seca mBCA 525 c

Instructions for use

TABLE OF CONTENTS

1 ABOUT THIS DOCUMENT

1.1 Representation in text

Symbol	Description
✓	Requirement for actions
►	Action
1. 2.	Actions with specified sequence
a) b)	Steps of an action with specified sequence
⇨	Result of an action
• •	First level of a list
– –	Second level of a list

1.2 Representation in diagrams

Symbol	Description
➚	Indicates relevant points on the device or on device components
➡	Indicates directions of movement of the device or of device components
✔	Correct action Correct result of action
✖	Incorrect action Incorrect result of action
⇨	Points to the next step of a procedure
👆	Points to an element the user is clicking
✓	End of a procedure, e.g. the installation of a part

2 DESCRIPTION OF DEVICE

→ Intended use
→ Clinical benefit
→ Contraindications
→ Patient target group
→ User qualification
→ Functional description

2.1 Intended use

The device supports physicians in making a diagnosis or deciding on a course of treatment based on bioimpedance measurement.

To calculate further parameters, the device can be combined with cloud-based software.

2.2 Clinical benefit

The device assists physicians when deciding on the diagnosis or treatment according to the measured and calculated parameters (indirect clinical benefit).

2.3 Contraindications

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

• Electronic implants, e.g. cardiac pacemakers
• Active prostheses

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

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

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

• Cardiac arrhythmias
• Pregnancy

2.4 Patient target group

The device is intended for persons over 5 years of age.

2.5 User qualification

→ Administration/network operation
→ Measuring mode

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

Measuring mode Typical professional background: Physician, health care professional/nurse, therapist, sports instructor/teacher or similar profession.

Users are capable of operating and servicing the device and the software according to the instructions for use. No further training is required. All age groups from adulthood are permitted.

2.6 Functional description

→ Device components
→ Power supply
→ Measuring bioimpedance
→ Entering weight, height, waist circumference
→ Network functions
→ Compatibility

Device components The device consists of a monitor and a storage compartment.

The monitor is for preparing and analyzing measurements. The storage compartment is for storing the measuring mat.

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

The measuring mat is powered by a lithium-ion battery pack. The battery pack is charged via the inductive charging interface of the monitor.

Measuring bioimpedance Bioimpedance measurement is performed with the patient lying down using a measuring mat developed by seca.

Measurements with the 8-point method (whole body) and the 4-point method (right half of body only) are possible.

The low alternating current is provided and impedance is measured by the electrode cables of the measuring mat. The electrode cables are connected to two pairs of adhesive electrodes for each half of the body. The adhesive electrodes are attached to the patient's hands and feet.

Following bioimpedance measurement, the device displays the parameters "reactance (Ω)", "resistance (Ω)" and "phase angle (ϕ)". The body composition is analyzed in the **seca analytics 125** software.

Entering weight, height, waist circumference Weight, height and waist circumference are required to analyze the body composition. The parameters can be entered on the device in the **seca analytics 125** software following bioimpedance measurement or at a later date.

Network functions   The device can be integrated into a PC network via a LAN interface or via WiFi in order to set up a connection to the **seca analytics 125** software.

The **seca analytics 125** software receives measurement data and processes them in graphical form. The software thus assists the attending physician in analyzing measured results and making a diagnosis.

Compatibility   **seca analytics 125** analysis software: Release 2.2 or higher.

3   SAFETY INFORMATION

➜ Safety information in these instructions for use
➜ Basic safety information

3.1   Safety information 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.

17-10-05-409-002_2024-10S

3.2   Basic safety information

Handling device

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

► Keep the instructions for use in a safe place. The instructions for use are a component of the device and must be available at all times.

► In the interest of patient safety, you and your patients are obliged to report serious events that occur in connection with this product to the manufacturer and to the authority responsible in your country.

⚠ **DANGER!**
Risk of explosion

► Do not use the device in an environment in which one of the following gases has accumulated:
  – oxygen
  – flammable anesthetics
  – other flammable substances/air mixtures

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

► Additional devices connected to medical electrical 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 medical electrical devices is considered a system configurator and therefore responsible for ensuring that the system complies with the requirements of standards for systems. This also applies to additional devices recommended by seca. 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.

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

► Have servicing carried out regularly as described in the relevant section of this document.

► Technical modifications may not be made to the device. The device does not contain any user-serviceable parts. Only have servicing and repairs performed by an authorized seca service partner. You can find a service partner in your vicinity at www.seca.com or by emailing service@seca.com.

► Use only seca original accessories and spare parts, otherwise seca will not grant any warranty.

⚠ **CAUTION!**
Patient hazard, malfunction

► Keep other medical electrical devices, e.g. high-frequency surgical devices, a minimum distance of approx. 1 meter away to prevent faulty measurements or wireless transmission interference.

► Keep HF devices such as cellphones at a minimum distance of approx. 1 meter to prevent faulty measurements or wireless transmission interference.

► The actual transmission output of HF devices may require minimum distances of more than 1 meter. For details, go to www.seca.com.

Handling a wheeled stand

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

► Ensure that the device is securely mounted on the wheeled stand, as described in the corresponding assembly instructions.

► Ensure that cables and other accessories are properly stowed in the basket of the wheeled stand.

⚠ **CAUTION!**
Damage to device

► Do not pull on cables to move the device or the wheeled stand.

► Do not move the wheeled stand when the power cord of the device is plugged into a power supply socket.

Preventing electric shock

⚠ **WARNING!**
Electric shock

► Set up devices which can be operated with a power supply unit so that the power supply socket is within easy reach and the power supply can be disconnected quickly.

► Ensure that your local electricity supply matches the details on the power supply unit.

► Connect this device only to a power supply with a protective earth facility.

► Do not connect the device to a power supply if there is any uncertainty about the functionality of protective earth. In this case, use the device only in rechargeable battery operation.

► Do not connect the device to power supply sockets that are switched by an on/off switch or a dimmer.

► Never touch the power supply unit with wet hands.

► Do not use extension cables and multiple outlets.

► Ensure that cables are not crushed or damaged by sharp edges.

► Ensure that cables do not come into contact with hot objects.

► Do not operate the device above an altitude of 3000 m above sea level.

► Only devices that are approved as medical devices and that have no separate power supply may be connected to the USB interface.

Preventing injuries and infections

⚠️ **WARNING!**
Injury from falling

▶ Ensure that the device is steady and level.

▶ Route connector cables (if present) so that neither users nor the patient can trip over them.

⚠️ **WARNING!**
Patient hazard due to infections

Diseases can be transmitted due to poor hygiene.

▶ Ensure that the patient does not have any infectious diseases.

▶ Make sure that the patient's hands and feet are clean.

▶ Make sure that the patient does not have any open wounds on the palms or the soles of the foot.

▶ Do not reuse adhesive electrodes and do not subject them to a hygiene treatment. Adhesive electrodes are consumables. Dispose of them after each measurement, as described in the relevant section of this document.

Preventing damage to device

NOTICE!
Damage to device

▶ If liquids have penetrated the device, the device may possibly 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 the device is not to be used for an extended period, take the power supply connector out the power supply socket. Only then is the device de-energized.

▶ Do not drop the device.

▶ Do not subject the device to shocks or vibrations.

▶ Do not place the device in direct sunlight and ensure that it is not placed in the direct proximity of a heat source. The excessive temperatures could damage the electronics.

▶ Ensure that the ventilation openings of the device are not covered.

▶ Perform a function check at regular intervals as described in the corresponding section in this document. Do not operate the device if it is not working properly or is damaged.

▶ Avoid rapid temperature fluctuations. If the device is transported so that a temperature difference of over 20 °C occurs, the device must be left to stand for at least 2 hours before it is switched on. otherwise condensation may form; this may damage the electronics.

▶ Use the device only in the intended ambient conditions.

▶ Store the device only in the intended storage conditions.

▶ Use only cleaning agents and disinfectants which match the details in the section entitled "Hygiene treatment".

Handling rechargeable batteries

⚠ **WARNING!**
Injury, damage to device

Lithium-ion rechargeable batteries contain harmful substances (electrolyte, conducting salt), which may explode and so escape or cause fires if not handled properly.

► Do not remove the rechargeable batteries from the device. The rechargeable batteries may be handled only by seca Service or an authorized service partner.

► If harmful substances have leaked out, avoid contact with the skin, eyes, and mucous membranes. Rinse affected areas of the body with plenty of clean water and seek medical help at once.

► If harmful substances have penetrated the device, do not continue using it. Have the device inspected, and if necessary, repaired by seca Service or an authorized service partner.

► Have the rechargeable batteries replaced only by seca Service or an authorized service partner.

Handling measuring results

⚠ **CAUTION!**
Patient hazard

To prevent misinterpretations, measuring results for medical purposes must only be displayed and used in SI units (kilograms/grams, meters/centimeters). Some devices have the option of displaying measuring results in different units. This is purely an additional function.

► Only use measuring results in SI units.

► The user takes sole responsibility for the use of measuring results in non-SI units.

NOTICE!
Inconsistent measuring results

► Before you save and continue using measured values determined using this device (e.g. in seca software or in an EMR system), ensure that the measured values are plausible.

► If measured values have been sent to seca software or to an EMR system, ensure before continuing to use them that the measured values are plausible and assigned to the correct patient.

NOTICE!
Measuring results from other devices not compatible

Bioimpedance measurements performed by devices from different manufacturers are not compatible. Follow-up measurements not performed on a seca device may lead to inconsistent data and to misinterpreted measuring results.

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

Handling packaging material

⚠️ **WARNING!**
Risk of suffocation

Packaging materials made of plastic film (bags) present a risk of suffocation.

► Store packaging material out of the reach of children.

► If the original packaging material is no longer available, only use plastic bags with safety holes to reduce the risk of suffocation. Use recyclable materials if possible.
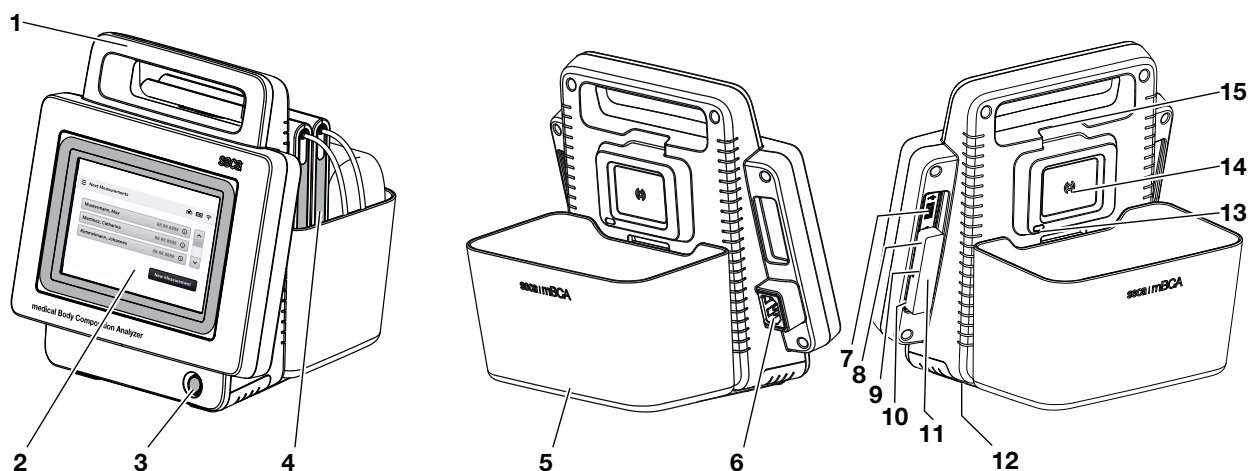
NOTE

Store the original packaging material for future use (e.g. returning for servicing).

4 OVERVIEW

4.1 Monitor controls
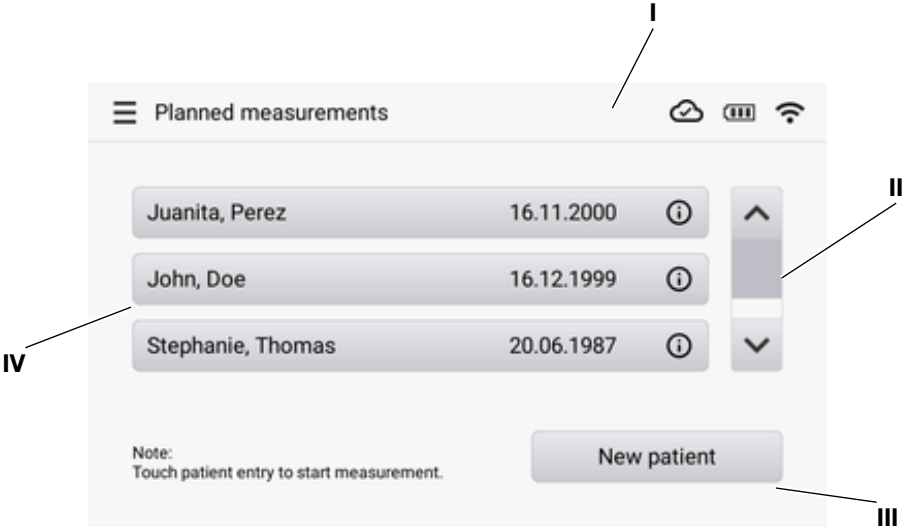
17-10-05-409-002_2024-10S

Item	Control	Function
1	Handle	Transporting the device
2	Touchscreen display	Central control and display element
3	ON/OFF button with LED	• LED white: Device on • LED green: Device on standby • LED off: Device off
4	Measuring mat	For performing bioimpedance measurement
5	Storage compartment	For transporting and storing the measuring mat
6	Power supply con-nection socket	For connecting the power supply cable
7	USB interface	• For connecting the barcode scanner • For updating the monitor and the measuring mat (USB memory stick) • For exporting logfiles (USB memory stick)
8	USB WiFi adapter (under protective cap)	Data transmission to the **seca analytics 125** software with mobile use
9	ISIS interface (under protective cap)	Advance feature for system upgrade (currently no function)
10	LAN interface (under protective cap)	Data transmission to the **seca analytics 125** software with stationary use
11	Protective cap, re-movable	Protects USB WiFi adapter, ISIS and LAN interface
12	Battery pack com-partment	Contains lithium-ion battery pack supplied (inserted ready for operation)
13	Infrared interface	• Data transmission between monitor and measuring mat (backup if WiFi not available) • For updating measuring mat software (from monitor via USB memory stick)
14	Inductive charging in-terface with magnetic catch	For charging measuring mat battery pack
15	Internal WiFi adapter	Data transmission between monitor and measuring mat

4.2 Measuring mat controls
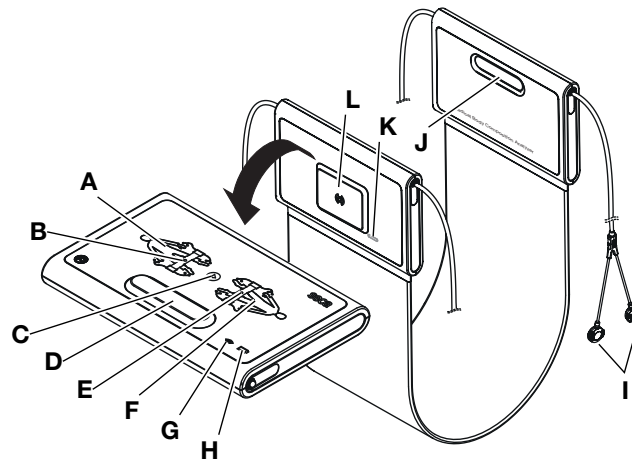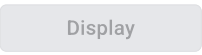
Item	Control	Function
A	LEDs, electrodes on left	• Briefly lit up green, then red: Self-test after switch-on • Lit up green: Self-test successful, measuring mat ready to measure
B	Key with LED, patient position left	• LED green: Patient position left (factory default) • LED green, flashing: Measurement in progress • LED red: Error during measurement
C	Start key	For switching measuring mat on and off
D, J	Magnetic catch	For folding measuring mat up for transport and storage
E	Key with LED, patient position right	No function at present
F	LEDs, electrodes on right	Briefly lit up green, then red and extinguished: Self-test after switch-on successful
G	LED, WiFi	• LED green: WiFi connection to monitor active • LED off: No WiFi connection to monitor
H	LED, charging status	• LED green: Battery pack fully charged • LED green, flashing: Battery pack charging • LED red: Battery pack discharged
I	Push-button adapter	For connecting to adhesive electrodes
K	Infrared interface	Data transmission between monitor and measuring mat
L	Inductive charging interface with magnetic catch	• For charging measuring mat battery pack • Is suspended in the magnetic catch of the monitor

4.3 Fields in the display

Item	Control	Function
I	Header	• Burger menu ☰: Access to device settings • Active function (in this case: **Planned measurements**) • Status display for network and battery pack charging status (in this case: Connection to **seca analytics 125** software active, rechargeable battery for the monitor fully charged, network connection via WiFi) See also: → Symbols in the display: Operating state
II	Scroll bar	• With more than three list entries • Use navigation arrows ∧ ∨ for scrolling through
III	Button	Press to execute a function
IV	List entry	Press to view details • Press list entry to start measurement • Press ⓘ to view details

4.4 Buttons and symbols in the display: Navigation
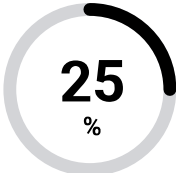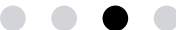
Symbol	Meaning
Display	Button, recommended function
Display	Button, alternative function
Display	Button, function not available
☰	Open menu

Symbol	Meaning
‹ ›	• Navigate back/forward • Navigate to the left/right
∧ ∨	Navigate up/down
− +	Reduce/increase value
☑ ☐	Item from list selected/not selected, multiple selection
◉ ○	Alternative from list selected/not selected, multiple selection
‹	Return to previous screen
↵	Save setting/selection
✕	• Exit function without saving • Close dialog window
👁 👁̸	Entered text visible/not visible (e.g. WiFi connection: entry of SSID)
ⓘ	• Information for current operating step • Press to display detailed information (context-related)
⊗	Error message
🔍	Search patient

4.5 Symbols in the display: Operating state

Symbol	Meaning
🔋	Rechargeable battery for the monitor • Controls permanently lit up: Battery pack full • Controls flashing: Battery pack charging
🔋	Rechargeable battery for the monitor Battery pack discharged
品	LAN connection set up and active
◠	Searching for WiFi network
📶	WiFi connection: • 📶 WiFi active, signal optimal • 📶 WiFi active, signal weak • 📶 WiFi, active, signal very weak • 📶̸ WiFi deactivated or not set up
☁ ☁	Connection to **seca analytics 125** software: Active/not active

Symbol	Meaning
🟢	Electrode status: • 🟢 Permanently lit up: Electrode OK • ❌ Electrode not OK or implausible measured values • 〰️ Skin contact error
25 %	Measurement procedure running
● ● ● ●	Data transfer running

4.6   Labels

Markings on the device and on the type plate	
Symbol	**Meaning**
🏭	Name and address of manufacturer, date of manufacture
UDI	Unique Device Identifier (product identification number)
REF	Article number
SN	Serial number
ProdID	Product identification number
Mat.No.	Variant number
📖	Follow instructions for use
eIFU	Electronic instructions for use, directly accessible on the device ➜ Calling up the instructions for use
🚫	Do not use device on individuals with cardiac pacemakers or implanted defibrillators
🏃	Medical electrical device, type BF
▢	Insulated device in accordance with IEC 60601-1: Protection class II
Li-ion	Lithium-ion battery

Markings on the device and on the type plate	
Symbol	**Meaning**
	Device with functional grounding in accordance with IEC 60601-1: The third wire of the power supply connecting cable is the functional ground
IP21	Type of protection in accordance with IEC 60529: • Protection against ingress of solid foreign bodies with a diameter of over 12.5 mm • Protection against access with fingers • Protection against dripping water
IP44	Type of protection in accordance with IEC 60529: • Protection against ingress of solid foreign bodies with a diameter of over 1.0 mm • Protection against access with wires • Protection against splashes from all directions
C E 0123	Device complies with EU directives **0123**: Notified Body for Medical Devices
MD	Medical device in accordance with Regulation (EU) 2017/745
TÜV SÜD	Device meets the requirements of the USA and Canada. Certified and tested by a licensing laboratory (NRTL) of TÜV SÜD Product Services GmbH.
UKCA xxxx	Device complies with United Kingdom directives **xxxx**: Notified Body for Medical Devices of the United Kingdom
UK REP	Importer/representative in the United Kingdom: seca Ltd 40 Barn Street B5 5QB Birmingham United Kingdom
CH REP	Importer/representative in Switzerland: seca ag (schweiz) Medizinische Waagen und Messsysteme Schönmatt Str. 2 CH-4153 REINACH
FC	Symbol of the US authority Federal Communications Commission (FCC)
FCC ID	Device license number from the US Federal Communications Commission (FCC)
IC ID	Device license number from Industry Canada
xxx-yyy V **min xx-yy Hz** **xx A**	Type plate on the power supply connection socket: Permitted supply voltage Permitted power supply frequency Current consumption

Markings on the device and on the type plate	
Symbol	**Meaning**
	Inductive charging interface
	LAN interface
	USB interface
	Do not dispose of device in household waste

Markings on the packaging	
Symbol	**Meaning**
	Protect from moisture
	Arrows indicate top of product Transport and store in an upright position
	Fragile, do not throw or drop
	Permitted min. and max. temperature for transport and storage
	Permitted min. and max. humidity for transport and storage
	Permitted min. and max. air pressure for transport and storage
	Open packaging here
	Packaging material can be disposed of through recycling programs

5 STARTING UP DEVICE

5.1 Calling up the instructions for use

The device is supplied without any printed instructions for use. In addition to the PDF version available on the www.seca.com website, you can view the instructions for use directly on the device.

1. Press the ≡ key.
   ⇨ The **Settings** menu is displayed.

2. Press the **Instructions for use** menu item.
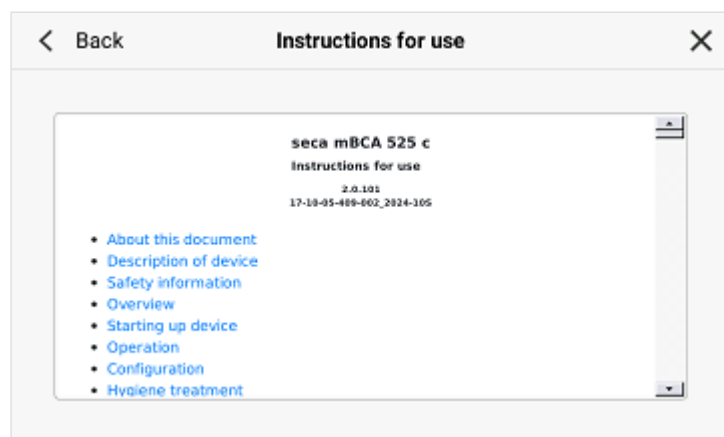
   ⇨ The instructions for use are displayed in the selected display language.

   ⇨ If no instructions for use are available in the display language, the English-language version will be displayed.

3. Press individual sections of the instructions for use to open them.

4. Press the ⋀ or ⋁ key to page through the instructions for use.

5. To close the instructions for use, press the ✕ key.

5.2   Scope of delivery
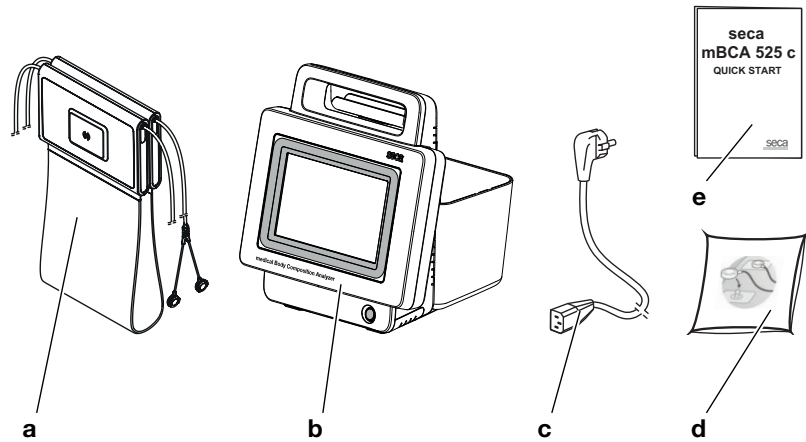
Item	Component	Pcs.
a	Measuring mat with electrode cables and battery pack	1
b	Monitor with USB WiFi adapter (under protective cap) and battery pack	1
c	Power supply cable (country-specific)	1-4
d	Push-button electrodes for single use, for affixing to patient, pack of 100.	1
e	Quick Start brief instructions, printed	1

5.3   Suspending the measuring mat in the magnetic catch

NOTICE!
Malfunction

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

► After every measurement, suspend the measuring mat back in the magnetic catch. This ensures that the measuring mat battery pack is always adequately charged.

1. Fold up the measuring mat as shown in the illustration below.
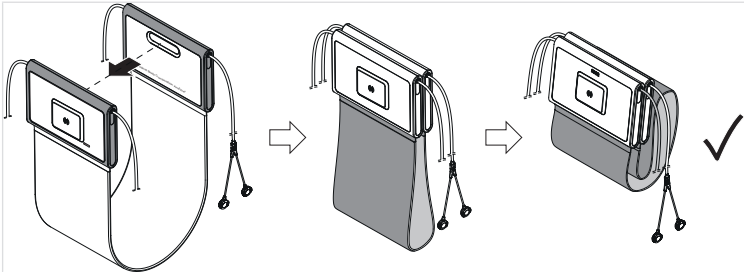
2. Suspend the measuring mat in the magnetic catch as shown in the illustration below.
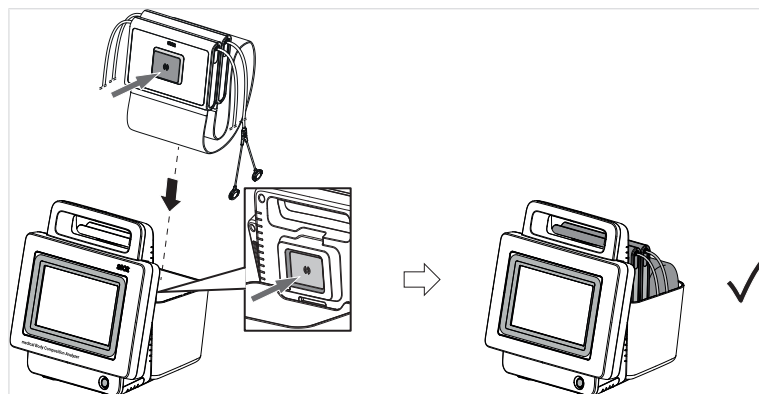
3. Ensure that the measuring mat is correctly located in the magnetic catch of the monitor.
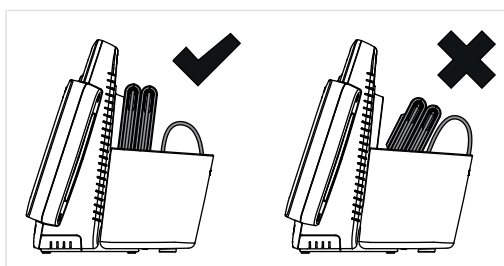
5.4 Connecting a barcode scanner (optional)

A barcode scanner can be connected to the device to record patient IDs.

⚠️ **WARNING!**
Injury

► Route the connector cable so that patients cannot become caught or strangle themselves in it.

► Route the connecting cable so as to prevent patients and users tripping.

NOTE

► Observe the maximum permitted current consumption of the barcode scanner.

► Use only barcode scanners recommended by seca.

► The device is compatible with NFC/RFID scanners. For details, contact seca Service.

To connect a barcode scanner, proceed as follows:

1. Ensure that the device is disconnected from the power supply.

2. Plug the USB connector of the barcode scanner into the USB socket of the device.
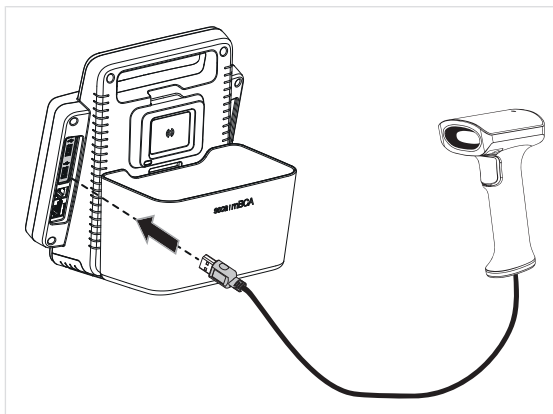
3. Hang the barcode scanner in a suitable holder.

4. Establish the power supply → Establishing power supply.

5.5 Establishing power supply
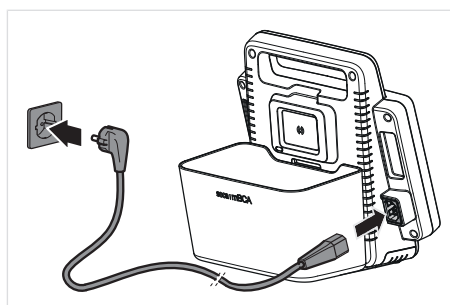
1. Insert the device connector of the power supply unit into the power supply connection socket of the device.

2. Plug the power supply connector into a power supply socket.

5.6 Charging rechargeable batteries

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

✓ The measuring mat is correctly suspended in the magnetic catch of the monitor → Suspending the measuring mat in the magnetic catch.

► Establish the power supply for the monitor → Establishing power supply.

⇨ The ⊘ key lights up white.

⇨ The charging process starts.

⇨ The current charging status is displayed.

⇨ The key ⊙/⭮ flashes green.

NOTE

Leave the device connected to the power supply for approx. 4 hours on initial commissioning. This ensures that the rechargeable batteries for the monitor and the measuring mat are fully charged.

5.7 Network and device settings

You can find information on setting up network connections and other configuration options here: → Configuration

6 OPERATION

→ Switching the device on and off
→ Calling up patient data
→ Using the "Planned measurements" list
→ Measuring

⚠ **CAUTION!**
Personal injury/faulty measurement

► Before using the device each time, perform a function check as described in the corresponding section of these instructions for use.

6.1 Switching the device on and off

→ Switching on the device
→ Saving energy
→ Switching off the device

Switching on the device

✓ The measuring mat is suspended in the magnetic catch of the monitor → Suspending the measuring mat in the magnetic catch.

1. Press the ⊙/⭮ key of the monitor.

⇨ The LED of the ⊙/⭮ key lights up white.

⇨ The start screen is displayed.

⇨ The device starts up. This takes a few seconds.

NOTICE!
Data access by unauthorized persons

If no PIN code was set up or the PIN code is easily accessible, there is the risk that unauthorized persons might access patient data or device settings.

► Set up a PIN code on initial commissioning.

► Only pass the PIN code on to users who are entitled to operate or configure the device.

2. Once set up on the device, enter the four-digit PIN code:

⇨ The main screen is displayed (in this case: three planned measurements):
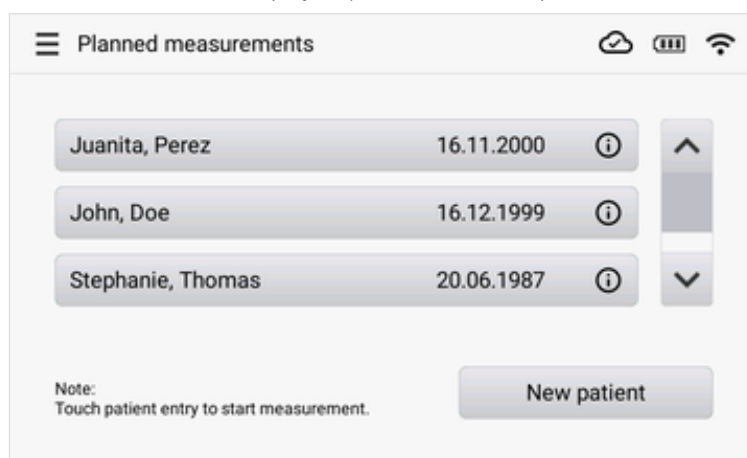
3. Then proceed as follows:

    ► Call up patient data → Calling up patient data

    ► Measure bioimpedance → Measuring

Saving energy If the device is not operated for an extended period, it will automatically switch to standby mode after a set period of time → Setting the standby timer. To directly switch the device to standby mode, proceed as follows:

1. Press and hold the ⏻ key of the monitor until the **Power** dialog window is displayed.
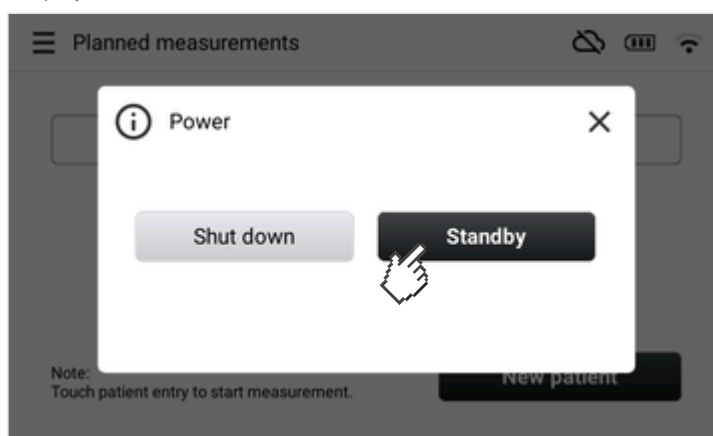
2. Press the **Standby** key.

⇨ The screen goes out.

⇨ To switch the screen on again, briefly press the ⊙/⊙ key of the monitor.

Switching off the device

1. Press the ⊙/⊙ key of the monitor.

⇨ The **Power** dialog window is displayed:
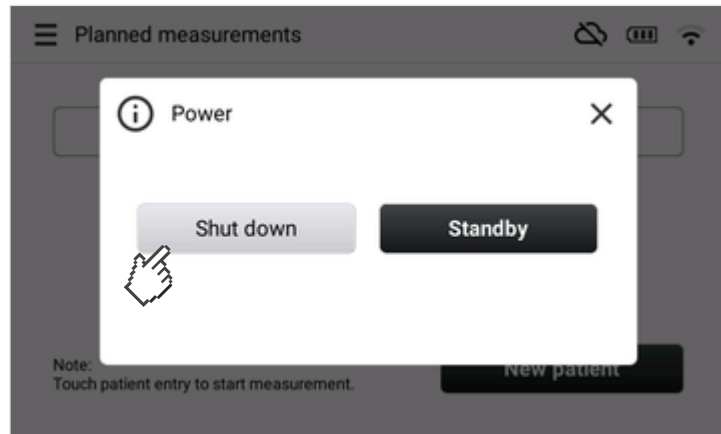
2. Press the **Shut down** key.

⇨ Rechargeable battery operation: The device shuts down.

⇨ Power supply operation: The rechargeable batteries of the device (monitor and measuring mat) are charged. Once the charging process is complete, the device shuts down.

NOTE

Connect the device to the power supply again after each mobile use (rechargeable battery operation) to ensure that the rechargeable batteries of the device are recharged.

6.2 Calling up patient data

→ Searching for patient data
→ Scanning patient ID
→ Creating patient data

To perform bioimpedance measurement, patient data must first be called up. The measuring results are assigned to the patient data and submitted to the **seca analytics 125** software for analysis.

Use the options described below to call up patient data.

Searching for patient data
You can search for patient data manually in the **seca analytics 125** software by entering the patient's name on the device.

✓ Connection to **seca analytics 125** software is active

✓ Main screen is displayed

1. Press the **New patient** key.
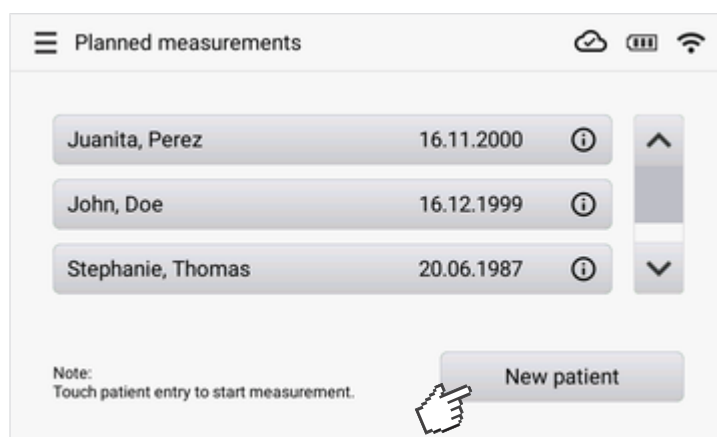
2. Press the 🔍 input field.
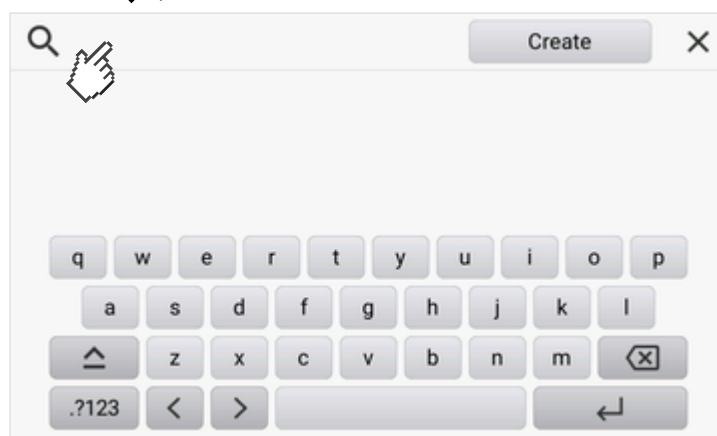
⇨ A screen keypad is displayed

3. Begin making the entry.
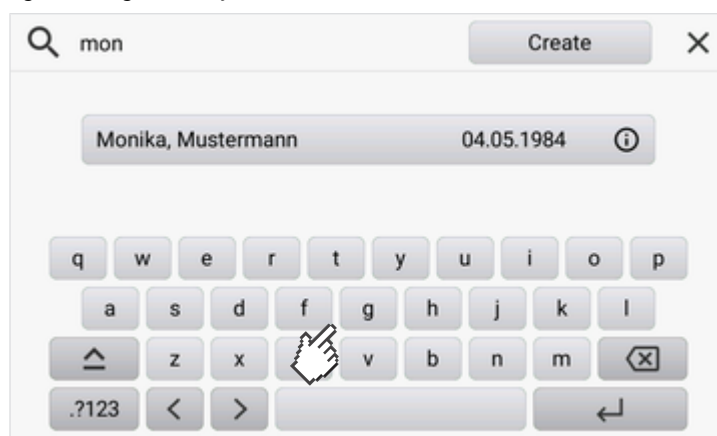
⇨ The search for patient data starts automatically.

⇨ If you complete the entry or interrupt it for more than three seconds, hits will displayed.

NOTE

If there are more than three hits, a button is displayed with the number of hits. Press the button to view the hit list (names and dates of birth, max. 20 hits).

4. Select the desired entry.

5. Perform bioimpedance measurement ➜ Measuring.

Scanning patient ID If you use barcodes or RFID tags for patient identification, you can scan them on the device to call up patient data in the **seca analytics 125** software.

✓ Connection to **seca analytics 125** software is active

✓ Barcode or RFID tag reader is connected to the device

✓ Main screen is displayed

1. Scan the patient's barcode or RFID tag.
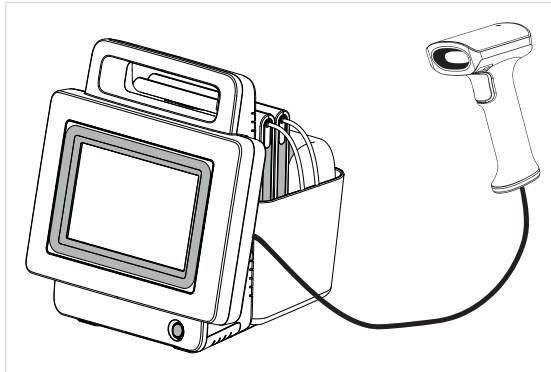
⇨ The patient data are displayed.

2. Press the **Measure now** key.

3. Perform bioimpedance measurement ➜ Measuring.

Creating patient data If there is not yet any data available for a patient in the **seca analytics 125** software, you can create this directly on the device. The patient data are transmitted to the **seca analytics 125** software together with the measuring results and saved there.

✓ Main screen is displayed

✓ Patient data are known

> **NOTICE!**
> **Inconsistent measuring results**
>
> If you create patient data multiple times, this can lead to the incorrect assignment of measuring results and falsify the analysis.
>
> ► Use the search function described in these instructions for use to call up patient data from the **seca analytics 125** software.
>
> ► Only create patient data on the device if you are sure that they do not yet exist in the **seca analytics 125** software.

1. Press the **New patient** key.
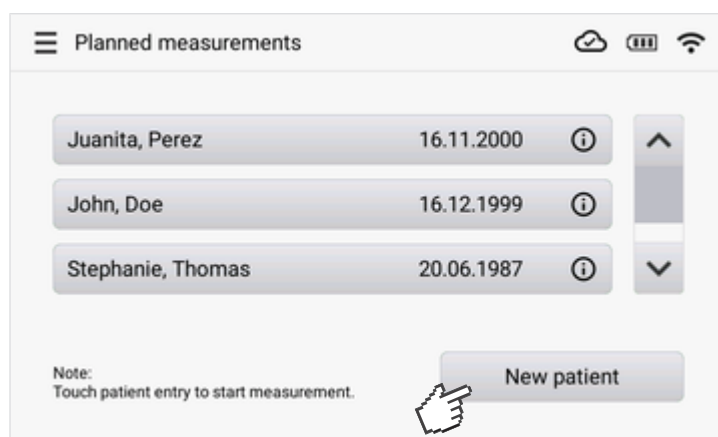
2. Press the **Create** key:
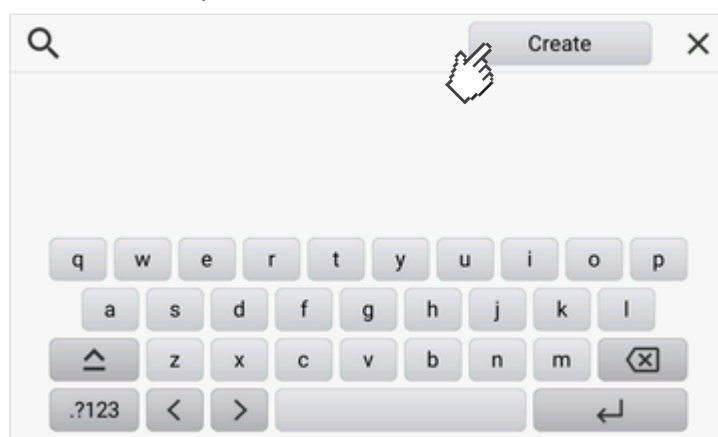
3. Enter the patient's last and first name, followed by the date of birth (in this case: last name):

4. Confirm each entry with the ❯ key.

5. Enter the patient's gender and ethnicity.

   NOTE

   Bioimpedance analysis is based on comparison with reference populations. Information on gender and ethnicity are required for meaningful analysis. Always enter gender and ethnicity in consultation with your patient.

   ⇨ The patient data entered are displayed:

6. Press the **Measure now** key.

7. Perform bioimpedance measurement → Measuring.

6.3 Using the "Planned measurements" list

→ Creating the "Planned measurements" list on the device
→ Editing the "Planned measurements" list in the seca analytics 125 software
→ Calling up patient data from the "Planned measurements" list
→ Removing patient data from the "Planned measurements" list

The **Planned measurements** list allows you to plan measurements for up to 30 patients. You can create the list manually on the device or in the **seca analytics 125** software.

The **Planned measurements** list remains available if there is temporarily no connection to the **seca analytics 125** software. This is for example the case if you perform measurements outside of the reception range of your WiFi network.

Creating the "Planned measurements" list on the device

You can create the **Planned measurements** list directly on the device. To do so, proceed as follows:

✓ Device is switched on and online

✓ Connection to **seca analytics 125** software is active

1. Call up the patient data as described in the section → Calling up patient data.

   ⇨ The patient data are displayed:

2. Press the **Add to list** key.

⇨ The entry is displayed in the **Planned measurements** list.
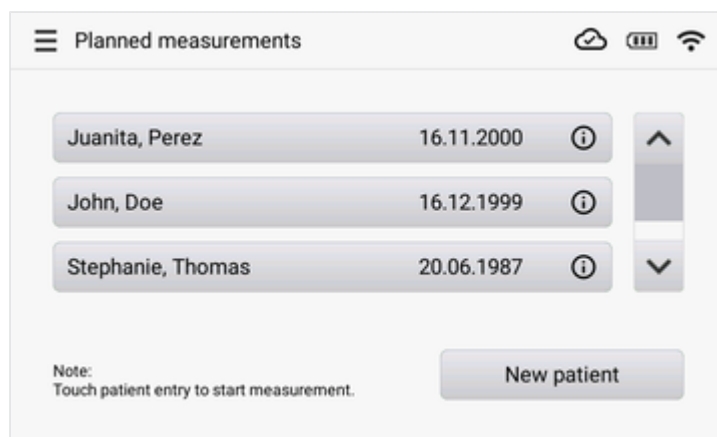
3. Repeat the process for all patients for whom the measurements are intended.

Editing the "Planned measurements" list in the seca analytics 125 software

You can call up and edit the **Planned measurements** list in the **seca analytics 125** software. In this case the **seca analytics 125** software will directly access the list on the device.

✓ Device is switched on and online

✓ Connection to **seca analytics 125** software is active

1. Call up the device in the **seca analytics 125** software, as described in the instructions for use of the software.

2. Edit the **Planned measurements** list on the device, as described in the instructions for use of the software.

⇨ Changes are displayed both in the software and on the device.

Calling up patient data from the "Planned measurements" list

To call up patient data in the **Planned measurements** list, proceed as follows:

1. Press the ∧ or ∨ key until the desired patient data are visible:

2. Select the desired entry.
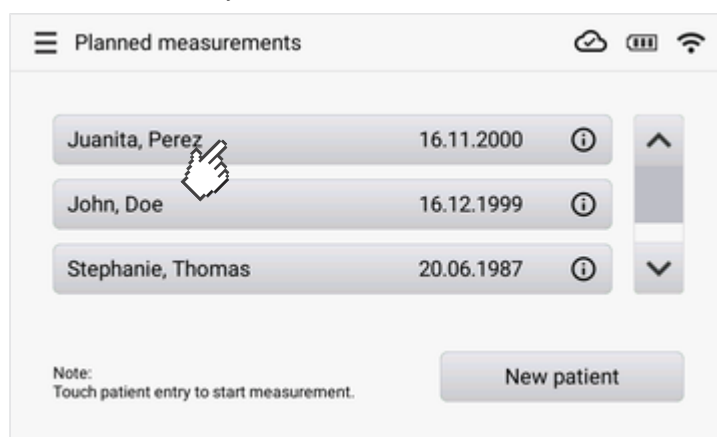
NOTE

If you wish to view details for a data record, press the ⓘ symbol in the relevant entry.

3. Perform bioimpedance measurement → Measuring.

Removing patient data from the "Planned measurements" list

To remove patient data from the **Planned measurements** list, proceed as follows:

1. Press the ∧ or ∨ key until the desired patient data are visible:

2. Press the ⓘ symbol in the desired entry.
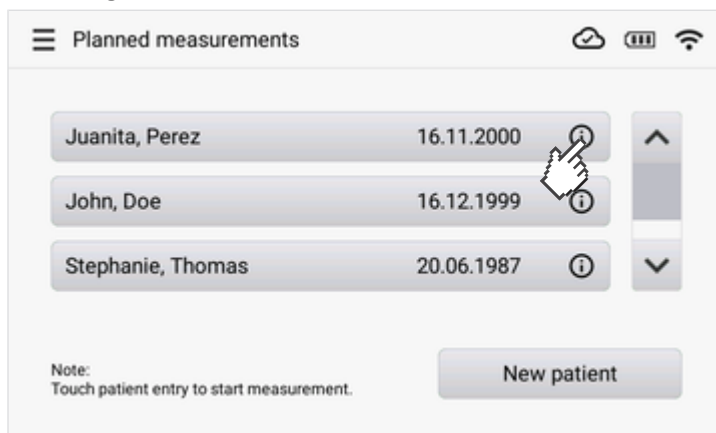
3. The details of the entry are displayed.
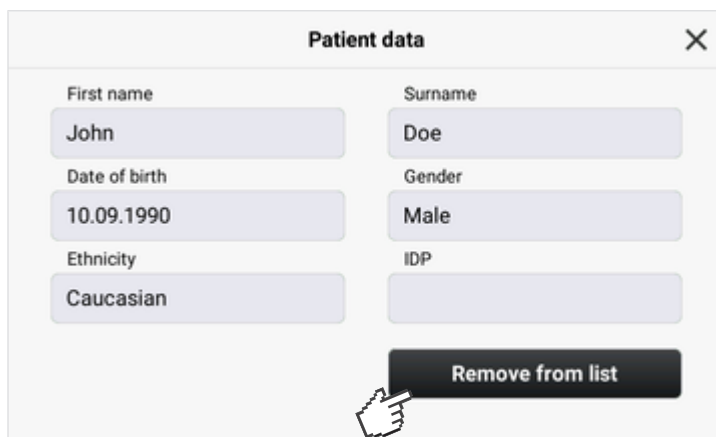
4. Press the **Remove from list** button.

⇨ The entry is no longer displayed.

   NOTE

   The patient data have only been deleted from the device; you can call them up again in the **seca analytics 125** software at any time.

6.4   Measuring

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

► Set up the device so that it cannot fall on patients.

► Route the cable of the measurement accessory so that the patient cannot become entangled or be choked.

► The device has **no** alarm function. Never leave the patient unattended during a measurement.

► Always connect only one individual patient to the device for each measurement procedure.

After you have selected a patient (→ Calling up patient data, → Using the "Planned measurements" list), a confirmation question about contraindications will be displayed.
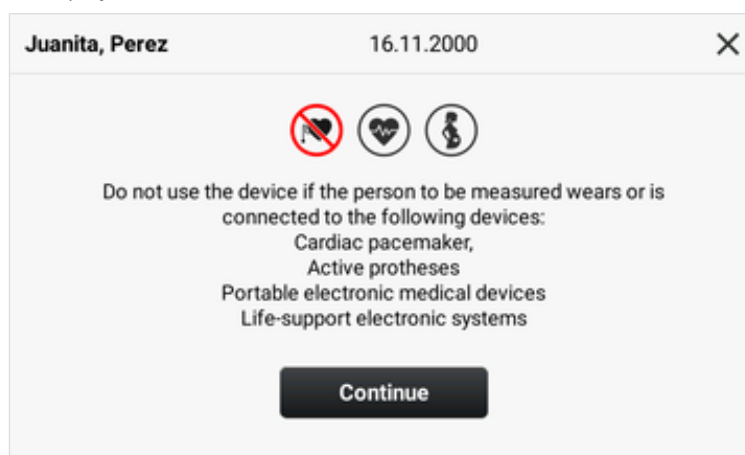
1. Check whether one or more of the listed contraindications apply to your patient.

    ⇨ You have the following options for continuing:

    ► None of the contraindications listed apply: Press **Continue** key

    ► At least one of the contraindications listed apply: Press ✕ key to cancel the measurement procedure

Connecting the measuring mat (measuring whole body)

You can perform bioimpedance measurement according to the 8-point method (measuring the whole body). To do so, proceed as described below:

✓ Patient data are called up → Calling up patient data

✓ None of the contraindications apply

NOTE

The device will assist you during the procedure. Follow the relevant instructions on the monitor. If you press the ⓘ symbol, you will see additional information.

1. Position the patient so that the patient's head is on your left-hand side.

Position patient

2. Attach two adhesive electrodes to each of the patient's hands and feet.
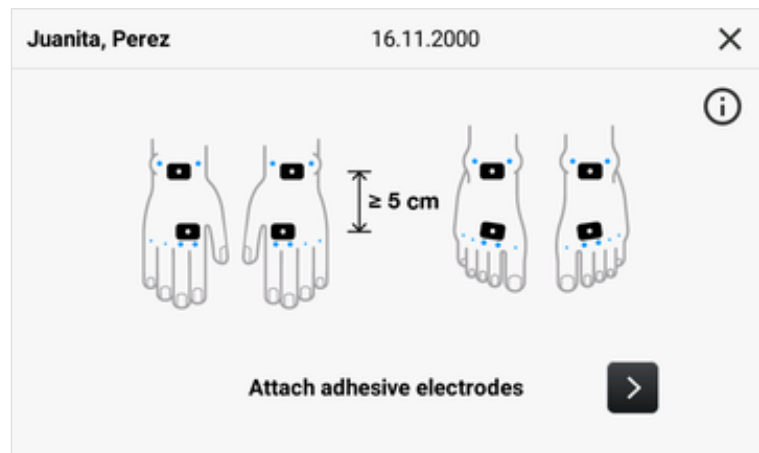
Attach adhesive electrodes

NOTE

The adhesive electrodes must be attached at a distance of approx. 5 cm from each other. If this not possible, e.g. with children, the distal adhesive electrodes can be attached to the palms and the soles of the foot.

3. Lay the measuring mat on the patient's knees.

    ► The side with the writing on it should be facing upwards

    ► The keypad should be facing the user

4. Ensure that the **Only right half of body** checkbox is deactivated.

Connect electrode cables

5. Connect the measuring mat to the electrodes:

► Place the push-button adapters on the electrodes (black: proximal; red: distal)

► Arrange the electrode cables so that they do not cross over one another

► Do not route electrode cables over or underneath the patient

6. Ask the patient to do the following during the measurement:

► Lie for approx. 10 minutes before measurement

► Hold arms and legs away from the body

► Lie still

► Do not touch metal parts on the bed surface

7. Press the ❯ key.

⇨ The device performs an electrode test.

8. Wait until the electrode test has finished.

9. Ensure that the measuring mat is connected to the monitor.

⇨ The 📶 WiFi symbol is displayed, see illustration.

10. Start the measurement ➜ Perform a measurement.

Connecting the measuring mat (measuring right half of body)

You can perform bioimpedance measurement according to the 4-point method (measuring the right half of the body). To do so, proceed as described below:

✓ Patient's data record is called up ➜ Calling up patient data

✓ None of the contraindications listed apply

> **NOTE**
>
> The device will assist you during the procedure. Follow the relevant instructions on the monitor. If you press the ⓘ symbol, you will see additional information.

1. Position the patient so that the patient's head is on your left-hand side.

2. Attach two adhesive electrodes to the patient's right hand and two to the patient's right foot.
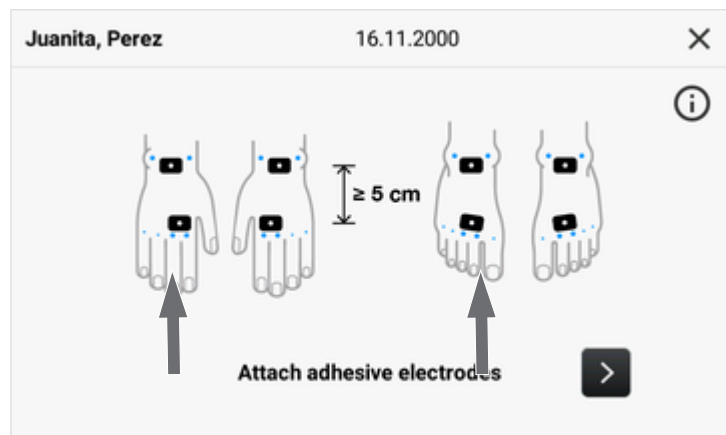
> **NOTE**
>
> The adhesive electrodes must be attached at a distance of approx. 5 cm from each other. If this not possible, e.g. with children, the distal adhesive electrodes can be attached to the palms and the soles of the foot.

3. Lay the measuring mat on the patient's knees.

   ► The side with the writing on it should be facing upwards

   ► The keypad should be facing the user

4. Ensure that the **Only right half of body** checkbox is activated.

5. Connect the measuring mat to the electrodes:
    - ► Place the push-button adapters on the electrodes (black: proximal; red: distal)
    - ► Arrange the electrode cables so that they do not cross over one another
    - ► Do not route electrode cables over or underneath the patient
6. Ask the patient to do the following during the measurement:
    - ► Lie for approx. 10 minutes before measurement
    - ► Hold arms and legs away from the body
    - ► Lie still
    - ► Do not touch metal parts on the bed surface
7. Press the ❯ key.
    - ⇨ The device performs an electrode test.
8. Wait until the electrode test has finished.

9. Ensure that the measuring mat is connected to the monitor.
    - ⇨ The WiFi 🛜 symbol is displayed, see illustration.
10. Start the measurement ➜ Perform a measurement.

Perform a measurement

✓ The measuring mat is connected

✓ The automatic electrode test was successful

1. Press the **Start** key (in this case: 8-point method).
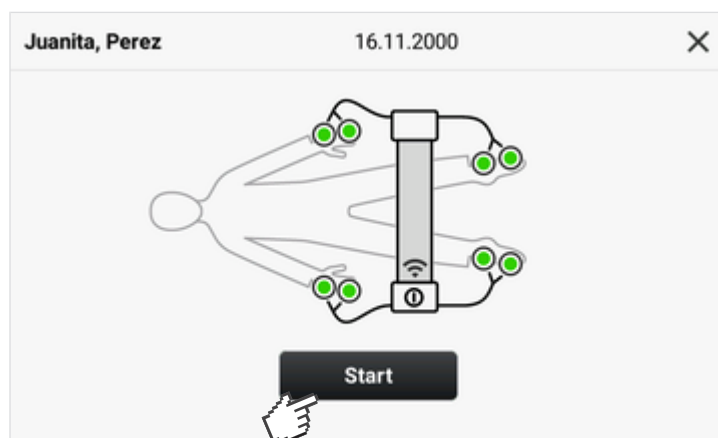
⇨ The measurement starts.

⇨ The measuring progress is displayed.
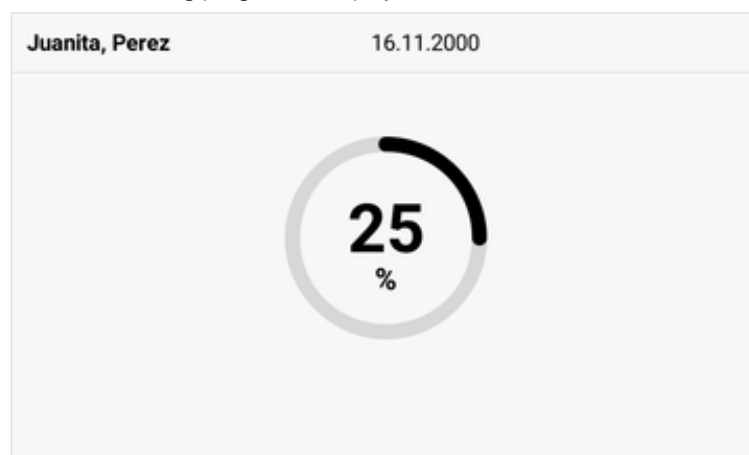
2. Wait until the measurement has finished.

⇨ The measuring results are displayed:
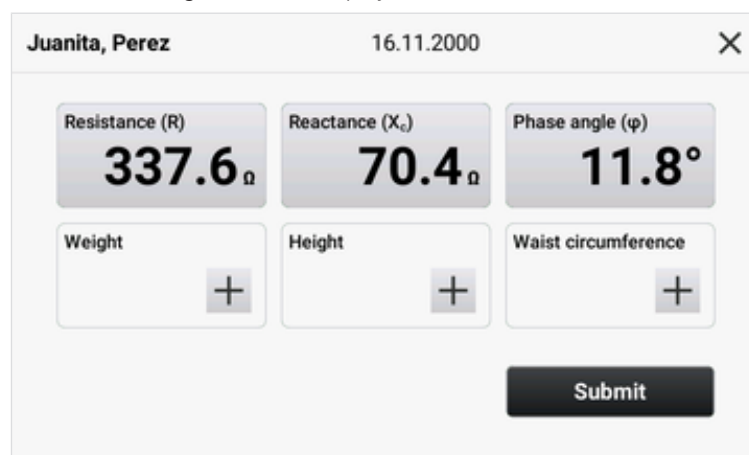
⇨ You have the following options for continuing:

► → Adding weight, height, waist circumference (optional)

► Save measurement in the **seca analytics 125** software: Press the **Submit** key

3. If set up on the device, enter your user-ID (depending on configuration).

> **NOTE**
>
> The device performs a quality check on every bioimpedance measurement. If the bioimpedance measurement does not satisfy the quality requirements, this will be displayed on the monitor. Further information is available here: → Plausibility check.

Adding weight, height, waist circumference (optional)

Before submitting the results of the bioimpedance measurement to the **seca analytics 125** software, you can add the patient's **Weight**, **Height** and **Waist circumference**.

✓ The bioimpedance measurement was carried out successfully

✓ The measuring results are displayed

> **NOTE**
>
> Entry directly on the device is optional. You can add the data in the **seca analytics 125** software at a later date.

1. Press the desired parameter (in this case: **Weight**).

⇨ A number keypad is displayed.

2. Enter the weight value.

3. Press the ✓ key.

⇨ The value is adopted.

4. Repeat the process for the parameters **Height** and **Waist circumference**.

| Juanita, Perez | 16.11.2000 | ✕ |

| Resistance (R) | Reactance (X$_c$) | Phase angle (φ) |
| 337.6 Ω | 70.4 Ω | 11.8° |

| Weight | Height | Waist circumference |
| 65 kg | 170 cm | 80 cm |

Submit

5. Press the **Submit** key.

   ⇨ The measuring results and added parameters are submitted to the **seca analytics 125** software.

Ending measurement

✓ No repeat measurement is foreseen for the current patient

1. Remove the electrode cables from the push-button electrodes.
2. Suspend the measuring mat in the magnetic catch of the monitor.
3. Carefully detach the push-button electrodes from the patient's skin.
4. Dispose of the push-button electrodes ➜ Disposing of consumables.

Viewing the bioimpedance measurement analysis

The **seca analytics 125** software is required to display bioimpedance measured results and analyses ➜ Compatible seca products.

7 CONFIGURATION

7.1 Calling up/exiting a menu

1. Press the ☰ key.
   ⇨ The **Settings** menu is displayed:

☰ Settings	✕
Device	>
WiFi	>
Connection seca analytics 125	>
Instructions for use	>

2. To exit the menu, press the ✕ key.
   ⇨ The main screen is displayed.

7.2 Setting up a network connection

Managing WiFi connections

Setting up a WiFi connection
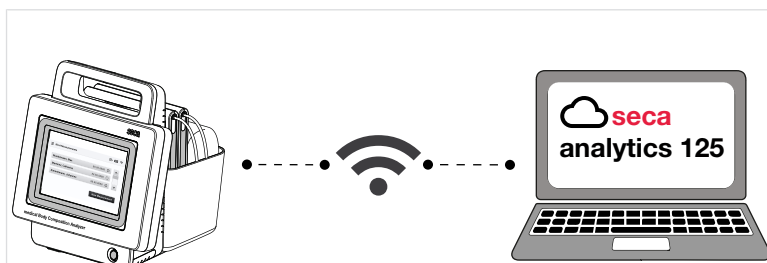
For mobile use you can integrate the device in a WiFi network or connect it to a mobile WiFi hotspot.

17-10-05-409-002_2024-10S

To be able to use the full functional scope, the device must then be connected to the **seca analytics 125** software → Setting up a connection to the seca analytics 125 software.

✓ WiFi access data are available

✓ The device is disconnected from any WiFi networks already set up → Disconnecting the WiFi connection

✓ The measuring mat is suspended in the magnetic catch of the monitor

> **NOTICE!**
> **Data loss, access to data by unauthorized persons**
> ► Note the instructions on IT security in our White Paper entitled "Cyber Security". The document can be found as a download in the Support area at www.seca.com.

1. Press the ☰ key.

2. Press the **WiFi** menu item.

   ⇨ The WiFi function is activated at the factory.

   ⇨ The device automatically starts to search for WiFi networks.
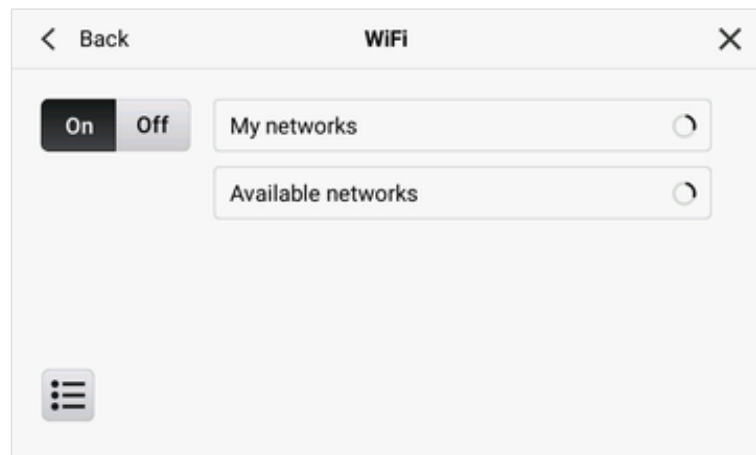
   ⇨ Found WiFi networks are displayed in the **Available networks** list.
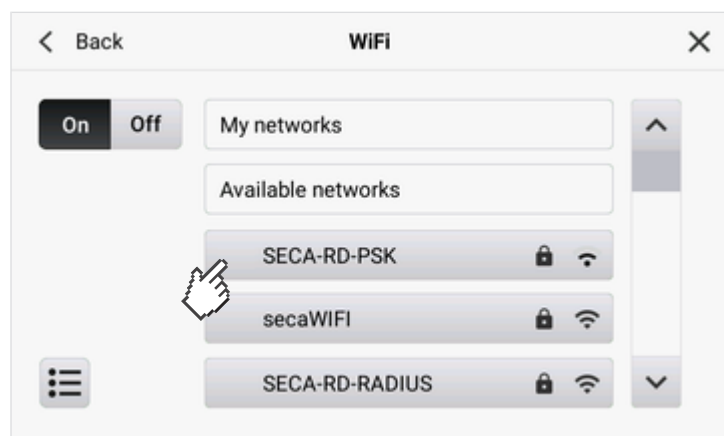
3. Press the desired entry in the **Available networks** list.

4. Enter the access data:

   ► Network with PSK encryption: Enter network code

   ► Network with EAP-PEAP encryption: Enter user name and password
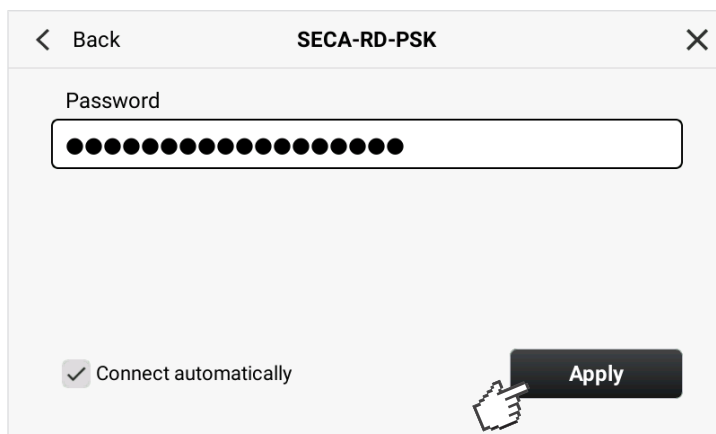
5. Press the **Connect** key.

   ⇨ The WiFi network is displayed in the **My networks** list.
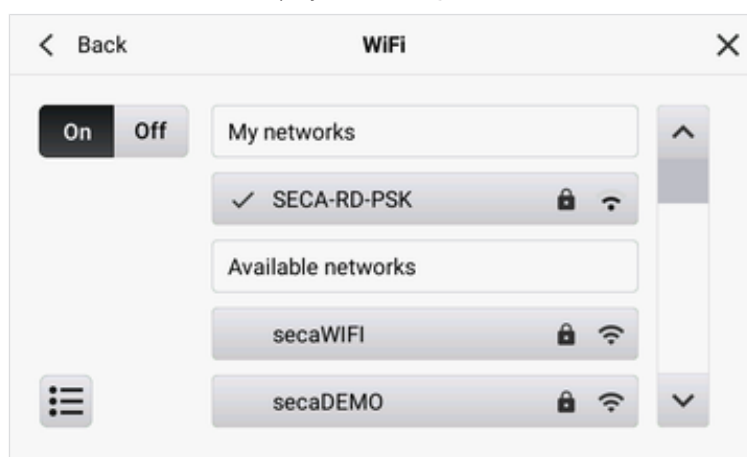
6. If wished, connect the device to further networks in the **Available networks** list.

   ⇨ These WiFi networks are also added to the **My networks** list.

   ⇨ The device automatically connects – depending on the reception range – to one of the WiFi networks displayed under **My networks**.

7. You can deactivate the WiFi function with the **Off** key.

   ⇨ The WiFi function is deactivated.

   ⇨ The **My networks** list is retained.

   ⇨ The WiFi function can be activated again with the **On** key.

Disconnecting the WiFi connection

If you wish to manually switch to another WiFi network in the **My networks** list or to add a further WiFi network to the list, you must disconnect the existing WiFi connection.

1. Press the ☰ key.

2. Press the **WiFi** menu item.

   ⇨ The network currently connected is displayed.

3. Press the active network in the list **My networks**.
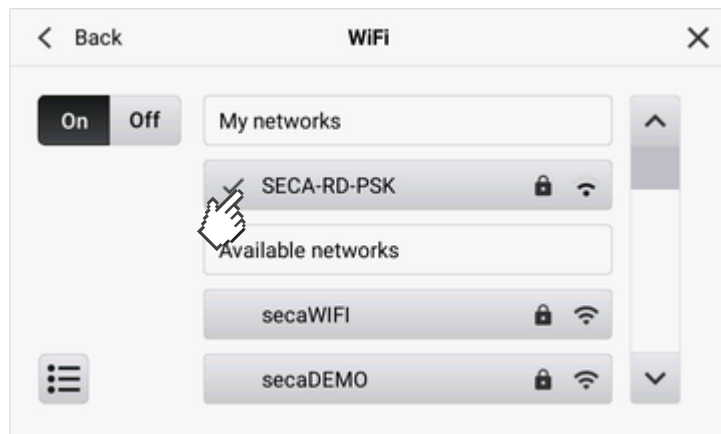
⇨ Details of the network are displayed:
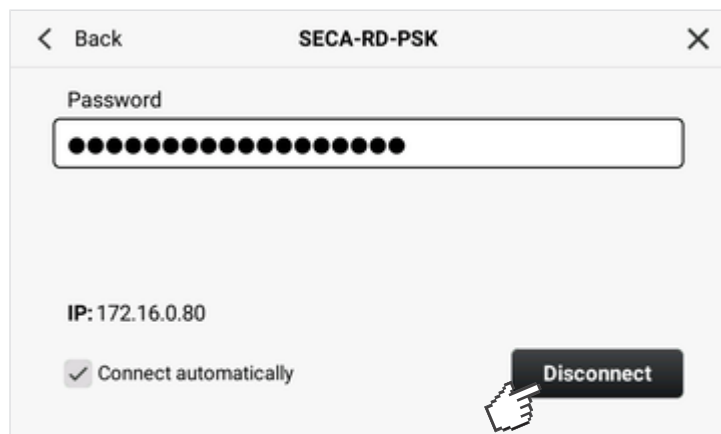
4. Press the **Disconnect** key.

    ⇨ The connection is disconnected.

    ⇨ The network is retained in the **My networks** list, and the ✓ symbol is no longer displayed.

5. To reconnect the device with the network, press the relevant entry in the **My networks** list.

Setting up a LAN connection
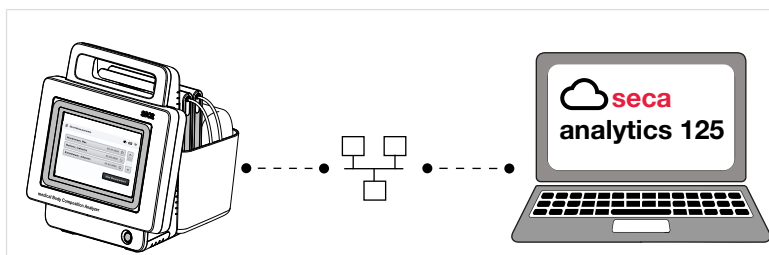
For stationary use, e.g. in a specific treatment room of your practice, you can integrate the device in a LAN network.

To be able to use the full functional scope, the device must then be connected to the **seca analytics 125** software → Setting up a connection to the seca analytics 125 software.

✓ Protective cap on the rear of the device has been removed (e.g. with a small slot-head screwdriver)

✓ Device is connected to a network connection with a LAN cable

✓ For a static network connection (manual setup): Network data are available

NOTICE!
Data loss, access to data by unauthorized persons

► Note the instructions on IT security in our White Paper entitled "Cyber Security". The document can be found as a download in the Support area at www.seca.com.

1. Press the ☰ key.

2. Select the menu item **Device > LAN**.

⇨ The LAN function is activated at the factory.

⇨ The **DHCP** checkbox is activated at the factory.

⇨ The LAN connection is set up automatically.

NOTE

If you wish to set up a static network connection, deactivate the **DHCP** checkbox. Set up the connection according to our White Paper entitled "Cyber Security" and the regulations of your institution.

3. Press the **Save** key.

⇨ The change is saved.

4. You can deactivate the LAN connection with the **Off** key.

⇨ If **DHCP** is activated: The network data are discarded.

⇨ If **DHCP** is deactivated: The network data are retained.

Setting up a connection to the seca analytics 125 software
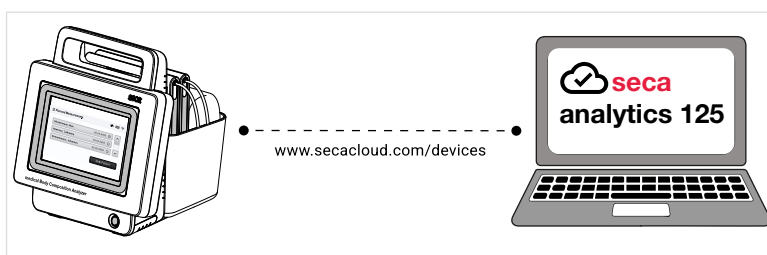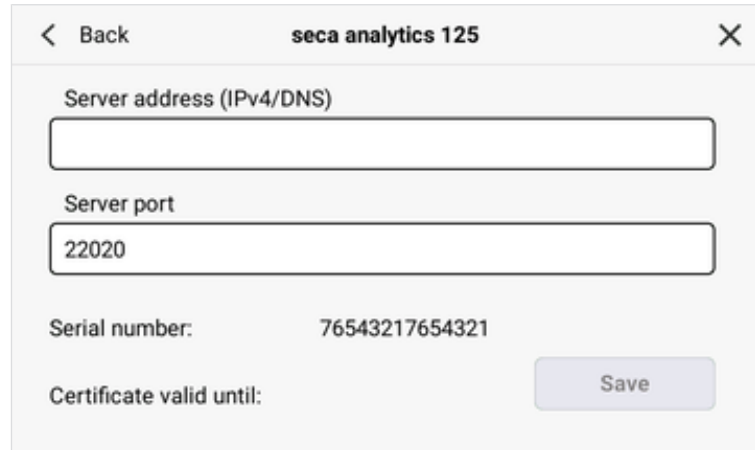
If the device is connected to the **seca analytics 125** software, the following functions are available, in the **seca analytics 125** software:

• View patient data

• Save measuring results

• Analyze measuring results
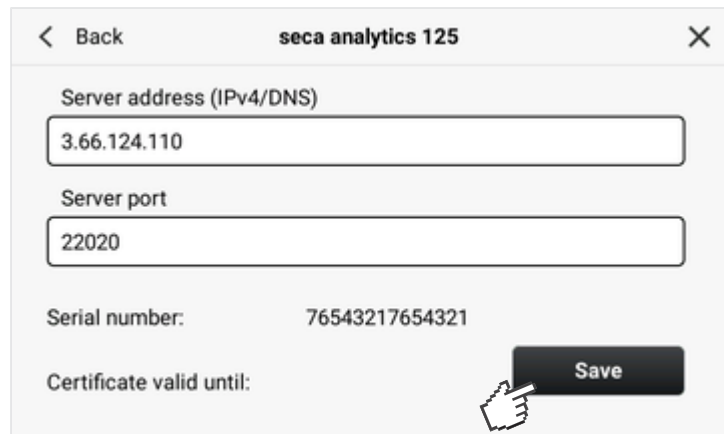
To connect the device to the **seca analytics 125** software, proceed as follows:

✓ The device is connected to a network via LAN or WiFi

✓ The server address (IPv4 or DNS) and server port for the **seca analytics 125** software are known

1. Press the ☰ key.

2. Select the **Connection seca analytics 125** menu item.

⇨ The serial number of the device is displayed.

3. In the **Server address (IPv4/DNS)** field enter the server address (IPv4 or DNS) of the analysis software.

4. If necessary, edit the **Server port** (default: 22020, recommended) for the analysis software.

5. Press the **Save** key.

⇨ The connection data are saved and submitted to the **seca analytics 125** software.

6. Activate the connection in the **seca analytics 125** software, as described in its instructions for use.

⇨ A certificate is generated in the **seca analytics 125** software.

⇨ If a validity date for the certificate is displayed on the device, the connection is set up.

NOTE

The connection data are retained when network connections (WiFi/LAN) are deactivated. When the network connections reactivated, the connection to the **seca analytics 125** software thus does not need to be set up again.

Changing workflow settings

Selecting the language style

Selection of the language style influences the texts of the user interface of the device. Functions do not change. The following table illustrates the differences:

Medical	Fitness
Patient	Customer

NOTE

To utilize these instructions for use, please select the **Medical** option on the device, and the designations on the user interface will then correspond to those in the instructions for use.

1. Press the ☰ key.

2. Select the menu item **Device > Workflow settings**.

3. In the **Language style** field press the ⌄ key and select the desired setting in the dropdown menu:

4. Press the **Save** key.

   ⇨ The change is saved.

Activating user identification

You can specify whether a user name must be entered when completing a measurement procedure. This way you can ensure the traceability of measurement procedures. If this function is activated, a dialog window for entry of the user name will appear at the end of every measurement procedure.

> **NOTE**
>
> If this function is activated, the user name is entered in a text field manually. There is no authentication here, e.g. against a user database.

1. Press the ☰ key.

2. Select the menu item **Device > Workflow settings**.

3. In the **User ID** field press the ∨ key and select the desired setting in the dropdown menu:
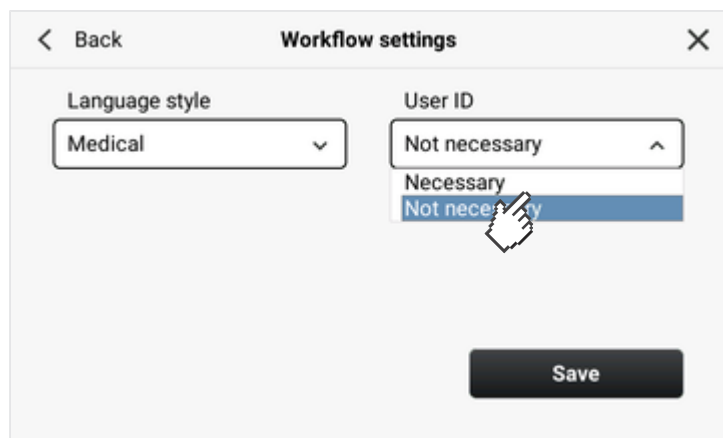
4. Press the **Save** key.

   ⇨ The change is saved.

7.3 Device settings

→ Setting up/changing the PIN code
→ Adjusting the display settings
→ Changing the audio settings
→ Setting the display language
→ Changing regional settings
→ Changing units of measurement
→ View history
→ Viewing system information
→ Factory settings
→ Performing software updates
→ Enabling/locking device for external access (VNC)
→ Exporting logfiles/audit trail

Setting up/changing the PIN code

NOTICE!
Data access by unauthorized persons

If no PIN code was set up or the PIN code is easily accessible, there is the risk that unauthorized persons might access patient data or device settings.

► Set up a PIN code on initial commissioning.

► Only pass the PIN code on to users who are entitled to operate or configure the device.
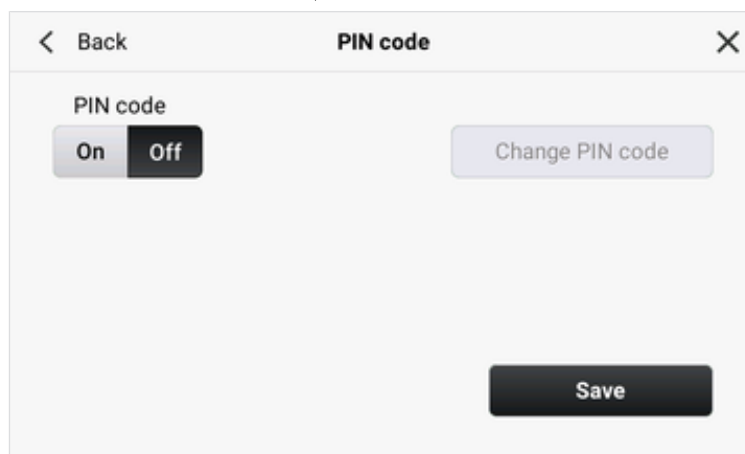
NOTICE!
Data loss, access to data by unauthorized persons

► Note the instructions on IT security in our White Paper entitled "Cyber Security". The document can be found as a download in the Support area at www.seca.com.

You can set up the device so that a PIN code is queried during the switch-on procedure. No PIN code is set up at the factory. To set up a PIN code and activate the PIN code query, proceed as follows:

1. Press the ☰ key.

2. Select the menu item **Device > PIN code**.

3. Activate the function with the **On** key.

4. Press the **Change PIN code** key.

5. Enter a PIN code.

6. Enter the PIN code again.

7. Confirm the **PIN code successfully updated** message with **Ok**.

    ⇨ The PIN code is set up and the PIN code query is active.

    NOTE

    If you deactivate the function (**Off** key), the PIN code will be deleted. To reactivate the function, a new PIN code must be assigned.

Adjusting the display settings

Setting the display brightness

1. Press the ☰ key.

2. Select the menu item **Device > Display settings**.
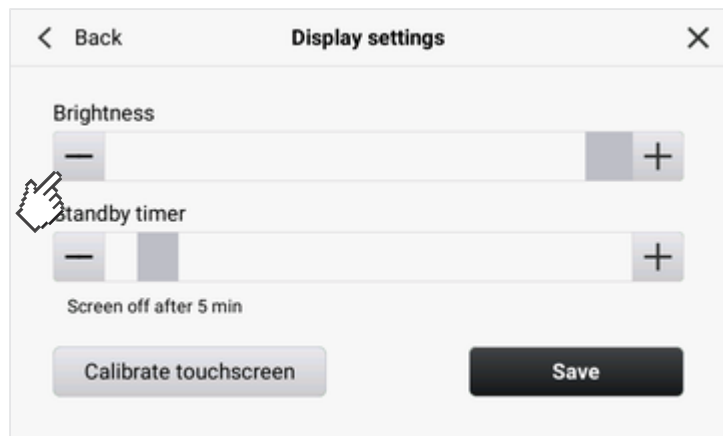
3. Under **Brightness** press the ━ or ✚ key until you reach the desired setting.

    ⇨ Changes are directly visible whenever a key is pressed.

4. Press the **Save** key.

    ⇨ The change is saved.

Setting the standby timer

You can specify the time period after which the device switches to standby.

1. Press the ☰ key.

2. Select the menu item **Device > Display settings**.
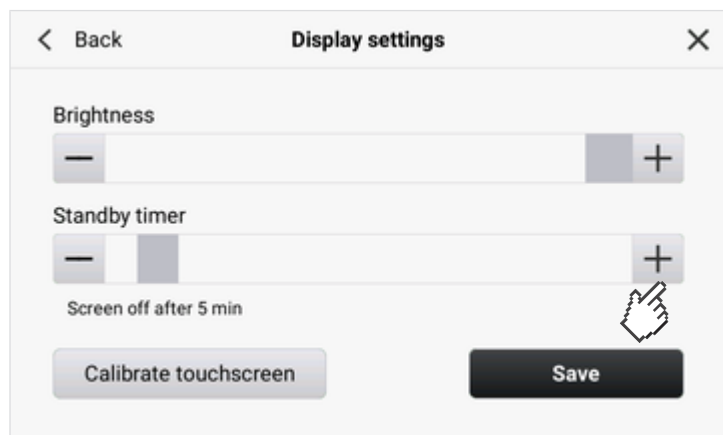
3. Under **Standby timer** press the ━ or ✚ key until you reach the desired setting.

⇨ If no entry is made during the time period selected here, the device will switch to standby.

4. Press the **Save** key.

⇨ The change is saved.

Calibrating the display

1. Press the ☰ key.

2. Select the menu item **Device ⟩ Display settings**.
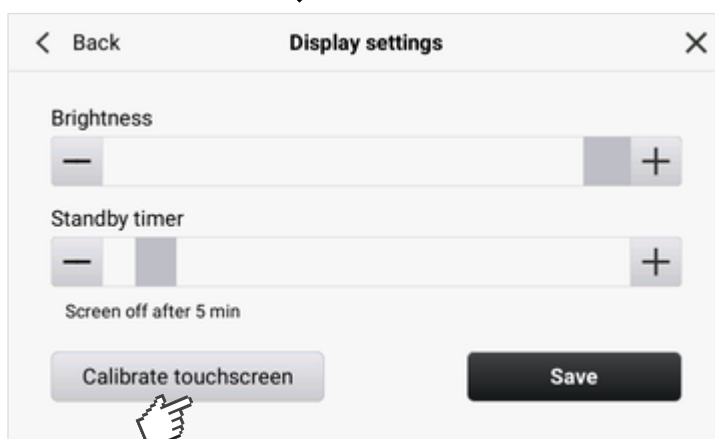
3. Press the **Calibrate touchscreen** key.

4. Confirm that you wish to proceed.

⇨ The calibration display appears.
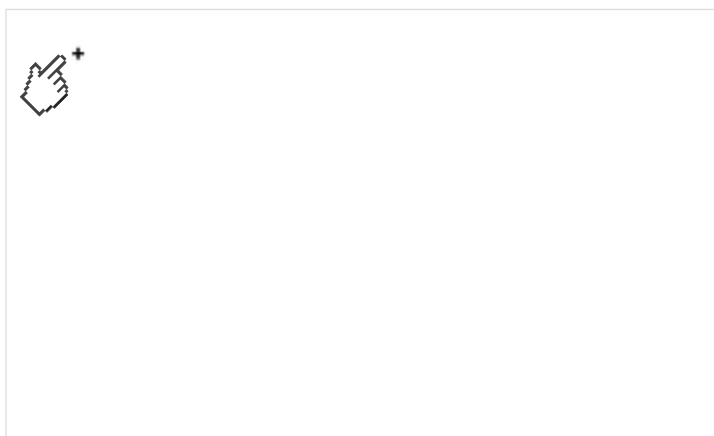
5. Press the ✛ symbol.

⇨ The symbol changes position.

6. Press the ✛ symbol until you are prompted to confirm calibration.

7. Confirm calibration.

⇨ The display is calibrated.

NOTE

If calibration is not confirmed, the procedure restarts after a few seconds.

Changing the audio settings You can set the volume for **Warning & info tones** and for **Key sounds**:

1. Press the ☰ key.
2. Select the menu item **Device ❯ Audio settings**.

‹ Back	Audio settings	✕

Warning & info tones

— ▮ +

Key sounds

— ▮ +
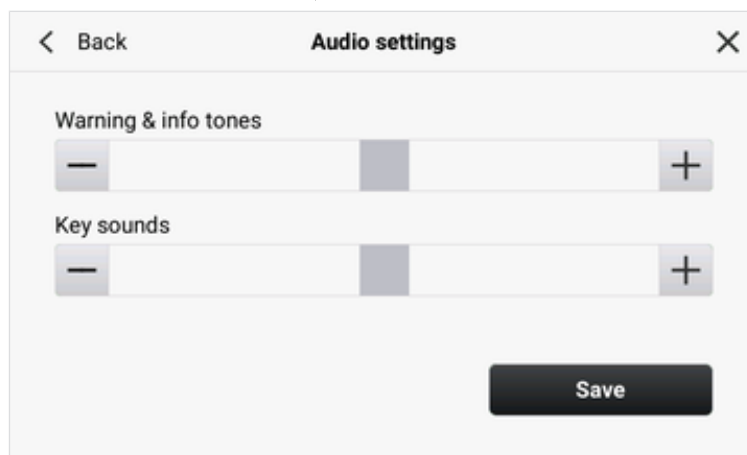
Save

3. Press the — or + key until you reach the desired setting.
   ⇨ Changes are directly audible whenever a key is pressed.
4. Press the **Save** key.
   ⇨ The change is saved.

Setting the display language
1. Press the ☰ key.
2. Select the menu item **Device ❯ Language**.

‹ Back	Language	✕

Deutsch   ∧

U.S. English   ✓

español

français

italiano   ∨
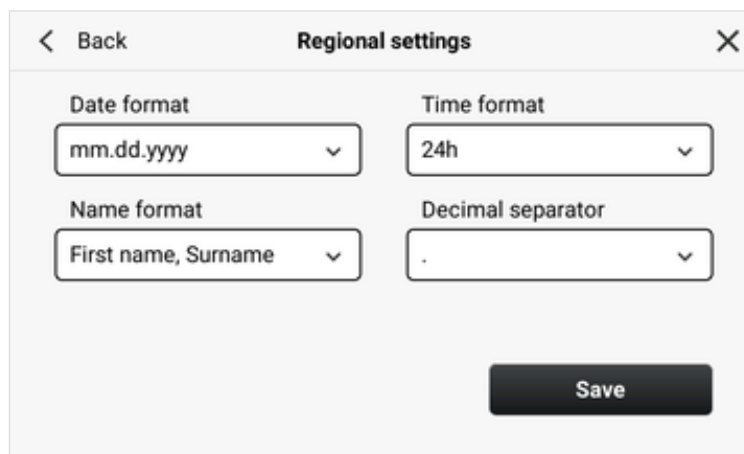
⇨ The active language is identified with the ✓ symbol.
3. Press the ∧ or ∨ key until the desired language is visible.
4. Press the desired language.
5. Confirm that you wish to proceed.
   ⇨ The selected language is active.

Changing regional settings

NOTE

The date and time cannot be set on this device. The settings are adopted from the **seca analytics 125** software ➔ Setting up a connection to the seca analytics 125 software.

1. Press the ☰ key.

2. Select the menu item **Device ❯ Regional settings**.

❮ Back	**Regional settings**	✕

Date format
| mm.dd.yyyy ⌄ |

Time format
| 24h ⌄ |

Name format
| First name, Surname ⌄ |

Decimal separator
| . ⌄ |

Save

3. Press each ⌄ key and select the desired setting in the dropdown menu:

   ▶ **Date format**

   ▶ **Time format**

   ▶ **Name format**

   ▶ **Decimal separator**

4. Press the **Save** key.

   ⇨ The change is saved.

Changing units of measurement

⚠ CAUTION!
Patient hazard

To prevent misinterpretations, measuring results for medical purposes must only be displayed and used in SI units (kilograms/grams, meters/centimeters). Some devices have the option of displaying measuring results in different units. This is purely an additional function.

▶ Only use measuring results in SI units.

▶ The user takes sole responsibility for the use of measuring results in non-SI units.

NOTE

Settings which you make under this menu item do not influence display of the units in the **seca analytics 125** software.

1. Press the ☰ key.

2. Select the menu item **Device ❯ Units**.

3. In the **Weight** field press the ⌄ key.
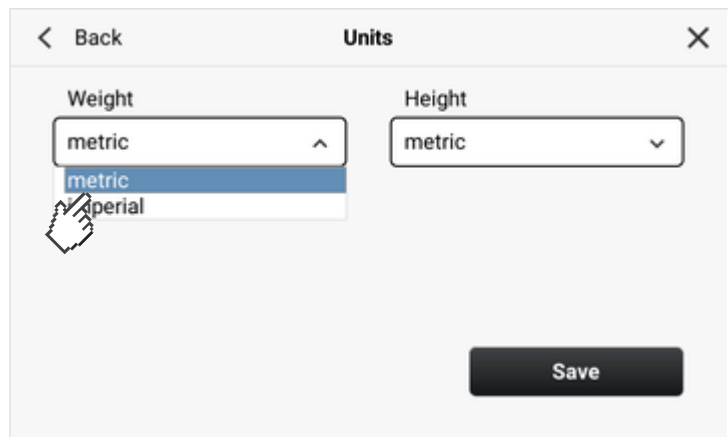
4. Press the desired setting in the dropdown menu.

5. In the **Height** field press the ∨ key.
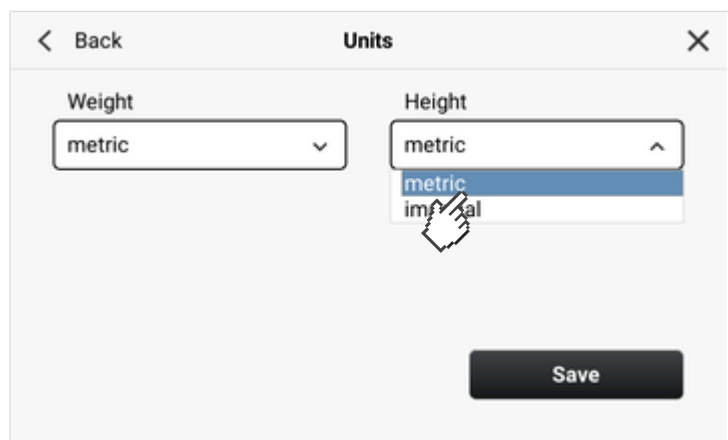
6. Press the desired setting in the dropdown menu.

7. Press the **Save** key.

   ⇨ The change is saved.

View history   You can check in the **History** menu whether all measurements were submitted to the **seca analytics 125** software. The list contains up to 50 measurements. Older measurements are overwritten.

>   **NOTE**
>   You can view details and analyses for the measurements in the **seca analytics 125** software.

1.   Press the ≡ key.

2.   Select the menu item **Device › History**.

‹ Back	**History**	✕
☁ Today	09:46 John Doe	
☁ 23.09.2024	14:29 Juanita Perez	
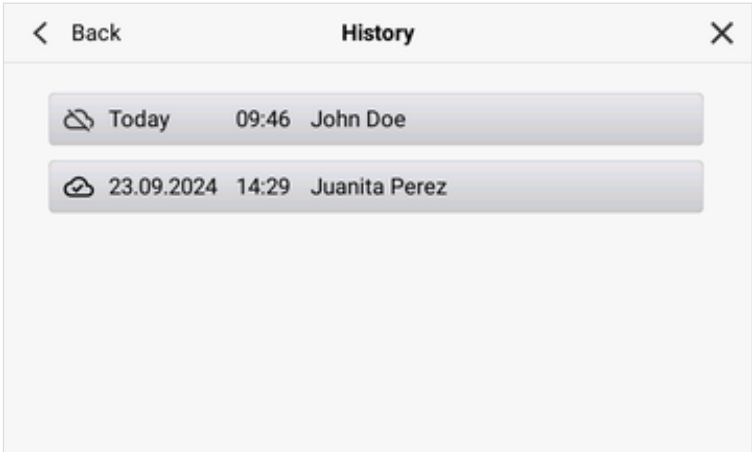
⇨   Measurements with the ☁ symbol were submitted to the **seca analytics 125** software.

⇨   Measurements with the ☁ symbol were not yet submitted to the **seca analytics 125** software, e.g. because the device had no network connection. The device will submit these measurements automatically as soon as it is connected to a network again.

3.   To close the view, press the ✕ key.

Viewing system information   1.   Press the ≡ key.

2.   Select the menu item **Device › System information**.

‹ Back	**System information**	✕

Details Monitor
Serial number:: 76543217654321
Software version: 2.0.1001
Certificate: seca analytics 125: No certificate installed
Version of instructions for use: 1.0.2
Version of GUI texts: 1.0.26 (medical)
Monitor hardware ID:
Linux version: 4.19.299-jumpnow armv7l
Linux build: 270
Bootloader build: 242
Main board hardware version: 08-06-18-249-H
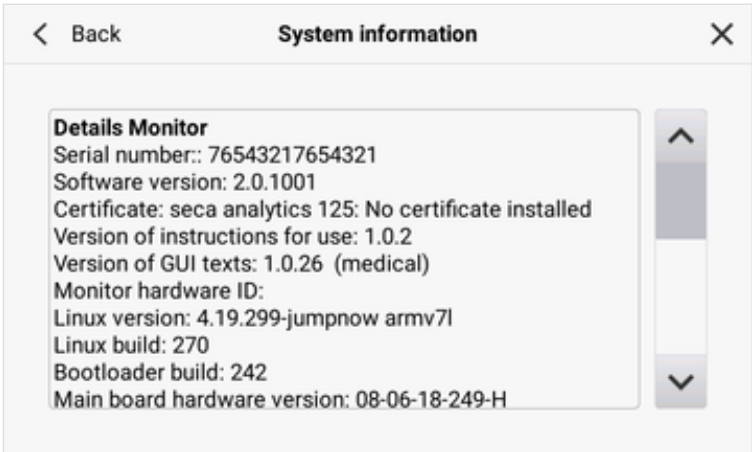
3.   Press the **System information** menu item.

4.   Press the ⌃ or ⌄ key to navigate in the system information.

5.   To close the view, press the ✕ key.

Factory settings

Overview of factory settings

You can reset the device to the following factory settings:

Function	Setting
Access lock: • **PIN code** • **Input prompt** **when device starts up**	 None Off
Display settings: • **Brightness** • **Standby timer**	 100 % 5 mins.
Workflow settings: • **Language style** • **User ID**	 Medical Off
Regional settings: • **Date format** • **Time format** • **Name format** • **Decimal separator**	 dd.mm.yyyy 24 h Last name, First name Comma
Audio settings: • **Warning & info tones** • **Key sounds**	 70 % 70 %
Units: • **Weight** • **Height**	 kg cm
LAN	On
DHCP	Activated
WiFi	On
Connection seca analytics 125: **Server address (IPv4/DNS)** **Server port**	 None 22020
Battery capacity, **Automatic switch-off at**	≤ 20 %
Language	English
Device name	[Serial number]

Resetting to the factory settings

To reset the device to the factory settings (→ Overview of factory settings), proceed as follows:

1. Press the ☰ key.

2. Select the menu item **Device ❯ Reset**.

```
┌─────────────────────────────────────────────┐
│  ‹  Back              Reset              ✕   │
├─────────────────────────────────────────────┤
│                                             │
│            Restoring factory settings.      │
│                                             │
│                                             │
│               ┌──────────────────┐          │
│               │   Reset device   │          │
│               └──────────────────┘          │
│                      🖑                       │
│                                             │
│                                             │
│                                             │
│                                             │
└─────────────────────────────────────────────┘
```
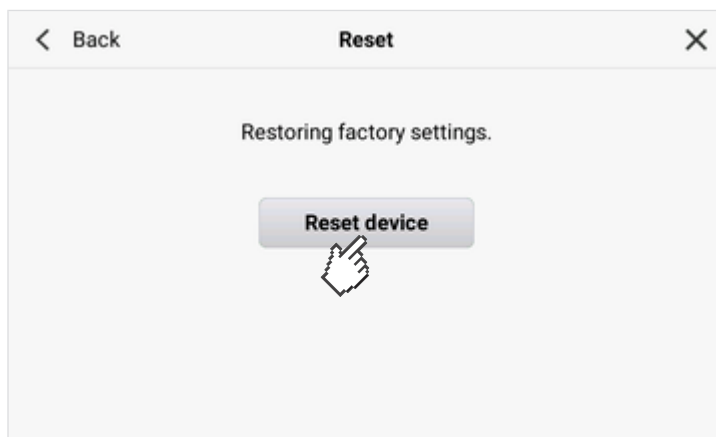
3. Press the **Reset device** key.

   ⇨ The device will be reset to the factory settings.

Performing software updates You can update the software of the monitor and the measuring mat using a USB memory stick. Current software packages are available to download under www.seca.com.

✓ The measuring mat is suspended in the magnetic catch of the monitor → Suspending the measuring mat in the magnetic catch

✓ All measurements were submitted to the **seca analytics 125** software → View history

✓ The USB memory stick (format: FAT 32) contains only the currently downloaded software package

1. Press the ☰ key.

2. Select the menu item **Device ❯ Software update**.

   ⇨ The software version currently in use is displayed.

```
┌─────────────────────────────────────────────┐
│  ‹  Back          Software update        ✕   │
├─────────────────────────────────────────────┤
│                                             │
│                                             │
│                 ┌──────────┐                │
│              ▪  │          │                │
│              ▪  │          │                │
│                 └──────────┘                │
│                                             │
│   Connect USB memory stick containing the   │
│   new software version.                     │
│                                             │
│   Active software version:                  │
│                              ┌────────────┐ │
│   New software version:      │  Install   │ │
│                              └────────────┘ │
└─────────────────────────────────────────────┘
```

3. Connect the USB memory stick to the device.

   ⇨ The software version contained on the USB memory stick is checked.
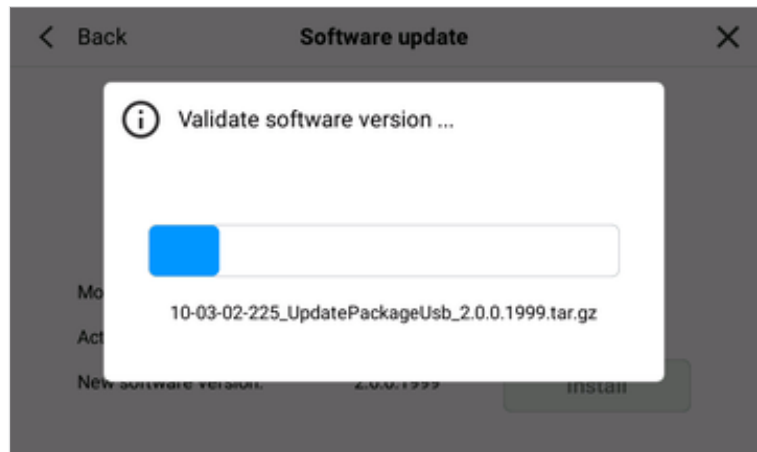
⇨ After successful checking, the software version contained on the USB memory stick is displayed.
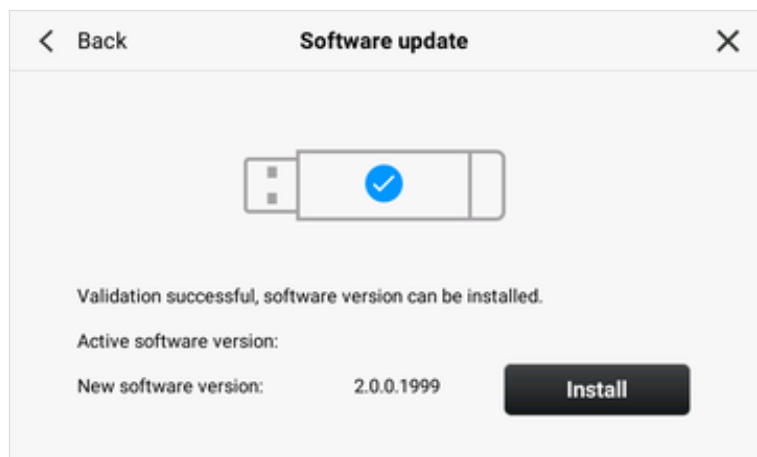
4. Press the **Install** key.

⇨ The software update starts.

5. Wait until installation is complete.
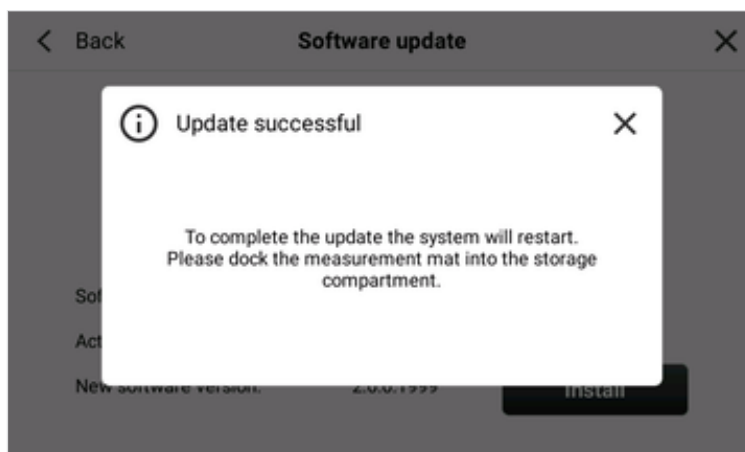
6. Remove the USB memory stick from the device.

7. Suspend the measuring mat in the magnetic catch of the monitor if not already done.

   ⇨ The device restarts automatically.

   ⇨ Software updates for the measuring mat are automatically installed during the restart.

   NOTE

   As an alternative to the USB memory stick, software updates can also be carried out via a network connection. If you have any questions about this function, please contact seca Service.

Enabling/locking device for external access (VNC)

NOTICE!
Data loss, access to data by unauthorized persons

► Note the instructions on IT security in our White Paper entitled "Cyber Security". The document can be found as a download in the Support area at www.seca.com.

1. Press the ☰ key.

2. Select the menu item **Device ❯ Remote access (VNC)**.
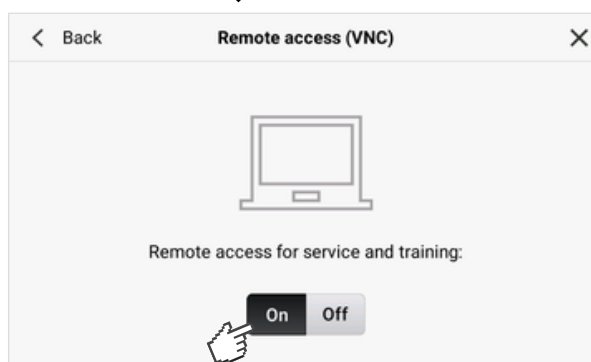
3. Press the **On** key.

4. Press ❮ **Back**.

5. Confirm the confirmation question with **Yes**.

6. Switch the device off and on again ➔ Switching the device on and off.

   ⇨ The device is enabled for remote access.

7. Set up the connection with the VNC viewer of your PC.

8. To deactivate the function, press the **Off** key and perform steps 4. - 6. again.

Exporting logfiles/audit trail For service purposes you can export the following data to a USB memory stick:

- Logfiles
- Log properties
- Audit trail
- seca Log database
- seca System database
- Configuration file

✓ USB memory stick (format: FAT 32) available

1. Press the ☰ key.
2. Select the menu item **Device ❯ Export logfiles**.
3. Connect a USB memory stick to the device.
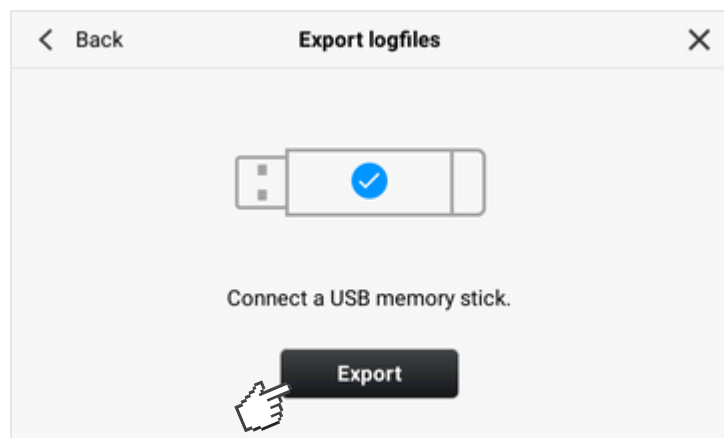
4. Press the **Export** key.

   ⇨ The data is exported.

5. Wait until the export has finished.
6. Remove the USB memory stick from the device and manage the data according to the regulations of your institution.

8 HYGIENE TREATMENT

→ Cleaning

→ Disinfecting

→ Sterilizing

⚠ **WARNING!**
Electric shock

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

► Before each hygiene treatment, ensure that the device is switched off.

► Disconnect the power supply connector before each hygiene treatment.

► Take the batteries out of the device before every hygiene treatment.

► Ensure that no fluids penetrate the device.

⚠ **WARNING!**
Risk of infection

► Subject the device to a hygiene treatment at regular intervals as described in this section.

NOTICE!
Damage to device

Unsuitable cleaning agents and disinfectants may damage the sensitive surfaces of the device and lead to transparent components becoming clouded.

► Do not use aggressive or abrasive cleaning agents.

► Do not use organic solvents (e.g. white spirit or petroleum spirit).

8.1 Cleaning

► Clean the device as described in the table:

Component	Interval	Cleaning
Monitor with storage compartment	As required	• Remove the measuring mat from the storage compartment • Moisten a soft cloth with a mild soap solution • Wipe over all surfaces • Allow to air-dry for approx. 30 minutes
Measuring mat	As required	• Moisten a soft cloth with a mild soap solution • Wipe over all surfaces • Allow to air-dry for approx. 30 minutes
Adhesive electrodes	After each measurement	Do not clean, dispose of used adhesive electrodes

8.2   Disinfecting

1. Disinfect the device at regular intervals with a disinfectant suitable for sensitive surfaces and acrylic glass (e.g. 70 % ethanol).
2. Follow the instructions for use of the disinfectant.
3. Disinfect the device as described in the table:

Component	Interval	Disinfecting
Monitor with storage compartment	As required	• Remove the measuring mat from the storage compartment • Moisten a soft cloth with disinfectant • Wipe over all surfaces • Allow to air-dry for approx. 30 minutes
Measuring mat	Before and after each measurement	• Moisten a soft cloth with disinfectant • Wipe over all surfaces • Allow to air-dry for approx. 30 minutes
Adhesive electrodes	After each measurement	Do not disinfect, dispose of used adhesive electrodes

8.3   Sterilizing

The device must not be sterilized.

9   FUNCTION CHECK

► Perform a function check before each use.

A complete function check includes:

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

If you find faults or deviations during the function check, first try to remedy the fault with the aid of the "Troubleshooting" section in this document.

⚠ **CAUTION!**
Personal injury

If you find faults or deviations during the function check which you are unable to remedy with the aid of the "Troubleshooting" section in this document, you must not use the device.

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

► Follow the section entitled "Servicing" in this document.

10 TROUBLESHOOTING

10.1 Troubleshooting: Monitor

Fault	Cause	Remedy
Monitor cannot be switched on	No electricity supply	Provide electricity supply
	Battery pack discharged	Provide electricity supply and charge battery pack
	Battery pack faulty	Replace battery pack
Display remains dark	Device on standby	• Touch the touchscreen display • Press the ON/OFF button
	Device not switched on	Press the ON/OFF button
	No power supply	Check whether the network cable is connected
	Touchscreen display faulty	Inform seca Service
Display not reacting	Device is in an undefined state following implausible inputs	• Press and hold ON/OFF button for approx. 15 seconds to switch off the device • Press ON/OFF button to switch device on again
Image on display faulty	Display faulty	Inform seca Service
PIN code is not accepted	PIN code was changed	• Use current PIN code • If PIN code is not known, contact administrator

17-10-05-409-002_2024-10S

10.2   Troubleshooting: Bioimpedance measurement

→ Measuring mat and measuring sequence
→ Plausibility check

Measuring mat and measuring sequence

Fault	Cause	Remedy
LEDs of measuring mat not lit up	Measuring mat switched off	Press start key of measuring mat
	Measuring mat faulty	Replace measuring mat
Measuring mat cannot be switched on	Battery pack discharged	Suspend measuring mat in magnetic catch of monitor and charge battery pack
	Measuring mat faulty	Replace measuring mat
	Battery pack faulty	Battery pack not removable, replace measuring mat
	Measuring mat: Inductive charging interface faulty	Replace measuring mat
	Monitor: Inductive charging interface faulty	Inform seca Service
One or more LEDs on measuring mat not lit up	Measuring mat faulty	Replace measuring mat
No WiFi connection to monitor (WiFi 📶 symbol not displayed)	Distance between measuring mat and monitor is too great	• Suspend measuring mat in magnetic catch of monitor • Wait until the 📶 WiFi symbol is displayed
	WiFi module of measuring mat faulty	Replace measuring mat
Electrode check: An electrode with the ⦿ symbol is displayed on the monitor	Skin transition resistance too high	Apply electrode gel at the appropriate point
	Adhesive electrode faulty	Replace adhesive electrode
	Electrode cable faulty	Replace measuring mat
Electrode check: An electrode with the ✖ symbol is displayed on the monitor	Adhesive electrode faulty	Replace adhesive electrode
	Electrode cable not connected correctly	Ensure that the push-button adapter of the electrode cable is securely engaged on the adhesive electrode.
	Electrode cable faulty	Replace measuring mat
Plausibility check of bioimpedance measurement failed	Medical reasons involving the patient: • Cannula, drainage, intravenous access, etc. • Pronounced edema • Severe cachexia	• Repeat measurement • Evaluate and comment measuring result in the **seca analytics 125** software

Fault	Cause	Remedy
	Patient not correctly positioned	Ensure that patient adopts the following position: • Arms held far enough away from the torso so that there is also sufficient distance from the torso with the hands opened • Legs held far enough away so that the thighs are not touching • Lying still, muscles relaxed
	Patient is touching metal parts on the bed surface	Ensure that the following points are satisfied: • Patient is not touching any metal parts on the bed surface • Patient is lying as far as possible at the head of the bed so that the feet are not touching any metal parts of the bed surface • Electrode cables not touching any metal parts of the bed surface • No metal objects on the bed surface • Bed surface is not electroconductive
	Electrode cables not correctly routed	Check cable routing: • Arrange cables so they do not cross over, are not twisted, without loops • Do not route cables over or underneath the patient
	Measuring mat incorrectly positioned	Position measuring mat correctly ➜ Connecting the measuring mat (measuring whole body): • Control panel (keys, LEDs) visible • Control panel (keys, LEDs) facing user
	8-point measurement: **Only right half of body** checkbox activated	• Deactivate **Only right half of body** checkbox ➜ Connecting the measuring mat (measuring whole body) • Repeat measurement
	4-point measurement: All electrodes connected	• Connect only electrode for the right half of the body ➜ Connecting the measuring mat (measuring whole body) • Repeat measurement

Plausibility check   The device automatically performs a plausibility check on every bioimpedance measurement. If the check fails, the parts of the body that delivered implausible measuring results are displayed (in this case: torso, left arm).

If a plausibility check fails, proceed as follows:

> **NOTICE!**
> **Implausible or inconsistent measuring results**
>
> If you save implausible measuring results from a bioimpedance measurement unchecked, the patient's state of health cannot be correctly evaluated.
>
> ► Only save implausible measured values if you have sufficient specialist knowledge about bioimpedance measurement technology and interpretation of the measuring results.

1. Press the ⓘ symbol.

   ⇨ Information on troubleshooting is displayed.

2. Check the device, cable connections and patient position according to the information on the monitor (see also: → Troubleshooting: Bioimpedance measurement\→ Measuring mat and measuring sequence).

3. Press the **Repeat** key.
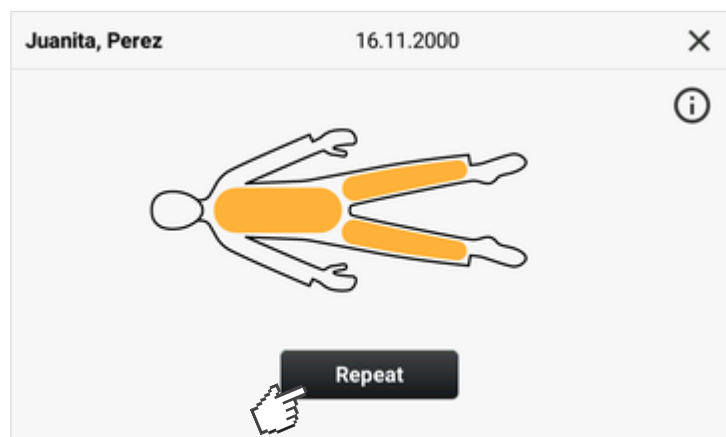
⇨ Bioimpedance measurement starts.

⇨ Should bioimpedance measurement fail again, you have the following options for continuing:

▶ Repeat bioimpedance measurement: Press **Repeat** key

▶ Accept bioimpedance measurement: Press **Accept** key

▶ Cancel measurement procedure: Press ✕ symbol

> **NOTE**
>
> If you accept an implausible measuring result, it will be submitted to the **seca analytics 125** software with the note "Failed". seca recommends evaluating and commenting this measurement directly after submission to the **seca analytics 125** software.

10.3 Troubleshooting: Data transmission to the seca analytics 125 software

Fault	Cause	Remedy
No WiFi connection	WiFi function of device deactivated	→ Setting up a WiFi connection
	Distance between monitor and router/mobile hotspot too great	• Reduce distance • Measuring results transmitted to **seca analytics 125** software via LAN
	WiFi not available at your institution	• Check whether WiFi can be activated at your institution • Measuring results transmitted to **seca analytics 125** software via LAN
	WiFi function of router/mobile hotspot deactivated	Activate WiFi function as described in the instructions for use of the router/mobile hotspot
	USB WiFi module (under protective cap) faulty	Inform seca Service
No LAN connection	LAN function of device deactivated	→ Setting up a LAN connection
	No LAN cable connected	Establish cable connection
	LAN cable faulty	Replace cable
No network connection	Windows firewall port block is active, required ports are blocked	Administrator: Enable required ports in firewall → Technical data: Network
	Firewall/gateway configuration does not permit use of LAN and WiFi in parallel	Disable one of the two submission options on the device

Fault	Cause	Remedy
	No network connection set up	Set up network connection: ➜ Setting up a WiFi connection ➜ Setting up a WiFi connection ➜ Setting up a connection to the seca analytics 125 software
Unable to find patient data	No data have been created for the patient in the **seca analytics 125** software	➜ Creating patient data
	Windows firewall port block is active, required ports are blocked	Administrator: Enable required ports in firewall ➜ Technical data: Network

11 SERVICING

The measurement technology for the device must be inspected every two years. seca recommends having the entire device serviced during this inspection.

⚠ **CAUTION!**
Faulty measurements as a result of poor servicing

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

► You can find your local service partner at www.seca.com.

12   TECHNICAL DATA

12.1   Technical data: Device

Technical data: seca mBCA 525 c – Monitor	
Dimensions:	
• Depth	230 millimeters
• Width	252 millimeters
• Height	262 millimeters
Net weight	Approx. 2 kg
Ambient conditions, operation:	
• Temperature	+10 °C to +40 °C (50 °F to 104 °F)
• Air pressure	700 hPa – 1060 hPa
• Humidity	20 % – 80 %, no condensation
Ambient conditions, storage:	
• Temperature	-10 °C to +55 °C (14 °F to 131 °F)
• Air pressure	700 hPa – 1060 hPa
• Humidity	15 % – 95 %, no condensation
• Warm-up time from lowest storage temperature to operational temperature	
– At ambient temperature 20 °C	8 h
– At ambient temperature 20 °C with condensation	24 h
• Cooling time from highest storage temperature to operational temperature (at ambient temperature 20 °C)	8 h
Ambient conditions, transport:	
• Temperature	-10 °C to +55 °C (14 °F to 131 °F)
• Air pressure	700 hPa – 1060 hPa
• Humidity	15 % – 95 %, no condensation
Setup location, maximum altitude above MSL	3000 m
Display type	7" touchscreen display

Technical data: seca mBCA 525 c – Monitor	
Power supply, input: • Type • Mains voltage • Power supply frequency • Current consumption Insulated device in accordance with IEC 60601-1	Internal power supply unit, connector type in accordance with IEC 60320: C13 100 V ~ - 240 V ~ 50 Hz – 60 Hz 0.85 A Protection class II ▫
Mobile power supply, input: • Type • Voltage • Capacity • Range (full brightness, new battery pack)	Lithium-ion battery 11.25 V 2950 mAh Approx. 5 h
Charging interface for measuring mat battery pack	Inductive
Power consumption: • Standby (touchscreen display off, ON/OFF button lit up green) • In operation (ON/OFF button lit up white) • Operation (charging rechargeable battery for the monitor and measuring mat, ON/OFF button lit up white)	< 5 W < 9 W < 35 W
Medical device in accordance with Regulation (EU) 2017/745	Class IIa
IEC 60601-1	Medical electrical device, type BF
Type of protection in accordance with IEC 60529	IP 21
Duty cycle	Continuous duty
Fulfilled standards	IEC 60601-1 Medical electrical equipment: General requirements for basic safety and essential performance IEC 60601-1-2 Medical electrical equipment: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances IEC 60601-11 Medical electrical equipment: Particular requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Technical data: seca mBCA 525 c – Measuring mat	
Dimensions:	
• Depth	783 millimeters
• Width	120 millimeters
• Height	20 millimeters
Net weight	Approx. 1 kg
Ambient conditions, operation:	
• Temperature	+10 °C to +40 °C (50 °F to 104 °F)
• Air pressure	700 hPa – 1060 hPa
• Humidity	20 % – 80 %, no condensation
Ambient conditions, storage:	
• Temperature	-10 °C to +60 °C (14 °F to 140 °F)
• Air pressure	700 hPa – 1060 hPa
• Humidity	15 % – 95 %, no condensation
Ambient conditions, transport:	
• Temperature	-10 °C to +60 °C (14 °F to 140 °F)
• Air pressure	700 hPa – 1060 hPa
• Humidity	15 % – 95 %, no condensation
Setup location, maximum altitude above MSL	3000 m
Power supply	Lithium-ion battery
Range (measuring mode)	Approx. 5 h
Charging interface	Inductive
Medical device in accordance with Regulation (EU) 2017/745	Class IIa
IEC 60601-1	Medical electrical device, type BF
Application parts according to IEC 60601-1	Control panel, mat, electrode cables with push-button adapters
Type of protection in accordance with IEC 60529	IP 44
Duty cycle	Continuous duty

Technical data: seca mBCA 525 c – Measuring mat	
Fulfilled standards	IEC 60601-1 Medical electrical equipment: General requirements for basic safety and essential performance
	IEC 60601-1-2 Medical electrical equipment: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances
	IEC 60601-11 Medical electrical equipment: Particular requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Technical data: seca mBCA 525 c – Bioimpedance measurement	
Measuring method	8-point bioimpedance measurement
	4-point bioimpedance measurement (right half of body)
Electrode type	Measuring mat: cable with push-button adapter
	Patient: push-button electrodes for affixing to patient
Measuring frequencies	1; 2; 5; 10; 20; 50; 100; 200; 500 kHz
Measured values	Impedance (Z), resistance (R), reactance (X_c), phase angle (ϕ)
Phase angle measuring range	0° to 20°
Impedance measuring range	10 Ω to 1000 Ω
Measuring segments	Right arm, left arm, right leg, left leg, right half of body, left half of body, torso
Measuring current	100 µA (+20 %, -50 %)
Measuring time	max. 30 s
Accuracy (frequencies: 5 and 50 kHz, segments: right half of body, left half of body): • Impedance (phase angle 0°) • Phase angle (phase angle 0°), impedance 200 Ω to 1000 Ω	 ± 5 Ω ± 0.5°
Minimum age of patient	5 years
Analysis parameters	No result displayed on the device, see instructions for use of the **seca analytics 125** software

12.2 Technical data: Network

seca mBCA 525 c – Interfaces and ports			
Interface	**Protocol**	**Data transmission rate**	**Factory setting**
WiFi, internal adapter	2.4 GHz, IEEE 802.11 b/g/n Encryption: WPA, WPA2 PSK, WPA2 Enterprise PEAP RADIUS)	up to 72.2 Mbit/s	On
WiFi, USB adapter	2.4 GHz, IEEE 802.11 b/g/n Encryption: WEP, WPA + WPA2	up to 300 Mbit/s	On
	5 GHz, IEEE 802.11 ac/a/n Encryption: WEP, WPA + WPA2	up to 867 Mbit/s	On
LAN	IEEE 802.3u, Ethernet (10/100 Base-T)	100 Mbit/s	On
TCP port	Transmission Control Protocol	–	20020
USB (2 ports, max. 500 mA)	USB 2.0	480 Mbit/s per port	On
Infrared interface	IrDA	115200 baud	On

seca mBCA 525 c – Recommended WiFi settings		
Parameter	**Recommended settings**	**Consequences in the event of different settings**
Authentication/encryption	• WPA2 Personal (PSK) • WPA2 Enterprise (EAP-TLS)	No network connection, other encryption methods not supported
Network configuration	DHCP	–
Firewall/ports to be opened	TCP port: 22020	No synchronization

seca mBCA 525 c – Recommended WiFi settings		
Parameter	Recommended settings	Consequences in the event of different settings
Separate VLAN	No special requirements	–
QoS	No special requirements	–
VoiP	No special requirements	–
WiFi multimedia	No special requirements	–

13 OPTIONAL ACCESSORIES AND SPARE PARTS

Accessory/spare part	Article number
Measuring mat	68 53 00 001 509
Push-button electrodes for single use, for affixing to patient; pack of 100	68 90 00 043 009
Push-button electrodes for single use, for affixing to patient; pack of 450	490 0022 001
seca wheeled stand **seca 475**	475 00 00 009
seca carry case **seca 432**	432 00 00 009
Barcode scanner	Recommendations at www.seca.com

14 COMPATIBLE SECA PRODUCTS

seca product	Article number
seca analytics 125 analysis software	Application-specific license packages Details at www.seca.com

15   DISPOSAL

→ Disposing of the device
→ Disposing of batteries and rechargeable batteries
→ Disposing of consumables

15.1   Disposing of the device

Do not dispose of the device in your household waste. The device must be properly disposed of as electronic scrap. Follow your respective national regulations. For more information, please contact seca Service at **service@seca.com**.

15.2   Disposing of batteries and rechargeable batteries

Do not dispose of used batteries and rechargeable batteries in household waste, regardless of whether they contain harmful substances or not. As a consumer, you are legally obliged to dispose of batteries and rechargeable batteries via local authority collection points or trade collection points. Only dispose of batteries and rechargeable batteries once they are completely discharged.

15.3   Disposing of consumables

Do not dispose of consumables such as adhesive electrodes in household waste. Used adhesive electrodes must be treated as infectious biological waste. Observe the regulations in your institution and your respective national regulations.

16   WARRANTY

There is a two-year warranty period from delivery for defects attributable to poor materials or workmanship. All movable parts, e.g. batteries, cables, power supply units, rechargeable batteries etc. are exempt. Defects which come under the warranty will be repaired for the customer free of charge against proof of purchase. Additional claims cannot be considered. Costs of transport to and from seca are the responsibility of the customer if the device is located somewhere other than the customer's headquarters. In the event of transport damage, claims under warranty can only be made if the complete original packaging was used for transport and the device was secured and fastened in it according to its originally packaged condition. You should therefore keep all packaging parts.

The warranty will be voided if the device is opened by persons not expressly authorized by seca to do so.

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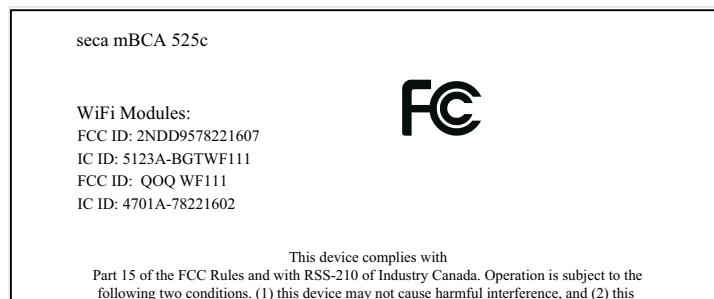
17 DECLARATIONS OF CONFORMITY

17.1 Declaration of conformity

CE 0123

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

17.2 USA and Canada

seca mBCA 525c

WiFi Modules:
FCC ID: 2NDD9578221607
IC ID: 5123A-BGTWF111
FCC ID: QOQ WF111
IC ID: 4701A-78221602

FC

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

NOTE

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

• This device may not cause harmful interference.

• This device must accept any interference received, including interference that may cause undesired operation.

NOTE

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

NOTE

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

17-10-05-409-002_2024-10S

Medical Measuring Systems and Scales since 1840

seca operates worldwide with headquarters
in Germany and branches in:
seca france
seca united kingdom
seca north america
seca schweiz
seca zhong guo
seca nihon
seca mexico
seca austria
seca polska
seca middle east
seca suomi
seca américa latina
seca asia pacific
seca danmark
seca benelux
seca lietuva
and with exclusive partners in
more than 110 countries.
All contact data at seca.com