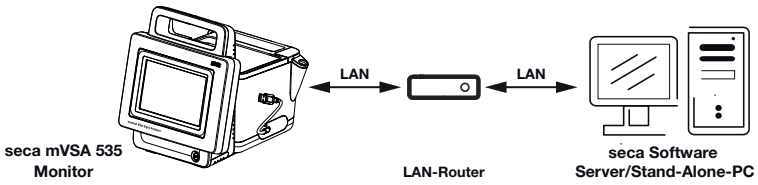
5. SETTING UP PERIPHERALS

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

Introduction

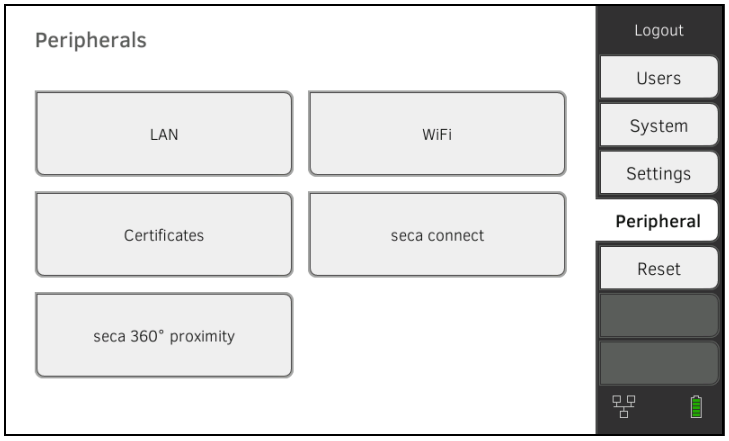
For stationary use, for example, in a treatment room in your practice, you can connect the monitor to your LAN network to exchange data using the **seca connect 103** software.

A requirement for exchanging data with the **seca connect 103** software is that the **seca connect 103** software is installed on a server and the configuration of the **seca connect 103** software (server IP and connect port) is known.



Activating the LAN connection

1. Press the **Peripherals** tab.



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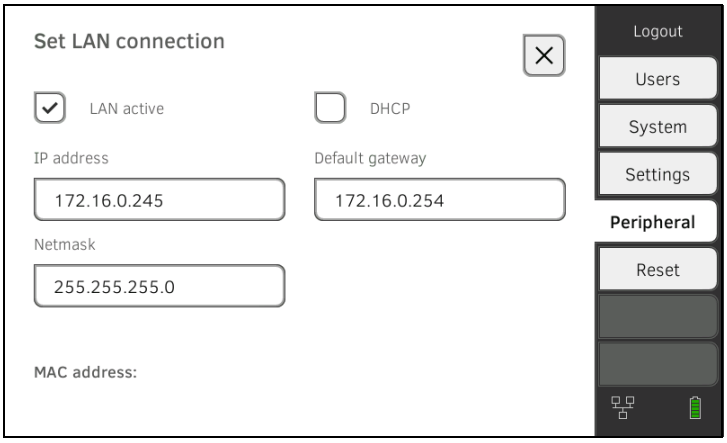
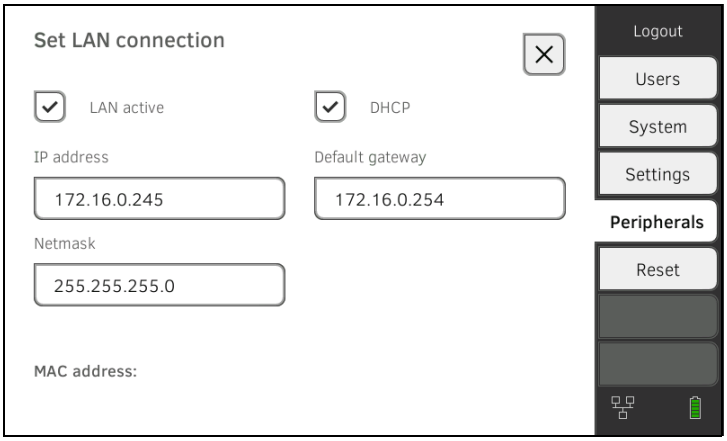
2. Press the **LAN** key.



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 automatic connection: Press the **DHCP** key and continue with ➔ Setting up a connection to the seca connect 103 software



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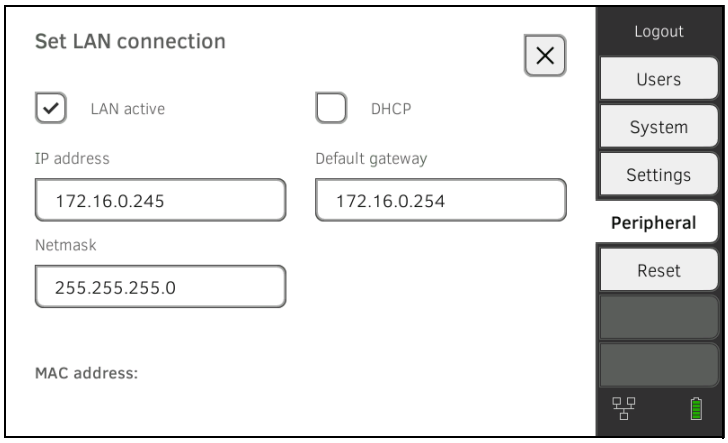
5. Make the settings relevant to your network:
   - Enter the IP address of the monitor (last three digits must be different from the PC address)
   - Enter netmask (must match the netmask of the PC)
   - Enter default gateway (if available)



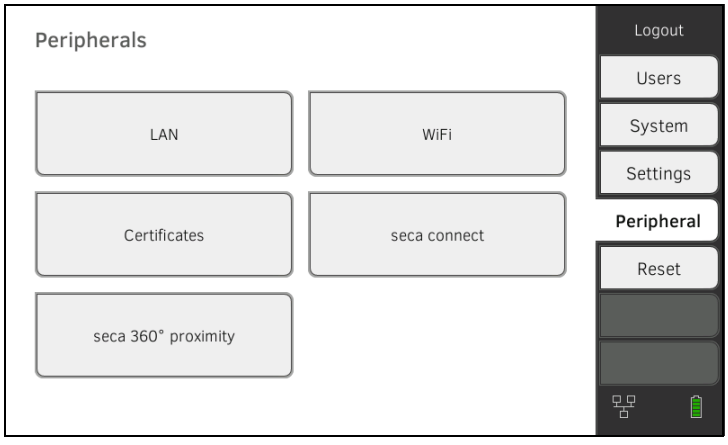
The  symbol is displayed on the monitor.
The LAN connection is set up.

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

6. Press the  key to confirm your entry.
7. Set up the connection to the **seca connect 103** software ➔ Setting up a connection to the seca connect 103 software

Deactivating the LAN connection

1. Press the **Peripherals** tab.



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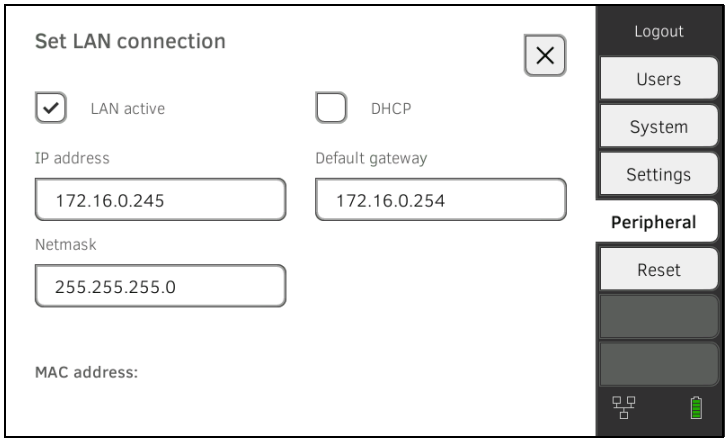
2. Press the **LAN** key.



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

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5.2 Setting up a WiFi connection (mobile operation)

➔ Introduction

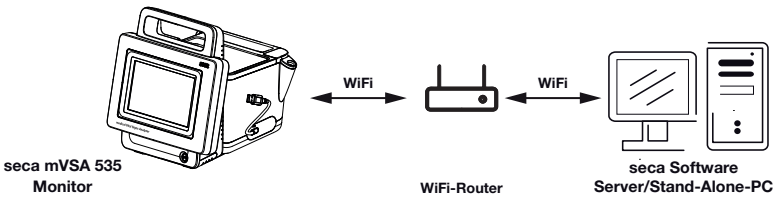
➔ Activating the WiFi connection

➔ Deactivating the WiFi connection

Introduction

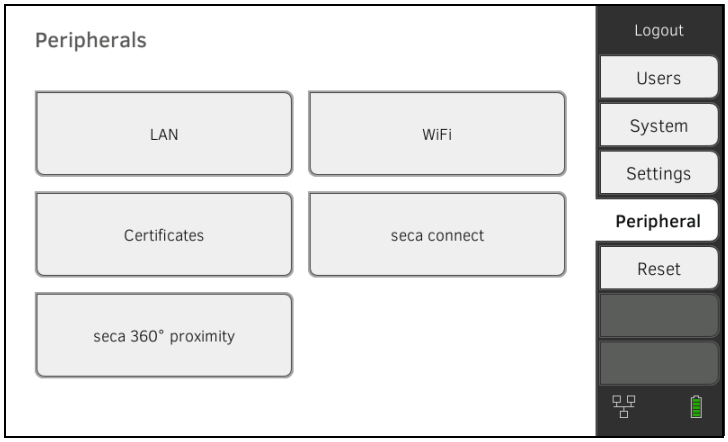
For mobile use, for example, on the ward of a hospital, you can integrate the device into your network as a WiFi client to exchange data with the **seca connect 103** software.

A requirement for exchanging data with the **seca connect 103** software is that the **seca connect 103** software is installed on a server and the configuration of the **seca connect 103** software (server IP and connect port) is known.

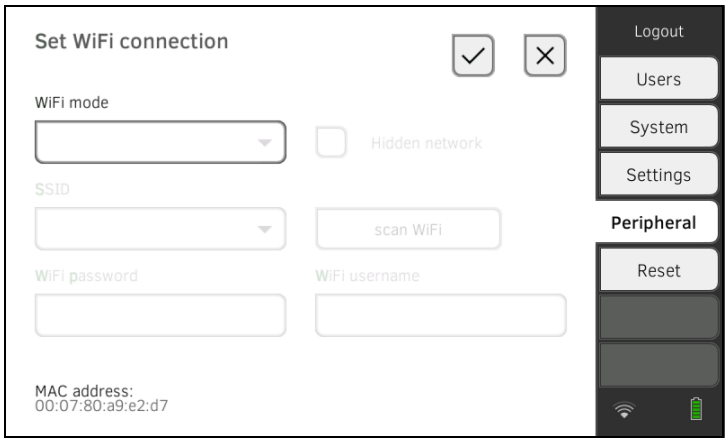


Activating the WiFi connection

1. Press the **Peripherals** tab.



2. Make sure that the LAN connection to the network is **not** active
   ➔ Deactivating the LAN connection.
3. Press the **WiFi** key.



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4. In the **WiFi mode** drop-down menu, press the **WiFi client (network)** setting.
5. Make the setting applicable to your WiFi network:
   - Visible network: Press the **Scan WiFi** key
   - Hidden network: Press the **Hidden network** key
6. Enter the SID for your network:
   - Visible network: Select SSID from drop-down menu
   - Hidden network: Enter SSID manually
7. Enter the user name and password for the network.

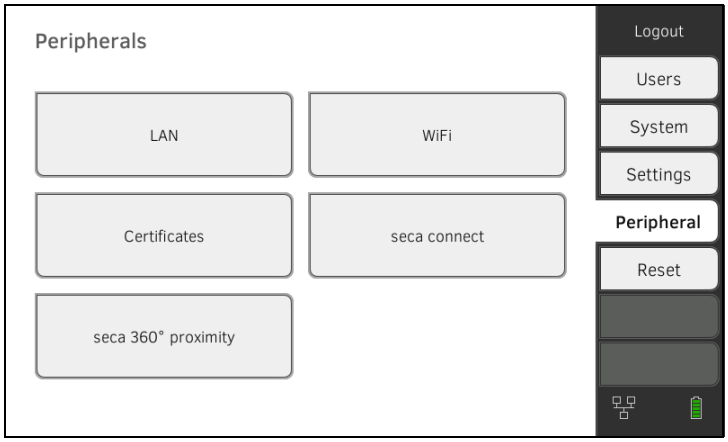
   NOTE
   In some networks, no user name is required. In this case, the input field is grayed out.

8. Press the  key to confirm your entry.
   The connection is established.

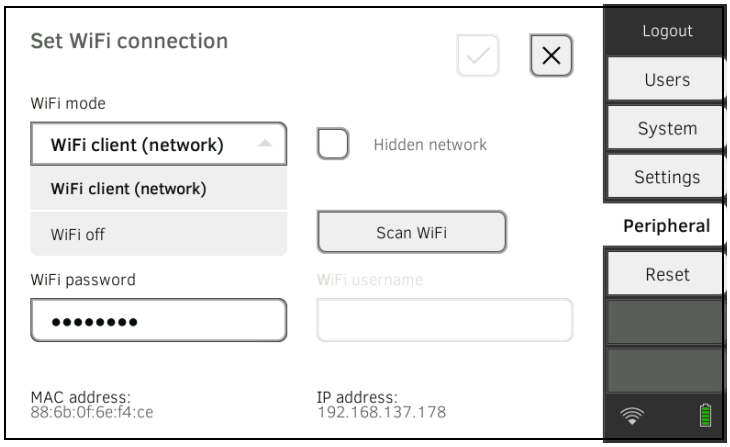
   The  symbol is displayed on the monitor.
   The device is connected to your network via WiFi.
9. Set up the connection to the **seca connect 103** software ➔ Setting up a connection to the seca connect 103 software

Deactivating the WiFi connection

1. Press the **Peripherals** tab.



2. Press the **WiFi** key.



3. In the **WiFi mode** drop-down menu, press the **WiFi off** setting.

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4. Press the  key to confirm your entry.
   The WiFi function is deactivated.
   The connection data are deleted.

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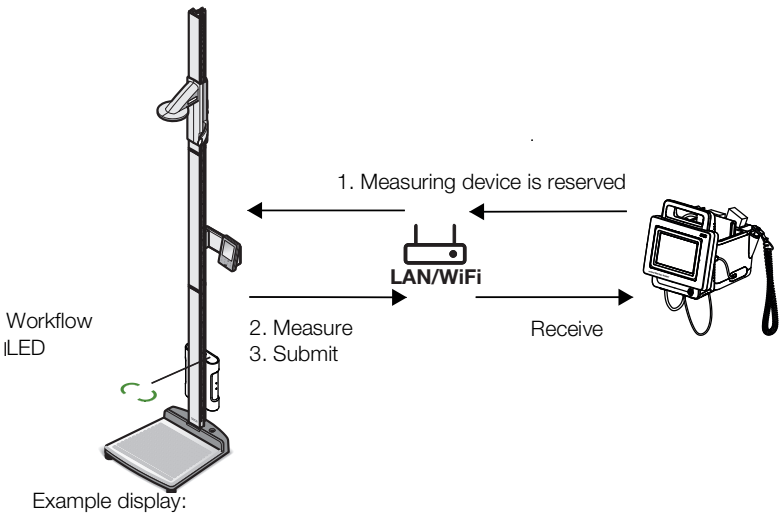
5.3 Setting up a seca 360° proximity connection

Use a **seca 360° proximity** connection to adopt measured values from compatible seca measuring devices (scale, measuring rod, measuring station).



Example display:
seca 285 measuring station with **seca 452** interface module and **seca mVSA 535**

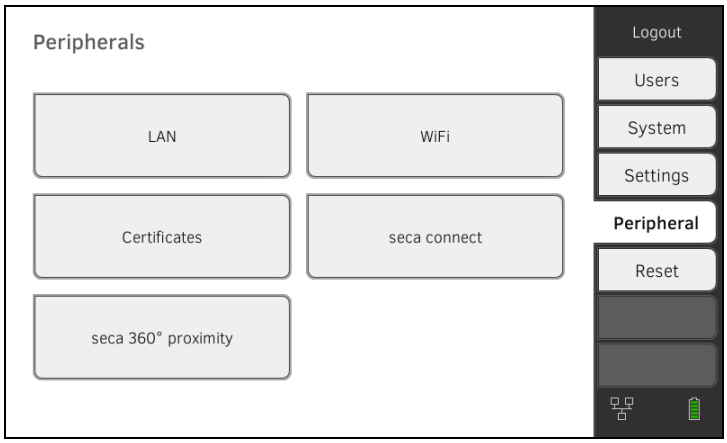
The following requirements must be met in order to connect:

- The seca measuring device is equipped with either a **seca 452** external interface module or with an internal interface module (in each case firmware version R1.3 Build 79 or higher).
- The seca measuring device is connected to your LAN or WiFi network.
- The seca measuring device is configured as follows:
  - Scan user ID: Required
  - Scan patient ID: Required
  - Confirmation of measurement on seca measuring device: Required
  - Port used: Port configured for communication with the **seca connect 103** software (default: 22020) ➔ Setting up a connection to the seca connect 103 software

NOTE
Information about how to configure your seca measuring device can be found in the **seca 103/452** system instructions for use.

Proceed as follows to connect the seca measuring device:

1. Press the **Peripherals** tab.



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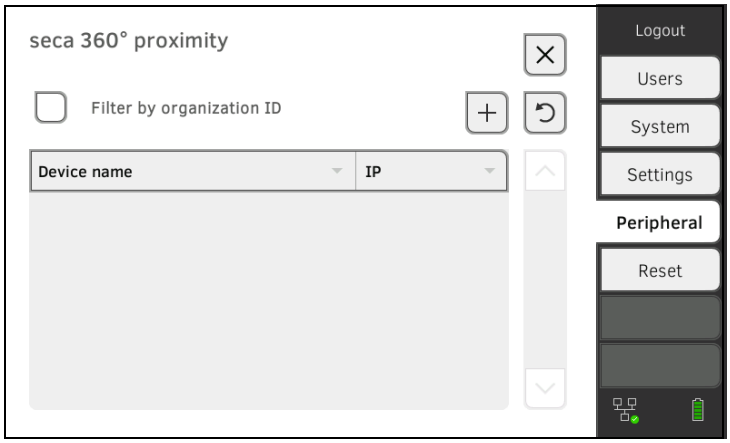
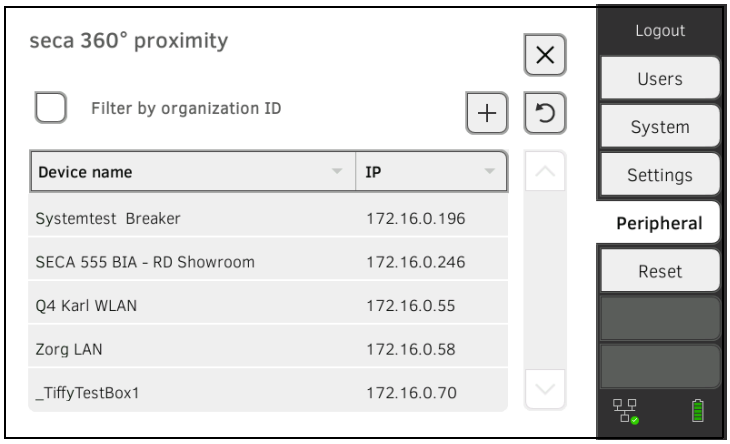
2. Press the **seca 360° proximity** key.
   The **seca 360° proximity (seca 360° proximity)** dialog window opens



3. Search for available devices:

   - Press the  key: Search for devices on the network
   - Press the  key: Enter the IP address of a device
   - Put a tick next to **Filter by organization ID**: Only devices with the same organization ID as the **seca mVSA 535** are displayed

   Available devices are displayed.



NOTE
Information about how to assign organization IDs can be found in the **seca 103/452** system instructions for use. Contact seca Service.

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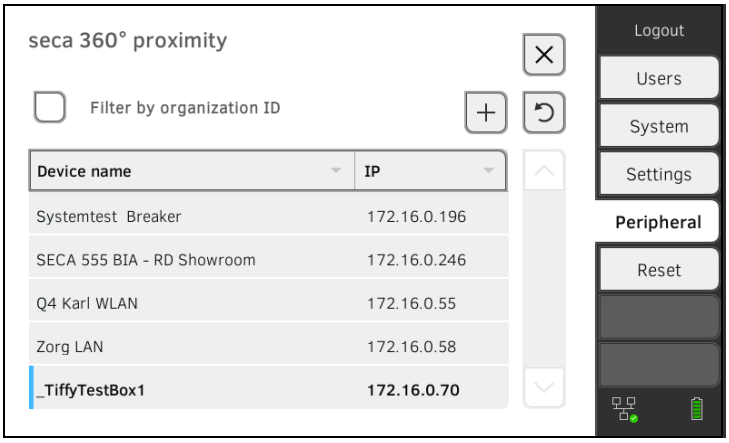
4. Press the desired device in the list.



The device is marked blue in the list.
The connection is set up.
In measuring mode, the seca measuring device is reserved as soon as a patient file is called up. The device is released again once the measurement is stopped ➜ Receiving weight and height (seca 360° proximity).

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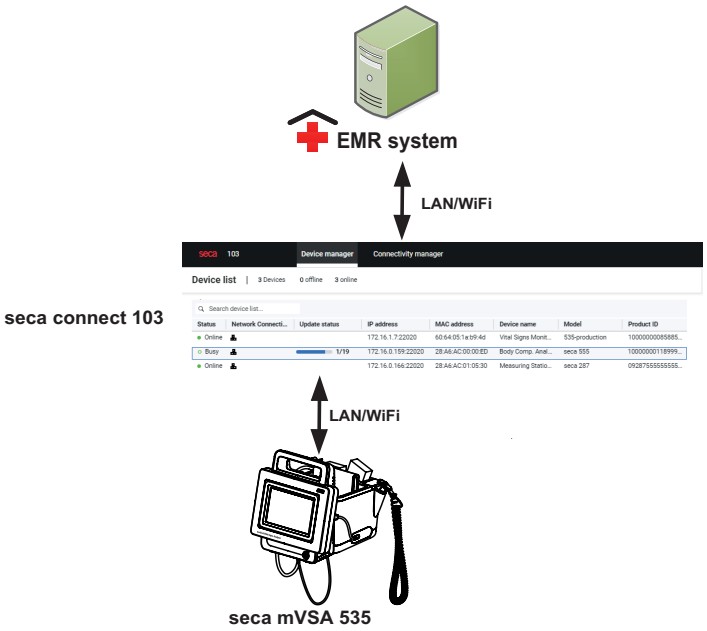
6. CONNECTING TO AN EMR SYSTEM

You can connect the device to compatible EMR systems via the **seca connect 103** software.

seca recommends performing this integration exclusively in collaboration with seca Service and the manufacturer of your EMR system.



The following functions are available when you connect to an EMR system:

- Log in to device with EMR system user ID
- Call up EMR system patient data on the device
- Submit measured results to the EMR system

Information about the measuring sequence when you connect to an EMR system can be found here: ➔ Operation when connected to an EMR system.

6.1 Information about user and patient data

When connecting to an EMR system, the following changes apply to the management of user and patient data:

- User IDs for medical staff can only be set up in the EMR system.
- Patient files can only be managed in the EMR system.
- User IDs for administrators and service technicians can only be set up on the device.

In order to call up patient data from the EMR system, you can search for patients either by name or by patient ID. The functions are not available simultaneously. The **seca connect 103** software specifies which function is available. Please contact seca Service for the configuration.

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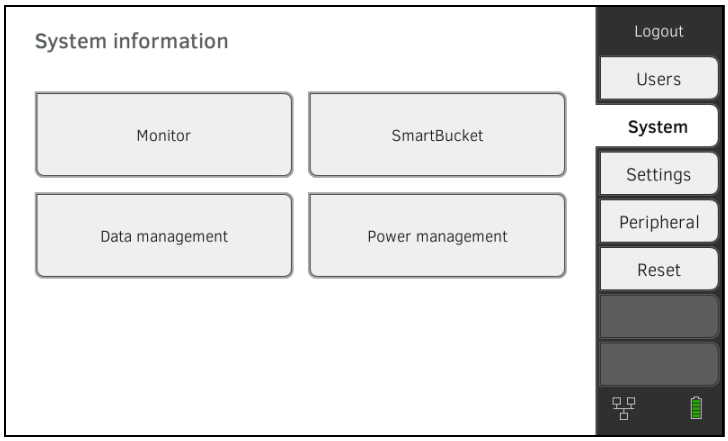
6.2 Assigning a clear device name

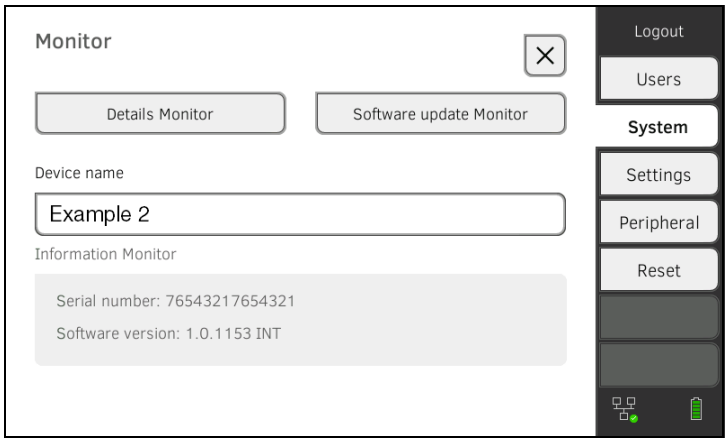
For the device to be connected to an EMR system, it needs to be assigned a clear device name. The device transmits a heartbeat to the network under this device name every 30 seconds.

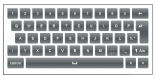
To assign a device name, proceed as follows:

1. Log in as administrator.
2. Press the **System** tab.



3. Press the **Monitor** key.
   The **Monitor** dialog window is shown:



4. Enter a clear device name in line with the naming conventions of your institution:
   a) Press the **Device name** input field
   b) Use the keypad  : Enter the device name
   c) Press the  key: Confirm entry

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6.3 Setting up a connection to the seca connect 103 software

The device must be connected to the **seca connect 103** software in order to be able to communicate with your EMR system.

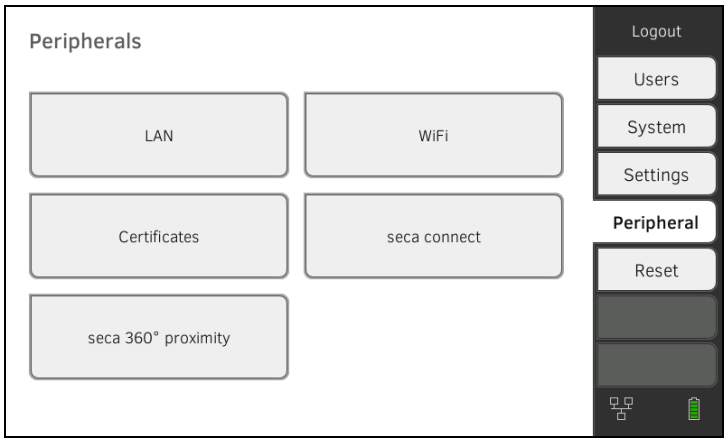
The following requirements must be met for this:

- The device is connected to your LAN or WiFi network
- The server address and port for the **seca connect 103** are known
- The EMR system is connected to the **seca connect 103** software. Information on this can be found in the **seca 103/452** system instructions for use (from version 2.0 or higher)

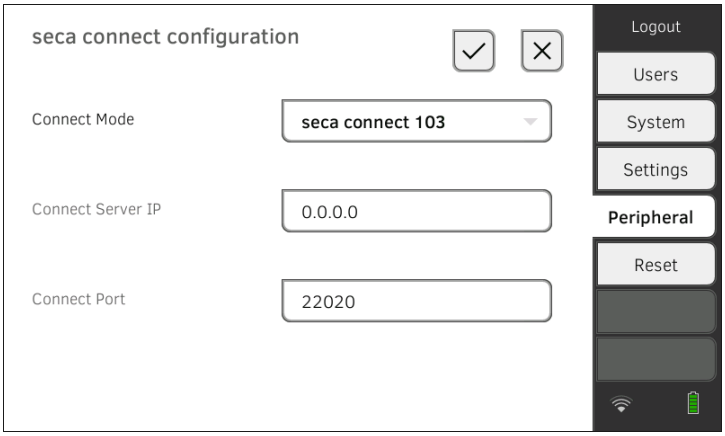
NOTE

- Follow the information in this section of the document ➔ Monitor interfaces and network ports.
- Information on connecting the EMR system to the **seca connect 103** software can be found in the **seca 103/452** system instructions for use (from version 2.0 or higher)

1. Press the **Peripherals** tab.



2. Press the **seca connect** key.
   The **seca connect configuration** dialog window opens.
3. In the **Connect Mode** drop-down menu, select the option **seca connect 103**.



4. Enter the connection data for the **seca connect 103** software:
   - ► Enter the IP address of the server on which the **seca connect 103** is installed
   - ► Enter the port for the **seca connect 103** (recommended: 22020)

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5. Press the  key.
   The settings are saved.
   The connection is set up.

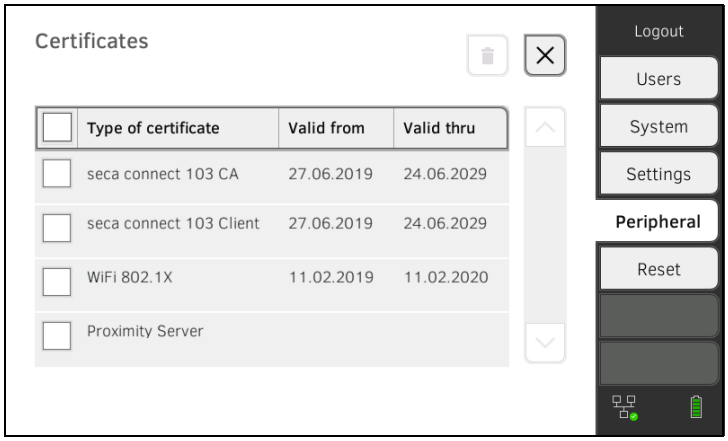
6.4 Configuring data transfer to the EMR system

seca recommends performing the data transfer to the EMR system only in collaboration with seca Service and the manufacturer of your EMR system.

NOTE
More information on this can be found in the **seca 103/452** system instructions for use (from version 2.0 or higher).

6.5 Use of certificates

The device is prepared for the use of certificates. If you wish to use this function, please contact seca Service.



6.6 Summary: Device behavior when connected to an EMR system

Function	Stand-alone (factory setting)	Connection to EMR system via seca connect 103
User identification (measure)	seca user account, role: Physician	EMR user ID
User identification (manage)	seca user account, role: Administrator	Device-specific user account, role: Administrator
Login	Select from list	• Scan barcode • Manual
Password	Manual	Manual
Patient identification	Select from list	• Scan barcode • Enter manually
Source of patient data	Device	EMR system
Create/edit patient data on device	Possible	Not possible
Storage location for measurements	Device database	• Unsubmitted measurements list • EMR system
Unsubmitted measurements list	Not available	Available

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7. CLINICAL OBSERVATIONS

➔ Specified settings for the configuration file

➔ Loading the configuration file onto the device and updating it

➔ Deleting configuration file

The device gives you the option of recording clinical observations. Your institution can specify the content individually in a configuration file which is loaded onto the device.

NOTE

- This function is only available to you if the device is connected to an electronic medical records system (EMR).
- Inform the staff in your in your institution about the option of recording clinical observations on the device before this function is available.
- Ensure that all the settings for this function meet the specifications of your institution and are compatible with your EMR system.

The configuration file is not part of the scope of delivery. You create the configuration file for the overall integration solution in consultation with seca Service.

If you wish to use this function, please contact seca Service.

7.1 Specified settings for the configuration file

➔ Options for input

➔ Definition of mandatory fields

➔ Language selection

Options for input

Three types of options for input with configurable limit values are available for recording clinical observations:

- Simple selection via option field: Selection from a freely-definable list with a maximum of seven entries
- Free text: Input of any alphanumerical text with a freely-configurable minimum and maximum length
- Numerical value: Input of any numerical value in a freely-configurable range of values

A maximum of 24 parameters can be defined in total.

Definition of mandatory fields

It is possible to define for each parameter whether the input is mandatory or optional:

- Mandatory field (marked orange): Clinical observations can only be submitted to the EMR system if this parameter has been filled in by the user.
- Optional field: Clinical observations can be submitted even if this parameter has not been filled in.

Language selection

The configuration file cannot be translated. The texts in the “Clinical observations” section of the device are displayed in the way they were defined as text in the configuration file.

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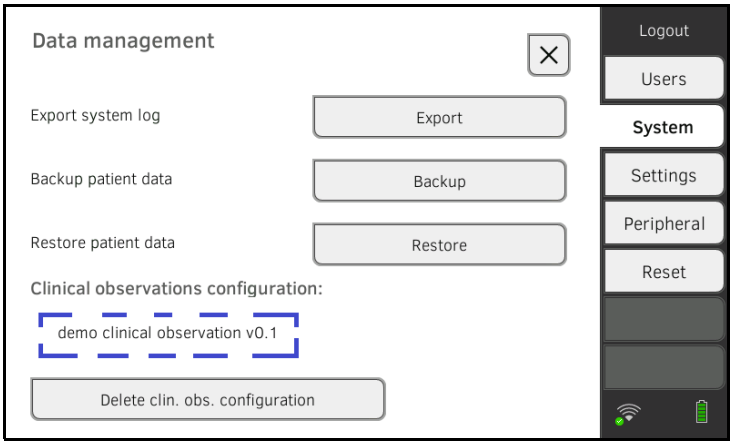
7.2 Loading the configuration file onto the device and updating it

The configuration file for clinical observations is loaded onto the device via the connection to the **seca connect 103** software. Further information is available in the **seca 103/452** system instructions for use.

The configuration can be changed by loading another configuration file onto the device.

NOTE

- If you want to update or delete the configuration file, there must not be any unsubmitted clinical observations saved on the device. Submit all saved clinical observations ➔ Submitting the measurement.
- You can assign a version name in the configuration file in the form of free text. The version name of the currently loaded configuration file is displayed in the **System** tab, **Data management** key.

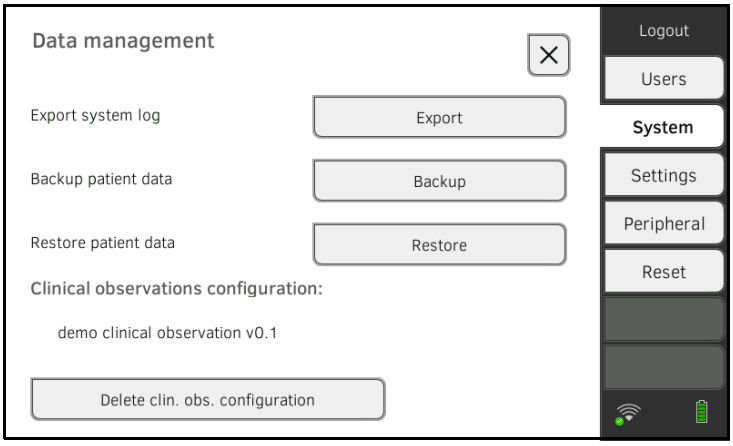


7.3 Deleting configuration file

NOTE

If you want to update or delete the configuration file, there must not be any unsubmitted clinical observations saved on the device. The configuration file cannot be updated or deleted otherwise. Submit all saved clinical observations ➔ Submitting the measurement.

1. Press the **System** tab.
2. Press the **Data management** key.
3. Press the **Delete clin. obs. configuration** key.
   The configuration is deleted.



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8. FACTORY SETTINGS

8.1 Overview 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: International	 dd.mm.yyyy
Time format: International	 24 h
Naming convention: International	 Surname, first name
Name hyphen	Dot
Display brightness	100 %
Volume for warning and information sounds Volume for key sounds	70 % 70 %
Rechargeable battery capacity, automatic switch-off at:	≤ 50 %
Weight: International	 kg
Height: International	 m
Blood pressure: Unit Presets	 mmHg Upward measurement, single measurement
Temperature: Unit COVIDIEN™ FILAC™ 3000 Blue Red	 °C Oral measurement, predictive measurement Predictive measurement
Pulse rate: Unit Preset (seca measuring equipment only)	 min^{-1} Default
Oxygen saturation: Unit Mode	 % Normal
Decimal separator: International	 Comma
LAN Connection data	On None
WiFi client (device <-> network): Connection data	Off None
Device name	[Serial number]
Integration mode	Stand-alone

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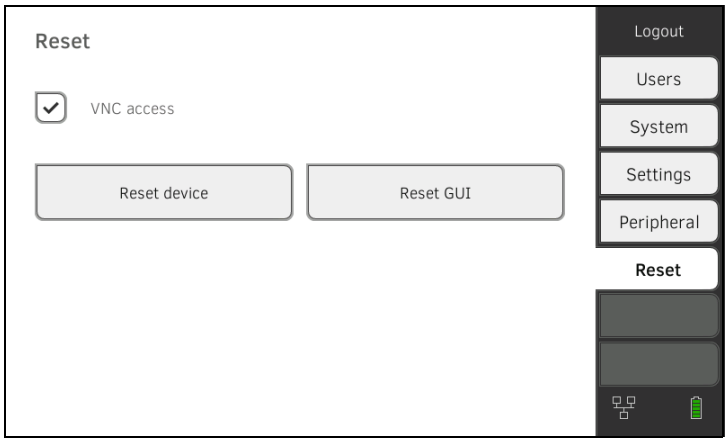
Function	Setting
seca **seca connect 103** software:	
Communication server IP	None
Connect port	22020
Org ID	None
Tenant ID	None
Active analysis modules **seca mVSA 535**	Vital signs

8.2 Resetting the device

Use the **Reset device** function to reset the device to factory settings (➔ Overview of factory settings). seca patient files and user accounts are deleted from the device in this process.

NOTE
If seca patient files and user accounts are to be retained, proceed as described in the section entitled ➔ Resetting the user interface.

1. Press the **Reset** tab.



2. Ensure that seca patient files and user accounts have been exported.
3. Press the **Reset device** key.
   seca patient files and user accounts will be deleted.
   The device will be reset to factory settings (➔ Overview of factory settings).

8.3 Resetting the user interface

Use the **Reset GUI** function to reset the user interface (GUI = Graphical User Interface) of the device to factory settings (➔ Overview of factory settings). seca patient files and user accounts will be retained in this process.

NOTE
If all seca patient files and user accounts are to be removed from the device, proceed as described in the section entitled ➔ Resetting the device.

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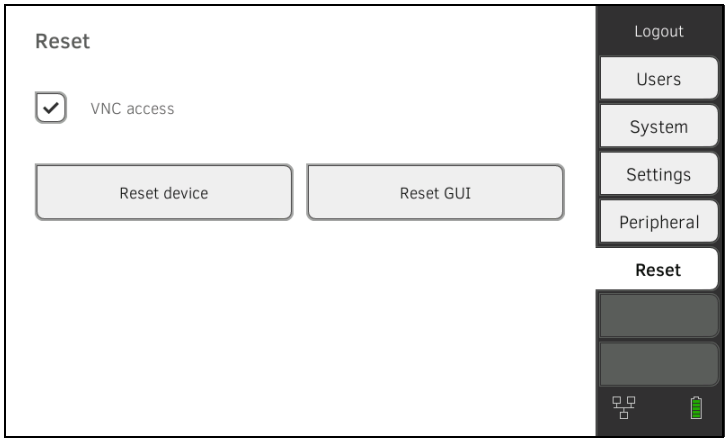
1. Press the **Reset** tab.

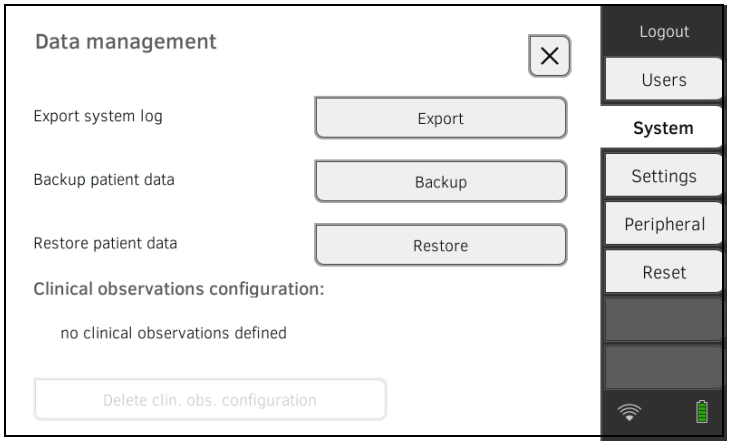


2. Press the **Reset GUI** key.
   The graphical user interface will be reset to factory settings (➔ Overview of factory settings).
   seca patient files and user accounts will be retained.

8.4 Exporting the system log/audit trail

This function allows you to export the system log/audit trail and make it available to seca Service for support purposes, for example.

1. Press the **System** tab.
2. Press the **Data management** key.



3. Press the **Export** key.
4. Connect a USB memory stick to the monitor.
5. Press the **Export system log** key.
   The system log/audit trail is exported.

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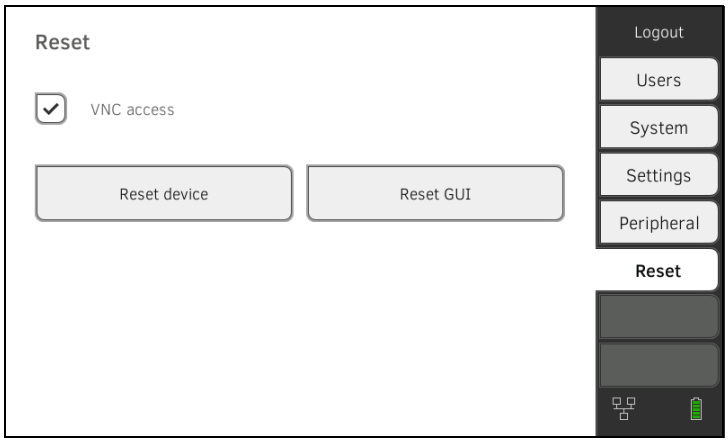
8.5 Enabling VNC access

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.

NOTE
This function is intended purely for demonstration purposes. The monitor display on the PC screen varies depending on the setting of your VNC connection. We recommend a low bandwidth for a stable VNC connection.

1. Press the **Reset** tab.



2. Press the **VNC access** checkbox.
3. Restart the device.
   The VNC service of the device is started.
4. Set up the VNC connection using the VNC viewer of your PC.

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