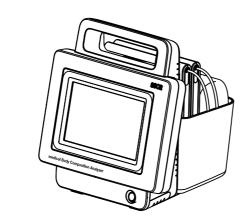
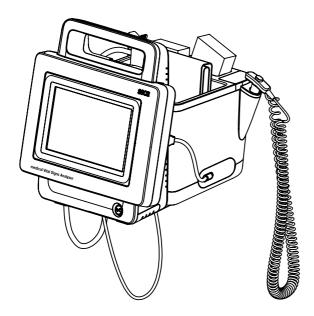
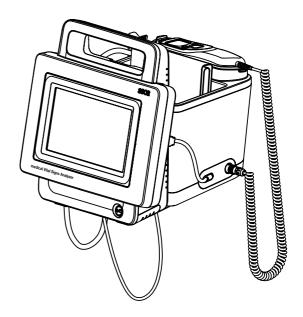
seca 535/525

Instructions for use

Software version 1.0 from Build 999









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INSTRUCTIONS FOR USE FOR SECA 535/SECA 525

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- → Start up device
- → Operation
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NOTE

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

1. DEVICE DESCRIPTION

- → Intended use seca 535
- → Intended use seca 525
- → Description of function
- → User qualification
- → Contraindications

1.1 Intended use seca 535

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

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

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

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

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

1.2 Intended use seca 525

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

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

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

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

1.3 Description of function

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

Device components

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

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

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

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

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

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

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

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Power supply

	The measuring mat is powered by a lithium-ion rechargeable battery. The rechargeable battery is charged by an inductive charging interface in the magnetic catch of the monitor.
Bioimpedance measurement	The bioimpedance measurement is performed with a measuring mat developed by seca.
	The bioimpedance measurement is carried out with the patient lying down, using the 8-point method. The 4-point method (measuring the right half of the body) is likewise possible. The low alternating current is provided and impedance is measured by the electrode cables of the measuring mat. The electrode cables are connected to two pairs of electrodes for each half of the body. The electrodes are affixed to the patient's hands and feet.
Vital signs measurement	Blood pressure is measured non-invasively with seca measuring equipment and seca blood pressure cuffs.
	Temperature is measured with COVIDIEN [™] measuring equipment and, depending on the device version, as an oral/axillary (blue temperature probe), rectal (red temperature probe) or in-ear thermometer procedure.
	Depending on the device version, oxygen saturation is measured with Masimo SET [®] or with seca measuring equipment and with the corresponding SpO ₂ sensors and patient cables.
	Depending on device version, pulse rate is determined using either oxygen saturation or blood pressure.
Alarms	The device is intended for discontinuous measurement of vital signs, so it does not have an alarm function.
Record weight and height	Scales and stadiometers from the seca 360° wireless system can transmit measured results to the device wirelessly. Alternatively, the patient's weight and height can be recorded manually.
Administration of seca user accounts	User accounts can be set up and administered directly on the device. The user accounts for the device can be synchronized automatically with the user accounts of the seca analytics 115 PC software. This allows access to both the device and the PC software with the same user account.
Administration of seca patient files	Measured results are administered in seca patient files. seca patient files can be created directly on the device. With administrator rights, seca patient files can be edited directly on the device.
	The device can be configured so that the seca patient files of the device are automatically synchronized with the seca patient files of the seca analytics 115 PC software.
	seca patient files and seca patient databases contain exclusively data neces- sary for working with seca products or which were determined using seca products.
	The export and import functions of the seca analytics 115 PC software can be used for exchanging data with practice and hospital information systems.
Analysis of measured results	Bioimpedance measurements are analyzed in graphical form based on scientifically-validated formulas. In-house studies by seca generated predictive formulas for determining the parameters total body water (TBW), extracellular water (ECW), fat-free mass (FFM) and skeletal muscle mass (SMM) for arms, legs, torso and the whole body. Further studies generated normal ranges for the following parameters: Bioelectric impedance vector analysis (BIVA), mass indices (FMI, FFMI), phase angle(ϕ), fat mass (FM) and skeletal muscle mass (SMM).

	Measured results for the vital signs blood pressure (NIBP), temperature (TEMP), pulse rate (PR) and oxygen saturation (SpO ₂) are displayed in graphical form.
Data transmission and network functions	The device can be incorporated in a PC network via a LAN interface or via WiFi. The device can thus communicate with the databases of seca analytics 115 PC software and use the seca directprint function of the seca analytics 115 PC software.
	Monitor and measuring mat communicate with each other via a WiFi direct connection or via an infrared interface.
	The monitor and the measuring mat communicate with one another via WiFi. If WiFi is unavailable, the infrared interface in the magnetic catch of the monitor is used.
	Measured results for the parameters blood pressure, body temperature, pulse rate and oxygen saturation are transmitted from the SmartBucket to the monitor over a USB connection.
	Scales and stadiometers from the seca 360° wireless system can transmit measured results to the device wirelessly.
Compatibility	This device (software version 1.0, Build 999 or higher) is only compatible with version 1.4 (Build 936 or higher) of the PC software seca analytics 115 . There is no downward compatibility with older versions of the seca analytics 115 .
	medical Body Composition Analyzer seca mBCA 525 from serial number 10000000090505 can be retrofitted by the user with the SmartBucket seca mVSA 526 to measure vital signs.
1.4 Usor qualification	

1.4 User qualification

	→ Administration/network connection
	→ Measuring mode
Administration/network connection	The device may only be set up and incorporated in a network by experienced administrators or hospital technicians.
Measuring mode	The device and the seca analytics 115 PC software may only be operated by persons with sufficient specialist expertise.
	Basic knowledge for measuring vital parameters is not the subject of this manual.

1.5 Contraindications

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

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

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

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

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

- Cramps
- Tremors

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

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

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

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

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

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

- cardiac arrhythmias
- pregnancy

2. SAFETY PRECAUTIONS

- → Safety precautions in these Instructions for Use
- → Basic safety precautions

2.1 Safety precautions in these Instructions for Use



DANGER!

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



WARNING!

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



CAUTION!

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

NOTICE!

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

NOTE

Includes additional information about use of the device.

2.2 Basic safety precautions

- → Handling the device
- → Handling a wheeled stand
- → Prevent electric shock
- → Prevent injuries and infections
- → Prevent device damage
- → Handling measured results
- → Handling packaging material
- → Handling batteries and rechargeable batteries

Handling the device

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



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.

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.

Prevent electric shock

WARNING! Electric shock

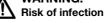
- Set up devices which can be operated with the electricity supply so that the power supply socket is within easy reach and the power supply can be disconnected quickly.
- Ensure that your local power supply matches the details on the ► device.
- ► Connect this device only to a power supply with a protective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

Prevent injuries and infections

WARNING! Injury from falls

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

WARNING!



- ► 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.

NOTICE! Damage to device

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



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 measurement results in non-SI units is the sole responsibility of the user.

NOTICE!

Inconsistent measuring results

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

Handling measured results

NOTICE

Results not comparable to other devices

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

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

NOTE

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

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).

WARNING! Personal inju

Personal injury as a result of improper handling

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

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

NOTICE!

Damage to device and malfunctions with improper handling

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

Handling packaging material

Handling batteries and rechargeable batteries

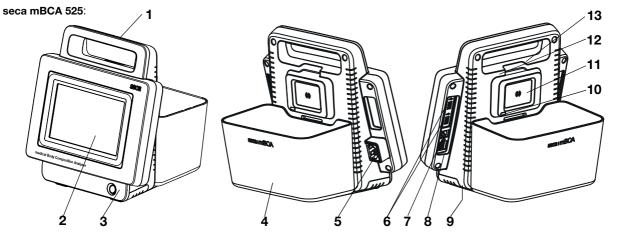
3. DEVICE OVERVIEW

- → Monitor controls for seca 535/seca 525
- → Measuring mat controls (bioimpedance analysis)
- \rightarrow In-ear thermometer controls
- \rightarrow Fields in the touchscreen display
- → Login/navigation: Buttons and symbols in the touchscreen display
- → Operating state: Symbols
- → Measuring mode: Buttons and symbols
- → Markings on the device and on the type plate
- → Markings on the blood pressure cuff
- → Markings on the packaging

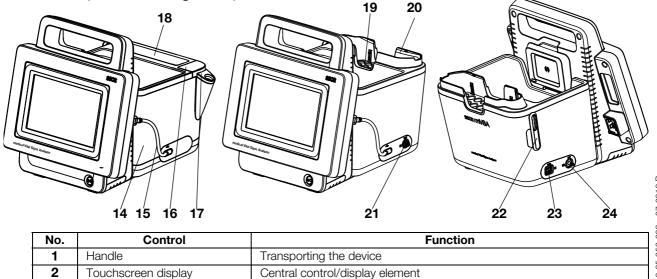
3.1 Monitor controls for seca 535/seca 525

NOTE

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

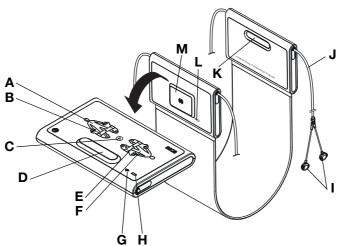


seca mVSA 535 (additional/deviating controls):



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

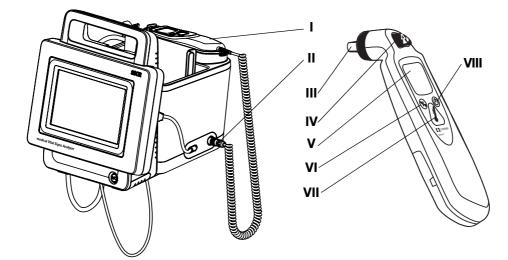
3.2 Measuring mat controls (bioimpedance analysis)



No.	Control	Function
110.		LED green: Electrode contact good
Α	LEDs, electrodes on left	LED green, flashing: Measurement in progress
	LED red: Electrode contact poor	
		Enter patient position
_	Button with LED,	LED green: seca patient file loaded, patient position selected
В	patient position left	LED green, flashing: Measurement stopped
		LED red: No seca patient file loaded
С	Start button	Start measurement
D, K	Magnetic catch	For folding up measuring mat for transport/storage
_,		Enter patient position
_	Button with LED,	LED green: seca patient file loaded, patient position selected
Е	patient position right	LED green, flashing: Measurement stopped
		LED red: No seca patient file loaded
		LED green: Electrode contact good
F	LEDs, electrodes on right	LED green, flashing: Measurement in progress
		LED red: Electrode contact poor
		LED green: WiFi connection to monitor OK
~		LED green, flashing: WiFi connection being set up
G	LED, WiFi	LED red: No WiFi connection to monitor
		LED off: WiFi deactivated
		LED green: Rechargeable battery full
н	LED, charging status	LED green, flashing: Rechargeable battery almost discharged, charge as
	LLD, Charging status	soon as possible
		LED red: Rechargeable battery discharged
Ι	Electrode connections	For connecting to electrodes
J	Electrode cables	For transmitting signals from electrodes to the measuring mat
L	Infrared interface	Automatic data transmission: Monitor/measuring mat
-		Alternative if no WiFi available
М	Inductive charging interface with magnetic catch	For charging measuring mat rechargeable battery

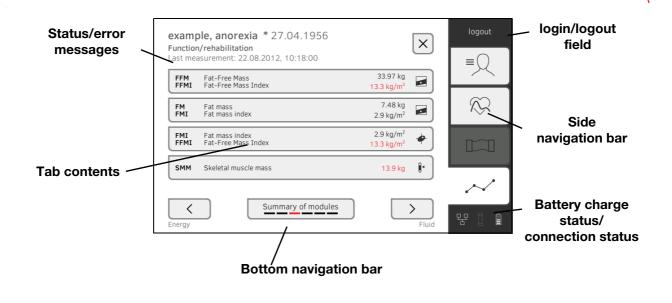
NOTE

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



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

3.4 Fields in the touchscreen display



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

Button/ovmbol	Magning
Button/symbol	Meaning
=	patient tab
\sim	vital signs tab
	bia tab
\sim	analysis tab
i	Open Instructions for Use
	Instructions for Use: Return to section summary
	Enter text or numbers
	No input or input faulty
•	Select user account
9	Enter password
\checkmark	 Navigation: Confirm entry Measuring: Save measuring procedure
	Process running
create	Button available
create	Button pressed
create	Button not available
$\langle \rangle$	Navigate left/right
	Navigate up/down

Button/symbol	Meaning
✓	One or more items from list selected/not selected
	Alternative from list selected/not selected
×	 Back to previous screen Vital signs: Measurement is stored anonymously Administrator menu: Changes are accepted
Logout	Log off/switch user

3.6 Operating state: Symbols

- → Operating state: Symbols in the touchscreen display
- \black Operating state: Symbols on the measuring mat

Operating state: Symbols in the	e
touchscreen display	

Symbol	Operating state
60 %	Monitor: Controls permanently on: Rechargeable battery charging status (%) Controls flashing: Rechargeable battery charging
50 %	Measuring mat: Controls permanently on: Rechargeable battery charging status (%) Controls flashing: Rechargeable battery charging
	Monitor: Controls permanently on: Rechargeable battery full Controls flashing consecutively: Rechargeable battery charging
	Monitor: Rechargeable battery discharged
I	Measuring mat: Controls permanently on: Rechargeable battery full Controls flashing consecutively: Rechargeable battery charging
I	Measuring mat: Rechargeable battery discharged
모모	LAN available
(())	WiFi available
	Measuring mat detected

Symbol	Operating state
	Measuring mat not detected
i	Popup window: Information for the user
\otimes	Popup window: Error message
٢	Popup window: Setting option for the user
	Error message during vital signs measurement

Operating state: Symbols on the measuring mat

Symbol	Operating state
	LED green: Rechargeable battery full Green, flashing: Charge rechargeable battery as soon as possible
	LED red: Rechargeable battery discharged
•(((•	LED green: WiFi available Green, flashing: WiFi connection being set up
•(((+	LED red: WiFi not available LED off: WiFi deactivated

3.7 Measuring mode: Buttons and symbols

- → "patient" tab
- → "vital signs" tab
- → "bia" tab

- → Measuring mat
- → "analysis" tab

"patient" tab

$-\bigcirc$	Button/symbol	Meaning
=	9	Search for seca patient file
	• •	Switch sorting direction
		Enter weight
	<u>t</u>	Enter height
	Ŕ	Enter waist circumference
	Ŕ	Enter Physical Activity Level (PAL)

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

"vital signs" tab

Button/symbol	Meaning
NIBP	Blood pressure measured non-invasively
\bigcirc	Start blood pressure measurement
	Blood pressure measurement in progress
SYS/DIA	Blood pressure: Systolic/diastolic pressure
MAD	Blood pressure: Mean arterial pressure
≈ »́	Blood pressure: Upward measurement, downward measurement
• :	Blood pressure: Single measurement, multiple measurement
TEMP	Temperature
▶	Temperature measurement mode: Predictive, direct
י ווי יווי	temperature probe COVIDIEN™ FILAC™ 3000 Measuring position: Oral, axillary, rectal
• m	COVIDIEN [™] GENIUS [®] 2 in-ear thermometer Measuring position: Oral
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 %)

Button/symbol	Meaning
	Devices with Masimo SET [®] measuring equipment, oxygen saturation measuring mode: Normal, APOD, maximum
<u>^</u> ^^;	Devices with seca measuring equipment, oxygen saturation measuring mode: Stable, default, sensitive
\checkmark	Save measuring procedure
\times	Discard measurement
	Display list of all vital sign measurements

"bia" tab

Π

Button/symbol	Meaning
·	Enter patient position
\bigcirc	Start measurement
	Measurement in progress
	Permanently on: Electrode OK Flashing: Measurement in progress
8	Electrode not OK
0	Measurement successful
	Write comment
\checkmark	Save measuring procedure
\times	Discard measurement
	Button/symbol

Measuring mat

Button/symbol	Meaning
•	Enter patient position LED green: seca patient file loaded, patient position selected LED green, flashing: Measurement stopped LED red: No seca patient file loaded

Button/symbol	Meaning
$igodoldsymbol{igodolby}igodolby$	Start measurement
•	Electrode LEDs: LED green: Electrode OK LED green, flashing: Measurement in progress
•	Electrode LEDs: LED red: Electrode not OK

"analysis" tab

~

Button/symbol	Meaning
	View history
	Print results report (seca directprint : Function of seca analytics 115 PC software)
	Position indicator for analysis modules, Here: second module of 5
	Position indicator for analysis parameters, Here: second analysis parameter of 4
8-	Detail view available for analysis parameter: Bar chart
	Detail view available for analysis parameter: Percentile curve
•	Detail view available for analysis parameter: Tolerance ellipse
• •	Parameter-dependent symbols, red: Value outside normal range
• •	Parameter-dependent symbols, gray: Value within normal range
28.6 kg/m ²	Text red: Value outside normal range
15.3 kg/m²	Text black: Value within normal range
3.5 tow town increased high 1.5 5.7 9.0	Green: Value within normal range
7.6 tow normal research high 1.5 5.7 0.0	Orange: Value elevated
12.9 tor normal increased top 3.8 8.7 12.4	Red: Value outside normal range
്	Male
Ŷ	Female

3.8 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
E	Follow Instructions for Use
	Do not use device on individuals with cardiac pacemakers or implanted defibrillators
X	Medical electrical device, type BF
⊣★⊦	Medical electrical device, type BF (defibrillation-protected)
\bowtie	No alarm function
Li-ion	Lithium-ion rechargeable battery
CE 0123	Device complies with EC directives • 0123: appointed office for medical devices
F©	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
Segurança	The device meets the regulatory requirements of INMETRO/ANVISA certification
Contractional de Récommission Contractional de Récommissions Contractional de Récommissions HHHHH-AA-FEFFEF Liste equiparent autoritations de récommission de la contraction de la contraction en sistemas devidamente substanted.	 The device meets the requirements of the Agência Nacional de Telecomunicações [National Telecommunications Agency (ANATEL), Brazil]. Details of the wireless device license: HHHHH: license number of device AA: year of license FFFFF: identification number of the manufacturer
P	The device meets the regulatory requirements of GOST R certification (Russia)
ΓA	License number of the
	Chinese Pharmaceutical Association (CPA)

Text/symbol	Meaning
	The device meets the regulatory requirements on wireless equipment in Japan. License number: VORL.202WW09118012
xxx-yyy V ~ min xx-yy Hz xx A	Type plate for power supply socket: • Permitted supply voltage • Permitted power supply frequency • Power consumption
⊙/Ò	ON/OFF key
	Inductive charging interface
모모	LAN interface
•	USB interface
NIBP	Connection of blood pressure cuff
TEMP	Connection of temperature sensor
SpO ₂	Connection of SpO ₂ sensor
X	Do not dispose of device with household waste

3.9 Markings on the blood pressure cuff

Text/symbol	Meaning
	Follow instructions for use
Ĝ Ĝ Ĝ Ĝ s m () xl	Cuff size (here: L)
size L © 32-42 cm	Cuff suitable for specified arm size
	Artery position: These arrows must be on the brachial or femoral artery when blood pressure cuff is put on.
	Cuff end: These markings must be within the adjustment range when closing the blood pressure cuff.
	Adjustment range: The marking "Cuff end" must be in this range when closing the blood pressure cuff. This area also contains the cuff size (here: L).
LATEX	Latex-free
CE	The blood pressure cuff complies with EU directives

3.10 Markings on the packaging

	1
Ť	Protect from moisture
<u> 11 1 1 1 1 1 1 </u>	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
<u></u>	Permitted min. and max. moisture for transport and storage
NON	Not sterile
\otimes	Do not reuse
	Open packaging here
0	Packaging material can be disposed of through recycling programs

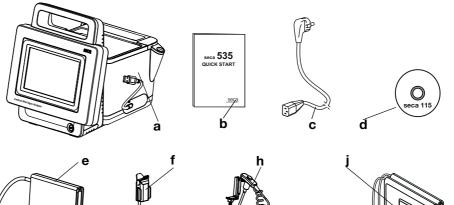
4. START UP DEVICE

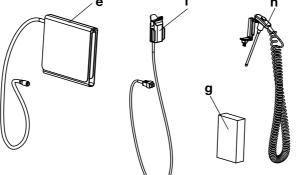
- → Scope of delivery
- → Set up device
- → Establish power supply
- → Charge rechargeable batteries
- → Set date and time
- → Initial login
- \rightarrow Configure the device

4.1 Scope of delivery

NOTE

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







No.	Standard scope of delivery	Pcs
а	Monitor to suit the version ordered	1
b	"Quick Start" brief instructions, printed	1
С	Power supply cable (country-specific)	1-3
-	Accessories to suit the version ordered (for details of version shown, see below)	-
No.	Accessory for the version shown	Pcs.
d	DVD with seca analytics 115 PC software and license for one permanent workstation	1
е	seca Blood pressure cuff, size L	1
e		1

No.	Accessory for the version shown	Pcs.
a	COVIDIEN™ FILAC™ 3000 probe covers	1
g	(pack of 20)	
h	COVIDIEN™ FILAC™ 3000 temperature probe	1
i	Push-button electrodes for affixing to patient (pack of 100)	1
:	Measuring mat with rechargeable battery and electrode	1
1	cables	

4.2 Set up device

- → Connect SmartBucket
- → Connect blood pressure cuff
- → Connect temperature probe
- → Connect in-ear thermometer
- → Connect SpO₂ sensor
- → Suspend measuring mat in magnetic catch

NOTE

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

NOTICE!

Device damage, malfunction

Excessive use of force may damage tubes and cables.

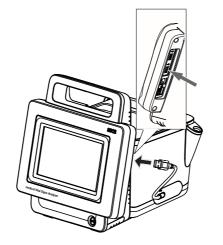
- Only take hold of tubes at the tube coupling when attaching measuring accessories to the device or removing them from it.
- Only take hold of cables at the connectors when attaching measuring accessories to the device or removing them from it.
- Use only measuring accessories which have no externally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

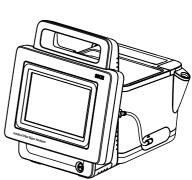
NOTICE!

Malfunction

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

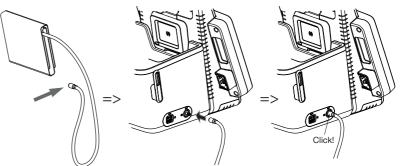
- ► Always keep the SmartBucket connected to the USB interface.
- Only connect accessories, for example, a USB memory stick, to the other USB interface.



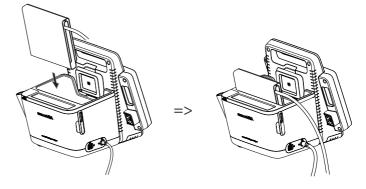


Connect SmartBucket

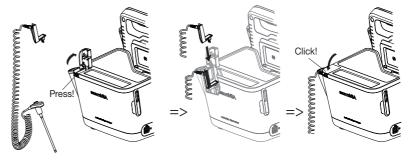
- Connect the USB cable of the SmartBucket to a free USB port of the monitor.
- Connect blood pressure cuff
- 1. Connect the tube coupling for the blood pressure cuff to the compressed air connection of the device until you hear the tube coupling engage.



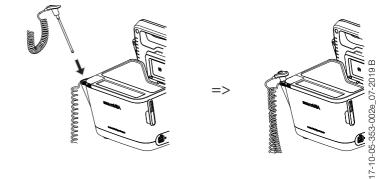
2. Stow the blood pressure cuff in the SmartBucketas shown in the illustration below.



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



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



ATTENTION

Device damage, malfunction

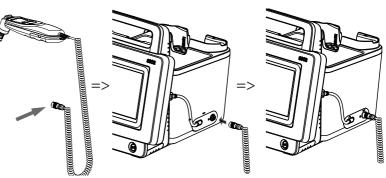
The temperature probe can only be pushed right into the probe holder if it does not have a probe cover on.

• Ensure that there is no probe cover on the temperature probe.

NOTE

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

Connect in-ear thermometer

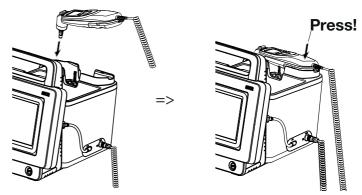


1. Put the connector for the in-ear thermometer in the socket on the Smart-Bucket until you feel the connector engage.

NOTE

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

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



Connect SpO₂ sensor

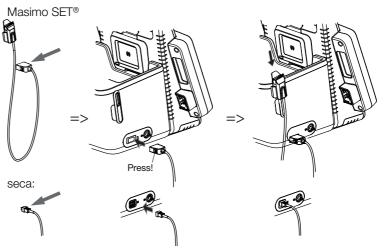
NOTICE!

Device damage, malfunction

The SpO_2 sensor must be compatible with the SpO_2 measuring equipment (Masimo SET^{\tiny (8)</sup> or seca) fitted.

- ► Ensure that the SpO₂ sensor is compatible with the SpO₂ 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 SpO₂ 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

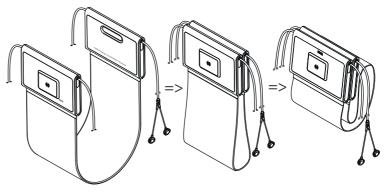
The holder above the SpO_2 connection is for storing the SpO_2 sensor.

NOTICE!

Malfunction

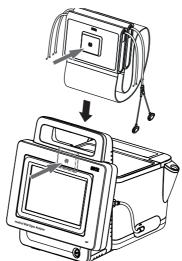
The measuring mat rechargeable battery is only charged via the inductive charging interface of the monitor.

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



Suspend measuring mat in magnetic catch

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



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



4.3 Establish power supply

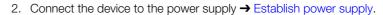


- 1. Plug the device connector of the power supply cable into the connecting socket of the device.
- 2. Plug the power supply connector into a power supply socket.

4.4 Charge rechargeable batteries

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

1. Ensure that the measuring mat is correctly suspended in the magnetic catch of the monitor → Suspend measuring mat in magnetic catch.

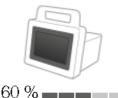




- 3. Press the ON/OFF button of the monitor.
 - The LED of the ON/OFF button is white. The charging process starts.

The current charging status is displayed for approx. 15 seconds:





After approx. 5 minutes, the device switches to standby. The screen goes dark.

The ON/OFF button LED flashes green.

When the rechargeable batteries are fully charged, the device switches off automatically.

The LED of the ON/OFF button goes out.

NOTE

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

4.5 Set date and time

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



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

$\bigcirc \bigcirc \bigcirc \bigcirc$	3.	Press the ON/OFF button of the monitor. The LED of the button is white. The initial start screen appears.
		Login
		seca ≡Q
		05:59:24
		05.04.2015
		명 🛽 🔒
	4.	Enter the current date:
		a) Press input field
		b) Enter the current date using the keypad
	5.	c) Confirm your entry by pressing the button Enter the current time:
		a) Press input field
		b) Enter the current time using the keypad
		c) Confirm your entry by pressing the 🛃 button
	6.	Press the button.
	7.	Continue operating the device - you have the following options:
	•	Leave device switched on, charge rechargeable batteries (recommended): → Charge rechargeable batteries

- Perform measurements using the power supply: → Operation
 Configure device using the power supply: → For administrators: Configure
 - Configure device using the power supply: → For administrators: Configure seca 535/seca 525

1.	Press the Login key.
	The login window is displayed.
2.	Press the input field .
3	The list of user accounts is displayed. Press the admin account.
0.	The admin account is displayed in the input field.
4.	Press the input field
5.	Enter the initial admin password "1357" with the keyboard You are prompted to change the initial admin password.
6.	Enter a new admin password.
	 NOTICE! Data access by unauthorized persons An insecure password may allow unauthorized persons to access patient data or device settings. Select a password that meets your institution's security requirements.
7.	Enter the new admin password again to confirm. The login window is displayed.
8.	Continue operating the device – you have the following options:
	Log in as administrator and create user account → Set up a user account
	• Perform measurements using the electricity supply \rightarrow Operation
	 Configure device using the electricity supply → For administrators: Configure seca 535/seca 525

4.7 Configure the device

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

5. OPERATION

- → Switch system on/off
- \rightarrow Prepare seca patient file
- → Measure bioimpedance
- → Measure vital signs
- → Analyze measurement

5.1 Switch system on/off

- → Switch on
- → Log in
- → Log out/switch user
- → Save energy
- → Switch the monitor to standby
- → Switch off

Switch on



- Ensure that the measuring mat if there is a measuring mat is correctly suspended in the magnetic catch of the monitor → Suspend measuring mat in magnetic catch.
- Press the ON/OFF button of the monitor. The LED of the ON/OFF button is white. The device starts up. This takes a few seconds.

No patient f			Login
	NIBP mmHg	- ®	≡Q
\odot	SYS/DIA		\bigotimes
TEMP °C	MAP		
		PI	\sim
🛓 kg] <u>t</u> m)	· · · · · · · · · · · · · · · · · · ·

The **vital signs** tab is displayed.

The measuring mat - if there is one - switches on automatically. You have the following options:

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

Log 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 system
- 1. Press the **Login** button.

	Login
seca	
	\sim
	\sim
	명 [] []

The login window is displayed.

2. Press the input field

The list of user accounts is displayed. If you do not have a user account, contact your administrator to create a user account \rightarrow Set up a user account.

- 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 keypad6. The **patient** tab is disclosule 6. The **patient** tab is displayed. Continue with \rightarrow Prepare seca patient file.

Press the **logout** button. ►

	ole, anorexia * 27.04.1956	-	logout
	<pre>i/rehabilitation asurement: 22.08.2012, 10:18:00</pre>		≡Q
FFM FFMI	Fat-Free Mass Fat-Free Mass Index	33.97 kg 13.3 kg/m ²	
FM FMI	Fat mass Fat mass index	7.48 kg 2.9 kg/m ²	\bigotimes
FMI FFMI	Fat mass index Fat-Free Mass Index	2.9 kg/m ² 13.3 kg/m ²	
SMM	Skeletal muscle mass	13.9 kg 🔒	
Energy	Summary of modules	Fluid	·····································

You will be logged out.

The login window is displayed.

Another user can log in \rightarrow Log in.

17-10-05-353-002e_07-2019 B

Log out/switch user

Save energy



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

After 5 minutes, the device switches to standby:

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

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

After 10 minutes, the device goes to sleep:

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

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

After 20 minutes, the device behaves as follows:

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

Switch the monitor to standby



Switch off



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



Electric shock

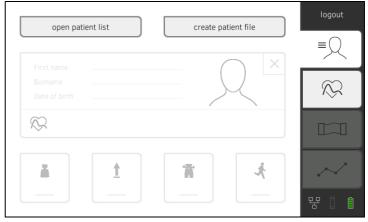
The monitor cannot be de-energized by pressing the ON/OFF button.

- Always remove the power supply connector and remove the re-► chargeable battery (if present and intended for technical purposes) if the device needs to be de-energized, e.g. for the hygiene treatment.
- 1. Ensure that the measuring mat if there is a measuring mat is correctly suspended in the magnetic catch of the monitor \rightarrow Suspend measuring mat in magnetic catch.
- 2. Keep the ON/OFF button of the monitor pressed until the touchscreen display and the LED of the ON/OFF button go out. The device is switched off. The measuring mat switches off automatically.

- → Introduction
- → Call up seca patient file
- → Create seca patient file
- → Enter basic parameters

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

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



Preparation of the seca patient file includes the following items:

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

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Introduction

Call up seca patient file

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

07			×		create file	
-	Name	~	Date of birth	~	ID	-
ę	Steve John, Smith		03.07.1964		_a%12346	
ď	GeorgeMathew, AustinSilva		07.09.2000		aaa123456	
ď	anonymer, Patient		05.02.0001		seca_20150	

- 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:





- b) Enter patient name or patient ID using the keypad



c) Confirm your entry by pressing the A hit list is displayed.

5. Press the desired entry.

The selected seca patient file appears in the Patient information dialog field.

- 6. Press the **confirm** button. The seca patient file is opened.
- 7. Enter the basic parameters \rightarrow Enter basic parameters.

NOTICE!

Inconsistent measured results

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

- ► If there is no seca patient file on the device for the current patient, check whether there is already a seca patient file in the seca analytics 115 PC software.
- If there is a seca patient file for the current patient in the seca analytics 115 PC software, ask your administrator to synchronize the data of the device and the PC software.
- Only create a new seca patient file directly on the device if you are ► sure that there is no seca patient file for the current patient in the seca analytics 115 PC software.
- 1. Ensure that the measuring mat if there is a measuring mat is correctly suspended in the magnetic catch of the monitor \rightarrow Suspend measuring mat in magnetic catch.
- 2. Press the patient tab.

Create seca patient file

3. Press the create patient file button.

Create patient file Page 1 of 2		×
Anonymous patient		
First name	Attending physician:	
	Not assigned	~
Surname	ID	
		>

NOTICE!

Restricted function

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

- Always fill in **both** input screens in order to be able to show measured value graphs (histories).
- 4. Enter the first name and surname of the patient:
 - a) Press input field
 - b) Enter text using the keypad



c) Confirm your entry by pressing the button

NOTICE!

Unauthorized data access

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

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



b) Press the attending physician in the dropdown menu

NOTE

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

6. Press the button.	
Page 2 of 2	
Date of birth	Ethnicity
DD.MM.YYYY	O caucasian
Gender	O asian
O d' male	O african american
O 9 female	O south and central american
	O other
<	
7. Enter the date of birth:	
a) Press input fieldb) Enter dates using the keyp	2 2 2 • 4 2 2 • 5 2 4 • 5 2 4 •
a) Press input fieldb) Enter dates using the keyp	
a) Press input fieldb) Enter dates using the keypc) Confirm your entry by pres	
 a) Press input field b) Enter dates using the keyp c) Confirm your entry by press 8. Press the appropriate gender. 	
 a) Press input field b) Enter dates using the keyp c) Confirm your entry by press 8. Press the appropriate gender. 9. Press the appropriate ethnicity. 	
 a) Press input field b) Enter dates using the keyp c) Confirm your entry by press 8. Press the appropriate gender. 	ising the button

Enter basic parameters

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

open p	patient list	create patient file	logout
First name			≡Ω
			\approx
\mathcal{R}			
ä	<u>1</u>	<i>k</i> #	\sim
			뀸 🛛 🔒

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

• = possible, - = not possible

Button	Meaning	Enter manually	seca 360° Adopt value	Re-use old value
	Weight	•	•	•
<u>1</u>	Height	•	•	•
X	Waist circumf.	•	-	•
Ŕ	Physical Activity Level (PAL)	•	-	•

NOTE

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

- 1. Ensure that the measuring mat if there is a measuring mat is correctly suspended in the magnetic catch of the monitor → Suspend measuring mat in magnetic catch.
- 2. Press a basic parameter.

You have the following options for entering the value:



Enter value using the keypad

360°

button

- seca 360° wireless Confirm the value using the
- Adopt the value from the previous measurement using the button
- 3. Confirm the entry with the button.
- 4. Repeat steps 2. and 3. for the remaining basic parameters.

Press the button. The seca patient file is prepared and is displayed.

Press the **bia** tab.
 The seca patient file is transmitted to the measuring mat.
 You can start with the measurement → Measure bioimpedance.

5.3 Measure bioimpedance

- → Performing a measurement (with WiFi direct connection to the measuring mat)
- → Performing a measurement (without WiFi direct connection to the measuring mat)
- → Connecting the measuring mat
- → Cancel a measurement procedure

WARNING!

$f \Delta$ Hazard to patient, malfunction, damage to device

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

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

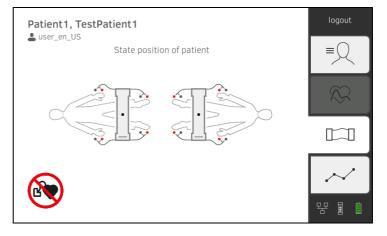
- Amount of time patient should lie **before** each measurement: Approx. 10 minutes
- If possible, arrange follow-up measurements at the same time of day

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

NOTE

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

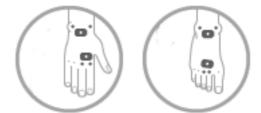
- 1. Switch on the system \rightarrow Switch system on/off.
- Prepare the seca patient file → Prepare seca patient file. The seca patient file is transmitted to the measuring mat.
- 3. Press the **bia** tab.
- 4. Wait until the position keys on the monitor are active.



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

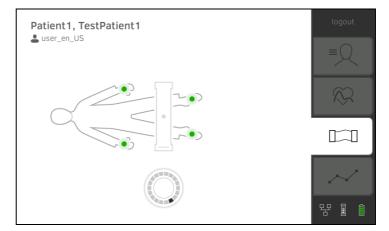


5. Attach the electrodes to all extremities as shown.

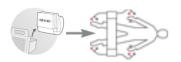


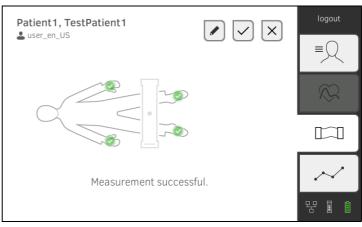
- 6. Take the measuring mat out of the magnetic catch on the monitor.
- 7. Connect the measuring mat to the electrodes → Connecting the measuring mat.
- 8. Perform the following steps on the monitor or on the measuring mat:a) Enter patient position: press the relevant position key

b) Start the measurement procedure: Press button9. Watch the measurement progress on the monitor:



	Monitor				
	Measurement progress	Electrode symbol	Progress symbol		
1.	Electrodes being tested	•			
2.	Measurement in progress Measured results are stored on the measuring mat	٠	\bigcirc		
3.	Measured result are transmitted to the monitor	٠			
4.	Measurement end: Measured results were transferred to the monitor	0	Off		





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

You have the following options to continue:

- Press button: Add comments.
- Press button: Save measurement
- ► Press analysis tab → Analyze measurement.
- ► Press vital signs tab: → Measure vital signs

Press button: Discard measurement

10. Remove the electrode cables from the electrodes.

11. Remove the electrodes from the patient.

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

NOTE:

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

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



e 📛 symbol is displayed on the monitor.

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

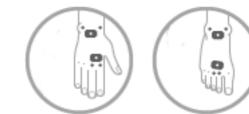
Performing a measurement (without WiFi direct connection to the measuring mat) 4. Press the **bia** tab.



NOTE

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

5. Attach the electrodes to all extremities as shown.

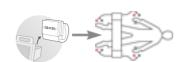


- 6. Take the measuring mat out of the magnetic catch.
- 7. Connect the measuring mat to the electrodes → Connecting the measuring mat.
- 8. Use the keyboard of the measuring mat for the following steps:a) Enter patient position: press the relevant position key



b) Start the measurement procedure: Press9. Observe the measuring progress on the measuring mat:

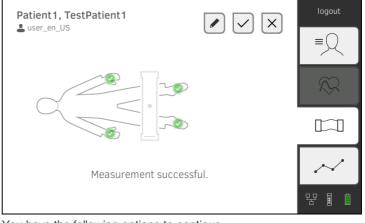
	Measuring mat				
	Measurement progress	Electrodes	Patient position		
1.	Patient position is givenElectrodes being tested	On	On		
2.	 Measurement in progress Measured results are stored on the measuring mat 	Flashing	On		
3.	Measurement end: Measurement results are stored on the measuring mat, waiting for transmission to the monitor	Off	Flashing		





- 10. Remove the electrode cables from the electrodes.
- 11. Remove the electrodes from the patient.
- 12. Suspend the measuring mat in the storage compartment of the monitor → Suspend measuring mat in magnetic catch.

The updated seca patient file is transmitted to the monitor. The measurement procedure is completed when the message Measurement successful appears.

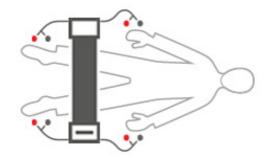


You have the following options to continue:

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

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

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



NOTE

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

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Connecting the measuring mat

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



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

Cancel a measurement procedure

- You can cancel the measurement procedure at any time.
 - 1. Press the **logout** button. The measurement procedure will be discarded.
 - 2. Log in again \rightarrow Log in.

5.4 Measure vital signs

- → Introduction
- → Measure blood pressure
- → Measure temperature orally/axillary (COVIDIENTM FILACTM 3000, blue)
- → Measure temperature rectally (COVIDIENTM FILACTM 3000 red)
- \rightarrow Measuring temperature in-ear (COVIDIENTM GENIUS[®]2)
- → Read off pulse rate
- \rightarrow Measure oxygen saturation (SpO₂)
- → Display weight and height
- → Stop a measurement procedure
- → Assigning anonymous measurement procedure to a seca patient file
- → Display "Measurements vital signs" list

WARNING!

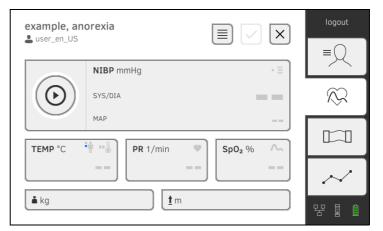
old L Hazard to patient, malfunction, damage to device

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

Introduction

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

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



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

Measure blood pressure

→ Start blood pressure measurement

→ Modify presets



- 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 "What to do if...".

WARNING!

Patient hazard, incorrect measurement

- Do not place the blood pressure cuff on the arm on the side on which a mastectomy has been performed.
- Apply the blood pressure cuffs so that the blood circulation of the patient is not compromised.
- Do not apply the blood pressure cuffs on spots that have weak circulation or on extremities on which intravenous routes lie.
- High cuff pressures may be unpleasant for sensitive patients. Keep the patient's general condition under observation during the measurement.

WARNING!

Incorrect measurement

- Inflating the blood pressure cuff may lead to occasional malfunctions of other medical electrical devices used on the same limb.
- Use only blood pressure cuffs from seca.
- Before every measurement, ensure that the blood pressure measurement tubes and connections are free of damage and airtight.
- Ensure that the arm on which the blood pressure cuff is attached does not move during the measurement.
- Ensure that the blood pressure cuff is applied according to the printed mark "Artery".

Incorrect measurement

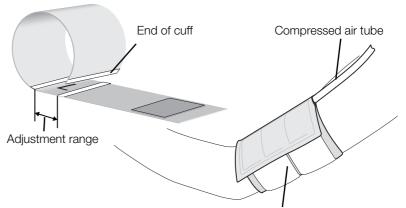
If the blood pressure cuff is too mall, the measured blood pressure values will be too high. If the blood pressure cuff is too large, the measured blood pressure values will be too small.

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

Start blood pressure measurement

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

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



Blood pressure cuff on the upper arm

NOTE:

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

3. Press the button on the monitor.

Blood pressure measurement starts:



Current cuff pressure is displayed.

The symbols for measurement procedure and measuring mode (in this case: Single measurement, upward measurement) flash.

The measurement is automatically stopped as soon as valid blood pressure values are recorded.



The values for systolic/diastolic blood pressure **SYS/DIA** and mean arterial pressure **MAP** are displayed.

You have the following options to continue:

- ► Measure further vital signs → Measure vital signs
- ► Measure bioimpedance → Measure bioimpedance
- ► Stop measurement procedure → Stop a measurement procedure.

NOTE

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

Modify presets

NOTE

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

- 1. Ensure that the blood pressure cuff is not applied.
- 2. Press the NIBP field.

The **NIBP settings** dialog window opens.

The presets are displayed.

Туре			
● 🔶 Inflation	0	š	Deflation
Starting pressure			
180 mmHg 🔹 👻			
Number			
 • Single 	0	:	Multiple

- 3. Press the desired measurement method.
 - Upward measurement (inflation), continue with Step 5.
 - Downward measurement (deflation), continue with Step 4.
- 4. If necessary, modify the starting pressure.
- 5. Press the desired number of measurements.
 - Single measurement
 - Multiple measurement

 Press the confirm button. The dialog window closes. Changed settings are used for the current measurement.

 Start the blood pressure measurement as described in the section entitled → Start blood pressure measurement.

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

- → Start an oral/axillary temperature measurement
- → Modify presets

WARNING! Patient hazard, incorrect measurement

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

WARNING! Patient hazard, incorrect measurement

- Ensure that in "Direct" measuring mode, oral temperature measurements do not last longer than 3 minutes and axillary measurements do not last longer than 5 minutes.
- Only perform oral/axillary measurement with devices that are equipped with a blue temperature probe and a blue probe holder.
- ► For devices with COVIDIENTM FILACTM 3000 measurement equipment, only use COVIDIENTM 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.

Start an oral/axillary temperature measurement

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

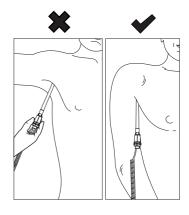


- a) Insert the probe in a probe cover in the pack
- b) Allow the probe cover to engage audibly with the probe
- c) Remove probe and probe cover from the pack
- d) Ensure that the probe cover is undamaged
- 3. Position the temperature probe as shown in the illustration:

Oral measurement:

Axillary measurement:





Measurement starts automatically.

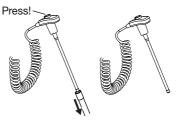
The measured value and the symbol for the measuring procedure (in this case predictive) flash until a valid measured value is obtained.



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



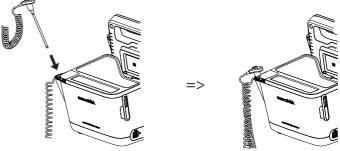
4. Discard the probe cover and dispose of it in line with your institution's policy.



NOTE

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

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



You have the following options to continue:

- ► Measure further vital signs → Measure vital signs
- ► Measure bioimpedance → Measure bioimpedance
- ► Stop measurement procedure → Stop a measurement procedure.

Modify presets

NOTE

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

- 1. Ensure that the temperature probe is pushed completely into the probe holder.
- 2. Press the **TEMP** field

The **TEMP settings** dialog window opens. The presets are displayed.

Temperature settings
● ► Predictive
O 🌡 Direct
vral
O 🛉 Axillary
cancel confirm

- 3. Press the desired measurement method.
 - Predictive
 - Direct
- 4. Press the desired measuring position.
 - Oral
 - Axillary
- 5. Press the **confirm** button. The dialog window closes.

Changed settings are used for the current measurement.

6. Perform a temperature measurement as described in the section entitled
 → Start an oral/axillary temperature measurement.

Measure temperature rectally (COVIDIEN™ FILAC™ 3000 red)

→ Start a rectal temperature measurement

→ Modify presets

WARNING! Patient hazard, incorrect measurement

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

WARNING! Patient hazard, incorrect measurement

- Ensure that rectal temperature measurements in "Direct" measuring mode do not last longer than 5 minutes.
- Only perform rectal measurement with devices that are equipped with a red temperature probe and a red probe holder.
- ► For devices with COVIDIENTM FILACTM 3000 measurement equipment, only use COVIDIENTM 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.

Start a rectal temperature measurement

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



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

The measurement starts automatically.

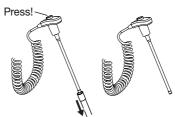
The symbol for the measurement procedure (in this case: Predictive) flashes until a valid measured value is obtained.



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



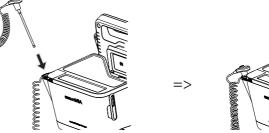
5. Discard the probe cover and dispose of it in line with your institution's policy.



NOTE

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

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



You have the following options to continue:

- ► Measure further vital signs → Measure vital signs
- ► Measure bioimpedance → Measure bioimpedance
- ► Stop measurement procedure → Stop a measurement procedure.

Modify presets

NOTE

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

- 1. Ensure that the temperature probe is pushed completely into the probe holder.
- 2. Press the **TEMP** field

The **TEMP settings** dialog window opens.

The presets are displayed.

O 🌡 Direct
5

- 3. Press the desired measurement method.
 - Predictive
 - Direct
- 4. Press the **confirm** button.

The dialog window closes. The modified settings are adopted.

5. Start the temperature measurement as described in the section entitled → Start a rectal temperature measurement.

Measuring temperature in-ear (COVIDIEN™ GENIUS®2)

WARNING! Patient hazard, incorrect measurement

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

WARNING!

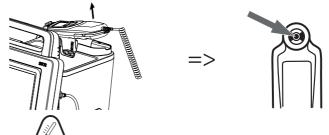
Patient hazard, incorrect measurement

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

Incorrect measurement

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

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



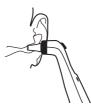
- 3. Press the 🖉) button to switch on the in-ear thermometer.
- 4. Pick up a probe cover:
 - a) Push the measuring head firmly into a probe cover in the magazine
 - b) Ensure that the probe cover engages audibly with the measuring head.
 - c) Remove the probe cover and thermometer from the magazine.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



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



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



6. Measure the patient's temperature:



- a) Press the button on the in-ear thermometerb) Wait until you hear a triple acoustic signal
- c) Take the measuring head out of the patient's ear
- The monitor displays the temperature value.

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



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

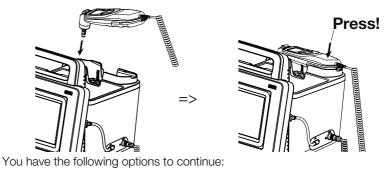
NOTE

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

7. Press the \frown 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.



► Measure further vital signs → Measure vital signs

- ► Measure bioimpedance → Measure bioimpedance
- ► Stop measurement procedure → Stop a measurement procedure.

- → Interrogate pulse rate source
- → Modify presets (seca measuring equipment only)

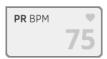


Patient hazard, incorrect measurement

A pulse rate determined on the basis of blood pressure or oxygen saturation is susceptible to artifacts.

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

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



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



Interrogate pulse rate source

- Press the **PR** field.
 The **PR settings** dialog window opens.
 The source of the pulse rate (NIBP or SpO₂) is displayed.
- 2. Press the **confirm** button. The dialog window closes.

Modify presets (seca measuring equipment only)

NOTE

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

1. Ensure that neither the blood pressure cuff nor the SpO₂ sensor are applied.

2. Press the **PR** field.

The **PR settings** dialog window opens. The presets are displayed (in this case: Default)

O P	R
Source:	NIBP
	Standard
0 \$¶	Sensitive
	cancel confirm

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3. Press the desired measuring mode.

	seca measuring equipme	ent
Mode	Measuring range	Motion tolerance
Default	0 - 240 bpm	High
Sensitive	20 - 300 bpm	Low

- 4. Press the **confirm** button. The dialog window closes. Changed settings are used for the current measurement.
- Start a blood pressure or an SpO₂ measurement as described in the sections entitled → Start blood pressure measurement and → Start an SpO₂ measurement.

Measure oxygen saturation (SpO₂)

→ Start an SpO₂ measurement

→ Modify presets



WARNING! Patient hazard, incorrect measurement

- The device has **no** alarm function. Never leave the patient unobserved during a measurement.
- The pulse oximeter is not an apnea monitoring device.
- ► The pulse oximeter must not be used to analyze arrhythmia.
- Incorrectly-applied sensors may lead to injuries at the point of application. Follow the Instructions for Use from the sensor manufacturρr
- ► Apply the blood pressure cuff and SpO₂ sensor to different extremities to avoid falsifying measured results.
- Apply the intravenous pressure catheter and SpO₂ sensor to different extremities to avoid falsifying measured results.
- Red and infrared light at fixed wavelengths is used for SpO₂ measurement. These wavelengths can affect other optical applications. Information about the wavelengths used can be found in the Instructions for Use for the sensor used.
- ► As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the pulse oximeter or accessories in any position that might cause it to fall on the patient.
- Do not start or operate the pulse oximeter unless the setup was verified to be correct.
- Do not use the pulse oximeter during magnetic resonance imaging (MRI) or in an MRI environment.
- Do not use the pulse oximeter if it appears or is suspected to be damaged.
- Explosion hazard: Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
- To protect against injury, follow the directions below:
 - Avoid placing the device on surfaces with visible liquid spills.
 - Do not soak or immerse the device in liquids.
 - Do not attempt to sterilize the device.
 - Use cleaning solutions only as instructed in this operator's manual.
 - Do not attempt to clean the device while monitoring a patient.
- ► To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.
- If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning. Follow the section entitled "What do I do if ...?".
- Inaccurate SpO₂ 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 SpO2. 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

- 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.
- SpO₂ 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.

Patient hazard, damage to device

- ► For devices equipped with Masimo SET[®] SpO₂ measurement equipment, only use Masimo sensors and patient cables.
- For devices equipped with seca SpO₂ measurement equipment, only use seca sensors and patient cables.

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 SpO₂ values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
- If the Low Perfusion or Low Signal Quality 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.

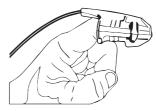
NOTE:

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

- 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-CalTM technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.

Start an SpO₂ measurement

- Apply the SpO₂ sensor according to the Instructions for Use from the sensor manufacturer.
 - a) Ensure that the SpO₂ sensor is the correct size.
 - b) Prepare measuring point (e.g. remove jewelry or nail varnish)
 - c) Position the SpO₂ sensor on the measurement point (in this case, Softclip sensor)



Measurement starts automatically.



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



The SpO₂ value is displayed.

You have the following options to continue:

- ► Measure further vital signs → Measure vital signs
- ► Measure bioimpedance → Measure bioimpedance
- ► Stop measurement procedure → Stop a measurement procedure.

NOTE

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

Modify presets

NOTE

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

- 1. Ensure that no SpO_2 sensor has been applied to the patient.
- 2. Press the SpO₂ field.

The SpO₂ settings dialog window opens.

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

Normal Maximum
O 📩 Maximum

3. Press the desired sensitivity:

Masimo SE	T [®] SpO ₂ module
Mode	Indication
Normal	Normal perfusionMild 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 Sp	O ₂ module
Mode	Motion tolerance
Stable	High
Normal	Normal
Sensitive	Low

4. Press the **confirm** button. The dialog window closes. The changed settings are used for the current measurement.

 Start the SpO₂ measurement as described in the section entitled → Start an SpO₂ measurement.

→ Receive weight and height from seca 360° wireless device

→ Adopt weight and height from seca patient file

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

Display weight and height

NOTE

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

Receive weight and height from seca 360° wireless device

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



2. Transmit the measured values as described in the Instructions for Use for the **seca 360° wireless** device.

The values received appear in the **vital signs** tab of the mVSA.

i kg 41.45	<u>t</u> m	1.600
-------------------	-------------------	-------

Adopt weight and height from seca patient file

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



Stop a measurement procedure

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

- Save measuring procedure: Press button
- ► Assign anonymous measurement to a seca patient file: → Assigning anonymous measurement procedure to a seca patient file



 Discard measurement procedure: Press button (anonymous measurements are added to list Measurements vital signs)

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

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

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

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

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

Date	NIBP		PR		Sp0 ₂	ТЕМР	
08.12.2016 06:46:13	120 SYS 80 DIA	93 MAD mmHg	75	BPM	98 %	36.5 °C	
08.12.2016 06:41:04	120 SYS 80 DIA	93 MAD mmHg	75	BPM	98 %	36.5 °C	
08.12.2016 06:35:50	120 SYS 80 DIA	93 MAD mmHg	75	BPM	98 %	36.5 °C	
22.08.2012 10:18:00	120 SYS 80 DIA	93 MAD mmHg	75	BPM	98 %	36.5 °C	

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

Assigning anonymous measurement procedure to a seca patient file

Display "Measurements vital signs" list

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3. To close the list, press the button.

5.5 Analyze measurement

- → View analysis
- → View the history of an analysis parameter

NOTE

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

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

1. Press the **analysis** tab.

The module summary is displayed.

example, anorexia * 27.04.1956		logout
		≡Q
Development/growth	Energy	ŝ
Function/rehabilitation	Fluid	
Health risk	Vital signs	\sim
		묵 🛛 🗎

You have the following navigation options:

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

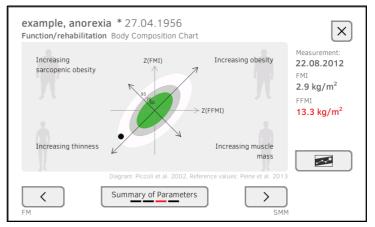
The summary of parameters is displayed, in this case: **Function/** rehabilitation.

	ble, anorexia * 27.04.1956	X	logout
	asurement: 22.08.2012, 10:18:00		≡◯
FFM FFMI	Fat-Free Mass Fat-Free Mass Index	33.97 kg 13.3 kg/m ²	
FM FMI	Fat mass Fat mass index	7.48 kg 2.9 kg/m ²	\otimes
FMI FFMI	Fat mass index Fat-Free Mass Index	2.9 kg/m ² 13.3 kg/m ²	
ѕмм	Skeletal muscle mass	13.9 kg 📲	
			\sim
Energy	Summary of modules	Fluid	묵 🛛 🏦

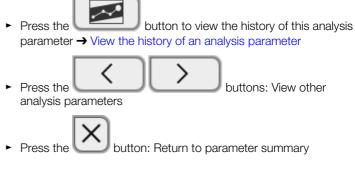
View analysis

You have the following navigation options:

- Press buttons: View other analysis modules
- Press button: Return to module summary
- ► To view details of an analysis parameter: Continue with Step 3.
- 3. Press an analysis parameter. The detail view is displayed, in this case: **Body Composition Chart**.



You have the following navigation options:



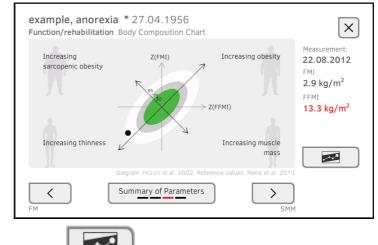
NOTE

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

View the history of an analysis parameter

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

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



2. Press the button.

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

example, anorexia * 27.04.195 Function/rehabilitation Body Composition select all	
22.08.2012 10:18:00 2.9 kg/r 13.3 kg/r	
25.05.2012 10:35:00 2.7 kg/r 13.2 kg/r	
24.02.2012 11:40:00 1.6 kg/r 12.9 kg/r	
11.01.2012 11:15:00 1.7 kg/r	
History: 1 selected	\checkmark

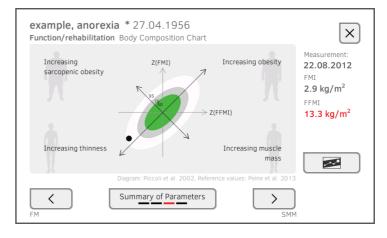
You have the following navigation options:

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

NOTE

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

- 3. Press the checkboxes for all the values you want to look at in the history.
- 4. Press the button. The history will be displayed.



6. HYGIENE TREATMENT

- → Cleaning
- → Disinfecting

- → Remove/fit probe holder (versions with temperature probe)
- → Remove/fit magazine holder (versions with in-ear thermometer)

→ Sterilizing



WARNING! Electric shock

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

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

NOTICE!

Damage to device

Inappropriate detergents and disinfectants may damage the sensitive surfaces of the device.

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

6.1 Cleaning

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

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

6.2 Disinfecting

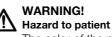
- 1. Follow the instructions on the disinfectant.
- 2. Disinfect device and accessories as indicated in the table below.

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

6.3 Sterilizing

The device and accessories may not be sterilized.

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



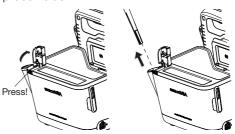
The color of the probe holder indicates whether a device is intended for oral/axillary or rectal temperature measurement. This distinction can no longer be made once the probe holder has been removed. Confusing the probe holders can lead to cross-contamination.

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

Remove probe holder

Fit probe holder

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



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

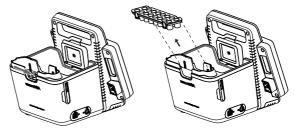


2. Close the cover cap until you hear it engage.

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

Remove magazine holder

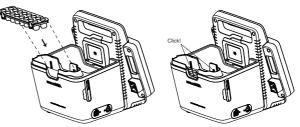
- 1. Lift the magazine holder with a finger until the magazine holder comes out of its catch.
- 2. Remove the magazine holder.



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Fit magazine holder

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



7. FUNCTION CHECK

Perform a function check prior to each use.

A complete function check includes:

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

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



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

- Have the device repaired by seca Service or by an authorized service partner.
- ► Follow the section entitled "Servicing" in this document.

8. MAINTENANCE

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

NOTICE!

Incorrect measurements as a result of poor servicing

- ► Have servicing and repairs carried out exclusively by seca Service or by an authorized service partner.
- You can find service partners in your area at www.seca.com or by sending an e-mail to service@seca.com.

9. WHAT DO I DO IF ...?

- → Monitor
- → Measuring mat
- → Bioimpedance measurement
- → Vital signs measurement
- → Data connection
- → Print

9.1 Monitor

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

Problem	Cause	Remedy
bia tab not active	No seca patient file prepared	Prepare seca patient file \rightarrow Prepare seca patient file
	Measuring mat not activated	Administrator: Activate measuring mat: → Administer system components in the Administrator menu
	No measuring mat present	 Administrator, if desired: Retrofit measuring mat Activate measuring mat: → Administer system components in the Administrator menu
Patient and user data can	USB stick contains several backup copies	Make sure that there is only one folder on the USB stick with the designation <time_stamp> _seca_monitor_backup (if necessary rename other folders)</time_stamp>
not be restored manually	Backup copy on the USB stick has been renamed	Make sure backup copies are saved in the folder with the designation <time_stamp> _seca_monitor_backup (if necessary, rename folders)</time_stamp>
Patient and user data cannot be initially encrypted after software update	There is not enough memory for initial encryption on the monitor	 Initial manual encryption by administrator: → Export patient and user data manually → Reset device → Restore patient and user data manually If necessary, set previous device settings (for example, WiFi connection) manually

9.2 Measuring mat

Problem	Cause	Remedy
Measuring mat cannot be switched on	Rechargeable battery discharged	Suspend measuring mat in storage compartment of monitor and charge rechargeable battery
	Measuring mat faulty	Replace measuring mat
	Rechargeable battery discharged	Suspend measuring mat in storage compartment of monitor and charge rechargeable battery
"Charging state" LED is	Rechargeable battery faulty	Replace measuring mat
red	Inductive charging interface of monitor covered, e.g. by other measuring accessories	Suspend the measuring mat in the magnetic catch first, then stow other measuring accessories
	Inductive charging interface faulty	Inform seca Service
"WiFi" LED is red	No WiFi connection to monitor	Administrator: Check settings for WiFi connection and correct if necessary
	WiFi module of measuring mat faulty	Replace measuring mat
One or more "Electrode	Electrode cables not connected to electrodes	Ensure that all electrode cables are engaged in the push-buttons of the electrodes
contact" LEDs is red	Electrodes faulty	Replace electrodes
	Electrode cables or measuring mat faulty	Replace measuring mat
One or more LEDs on the measuring mat not on	Measuring mat faulty	Replace measuring mat

Problem	Cause	Remedy
seca patient files cannot be transmitted to the measuring mat	No WiFi connection	 Suspend the measuring mat in the storage compartment of the device Call up seca patient file again, data will be transmitted via the infrared interface
	Infrared interface faulty	Inform seca Service
	WiFi function of device is deactivated	Administrator: Activate WiFi
	Distance between measuring mat and monitor is too big	Reduce distancePerform offline measurement
No WiFi connection	Distance between monitor and WiFi router is too big	 Reduce distance Transmit measured results to seca analytics 115 PC software via LAN
	WiFi not available in your institution	 Perform offline measurement Transmit measured results to seca analytics 115 PC software via LAN

9.3 Bioimpedance measurement

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

- → General
- → Blood pressure measurement
- → COVIDIENTM FILACTM 3000 temperature measurement
- → COVIDIENTM GENIUS[®]2 temperature measurement
- → SpO₂ measurement

Problem	Cause	Remedy
vitel cirre tek is net	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
vital signs tab is not displayed	SmartBucket not activated	Administrator: Activate SmartBucket: → Administer system components in the Administrator menu
The fields "Weight" and "Height" are not displayed in the vital signs tab	seca 360° wireless module of the mVSA not activated	Administrator: Activate the seca 360° wireless module of the mVSA: → Set up peripherals in the Administrator menu
seca mVSA 535 is being operated on a wheeled stand: Measured results for vital signs are implausible	 Original seca USB connecting cable not being used USB extension cable also in use 	 Use original seca USB connecting cable (in scope of supply for wheeled stand) Do not use a USB extension cable

Blood pressure measurement

Problem	Cause	Remedy
	Excessive patient movement	Ask the patient to move as little as possible
Implausible measured	Incorrect blood pressure cuff used	 Use correct size of blood pressure cuff Only use seca blood pressure cuffs
results	Blood pressure cuff not applied correctly	Correctly apply blood pressure cuff, see Instructions for Use for blood pressure cuff
	Blood pressure cuff applied to an extremity to which there is intravenous access	Apply blood pressure cuff to a different extremity
	Incorrect blood pressure cuff used	 Use correct size of blood pressure cuff Only use seca blood pressure cuffs
Insufficient cuff pressure	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

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COVIDIEN™ FILAC™ 3000 temperature measurement

Problem	Cause	Remedy		
No temperature measurement possible	Temperature module of the SmartBucket not activated	Activate temperature module (administrator rights required): → Retrofit SmartBucket (seca mBCA 525 only)		
	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		
Implausible measured results, temperature measurement unsuccessful	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 according to the probe in use Set correct measuring position on device 		
	No probe cover used	 Desinfect probe/ear thermometer 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[®]2 temperature

measurement

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

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

SpO₂ measurement

Problem	Cause	Remedy	
	Intra aortic balloon pump affecting pulse rate	Check pulse rate using ECG	
	Sensor damp	Dry sensorUse dry sensor	
	Sensor not applied correctly	Apply sensor correctly, see Instructions for Use for sensor	
	Strong ambient light	Cover application site with opaque material	
Implausible measured results	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 it 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	

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Problem	roblem Cause Remedy	
Pulse is not found or is lost	Sensor too rigid	Use suitable size of sensorApply 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

9.5 Data connection

Problem	Cause	Remedy	
Data transmission cannot be set up between device and seca analytics 115	Software versions not compatible	Use a compatible version of the seca analytics 115 : 1.4 Build 936 or higher	
	No seca patient file set up yet	Create seca patient file → Create seca patient file	
seca patient file not found when searching for a patient on the device	seca patient file is not assigned to the user in the seca analytics 115	Check whether the seca patient file can be assigned to the user in the seca analytics 115	
	Windows firewall port-blocking is active, required ports are blocked	Administrator: Release the ports required	
No access to seca patient database of the seca analytics 115 PC	No network connection set up between the device and the PC on which the seca analytics 115 PC software is installed	Administrator: → Setting up LAN connection to the network (stationary operation) → Set up WiFi connection (mobile operation) → Setting up a data connection to the seca analytics 115 PC software	
software	The PC on which the seca analytics 115 PC software is installed is not switched on	Switch on PC	
	Automatic synchronization is deactivated on the device	Administrator: → Activate automatic synchronization	
The fields "Weight" and "Height" are not shown in the display	seca 360° wireless module of the device not activated	Administrator: → Set up seca 360° wireless network	
	seca 360° wireless module of the scale/stadiometer not activated	Administrator:	
Neither weight nor height values are shown in the	No seca 360 ° wireless connection set up	→ Set up seca 360° wireless network	
display	No seca 360° wireless module included in scale/stadiometer	Enter measured values manually: → Enter basic parameters	

9.6 Print

Problem	Cause	Remedy
Print function not available	Software versions not compatible	Use a compatible version of the seca analytics 115 PC software: 1.4 Build 936 or higher
	PC printer not switched on	Switch on PC printer
Results report not being printed	The PC on which the seca analytics 115 PC software is installed is not switched on	Switch on PC
	No network connection set up between device and seca analytics 115 PC software	Administrator: Set up LAN connection
	No connection set up between seca analytics 115 PC software and PC printer	Administrator: Set up connection between seca analytics 115 PC software and PC printer

10.TECHNICAL DATA

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

10.1 Monitor

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

Ambient conditions, transport	
Temperature	-10 °C to +55 °C (14 °F to 131 °F)
Air pressure	700 hPa - 1060 hPa
Humidity	15 % - 95 %, no condensation
Setup location, maximum altitude above mean sea level	3000 m
Display type	7" touchscreen display
Power supply for monitor, input	
• Type	Internal power supply unit, IEC 60320 C13
Supply voltage	100 V ~ - 240 V ~
Supply frequency	50 Hz - 60 Hz
Current consumption	0.85 A
Mobile power supply	Lithium-ion battery
Voltage	11.25 V
Capacity	2950 mAh
Range (seca mVSA 535: full brightness, new battery pack)	approx. 5 h
Power consumption	
 Standby (touchscreen display off, ON/OFF button green) 	< 5 W
 In operation (ON/OFF button white) 	< 9 W
Operation (battery charging, monitor and measuring mat,	< 35 W
on/off button illuminated white)	
Medical device in accordance with Directive 93/42/EEC	Class Ila
EN 60601-1:	
Insulated device, protection class:	
Type of protection seca mBCA 525	IP20
Type of protection seca mVSA 535	IP21
Duty cycle	Continuous duty
	seca 360° wireless
	2 x USB 2.0 (max 500 mA)
	LAN: Ethernet (10/100 Base-T)
Interfaces	WiFi : 2.4 GHz (WPA, WPA2 PSK,
	WPA2 Enterprise PEAP RADIUS)
	Infrared
	Inductive charging of rechargeable battery for
	measuring mat
Correctible printer	
Compatible printer	Microsoft [®] Windows [®] -compatible printer via
	seca analytics 115 PC software

10.2 Measuring mat

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

10.3 Bioimpedance measurement

- → Measuring method
- \rightarrow Clinical studies
- → Accuracy of predictive formulas

Measuring method

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

Clinical studies

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

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

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

Standard deviation (SEE) for predictive formulas in this device ^a					
Ethnicity:	Caucasian	Afro-American	Asian	South and Central American	Other
Parameter	SEE	SEE	SEE	SEE	SEE
FFM	2.50 kg	2.21 kg	2.54 kg	2.62 kg	2.49 kg
TBW	2.01	1.81	1.4	1.41	1.71
ECW	1.11	0.91	0.91	0.71	0.91
SMM left arm	0.19 kg	0.28 kg	0.19 kg	0.16 kg	0.21 kg
SMM right arm	0.22 kg	0.30 kg	0.21 kg	0.17 kg	0.23 kg
SMM left leg	0.81 kg	0.71 kg	0.81 kg	0.83 kg	0.79 kg
SMM right leg	0.68 kg	0.66 kg	0.76 kg	0.71 kg	0.70 kg
SMM total	1.8 kg	2.0 kg	1.7 kg	1.7 kg	1.8 kg
VAT	0.5	0.6	0.6	1.21	0.81

Accuracy of predictive formulas

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

- → Blood pressure measurement
- → Temperature measurement COVIDIENTM FILACTM 3000
- → SpO₂ measurement Masimo SET[®]
- → seca SpO₂ measurement

Blood pressure measurement

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

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

Temperature measurement COVIDIEN[™] FILAC[™] 3000

General technical data

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

Clinical accuracy ^{a b}			
Measurement site:	Oral	Axillary	Rectal
d (age group I)	-0.44	-0.01	0.09
L _A (age group I)	1.01	0.86	0.99
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 COVIDIENTM FILACTM 3000 was determined in a clinical study in accordance with EN 80601-2-56. Clinical bias \overline{d} and limits of agreement L_A are quoted for the age group and measurement site in question. Clinical repeatability σ_r is independent of age. The reference body sites of the reference thermometer used in the clinical study correspond to the measurement sites quoted.

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

Temperature measurement COVIDIEN™ GENIUS®2

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

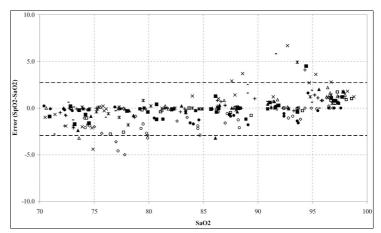
SpO₂ measurement Masimo SET®

Masimo SET [®] SpO ₂ module ^a	bcdefg
Measurement	Functional oxygen saturation
Measuring method	Spectrophotometry (red/infrared)
LED wavelength:	
Red	660 nm
Infrared	905 nm
Maximum light output	15 mW
This information may be of particular interest to clinicians	
Measuring time:	
 Device switched on, sensor not applied 	≤ 12 sec
 Device switched off, sensor applied 	≤ 8 sec
Measuring range:	
• SpO ₂	0 % - 100 %
Pulse rate	25 min ⁻¹ - 240 min ⁻¹
Perfusion Index	0,02 % - 20 %
Measuring accuracy:	
Measuring range	70 % - 100 %
 SpO₂ (no patient movement) 	70% - 100% ± 2 digits
	0% - 69% not specified
 SpO₂ (patient movement) 	70% - 100% ± 3 digits
	0% - 69% not specified
 Pulse rate (no patient movement) 	$25 \text{ min}^{-1} - 240 \text{ min}^{-1} \pm 3 \text{ digits}$
 Pulse rate (patient movement) 	$25 \text{ min}^{-1} - 240 \text{ min}^{-1} \pm 5 \text{ digits}$
Low perfusion performance	
Pulse amplitude	> 0.02%
• Transmission	> 5%
Oxygen saturation (SpO ₂)	± 2 digits
Pulse frequency	± 3 digits
Resolution:	
• Oxygen saturation (SpO ₂)	1 %
• Pulse rate	1 min ⁻¹
EN 60601-1: Medical electrical device, type BF	<u>*</u>

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

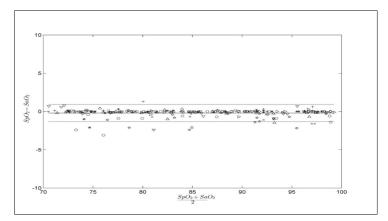
- b. The Masimo SET technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation, which encompasses 68% of the population.
- c.The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2[™] simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
- d.The Masimo SET Technology with Masimo Neo sensors has been validated for neonatal motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 1% has been added to the results to account for the effects of fetal hemoglobin present in neonates.
- e. The Masimo SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25 -240 min⁻¹ in bench top testing against a Biotek Index 2[™] simulator. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
- f.See sensor directions for use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.
- g.Sensor accuracy specified when used with Masimo technology using a Masimo patient cable for LNOP sensors, RD SET sensors, the LNCS sensors, or the M-LNCS sensors. Numbers represent Arms (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of ± Arms compared to the reference value. Unless otherwise noted, SpO2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 min⁻¹.

Accuracy of Masimo SET® adults/children



Measured values			
Measuring range A _{RMS}			
90-100%	1.64%		
80-90%	1.07%		
70-80%	1.55%		
Total value			
70-100%	± 2%		

Accuracy of Masimo SET® DCI/DCIP sensors



Measured values		
Measuring range	A _{RMS}	
90-100%	0.60%	
80-90%	0.54%	
70-80%	0.67%	
Total value		
70-100%	2%	

Masimo Patent Information

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

No Implied License Statement

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

seca SpO₂ measurement

seca SpO ₂ module ^{a b}		
Measurement	Functional oxygen saturation	
Measuring method	Spectrophotometry (red/infrared)	
LED wavelength:		
Red	660 nm	
Infrared	905 nm	
Maximum light output	5 mW	
This information may be of particular interest to clinicians		
Measuring range:		
• SpO ₂	0 % - 100 %	
 Pulse frequency (default) 	30 min ⁻¹ - 240 min ⁻¹	
 Pulse frequency (enhanced) 	20 min ⁻¹ - 300 min ⁻¹	
Measuring accuracy:		
 SpO₂ (no patient movement) 	60% - 70% ± 3 A _{rms}	
	60% - 100% ± 2 A _{rms}	
	<60% not specified	
 SpO₂ (patient movement) 	70% - 100% ± 3 A _{rms} ^c	
	<70% not specified	
 Pulse rate (no patient movement) 	$< 2 \text{ min}^{-1}$	
Pulse rate (patient movement)		

seca SpO ₂ module ^{a b}		
Resolution:		
 Oxygen saturation (SpO₂) 	1 %	
Pulse rate	1 min ⁻¹	
EN 60601-1: Medical electrical device, type BF		

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

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

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

10.5 Analysis parameters

NOTE

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

Analysis parameter	Display	Analysis module
Bioimpedance vector analysis (BIVA)	 Normal range display of R and X_c in co-ordinate system in relation to height 50 %, 75 %, 95 % percentiles in the form of tolerance ellipses 	Fluid Health risk
Body mass index (BMI)	 Absolute in kg/m² Graph of WHO reference values 	Development/growth
Extracellular water (ECW)	Absolute in I	Fluid
Fat-free mass (FFM)	Absolute in kg	Function/rehabilitation
Fat mass (FM)	 Absolute in kg Relative to weight in % Normal range display 	Energy Function/rehabilitation
Total energy expenditure (TEE)	Absolute in MJ/d or kcal/d	Energy
Total body water (TBW)	Absolute in I	Fluid
Weight (W)	Absolute in kg	Development/growth
Height (H)	Absolute in m	Development/growth
Extracellular water (ECW)/total body water (TBW)	Relative in %	Fluid (international)
Energy stored in the body (E _{body})	Absolute in MJ or kcal	Energy
Body composition chart (BCC): Mass indices Fat-free mass index (FFMI) Fat mass index (FMI)	 Absolute in kg/m² Normal range display 50 %, 75 %, 95 % percentiles in the form of tolerance ellipses 	Function/rehabilitation Health risk
Phase angle (φ)	 Absolute in degrees Normal range display 	Health risk
Reactance (X _c)	Absolute in ohms	Fluid Health risk
Resistance (R)	Absolute in ohms	Fluid Health risk
Resting energy expenditure (REE)	Absolute in MJ/d or kcal/d	Energy
Skeletal muscle mass (SMM)	Absolute in kgNormal range display	Function/rehabilitation
Visceral adipose tissue (VAT)	Absolute in I	Health risk
Blood pressure, non-invasive (NIBP)	Absolute in mmHg	Vital signs
Body temperature (TEMP)	Absolute in °C	Vital signs
Pulse rate: (PR)	Absolute in bpm (based on NIBP or SpO ₂)	Vital signs

Analysis parameter	Display	Analysis module
Oxygen saturation (SpO ₂)	Relative in %	Vital signs

10.6 Analysis modules

NOTE

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

Analysis module	Description	Analysis parameter	
Development/growth	Supports the monitoring of weight changes	WeightHeightBody mass index (BMI)	
Energy	 Determination of energy expenditure and energy reserves Required: Weight, height, PAL 	 Fat mass (FM) Energy stored in the body (E_{body}) Resting energy expenditure (REE) Total energy expenditure (TEE) 	
Function/rehabilitation	 Determining fitness level Assessing the success of a training program Required: Weight, height 	 Fat-free mass (FFM) Fat mass (FM) Body composition chart (BCC) Skeletal muscle mass (SMM) 	
Fluid	Determination of fluid statusRequired: Weight, height	 Total body water (TBW) Extracellular water (ECW) ECW/TBW [%] Bioimpedance vector analysis (BIVA) 	
Health risk	 Summary of body composition Estimate of health risk Required: Weight, height, waist circumference 	 Phase angle (φ) Visceral adipose tissue (VAT) Bioimpedance vector analysis (BIVA) Body composition chart (BCC) 	
Vital signs	Overview of vital signs to support a diagnosis	 Blood pressure (NIBP) Body temperature (TEMP) Pulse rate: (PR) Oxygen saturation (SpO₂) 	

10.7 seca 360° wireless system

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

11.OPTIONAL ACCESSORIES AND SPARE PARTS

Optional accessories and spare parts	Article number
SmartBucket seca mVSA 526	Version overview at
(mBCA seca mBCA 525 compatible from serial number 1000000090505)	www.seca.com
Bioimpedance measurement:	
seca mBCA 531 measuring mat	531-20-00-001
Blood pressure measurement:	
• Cuff, size S	490-0001-001
• Cuff, size M	490-0002-001
Cuff, size L	490-0003-001
Cuff, size XL	490-0004-001
 Extension for compressed air tube 	490-0005-001
Masimo SET [®] SpO ₂ measurement:	Obtainable directly
Masimo RD SET [®] Series sensors and patient cables	from the manufacturer,
Not compatible: Sensors for neonates	see www.masimo.com
seca SpO ₂ measurement:	
Finger Clip SF7500 (adults)	490-0006-001
Soft sensor SC7500 (adults)	490-0007-001
Soft sensor SCM7500 (children)	490-0008-001
Patient cable XT6500	490-0012-001
Temperature measurement:	
 COVIDIEN™ FILAC™ 3000 blue for oral/axillary measurement 	68-90-00-044-009
 COVIDIEN[™] FILAC[™] 3000 red for rectal measurement 	68-90-00-045-009
 COVIDIEN[™] GENIUS[®]2 in-ear thermometer 	68-90-00-048-009
Push-button electrodes for affixing to patient;	
pack of 100	68-90-00-043-009
Probe covers for COVIDIEN™ FILAC™ 3000;	
100 packs, pack of 20 probe covers	490-0015-001
Probe covers for COVIDIEN™ GENIUS [®] 2;	
22 packs, pack of 6 magazines (16 probe covers per magazine)	490-0016-001
PC software	Application-specific license packages
seca analytics 115	Details at www.seca.com
seca 475 wheeled stand for seca mBCA 525	475-00-00-009
Bracket for SmartBucket (retrofit for 475-00-00-009)	490-0017-009
seca 475 wheeled stand for seca mVSA 535	475-05-35-009
seca carry case seca 432	432-00-009

12.COMPATIBLE SECA MEASURING DEVICES

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

13. DISPOSAL

- → Measuring mat and device
- → Batteries and rechargeable batteries
- → Consumables

13.1 Measuring mat and device



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

service@seca.com

13.2 Batteries and rechargeable batteries



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

13.3 Consumables



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

14.WARRANTY

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

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

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

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

15.DECLARATIONS OF CONFORMITY

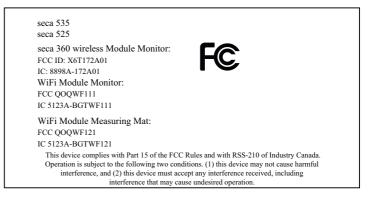
- → For Europe
- → For USA and Canada

15.1 For Europe

CE

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

15.2 For USA and Canada



NOTE

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

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

NOTE

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

NOTE

Radiofrequency radiation exposure information:

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

FOR ADMINISTRATORS: CONFIGURE SECA 535/SECA 525

- → Prepare configuration
- → Administer patient files
- → Administer user accounts
- → Make settings for measuring operation
 - NOTE

- → Set up peripherals
- → Administer system components
- → Factory settings
- → Instructions for Use for seca 535/ seca 525

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

NOTE

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

1. PREPARE CONFIGURATION

→ Log in

→ Configuration options

1.1 Log in

NOTICE!

Faulty configuration

During configuration, data are transmitted to the measuring mat via the infrared interface. The infrared interface is located in the magnetic catch of the monitor.

- Ensure that the measuring mat is correctly suspended in the magnetic catch of the monitor throughout the entire configuration process \rightarrow Suspend measuring mat in magnetic catch.
- 1. Switch on the device.

The measuring mat switches on automatically.

- 2. Log on as the administrator (default user account: "admin", initial password at initial commissioning: "1357") \rightarrow Log in.
- 3. Continue according to your password status:
 - ► First log in after device start-up with initial admin password: You are prompted to change the initial admin password. Continue with step
 - Initial admin password already changed: continue with step 6
- 4. Enter a new admin password.

NOTICE!

Data access by unauthorized persons

An insecure password may allow unauthorized persons to access patient data or device settings.

- Select a password that meets your institution's security requirements.
- 5. Enter the new admin password again to confirm. The login window is displayed.
- 6. Log in as administrator with your new password → Log in. The administrator area is displayed.

System information	logout
	patients
Monitor Measuring mat	users
	system
SmartBucket	settings
	peripherals
	reset
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1.2 Configuration options

- → Network functions
- → User role model

Network functions

• = possible, - = not possible

Function	LAN	WiFi	seca 360°	Infrared
Transmit weight to monitor	-	-	•	-
Transmit height to monitor	-	-	•	-
Communication between monitor and measuring mat	-	٠	-	•
seca directprint Use (function of the seca analytics 115 PC software)	•	•	-	-
Synchronize seca patient files and user accounts with the seca analytics 115 PC software	•	•	-	-

User role model

• = possible, - = not possible

Function	Administrator	User
Create seca patient files	•	•
Call up seca patient files	-	•
Enter basic parameters (weight, height, waist circumference, PAL)	-	•
Edit seca patient files	•	-
Delete seca patient files	•	-
Restore seca patient files	•	-
Perform measurements	-	٠

Function	Administrator	User
View examination results	-	•
Print examination results	-	•
Analysis parameters: Add comments	-	•
Administer patient database	•	-
Administer user database	•	-
Modify basic settings (e.g. time, date)	•	-
Modify units for measured values	•	-
Modify analysis parameters which can be	•	_
displayed		_
Set up network connections	•	-
Configure automatic database	•	_
synchronization	-	
Configure automatic export	•	-
Import data from USB memory stick	•	-
Restore factory settings	•	-
Reset user interface	•	-
Export data to USB memory stick	•	-
Updating the monitor software	•	-

2. ADMINISTER PATIENT FILES

- → Create a seca patient file
- → Edit a seca patient file
- \rightarrow Delete a seca patient file
- → Restore a seca patient file

NOTICE!

Inconsistent measured results

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

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

2.1 Create a seca patient file

1.

Administ	er patient database			logout patient
search		? + 💼	5	users
-	Name	Date of birth		systen
P	example, healthy Asian	15.11.1977		setting
o*	example, healthy Afro-Americ	27.06.1971		peripher
o*	example, weight reduction	01.08.1961		reset
	example, anorexia	27.04.1956		10000
ď	example, obesety	14.02.1967	$\overline{}$	 뫄 [
				<u> </u>

3. Create a seca patient file as described in the relevant section of the Instructions for Use \rightarrow Create seca patient file.

2.2 Edit a seca patient file

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

2.3 Delete a seca patient file

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

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

NOTICE!

Unintentional synchronization of data

If your device is synchronized with an external patient database, patient data may be accidentally transferred to the device.

 Configure your external patient database so that only patient files which are required on the device are transferred.

1. Press the **patients** tab.

	Administ	er patient database		logout
				patients
	search			users
	-	Name	Date of birth	system
	Ŷ	example, healthy Asian	15.11.1977	settings
	ੱ	example, healthy Afro-Americ	27.06.1971	peripherals
	o'	example, weight reduction	01.08.1961	reset
	Ŷ	example, anorexia	27.04.1956	
	ď	example, obesety	14.02.1967	
2. 3.	delete. Press the	checkboxes of of button. d seca patient files will	all seca patient files y be deleted.	ou would like to

2.4 Restore a seca patient file

1. Press the **patients** tab.

	Adminis	ter patient database			logout
				_ [patients
	search		? + 1	5	users
	-	Name	Date of birth		system
		example, healthy Asian	15.11.1977		settings
	o''	example, healthy Afro-Americ	27.06.1971		peripherals
	o'	example, weight reduction	01.08.1961		reset
		example, anorexia	27.04.1956		
	o'	example, obesety	14.02.1967		명 [[
A 3. F		button. leted seca patient files checkboxes of	is displayed. all seca patient f	iles you v	vould like
Т	he marke	restore button. d seca patient files will or measuring operation		e patient l	ist and be

3. ADMINISTER USER ACCOUNTS

- → Set up a user account
- → Edit a user account
- → Delete a user account

3.1 Set up a user account

NOTICE!

Inconsistent measured results

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

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

2.

Administer user database		logout
		patients
search		users
Name	Role	system
admin	Admin	settings
admin_da	Admin	peripherals
admin_de_DE	Admin	reset
admin_en_US	Admin	
admin_es_MX	Admin 🗸	명 []
Create user Role User name	Display lanquaqe	×
Password-protected	Repeat password	
		save

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

NOTE

The "display language" is specified for each user individually. If no user is logged in, the user interface is displayed in the "system language" \rightarrow Make regional settings.

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 that meets your institution's security requirements.
- 5. Repeat the password.
- 6. Let the user know his or her password.
- 7. Ensure that the Password-protected field is activated (default).
- 8. Press the **save** button.
 - The user account is set up.

The user account can be synchronized with the **seca analytics 115** PC software.

NOTE

- To protect patient data, we recommend always assigning a password to user accounts. User accounts without password protection should only be set up for special applications (e.g. configuring interfaces to practice or hospital information systems). seca service will be pleased to assist if you have any questions relating to "interface configuration".
- Specification of the **Assistance** or **Physician** roles is relevant for use of the user account in the **seca analytics 115** PC software. Details on this can be found in the Administrator Manual for the PC software.

3.2 Edit a user account

1. Press the **users** tab.

admin_de_DE Admin admin_en_US Admin admin es MX Admin	Administer user datab	ase		logout
Name Role system admin Admin settings admin_da Admin peripheral admin_de_DE Admin reset admin_en_US Admin Y				patients
admin Admin admin_da Admin admin_de_DE Admin admin_en_US Admin admin es MX Admin	search	? + 1		users
admin_da Admin admin_de_DE Admin admin_en_US Admin admin es MX Admin	Name	- Role -		system
admin_de_DE Admin admin_en_US Admin admin es MX Admin	admin	Admin		settings
admin_en_US Admin	admin_da	Admin		peripherals
admin_en_US Admin	admin_de_DE	Admin		reset
admin_es_MX Admin	admin_en_US	Admin		
	admin_es_MX	Admin	\sim	목 🛛 🔒

You have the following navigation options:

- Desired entry visible: Continue at Step 3.
- Desired entry not visible: Continue at Step 2.

- 2. Search for the desired user account in the list:
 - a) Press input field



b) Enter the user name using the keypad
 A hit list is displayed.

- Press the desired entry. The selected user account is displayed.
- 4. Edit the user account to the extent necessary.

NOTE

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

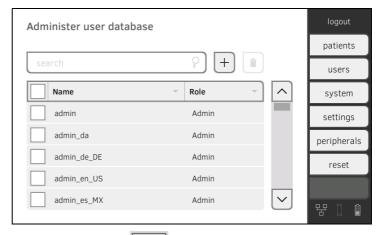
3.3 Delete a user account

NOTICE!

Loss of data

In contrast to seca patient files, it is $\ensuremath{\text{not}}$ possible to restore deleted user accounts.

- Ensure that user accounts you would like to delete really are no longer required.
- 1. Press the **users** tab.



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

4. MAKE SETTINGS FOR MEASURING OPERATION

- → Make regional settings
- → Set display brightness and volume
- → Set units of measurement
- → Deactivate analysis modules
- → Make presets for vital signs measurement

4.1 Make regional settings

CAUTION!

Loss of data, misinterpretation of measurements

Incorrect settings for date and time may lead to measurements being misinterpreted.

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

Settings		logout
		patients
Display and volume	Regional settings	users
	system	
Units	Analysis modules	settings
		peripherals
Measurement vital signs		reset
Fields are fine free signs		
		뮴 [] (1

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

Regional Settings	×	logout
Queter la sues		patients
System language	Decimal separator	users
U.S. English 📃	· · · ·]	users
Date		system
08.12.2016	dd.mm.yyyy	settings
Time		peripherals
08:01:33	24 h -	reset
Name style		
First name Surname	With separator	육 [] (1

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

The settings will be transmitted to the measuring mat automatically.

NOTE

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

4.2 Set display brightness and volume

1. Press the settings tab.

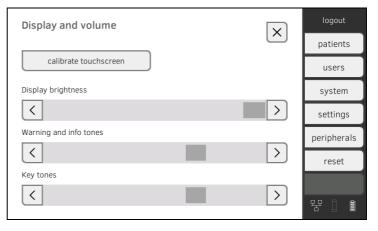
 Settings
 logout

 Display and volume
 Regional settings

 Units
 Analysis modules

 Measurement vital signs
 reset

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





- Set display brightness
- ► Set volume for warning and information sounds
- Set volume for button sounds

NOTE

Amended settings can immediately be seen/heard each time a button is pressed.

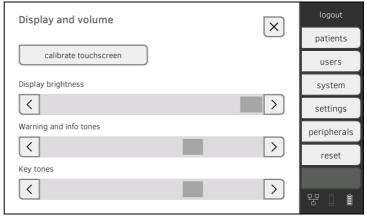
4. Press the **confirm** button. The settings will be saved.

4.3 Calibrate touchscreen display

1. Press the **settings** tab.

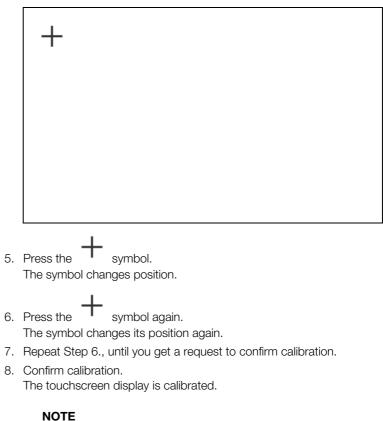
Settings		logout
		patients
Display and volume	Regional settings	users
Units	Analysis modules	settings
		peripherals
Measurement vital signs		reset
		묵 [] 🏾

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



3. Press the calibrate touchscreen button.

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



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

4.4 Set units of measurement



CAUTION! Patient hazard

In order to avoid misinterpretations, 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 measurement results in non-SI units is the sole responsibility of the user.

1. Press the **settings** tab.

Settings		logout
		patients
Display and volume	Regional settings	users
		system
Units	Analysis modules	settings
		peripherals
Measurement vital signs		reset
		暏 🛛 🌒

2. Press the **units** button.

Units		×	logout
Dooting anargy avponditure	Waisht	\frown	patients
Resting energy expenditure	Weight		users
FAO/WHO/UNU 2004	kg	~	system
Length	Blood pressure		System
metric -	mmHg	J	settings
Energy	Temperature		peripherals
MJ –	°C	-	reset
			· 문 [Î

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

NOTE

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

4.5 Deactivate analysis modules

Settings			logout
			patients
Displa	ay and volume	Regional settings	users
			system
	Units	Analysis modules	settings
			peripheral
Measure	ement vital signs		reset
			물 [
Press the an	alysis modu	les button.	
Analysis m	rodules		logout
_			patients
✓ Devel	opment/growth	Vital signs	users
Energy	У		system
Funct	ion/rehabilitation		settings
✓ Fluid			peripheral
Health	nrick		reset
✓ nealtr	I I ISK		
			맘 [] [

3. Press the checkboxes of all analysis modules you would like to deactivate.

The deactivated analysis modules are no longer displayed in the analysis \rightarrow Analyze measurement.

4. To reactivate analysis modules, press the checkboxes _____ of the deactivated analysis modules again.

The reactivated analysis modules will be displayed in the analysis → Analyze measurement again.

NOTE

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

4.6 Make presets for vital signs measurement

- → Presets for blood pressure
- → Presets for pulse rate (seca measuring equipment only)
- \rightarrow Presets for SpO₂
- → Presets for temperature (COVIDIENTM FILACTM 3000 only)
- → Select color mode for "Vital signs" tab

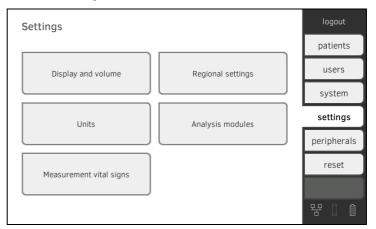
In the **settings** tab, you can set up your institution's preferred settings for blood pressure, temperature and SpO_2 measurements.

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

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

Presets for blood pressure

1. Press the **settings** tab.



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

Measurement vital signs	×	logout
		patients
NIBP	Pulse	users
		system
Sp0 ₂ Temperature		settings
		peripherals
Color mode		reset
Standard 🚽		
		목 [] (1

17-10-05-353-002e_07-2019 B

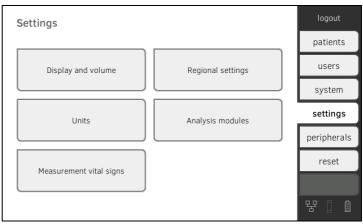
- 3. Press the **NIBP** button.
 - The presets are displayed.

Туре			
● 🔶 Inflation	0	š	Deflation
Starting pressure			
180 mmHg 🔹 👻			
Number			
• Single	0	:	Multiple

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

Presets for pulse rate (seca measuring equipment only)

1. Press the **settings** tab.



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

Measurement vital signs	logout
	patients
NIBP Pulse	users
	system
SpO ₂ Temperature	settings
	peripherals
Color mode	reset
Standard -	
	명 [] []

3. Press the **PR** button.

O PR
 Standard Sensitive
cancel confirm

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

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

5. Press the **confirm** button.

The dialog window closes.

The modified settings are adopted.

Presets for SpO₂

1. Press the **settings** tab.

Settings		logout
		patients
Display and volume	Regional settings	users
Units	Analysis modules	settings
		peripherals
Measurement vital signs		reset
		묵 🛛 🏛

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

Measurement vital signs	×	logout
		patients
NIBP	Pulse	users
		system
SpO ₂	Temperature	settings
		peripherals
Color mode		reset
Standard -		
		묵 [] []

3. Press the **SpO₂** button.

The presets are displayed (in this case: Masimo $\mathsf{SET}^{\textcircled{B}}\text{-pulse}$ oximetry:

ONL APOD	
🖲 🥿 Normal	
🕽 📩 Maximum	

4. Press the desired sensitivity:

NOTE:

The "Maximum" setting (Masimo SET[®]-pulse oximetry) is not available as a preset. Select this setting for each session directly \rightarrow Measure oxygen saturation (SpO₂).

Masimo SET [®] SpO ₂ module		
Mode	Indication	
Normal	Normal perfusion	
	 Mild perfusion disorders 	
Adaptive Probe Off Detection (APOD)	Vigorous patient movements	
	 Poor perfusion 	
Maximum	 Severely disrupted signal, for example due to indoor lighting or direct sunlight 	

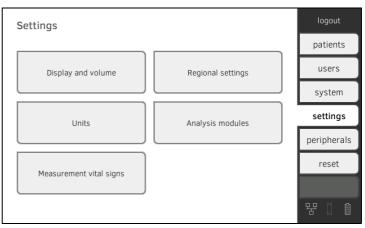
seca SpO ₂ module		
Mode	Motion tolerance	
Stable	High	
Normal	Normal	
Sensitive	Low	

^{5.} Press the **confirm** button.

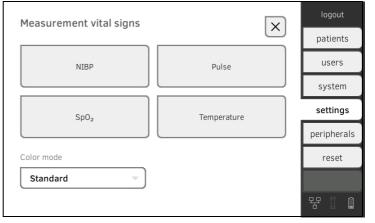
The dialog window closes.

The modified settings are adopted.

1. Press the **settings** tab.



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



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

Presets for temperature (COVIDIENTM FILACTM 3000 only) 4. Press the **TEMP** field.

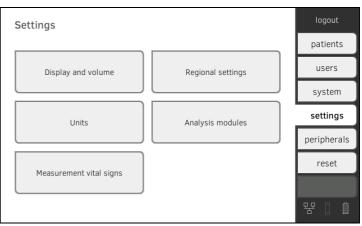
The presets are displayed (in this case: COVIDIENTM FILACTM 3000 blue):

٢	Те	mperature settings
۲	••	Predictive
0	٩	Direct
	"	Oral
0	•	Axillary
	C	ancel confirm

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

Select color mode for "Vital signs" tab

1. Press the **settings** tab.



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

Measurement vital signs	logout
	patients
NIBP Pulse	users
	system
Sp02 Temperature	settings
	peripherals
Color mode	reset
Standard 🚽	
	목 [] (1

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

The vital signs tab is displayed in the selected color mode.

5. SET UP PERIPHERALS

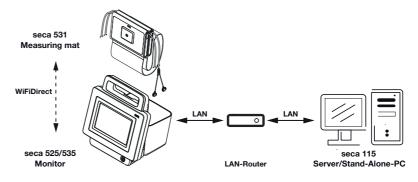
- → Setting up LAN connection to the network (stationary operation)
- → Set up WiFi connection (mobile operation)
- → Setting up a data connection to the seca analytics 115 PC software
- → Set up seca 360° wireless network

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

- → Introduction
- → Activating the LAN connection
- → Deactivate LAN connection

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

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

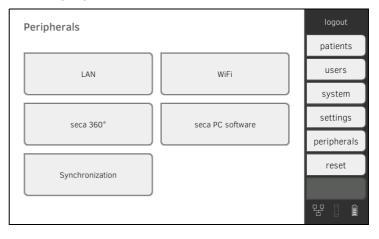


If you connect the device to your network via LAN cable, the measuring mat, if present, can communicate with the monitor via the factory-activated **WiFi direct** connection. This allows data to be exchanged even when the measur-

Activating the LAN connection

1. Press the **peripherals** tab.

ing mat is not hung in the magnetic catch of the monitor.



Introduction

2. Press the LAN button.

Set LAN connection			logout
		×	patients
LAN active	DHCP		users
IP address	Default gateway		system
172.16.0.245	172.16.0.254		settings
Netmask			peripherals
255.255.255.0			reset
MAC address:			
			뀸 🛛 🌒

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

Set LAN connection	×	logout
		patients
LAN active	DHCP	users
IP address	Default gateway	system
172.16.0.245	172.16.0.254	settings
Netmask		peripherals
255.255.255.0		
		reset
MAC address:		
		묵 🛛 🏦

- 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)

Set LAN connection	×	logout
		patients
LAN active	DHCP	users
IP address	Default gateway	system
172.16.0.245	172.16.0.254	settings
Netmask		peripherals
255.255.255.0		reset
MAC address:		목 [] []

모모

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. Continue based on your device variant.
 - Measuring mat present: continue with step 7.
 - ► No measuring mat present: continue with step 11.
- 7. Ensure that the measuring mat is correctly suspended in the magnetic catch of the monitor.
- 8. In the **peripherals** tab, press the **WiFi** button.
- 9. In the drop-down menu WiFi Mode, tap on the desired mode:
 - WiFi direct: The monitor and the measuring mat communicate with one another via a direct WiFi connection
 - ► WiFi off: The monitor and the measuring mat communicate with one another via an infrared interface

Set WiFi connection		logout
W/Cimeda	×	patients
WiFi mode		users
WiFi client		system
WiFi direct		settings
WiFi off		peripherals
		reset
MAC address: 00:07:80:a9:e2:d7		₹] 1

NOTE

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



10. Press the key by to confirm your entry.

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

Deactivate LAN connection

1. Press the **peripherals** tab.

Peripherals		logout
		patients
LAN	WiFi	users
		system
seca 360°	seca PC software	settings
		peripherals
Synchronization		reset
		뮴 [] (1

2. Press the LAN button.

Set LAN connection		×	logout
			patients
LAN active	DHCP		users
IP address	Default gateway		system
172.16.0.245	172.16.0.254		settings
Netmask			settings
255.255.255.0			peripherals
			reset
MAC address:			
			뮴 🛛 🌒

- 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) \rightarrow Activating the LAN connection

5.2 Set up WiFi connection (mobile operation)

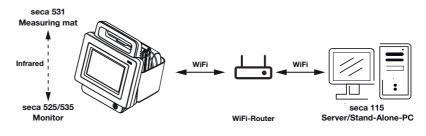
- → Introduction
- → Activating the WiFi connection
- → Deactivate WiFi

Introduction

Activating the WiFi connection

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

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



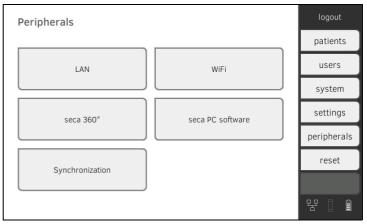
If you connect the device to your network as a WiFi client, the measuring mat, if present, can only communicate with the monitor via the infrared interface.

NOTICE!

Malfunction

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

- Ensure that the measuring mat is suspended in the magnetic catch of the monitor before and after each measurement.
- 1. Ensure that the measuring mat is correctly suspended in the magnetic catch of the monitor.
- 2. Press the **peripherals** tab.



 Make sure that the LAN connection to the network is **not** active → Deactivate LAN connection. 4. Press the WiFi button.

Set WiFi connection	logout
	patients
WiFi mode	users
SSID	system
~	settings
	peripherals
	reset
MAC address: 00:07:80:a9:e2:d7	₹] 1

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



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

The settings will be transmitted to the measuring mat.



The device is connected to your network via WiFi.

- 10. Connect the device with the PC software seca analytics 115.
 - ➤ → Setting up a data connection to the seca analytics 115 PC software

Deactivate WiFi

1. Press the **peripherals** tab.

2.

Peripherals	logout
	patients
LAN WiFi	users
	system
seca 360° seca PC software	settings
	peripherals
Synchronization	reset
Synchronization	
	명 🛛 🗎
Press the WiFi button.	

Set WiFi connection	×	
/iFi mode		patient
WiFi direct	Hidden network	users
WiFi client		system
WiFi direct		settings
WiFi off		periphera
		reset
1AC address: 0:07:80:a9:e2:d7		

- 3. In the WiFi Mode drop-down menu, press the setting WiFi off.
- Press the key to confirm your entry. The WiFi function is deactivated. The connection data are deleted.

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

- → Introduction
- → Connecting the device automatically (UDP)
- → Manually connecting the device (TCP)

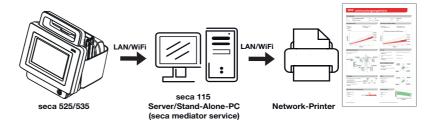
Introduction

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

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

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

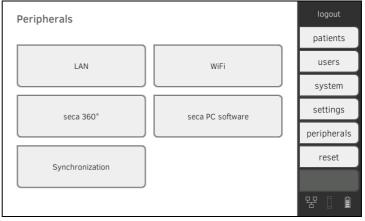
- → Setting up LAN connection to the network (stationary operation)
- → Set up WiFi connection (mobile operation)



NOTE

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

1. Press the **peripherals** tab.



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

Connecting the device automatically (UDP)

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

Set connection to seca PC software		logout	
		$(\)$	patients
Link active	Link via UDP		users
	UDP Port		system
	20011		-
	Integration mode		settings
	seca	-	peripherals
File Transfer Port			reset
20012			
			명 🛛 🗎

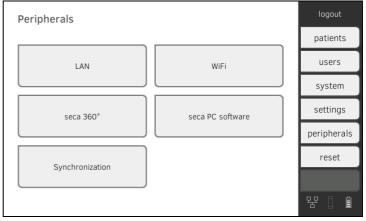
- 5. Adapt the default settings if necessary.
- 6. Make sure these settings match those in the PC software **seca analytics 115** (menu: Extras\Settings\Synchronization).
- 7. Ensure that in the drop-down menu **Integration mode** the mode **seca** is selected.

NOTE

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

Manually connecting the device (TCP)

1. Press the **peripherals** tab.



2. Press the seca PC software button.

The dialog window Set connection to seca PC software is opened.

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

Set connection to seca PC software		×	logout
		\frown	patients
Link active	Link via UDP		users
Communication Server IP			system
172.16.0.192	20011		
TCP Port	Integration mode		settings
		_	peripherals
20010	seca		reset
File Transfer Port			Teset
20012			
	,		뫄 [] []

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

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

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

NOTE

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

Synchronization and backup 5.4

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

Activate automatic synchronization

If you are using the device in combination with the seca analytics 115 PC software, you should activate automatic synchronization. The following data software, you should activate automatic synchronization. The following data are then synchronized as soon as they are changed either on the device or in the PC software: • seca patient files • User accounts and passwords • Automatic export settings

NOTICE! Malfunction

In order to be able to use automatic synchronization, a connection to the PC software must be set up \rightarrow Setting up a data connection to the seca analytics 115 PC software.

- Ensure that the connection to the PC software is set up before you activate automatic synchronization.
- 1. Press the **peripherals** tab.

Peripherals		logout
		patients
LAN	WiFi	users
		system
seca 360°	seca PC software	settings
		peripherals
Synchronization		reset
Synchronization		
		무 🛛 🇯

2. Press the **Synchronization** button.

Synchronization	X	logout
	\frown	patients
Synchronize automatically with seca PC-Software		users
Automatic export (CSV)		system
Automatic Export (PDMS)		settings
Last synchronization: -	5	peripherals
		reset
Back up patient and user data manually		
export restore		명 [[

3. Press the **Synchronize automatically with seca PC software** checkbox.

Automatic synchronization is activated.

NOTE

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

Set up automatic export

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

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

Peripherals		logout
		patients
LAN	WiFi	users
		system
seca 360°	seca PC software	settings
		peripherals
Synchronization		reset
		무모 🗍 📋

3. Press the **Synchronization** button.

Synchronization		logout
	×	patients
Synchronize automatically with seca PC-Software		users
Automatic export (CSV)		system
Automatic Export (PDMS)		settings
Last synchronization: -	5	peripherals
		reset
Back up patient and user data manually		
export restore		명 [[

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

NOTE

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

Export patient and user data manually

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

1. Press the **peripherals** tab.

Peripherals		logout
		patients
LAN	WiFi	users
		system
seca 360°	seca PC software	settings
		peripherals
Synchronization		reset
Synchronization		
		무 🛛 🇯

2. Press the **Synchronization** button.

Synchronization	X	logout
	\bigcirc	patients
Synchronize automatically with seca PC-Software		users
Automatic export (CSV)		system
Automatic Export (PDMS)		settings
Last synchronization: -	5	peripherals
		reset
Back up patient and user data manually		
export restore		목 [] []

- 3. Connect a USB memory stick to the monitor.
- 4. Press the **export** button.
- 5. Enter a new 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 that meets your institution's security requirements.
- 6. Enter the new password again to confirm. The data are exported to the USB memory stick.
- 7. Archive the data in line with your institution's policy.

Restore patient and user data manually

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

NOTICE!

Loss of data

When you restore externally backed-up data, the current data on the device will be overwritten.

- Export seca patient files and user accounts manually before restoring older data manually (operate without seca analytics 115 PC software).
- Before restoring manually, ensure that all the data on the device have been synchronized with the seca analytics 115 PC software (operate with seca analytics 115 PC software).
- 1. Load the archived seca patient files and user accounts onto a USB memory stick.
- 2. Press the **peripherals** tab.

Peripherals		logout
		patients
LAN	WiFi	users
		system
seca 360°	seca PC software	settings
		peripherals
Synchronization		reset
Synchronization		
		뫅 [] []

3. Press the **Synchronization** button.

Synchronization		logout
	×	patients
Synchronize automatically with seca PC-Software		users
Automatic export (CSV)		system
Automatic Export (PDMS)		settings
Last synchronization: -	5	peripherals
		reset
Back up patient and user data manually		
export restore		목 [] (]

- 4. Connect the USB memory stick to the monitor.
- 5. Press the **restore** button.
- 6. Enter the password for decrypting the data. The data will be imported.

5.5 Set up seca 360° wireless network

- → Activate/deactivate seca 360° wireless module
- → Set up a seca 360° wireless connection

Introduction

Activate/deactivate seca 360°

wireless module

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

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

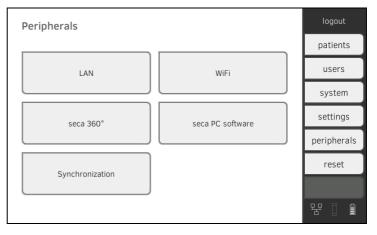


In order to be able to communicate with devices from the **seca 360° wireless** system, the **seca 360° wireless** module of the mVSA/mBCA must be activated and a wireless group set up.

NOTE

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

1. Press the **peripherals** tab.



2. Press the seca 360° button.



Press the Send/receive on checkbox.
 The seca 360° wireless module is activated.

- 4. To deactivate the **seca 360° wireless** module, press the **Send/receive on** checkbox again.
- 1. Ensure that the **seca 360° wireless** modules of the mVSA/mBCA and of all the devices you want to connect to the mVSA/mBCA are activated.
- 2. Switch off all the devices you want to connect to the mVSA/mBCA.
- 3. Press the **peripherals** tab.

Peripherals		logout
		patients
LAN	WiFi	users
		system
seca 360°	seca PC software	settings
		peripherals
Synchronization		reset
		뮴 🛛 🏦

4. Press the **seca 360°** button.

Set seca 360° connect	on		$\left \times \right $	logout
Send/receive on		set up		patient
		set up		users
Device type	w/less gp.	Channels -		system
				setting
				setting: periphera reset

Set up a seca 360° wireless connection

6. Press one of the three wireless groups.

The device searches for **seca 360° wireless** devices which are switched on.

The device will suggest three wireless channels.

NOTICE!

Incorrect device assignment

Only one example of a device category (e.g. personal scale or stadiometer) can be integrated in each wireless group.

► Take note of the Technical Data in the section of the Instructions for Use entitled → seca 360° wireless system.

NOTICE!

Data transmission interference

The proposed channel numbers can be edited. This function is intended purely for special reception situations. Devices may be assigned to the wrong wireless groups or unreliable wireless connections may arise.

- Only change the channel numbers if the proposed channel numbers do not result in a reliable wireless connection.
- Ensure that the new channel numbers are not being used for other wireless groups.
- Ensure that the channel numbers are at least 30 apart from one another.
- 7. Switch on all **seca 360° wireless** devices you wish to incorporate in the wireless group.

When devices are detected, a beep will be heard. Detected devices will be displayed on the monitor.

8. Press the **finish** button once all **seca 360° wireless** devices have been detected.

6. ADMINISTER SYSTEM COMPONENTS

- → View system information
- → Update monitor software
- → Update the measuring mat software
- → Retrofit SmartBucket (seca mBCA 525 only)
- → Retrofit measuring mat (seca mVSA 535 only)
- → Retrofit in-ear thermometer (seca mVSA 535 only)

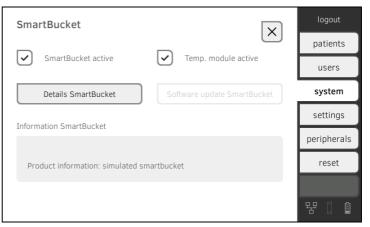
View system information

1. Press the **system** tab.

System information	logout
	patients
Monitor Measuring mat	users
	system
SmartBucket	settings
	peripherals
	reset
	뭥 [] []

2. Select a system component.

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



You have the following options:

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

Update monitor software

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

NOTICE!

Loss of data

The device will be reset to factory settings. seca patient files and user accounts will be deleted.

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

System information		logout
		patients
Monitor	Measuring mat	users
		system
SmartBucket		settings
		peripherals
		reset
		명 [] 문

2. Press the **Monitor** button.

Monitor X	logout patients
Details Monitor Software update monitor	users
Device name	system
ETAPS201703221842	settings
Information monitor	peripherals
Serial number: ETAPS201703221842 Software version: 1.0.26 INT	reset
	뭥 [] (]

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

NOTE

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

Update the measuring mat software

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

 Monitor software has been updated (seca mVSA 535, seca mBCA 525)

→ Update monitor software

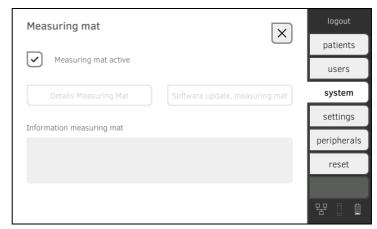
- System has had a measuring mat added (seca mVSA 535)
 → Retrofit measuring mat (seca mVSA 535 only)
- Measuring mat has been replaced with a new one (seca mVSA 535, seca mBCA 525)

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

1. Press the **system** tab.

System information	logout
	patients
Monitor Measuring mat	users
	system
SmartBucket	settings
	peripherals
	reset
	명 [] (1

2. Press the Measuring mat button.



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

Retrofit SmartBucket (seca mBCA 525 only)

medical Body Composition Analyzer **seca mBCA 525** from serial number 1000000090505 can be retrofitted with the SmartBucket **seca 526** to measure vital signs \rightarrow Optional accessories and spare parts.

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

System information	logout
	patients
Monitor Measuring mat	users
	system
SmartBucket	settings
	peripherals
	reset
	묵 🛛 🌒

- b) Press the **SmartBucket** button
- c) Activate the $\ensuremath{\textbf{SmartBucket}}$ active checkbox
- d) If SmartBucket contains a temperature module: Activate the **Temp. module active** checkbox.

SmartBucket	logout
	patients
SmartBucket active	users
Details SmartBucket Software update SmartBucket	system
Information SmartBucket	settings
Information Sinal toucket	peripherals
Product information: simulated smartbucket	reset
	뫅 [] []

3. Follow the on-screen instructions.

Retrofit measuring mat (seca mVSA 535 only)

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

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

System information	logout
	patients
Monitor Measuring mat	users
	system
SmartBucket	settings
	peripherals
	reset
	뮴 🛛 🕯

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

Measuring mat	logout
	patients
Measuring mat active	users
Details Measuring Mat Software update, measuring mat	system
Information measuring mat	settings
mormation measuring mat	peripherals
	reset
	뮴 [] []

3. Follow the on-screen instructions.

Retrofit in-ear thermometer (seca mVSA 535 only)

medical Vital Signs Analyzer **seca mVSA 535** without temperature measurement can be retrofitted with the COVIDIENTM GENIUS[®]2 in-ear thermometer \rightarrow Optional accessories and spare parts.

- Connect the in-ear thermometer as described in the section entitled → Connect in-ear thermometer.
- 2. Activate the temperature module in the device.
 - a) Press the **system** tab.

System information	logout
	patients
Monitor Measuring mat	users
	system
SmartBucket	settings
	peripherals
	reset
	명 [[

- b) Press the SmartBucket button
- c) Activate the Temp. module active checkbox

SmartBucket	logout
	patients
SmartBucket active Temp. module active	users
Details SmartBucket Software update SmartBucket	system
Information SmartBucket	settings
	peripherals
Product information: simulated smartbucket	reset
	· 문 🛛 🇯

3. Follow the on-screen instructions.

7. FACTORY SETTINGS

- → Summary of factory settings
- → Reset device
- → Reset user interface
- → Export system log
- → Release VNC access

7.1 Summary of factory settings

In the **reset** tab, you can reset the device to the following factory settings:

Function	Setting
Administrator password	1357
Display language	English
Date format:	
International	dd.mm.yyyy
Time format:	
International	24 h
Naming convention:	
International	First name, surname
Name separator	Period
Display brightness	100 %
Volume for warning and	
information sounds	70 %
Volume for button sounds	70 %
Weight:	
International	kg
Height:	
International	m
Blood pressure:	
Unit:	mmHg
Presets	Upward, single measurement
Temperature:	
Unit	C°
COVIDIEN TM FILAC TM 3000	
Blue	Oral, predictive measurement
Red	Predictive measurement
Pulse rate:	
Unit	min ⁻¹
Preset (seca measuring	
equipment only)	Standard
Oxygen saturation:	24
Unit:	%
Mode:	Normal
Decimal separator:	
International	Period
Energy:	MJ
Reference resting energy	FAO/WHO/UNU
expenditure:	~
LAN Connection data:	On
Connection data:	None

Function	Setting
WiFi client (device <->	
network):	Off
Connection data	None
WiFi direct (device <->	On
measuring mat)	
Device name	None
Integration mode	seca
seca 360° wireless:	Off
Connection data:	None
seca PC software:	Off
UDP	Off
Communication server IP:	None
TCP port:	20010
UDP port:	20011
File transfer port:	20012
Active analysis modules	All

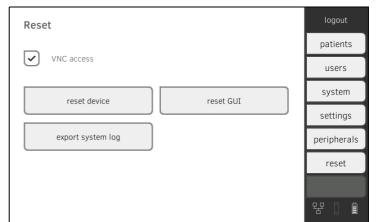
7.2 Reset device

Use the **reset device** function to reset the device to \rightarrow Factory settings; seca patient files and user accounts are deleted from the device with this process.

NOTE

If seca patient files and user accounts are to be retained, proceed as described in the section entitled \rightarrow Reset user interface.

1. Press the **reset** tab.



- 2. Ensure that seca patient files and user accounts have been exported or synchronized using the **seca analytics 115** PC software.
- Press the reset device button. seca patient files and user accounts will be deleted. The device will be reset to → Factory settings.

7.3 Reset user interface

Use the **reset GUI** function to reset the user interface (GUI = Graphical User Interface) of the device to \rightarrow Factory settings; seca patient files and user accounts are retained with this process.

NOTE

If all seca patient files and user accounts are to be deleted from the device, proceed as described in the section entitled \rightarrow Reset device.

1. Press the reset tab.

Reset	logout
	patients
VNC access	users
reset device reset GUI export system log	system
	settings
	peripherals
	reset
	뭑 [] (1)

2. Press the **reset GUI** button.

The user interface will be reset to \rightarrow Factory settings. seca patient files and user accounts will be retained.

7.4 Export system log

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

1. Press the reset tab.

Reset	logout
VNC access reset device reset GUI export system log	patients
	users
	system
	settings
	peripherals
	reset
	육 🛛 🏛

2. Press the export system log button.

- 3. Select the export destination:
 - ► USB memory stick: Continue with Step 4.
 - ► Network: Continue with Step 5.
- 4. Connect a USB memory stick to the monitor.
- 5. Press the **export system log** button. The system log will be exported.

NOTE

If you have selected "Network" as the export destination, the system log in the installation directory of the **seca analytics 115** PC software (server or standalone PC) will be exported to the "Program-Data\seca\LogExports" folder.

7.5 Release VNC access

With a VNC connection, you can reproduce the user interface of the device on a PC screen and remotely control the device from the PC. The requirement is that a VNC viewer is installed on the PC.

1. Press the reset tab.

Reset	logout
	patients
VNC access	users
reset device reset GUI	system
	settings
export system log	peripherals
	reset
	뀸 🛛 🇎

- 2. Press the **VNC access** checkbox.
- 3. Restart the device.

The VNC service of the device will be started.

4. Set up the VNC connection using the VNC viewer of your PC.

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