

seca mVSA 535

Instructions for use

Software version 1.0 from Build 1163 Art no: 17-10-05-368-002b_10-2020 S





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INSTRUCTIONS FOR USE FOR seca mVSA 535

- → About this document
- → Description of device
- → Safety precautions
- → Device overview
- → Starting up the device
- → Operation
- → Operation when connected to an → Warranty EMR system
- → Hygiene treatment
- → Function check
- Software version: 1.0 from Build 1163

Article number of this document: 17-10-05-368-002b_10-2020 S

1. ABOUT THIS DOCUMENT

NOTE

This document describes the maximal equipment of the **seca mVSA 535** product family: measurement of blood pressure, temperature and oxygen saturation. 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.

→ Servicing

parts

→ Disposal

→ Troubleshooting

→ Technical data

→ Optional accessories and spare

→ Compatible seca products

→ Declaration of conformity

seca mVSA 535

→ For administrators: Configuring

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

2. DESCRIPTION OF DEVICE

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

2.1 Intended use seca mVSA 535

The medical Vital Signs Analyzer **seca mVSA 535** is a Spot-Check device used for non-invasive, discontinuous measurement and display of NIBP (blood pressure), SpO2 (oxygen saturation of arterial hemoglobin), TEMP (body temperature) and PR (pulse rate).

The vital signs monitor model **seca mVSA 535** is mainly used in inpatient facilities (hospitals, medical practices and care facilities) in accordance with national regulations and is intended to be used on adult and pediatric individuals (3 years of age or older).

The **seca mVSA 535** can be used in conjunction with an optional PC software accessory for data management, calculations and display of information.

If used in conjunction with seca medical weight and height measurement devices the **seca mVSA 535** can receive and display weight and height values.

2.2 Description of function

- → Device components
- → Power supply
- → Vital signs measurement
- → Alarms
- → Weight and height
- \rightarrow seca user accounts
- → User IDs of EMR systems
- → seca patient files
- → Patient data from EMR systems
- → Measuring results
- → Data transmission and network functions
- → Compatibility

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

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

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

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

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.

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Device components

	The SmartBucket is supplied with power via a USB connection from the monitor.
Vital signs measurement	Blood pressure is measured non-invasively with seca measuring equipment and seca blood pressure cuffs.
	Temperature is measured with COVIDIEN [™] measuring equipment and, depending on the device version, as an oral/axillary (blue temperature probe) or rectal (red temperature probe) procedure.
	On device versions without integrated temperature measurement, temperature values can be entered manually.
	Oxygen saturation is measured with Masimo SET $^{\rm @}$ and with the corresponding ${\rm SpO}_2$ 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.
Weight and height	Scales and measuring rods from the seca 360° wireless system can transmit measuring results to the device wirelessly.
	Scales and measuring rods with an internal interface module or a seca 452 external interface module can transmit measuring results to the device via LAN or WiFi.
	Alternatively, the patient's weight and height can be recorded manually.
seca user accounts	The user accounts for the device can be synchronized automatically with the seca user accounts of the seca analytics 115 PC software. This allows access to both the device and the PC software with the same seca user account.
User IDs of EMR systems	If the device is connected to an EMR system via the seca connect 103 software, the user IDs of the EMR system can be used for measurements. Local user accounts on the device are required for administration and service tasks.
seca patient files	seca patient files and seca patient databases contain exclusively data neces- sary for working with seca products or which were determined using seca products.
	In standalone mode or when connected to the seca analytics 115 PC soft- ware, measuring results are managed in seca patient files. seca patient files can be set up, edited, exported and deleted 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.
Patient data from EMR systems	Depending on the EMR system in question, patient data from EMR systems may be used via the export and import functions of the seca analytics 115 PC software or via a connection to the seca connect 103 software.
Measuring results	Measured results for the vital signs blood pressure (NIBP), temperature (TEMP), pulse rate (PR) and oxygen saturation (SpO ₂) are displayed in graphical form.
Data transmission and network functions	The device can be integrated in a network via a LAN interface or via WiFi in order to use the following functions:
	 Connection of the device to the seca analytics 115 PC software avail- able as an option: Communication with the databases of the

seca analytics 115 PC software and use of the seca directprint function

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

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

The device has a **seca 360° wireless** module and can receive measuring results from compatible seca scales and measuring rods.

seca analytics 115 PC software

This device (software version 1.0, Build 1163 or higher) is only compatible with version 1.4 (Build 6657 or higher) of the **seca analytics 115** PC software. There is no downward compatibility with older versions of **seca analytics 115**.

seca connect 103 software

This device (software version 1.0, Build 1163 or higher) is only compatible with version 2.2 or higher of the **seca connect 103** software. There is no downward compatibility with older versions of the **seca connect 103** software.

Internal interface module/seca 452 interface module

This device (software version 1.0, Build 1163 or higher) is only compatible with interface modules on which firmware version Q2_2020_Build_615 or higher is installed.

2.3 User qualification

Compatibility

	 → Administration/network connection → Measuring mode
Administration/network connection	The device may only be set up and incorporated in a network by experienced administrators or hospital technicians.
Measuring mode	The device may only be used by persons with sufficient expertise. Basic knowledge required for measuring vital parameters is not the subject of these instructions for use.
	Connecting the device to an EMR system affects the measuring sequence and operation of the device: \rightarrow Operation when connected to an EMR system. People operating the device must be informed about these effects.
2.4 Contraindications	
	The device is not intended for permanent monitoring of patients.
	The device is not intended for patient monitoring during either transport (for example, in ambulances or helicopters) or transfer within an institution.
	The device is not intended for operation in the vicinity of an MRI device or in a pressurized chamber.

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

This device is not suitable for 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.

3. SAFETY PRECAUTIONS

- → Terms and definitions
- → Safety precautions in these instructions for use
- → Basic safety precautions

3.1 Terms and definitions

Term Definition	
Term	
	The use of this device is focused on but not
Patient	limited to a medical environment. To keep
	wording concise a person being measured with
	this device is referred to as "patient".
	A person with access rights to operate the device
	as follows:
User	Performing measurements
	Anlayzing measurment results
	Saving data to a patient database
	A person with access rights to operate the device
	as follows:
Administrator	Setting up the device
	Setting up network connections
	Modifying settings as necessary

3.2 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.

3.3 **Basic safety precautions**

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

Please take note of the information in these instructions for use.

- Keep the instructions for use in a safe place. The instructions for use are a component of the device and must be available at all times.
- In the interest of patient safety, you and your patients are obliged to report serious events that occur in connection with this product to the manufacturer and the authority responsible in your country.



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.

Handling the device



- 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.

old L 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.

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.

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.

Handling a wheeled stand

Preventing electric shock

Prevent injuries and infections



- 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

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

Preventing damage to device

Handling measuring results

CAUTION! Patient hazard

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

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

NOTICE! Inconsistent measuring results

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

NOTE

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

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 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

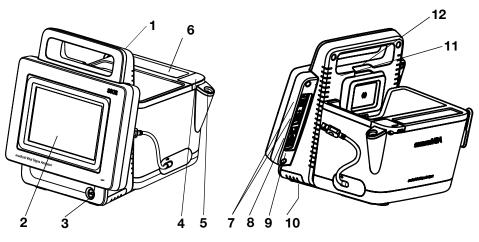
4. Device overview

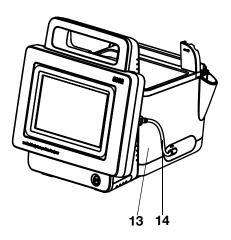
- → Monitor controls for seca mVSA 535
- → Fields in the touchscreen display
- → Login/navigation: Buttons and symbols in the touchscreen display
- → Operating state: Symbols
- → Measuring: Buttons and symbols
- → Unsubmitted measurements list: Symbols
- → Markings on the device and on the type plate
- → Markings on the blood pressure cuff
- → Markings on the packaging

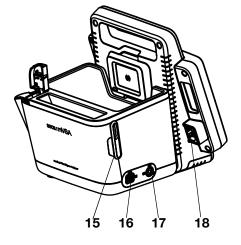
4.1 Monitor controls for seca mVSA 535

NOTE

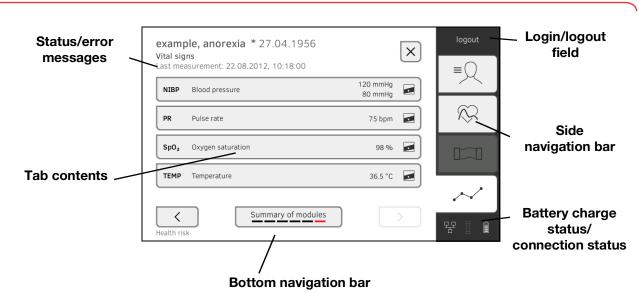
This section shows product versions. The functional scope of your device may deviate from this.







No.	Control	Function
1	Handle	Transporting the device
2	Touchscreen display	Central control/display element
		LED white: Device on
3	ON/OFF button with LED	LED green: Device on standby
		LED off: Device off
	Connection for temperature measurement	For COVIDIEN™ FILAC™ 3000 temperature probes
4		Blue: Oral/axillary measurement
		Red: Rectal measurement
		For COVIDIEN™ FILAC™ 3000 temperature probes
5	Probe holder	Blue: Oral/axillary measurement
		Red: Rectal measurement
6	Storage compartment for probe covers	Capacity: 2 packs for COVIDIEN™ FILAC™ 3000
		For transmitting data via a USB memory stick
7		Transmit data between monitor and SmartBucket
	USB port, 2 pcs	Supply SmartBucket with power
		Connect a scanner
8	ISIS port	Advance feature for future system upgrade (currently no function)
9	LAN port	Integrate device in a PC network, use with seca analytics 115 PC software
10	Rechargeable battery compartment	To take lithium-ion rechargeable battery supplied
11	Internal seca 360° wireless	For connecting scales and stadiometers from the seca 360° wireless
	module	system
12	Internal WiFi module	Integrate device in a PC network, use with seca analytics 115 PC software
13	SmartBucket	Transporting/storing measuring equipment (vital signs)
10		For storing consumables
14	Connecting cable with USB connector	Power supply and data transmission between monitor and SmartBucket
15	Holder	For SpO ₂ sensor
16	Connection for SpO ₂	Maaima SET® patient applies and especies
10	measurement	Masimo SET [®] patient cables and sensors
17	Connection for blood pressure	For seca blood pressure cuffs
-	measurement	· · · · · · · · · · · · · · · · · · ·
18	Power supply socket	For connecting the power supply cable



4.2 Fields in the touchscreen display

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

Button/symbol	Meaning
≡	Patient tab
\sim	Vital signs 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
0	Enter password
\checkmark	Select user account Enter password Navigation: Confirm entry Measuring: Save measurement procedure

Button/symbol	Meaning
	Process running
create	Button available
create	Button pressed
create	Button not available
$\langle \rangle$	Navigate to the left/right
~ ^	Navigate up/down
✓	One or more items from list selected/not selected
	Alternative from list selected/not selected
\times	Return to previous screen
Login	Log in user
Logout	Log out/switch user

4.4 Operating state: Symbols

Symbol	Operating state
60 %	Monitor: Controls permanently on: Rechargeable battery charge status (%) Controls flashing: Rechargeable battery charging
Î	Monitor: Controls permanently on: Rechargeable battery full Controls flashing consecutively: Rechargeable battery charging
	Monitor: Rechargeable battery discharged
물물	LAN connection set up: on/off
() ()	WiFi connection set up: on/off

Symbol	Operating state
묻 🛜	seca connect 103 (EMR)/seca analytics 115: connection active
87 💿	seca connect 103 (EMR)/seca analytics 115: connection interrupted
锯 📚	Connection to seca analytics 115 : Synchronization in progress
i	Pop-up window: Information for the user
\otimes	Pop-up window: Error message
	Pop-up window: Setting option for the user
	Error message during vital signs measurement

4.5 Measuring: Buttons and symbols

≡(_____

- → Patient tab
- → Vital signs tab
- → Analysis tab

Patient tab

	Button/symbol	Meaning
\ \		Search for seca patient file
	• •	Switch sorting direction
		Edit seca patient file
	Ŀ	Export seca patient file
		Delete seca patient file
		Weight (W)
	<u>t</u>	Height (H)
	360°	Adopt seca 360° wireless value
	Q	Adopt value from previous measurement
	×	Close seca patient file, changes will not be saved

Vital signs tab

\sim	Button/symbol	Meaning
\sim	NIBP	Blood pressure measured non-invasively
	\bigcirc	Start blood pressure measurement
		Blood pressure measurement in progress
	1. 117/77 2.116/63 3.123/80	Blood pressure: Multiple measurement: First measurement will be discarded

Button/symbol	Meaning
	Blood pressure: Multiple measurement: Waiting time until next part-measurement running
SYS/DIA	Blood pressure: Systolic/diastolic pressure
~~~ >>> ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Blood pressure: Inflation, deflation
• :	Blood pressure: Single measurement, multiple measurement
TEMP	Temperature
▶ .	Temperature measuring mode: Predictive, direct
Ŀ	Manual temperature input (Only for device versions without integrated temperature measurement)
°m° •m°	Temperature input, measuring method oral, axillary, rectal
<u>ር</u> ፲ ፡፡	in-ear, on the skin, contactless
•m •m	COVIDIEN [™] FILAC [™] 3000 temperature probe Measuring position: Oral, axillary, rectal
PR	Pulse rate
♥ ≑♥	Measuring range for pulse rate: Standard, extended
SpO ₂	Oxygen saturation in %
PI	Devices with Masimo SET [®] measuring equipment: Perfusion index, information on the quality of perfusion (min: 0.02 %, max: 20 %)
	Devices with Masimo SET [®] measuring equipment, oxygen saturation measuring mode: Normal, APOD, maximum
$\checkmark$	Save measurement procedure
×	Discard measurement

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## Analysis tab

	Button/symbol	Meaning
$\sim$	N	View history
		Forward results report for printing (seca directprint: Function of the seca analytics 115 PC software)
		Position indicator for analysis modules, in this case: Second module of 5
		Position indicator for analysis parameters, in this case: Second analysis parameter of 4
		Detail view available for analysis parameter: Percentile curve
	Average (NIBP)	Blue marking: Mean value

# 4.6 Unsubmitted measurements list: Symbols

Button/symbol	Meaning
凸	Weight (W)
$\uparrow$	Height (H)
-⁄v-	Pulse rate (PR)
$\bigcirc$	Blood pressure (NIBP)
<u>(02</u> )	Oxygen saturation (SpO ₂ )
J	Temperature (Temp)
Average (NIBP)	Blue marking: Mean value
FN222225852 FN222225852	Yellow marking (when connected to EMR system): Unconfirmed offline measurement

# 4.7 Markings on the device and on the type plate

Text/symbol	Meaning
Text Symbol	weating
	Name and address of manufacturer, date of manufacture
REF	Model number
SN	Serial number, consecutive
ProdID	Product identification number
Mat.No.	Variant number
Rx	Warning: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed health care practitioner
	Follow Instructions for Use
<b>T</b>	Medical electrical device, type BF
⊣★	Medical electrical device, type BF (defibrillation-protected)
$\bowtie$	No alarm function
IP21	<ul> <li>Type of protection in accordance with DIN EN 60 529:</li> <li>Protection against ingress of solid foreign bodies with a diameter of over 12.5 mm</li> <li>Protection against access with fingers</li> <li>Protection against dripping water</li> </ul>
Li-ion	Lithium-ion rechargeable battery
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
	Symbol used for products meeting U.S. and Canadian standards. Certified and tested by the Nationally Recognized Testing Laboratory, the TÜV Süd Product Services GmbH.
xxx-yyy V ~ min xx-yy Hz xx A	Type plate for power supply socket: • Permitted supply voltage • Permitted power supply frequency • Power consumption
. O∕Ò	ON/OFF key
	Inductive charging interface

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Text/symbol	Meaning
뫄	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

Device overview • 23

# 4.8 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).
	This side facing the patient
LATEX	Latex-free
	Name and address of manufacturer
	Date of manufacture
	Name and address of distributor
REF	Model number
LOT	Lot number
CE	The blood pressure cuff complies with EU directives

## 4.9 Markings on the packaging

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

# 4.10 Other symbols

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

Text/symbol	Meaning			
NON	Not sterile			
(	Do not reuse			
R	Small parts present a danger of suffocation if swallowed.			
×	Keep out of sunlight			
	Only use indoors			
$((\bullet))$	Non-ionizing radiation			
DEHP	DEHP-free			
LATER	Latex-free			
MR	Not resistant to magnetic resonance			
	Do not use if packaging damaged			
LOT	Lot number			
EC REP	Person with authority in the EU			

# 5. STARTING UP THE DEVICE

- → Scope of delivery
- → Setting up device
- → Establishing a power supply
- → Charging rechargeable battery
- → Setting the date and time
- $\rightarrow$  Initial login
- → Configuration options

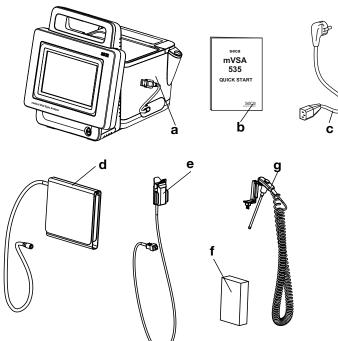
(pack of 20)

g

## 5.1 Scope of delivery

### NOTE

This section shows version 535-1210-131 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			
а	a Monitor to suit the version ordered			
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			
d	seca Blood pressure cuff, size L	1		
•	<ul> <li>SpO₂ sensor (Masimo SET[®])</li> </ul>	1		
е	<ul> <li>Patient cable (Masimo SET[®])</li> </ul>	1		
f COVIDIEN™ FILAC™ 3000 probe covers		1		

COVIDIEN™ FILAC™ 3000 temperature probe

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#### Setting up device 5.2

- → Connecting the SmartBucket
- → Connecting the blood pressure cuff
- → Connecting the temperature probe
- → Connecting the Masimo SET[®] SpO₂ sensor

#### NOTE

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

#### NOTICE!

#### Damage to device, malfunction

Excessive use of force may damage tubes and cables.

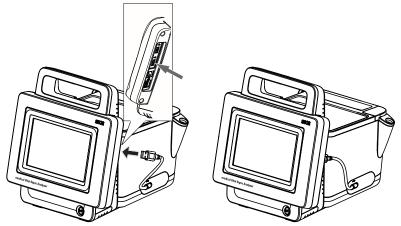
- ► In order to connect measuring accessories to the device or remove them from it, take hold of tubes only by the tube coupling.
- ► In order to connect measuring accessories to the device or remove them from it, take hold of cables only by the connectors.
- ► Use only measuring accessories which have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

## NOTICE!

#### Malfunction

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

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

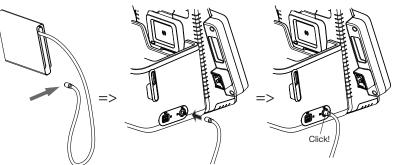


Connect the USB cable of the SmartBucket to a free USB interface of the monitor.

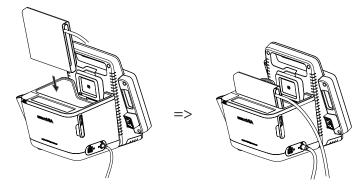
#### **Connecting the SmartBucket**

## Connecting the 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.

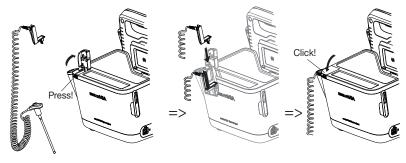


2. Stow the blood pressure cuff in the SmartBucketas shown in the illustration below.

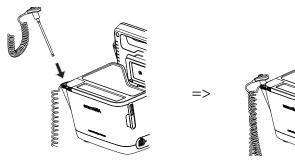


## Connecting the temperature probe

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



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





## NOTICE!

## Damage to device, malfunction

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

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

#### NOTE

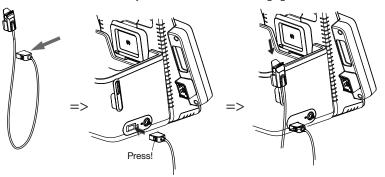
The storage compartment on the probe connection provides space for two packs of probe covers.

#### NOTICE!

#### Damage to device, malfunction

The SpO $_2$  sensor must be compatible with the SpO $_2$  measuring equipment 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 SpO₂ sensor/the patient cable in the socket on the SmartBucket until you feel the connector engage.



NOTE

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

Connecting the Masimo SET®  $\mbox{SpO}_2$  sensor

## 5.3 Establishing a power supply



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

## 5.4 Charging rechargeable battery

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



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

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



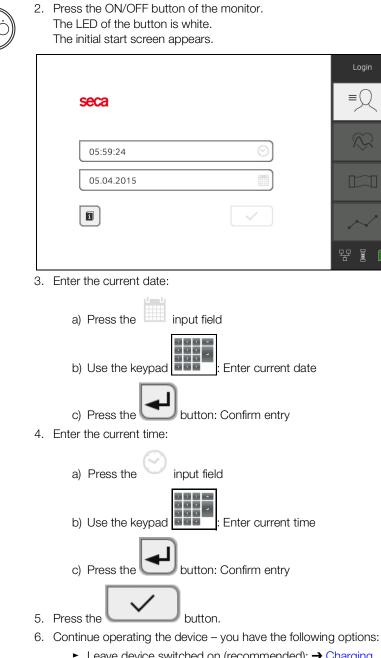
The screen goes off.

The LED of the ON/OFF button flashes green. When the rechargeable battery is fully charged, the device switches off. The LED of the ON/OFF button goes off.

## 5.5 Setting the date and time

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

1. Connect the device to the power supply.



- ► Leave device switched on (recommended): → Charging rechargeable battery
  - ► Perform measurements using the power supply: → Operation
- Configure device using the power supply: → For administrators: Configuring seca mVSA 535

The following user accounts are available on the device initially:

- Admin: Configure and manage device
- User: Perform and manage measurements
- Service: For authorized service technicians

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

Additional user accounts can only be set up in the **seca analytics 115** PC software and must be synchronized with the device.

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

## 5.7 Configuration options

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

# 6. OPERATION

- → Switching the system on/off
- → Managing seca patient files
- → Measuring vital signs
- → Adding weight and height
- → Analyzing measurement

## 6.1 Switching the system on/off

- → Switching on
- → Logging in
- → Logging out/switching user
- → Saving power/switching off

### Switching on



 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.



The Vital signs tab is displayed.

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

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

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

Logging in

## 1. Press the **Login** button.

The login window is displayed:

		Login				
	seca	≡Q				
		$\sim$				
		$\sim$				
		목 (				
2.	Press the input field. The list of user accounts is displayed.					
3.	<b>NOTE</b> If you have no user account, please contact your administrator. Press your user account. Your user account is displayed in the input field.					
4.	Press the input field.					
5.	Enter your password using the keypad					
6.	Continue with $\rightarrow$ Managing seca patient files.					
•	Press the <b>Logout</b> button.					
	example, weight reduction * 01.08.1961 Vital signs Last measurement: 12.01.2016, 16:01:00	Logout				
	NIBP         Blood pressure         129 mmHg 70 mmHg         Image: Comparison of the second	-×				
	PR Pulse rate 70 1/min	$\sim$				
	SpO ₂ Oxygen saturation -					
	TEMP Temperature -					
	Summary of modules	$\sim$				
	Health risk	윰 🏾				

You will be logged out. The login window is displayed.

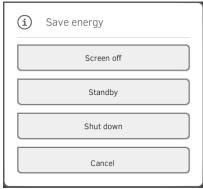
Another user can log in  $\rightarrow$  Logging in.

## Logging out/switching user

### Saving power/switching off



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



3. Select an option in accordance with the table:

## NOTE

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

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

#### NOTE

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

## 6.2 Managing seca patient files

- → Creating a seca patient file
- → Calling up a seca patient file
- → Editing a seca patient file
- → Exporting a seca patient file
- → Deleting a seca patient file

## NOTICE!

#### Inconsistent measuring results

If you create seca patient files several times, this can lead to incorrect assignment of measuring 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 → Activating automatic synchronization.
- Only create a new seca patient file on the device if you are sure that there is no seca patient file for the patient in the seca analytics 115 PC software.

#### 1. Log in $\rightarrow$ Logging in.

## 2. Press the Patient tab.

The patient list is displayed.

Search       P         Name       Date of birth       A         Q       example, healthy Asian       15.11.1977         of       example, healthy Afro-American       27.06.1971         of       example, weight reduction       01.08.1961         Q       example, anorexia       27.04.1956         of       example, obesety       14.02.1967	Patie Luse	ent list er		Create patie	nt file			Logout
Q       example, healthy Asian       15.11.1977         of       example, healthy Afro-American       27.06.1971         of       example, weight reduction       01.08.1961         Q       example, anorexia       27.04.1956         of       example, obesety       14.02.1967	sea	arch				9	_	=
o       example, healthy Afro-American       27.06.1971         o       example, weight reduction       01.08.1961         o       example, anorexia       27.04.1956         o       example, obesety       14.02.1967	~	Name	-	Date of birth	Ŧ	^	ſ	$\mathcal{R}$
of   example, weight reduction   01.08.1961     Q   example, anorexia   27.04.1956     of   example, obesety   14.02.1967	ę	example, healthy Asian		15.11.1977				
<b>Q</b> example, anorexia         27.04.1956 <b>o</b> *         example, obesety         14.02.1967	ď	example, healthy Afro-American		27.06.1971				
of example, obesety 14.02.1967 ✓	ď	example, weight reduction		01.08.1961			-	
	ę	example, anorexia		27.04.1956				$\sim$
	ď	example, obesety		14.02.1967		$\sim$	l	뭐 ()

#### 3. Press the Create patient file button.

Create patient file Page 1 of 2	×
Anonymous patient First name	Attending physician           Not assigned
Surname	ID
	$\rightarrow$

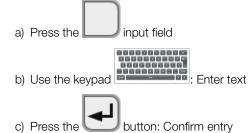
#### NOTICE!

#### **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.

#### Creating a seca patient file

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



#### NOTICE!

#### Data access by unauthorized persons

If you do not enter an attending physician, the patient file is accessible to all physicians with access to the device.

- Enter an attending physician to prevent access by unauthorized persons. If the attending physician has not been determined at the time of the measurement, make the entry as soon as possible afterwards.
- 5. Enter the attending physician:



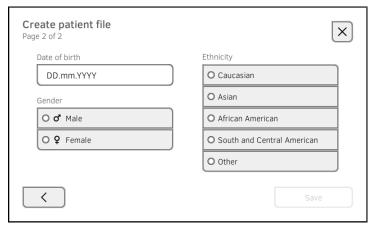
- b) Press the name of the attending physician in the drop-down menu
- c) Enter patient ID

#### NOTE

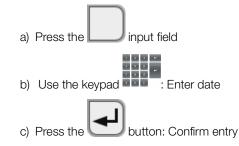
You only need to assign a patient ID if a specific structure is provided for this in your institution. If you leave the **ID** input field empty, the device will automatically assign an ID when the data are saved.



The second page of the **Create patient file** dialog is displayed.



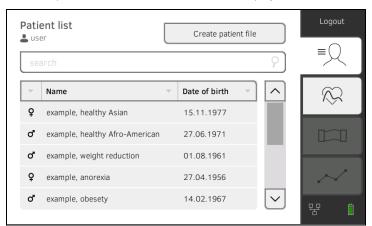
7. Enter the date of birth:



- 8. Enter the appropriate gender.
- 9. Enter the appropriate ethnicity.

#### 10. Press the **Save** button.

The seca patient file has been created and is displayed.



You have the following options for continuing:

► Measure vital signs: → Measuring vital signs

## Calling up a seca patient file

- 1. Log in  $\rightarrow$  Logging in.
- 2. Press the Patient tab. The patient list is displayed.

Patient list		Create patient file		Logout
sea	arch		?	=
-	Name	Date of birth		
ę	example, healthy Asian	15.11.1977		
ď	example, healthy Afro-American	27.06.1971		
ď	example, weight reduction	01.08.1961		
ę	example, anorexia	27.04.1956		$\sim$
ď	example, obesety	14.02.1967	$\checkmark$	명 ()

- 3. Select a seca patient file:
  - Desired entry not visible: Continue at step 4.
  - Desired entry visible: Continue at step 5.
- 4. Search for the desired seca patient file in the list:

a) Press the input field
b) Use the keypad
c) Press the button: Confirm entry

A hit list is displayed.

5. Press the desired entry.

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

6. Press the **Confirm** button.

The seca patient file is opened.

You have the following options for continuing:

► Measure vital signs: → Measuring vital signs

Editing a seca patient file

1. Call up a seca patient file  $\rightarrow$  Calling up a seca patient file.

button.



3. Edit the entries on the first page.

- 5. Edit the entries on the second page.
- 6. Press the **Save** button. The changes are saved.
- **Exporting a seca patient file** 1. Connect a USB memory stick to the monitor.
  - 2. Call up a seca patient file  $\rightarrow$  Calling up a seca patient file.
  - Press the button.
     A confirmation dialog opens.
  - 4. Press the **Confirm** button. The patient file is exported.

## Deleting a seca patient file

1. Call up a seca patient file  $\rightarrow$  Calling up a seca patient file.



 Press the **Delete** button. The patient file is deleted.

## 6.3 Measuring vital signs

- → Introduction
- → Measuring blood pressure
- → Measuring temperature, oral/axillary (COVIDIENTM FILACTM 3000, blue)
- → Measuring temperature, rectal (COVIDIENTM FILACTM 3000 red)
- → Entering temperature manually
- → Reading off pulse rate
- $\rightarrow$  Measuring oxygen saturation (SpO₂)
- → Stopping a measurement procedure
- → Assigning anonymous measurement procedure to a seca patient file

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

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



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

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

## Measuring blood pressure

- → Preparing the blood pressure measurement
- → Starting a single measurement
- → Starting a multiple measurement
- → Modifying presets

## Introduction

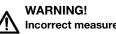
WARNING! Hazard to patient

- Do not use luer lock adapter on the blood pressure measurement tubes. The use of luer lock adapters can lead to accidental connection of the blood pressure tubes to intravenous lines and thus lead to an infusion of air into the bloodstream of the patient.
- The decision to use this device with pregnant or preclamptic patients is the responsibility of the user.
- ► The device has **no** alarm function. Never leave the patient unobserved during a measurement.
- Frequent measurements may lead to perfusion disorders and consequently to severe harm to the patient.
- Route the compressed air tube so that it cannot kink. A kinked compressed air tube leads to sustained cuff pressure. This may lead to perfusion disorders and consequently to severe harm to the patient.
- Do not place the blood pressure cuff over open wounds. This may lead to further harm to the patient.
- Do not apply any external pressure onto the blood pressure measurement tubes or onto the blood pressure cuff.
- For patients with moderate to severe cardiac arrhythmias, inaccurate measurements may result with the blood pressure measurement.
- ► The following factors may affect the measurement result:
  - Measuring location (e.g. altitude)
  - Patient position (standing, sitting, lying)
  - Physiological state of the patient (e.g. exertion, movement, shaking, shivering)
  - Patient's age
  - Arteriosclerosis
  - Poor perfusion
  - Diabetes
  - Kidney disease
- If the measurements seem implausible, check and evaluate the vital signs of the patient using alternative means. Then check the measurement function of the device with the help of the section "Troubleshooting".

# M 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.



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 mea-► surement tubes and connections are free of damage and airtight.
- Ensure that the arm on which the blood pressure cuff is attached does not move during the measurement.
- Ensure that the blood pressure cuff is applied according to the ► printed mark "Artery".



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

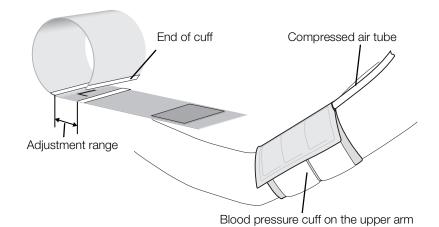
If the blood pressure cuff is too mall, the measured blood pressure values will be too high. If the blood pressure cuff is too large, the measured blood pressure values will be too small.

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

## Preparing the blood pressure measurement

1. Ensure that the patient adopts the following position:

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



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## NOTE

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

You have the following options for continuing:

- ► → Starting a single measurement
- ► → Starting a multiple measurement

#### NOTICE!

#### Faulty operation, missing measuring results

Results from multiple measurements cannot be transmitted to EMR systems or the **seca analytics 115** PC software.

Switch to Single measurement, if necessary, if you want to transmit blood pressure values to an EMR system or the seca analytics 115 PC software → Modifying presets.

#### NOTE

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

#### Starting a single measurement

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



Current cuff pressure is displayed.

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

Measurement stops automatically as soon as valid blood pressure values are detected.



The values for systolic/diastolic blood pressure SYS/DIA are displayed.

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

#### NOTE

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

#### Starting a multiple measurement

Press the button on the monitor.
 The first part-measurement starts (in this case: 6 part-measurements).



Current cuff pressure is displayed.

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

The part-measurement stops automatically as soon as valid blood pressure values are detected.

The waiting time until the next part-measurement starts.



The values for systolic/diastolic blood pressure **SYS/DIA** are displayed. The next part-measurement starts automatically.

Once all part-measurements are present, mean blood pressure (mean value) is displayed.



You have the following options for continuing:

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

#### NOTE

- Use the Start button to cancel the mean measurement and continue or to cancel and re-start.
- If inflation does not deliver a measured value, the device automatically switches to deflation.
- If necessary, the device re-pumps several times during the deflation (re-pumping: Increasing cuff pressure by approx. 50 mmHg followed by incremental releasing of that pressure). If no measured value is delivered even after several re-pumping steps, the procedure is canceled.

## Modifying presets

#### NOTE

Your settings apply only to the current measurement procedure. If you stop the measurement procedure  $\rightarrow$  Stopping 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	ž	Deflation
Starting pressure			
180 mmHg 🗾 👻			
Procedure			
O • Single measurement		:	Multiple measurement

- 3. Press the desired measurement method.
  - Inflation, continue at step 5.
  - Deflation, continue at step 4.
- 4. Adapt initial pressure if necessary.
- 5. Press the desired measuring sequence:
  - Single measurement
  - Multiple measurement or if a measuring profile has been configured for the multiple measurement name of the measuring profile

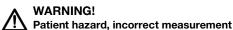
#### NOTE

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

- Press the **Confirm** button. The dialog window closes. Changed settings are adopted for the current measurement.
- Start the blood pressure measurement as described in the section entitled → Preparing the blood pressure measurement.

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

- → Starting an oral/axillary temperature measurement
- → Modifying presets



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

## WARNING!

## Patient hazard, incorrect measurement

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

## Starting an oral/axillary temperature measurement

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

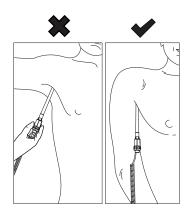


- a) Insert the probe in a probe cover in the pack
- b) Allow the probe cover to engage audibly with the probe
- c) Remove probe and probe cover from the pack
- d) Ensure that the probe cover is undamaged
- 3. Position the temperature probe as shown in the illustration:

Oral measurement:

Axillary measurement:





Measurement starts automatically.

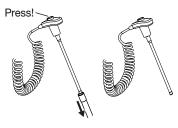
The measured value and the symbol for the measurement procedure (in this case: Predictive) flash until a valid measured value is obtained.



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



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

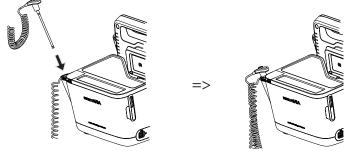


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#### NOTE

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

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



You have the following options for continuing:

- ► Measure further vital signs → Measuring vital signs
- ► Stop the measurement procedure → Stopping a measurement procedure

#### Modifying presets

#### NOTE

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

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

٢	-	Temperature settings
	•	Predictive
0	٩	Direct
	<b>*</b>	Oral
0	'n	Axillary
	C	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 adopted for the current measurement.

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

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

- → Starting a rectal temperature measurement
- → Modifying presets

#### WARNING! Patient hazard, incorrect measurement

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

## WARNING!

## Patient hazard, incorrect measurement

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

### Starting a rectal temperature measurement

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



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

Measurement starts automatically.

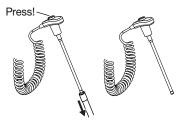
The symbol for the measurement procedure (in this case: Predictive) flashes until a valid measured value is obtained.



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

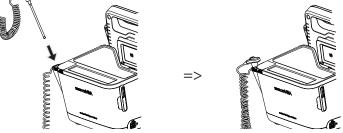


5. Discard the probe cover and dispose of it in line with your institution's policy.



#### NOTE

You can only perform a further temperature measurement if you discard the probe cover and push the temperature probe back into the probe holder completely. 6. Push the temperature probe into the probe holder completely.



You have the following options for continuing:

- ► Measure further vital signs → Measuring vital signs
- Stop the measurement procedure → Stopping a measurement procedure

#### Modifying presets

#### NOTE

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

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

The Temperature settings dialog window opens.

The presets are displayed.

Predictive
O 🌡 Direct
Cancel Confirm

- 3. Press the desired measurement method.
  - Predictive
  - Direct
- Press the **Confirm** button. The dialog window closes. The modified settings are adopted.
- Start the temperature measurement as described in the section entitled
   → Starting a rectal temperature measurement. You have the following options for continuing:
  - ► Measure further vital signs → Measuring vital signs
  - Stop the measurement procedure → Stopping a measurement procedure

## **Entering temperature manually**

## NOTICE!

#### Faulty operation, missing measuring results Manual temperature entries cannot be transmitted to the

seca analytics 115 PC software.

 Enter these values manually in the seca analytics 115 PC software as well.

#### NOTE

- The option of entering temperatures manually is available on device versions delivered **without** integrated temperature measuring equipment. On other device versions, your administrator can deactivate the integrated temperature measuring equipment in order to allow manual temperature input.
- Follow the safety precautions in the instructions for use for your thermometer.
- 1. Measure body temperature as described in the instructions for use for your thermometer.
- 2. In the Vital signs tab, press the **TEMP** field:

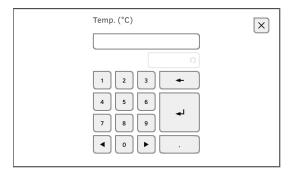


#### The Temperature: manual entry dialog window is displayed:

O Temperature: manual entry				
Enter method				
🖲 🛉 Oral	O 🝞 Ear			
O 🛉 Axillary	O 🐺 Skin			
O 📲 Rectal	O ₽·1 Contactless			
Cancel	Confirm			

- 3. State the measuring method:
  - a) Press the appropriate button
  - b) Press the **Confirm** button

A numerical keypad appears:



## 4. Enter body temperature:

#### a) Enter the value



The value entered appears in the **TEMP** field of the Vital signs tab.

No patient file		Login
SpO ₂ No Sensor	r connected.	≡◯
	NIBP mmHg SYS/DIA • 🔶	
$\odot$		$\bigotimes$
	MAP	
TEMP °C		
37	.5	$\sim$
<b>å</b> kg	<u>t</u> m	명 (1

You have the following options for continuing:

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

Reading off pulse rate

#### → Interrogate pulse rate source



## A 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

→ Stopping 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.

## Measuring oxygen saturation (SpO₂)

- $\rightarrow$  Starting an SpO₂ measurement
- → Modifying presets



#### Patient hazard, incorrect measurement

- The device has **no** alarm function. Never leave the patient unobserved during a measurement.
- The pulse oximeter is not an apnea monitoring device.
- The pulse oximeter must not be used to analyze arrhythmia.
- Incorrectly-applied sensors may lead to injuries at the point of application. Follow the Instructions for Use from the sensor manufacturer.
- ► Apply the blood pressure cuff and SpO₂ sensor to different extremities to avoid falsifying measuring results.
- Apply the intravenous pressure catheter and SpO₂ sensor to different extremities to avoid falsifying measuring 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 instructions for use.
  - Do not attempt to clean the device while monitoring a patient.
- To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.
- If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning. Follow the section entitled "Troubleshooting".
- Inaccurate 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.

## 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.

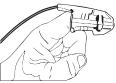
## NOTE:

• 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.

#### Starting an SpO₂ measurement

- Apply the SpO₂ sensor according to the sensor manufacturer's instructions for use.
  - a) Ensure that the SpO₂ sensor is the correct size
  - b) Prepare measuring point (e.g. remove jewelry or nail varnish)
  - c) Apply the  $\text{SpO}_2$  sensor to 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 for continuing:

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

#### NOTE

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

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#### **Modifying presets**

## NOTE

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

1. Ensure that no SpO₂ sensor has been applied to the patient.

#### 2. Press the $\mathbf{SpO}_2$ field.

The **SpO**₂ settings dialog window opens.

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

SpO ₂
O 🕿 Stable
🖲 🟊 Normal
O 🕅 Sensitive
Cancel Confirm

3. Press the desired sensitivity:

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

4. Press the **Confirm** button.

The dialog window closes. The changed settings are used for the current measurement.

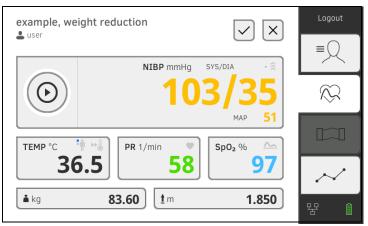
Start the SpO₂ measurement as described in the section entitled
 → Starting an SpO₂ measurement.

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

# Weight and height

## Stopping a measurement procedure

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



You have the following options:

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

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

- 1. Log in  $\rightarrow$  Logging in.
- 2. Press the Patient tab.

You have the following options for continuing

- $\rightarrow$  Calling up a seca patient file
- $\rightarrow$  Creating a seca patient file
- Confirm the Assign measurement? message. The measurement procedure is assigned to the patient file.



The measurement procedure is saved.

Assigning anonymous measurement procedure to a seca patient file

## 6.4 Adding weight and height

<ul> <li>Receiving weight and height (seca 360° proximity)</li> <li>Receiving weight and height (seca 360° wireless)</li> <li>Entering weight and height manually</li> <li>You can add the parameters weight  <ul> <li>and height</li> <li>as follows:</li> </ul> </li> <li>In the Patient tab</li> <li>In the Vital signs tab</li> </ul> <li>Steve, James <ul> <li>User_en_US <ul> <li>First name</li> <li>James</li> <li>Date of birth 10.03.1976</li> <li>Image: Steve</li> <li>Image: Stev</li></ul></li></ul></li>
<ul> <li>In the Patient tab</li> <li>In the Vital signs tab</li> </ul> Steve, James <ul> <li>User_en_US</li> <li>User_en_US</li> <li>First name</li> <li>Steve</li> <li>James</li> <li>Date of birth</li> <li>10.03.1976</li> <li>Image: Steve</li> <li>Image: St</li></ul>
Steve, James   Juser_en_US   First name   Steve   Surname   James   Date of birth   10.03.1976
Surname James Date of birth 10.03.1976
1 i i i
No patient file loaded       ✓       ✓       Login            ▲ No user logged in        ✓       ✓       ✓            ③ SpO₂ No Sensor connected.        Image: SYS/DIA       Image: SYS/DIA       Image: SYS/DIA
TEMP °C     PR 1/min     Sp02 %

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

- ► → Receiving weight and height (seca 360° proximity)
- ► → Receiving weight and height (seca 360° wireless)

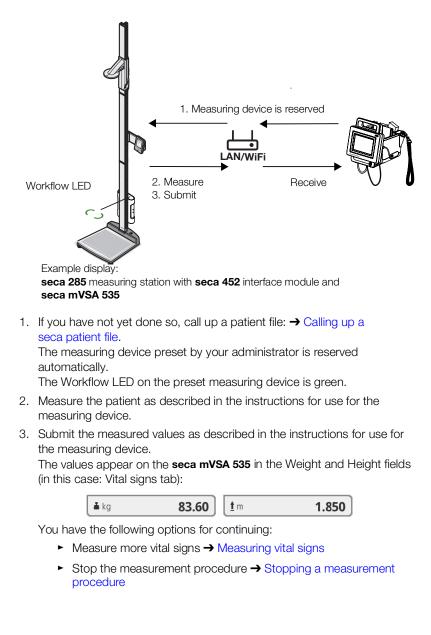
#### NOTE

If you are uncertain of which options you can use, contact your administrator.

You can also enter weight and height manually:  $\rightarrow$  Entering weight and height manually.

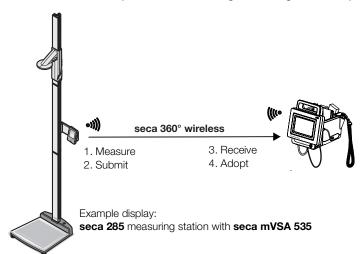
Receiving weight and height (seca 360° proximity)

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



# Receiving weight and height (seca 360° wireless)

If your seca scale or your seca length measuring device is equipped with a **seca 360° wireless** module you can transmit weight and height wirelessly.



- 1. Measure the patient as described in the instructions for use for the measuring device.
- 2. Submit the measured values as described in the instructions for use for the measuring device.
- 3. On the **seca mVSA 535** press the Weight or Height field. A numerical keypad appears (in this case: Weight):

	Weight (kg)
	83,6 360'
	1 2 3 +
	4 5 6
	7 8 9
	360°
The value received appe	ears in the field.
4. Adopt the value:	
a) Press the	field.
	1
b) Press the 🕒	button.

The adopted values appear in the Weight and Height fields (in this case: Vital signs tab):



You have the following options for continuing:

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

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

1. Press the Patient tab.

manually

Entering weight and height

- 2. If you have not yet done so, select a patient file.
- 3. Press the Weight or Height field.

4.

A numerical keypad appears (in this case: Weight):

	Weight (kg)	
	360" 83,6 )	
	1 2 3 -	
	4 5 6	
You have	the following options for entering a value:	1
► Us	se the keypad	
	ess the button: Adopt the value from the pre	evious
Press the	button.	
	es appear in the Weight and Height fields:	
	83.60 kg 1.850 m	
	Patient tab	
	t kg 83.60 t m 1.850	]
	Vital signs tab	-
Maria Iana ia		

You have the following options for continuing:

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

## 6.5 Analyzing measurement

- → Viewing current measuring results
- → Analyzing vital signs (history)

#### NOTE

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

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

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

example, weight reduction	Logout
Last measurement: 12.01.2016, 16:01:00	≡Q
Development/growth Energy	$\otimes$
	$\sim$
	윰 ()

You have the following options for continuing:

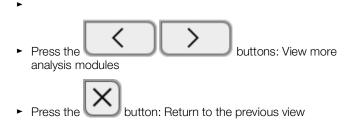
- To view an analysis module: continue at step 2.
- Press the button: submit a results report to the seca analytics 115 PC software for printing (seca directprint function of the seca analytics 115 PC software)

## Viewing current measuring results

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

	example, weight reduction * 01.08.1961		Logout
Vital sig Last mea	ns Isurement: 12.01.2016, 16:01:00		≡◯
NIBP	Blood pressure	129 mmHg 70 mmHg	
PR	Pulse rate	70 1/min	$\bigotimes$
Sp02	Oxygen saturation	-	
TEMP	Temperature	- 🗖	
			$\sim$
Kealth ris	Summary of modules	>	뫙 自

You have the following options for continuing:



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

1. Call up a parameter overview  $\rightarrow$  Viewing current measuring results.

Vital sig	nle, weight reduction * 01.08.1967 ns Isurement: 12.01.2016, 16:01:00	×	Logout
NIBP	Blood pressure	129 mmHg 70 mmHg	
PR	Pulse rate	70 1/min	$\sim$
Sp0₂	Oxygen saturation	-	
ТЕМР	Temperature	- 🗖	
Health ris	Summary of modules	$\rightarrow$	우 (1

## Analyzing vital signs (history)

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

example, w Vital signs NIE		ion *01.0	18.1961 X
✓ 12.01	.2016 16:01:00	129 mmHg 70 mmHg	
12.12	.2015 19:26:00	149 mmHg 91 mmHg	
21.11	.2015 17:14:00	135 mmHg 83 mmHg	
03.10	.2015 13:51:00	139 mmHg 89 mmHg	
History: <b>1</b> selec	ted		$\checkmark$

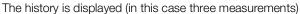
You have the following navigation options:

- Press the drop-down menu: Filter measuring results by period. Then continue at step 3.
- Press the button: Add a comment
- Press the button: Return to the previous view

## NOTE

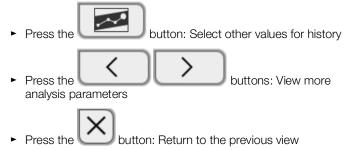
Just a single comment can be added to each measured result. Existing comments will be overwritten.

- 3. Press the _____ checkboxes for all the measurements you want to look at in the history.
- 4. Press the button.





You have the following navigation options:



# 7. OPERATION WHEN CONNECTED TO AN EMR SYSTEM

- → Switching on the device
- → Measuring
- → Logging in with EMR user ID
- → Calling up patient data from the EMR system
- → Saving measurements in the EMR system

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

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

## NOTICE!

#### Faulty operation, implausible measuring results

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

## 7.1 Switching on the device

### NOTE

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

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

No patient f			Login
L No user logg	NIBP mmHg		≡Q
$\mathbf{O}$	SYS/DIA		$\approx$
TEMP °C	MAP <b>PR</b> 1/min		
		PI	$\sim$
🛓 kg	] ( <u>†</u> m		琚. ①

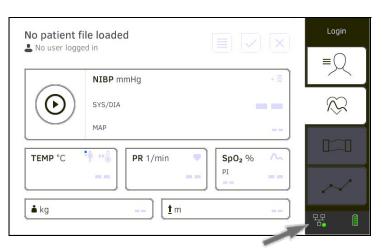
You have the following options for continuing:

- ► → Measuring with an active connection to an EMR system
- ► → Measuring with an interrupted connection to an EMR system

- → Measuring with an active connection to an EMR system
- → Measuring with an interrupted connection to an EMR system

# Measuring with an active connection to an EMR system





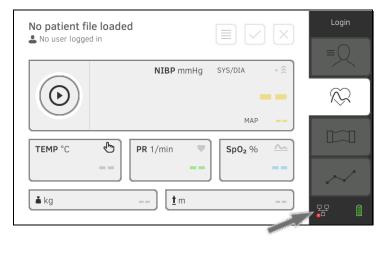
If the device has an active connection to the EMR system, proceed as described in the following sections:

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

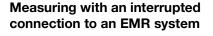
The device provides the option of performing measurements with an interrupted connection to the EMR system. The measurements are temporarily saved on the device and can be submitted as soon as the connection to the EMR system is active again.

#### NOTE

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



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

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

The User ID not verfied message appears.

No patient file loaded	Logout
NIBP mmHg SYS/DIA	≡Q
	$\bigotimes$
MAP        TEMP °C     **       PR 1/min     ▼       SpO2 %     ^-	
	$\sim$
▲ kg ( <u>†</u> m)	

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

The patient ID is displayed:

FN222225852 Luser ID not verified		Logout
NI	BP mmHg SYS/DIA 🛛 🔅	≡
$( \bigcirc )$		$\approx$
	MAP	
TEMP °C	nin V SpO ₂ %	
▲ kg	<u>t</u> m	

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

The measurement is saved in the Unsubmitted measurements list.

- 4. Log in again when the connection to the EMR system is active again.
- 5. Proceed as described in this section: → Using the Unsubmitted measurements list.

## 7.3 Logging in with EMR user ID

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

- → Scanning EMR user ID (recommended)
- → Entering EMR user ID manually
- 1. Scan your EMR user ID.

Your EMR user ID is displayed in the — input field.

 Enter your EMR system password. The Vital signs tab is displayed. You can call up patient data from the EMR system → Calling up patient data from the EMR system.

## Entering EMR user ID manually

Scanning EMR user ID

(recommended)

1. Press the Login button.

seca		
		$\sim$
	9	
	$\checkmark$	$\sim$
		문 ()

The login window is displayed.

2. Enter your EMR user ID.

Your EMR user ID is displayed in the 🍈 input field:

 Enter your EMR system password. The Patient tab is displayed. You can call up patient data from the EMR system → Calling up patient data from the EMR system.

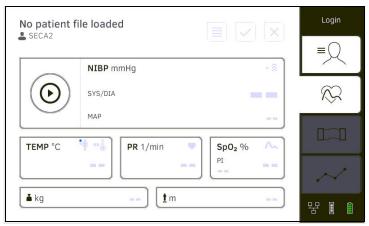
## 7.4 Calling up patient data from the EMR system

You have the following options for calling up patient data from the EMR system:

- → Scanning patient ID (recommended)
- → Manually entering patient ID

Scanning patient ID (recommended)

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



1. Scan the patient ID.

The patient data are shown in the Patient information dialog window.

First name		
Albert		
Surname Normal		
Date of birth:	02.01.1988	
Gender:	Male	
Ethnicity: Patient ID:	Caucasian FNSECA1	

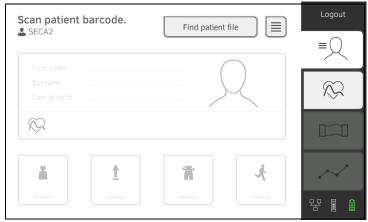
2. Ensure that the patient data displayed are correct.

З.

The patient data is transmitted to the device and displayed in the Vital signs tab.

## Manually entering patient ID

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



1. Press the Find patient file button.



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

(i) Patient	information	
First name Albert		
Surname <b>Normal</b>		
Date of birth: Gender: Ethnicity: Patient ID:	02.01.1988 Male Caucasian FNSECA1	
		<ul> <li>✓</li> </ul>

3. Ensure that the patient data displayed are correct.



The patient data is transmitted to the device and displayed in the Vital signs tab.

## 7.5 Saving measurements in the EMR system

- → Submitting the measurement directly to the EMR system
- → Saving measurement temporarily and submitting it later
- → Using the Unsubmitted measurements list

Submitting the measurement directly to the EMR system

Saving measurement temporarily

and submitting it later

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

- 1. In the Vital signs tab, press the button.
- 2. In the dialog window, press the **Submit** button.

(i) Measurements	
Save or submit measurement? "submit": Measurement will be submitted to your EMR. "save": Measurement will be saved on this device only, not sent.	
Submit Cancel Save	

The measurement is submitted to the EMR system and assigned to the EMR patient file.

The measurement procedure is complete.

The patient data are removed from the display.

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

- 1. In the Vital signs tab, press the button.
- 2. In the dialog window, press the **Save** button.

(i) Measurements					
Save or submit measurement? "submit": Measurement will be submitted to your EMR. "save": Measurement will be saved on this device only, not sent.					
Submit Cancel Save					

The measurement is assigned to the patient ID and saved temporarily on the device.

The measurement procedure is complete.

The measurement can be assessed in the Unsubmitted measurements list and submitted to the EMR system  $\rightarrow$  Using the Unsubmitted measurements list.

# Using the Unsubmitted measurements list

- → Confirm offline measurement (EMR system connection)
- → Viewing details
- → Submitting the measurement
- → Deleting a measurement

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

A measurement appears in the list under the following conditions:

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

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

- 1. Log in → Scanning EMR user ID (recommended).
- 2. Ensure that the Patient and Vital signs tabs are active.



The Unsubmitted measurements list is displayed:

Select all			
FN2222225852	10:19:54	<b>占</b>	
careaware2, jira12372	13.07.2020		)
FN2222225852	10:18:50		1
FN2222225852	13.07.2020	•	
FN2222225852	10:14:24		1
FN2222225852	13.07.2020	∿ @	J

## NOTE

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

#### Confirm offline measurement (EMR system connection)

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

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

nsubmitted measuremer SECA	its		×
Select all			
FN222225852	10:19:54	占 ⊥	
careaware2, jira12372	13.07.2020		
FN222225852	10:18:50		
FN222225852	13.07.2020	۲	
FN222225852	10:14:24		ĥ
FN2222225852	13.07.2020	∿ @	
asurements: 0 selected		1 1 1 I	



02.01.1988 Male Caucasian FNSECA1	
	Male Caucasian

3. Ensure that the patient data displayed are correct.



The measurement is confirmed. The yellow marking is no longer displayed in the **Unsubmitted measurements** list.

The details of the measurement are displayed  $\rightarrow$  Viewing details.

#### Viewing details

1. Press a measurement.

The details of the measurement are displayed:

Result	Value	Unit .	
Average (NIBP)	<b>120</b> SYS <b>100</b> MAP <b>92</b> DIA	mmHg	
Pulse rate	86	1/min	
SpO ₂	98	%	
Temperature	37.0	°C	

#### NOTE

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

2. Press the button to close Detail view.

#### Submitting the measurement

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

Select all			
FN2222225852	10:19:54	å ↑	
careaware2, jira12372	13.07.2020		
FN2222225852	10:18:50		
FN2222225852	13.07.2020	$\odot$	
FN222225852	10:14:24		
FN2222225852	13.07.2020	∿ @	
rements: 0 selected		=	

3. Press the button.

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

#### NOTE

In the EMR system, measurements from the **Unsubmitted measurements** list are not assigned to the user who performed the measurements, but to the user who submitted them.

## Deleting a measurement

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

	Unsul	bmitted measuremer	nts		×
		Select all			
		FN2222225852 careaware2, jira12372	10:19:54 13.07.2020	8 <u>1</u>	
		FN222225852 FN2222225852	10:18:50 13.07.2020	٩	
		FN222225852 FN2222225852	10:14:24 13.07.2020	∿ @	
	Measur	ements: 0 selected		Î	
2.	Press th	he button.	s are deleted.		

# 8. HYGIENE TREATMENT

- → Cleaning
- → Removing/fitting probe holder (devices with temperature probe)
- → Disinfecting
- → 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 including the active ingredient 70 % isopropanol only for measuring accessories for measuring vital signs.

## 8.1 Cleaning

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

Component (depending on version)	Interval	Cleaning
<b>seca mVSA 535</b> : Monitor with SmartBucket	As required	<ol> <li>Remove all the measuring accessories (measuring devices and consumables) from the device (depending on version)</li> <li>→ Removing the probe holder</li> <li>Moisten a soft cloth with a soap solution</li> <li>Wipe over all surfaces</li> <li>Allow to air-dry for approx. 30 minutes</li> </ol>
Blood pressure cuff and compressed air tube	As required	<ol> <li>Moisten a soft cloth with a mild soap solution</li> <li>Clean blood pressure cuff and compressed air tube</li> <li>Rinse thoroughly with water</li> <li>Allow to dry at room temperature</li> </ol>
Temperature probe (red/blue) with cable	As required	<ol> <li>Discard probe cover and dispose of it</li> <li>Moisten a soft cloth with a mild soap solution</li> <li>Clean temperature probe</li> <li>Shake out temperature probe so that no liquid remains in it</li> <li>Allow to air-dry for approx. 30 minutes</li> </ol>

Component (depending on version)	Interval	Cleaning
Probe holder (red/blue)	As required	<ol> <li>A Removing the probe holder</li> <li>Moisten a cotton bud with a mild soap solution</li> <li>Wipe over all the surfaces of the probe holder</li> </ol>
	As required	<ul> <li>Measuring head and lens:</li> <li>1. Carefully remove all foreign particles using a cloth moistened with alcohol (70 % isopropanol)</li> <li>2. Wipe dry the lens at the tip of the measuring head with a lint-free cloth (e.g. spectacle-cleaning cloth)</li> <li>3. Make sure that the lens at the tip of the measuring head does not have any fingerprints or marks on it</li> <li>4. Allow the in-ear thermometer to dry completely in air</li> </ul>
SpO ₂ sensor with cable	Follow the ma	anufacturer's instructions for use
Patient cable for SpO ₂ sensor	Follow the ma	anufacturer's instructions for use

## 8.2 Disinfecting

2. Disinfect the device and its accessories as described in the table:		
Component (depending on equipment)	Interval	Disinfecting
<b>seca mVSA 535</b> : Monitor with SmartBucket	As required	<ol> <li>Remove all the measuring accessories (measuring devices and consumables) from the device (depending on version)</li> <li>→ Removing the probe holder</li> <li>Moisten a soft cloth with disinfectant (active ingredient: quaternary ammonium compounds)</li> <li>Wipe over all surfaces</li> <li>Allow to air-dry for approx. 30 minutes</li> </ol>
Blood pressure cuff and compressed air tube	As required	<ol> <li>Moisten a soft cloth with disinfectant (active ingredient: 70 % isopropanol)</li> <li>Wipe over cuff and compressed air tube</li> <li>Rinse thoroughly with water</li> <li>Allow to dry at room temperature</li> </ol>
Temperature probes (red/blue) with cable	As required	<ol> <li>Discard probe cover and dispose of it</li> <li>Moisten a soft cloth with disinfectant (active ingredient: 70 % isopropanol)</li> <li>Wipe over temperature probe</li> <li>Shake out temperature probe so that no liquid remains in it</li> <li>Allow to air-dry for approx. 30 minutes</li> </ol>
Probe holder (red/blue)	As required	<ol> <li>A Removing the probe holder</li> <li>Moisten a cotton bud with disinfectant (active ingredient: 70 % isopropanol)</li> <li>Wipe over the inner surfaces of the probe holder</li> <li>Allow to air-dry for approx. 30 minutes</li> </ol>
$SpO_2$ sensor with cable	Follow the manufacturer's instructions for use	
Patient cable for SpO ₂ sensor	Follow the manufacturer's instructions for use	

1. Follow the instructions for use for the disinfectant.

## 8.3 Sterilizing

The device and accessories must not be sterilized.

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



# Patient hazard

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

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

Removing the probe holder

1. Open the covering cap.

2. Remove the probe holder.



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



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

## Fitting the probe holder

# 9. 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 "Troubleshooting" 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 "Troubleshooting" in this document, you may not use the device.

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

# 10.SERVICING

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.

# **11.TROUBLESHOOTING**

- → Monitor
- $\rightarrow$  Vital signs measurement
- → Network connection
- $\rightarrow$  Connection to the seca analytics 115 software
- $\rightarrow$  EMR system connection via seca connect 103 software
- → seca 360° proximity connection

## 11.1 Monitor

Fault	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	<ul><li>Touch the touchscreen display</li><li>Press the ON/OFF button</li></ul>
Touchscreen display remains off	Device not switched on	Switch on the device
	No power supply	Check whether power is being supplied
	Touchscreen display faulty	Inform seca Service
Touchscreen display not reacting	Device in undefined state following implausible input	<ul> <li>Switch off the device (press and hold the ON/OFF button for approx. 15 seconds)</li> <li>Switch the device back on</li> </ul>
Image on touchscreen display faulty	Touchscreen display faulty	Inform seca Service
	Password overwritten on last synchronization with the <b>seca analytics 115</b> PC software	<ul> <li>Use the new password</li> <li>If new password not known, contact administrator</li> </ul>
		Use the old password
Password not accepted	Following a backup, the old passwords are valid again	<ul> <li>Administrator:</li> <li>If you no longer know the old password, assign a new password</li> <li>Have the administrator password reset by seca Service</li> </ul>
The Vitel signs tob is not	USB connecting cable of the SmartBucket not connected to the monitor	<ul> <li>Connect the USB connecting cable of the SmartBucket to the monitor</li> <li>Restart the device</li> </ul>
The Vital signs tab is not active on a seca mVSA 535	SmartBucket not activated	Administrator: Activate SmartBucket: → Managing system components in the administrator menu

Fault	Cause	Remedy
Patient and user data can	USB stick contains several backup copies	Ensure that there is only one folder on the USB stick with the designation <ddmmyyyy_hhmm>_seca_monitor_b ackup (if necessary, rename other folders)</ddmmyyyy_hhmm>
not be restored manually	Backup copy on the USB stick has been renamed	Ensure that backup copies are saved in the folder with the designation <ddmmyyyy_hhmm>_seca_monitor_b ackup (if necessary, rename folders)</ddmmyyyy_hhmm>
Patient and user data cannot initially be encrypted after software update	There is not enough memory on the monitor for initial encryption	<ul> <li>Initial manual encryption by administrator:</li> <li>→ Exporting patient and user data manually</li> <li>→ Resetting the device</li> <li>→ Restoring patient and user data manually</li> <li>If necessary, make previous device settings (for example, WiFi connection) manually</li> </ul>

## **11.2 Vital signs measurement**

## → General

- → Blood pressure measurement
- → COVIDIENTM FILACTM 3000 temperature measurement
- → Manual temperature input
- → SpO₂ measurement

#### General

Fault	Cause	Remedy
Vital sizes tak is not	USB connecting cable of the SmartBucket not connected to the monitor	<ul> <li>Connect the USB connecting cable of the SmartBucket to the monitor</li> <li>Restart the device</li> </ul>
Vital signs tab is not displayed	SmartBucket not activated	Administrator: Activate SmartBucket: → Managing system components in the administrator menu
seca mVSA 535 is being operated on a wheeled stand: Measuring results for vital signs are implausible	<ul> <li>Original seca USB connecting cable not being used</li> <li>USB extension cable also in use</li> </ul>	<ul> <li>Use original seca USB connecting cable (in scope of delivery for the wheeled stand)</li> <li>Do not use a USB extension cable</li> </ul>

## **Blood pressure measurement**

Fault	Cause	Remedy
	Excessive patient movement	<ul> <li>Ask the patient to move as little as possible</li> </ul>
Implausible measuring	Incorrect blood pressure cuff used	<ul> <li>Use correct size of blood pressure cuff</li> <li>Only use seca blood pressure cuffs</li> </ul>
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

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Fault	Cause	Remedy
	Incorrect blood pressure cuff used	<ul><li>Use correct size of blood pressure cuff</li><li>Only use seca blood pressure cuffs</li></ul>
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
No option to select Multiple measurement in the NIBP settings dialog window	Administrator has configured a measuring profile. The name of the measuring profile is displayed.	<ul> <li>Not a malfunction</li> <li>Press the name of the measuring profile</li> <li>→ Starting a multiple measurement.</li> </ul>
Blood pressure values do not appear in the EMR system or in the seca analytics 115 PC software	Multiple measurement was performed	<ul> <li>For current measurement:</li> <li>→ Modifying presets and → Starting a single measurement</li> <li>Administrator:</li> <li>Specify Individual measurement as preset</li> <li>→ Presets for blood pressure</li> </ul>

#### COVIDIEN™ FILAC™ 3000 temperature measurement

Fault	Cause	Remedy
No temperature measurement possible	Temperature module of the SmartBucket not activated	Administrator: Activate temperature module: <b>System\SmartBucket</b> tab
	Special patient condition, such as hypothermia	<ul> <li>Assess patient vital signs using alternative means</li> <li>Switch from predictive measurement mode to direct mode</li> </ul>
	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 measuring 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	<ul> <li>Select measuring position to suit the probe used</li> <li>Set correct measuring position on device</li> </ul>
	No probe cover used	<ul> <li>Disinfect the temperature probe</li> <li>Disinfecting</li> <li>Use probe cover</li> </ul>
	Temperature probe faulty	Dispose of temperature probe, use replacement
Temperature probe cannot be pushed completely into the probe holder	Probe cover not discarded	<ul> <li>Carefully withdraw temperature probe and probe cover from the probe holder</li> <li>Discard probe cover</li> <li>Push the temperature probe into the probe cover</li> </ul>

## Manual temperature input

Fault	Cause	Remedy
	Measured values outside permitted range	Observe permitted temperature range, Technical data: → Manual temperature input
Manual temperature input not possible	Device has integrated temperature measurement (probe or in-ear thermometer)	<ul> <li>Not a malfunction</li> <li>Use the measuring equipment for the device</li> </ul>
	Temperature module of the SmartBucket activated	Administrator: Deactivate temperature module: <b>System\SmartBucket</b> tab
Manual temperature entries do not appear in the seca analytics 115 PC software	Manual temperature entries are not synchronized with the <b>seca analytics 115</b> PC software	Not a malfunction • Enter values in the <b>seca analytics 115</b> PC software manually

#### SpO₂ measurement

Fault	Cause	Remedy
	Intra-aortic balloon pump affecting pulse rate	Check pulse rate using ECG
	Sensor damp	<ul><li>Dry sensor</li><li>Use dry sensor</li></ul>
	Sensor not applied correctly	Apply sensor correctly, see instructions for use for sensor
	Strong ambient light	Cover application site with opaque material
Implausible measuring results	Electromagnetic interference	<ul> <li>Switch off devices in proximity, isolate interfering device</li> <li>Align interfering device differently or set up in a different location</li> <li>Increase the distance between this device and the interfering device</li> </ul>
	Poor perfusion	<ul> <li>Assess patient vital signs using alternative means</li> <li>Apply blood pressure cuff to location with better perfusion</li> </ul>
	Sensor service life expired	Use new Masimo SET® sensor.
Measurement not possible	Sensor or patient cable defective	Dispose of sensor or patient cable, use spare part
	Sensor too rigid	<ul><li>Use suitable size of sensor</li><li>Apply sensor to a different finger</li></ul>
	Strong ambient light	Cover application site with opaque material
Pulse is not found or is lost	Poor perfusion	<ul> <li>Assess patient vital signs using alternative means</li> <li>Apply sensor to a location with better perfusion</li> </ul>

## **11.3 Network connection**

Fault	Cause	Remedy
	WiFi function of device is deactivated	Administrator: Activate WiFi
No WiFi connection	Distance between monitor and WiFi router is too big	<ul> <li>Reduce distance</li> <li>Transmit measuring results to seca analytics 115 PC software or seca connect 103 via LAN</li> </ul>
	WiFi not available in your institution	Transmit measuring results to seca analytics 115 PC software or seca connect 103 via LAN
No network connection	Firewall: ports required are not enabled	Administrator: Enable required ports in firewall → Monitor interfaces and network ports
	Firewall/gateway configuration does not permit use of LAN and WiFi in parallel	Administrator: Deactivate one of the two transmission options on the device.

Fault	Cause	Remedy
Data transmission cannot be set up between device and seca analytics 115	Software versions not compatible	Use a compatible version of seca analytics 115 → Compatibility
	No seca patient file set up yet	Create seca patient file → Creating a 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 <b>seca analytics 115</b>	Check whether the seca patient file can be assigned to the user in <b>seca analytics 115</b>
	Windows firewall port-blocking is active, required ports are blocked	Administrator: Enable the ports required
No access to seca patient database of the	No network connection set up between the device and the PC on which the <b>seca analytics 115</b> PC software is installed	<ul> <li>Administrator:</li> <li>→ Setting up a LAN connection to the network (stationary operation)</li> <li>→ Setting up a WiFi connection (mobile operation)</li> <li>→ Setting up a connection to the seca analytics 115 PC software</li> </ul>
seca analytics 115 PC software	The PC on which the seca analytics 115 PC software is installed is not switched on	Switch on PC
	Automatic synchronization is deactivated on the device	Administrator: → Exporting patient and user data manually
Print function on device not available	Software versions not compatible	Use a compatible version of the <b>seca analytics 115</b> PC software: 1.4 Build 6657 or higher
	PC printer not switched on	Switch on PC printer
	The PC on which the <b>seca analytics 115</b> PC software is installed is not switched on	Switch on PC
Results report not being printed	No network connection set up between device and <b>seca analytics 115</b> PC software	Administrator: Set up LAN connection
5	No connection set up between <b>seca analytics 115</b> PC software and PC printer	Administrator: Set up connection between <b>seca analytics 115</b> PC software and PC printer
Blood pressure values do not appear in the seca analytics 115 PC software	Multiple measurement was performed	User: • → Modifying presets • → Starting a single measurement Administrator: • Specify Individual measurement as prese → Presets for blood pressure
Manual temperature entries do not appear in the seca analytics 115 PC software	Manual temperature entries are not synchronized with the <b>seca analytics 115</b> PC software	Not a malfunction <ul> <li>Enter values in the seca analytics 115 PC software manually</li> </ul>

# 11.4 Connection to the seca analytics 115 software

## 11.5 EMR system connection via seca connect 103 software

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

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

# 11.6 seca 360° proximity connection

<b>_</b>				
Fault	Cause	Remedy		
	No <b>seca 360° proximity</b> connection set up	Administrator: → Setting up a seca 360° proximity connection		
	Network connection interrupted	<ul> <li>LAN: Ensure that the network cable is correctly plugged in and is not damaged</li> <li>WiFi: Reduce distance from router</li> </ul>		
Weight or height values do not appear in the display	seca scale/measuring rod incorrectly configured	<ul> <li>Administrator: Configure seca scale/ measuring rod as follows:</li> <li>Scan user ID: Required</li> <li>Scan patient ID: Required</li> <li>Confirmation of measurement on seca measuring device: Required</li> <li>Port used: Port configured for communi- cation with the seca connect 103 software (default: 22020) → Setting up a connec- tion to the seca analytics 115 PC software</li> <li>Follow seca 103/452 system instructions for use</li> </ul>		
	No measurement has yet been performed using the seca scale/ measuring rod	Perform measurement as described in the instructions for use for the seca scale/seca measuring rod		
	seca scale/measuring rod has not submitted a value	Submit value as described in the instructions for use for the seca scale/seca measuring rod		
An error message appears in the Weight or Height field	An error occurred on the seca scale/ measuring rod	<ul> <li>Eliminate error as described in the instructions for use for the seca scale/seca measuring rod.</li> <li>Follow seca 103/452 system instructions for use</li> <li>If you are unable to eliminate the error, contact seca Service.</li> </ul>		

# 11.7 seca 360° wireless connection

Fault	Cause	Remedy	
	<b>seca 360° wireless</b> wireless module of the connected scale/measuring rod not activated	Administrator: → Setting up a seca 360° wireless connection	
Weight or height values do not appear in the display	No seca 360° wireless wireless connection set up		
	Scale/measuring rod not wireless- capable (do not contain a seca 360° wireless wireless module)	Enter measured values manually:	

# **12. TECHNICAL DATA**

- → Monitor
- → Monitor interfaces and network ports
- $\rightarrow$  Vital signs measurement
- → Analysis parameters
- $\rightarrow$  Analysis modules
- → Standards and directives

## 12.1 Monitor

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

Further technical data (all models)		
Ambient conditions, operation	+10 °C to +40 °C (50 °F to 104 °F)	
TemperatureAir pressure	700 hPa – 1060 hPa	
• Humidity	20 % – 80 %, non-condensing	
Ambient conditions, storage		
Temperature	-10 °C to +55 °C (14 °F to 131 °F)	
• Air pressure	700 hPa – 1060 hPa	
Humidity	15 % – 95 %, non-condensing	
Ambient conditions, transport		
Temperature	-10 °C to +55 °C (14 °F to 131 °F)	
Air pressure	700 hPa – 1060 hPa	
Humidity	15 % – 95 %, non-condensing	
Setup location, maximum altitude above mean sea level	3000 m	
Display type	7" touchscreen display	
Power supply for monitor, input		
•Туре	Internal power supply unit, IEC 60320 C13	
Power supply voltage	100 V ~ to 240 V ~	
Power 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 (full brightness, new rechargeable battery)	approx. 5 h	
Power consumption		
<ul> <li>Standby (touchscreen display off, ON/OFF button green)</li> </ul>	< 5 W	
<ul> <li>Operation (ON/OFF button white)</li> </ul>	< 9 W	
Operation (charging rechargeable battery for monitor, on/off button is	< 35 W	
white)		
FDA device class	Class II Medical Device	
IEC 60601-1:		
Insulated device, protection class:		
Type of protection seca mVSA 535	IP21	
Duty cycle	Continuous duty	

Further technical data (all models)		
	seca 360° wireless	
	2 x USB 2.0 (max 500 mA)	
Interference	LAN: Ethernet (10/100 Base-T)	
Interfaces	WiFi: 2.4 GHz (WPA, WPA2 PSK,	
	WPA2 Enterprise PEAP RADIUS)	
	Infrared	
Compatible printer	Microsoft [®] Windows [®] -compatible printer	
	via seca analytics 115 PC software	

# 12.2 Monitor interfaces and network ports

## Interfaces and network ports

Interfaces	Protocol	Data transmission rate	Factory setting
WiFi:	IEEE 802.11 b/g/n	Up to 72.2 Mbps	Off
LAN:	IEEE 802.3u	100 Mbit/s	On
TCP port:	Transmission Control Protocol	n/a	20010, Off
UDP port:	User Datagram Protocol	n/a	20011
File Transfer port:	File Transfer Protocol	n/a	20012
USB (2 ports):	USB 2.0	480 Mbit/s per port	On
seca 360° wireless:	Proprietary	50 kb/s	Off

## Recommended WiFi settings

This table contains settings for optional WiFi performance.

Settings	Recommended settings	Consequences in the event of different settings
Authentication/	WPA2 Personal	No network connection, other encryption methods
encryption	<ul> <li>WPA2 Enterprise (EAP-TLS)</li> </ul>	not supported
Frequency band	<ul><li>Single band 2.4 MHz</li><li>IEEE 802.11 b/g/n</li></ul>	_
Data transmission rate	Up to 72.2 Mbps	-
Network configuration	• DHCP     • UDP	_
Firewall/ ports to be opened	<ul> <li>TCP port: 20010</li> <li>UDP port: 20011</li> <li>File transfer port: 20012</li> </ul>	No synchronization
Separate VLAN	No special requirements	_
QoS	No special requirements	_
VoiP	No special requirements	_
WiFi multimedia	No special requirements	_
Network latency	No special requirements	_
IT support	No special requirements	-
Redundant power supply	No special requirements	_

## 12.3 Vital signs measurement

- → Blood pressure measurement
- → COVIDIENTM FILACTM 3000 temperature measurement
- → Manual temperature input
- → Masimo SET[®] SpO₂ measurement

## **Blood pressure measurement**

seca blood pressure module			
	Oscillometric		
	<ul> <li>Possible to switch between inflation</li> </ul>		
	and deflation		
Measuring method	<ul> <li>Single measurement</li> </ul>		
	Multiple measurement can be config-		
	ured: Max. 6 measurements in max.		
	30 minutes		
Initial cuff pressure, deflation	Can be set: 80 mmHg – 280 mmHg		
	(260 mmHg cannot be set)		
Maximum cuff pressure	300 mmHg		
Measuring range for blood pressure			
Inflation:			
Systolic BP	77 mmHg – 200 mmHg		
Diastolic BP	45 mmHg – 190 mmHg		
Mean arterial pressure	56 mmHg – 193 mmHg		
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 / 2 %,		
simulator from Fluke)	the larger value in each case applies		
Measuring accuracy for blood pressure (determined by the manufacturer			
of the measuring module in clinical trial in accordance with			
DIN EN ISO 81060)			
Inflation:			
<ul> <li>Mean deviation of systolic BP</li> </ul>	0.36 mmHg		
<ul> <li>Standard deviation of systolic BP</li> </ul>	4.27 mmHg		
<ul> <li>Mean deviation of diastolic BP</li> </ul>	-0.12 mmHg		
<ul> <li>Standard deviation of diastolic BP</li> </ul>	3.78 mmHg		
Deflation:			
<ul> <li>Mean deviation of systolic BP</li> </ul>	0.10 mmHg		
<ul> <li>Standard deviation of systolic BP</li> </ul>	3.24 mmHg		
Mean deviation of diastolic BP	-0.20 mmHg		
<ul> <li>Standard deviation of diastolic BP</li> </ul>	2.95 mmHg		
Pressure transducer:			
Accuracy	±1 mmHg		
Resolution	1 mmHg		
Leakage rate	< 3 mmHg/min		
Limit value for pressure	300 mmHg		
<ul> <li>Switch off and release pressure at (first fault)</li> </ul>	> 330 mmHg		
Measuring time for blood pressure:			
Normal	15 – 20 s		
Maximum (adults)	90 s		

seca blood pressure module		
Pulse rate:		
<ul> <li>Measuring range for inflation</li> </ul>	45 min ⁻¹ – 200 min ⁻¹	
Measuring range for deflation	30 min ⁻¹ – 240 min ⁻¹	
<ul> <li>Accuracy (under laboratory conditions, verified with CuffLink patient</li> </ul>	max. $\pm 3 \text{ min}^{-1} / 3 \%$ ,	
simulator from Fluke)	the larger value in each case applies	
IEC 60601-1: Medical electrical device, type BF (defibrillation-protected)	-  <b>†</b>  -	

## COVIDIEN™ FILAC™ 3000 temperature measurement

COVIDIEN [™] FILAC [™] 3000 temperature module		
Measurement modes	Direct, predictive	
Measuring position:		
Blue probes	Oral, axillary	
Red probes	Rectal	
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:		
<ul> <li>All measuring positions</li> </ul>	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		
<ul> <li>Measuring position not detected (following removal from probe cover)</li> </ul>	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)	
IEC 60601-1: Medical electrical device, type BF	$\mathbf{\dot{\mathbf{x}}}$	
Type of protection against ingress of liquids	IP21	

Clinical accuracy ^{a b}			
Measuring position: Oral Axillary Rec			
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 measuring position in question. Clinical repeatability  $\sigma_i$  is independent of age. The reference body sites of the reference thermometer used in the clinical study correspond to the measuring positions quoted.

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

#### Manual temperature input

Manual temperature input		
Device versions	Versions without integrated	
Device versions	temperature measurement	
Measuring methods	Oral, axillary, rectal,	
Measuring methods	in-ear, on the skin, contactless	
Temperature range	32 °C – 44 °C (89.6 °F – 111.2 °F)	

## Masimo SET[®] SpO₂ measurement

General technical data

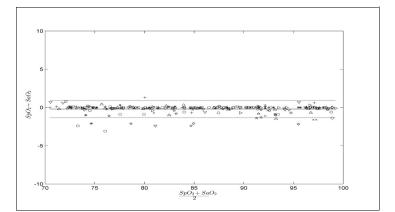
Masimo SET [®] SpO ₂ module ^{a b c d e f g}		
Measurement	Functional oxygen saturation	
Measuring method	Spectrophotometry (red/infrared)	
LED wavelength:		
Red	660 nm	
Infrared	905 nm	
Maximum light output	15 mW	
This information may be of particular interest to clinicians		
Measuring time:		
<ul> <li>Device switched on, sensor not applied</li> </ul>	≤ 12 sec	
<ul> <li>Device switched off, sensor applied</li> </ul>	≤ 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 %	
<ul> <li>SpO₂ (no patient movement)</li> </ul>	70 % – 100 % ± 2 digits ^h	
	0 % – 69 % not specified	
<ul> <li>SpO₂ (patient movement)</li> </ul>	70 % – 100 % ± 3 digits	
	0 ‰ – 69 % not specified	
<ul> <li>Pulse rate (no patient movement)</li> </ul>	25 min ⁻¹ – 240 min ⁻¹ ± 3 digits	
<ul> <li>Pulse rate (patient movement)</li> </ul>	25 min ⁻¹ – 240 min ⁻¹ ± 5 digits	
Low perfusion performance		
Pulse amplitude	> 0.02 %	
Transmission	> 5 %	
<ul> <li>Oxygen saturation (SpO₂)</li> </ul>	± 2 digits	
Pulse rate	± 3 digits	
Resolution:		
<ul> <li>Oxygen saturation (SpO₂)</li> </ul>	1 %	
Pulse rate	1 min ⁻¹	
IEC 60601-1: Medical electrical device, type BF	$\mathbf{\mathbf{\hat{x}}}$	

a. The accuracy of the Masimo SET[®] technology with Masimo sensors was validated with no movement in human blood studies with induced hypoxia on healthy adult male and female volunteers with light to dark skin pigmentation in the range from 70 – 100 % for SpO₂ compared to a laboratory CO oximeter and ECG monitor. This fluctuation corresponds to ± 1 standard deviation. Plus or minus one standard deviation covers 68 % of the population.

b. The accuracy of the Masimo SET[®] technology with Masimo sensors was validated with movement in human blood studies with induced hypoxia on healthy adult male and female volunteers with light to dark skin pigmentation, 2 to 4 Hz rubbing and tapping movements being performed at an amplitude of 1 to 2 cm and a non-repetitive movement being performed at 1 to 5 Hz at an amplitude of 2 to 3 cm in the range from 70 – 100 % for SpO₂ compared to a laboratory CO oximeter and ECG monitor. This fluctuation corresponds to ± 1 standard deviation and thus covers 68 % of the population.

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

- d.The accuracy of the pulse rate of the Masimo SET[®] technology with Masimo sensors was validated on the test bench for the range 25 -240 min-1 compared to a Biotek Index 2[™] simulator. This fluctuation corresponds to ± 1 standard deviation. Plus or minus one standard deviation covers 68 % of the population.
- e. The precise data can be found in the directions for use (DFU) for the sensors. Unless otherwise stated, the measuring position for reusable sensors should be changed at least every 4 hours and for adhesive sensors, at least every 8 hours.
- f.The sensor accuracy quoted applies in conjunction with the Masimo technology with a Masimo patient cable used for LNOP sensors, RD SET sensors, the LNCS sensors or the M-LNCS sensors. The numbers stand for ARMS (accuracy root mean square). Because pulse oximeter measurements are statistically distributed measuring procedures, only about two-thirds of the measurements are expected to be in a range of ± ARMS compared to the reference value. Unless stated otherwise, accuracy for SpO₂ of 70 % to 100 % is quoted. The accuracy of pulse rate is quoted from 25 to 240 min-1.
- g. Masimo M-LNCS, LNOP, RD SET, and LNCS sensor types have the same optical and electrical properties and may differ only in application type (adhesive/non-adhesive/hook & loop), cable lengths, optical component locations (top or bottom of sensor as aligned with cable), adhesive material type/size, and connector type (LNOP 8-pin modular plug, RD 15-pin modular plug, LNCS 9-pin, cable-based, and M-LNCS 15-pin, cable-based). All sensor accuracy information and sensor application instructions are provided with the associated sensor directions for use.
- h.Digit: Numerical value by which the last place of a value displayed can deviate from the actual measured value; used to state the accuracy of a measuring device (example: displayed SpO₂ value 70 %, accuracy  $\pm$  2 digits; actual value is between 68 % and 72 %).



## Accuracy of Masimo SET® DCI/DCIP sensors

Measured values			
Measuring range A _{RMS}			
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.

# 12.4 Analysis parameters

## NOTE

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

Analysis parameter	Display	Analysis module
Weight (W)	Absolute in kg	Development/growth
Height (H)	Absolute in m	Development/growth
Blood pressure, non-invasive (NIBP)	Absolute in mmHg	Vital signs
Body temperature (TEMP)	Absolute in °F	Vital signs
Pulse rate (PR)	Absolute in min ⁻¹ (based on NIBP or SpO ₂ )	Vital signs
Oxygen saturation (SpO ₂ )	Relative in %	Vital signs

# 12.5 Analysis modules

## NOTE

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

Analysis module	Description	Analysis parameter
Vital signs	Overview of vital signs to support a diagnosis	<ul> <li>Blood pressure (NIBP)</li> <li>Body temperature (TEMP)</li> <li>Pulse rate (PR)</li> <li>Oxygen saturation (SpO₂)</li> </ul>

## 12.6 seca 360° wireless system

seca 360° wireless		
Maximum number of wireless groups	3	
	1 baby scale	
Maximum configuration per wireless group	1 measuring station (or 1 personal scale and	
	1 measuring rod)	
	1 mVSA	
	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	

## 12.7 Standards and directives

This device complies with the following standards and directives:

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

# **13.OPTIONAL ACCESSORIES AND SPARE PARTS**

Optional accessories and spare parts	Article number
Blood pressure measurement:	
Cuff, size XS	490-0024-001
• Cuff, size S	490-0025-001
• Cuff, size M	490-0026-001
Cuff, size L	490-0027-001
Cuff, size XL	490-0028-001
Cuff, size XXL	490-0029-001
<ul> <li>Extension for compressed air tube (1.3 m)</li> </ul>	490-0033-001
<ul> <li>Extension for compressed air tube (3.0 m)</li> </ul>	490-0034-001
Masimo SET [®] SpO ₂ measurement:	Obtainable directly from the
Sensors and patient cables from the Masimo RD SET® product line	manufacturer, see
Not compatible: Sensors for neonates	www.masimo.com
Temperature measurement:	
<ul> <li>COVIDIEN[™] FILAC[™] 3000 blue for oral/axillary measurement</li> </ul>	68-90-00-044-009
<ul> <li>COVIDIEN[™] FILAC[™] 3000 red for rectal measurement</li> </ul>	68-90-00-045-009
Probe covers for COVIDIEN [™] FILAC [™] 3000:	490-0015-001
100 packs, pack of 20 probe covers	490-0015-001
Software:	
seca analytics 115	For details of application-specific
• seca connect 103	license packages
	go to www.seca.com
seca 475 wheeled stand for seca mVSA 535	475-05-35-009
seca 432 carry case	432-00-00-009
Scanner (medical device):	
Honeywell Xenon 1900H (2D)	Cannot be ordered through seca
Datalogic Gryphon I (GD4430 HC (2D)	

Product	seca 360° wireless [from serial number]	seca 360° proximity	Article number
seca 285/seca 284	No	Yes, with accessories ^a	For details of country apositio
seca 287/seca 286	restriction	res, with accessories	For details of country-specific versions, go to
seca 787		Yes, with accessories ^{a.}	www.seca.com
seca 797		Yes	www.seea.com
	Multifunctional scale	es	
seca 651	No	Yes	
seca 650	restriction	Tes	
seca 655	No	Yes	
seca 654	restriction	Tes	
seca 635	1000000026211		
seca 634	1000000027487		
seca 645	1000000027015		
seca 644	1000000027016		For details of country apositio
seca 657	1000000021683		For details of country-specific
seca 656	1000000026289		versions, go to www.seca.com
seca 665	1000000022821		www.seca.com
seca 664	1000000027014	Yes, with accessories ^{a.}	
seca 677	1000000020483		
seca 676	1000000024369		
seca 675	1000000026776		
seca 674	1000000023806		
seca 685	1000000017288		
seca 684	1000000017495		
	Column scales		
seca 704	5704209100721		For details of country-specific
seca 703 ^b	5703209102764	Yes, with accessories ^{a.}	versions, go to
seca 703	0100200102104		www.seca.com
	Chair scales ^{b.}		
seca 954 (1309007)	1000000005919		
seca 954 (1309377)	1000000011074		For details of country-specific
seca 959 (7021002)	, , , , , , , , , , , , , , , , , , , ,		versions, go to
seca 959 (7021092)			www.seca.com
seca 963	1000000045451		

a.**seca 452** external interface module (firmware version Q2_2020_Build_615 or higher) required b.**seca 452** external interface module can only be retrofitted by authorized service technicians

## 15. DISPOSAL

- → Batteries and rechargeable batteries
- → Consumables

## 15.1 Batteries and rechargeable batteries



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

## **15.2 Consumables**



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

## **16.WARRANTY**

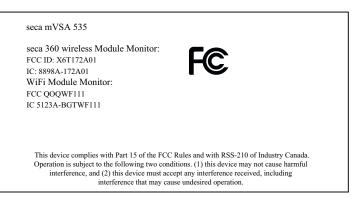
We offer a two-year warranty from the date of delivery for defects attributable to faulty material or poor workmanship. This excludes all moveable parts such as (rechargeable) batteries, cables, power supply units, etc. Defects which are covered by the warranty shall be rectified free of charge for customers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

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

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

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

# **17. DECLARATION OF CONFORMITY**



#### 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: CONFIGURING seca mVSA 535

- → Preparing configuration
- → User accounts
- → Making settings for measuring mode
- → Managing system components
- → Setting up peripherals
- → Connecting to an EMR system
- → Factory settings
- → Instructions for use for seca mVSA 535

#### **NOTE** This document describes the maximal equipment of the **seca mVSA 535** product family: measurement of blood pressure, temperature and oxygen saturation. Depending on the actual equ

temperature and oxygen saturation. Depending on the actual equipment of your device, some of this information may not be relevant to your device. Pay attention to the information in this document which is relevant to your device.

#### NOTE

- This part of the user documentation contains information about configuring the device for measuring mode and for integrating it in a network.
- Integrating this device in a network containing other devices may lead to previously unknown risks to patients, operators or third parties. It is the responsibility of the operating company to determine, analyze, evaluate, and control these risks.
- The functions described in this part of the user documentation are accessible only to users with administrator rights.
- Follow the information in the instructions for use → Instructions for use for seca mVSA 535.

# **1. PREPARING CONFIGURATION**

- → Administrator login
- → Configuration options

## 1.1 Administrator login

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

3. Press the **Login** button.

4.

5.

6.

7.

	•	Login =Q Q
	<ul> <li></li> </ul>	
The login window is displayed.		
Press the input field. The list of user accounts is displa Press your user account. Your user account is displayed in Press the input field. Enter your password using the ke The administrator area is displayed	eypad	
Administer user database		Logout Users
Search	9	System
Name	Role	Settings
admin	Admin	Peripherals
service		Reset
user	Physician	

## 1.2 Configuration options

- → Network functions
- → Overview of access rights

### **Network functions**

• = possible, - = not possible

Function	LAN	WiFi	seca 360° wireless	Infrared
Receiving patient weight from scale/measuring rod	●a.	●a.	•	-
Receiving patient height from measuring rod/measuring station	●a.	●a.	•	-
Using seca directprint (seca analytics 115 PC software function)	•	•	-	-
Synchronizing seca patient files and user accounts with the <b>seca analytics 115</b> PC software	•	•	-	-
Connecting to the EMR system via the <b>seca connect 103</b> software	•	•	-	-

a.seca 360° proximity connection: Available for seca measuring devices with an internal interface module or **seca 452** external interface module (firmware version Q2_2020_Build_615 or higher)

#### **Overview of access rights**

• = possible, - = not possible

Function	Administrator	User
Creating seca patient files	-	•
Calling up seca patient files	-	•
Entering basic parameters (weight, height,		•
waist circumference, PAL)	-	•
Editing seca patient files	-	•
Deleting seca patient files	-	•
Exporting a seca patient file	-	•
Performing measurements	-	•
Viewing examination results	-	•
Printing examination results	-	•
Analysis parameters: Adding comments	-	•
Managing the patient database	-	٠
Managing the user database	•	-
Modifying default settings (e.g. time, date)	•	-
Modifying units for measured values	•	-
Modifying analysis parameters which can be		_
displayed	•	-
Setting up network connections	•	-
Configuring automatic database		_
synchronization	•	-
Configuring automatic export	•	-
Importing backup from USB memory stick	•	-
Restoring factory settings	•	-
Resetting the user interface	•	-
Exporting backup to USB memory stick	•	-
Updating the monitor software	•	-

# 2. USER ACCOUNTS

- → Activating initial user accounts
- → Working with user accounts

## 2.1 Activating initial user accounts

The following user accounts are available on the device initially:

- Admin: (Configure and manage device)
- User: (Perform measurements and manage them).

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

- → Changing the password for the Admin user account
- → Assigning a password to the User user account

#### 1. Press the **Login** button.

Changing the password for the Admin user account

The login window is displayed.

seca		Login
		$\approx$
	9	
	$\checkmark$	$\sim$
-14		망 (1

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

#### NOTICE!

#### Data access by unauthorized persons

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

- Select a password to satisfy your institution's security requirements.
- 7. Enter the password again. The login window is displayed.
- 8. Activate the User user account → Assigning a password to the User user account.

S

## Assigning a password to the User user account

#### 1. Log in using the Admin user account.

2. Press the Users tab.

Administer user da	atabase		Logout
			Users
Search	9		System
Name	- Role	-	Settings
admin	Adm	in	Peripherals
			Reset
user	Phys	ician	

- 3. Select the User user account.
- 4. Enter a password.

#### NOTICE!

#### Data access by unauthorized persons

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

- ► Select a password to satisfy your institution's security requirements.
- 5. Enter the password again.
- 6. Press the **Save** button. The password has been saved.

The User user account can be used.

7. Configure the device as required for your specific situation → For administrators: Configuring seca mVSA 535.

#### 2.2 Working with user accounts

- → Setting up user accounts
- → Editing user accounts
- → Deleting user accounts

#### Setting up user accounts

User accounts can be created only in the **seca analytics 115** PC software. To make new user accounts available on the device, it must be synchronized with the PC software  $\rightarrow$  Activating automatic synchronization.

**Editing user accounts** 

#### To edit a user account, proceed as follows:

1. Press the **Users** tab.

Administer user data	base	Logout
		Users
Search	$\left( \left( \left$	System
Name	- Role -	Settings
admin	Admin	Peripherals
		Reset
user	Physician	

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:



b) Enter the user name using the keypad

- Press the desired entry. The selected user account is displayed.
- 4. Change the user data to the extent required by pressing the relevant input field:
  - Specify role
  - Change password
  - Select display language

#### NOTICE!

#### Data access by unauthorized persons

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

- ► Select a password to satisfy your institution's security requirements.
- Use the user accounts without password protection only for special applications (e.g. configuring interfaces with EMR systems). seca Service will be pleased to assist if you have any questions relating to interface configuration.

#### NOTE

- Specification of the **Assistance** or **Physician** role 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 **seca analytics 115** PC software.
- The display language is specified for each user individually. If no user is logged in, the user interface is displayed in the system language
   → Making regional settings.
- 5. Ensure that the **Password protected** field is activated (default setting).
- 6. Press the **Save** button.

The changes will be saved.

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

#### NOTE

If automatic synchronization is activated, changes you make to user accounts on the device are automatically adopted in the **seca analytics 115** PC software → Activating automatic synchronization.

#### **Deleting user accounts**

User accounts can only be deleted in the **seca analytics 115** PC software. For deletion to take effect on the device, it must be synchronized with the PC software  $\rightarrow$  Activating automatic synchronization.

## 3. MAKING SETTINGS FOR MEASURING MODE

- → Making regional settings
- → Setting display brightness and volume
- → Calibrating the touchscreen display
- → Setting units of measurement
- → Deactivating analysis modules
- → Making presets for vital signs measurement

#### Making regional settings 3.1



#### **CAUTION!** Loss of data, misinterpretation of measurements

Incorrect settings for date and time can lead to misinterpretation of measurements.

- ► Standalone operation: Ensure that the date and time information on the device is correct.
- Network operation: Ensure that the date and time information in the seca PC software is correct. These settings are adopted by the device.
- 1. Press the Settings tab.

Settings		Logout
		Users
Display and volume	Regional settings	System
		Settings
Units	Analysis modules	Peripheral
		Reset
Vital signs		
the signs		
		먛. ()

#### 2. Press the Regional settings button.

System language Decimal separator	Users
System language Decimal separator	
	System
U.S. English	Settings
Date	Peripheral
07.07.2020 dd.mm.yyyy ~	
Time	Reset
20:46:10 24 h	
Name style	
First name Surname Vith separator	琚. 🏾

- 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

1. Press the Settings tab.

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

#### 3.2 Setting display brightness and volume

Settings		Logout
		Users
Display and volume	Regional settings	System
		Settings
Units	Analysis modules	Peripheral
		Reset
Vital signs		
		垊 ()

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

Display and volume	X	Logout
	$\frown$	Users
Calibrate touchscreen		System
Display brightness	·	Settings
<	>	Peripheral
Warning and info tones		Reset
<	>	
Key tones		
	$\rightarrow$	뫄. ()

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

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

#### 3.3 Calibrating the touchscreen display

1. Press the **Settings** tab.

Settings		Logout
		Users
Display and volume	Regional settings	System
		Settings
Units	Analysis modules	Peripheral
		Reset
Vital signs		
		뮥. 1

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

Display and volume	Logout
	Users
Calibrate touchscreen	System
Display brightness	Settings
<	Peripheral
Warning and info tones	Reset
< >>	
Key tones	
< >>	

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

5.

+	
Press the symbol. The symbol changes position.	

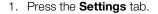
- Press the symbol again.
   The symbol changes its position again.
- 7. Repeat step 6. until you get a request to confirm calibration.
- 8. Confirm calibration.
  - The touchscreen display is calibrated.

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



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

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



Settings	Logout
	Users
Display and volume Re	gional settings System
	Settings
Units	alysis modules
	Reset
Vital signs	
vital signs	
	명, (1

#### 2. Press the Units button.

Units		×	Logout
		$\frown$	Users
Resting energy expenditure	Weight		Custom
FAO/WHO/UNU 2004 🚽	kg		System
Length	Blood pressure		Settings
metric -	mmHg	-	Peripherals
Energy	Temperature		Reset
– LW	°C	-	
			<b>₹</b> ] <b>1</b>

- 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.

## 3.5 Deactivating analysis modules

	Settings	Logout
		Users
	Display and volume Regional settings	System
		Settings
	Units Analysis modules	Peripheral
		Reset
	Vital signs	
F	Press the <b>Analysis modules</b> button.	
	Analysis modules X	Logout
	Development/growth     Vital signs	System
	Energy	Settings
		Peripherals
	Function/rehabilitation	Reset
	Fluid	
	Health risk	
	L All analysis modules are activated at the factory.	
	,, ,	
	Press the checkboxes of all the analysis module	es vou would
	to deactivate.	-
	The deactivated analysis modules are no longer displaye → Analyzing measurement.	ed in the ana
	To reactivate analysis modules, press the checkboxes	of the
	deactivated analysis modules again.	
	The reactivated analysis modules will again be displayed	d in the analy
	<ul> <li>→ Analyzing measurement.</li> <li>• Settings you make in this tab are active directly. You</li> </ul>	

#### 3.6 Making presets for vital signs measurement

- → Presets for blood pressure
- → Presets for SpO₂
- → Presets for temperature (COVIDIENTM FILACTM 3000 only)
- → Selecting color mode for Vital signs tab

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

The user can modify the settings during a measurement procedure

→ Measuring vital signs. The presets will be active again after the end of the measurement 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

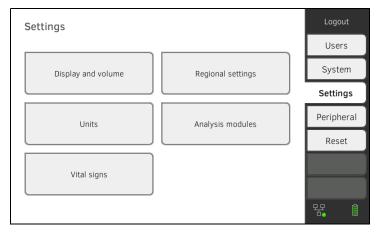
- → Making general settings
- → Configuring multiple measurement

#### NOTE

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

#### Making general settings

1. Press the Settings tab.



2. Press the **Vital signs** button.

Vital signs	×	Logout
		Users
NIBP	PR	System
		Settings
Sp02	ТЕМР	Peripheral
		Reset
Color mode		
Standard -		
		垊. 1

#### 3. Press the **NIBP** button.

The presets are displayed.

NIBP settings			×
Туре			
O â Inflation	ÿ	Deflation	
Starting pressure			
Procedure			
O • Single measurement	:	Multiple measurement	

- 4. Press the desired measurement method.
  - Inflation, continue at step 6.
  - Deflation, continue at step 5.
- 5. Adapt Starting pressure if necessary.
- 6. Press the desired measuring sequence:
  - Single measurement
  - Multiple measurement → Configuring multiple measurement

#### NOTICE!

#### Faulty operation, missing measuring results

Results from multiple measurements cannot be transmitted to EMR systems or the **seca analytics 115** PC software.

- Specify Single measurement as a preset if blood pressure values are to be transmitted to an EMR system or the seca analytics 115 PC software.
- 7. Press the **Confirm** button.

The dialog window closes.

The modified settings are adopted.

#### Configuring multiple measurement

#### NOTE

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

1. Press the **Settings** tab.

Settings		Logout
		Users
Display and volume	Regional settings	System
		Settings
Units	Analysis modules	Peripheral
		Reset
Vital signs		
		윰, 🏾

2. Press the Vital signs button.

Vital signs	Logout
	Users
NIBP PR	System
	Settings
SpO ₂ TEMP	Peripheral
	Reset
Color mode	
Standard	
	문, ()

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

NIBP settings			×
Туре			
O â Inflation	ž	Deflation	
Starting pressure			
Procedure			
O • Single measurement	:	Multiple measurement	

Press the button.
 The Configure multiple measurement dialog window appears:

Configure multiple	Configure multiple measurement		
Use measurements 1 - 4 - 2 - 5 - 3 - 6 -	Meas. profile (name) Delay (minutes) 00:00 Interval (minutes) 05:42		
Total (minutes): 30:00 Maximum total must not exceed 30 minutes.			

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

Example	Measuring sequence
1     4     Y       2     5     Y       3     6	Factory setting: 6 part- measurements Part-measurement 1 is discarded
1     -     4     -       2     V     5     -       3     V     6     V	Example: 6 part-measurements Part-measurements 1, 4 and 5 are discarded
$1 - 4 \checkmark$ $2 \checkmark 5$ $3 \checkmark 6$	Example: 4 part-measurements • Part-measurement 1 is discarded • Part-measurements 5 and 6 are not performed

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

8. Assign a name to the measuring profile.

Configure multiple measurement				
Use measurements	Meas. profile (name)			
1 - 4 -	Example 1			
2 🖌 5 – 3 🖌 6 🗸	Delay (minutes) 02:00 Interval (minutes) 04:00			
Total (minutes): 23:30 Maximum total must not exceed 30 minutes.				

# 9. Press the button. The measuring profile is saved.

The name of the measuring profile appears in the NIBP settings dialog window instead of the text Multiple measurement.

### Presets for SpO₂

#### 1. Press the **Settings** tab.

Settings		Logout
		Users
Display and volume	Regional settings	System
		Settings
Units	Analysis modules	Peripheral
		Reset
Vital signs		
		垊. 1

#### 2. Press the Vital signs button.

Vital signs	×	Logout
		Users
NIBP	PR	System
		Settings
SpO ₂	ТЕМР	Peripheral
		Reset
Color mode		
Standard -		
		垊. 1

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3. Press the **SpO₂** button.

The presets are displayed (in this case: Masimo SET[®] pulse oximetry):

SpO ₂	
O 🚣 Stable	
🖲 🟊 Normal	
O ₩ Sensitive	
Cancel Confirm	

4. Press the desired sensitivity:

#### NOTE

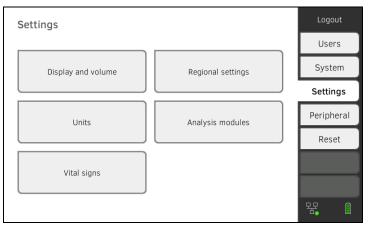
The Maximum setting (Masimo SET[®] pulse oximetry) is not available as a preset. Select this setting for each measurement directly  $\rightarrow$  Measuring oxygen saturation (SpO₂).

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

#### 5. Press the **Confirm** button.

The dialog window closes. The modified settings are adopted.

#### 1. Press the Settings tab.



## Presets for temperature (COVIDIENTM FILACTM 3000 only)

2. Press the Vital signs button.

Vital signs X	Logout	
		Users
NIBP	PR	System
		Settings
SpO₂	ТЕМР	Peripheral
		Reset
Color mode		
Standard		
		문. 1

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

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

•	Predictive
0 🌡	Direct
•	Oral
o 📬	Axillary

- 5. Press the desired measurement method.
  - Predictive
  - Direct
- 6. 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.

Selecting color mode for Vital signs 1. Press the Settings tab. tab

Settings		Logout
		Users
Display and volume	Regional settings	System
		Settings
Units	Analysis modules	Peripheral
		Reset
Vital signs		
		뫊 1

#### 2. Press the **Vital signs** button.

Vital signs		Logout
		Users
NIBP	PR	System
		Settings
SpO ₂	ТЕМР	Peripheral
		Reset
Color mode		
Standard -		
		뮹. 1

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

## 4. MANAGING SYSTEM COMPONENTS

- → Viewing system information
- → Updating the monitor software
- → Data export and backup
- → Power management

### 4.1 Viewing system information

#### 1. Press the **System** tab.

System information		Logout
		Users
Monitor	Measuring mat	System
		Settings
SmartBucket	Data management	Peripherals
		Reset
Power management		
		· 문 🛛 🏚

#### 2. Select a system component.

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

SmartBucket	Logout Users
SmartBucket active Temp. module active	System
Details SmartBucket Software update SmartBucket	Settings
Information SmartBucket	Peripherals
	Reset
Product information: simulated smartbucket	
	명 [ [

You have the following options:

- View details
- ► Perform software update (not for SmartBucket) → Updating the monitor software

#### 4.2 Updating the monitor software

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

#### NOTICE! Data loss

- Export seca patient files and user accounts manually before updating the software (for operation 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 (for operation with seca analytics 115 PC software).
- 1. Press the **System** tab.

System information	Logout
	Users
Monitor Measuring mat	System
	Settings
SmartBucket Data management	Peripherals
	Reset
Power management	
	· 문 [ Î

2. Press the Monitor button.

Monitor	×	Logout Users
Details Monitor	Software update Monitor	System
Device name		Settings
Example 2		Peripheral
Information Monitor		Reset
Serial number: 76543217654321		
Software version: 1.0.1153 INT		[
		琚. 🏾

- 3. Press the Software update Monitor button.
- 4. Select the source for the software update:
  - USB memory stick: continue at step 5.
    - ► Network: Continue at 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.
- Press the Start software update button. The software package will be installed. Following successful installation, the device restarts automatically.
- 7.

#### 4.3 Data export and backup

- → Exporting patient and user data manually
- → Restoring patient and user data manually

Exporting patient and user data manually

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

1. Press the **System** tab.

System information		Logout
		Users
Monitor	Measuring mat	System
		Settings
SmartBucket	Data management	Peripherals
		Reset
Power management		
		무무 🗋 📋

#### 2. Press the Data management button.

Data management	X	Logout
		Users
Export system log	Export	System
		Settings
Backup patient data	Backup	Peripherals
Restore patient data	Restore	Reset
seca analytics 115 Last synchronization: -	C	

- 3. Connect a USB memory stick to the monitor.
- 4. Press the **Backup** button.
- 5. Enter a password to encrypt the data.

#### NOTICE!

#### Data access by unauthorized persons

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

- Select a password to satisfy your institution's security requirements.
- 6. Enter the password again to confirm it.

The data are exported to the USB memory stick.

7. Archive the data in line with your institution's policy.

## Restoring patient and user data manually

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

#### NOTICE!

#### Data loss

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

- Export seca patient files and user accounts manually before restoring older data manually (operation 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 (operation with seca analytics 115 PC software).
- 1. Load the archived seca patient files and user accounts onto a USB memory stick.
- 2. Press the **System** tab.

System information	Logout
	Users
Monitor Measuring mat	System
	Settings
SmartBucket Data management	Peripherals
	Reset
Power management	
	무 [] (1)

#### 3. Press the **Data management** button.

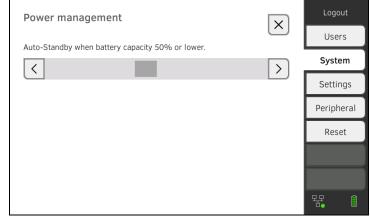
Data management	×	Logout
	$(\land)$	Users
Export system log	Export	System
		Settings
Backup patient data	Backup	Peripherals
Restore patient data	Restore	Reset
seca analytics 115 Last synchronization: -	C	<b>₹</b> 1 1

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

#### 4.4 Power management

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

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



- 3. Set the desired battery charge status from which the device is to shut down and switch off.
  - Press the button to switch off the device at a lower battery charge status (minimum: 10 %).
  - Press to switch off the device at a higher battery charge status (maximum: 100 %).

## 5. SETTING UP PERIPHERALS

- → Setting up a LAN connection to the network (stationary operation)
- → Setting up a WiFi connection (mobile operation)
- → Setting up a connection to the seca analytics 115 PC software
- → Setting up a connection to the seca connect 103 software
- → Setting up a seca 360° proximity connection
- → Setting up a seca 360° wireless connection

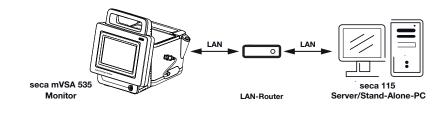
### 5.1 Setting up a LAN connection to the network (stationary operation)

- → Introduction
- → Activating the LAN connection
- → Deactivating the LAN connection

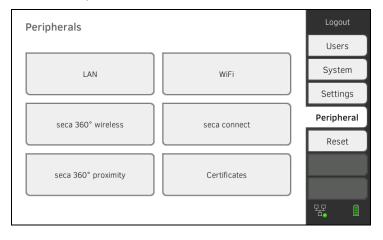
For stationary use, for example in a treatment room at your practice, you can connect the monitor to your LAN network to exchange data with the **seca analytics 115** PC software or the **seca connect 103**.

A requirement for exchanging data with the **seca analytics 115** PC software is that the **seca analytics 115** PC software is installed on a server or standalone PC and the network configuration (UDP or DHCP) is known.

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



#### 1. Press the **Peripherals** tab.



#### Introduction

Activating the LAN connection

2. Press the **LAN** button.

Set LAN connection		X	Logout
		(	Users
LAN active	DHCP		System
IP address	Default gateway		Settings
172.16.0.245	172.16.0.254		Peripherals
Netmask			Reset
MAC address:			
			<pre> </pre>

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

Set LAN connection		X	Logout
			Users
LAN active	DHCP		System
IP address	Default gateway		Settings
172.16.0.245	172.16.0.254		Peripherals
Netmask			Reset
255.255.255.0			
MAC address:			

- 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		X	Logout
		$\sim$	Users
LAN active	ОНСР		System
IP address	Default gateway		Settings
172.16.0.245	172.16.0.254		Peripherals
Netmask			Reset
255.255.255.0			
MAC address:			
			<pre></pre>

## 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. Press the button to confirm your entry.
- 7. You have the following options for continuing:
  - ► → Setting up a connection to the seca analytics 115 PC software
  - ► → Setting up a connection to the seca connect 103 software

### Deactivating the LAN connection

1. Press the **Peripherals** tab.

Perin	oherals		Logout
			Users
	LAN	WiFi	System
			Settings
	seca 360° wireless	seca connect	Peripheral
			Reset
	seca 360° proximity	Certificates	
			물 (
2. Press tl	ne <b>LAN</b> button.		
Set L	AN connection	×	Logout
			Users
$\checkmark$	LAN active	<b>ОНСР</b>	System
IP add		Default gateway	Settings
	2.16.0.245	172.16.0.254	Peripherals
Netma	5.255.255.0		Reset
250	5.255.255.0		
MAC a	ddress:		
The LA	ne <b>LAN active</b> check N function is deactiva nnection data are dele	ted.	

- 4. To reactivate the LAN function, proceed as outlined below:a) Press the LAN active checkbox
  - b)  $\rightarrow$  Activating the LAN connection

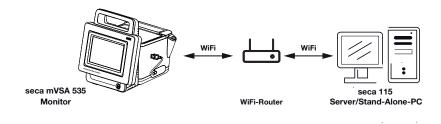
### 5.2 Setting up a WiFi connection (mobile operation)

- → Introduction
- → Activating the WiFi connection
- → Deactivating the WiFi connection

For mobile use, for example on the ward of a hospital, you can integrate the device in your network as a WiFi client to exchange data with the **seca analytics 115** PC software or **seca connect 103**.

A requirement for exchanging data with the **seca analytics 115** software is that the **seca analytics 115** PC software is installed on a server or standalone PC and access data for your WiFi network are known.

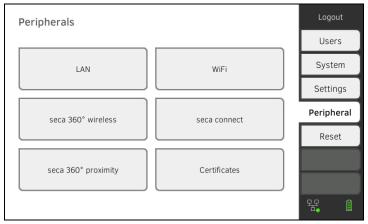
A requirement for exchanging data with the **seca connect 103** software is that the **seca connect 103** software is installed on a server and the configuration of the **seca connect 103** software (server IP and connect port) is known.



#### Activating the WiFi connection

Introduction

#### 1. Press the Peripherals tab.



 Make sure that the LAN connection to the network is **not** active → Deactivating the LAN connection. 3. Press the WiFi button.

Set WiFi connection		Logout
		Users
WiFi mode	Hidden network	System
\$SID		Settings
~	scan WiFi	Peripherals
		Reset
MAC address: 00:07:80:a9:e2:d7		<b>₹</b> ] <b>1</b>

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

#### NOTE

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

8. Press the button to confirm your entry.

The connection is established.

The Symbol is displayed on the Monitor. The device is connected to your network via WiFi.

- 9. You have the following options for continuing:
  - ► → Setting up a connection to the seca analytics 115 PC software
  - ► → Setting up a connection to the seca connect 103 software

#### **Deactivating the WiFi connection**

1. Press the **Peripherals** tab.

	Logout
	Users
WiFi	System
	Settings
seca connect	Peripheral
	Reset
Certificates	
	ห. 1
	seca connect

2. Press the WiFi button.

Set WiFi connection		Logout
		Users
WiFi mode WiFi direct (BIA mat)		System
WiFi client (network)		Settings
WiFi direct (BIA mat)	scan WiFi	Peripherals
WiFi off		Reset
MAC address: 00:07:80:a9:e2:d7		I
In the WiFi mode drop-dow	n menu, press the <b>WiFi off</b> se	etting.

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

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

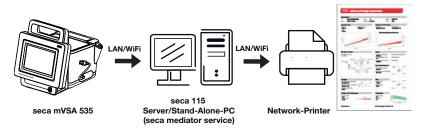
- → Introduction
- ightarrow Connecting the device automatically (UDP)
- $\rightarrow$  Connecting the device manually (TCP)
- → Exporting patient and user data manually
- → Setting up automatic export

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

- Synchronize patient and user data automatically → Exporting patient and user data manually.
- **seca directprint**: Issue results reports directly from the device on a network printer → Viewing current measuring results.

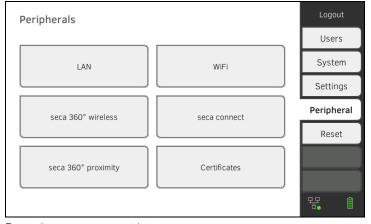
A requirement is that the device is connected to the LAN or WiFi network of your institution.

- → Setting up a LAN connection to the network (stationary operation)
- → Setting up a 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 connect button.
 The seca connect configuration dialog window opens.

## Connecting the device automatically (UDP)

Introduction

## 3. In the **Connect Mode** drop-down menu, select the option **seca analytics 115 UDP**.

The recommended presets are displayed.

seca connect configuration	on 🗸 🗙	Logout
		Users
Connect Mode	seca analytics 115 UDP	System
		Settings
Connect Server IP		Peripherals
		Reset
Connect Port	20011	
	$\rightarrow$	

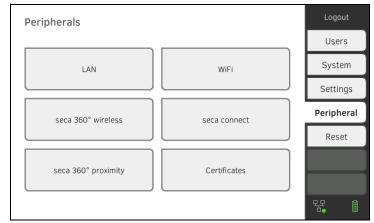
- 4. Adapt the presets if necessary.
- 5. Ensure these settings match those in the **seca analytics 115** PC software (menu: Extras\Settings\Synchronization).



- Press the button:
  Activating automatic synchronization
  Press the button:
  - Confirm settings, exit dialog

## Connecting the device manually (TCP)

1. Press the **Peripherals** tab.



2. Press the **seca connect** button.

The seca connect configuration dialog window opens.

## 3. In the **Connect Mode** drop-down menu, select the option **seca analytics 115 TCP**.

The recommended presets are displayed.

seca connect configurati	on 🗸 🗙	Logout
		Users
Connect Mode	seca analytics 115 TCP	System
		Settings
Connect Server IP	0.0.0.0	Peripherals
Connect Port	20011	Reset
	$\rightarrow$	<pre></pre>

- 4. Adapt the presets if necessary.
- 5. In the **Connect Server IP** line, enter the appropriate IP address.

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

 In the Connect Port line, enter the port of the PC selected under 5. (default setting: 20010).

You have the following options for continuing:



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

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

#### 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 connection to the seca analytics 115 PC software.

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

Activating automatic synchronization

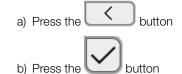
1. Press the **Peripherals** tab.

Peripherals		Logout
		Users
LAN	WiFi	System
		Settings
seca 360° wireless	seca connect	Peripheral
		Reset
seca 360° proximity	Certificates	
		垊. ()

- 2. Press the **seca connect** button.
- 3. In the **Connect Mode** drop-down menu, select the option seca analytics 115 TCP or seca analytics 115 UDP.
- 4. Press the button to reach the **seca analytics 115 configuration** page.

seca analytics 115 configuration	
Automatic synchronization	
Automatic export (CSV)	
Automatic export (EMR)	
File Transfer TCP Port 20012	
$\langle$	

- 5. Press the **Automatic synchronisation** checkbox. Automatic synchronization is activated.
- 6. To adopt the settings, proceed as follows:



The settings are adopted.

#### 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 device data will be overwritten.

#### Setting up automatic export

This function allows you to transmit measuring results to an EMR 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 EMR system.

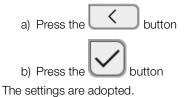
- 1. Establish which data format your EMR system accepts.
- 2. Press the **Peripherals** tab.

Peripherals		Logout
		Users
LAN	WiFi	System
		Settings
seca 360° wireless	seca connect	Peripheral
		Reset
seca 360° proximity	Certificates	
		못 1

- 3. Press the seca connect button.
- 4. In the **Connect Mode** drop-down menu, select the option **seca analytics 115 TCP** or **seca analytics 115 UDP**.
- 5. Press the **button**. The **seca analytics 115 configuration** page is displayed.

seca analytics 115 configuration		
Automatic synchronization		
Automatic export (CSV)		
Automatic export (EMR)		
File Transfer TCP Port 20012		
<		

- 6. Ensure that the Automatic synchronisation checkbox is activated.
- 7. Press the desired export format.
  - Automatic export (CSV)
  - Automatic export (EMR)
- 8. To adopt the settings, proceed as follows:

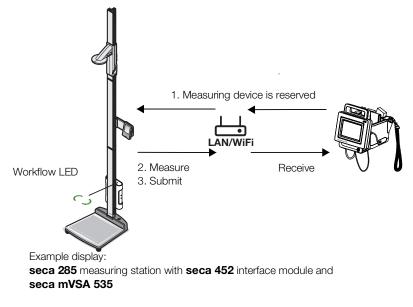


9. Set up an interface to the **seca analytics 115** PC software in your EMR system.

- Settings you make in this dialog window are transmitted to the **seca analytics 115** PC software → Exporting patient and user data manually.
- Note the user documentation for the EMR system used.
- seca Service will be pleased to assist if you have any questions relating to interface configuration.

#### 5.4 Setting up a seca 360° proximity connection

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



The following requirements must be met in order to connect:

- The seca measuring device is equipped with either a seca 452 external interface module or with an internal interface module (in each case firmware version Q2_2020_Build_615 or higher).
- The seca measuring device is connected to your LAN or WiFi network.
- The seca measuring device is configured as follows:
  - Scan user ID: Required
  - Scan patient ID: Required
  - Confirmation of measurement on seca measuring device: Required
  - Port used: Port configured for communication with the seca connect 103 software (default: 22020) → Setting up a connection to the seca connect 103 software

#### NOTE

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

Proceed as follows to connect the seca measuring device:

1. Press the **Peripherals** tab.

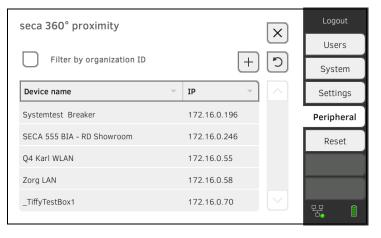
Peripherals		Logout
		Users
LAN	WiFi	System
		Settings
seca 360° wireless	seca connect	Peripheral
		Reset
seca 360° proximity	Certificates	
		뭥. ()

#### Press the seca 360° proximity button. The seca 360° proximity dialog window opens

seca 360° proximity	×	Logout
		Users
Filter by organization ID	(+) (S)	System
Device name		Settings
		Peripheral
		Reset
		뮹. (1

- 3. Search for available devices:
  - Press the button: Search for devices on the network

Press the button: Enter the IP address of a device
 Available devices are displayed.



#### NOTE

- If you have assigned organization IDs to your devices, you can filter them accordingly and thus shorten the list of results.
- Information about how to assign organization IDs can be found in the **seca 103/452** system instructions for use.
- 4. Press the desired device in the list:

seca 360° proximity			×	Logout
				Users
Filter by organization ID		+		System
Device name	-	IP –		Settings
Systemtest Breaker		172.16.0.196		Peripheral
SECA 555 BIA - RD Showroom		172.16.0.246		Reset
Q4 Karl WLAN		172.16.0.55		
Zorg LAN		172.16.0.58		
_TiffyTestBox1		172.16.0.70		

The device is shown blue in the list.

The connection is set up.

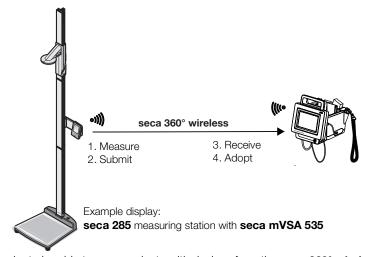
In measuring mode, the seca measuring device is reserved as soon as a patient file is called up. The device is released again once the measurement is stopped  $\rightarrow$  Receiving weight and height (seca 360° proximity).

## 5.5 Setting up a seca 360° wireless connection

- → Introduction
- → Activating/deactivating the seca 360° wireless module
- → Setting up a seca 360° wireless connection

## Introduction

If you use devices from the **seca 360° wireless** system in your institution, e.g. a measuring station, you can connect them to the **seca mVSA 535**. You can submit the parameters height and weight directly to the device and adopt them in a seca patient file.



In order to be able to communicate with devices from the **seca 360° wireless** system, the **seca 360° wireless** module of the **seca mVSA 535** must be activated and a wireless group set up.

#### NOTE

- The device can only receive data, not transmit it, via the **seca 360° wireless** connection.
- Follow the instructions in this section to achieve a stable connection of the desired **seca 360° wireless** devices and to prevent the undesired integration of other devices.
- You should also follow the instructions for use for the seca 360° wireless system devices being used.

#### 1. Press the Peripherals tab.



# Activating/deactivating the seca 360° wireless module

2. Press the seca 360° wireless button.



- 3. Press the **Send/receive on** checkbox. The **seca 360° wireless** module is activated.
- 4. To deactivate the **seca 360° wireless** module, press the **Send/receive on** checkbox again.
- 1. Ensure that the **seca 360° wireless** modules of the **seca mVSA 535** and of all devices you want to connect to the **seca mVSA 535** are activated.
- 2. Switch off all the devices you want to connect to the seca mVSA 535.
- 3. Press the **Peripherals** tab.

Peripherals		Logout
		Users
LAN	WiFi	System
		Settings
seca 360° wireless	seca connect	Peripheral
		Reset
seca 360° proximity	Certificates	
		器 ①

#### 4. Press the seca 360° wireless button.



5. Press the **Set up** button.

# Setting 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 measuring rod) can be integrated in each wireless group.

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

## 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.

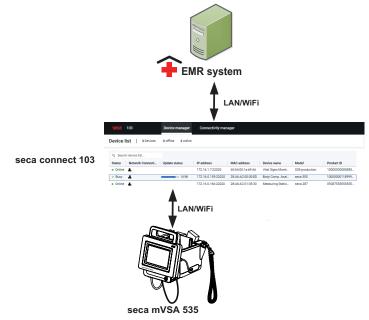
The seca 360° wireless connection is set up.

## 6. CONNECTING TO AN EMR SYSTEM

- → Information about user and patient data
- → Assigning a clear device name
- → Setting up a connection to the seca connect 103 software
- → Configuring data transfer to the EMR system
- → Use of certificates
- → Summary: Device characteristics when connected to EMR system

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

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



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

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

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

## 6.1 Information about user and patient data

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

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

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

To assign a device name, proceed as follows:

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

System information	Logout
	Users
Monitor Measuring mat	System
	Settings
SmartBucket Data management	Peripherals
	Reset
Power management	
	뫙 🛛 🌒

## 3. Press the **Monitor** button.

The **Monitor** dialog window is shown:

Monitor	Logout
	Users
Details Monitor Software update Monitor	System
Device name	Settings
Example 2	Peripheral
Information Monitor	Reset
Serial number: 76543217654321	
Software version: 1.0.1153 INT	
	묵. 🏾

- 4. Enter a clear device name in line with the naming conventions of your institution:
  - a) Press the Device name input field



## 6.3 Setting up a connection to the seca connect 103 software

- → Setting up a seca 360° proximity connection
- → Making workflow settings

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

The following requirements must be met for this:

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

## NOTE

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

## 1. Press the **Peripherals** tab.

Peripherals		Logout
		Users
LAN	WiFi	System
		Settings
seca 360° wireless	seca connect	Peripheral
		Reset
seca 360° proximity	Certificates	
		垊 (

## 2. Press the **seca connect** button. The **seca connect configuration** dialog window opens.

3. In the **Connect Mode** drop-down menu, select the option **seca connect 103**.

seca connect configuration		Logout
		Users
Connect Mode	seca connect 103 🚽	System
		Settings
Connect Server IP	0.0.0.0	Peripherals
		Reset
Connect Port	22020	
	$\rightarrow$	

## Entering connection data

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

You have the following options for continuing:



You can specify the following settings for the measuring sequence and communication with the EMR system:

- Password settings for the user ID
- Scan sequence for user and patient ID
- Permit offline measurements if the EMR system connection is interrupted (recommended for mobile use or difficult WiFi reception conditions)
- Enter an organization ID to assign the device to a department in your institution, for example
- 1. Press the **Peripherals** tab.

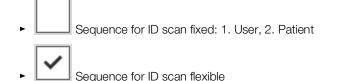
Peripherals		Logout
		Users
LAN	WiFi	System
		Settings
seca 360° wireless	seca connect	Peripheral
		Reset
seca 360° proximity	Certificates	
		程, 自

- 2. Press the **seca connect** button.
- 3. Ensure that in the **Connect Mode** drop-down menu the option **seca connect 103** is selected.
- Press the button.
   The seca connect 103: Workflow page is displayed.

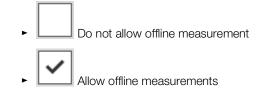
seca connect 103: Workflow		
User/patient ID: permit any scan sequence		
Allow offline measurements		
User ID	required, without password	
Organization ID	791430	
<		

## Making workflow settings

5. Specify the settings for the scan sequence for user and patient ID:



6. Specify whether measurements are to be possible even if the connection to the EMR system is interrupted (offline measurements):



#### NOTE

Offline measurements are temporarily saved in the **Unsubmitted measurements** list. When the connection to the EMR system is active again, the measurements can be called up, evaluated and submitted to the EMR system  $\rightarrow$  Using the Unsubmitted measurements list.

- 7. Under User-ID, specify whether a password is required for login:
  - Password must be entered (recommended)
  - No password required
- 8. If desired, enter an **Organization ID** to assign the device to a department in your institution, for example.
- 9. Adopt the settings:



## 6.4 Configuring data transfer to the EMR system

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

#### NOTE

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

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

			Users
Type of certificate	Valid from	Valid thru	System
seca connect 103 CA	27.06.2019	24.06.2029	Settings
seca connect 103 Client	27.06.2019	24.06.2029	Peripheral
WiFi 802.1X	11.02.2019	11.02.2020	Reset
Proximity Server			
			垊. ()

# 6.6 Summary: Device characteristics when connected to EMR system

Function	Standalone mode (factory setting)/ connection to seca analytics 115	Connection to EMR system via seca connect 103
User identification (measure)	seca user account, role: Physician	EMR user ID
User identification (manage)	seca user account, role: Admin	Device-specific user account, role: Admin
Login	Select from list	<ul><li>Scan barcode</li><li>Manual</li></ul>
Password	Manual	Manual
Patient identification	Select from list	<ul><li>Scan barcode</li><li>Enter manually</li></ul>
Source of patient data	<ul> <li>Device</li> <li>seca analytics 115</li> </ul>	EMR system
Create/edit patient data on device	Possible	Not possible
Storage location for measurements	<ul> <li>Device database</li> <li>seca analytics 115</li> </ul>	<ul><li>Unsubmitted measurements list</li><li>EMR system</li></ul>
Unsubmitted measurements list	Not available	Available

# 7. FACTORY SETTINGS

- → Overview of factory settings
- → Resetting the device
- $\rightarrow$  Resetting the user interface
- → Exporting the system log/audit trail
- → Enabling VNC access

## 7.1 Overview of factory settings

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

Function	Setting
Administrator password	1357
Display language	English
Date format:	
North America	mm/dd/yyyy
Time format:	
North America	12 h
Naming convention:	
North America	First name, surname
Name separator	Decimal point
Display brightness	100 %
Volume for warning and	
information sounds	70 %
Volume for button sounds	70 %
Rechargeable battery capacity,	≤ 50 %
automatic switch-off at:	≤ <b>3</b> 0 %
Weight:	
North America	lbs
Height:	
North America	ft
Blood pressure:	
Unit	mmHg
Presets	Inflation, single measurement
Temperature:	
Unit	C°
COVIDIEN [™] FILAC [™] 3000	
Blue	Oral measurement, predictive
	measurement
Red	Predictive measurement
Pulse rate:	
Unit	min ⁻¹
Preset	
(seca measuring equipment only)	Default setting
Oxygen saturation:	
Unit	%
Mode	Normal
Decimal separator:	
North America	Period
LAN	On
Connection data	None

Function	Setting
WiFi client (device <-> network):	Off
Connection data	None
Direct WiFi :	
seca mVSA 535	Off
Device name	[serial number]
Integration mode	Standalone
seca 360° wireless:	Off
Connection data	None
seca software	
seca connect 103:	
Communication server IP	None
Connect port	22020
seca software	
seca analytics 115:	Off
UDP	Off
Communication server IP	None
TCP port	20010
UDP port	20011
File transfer port	20012
Active analysis modules	
seca mVSA 535	Vital signs

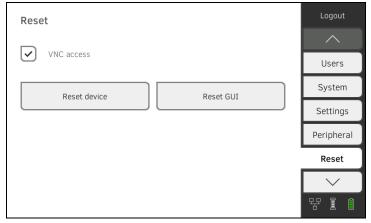
## 7.2 Resetting the device

Use the **Reset device** function to reset the device to factory settings  $(\rightarrow \text{Overview of factory settings})$ . seca patient files and user accounts are deleted from the device in this process.

## NOTE

If seca patient files and user accounts are to be retained, proceed as described in the section entitled  $\rightarrow$  Resetting the 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 → Overview of factory settings.

## 7.3 Resetting the user interface

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

#### NOTE

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

1. Press the Reset tab.

Reset	Logout
VNC access	
Vinc access	Users
Reset device Reset GUI	System
	Settings
	Peripheral
	Reset
	$\sim$
	8 🛛 🋈

## 2. Press the Reset GUI button.

The user interface will be reset to factory settings  $\rightarrow$  Overview of factory settings.

seca patient files and user accounts will be retained.

## 7.4 Exporting the system log/audit trail

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

- 1. Press the **System** tab.
- 2. Press the Data management button.

Data management	×	Logout
	$(\land)$	Users
Export system log	Export	System
		Settings
Backup patient data	Backup	Peripherals
Restore patient data	Restore	Reset
seca analytics 115		
Last synchronization: -	C	

- 3. Press the **Export** button.
- 4. Select the export destination:
  - ► USB memory stick: continue at step 5.
  - ► Network: Continue at step 6.

- 5. Connect a USB memory stick to the monitor.
- 6. Press the **Export system log** button. The system log/audit trail is 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 Enabling VNC access

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

1. Press the **Reset** tab.

Reset	Logout
VNC access	Users
Reset device Reset GUI	System
	Settings
	Peripheral
	Reset
	$\sim$
	윰 🛙 📋

- 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.

# Medical Measuring Systems and Scales since 1840

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