# seca 525

## Instructions for Use

Software version 1.0

seca®
Precision for health
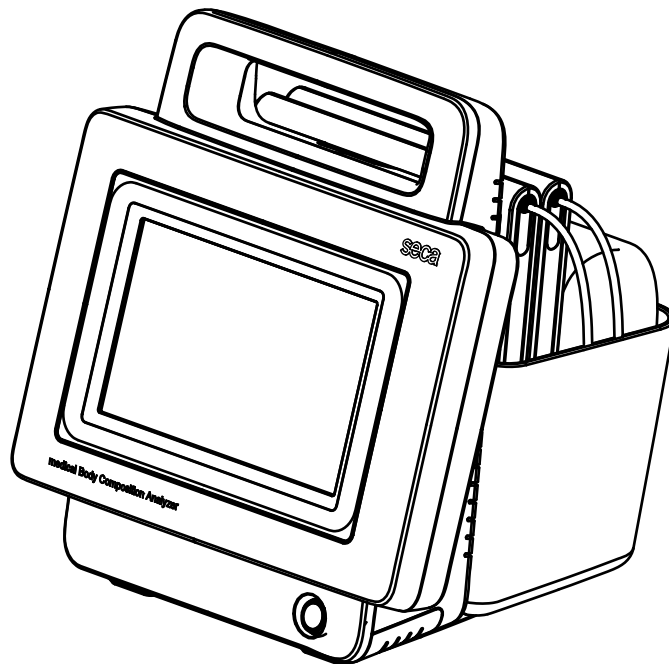
# CONTENTS

# INSTRUCTIONS FOR USE FOR SECA 525

# 1. DEVICE DESCRIPTION

## 1.1 Intended use

The **seca 525** medical Body Composition Analyzer is mainly used in hospitals, medical practices and inpatient care facilities in accordance with national regulations. The medical Body Composition Analyzer **seca 525** records weight, height and bioelectric impedance measurements and automatically calculates parameters such as fat-free mass (FFM) which can be derived from them. The results are displayed in graphical form and assist the attending physician with the following medical issues:

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

The **seca 525** is **not** a diagnostic device. To make an accurate diagnosis, the physician needs to commission specific examinations and take their results into account in addition to the results of the **seca 525**.

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

For North America: the device is intended for use on healthy individuals from 18 years of age upwards.

## 1.2    Description of function

**Device components**

The device consists of a monitor and a measuring mat.

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

The monitor has a storage compartment with a magnetic catch for storing the measuring mat.

The measuring mat is placed on the patient's legs for a bioimpedance measurement. Measured results are transmitted to the monitor unit by WiFi. The electrode cables of the measuring mat are equipped with connections for push-button electrodes.

**Power supply**

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

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

**Bioimpedance measurement**

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

**Recording weight and height**

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

**Administration of user accounts**

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

**Administration of seca patient files**

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

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

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

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

**Evaluating measured results**

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

**Data transmission and network functions**

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

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

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

**Compatibility**

This device (software version 1.0) is compatible only with Version 1.4 build 381 or higher of the **seca analytics 115** PC software. There is no downward compatibility with older versions of the **seca analytics 115**.

## 1.3 User qualification

➜ Administration/network connection

➜ Measuring mode

**Administration/network connection**

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

**Measuring mode**

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

## 1.4   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

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

- cardiac arrhythmias
- pregnancy

# 2.  SAFETY PRECAUTIONS

➜ Safety precautions in these Instructions for Use

➜ Basic safety precautions

➜ Handling batteries and rechargeable batteries

## 2.1   Safety precautions in these Instructions for Use

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

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

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

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

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

## 2.2 Basic safety precautions

**Handling the device**

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

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

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

  ▶ oxygen

  ▶ flammable anesthetics

  ▶ other flammable substances/air mixtures

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

  ▶ Additional devices which are connected to electrical medical devices must provide evidence of compliance with the relevant IEC or ISO standards (e.g. IEC 60950 for data-processing devices). Furthermore, all configurations must comply with the requirements of standards for medical systems (see IEC 60601-1-1 or Section 16 of the 3rd edition of IEC 60601-1 respectively). Anyone connecting additional devices to electrical medical devices is considered a system configurer and is therefore responsible for ensuring that the system complies with the requirements of standards for systems. Your attention is drawn to the fact that local laws take precedence over the above-mentioned requirements of standards. In the event of any queries, please contact your local specialist dealer or Technical Service.

  ▶ Please have servicing and BIA measuring technology checks performed every two years.

  ▶ Technical modifications may not be made to the device. The device does not contain any parts for servicing by the user. Only have servicing and repairs performed by an authorized seca service partner. You can find service partners in your area at www.seca.com or by sending an e-mail to service@seca.com.

  ▶ Only use original seca accessories and spare parts, otherwise seca will not grant any warranty.

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

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

► Keep HF devices such as cell phones a minimum distance of approx. 1 meter away to prevent incorrect measurements or wireless transmission interference.

► The actual transmission output of HF equipment may require minimum distances of more than 1 meter. Details can be found at www.seca.com.

**Preventing electric shock**

⚠ **WARNING!**
**Electric shock**

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

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

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

► Do not connect the device to a power supply network if there is any uncertainty about whether the protective earth is functioning. In this case, use the device exclusively in rechargeable battery mode.

► Never touch the power supply cable with wet hands.

► Do not use extension cables or power strips.

► Make sure that cables are not pinched or damaged by sharp edges.

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

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

**Preventing injuries and infections**

⚠ **WARNING!**
**Injury from falls**

► Ensure that the device is positioned firmly and level.

► Route connecting cables (if present) in such a way that neither user nor patient can trip over them.

⚠ **WARNING!**
**Risk of infection**

► Hygienically reprocess the scale regularly as described in the respective section in this document.

► Make sure that the patient has no infectious diseases.

► Make sure that the patient has no open wounds or infectious skin alterations, which may come into contact with the device.

## Preventing device damage

**NOTICE!**
**Damage to device**

► Ensure that no liquids enter the device. They can damage the electronics.

► Switch off the device before you take the power supply connector out of the power supply socket.

► If you are not going to use the device for an extended period, disconnect the power supply connector from the power supply socket and remove the rechargeable battery (if present and removable). Only then is the device de-energized.

► Make sure not to drop the device.

► Do not expose the device to any impacts or vibrations.

► Perform function controls regularly as described in the relevant section in this document. Do not operate the device if it is damaged or not working properly.

► Ensure that there is no heat source in the immediate vicinity. Do not expose to direct sunlight. The excessive temperature could damage the electronics.

► Avoid rapid temperature fluctuations. When the device is transported so that a temperature difference of more than 20 °C occurs, it must stay turned off for at least 2 hours before it can be turned on again. Otherwise, condensation water will form which can damage the electronics.

► Use the device only in the ambient conditions outlined in "Intended use".

► Store the device only in the storage conditions outlined in "Intended use".

► Use only disinfectants free of chlorine and alcohol which are explicitly suitable for acrylic sheet and other sensitive surfaces (active ingredient: quaternary ammonium compounds, for example).

► Do not use aggressive or abrasive cleaning agents.

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

## Using the measured results

**WARNING!**
**Patient hazard**

This device is **no** diagnostic device. It simply assists the treating physician in establishing a diagnosis.

► In order to make a precise diagnosis and initiate therapeutic measures, besides determination of the weight, further targeted examinations must be set up by the physician, and their results must be considered.

► The responsibility for diagnosis and treatment lies with the treating physician.

**CAUTION!**
**Patient hazard**

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

► Use the results exclusively in SI units.

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

**NOTICE!**
**Inconsistent measuring results**

► Before you electronically save measurement values determined using this device and use them further (e.g. in seca PC software or in a hospital information system), make sure that the measurement values are plausible.

► If measurement values are transmitted to seca PC software or a hospital information system, make sure prior to further use that the measurement values are plausible and are assigned to the correct patient.

**NOTICE**
**Results not comparable to other devices**
Results of bioelectric impedance measurements are not interchangeable with measurements obtained from different manufacturers' devices. Performing follow-up measurements using devices other than seca medical Body Composition Analyzers may produce inconsistent data and lead to misinterpretation of measurement results.

► Make sure to perform follow-up measurements using seca medical Body Composition Analyzers only.

**Dealing with packaging material**

⚠ **WARNING!**
**Risk of suffocation**
Packaging material made of plastic foil (bags) is a choking hazard.

► Keep packaging material out of reach of children.

► 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**
Keep the original packing material for future use (e.g. returning for maintenance service).

## 2.3 Handling batteries and rechargeable batteries

⚠ **Warning!**
**Personal injury due to improper handling**
Batteries and rechargeable batteries contain harmful substances which may explode if not handled properly.

► Do not try to recharge batteries.

► Do not expose (rechargeable) batteries to heat.

► Do not burn (rechargeable) batteries.

► If acid is leaking out, avoid contact with the skin, eyes and mucous membranes. Rinse affected areas with plenty of clean water and seek medical help at once.

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

► Only use the type of (rechargeable) battery specified in this document.

► When replacing (rechargeable) batteries, always replace a complete set at a time.

► Do not short-circuit (rechargeable) batteries.

► If you do not use the device for a long period of time, remove the batteries (incl. rechargeable batteries). This prevents acid from leaking into the device.

► If acid leaked into the device, discontinue use. Have the device checked by an authorised seca service partner and repaired if necessary.

# 3. DEVICE OVERVIEW

## 3.1 Monitor controls
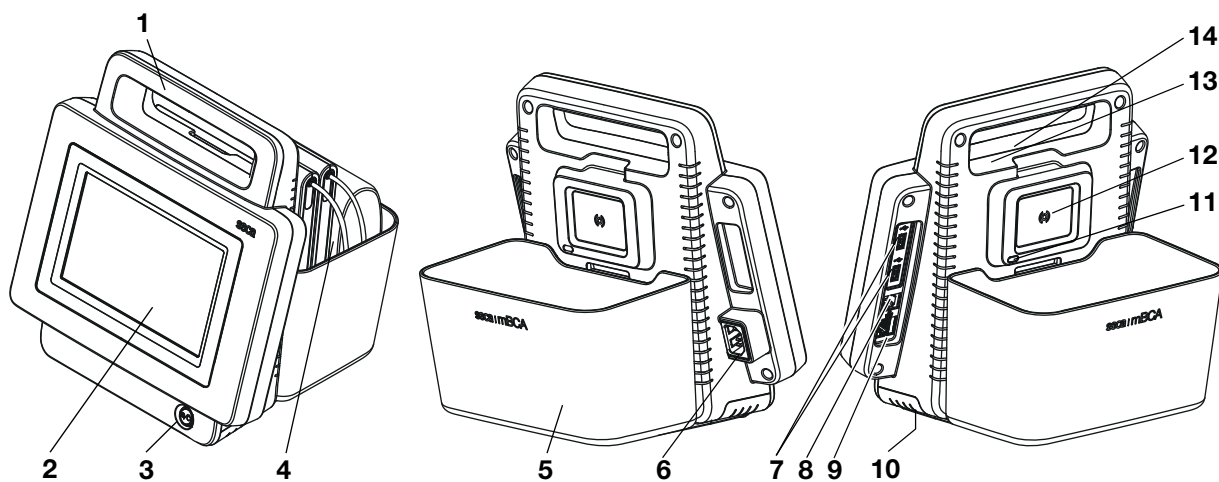


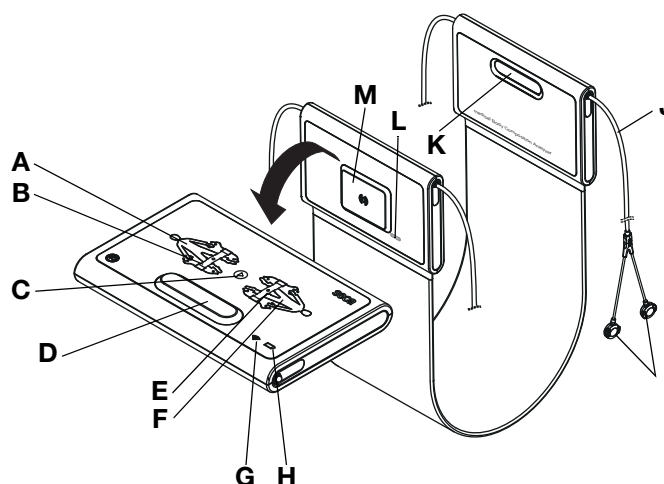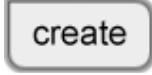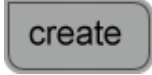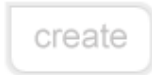| No. | Control | Function |
|---|---|---|
| 1 | Handle | For transporting the device |
| 2 | Touchscreen display | Central control/display element |
| 3 | ON/OFF button with LED | White LED: device on |
| | | Green LED: device on standby |
| | | LED off: device off |
| 4 | Measuring mat | For performing a bioimpedance measurement |
| 5 | Storage compartment | For transporting/storing the measuring mat |
| | | Data transmission: monitor/measuring mat |
| | | For charging measuring mat rechargeable battery |
| 6 | Power supply socket | For connecting the power supply cable |
| 7 | USB interface | For transmitting data via a USB memory stick |
| 8 | ISIS interface | Advance feature for future system upgrade (currently no function) |
| 9 | LAN interface | For integrating device in a PC network: use with **seca 115** PC software |
| 10 | Rechargeable battery compartment | To take lithium-ion rechargeable battery supplied |
| 11 | Infrared interface | Automatic data transmission: monitor/measuring mat Alternative if no WiFi available |
| 12 | Inductive charging interface with magnetic catch | For charging measuring mat rechargeable battery |
| 13 | Internal **seca 360°** wireless module | For connecting scales and length measuring devices from the **seca 360° wireless** system |
| 14 | Internal WiFi module | For automatic transmission of data, monitor/measuring mat |

## 3.2 Measuring mat controls



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

## 3.3 Login/navigation: buttons and symbols in the touchscreen display

| Button/symbol | Meaning |
|---|---|
| **i** | Open Instructions for Use |
| ☰ | Instructions for Use: return to chapter summary |
| ▢ | Enter text or numbers |
| ▢ | No input or input faulty |
| 👤 | Select user account |
| 🔑 | Enter password |
| ✓ | Confirm entry |
| ◯ | Process running |
| create | Button available |
| create | Button pressed |
| create | Button not available |
| ‹ › | Navigate left/right |
| ˅ ˄ | Navigate up/down |
| ✓ ▢ | One or more items from list selected/not selected |
| ● ○ | Alternative from list selected/not selected |
| ✕ | Back to previous screen |
| **Logout** | Log off/switch user |

## 3.4 Operating state: symbols
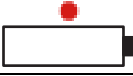
**Operating state: symbols in the touchscreen display**

| Symbol | Operating state |
|---|---|
| 60 % ▪▪▪▪▫▫ | Monitor:<br>controls permanently on: rechargeable battery charging status (%)<br>controls flashing: rechargeable battery charging |
| 50 % ▪▪▪▫▫ | Measuring mat:<br>controls permanently on: rechargeable battery charging status (%)<br>controls flashing: rechargeable battery charging |
| (battery full icon) | Monitor:<br>controls permanently on: rechargeable battery full<br>controls flashing consecutively: rechargeable battery charging |
| (battery discharged icon) | Monitor: rechargeable battery discharged |
| (mat battery full icon) | Measuring mat:<br>controls permanently on: rechargeable battery full<br>controls flashing consecutively: rechargeable battery charging |
| (mat battery discharged icon) | Measuring mat: rechargeable battery discharged |
| (LAN icon) | LAN available |
| (WiFi icon) | WiFi available |
| (mat detected icon) | Measuring mat detected |
| (mat not detected icon) | Measuring mat not detected |
| (i icon) | Pop-up: information for the user |
| (x icon) | Pop-up: error message |

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

| Symbol | Operating state |
|---|---|
| 🔋 (green LED) | LED green: rechargeable battery full<br>Green, flashing: charge rechargeable battery as quickly as possible |
| 🔋 (red LED) | LED red: rechargeable battery discharged |
| 📶 (green LED) | LED green: WiFi available<br>Green, flashing: WiFi connection being set up |
| 📶 (red LED) | LED red: WiFi not available<br>LED off: WiFi deactivated |

## 3.5 Measuring mode: buttons and symbols

➔ "patient" tab

➔ "measure" tab

➔ Measuring mat

➔ "evaluation" tab

**"patient" tab**

| Button/symbol | Meaning |
|---|---|
| 🔍 | Searching for seca patient file |
| ▲ ▼ | Switch sort direction |
| (weight icon) | Enter weight |
| ↑ | Enter height |
| (waist icon) | Enter waist circumference |
| 🏃 | Enter Physical Activity Level (PAL) |
| 360° | Adopt **seca 360° wireless** value |
| ↻ | Adopt value from previous measurement |
| × | Close seca patient file, changes will not be saved |

**"measure" tab**

| Button/symbol | Meaning |
|---|---|
| | Enter patient position |
| | Starting measurement |
| | Permanently on: electrode OK<br>Flashing: measurement in progress |
| | Electrode not OK |
| | Measurement in progress |
| | Measurement successful |
| | Write comment |

**Measuring mat**

| Button/symbol | Meaning |
|---|---|
| | Enter patient position<br>LED green: seca patient file loaded, patient position selected<br>LED green, flashing: end of measurement<br>LED red: no seca patient file loaded |
| | Starting measurement |
| | Electrode LEDs<br>LED green: electrode OK<br>LED green, flashing: measurement in progress |
| | Electrode LEDs<br>LED red: electrode not OK |

**"evaluation" tab**

| Button/symbol | Meaning |
|---|---|
| | View history |
| | Print results report (**seca directprint**: function of **seca 115** PC software) |
| | Position indicator for evaluation modules, in this case: second module of 5 |
| | Position indicator for evaluation parameters, in this case: second evaluation parameter of 4 |
| | Detail view available for evaluation parameter: bar chart |
| | Detail view available for evaluation parameter: percentile curve |
| | Detail view available for evaluation parameter: tolerance ellipse |
| ● ▶ | Parameter-dependent symbols, red: value outside standard range |
| ● ▶ | Parameter-dependent symbols, gray: value within standard range |
| 28.6 kg/m$^2$ | Text red: value outside standard range |
| 15.3 kg/m$^2$ | Text black: value within standard range |
| ♂ | Male |
| ♀ | Female |

## 3.6   Identification on the device and on the type plate

| Text/symbol | Meaning |
| --- | --- |
| **Fabr** | Manufacturer |
| **Mod** | Model number |
| **S/N** | Serial number, consecutive |
|  | Follow Instructions for Use |
|  | Do not use device on individuals with cardiac pacemakers or implanted defibrillators |
|  | Medical electrical device, type BF |
| **Li-ion** | Lithium-ion rechargeable battery |
| $CE$ 0123 | Device complies with EC directives<br>• **0123**: appointed office for medical devices: TÜV SÜD Product Service |
|  | Name and address of manufacturer, date of manufacture |
|  | Symbol of the US Federal Communications Commission (FCC) |
| FCC ID | Device license number from the Federal Communications Commission (FCC) |
| IC | Device license number from Industry Canada |
|  | The device meets the requirements of the Agência Nacional de Telecomunicações [National Telecommunications Agency (ANATEL), Brazil]. Details of the wireless device license:<br>  - HHHH: license number of device<br>  - AA: year of license<br>  - FFFF: identification number of the manufacturer |
|  | The device meets the regulatory requirements of GOST R certification (Russia) |
|  | License number of the Chinese Pharmaceutical Association (CPA) |
|  | The device meets the regulatory requirements on wireless equipment in Japan. License number: VORL.202WW09118012 |
| **xxx-yyy V ~**<br>**xx-yy Hz**<br>**xx A** | Type plate for power supply socket:<br>• Permitted supply voltage<br>• Permitted power supply frequency<br>• Power consumption |
| ⊙/Ȯ | ON/OFF key |
|  | Inductive charging interface |
|  | LAN interface |

| Text/symbol | Meaning |
| --- | --- |
|  | USB interface |
|  | Do not dispose of device with household waste |

## 3.7   Identification on the packaging

| | |
| --- | --- |
|  | 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. moisture for transport and storage |
|  | Open packaging here |
|  | Packaging material can be disposed of through recycling programs |

# 4. MAKING THE DEVICE OPERATIONAL

## 4.1 Scope of delivery



| No. | Component | Pcs. |
|-----|-----------|------|
| **a** | Measuring mat with rechargeable battery and electrode cables | 1 |
| **b** | Monitor with rechargeable battery | 1 |
| **c** | Power supply cable (country-specific) | 1-3 |
| **d** | "Quick Start" brief instructions, printed | 1 |
| **e** | DVD with **seca analytics 115** PC software and license for one permanent workstation | 1 |
| **f** | Push-button electrodes for affixing to patient, pack of 30 | 2 |

## 4.2 Establishing power supply
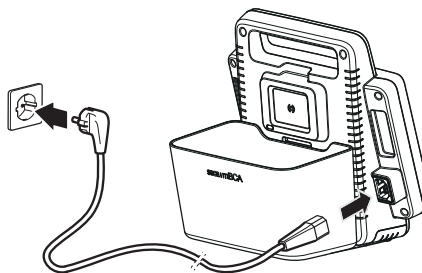


1. Plug the device connector of the power supply cable into the connecting socket of the device.
2. Plug the power supply connector into a power supply socket.

## 4.3 Suspending measuring mat in storage compartment

The monitor's storage compartment contains the following functional elements:

- inductive charging interface: for charging the measuring mat rechargeable battery
- infrared interface: for communicating between the monitor and the measuring mat

**ATTENTION**
**Malfunction**
The measuring mat rechargeable battery can only be charged by the inductive charging interface in the storage compartment of the monitor.
  ► After each measurement, suspend the measuring mat back in the storage compartment of the monitor. This ensures that the measuring mat rechargeable battery is always adequately charged.

Store the measuring mat in the storage compartment of the monitor when you are not performing a measurement.

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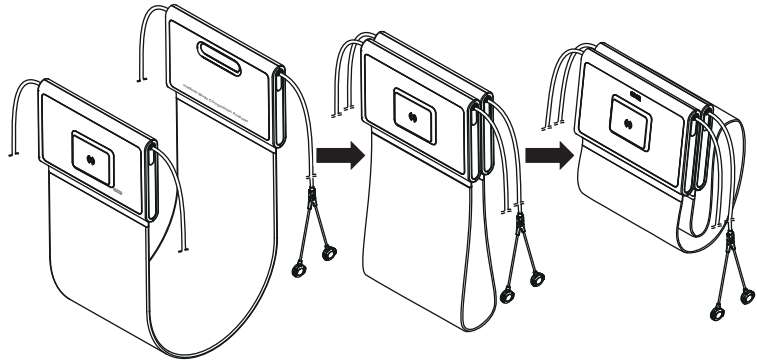


2. Suspend the measuring mat in the storage compartment as shown in the illustration below.
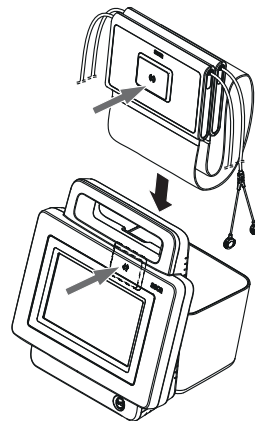


3. Ensure that the magnetic catch of the measuring mat is correctly located on the magnetic catch of the storage compartment.
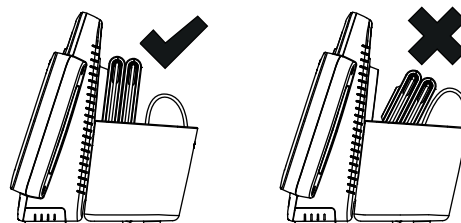
## 4.4 Setting the date and time

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

1. Ensure that the measuring mat is correctly suspended in the storage compartment of the monitor ➜ Suspending measuring mat in storage compartment.

2. Connect the device to the power supply.

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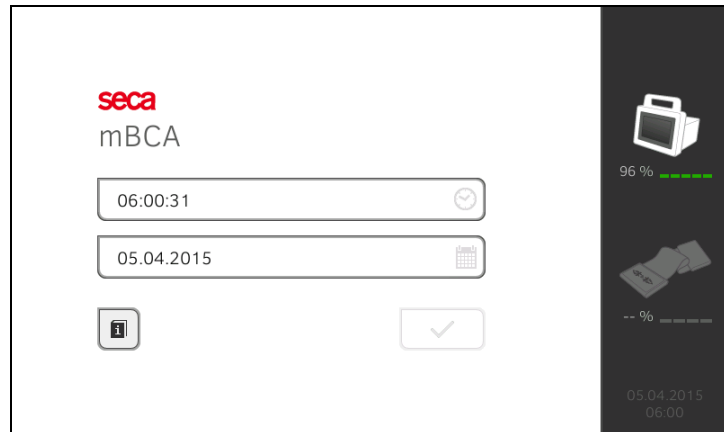


4. Enter the current date:

   a) Press input field

   b) Enter the current date using the keypad

   c) Confirm your entry by pressing the ⏎ button

5. Enter the current time:

   a) Press input field

   b) Enter the current time using the keypad

   c) Confirm your entry by pressing the ⏎ button

6. Press the ✓ button.

7. Continue operating the device - you have the following options:

   ► leave device switched on, charge rechargeable battery (recommended):
     ➜ Charging rechargeable batteries

   ► perform bioimpedance measurement using the power supply:
     ➜ Operation

   ► configure device using the power supply: ➜ For administrators: configuring seca 525

## 4.5 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.

1. Ensure that the measuring mat is correctly suspended in the storage compartment of the monitor ➔ Suspending measuring mat in storage compartment.

2. Connect the device to the power supply ➔ Establishing power supply.

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

50 % ▬▬ ▭ ▭ ▭          60 % ▬▬▬ ▭ ▭

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

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

## 4.6 Configuring the device

➔ Network functions

➔ User role model

➔ For administrators: configuring seca 525

**NOTE:**
This section is for your information. The device can only be configured by a user with administrator rights.

**Network functions**

• = possible, - = not possible

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

**User role model**

• = possible, **-** = not possible

| Function | Administrator | User |
|---|:---:|:---:|
| seca Create patient files | • | • |
| seca Call up patient files | - | • |
| Enter basic parameters | - | • |
| seca Edit patient files | • | - |
| seca Delete patient files | • | - |
| seca Restore patient files | • | - |
| Perform measurements | - | • |
| View examination results | - | • |
| Print examination results | - | • |
| Evaluation parameters: add comments | - | • |
| Administer patient database | • | - |
| Administer user database | • | - |
| Modify default settings (e.g. dialog language, time, date) | • | - |
| Modify units for measured values | • | - |
| Modify evaluation parameters which can be displayed | • | - |
| Set up network connections | • | - |
| Configure automatic database synchronization | • | - |
| Configure automatic export | • | - |
| Import data from USB memory stick | • | - |
| Export data to USB memory stick | • | - |

# 5. OPERATION

## 5.1 Switching system on/off

**Switching on**

1. Ensure that the measuring mat is correctly suspended in the storage compartment of the monitor ➜ Suspending measuring mat in storage compartment.

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



The login window is displayed.

The measuring mat switches on automatically.

3. Log in as described in the section entitled ➜ Logging in.

**Logging in**

When you have switched on the system, you have to log in on the monitor in order to be able to operate the device.
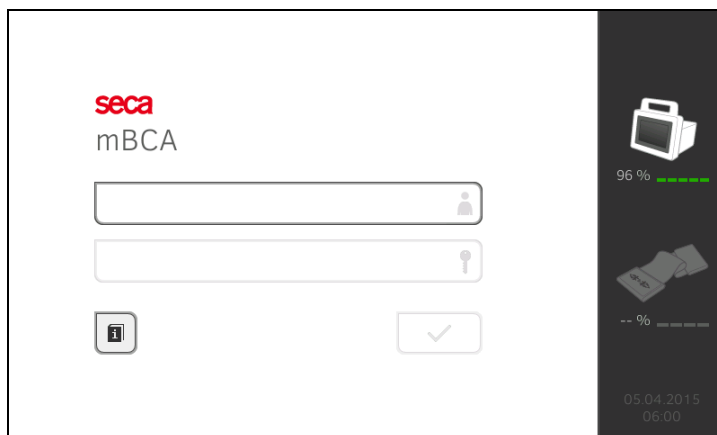


1. Press the input field .
   The list of user accounts is displayed.
   The following user accounts are available when you first start up the device:
   - Administrator: admin
   - User: demouser1

      **NOTE:**
      "demouser1" is an example user account for training purposes. If you log in as "demouser1", you can select example patient files, view existing measured results and perform training measurements.

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

3. Press the input field .

4. Enter your password using the keypad (admin: "1357", demouser1: "1234").

   The symbols and are displayed on the monitor.
   The system is ready for operation.

5. Continue depending on your login.
   ► Logged in as a user: the **patient** tab is displayed. Continue with
      ➔ Preparing seca patient file
   ► Logged in as administrator: the administrator area is displayed.
      Continue with ➔ For administrators: configuring seca 525

**Logging out/switching user**

► Press the **Logout** button.



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

**Automatic standby**

The device automatically switches to standby if there are no entries on the device for 5 minutes. This has the following effects:

- the LED of the ON/OFF button is green.
- the touchscreen display goes out.
- all entries are retained.
- the measuring mat remains switched on.
- after you switch back on, you have to log in again.
- operation can be continued.

If no entries are made for 10 minutes, the device switches off:

- the LED of the ON/OFF button goes out.
- data which have not been saved are lost.
- the measuring mat switches off.
- after you switch back on, you have to log in again.
- entries have to be made again.

**Switching the monitor to standby**

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

**Switching off**

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

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

1. Ensure that the measuring mat is correctly suspended in the storage compartment of the monitor ➜ Suspending measuring mat in storage compartment.

2. Keep the ON/OFF button of the monitor pressed until the touchscreen display and the LED of the ON/OFF button go out.
The device is switched off.
The measuring mat switches off automatically.

## 5.2 Preparing seca patient file

➔ Introduction

➔ Calling up seca patient file

➔ Creating a seca patient file

➔ Entering basic parameters

**Introduction**

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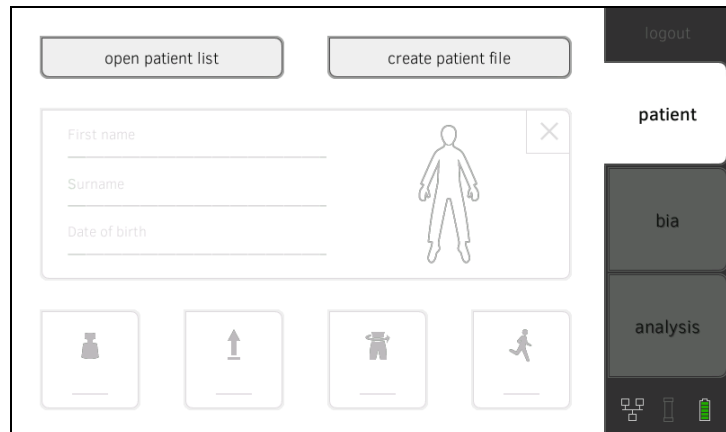


Preparation of the seca patient file includes the following items:

- seca call up or create patient file ➔ Calling up seca patient file or ➔ Creating a seca patient file
- enter weight, height, waist circumference and Physical Activity Level ➔ Entering basic parameters

**Calling up seca patient file**

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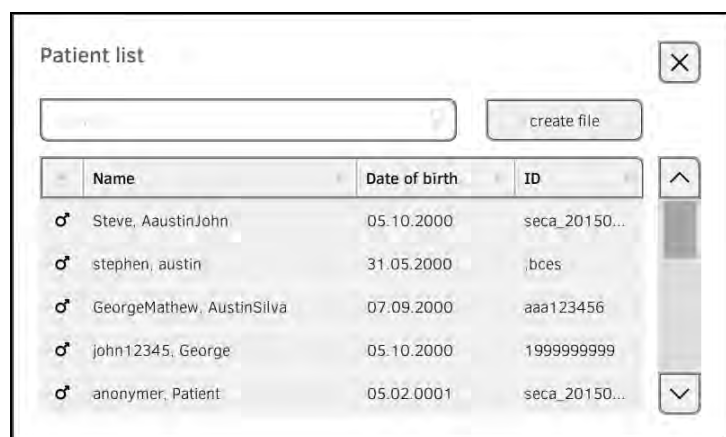


3. Select a seca patient file:
   ► Desired entry not visible: continue at Step 4.
   ► Desired entry visible: continue at Step 5.

4. Search for the desired seca patient file in the list:

   a) Press input field 

   b) Enter patient name or patient ID using the keypad 

   c) Confirm your entry by pressing the  button

   A hit list is displayed.

5. Press the desired entry.
   The selected seca patient file appears in the **Patient information** dialog field.

6. Press the **confirm** button.
   The seca patient file is opened.

7. Enter the basic parameters ➔ Entering basic parameters.

**Creating a seca patient file**

**ATTENTION!**
**Inconsistent measured results**
If you create seca patient files several times, this can lead to incorrect assignment of measured results and falsify the evaluation.
► If there is no seca patient file on the device for the current patient, check whether there is already a seca patient file in the **seca 115** PC software.
► If there is a seca patient file in the **seca 115** PC software for the current patient, ask your administrator to synchronize the data of the device and the PC software.
► Only create a new seca patient file directly on the device if you are sure that there is no seca patient file for the current patient in the **seca 115** PC software.

1. Ensure that the measuring mat is correctly suspended in the storage compartment of the monitor ➔ Suspending measuring mat in storage compartment.

2. Press the **patient** tab.

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

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

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

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

a) Press input field

b) Enter text using the keypad

c) Confirm your entry by pressing the ⏎ button

5. Enter the attending physician (optional):
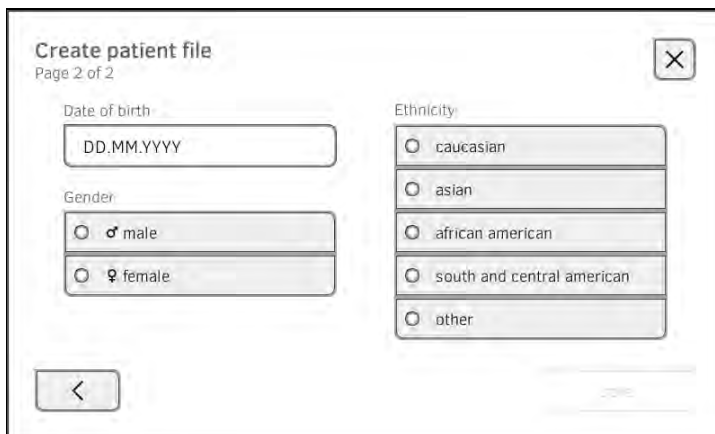
a) Press input field

b) Press the attending physician in the dropdown menu

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

6. Press the ⟩ button.



Create patient file
Page 2 of 2                                              ✕

Date of birth                        Ethnicity

DD.MM.YYYY                           ○ caucasian

                                     ○ asian

Gender                               ○ african american

○ ♂ male                             ○ south and central american

○ ♀ female                           ○ other

⟨

7. Enter the date of birth:

a) Press input field

b) Enter dates using the keypad .

c) Confirm your entry by pressing the ⏎ button

8. Press the appropriate gender.

9. Press the appropriate ethnicity.

10. Press the **save** button.
    The seca patient file has been created and is displayed.

    > **NOTE:**
    > If you realize that patient data need changing, contact your adminis-
    > trator.

11. Enter the basic parameters ➜ Entering basic parameters.

**Entering basic parameters**

After you have called up ➜ Calling up seca patient file or created ➜ Creating
a seca patient file a new seca patient file, you must enter basic parameters so
that the device can evaluate the measurement correctly.
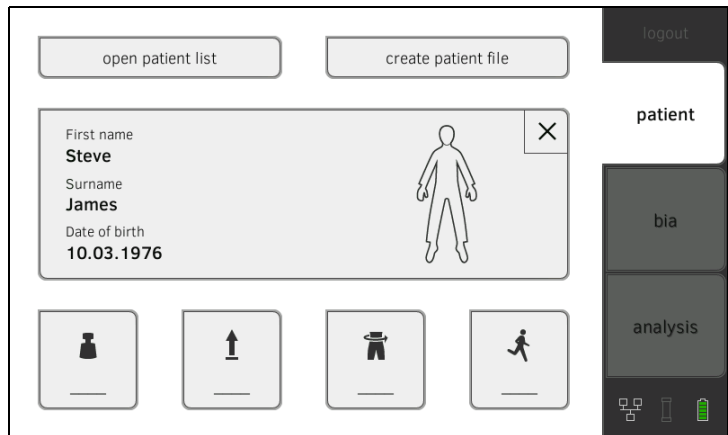


You can enter the values for basic parameters manually or take them from
other sources:

• = possible, **-** = not possible

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

1. Ensure that the measuring mat is correctly suspended in the storage
   compartment of the monitor ➜ Suspending measuring mat in storage
   compartment.

2. Press a basic parameter.
   You have the following options for entering the value:

   ► enter value using the keypad

   ► confirm the **seca 360° wireless** value using the 360° button

   ► adopt the value from the previous measurement using the button

3. Confirm the entry with the button.

4. Repeat steps 2. and 3. for the remaining basic parameters.

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

6. Press the **bia** tab.
   The seca patient file is transmitted to the measuring mat.
   You can start with the measurement ➜ Measurement.

## 5.3  Measurement

**Performing a measurement**

1. Switch on the system ➔ Switching system on/off.

2. Ensure that the measuring mat is correctly suspended in the storage compartment of the monitor ➔ Suspending measuring mat in storage compartment.

   The ⬚ symbol is displayed on the monitor.

3. Prepare the seca patient file ➔ Preparing seca patient file.

4. Press the **bia** tab.
   The seca patient file is transmitted to the measuring mat.
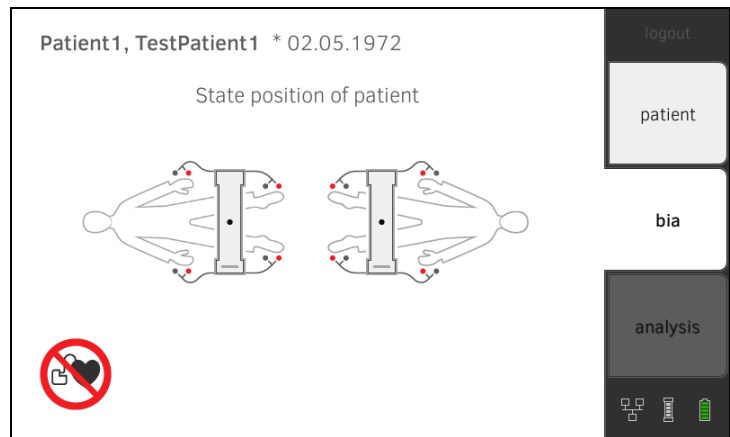


5. Enter the patient position using the ⬚ button of the monitor.
   The patient position entered is displayed on the monitor.
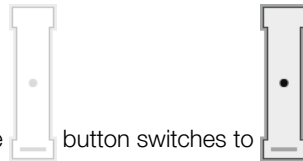
   The ⬚ button switches to ⬚.
   The patient position entered has been transmitted to the measuring mat.

   **NOTE**
   The patient position entered is saved as long as the measuring mat is switched on. This enables you to measure several patients without having to re-enter the patient position.

6. Take the measuring mat out of the storage compartment.

7. Continue the measurement as outlined below.

   ▸ The device asks you to use the control panel on the measuring mat:
   continue at Step 7. in the section entitled ➔ Performing offline mea-
   surement (WiFi not available)

   ▸ If there is no request to use the control panel on the measuring mat:
   continue at Step 8. in this section
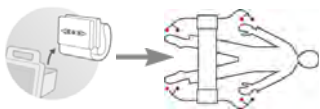
8. Connect the measuring mat ➔ Connecting the measuring mat.

9. Correct the patient position displayed if necessary, using the [▭] buttons
   of the measuring mat.
   The LED of the patient position entered is green.

10. Press the ⊙ button on the monitor.

    The measuring process starts:
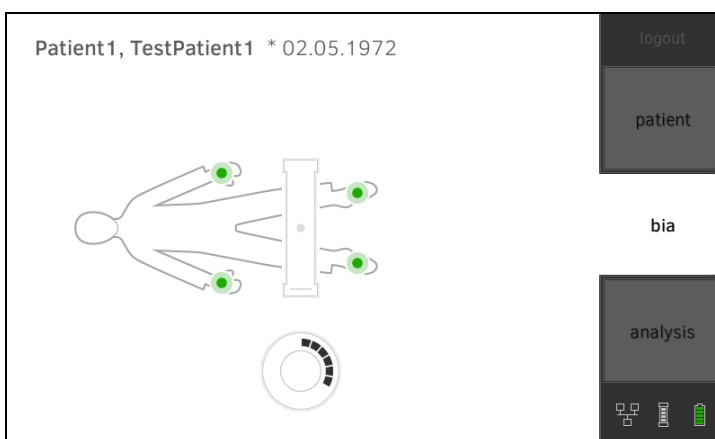


| Monitor | | | |
|---|---|---|---|
| | **Process step** | **Electrode symbol** | **Progress symbol** |
| **1.** | Electrodes being tested | 🟢 | ◔ |
| **2.** | Measurement in progress seca patient file being updated on the measuring mat | 🟢 | ◔ |
| **3.** | Updated seca patient file being transmitted to the monitor | 🟢 | ◔ |
| **4.** | Measuring process complete | ✅ | Off |

11. Remove the electrode cables from the electrodes.

12. Suspend the measuring mat in the storage compartment of the monitor.
    The measuring process is complete.
    You can now continue as outlined below.

    ▸ Press the **evaluation** tab ➔ Evaluating the measurement.

    ▸ Press the [✏️] button: add a comment.

**NOTE:**

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

**Performing offline measurement (WiFi not available)**

If no WiFi connection is available, data is transmitted between the measuring mat and the monitor before and after the measurement via the infrared interface. This results in the measuring sequence below.

1. Ensure that the measuring mat is correctly suspended in the storage compartment of the monitor ➜ Suspending measuring mat in storage compartment.

2. Switch on the system ➜ Switching system on/off.

   The [symbol] symbol is displayed on the monitor.

3. Prepare the seca patient file ➜ Preparing seca patient file.

4. Press the **bia** tab.
   The seca patient file is transmitted to the measuring mat.



5. Enter the patient position using the [button] button of the monitor.
   The patient position entered is displayed on the monitor.
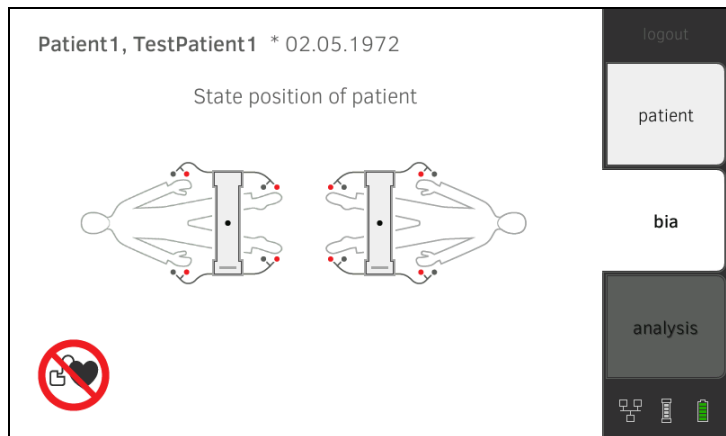
   The [button] button switches to [button].
   The patient position has been transmitted to the measuring mat.

   **NOTE**
   The patient position entered is saved as long as the measuring mat is switched on. This enables you to measure several patients without having to re-enter the patient position.

6. Take the measuring mat out of the storage compartment when the device asks you to do so.

   On the monitor, the [symbol] symbol switches to [symbol].
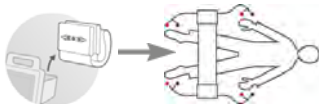
7. Connect the measuring mat ➜ Connecting the measuring mat.

8. Correct the patient position displayed if necessary, using the ▭ buttons of the measuring mat.
   The LED of the patient position entered is green.

9. Press the ⏵ button of the measuring mat.
   The measuring process starts:

| Measuring mat | | | |
|---|---|---|---|
| **Process step** | | **Electrodes** | **Patient position** |
| **1.** | Patient position is given<br>Electrodes being tested | On | On |
| **2.** | Measurement in progress<br>seca patient file being updated<br>on the measuring mat | Flashing | On |
| **3.** | Updated seca patient file being<br>transmitted to the monitor<br>Measuring process complete | Off | Flashing |

10. Remove the electrode cables from the electrodes.

11. Suspend the measuring mat in the storage compartment of the monitor.

   The measuring mat symbol switches from ▭ to ▭.
   The updated seca patient file is transmitted to the monitor.
   The measuring process is complete.
   You can now continue as outlined below.

   ► Press the **evaluation** tab ➜ Evaluating the measurement.

   ► Press the 🖉 button: add a comment.

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

**Connecting the measuring mat**

The **seca 525** is provided for bioimpedance measurement by the 8-point method (measuring the whole body) with the patient in a lying position. Measurement by the 4-point method (right half of the body) is likewise possible. To do this, use the electrode cables directly at the keypad of the measuring mat.

For the measurement, electrodes are attached to the patient's extremities and connected to the measuring mat.

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

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

1. Affix the electrodes to the patient's extremities.



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

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

   ► The control unit should be facing the user
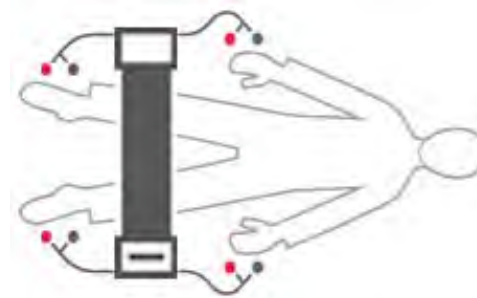


3. Connect the measuring mat to the electrodes.

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

   ► Put the push-button adapter on the electrodes (black: wrist/ankle, red: fingers/toes)



4. Ask the patient to lie still.

5. Continue with the measurement as described in the relevant section.

   ► Step 9. of the measurement

   ► Step 8. of the offline measurement

**Canceling a measurement**

You can cancel the measurement at any time.

1. Press the **Logout** button.
   The measurement will be discarded.

2. Log in again ➜ Logging in.

## 5.4 Evaluating the measurement

**Viewing the evaluation**

The **seca 525** determines a series of evaluation parameters from the bio-impedance measurement and groups these in evaluation modules.

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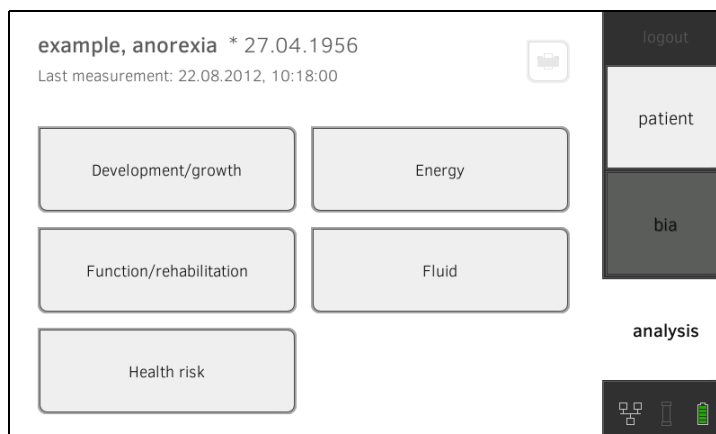


You have the following navigation options.

► Press the  button: print a results report (**seca directprint**: function of **seca 115**PC software)

► View an evaluation module: continue with Step 2.

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



You have the following navigation options.

► Press  buttons: view other evaluation modules

► Press  button: return to module summary

► To view details of an evaluation parameter: continue with Step 3.

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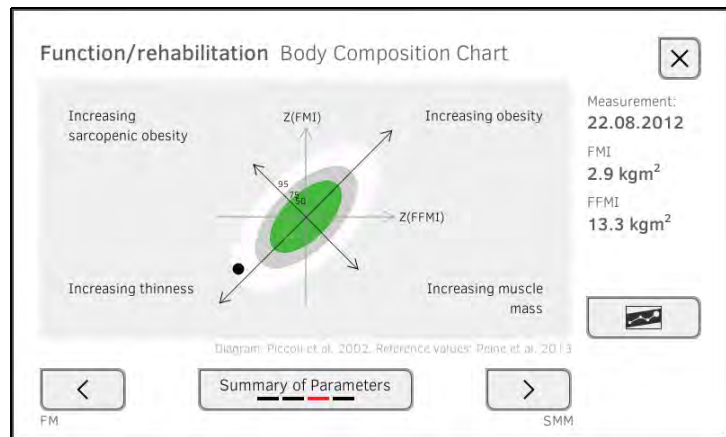


You have the following navigation options.

▸ Press the  button to view the history of this evaluation parameter ➔ Viewing the history of an evaluation parameter

▸ Press the  buttons: view other evaluation parameters

▸ Press the  button: return to parameter summary

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

**Viewing the history of an evaluation parameter**

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

1. In the **evaluation** tab, select an evaluation parameter ➔ Evaluating the measurement.
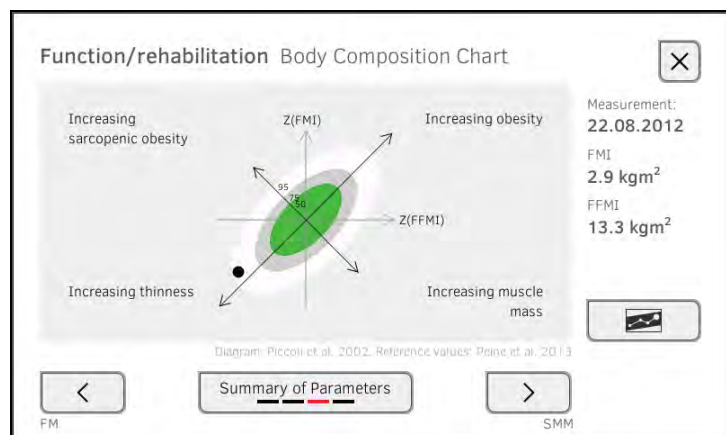
2. Press the [icon] button.
   All measurements for the current patient are displayed.
   The latest measurement is highlighted automatically.



You have the following navigation options.

▶ Press the checkboxes [icon] : select values for history: continue
   with Step 3.

▶ Press the [icon] button: add a comment.

▶ Press the [icon] button: return to the evaluation of the current
   measurement.

**NOTE:**
Just a single comment can be added to each measured result. Exist-
ing comments will be overwritten.

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

4. Press the [icon] button.
   The history will be displayed.
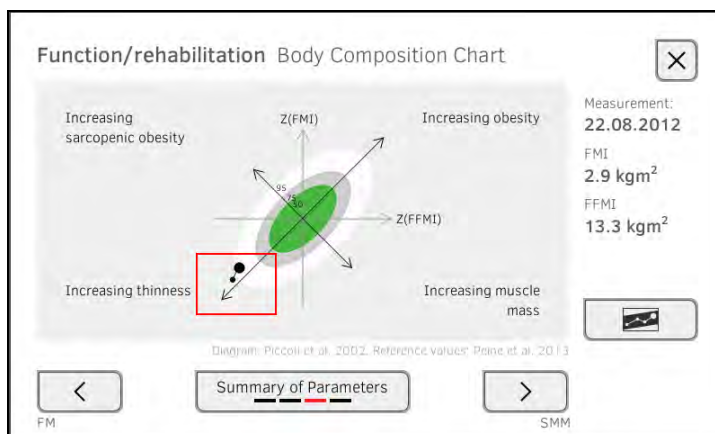
# 6. HYGIENE TREATMENT

➜ Cleaning

➜ Disinfecting

➜ Sterilizing

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

▸ Ensure that the device is switched off before performing any hygiene treatment.

▸ Disconnect the power supply connector before performing any hygiene treatment.

▸ Before each hygiene treatment , take the rechargeable battery out of the device (if present and removable).

▸ Ensure that no fluids penetrate the device.

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

▸ Use only disinfectants free of chlorine and alcohol which are explicitly suitable for acrylic sheet and other sensitive surfaces (active ingredient: quaternary ammonium compounds, for example).

▸ Do not use aggressive or abrasive cleaning agents.

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

## 6.1 Cleaning

▸ Use a soft cloth dampened with mild soapsuds to clean the surfaces of the device.

## 6.2 Disinfecting

1. Check that your disinfectant is suitable for sensitive surfaces and acrylic sheet.

2. Follow the instructions for use for the disinfectant.

3. Disinfect the device:

   ▸ Moisten a soft cloth with disinfectant and wipe down the device

   ▸ Comply with the intervals: see table

| **Prior** to every measurement with direct skin contact | Measuring mat, electrode cables |
|---|---|
| **After** every measurement with direct skin contact | Measuring mat, electrode cables |
| If required | Monitor, storage compartment |

## 6.3 Sterilizing

This device may not be sterilised.

# 7. FUNCTION CHECK

► Perform a function check prior to each use.

A complete function check includes:

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

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

⚠ **CAUTION!**
**Personal injury**
If you notice any faults or deviations during the function check which cannot be resolved with the aid of the section entitled "What do I do if ..." in this document, you may not use the device.
► Have the device repaired by seca service or by an authorized service partner.
► Follow the section entitled "Servicing" in this document.

# 8. SERVICING

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

**NOTICE!**
**Incorrect measurements as a result of poor servicing**
► Have servicing and repairs carried out exclusively by seca service or by an authorized service partner.
► You can find service partners in your area at www.seca.com or by sending an e-mail to service@seca.com.

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

➔ Monitor

➔ Measuring mat

➔ Bioimpedance measurement

➔ Data connection

➔ Printing

## 9.1 Monitor

| Problem | Cause | Remedy |
|---|---|---|
| **Monitor cannot be switched on** | No power supply | Provide power supply |
| | Rechargeable battery discharged | Provide power supply and charge rechargeable battery |
| | Rechargeable battery faulty | Replace rechargeable battery |
| **Touchscreen display remains dark** | Device on standby | • Touch the touchscreen display<br>• Press the ON/OFF button |
| | Device not switched on | Switch on device |
| | No power supply | Check whether power is being supplied |
| | Touchscreen display faulty | Inform seca service |
| **Touchscreen display not reacting** | Device in undefined state following implausible input | • Switch off the device (press and hold the ON/OFF button for approx. 15 seconds)<br>• Switch the device back on |
| **Image on touchscreen display faulty** | Touchscreen display faulty | Inform seca service |
| **Password not accepted** | Password overwritten on last synchronization with **seca 115** PC software | • Use the new password<br>• If new password not known, contact administrator |

## 9.2 Measuring mat

| Problem | Cause | Remedy |
|---|---|---|
| **Measuring mat cannot be switched on** | Rechargeable battery discharged | Suspend measuring mat in storage compartment of monitor and charge rechargeable battery |
| | Measuring mat faulty | Replace measuring mat |
| | Inductive charging interface faulty | Inform seca service |
| **"Charging state" LED is red** | Rechargeable battery discharged | Suspend measuring mat in storage compartment of monitor and charge rechargeable battery |
| | Rechargeable battery faulty | Replace measuring mat |
| | Inductive charging interface faulty | Inform seca service |
| **"WiFi" LED is red** | No WiFi connection to monitor | Administrator:<br>check settings for WiFi connection and correct if necessary |
| | WiFi module of measuring mat faulty | Replace measuring mat |

| Problem | Cause | Remedy |
|---|---|---|
| **One or more "Electrode contact" LEDs is red** | Electrode cables not connected to electrodes | Ensure that all electrode cables are engaged in the push-buttons of the electrodes |
| | Electrodes faulty | Replace electrodes |
| | Electrode cables or measuring mat faulty | Replace measuring mat |
| **One or more LEDs on the measuring mat not on** | Measuring mat faulty | Replace measuring mat |
| **seca patient files cannot be transmitted to the measuring mat** | No WiFi connection | • Suspend the measuring mat in the storage compartment of the device<br>• Call up seca patient file again, data will be transmitted via the infrared interface |
| | Infrared interface faulty | Inform seca service |
| **No WiFi connection** | WiFi function of device is deactivated | Administrator:<br>activate WiFi |
| | Distance between measuring mat and monitor is too big | • Reduce distance<br>• Perform offline measurement |
| | Distance between monitor and WiFi router is too big | • Reduce distance<br>• Transmit measured results to **seca 115** PC software via LAN |
| | WiFi not available in your institution | • Perform offline measurement<br>• Transmit measured results to **seca 115** PC software via LAN |

## 9.3 Bioimpedance measurement

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

## 9.4   Data connection

| Problem | Cause | Remedy |
|---|---|---|
| **Data transmission cannot be set up between device and seca 115** | Software versions incompatible | Use a compatible version of the **seca 115**: 1.4 build 381 or higher |
| **seca patient file cannot be found when searching for a patient on the device** | No seca patient file set up yet | Create a seca patient file ➜ Creating a seca patient file |
| | seca patient file is not assigned to the user in the **seca 115** | Check whether the seca patient file can be assigned to the user in the **seca 115** |
| | Windows firewall port-blocking is active, required ports are blocked | Administrator: release the ports required |
| **No access to seca patient database of the seca 115 PC software** | No network connection set up between the device and the PC on which the **seca 115** PC software is installed | Administrator: set up network connection |
| | The PC on which the **seca 115** PC software is installed is not switched on | Switch on PC |
| | Automatic synchronization is deactivated on the device | Administrator: activate automatic synchronization |

## 9.5   Printing

| Problem | Cause | Remedy |
|---|---|---|
| **Print function not available** | Software versions incompatible | Use a compatible version of the **seca 115** PC software: 1.4 build 381 or higher |
| **Results report not being printed** | PC printer not switched on | Switch on PC printer |
| | The PC on which the **seca 115** PC software is installed is not switched on | Switch on PC |
| | No network connection set up between device and **seca 115** PC software | Administrator: set up LAN connection |
| | No connection set up between the **seca 115** PC software and the PC printer | Administrator: set up connection between **seca 115** PC software and the PC printer |

# 10. TECHNICAL DATA

## 10.1 Monitor

| Monitor | |
|---|---|
| Dimensions<br>• Depth<br>• Width<br>• Height | <br>230 mm<br>252 mm<br>262 mm |
| Net weight | approx. 2 kg |
| Ambient conditions, operation<br>• Temperature<br>• Air pressure<br>• Humidity | <br>+10 °C to +40 °C (50 °F to 104 °F)<br>700 hPa - 1060 hPa<br>30 % - 80 %, no condensation |
| Ambient conditions, storage<br>• Temperature<br>• Air pressure<br>• Humidity | <br>-10 °C to +60 °C (14 °F to 140 °F)<br>700 hPa - 1060 hPa<br>0 % - 95 %, no condensation |
| Ambient conditions, transport<br>• Temperature<br>• Air pressure<br>• Humidity | <br>-10 °C to +60 °C (14 °F to 140 °F)<br>700 hPa - 1060 hPa<br>0 % - 95 %, no condensation |
| Setup location, maximum altitude above mean sea level | 3000 m |
| Display type | 7" Touchscreen display |
| Power supply<br>Mains voltage<br>Mains frequency<br>Power consumption | Internal power supply unit<br>100 V ~ - 240 V ~<br>50 Hz - 60 Hz<br>0.85 A |
| Mobile power supply<br>Range (measuring) | Lithium-ion rechargeable battery<br>approx.8 h |
| Power consumption<br>• Standby (touchscreen display off, ON/OFF button green)<br>• In operation (ON/OFF button white)<br>• Operation (charging rechargeable battery of monitor and measuring mat, ON/OFF button white) | <br>< 5 W<br>< 9 W<br>< 35 W |
| Medical device in accordance with Directive 93/42/EEC | Class IIa |
| EN 60601-1: Medical electrical device, type BF | 👤 |
| Type of protection | IP20 |
| Operating mode | Continuous duty |
| Interfaces | **seca 360° wireless**<br>USB 2.0 (max 500 mA)<br>LAN: Ethernet (10/100 Base-T)<br>WiFi<br>Infrared<br>Inductive charging of rechargeable battery<br>for measuring mat |
| Compatible printer | Microsoft® Windows®-compatible printer<br>via **seca analytics 115** PC software |

## 10.2 Measuring mat

| Measuring mat | |
|---|---|
| Dimensions | |
| • Depth | 783 mm |
| • Width | 170 mm |
| • Height | 20 mm |
| Net weight | approx. 1 kg |
| Ambient conditions, operation | |
| • Temperature | +10 °C to +40 °C (50 °F to 104 °F) |
| • Air pressure | 700 hPa - 1060 hPa |
| • Humidity | 30 % - 80 %, no condensation |
| Ambient conditions, storage | |
| • Temperature | -10 °C to +60 °C (14 °F to 140 °F) |
| • Air pressure | 700 hPa - 1060 hPa |
| • Humidity | 0 % - 95 %, no condensation |
| Ambient conditions, transport | |
| • Temperature | -10 °C to +60 °C (14 °F to 140 °F) |
| • Air pressure | 700 hPa - 1060 hPa |
| • Humidity | 0 % - 95 %, no condensation |
| Setup location, maximum altitude above mean sea level | 3000 m |
| Power supply | Lithium-ion rechargeable battery |
| Range (measurements) | approx.8 h |
| Medical device in accordance with Directive 93/42/EEC | Class IIa |
| EN 60601-1: Medical electrical device, type BF | |
| Type of protection | IP44 |
| Operating mode | Continuous duty |

## 10.3 Bioimpedance measurement

➜ Measuring method

➜ Evaluation parameters

➜ Evaluation modules

➜ Clinical studies

➜ Accuracy of predictive formulas

**Measuring method**

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

**Evaluation parameters**

| Evaluation parameters | Display | Evaluation module |
|---|---|---|
| Bioimpedance vector analysis (BIVA) | • Normal range display of R and $X_c$ in co-ordinate system in relation to height<br>• 50 %, 75 %, 95 % percentiles in the form of tolerance ellipses | Fluid<br>Health risk |
| Body mass index (BMI) | • Absolute in $kg/m^2$<br>• Graph of WHO reference values | Development/growth |
| Extracellular water (ECW) | Absolute in l | Fluid |
| Fat-free mass (FFM) | Absolute in kg | Function/rehabilitation |
| Fat mass (FM) | • Absolute in kg<br>• Relative to weight in %<br>• Normal range display | Energy<br>Function/rehabilitation |
| Total energy expenditure (TEE) | Absolute in MJ/d or kcal/d | Energy |
| Total body water (TBW) | Absolute in l | Fluid |
| Weight (W) | Absolute in kg | Development/growth |
| Height (H) | Absolute in m | Development/growth |
| Intracellular water (ICW) | Absolute in l | Fluid<br>(North America) |
| Hydration (HYD = ECW/ICW) | Relative in % | Fluid (international) |
| Energy stored in the body ($E_{body}$) | Absolute in MJ or kcal | Energy |
| BCC:<br>mass indices<br>Fat-free mass index (FFMI)<br>Fat mass index (FMI) | • Absolute in $kg/m^2$<br>• Normal range display<br>• 50 %, 75 %, 95 % percentiles in the form of tolerance ellipses | Function/rehabilitation<br>Health risk |
| Phase angle (φ) | • Absolute in degrees<br>• Normal range display | Health risk |
| Reactance ($X_c$) | Absolute in ohms | Fluid<br>Health risk |
| Resistance (R) | Absolute in ohms | Fluid<br>Health risk |
| Resting energy expenditure (REE) | Absolute in MJ/d or kcal/d | Energy |
| Skeletal muscle mass (SMM) | • Absolute in kg<br>• Normal range display | Function/rehabilitation |
| Visceral adipose tissue (VAT) | Absolute in l | Health risk |

## Evaluation modules

| Evaluation module | Description | Evaluation parameters |
|---|---|---|
| Development/growth | Supports the monitoring of weight changes | • Weight<br>• Height<br>• Body mass index (BMI) |
| Energy | • Determination of energy expenditure and energy reserves<br>• Required: weight, height, PAL | • Fat mass (FM)<br>• Energy stored in the body ($E_{body}$)<br>• Resting energy expenditure (REE)<br>• Total energy expenditure (TEE) |
| Function/rehabilitation | • Determining fitness level<br>• Assessing the success of a training program<br>• Required: weight, height | • Fat-free mass (FFM)<br>• Fat mass (FM)<br>• Body composition chart (BCC)<br>• Skeletal muscle mass (SMM) |
| Fluid | • Determination of fluid status<br>• Required: weight, height | • Total body water (TBW)<br>• Extracellular water (ECW)<br>• North America: intracellular water (ICW)<br>• International: hydration (HYD); HYD =(100 x ECW) / (TBW-ECW) [%]<br>• Bioimpedance vector analysis (BIVA) |
| Health risk | • Summary of body composition<br>• Estimate of health risk<br>• Required: weight, height, waist circumference | • Phase angle (φ)<br>• Visceral adipose tissue (VAT)<br>• Bioimpedance vector analysis (BIVA)<br>• Body composition chart (BCC) |

## Clinical studies

Clinical studies form the scientific basis for analysis of body composition with the mBCA **seca 525**. The study results are incorporated in the device software in the form of reference values.

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

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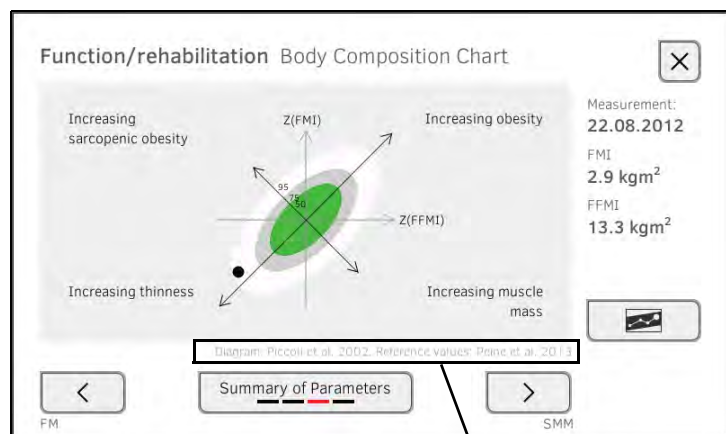


**Study used**

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

**Accuracy of predictive formulas**

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

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

## 10.4 seca 360° wireless system

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

# 11. OPTIONAL ACCESSORIES

| Accessory | Article number |
|---|---|
| **seca 360° wireless**devices: | |
| Measuring stations | |
| • **seca 285**/**seca 284** | Country-specific versions |
| Length measuring devices | |
| • **seca 274** | Country-specific versions |
| • **seca 264** | Country-specific versions |
| Personal scales | |
| • **seca 704**/**seca 703** | Country-specific versions |
| Multifunctional and platform scales | |
| • **seca 635**/**seca 634** | Country-specific versions |
| • **seca 645**/**seca 644** | Country-specific versions |
| • **seca 657**/**seca 656** | Country-specific versions |
| • **seca 665**/**seca 664** | Country-specific versions |
| • **seca 677**/**seca 676** | Country-specific versions |
| • **seca 685**/**seca 684** | Country-specific versions |
| PC software | |
| • **seca analytics 115** | Application-specific license packages |
| seca rolling stand **seca 475** | 475-00-00-009 |
| seca carry case **seca 432** | 432-00-00-009 |

# 12. SPARE PARTS

| Spare parts | Article number |
|---|---|
| Measuring mat | 12-04-03-036-601 |
| Push-button electrodes for affixing to patient, pack of 30 | 68-90-00-031-009 |
| DVD with **seca analytics 115** PC software and license for one permanent workstation | Country-specific versions |

# 13. DISPOSAL

## 13.1 Measuring mat and device

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

**service@seca.com**

## 13.2 Batteries and rechargeable batteries

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

# 14. WARRANTY

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

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

We ask customers based abroad to contact their local sales agent directly in the case of warranty claims.

# FOR ADMINISTRATORS: CONFIGURING SECA 525

**NOTE:**
- This part of the user documentation contains information about configuring the device for measuring mode and for integration in a PC network.

- The functions described in this section are accessible exclusively to users with administrator rights.

- Follow the information in the Instructions for Use.

# 1. PREPARING CONFIGURATION

**ATTENTION!**
**Faulty configuration**
During configuration, data are transmitted to the measuring mat via the infrared interface. The infrared interface is located in the storage compartment of the monitor.
➤ Ensure that the measuring mat is correctly suspended in the storage compartment of the monitor throughout the entire configuration process ➜ Suspending measuring mat in storage compartment.

1. Switch on the device ➜ Switching system on/off.
   The measuring mat switches on automatically.

2. Log on as the administrator (default user account: "admin"; password "1357") ➜ Logging in.
   The administrator area is displayed.
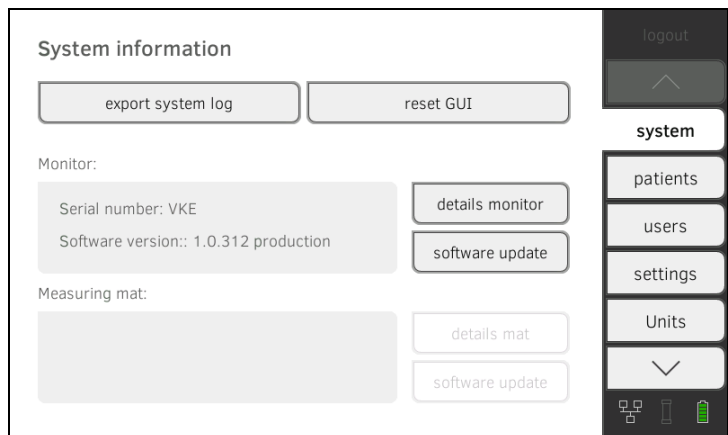
# 2. MEASURING MODE

➔ Administering the user database

➔ Administering the seca patient database

➔ Deactivating evaluation modules

➔ Modifying default settings

➔ Setting units of measurement

## 2.1 Administering the user database

➔ Setting up a user account

➔ Editing a user account

➔ Deleting a user account

**Setting up a user account**

**ATTENTION!**
**Inconsistent measured results**
If you create user accounts several times, this can lead to incorrect assignment of measured results and falsify the evaluation.

► If there is no user account for a user on the device, check whether there is already a user account in the **seca 115** PC software.

► If a user account for the user exists in the **seca 115** PC software, check the synchronization settings on the device to allow you to adopt the user account from the **seca 115** PC software➔ Activating automatic synchronization.

► Only create a new user account directly on the device if you are sure that there is no user account for this user in the **seca 115** PC software.

1. Press the **users** tab.
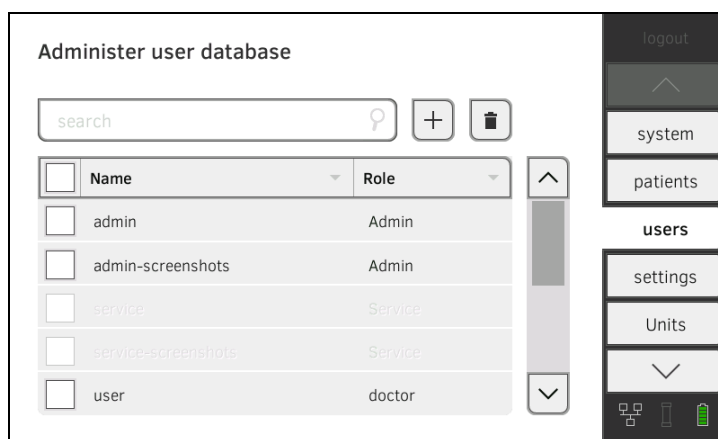
2. Press the ⊞ button.



Create user     ✕

Role                    Display language

User name                Password

☑ Password-protected       Repeat password

save

3. Enter the requested user data by pressing the relevant input field.

 ▸ Specify role

 ▸ Select display language

 ▸ Assign user name

4. Enter a password.

5. Repeat the password.

6. Let the user know his or her password.

7. Ensure that the **Password-protected** field is activated (default).

8. Press the **save** button.
 The user account is set up.
 The user account can be synchronized with the **seca 115** PC software ➔ Synchronization and backup.

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

**Editing a user account**

1. Press the **users** tab.
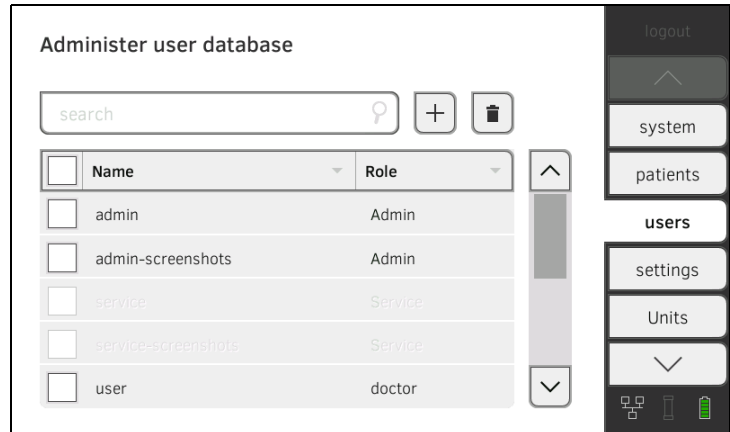


You have the following navigation options.

▶ Desired entry visible: continue at Step 3.

▶ Desired entry not visible: continue at Step 2.

2. Search for the desired user account in the list:

a) Press input field .

b) Enter the user name using the keypad .

A hit list is displayed.

3. Press the desired entry.
   The selected user account is displayed.

4. Edit the user account to the extent necessary.

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

**Deleting a user account**

**ATTENTION!**
**Loss of data**
In contrast to seca patient files, it is **not** possible to restore deleted user accounts.
► Ensure that user accounts you would like to delete really are no longer required.

1. Press the **users** tab.
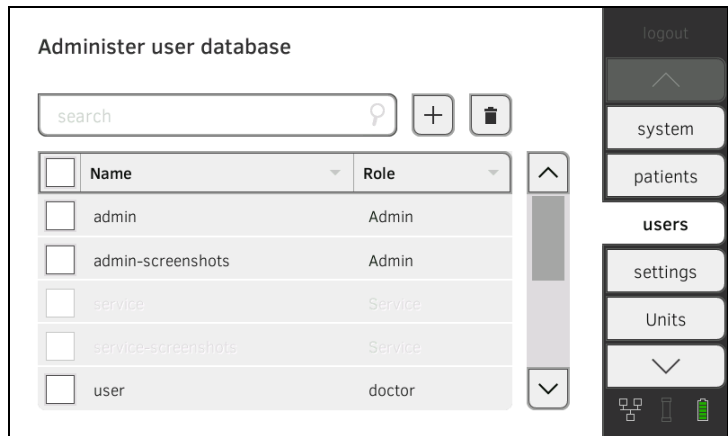


2. Press the checkboxes ⬜ of all user accounts you would like to delete.

3. Press the 🗑 button.

4. Confirm that you wish to proceed.
The marked user accounts will be deleted.

## 2.2 Administering the seca patient database

➔ Creating a seca patient file

➔ Editing a seca patient file

➔ Deleting a seca patient file

➔ Restoring a seca patient file

**ATTENTION!**
**Inconsistent measured results**
If you create seca patient files several times, this can lead to incorrect assignment of measured results and falsify the evaluation.
► If there is no seca patient file on the device for a patient, check whether there is already a seca patient file in the **seca 115** PC software.

► If a seca patient file for this patient exists in the **seca 115** PC software, check the synchronization settings ➔ Activating automatic synchronization.

► Only create a new seca patient file directly on the device if you are sure that there is no seca patient file for the patient in the **seca 115** PC software.

**Creating a seca patient file**

1. Press the **patients** tab.
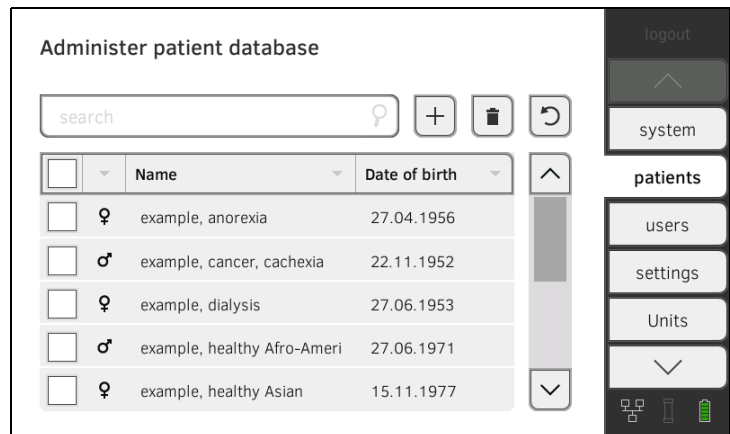


2. Press the ⊞ button.

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

**Editing a seca patient file**

1. Call up a seca patient file as described in the relevant section of the Instructions for Use ➔ Editing a seca patient file.

2. Edit the seca patient file.

3. Press the **save** button.
The changes will be saved.

**Deleting a seca patient file**

1. Press the **patients** tab.
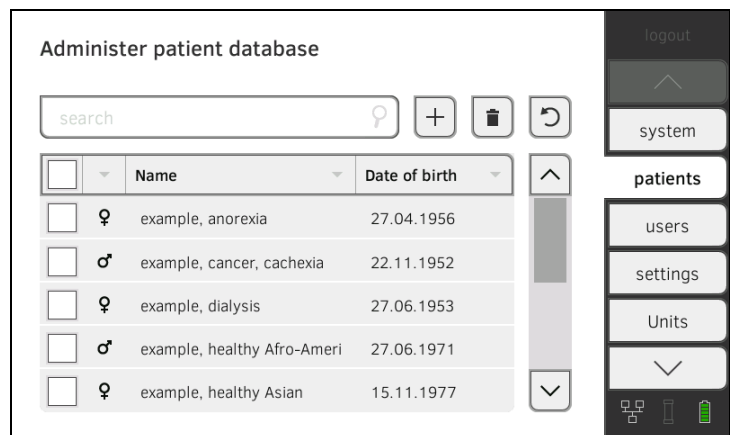


2. Press the checkboxes ☐ of all seca patient files you would like to delete.

3. Press the 🗑 button.
The marked seca patient files will be deleted.

**Restoring a seca patient file**

1. Press the **patients** tab.

Administer patient database

| | | Name | Date of birth | |
|---|---|---|---|---|
| | ♀ | example, anorexia | 27.04.1956 | |
| | ♂ | example, cancer, cachexia | 22.11.1952 | |
| | ♀ | example, dialysis | 27.06.1953 | |
| | ♂ | example, healthy Afro-Ameri | 27.06.1971 | |
| | ♀ | example, healthy Asian | 15.11.1977 | |

logout

system

**patients**

users

settings

Units
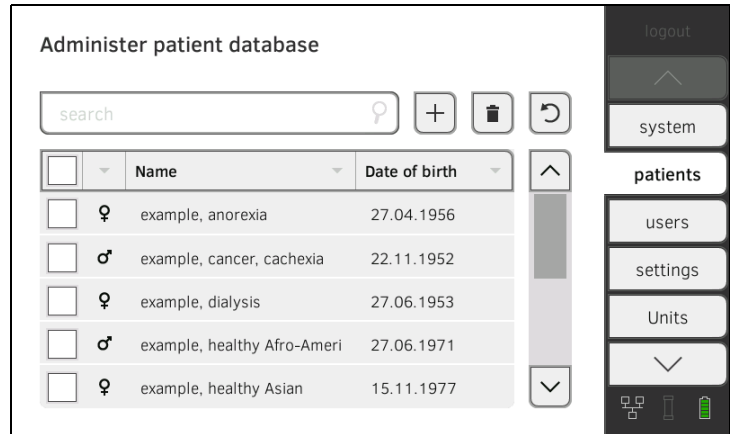
2. Press the button.
   A list of deleted seca patient files is displayed.

3. Press the checkboxes of all seca patient files you would like to restore.

4. Press the **restore** button.
   The marked seca patient files will be moved to the patient list and be available for measuring mode again.

## 2.3 Deactivating evaluation modules

1. Press the **modules** tab.

| Summary of modules | | logout |
|---|---|---|
| | | ∧ |
| ✓ | Development/growth | **modules** |
| ✓ | Energy | seca 360° |
| ✓ | Function/rehabilitation | LAN |
| ✓ | Fluid | WiFi |
| ✓ | Health risk | PC-softw. |
| | | ∨ |
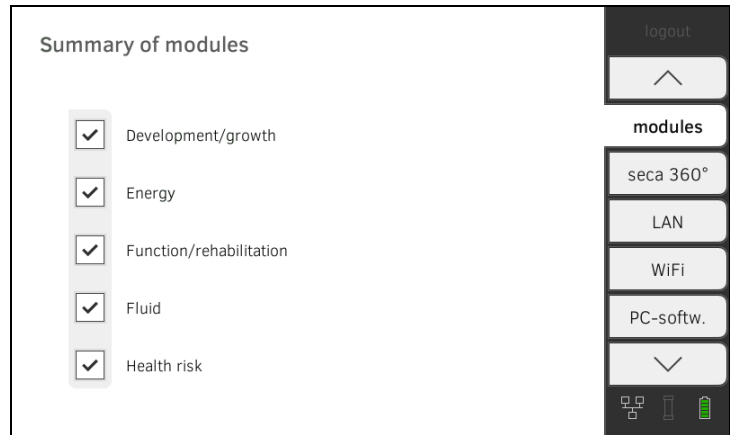
All evaluation modules are activated at the factory.

2. Press the checkboxes ☑ of all evaluation modules you would like to deactivate.
   The deactivated evaluation modules are no longer displayed in the evaluation ➔ Evaluating the measurement.

3. To reactivate evaluation modules, press the checkboxes ☐ of the deactivated evaluation modules again.
   The reactivated evaluation modules will be displayed in the evaluation ➔ Evaluating the measurement again.

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

## 2.4    Modifying default settings

➔ Making regional settings

➔ Calibrating touchscreen display

➔ Setting display brightness and volume

**Making regional settings**

**ATTENTION!**
**Loss of data, misinterpretation of measurements**
The settings for date and time are not automatically synchronized with the settings in the **seca 115** PC software. Different date and time information may lead to measurements being misinterpreted.
► Ensure that the same settings for date and time are made both on the device and in the **seca 115** PC software.

1. Press the **settings** tab.

| Global settings | | logout |
|---|---|---|
| Date | | |
| 05.04.2015 | dd.mm.yyyy ▾ | system |
| Time | | patients |
| 06:01:21 | 24 h ▾ | users |
| Name style | | **settings** |
| First name Surname ▾ | ☑ With separator | Units |
| calibrate touchscreen | brightness / volume | |

2. Specify the regional settings by pressing the relevant input field.
   ► Enter date
   ► Select date format
   ► Enter time
   ► Select time format
   ► Select naming convention
   ► Activate/deactivate name separator.

   The settings will be transmitted to the measuring mat.

   **NOTE:**
   • The dialog language cannot be specified on this tab. The dialog language is assigned to each user individually ➔ Setting up a user account.
   • Settings you make in this tab are active directly. You do not need to save or confirm them.

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**Calibrating touchscreen display**

1. Press the **settings** tab.

| Global settings | | logout |
|---|---|---|
| Date | | ∧ |
| 05.04.2015 | dd.mm.yyyy ▽ | system |
| Time | | patients |
| 06:01:21 | 24 h ▽ | users |
| Name style | | **settings** |
| First name Surname ▽ | ☑ With separator | Units |
| calibrate touchscreen | brightness / volume | ∨ |

2. Press the **calibrate touchscreen** button.

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

   $+$

4. Press the $+$ symbol.
   The symbol changes position.

5. Press the $+$ symbol again.
   The symbol changes its position again.

6. Repeat steps 4. and 5. until the **settings** tab is displayed again.
   The touchscreen display is calibrated.

**Setting display brightness and volume**

1. Press the **settings** tab.
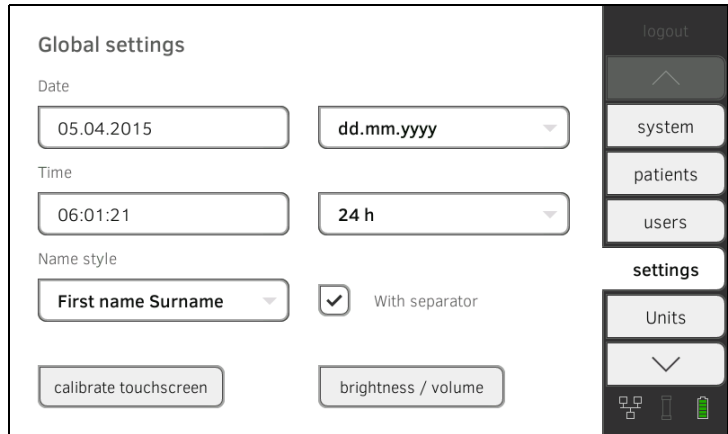


2. Press the **Brightness/volume** button.
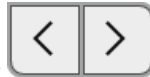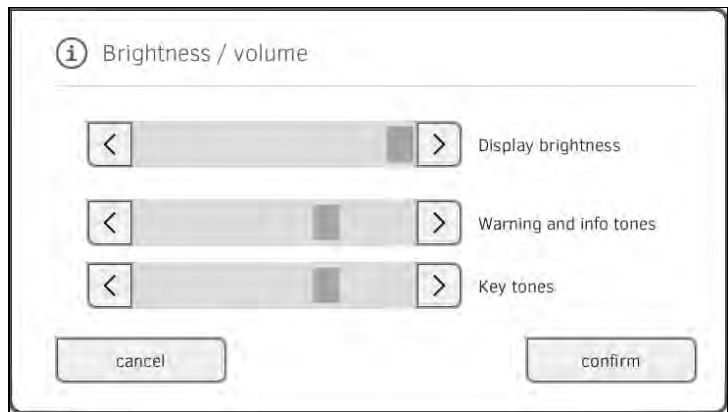


3. Press the  buttons as appropriate.

   ► Set display brightness

   ► Set volume for warning and information sounds

   ► Set volume for button sounds

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

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

## 2.5   Setting units of measurement

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

▶ Use the results exclusively in SI units.

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

1. Press the **units** tab.



2. Make the desired settings.

▶ Specify the reference for resting energy expenditure

▶ Specify the unit for energy

▶ Specify the decimal separator

▶ Specify the unit for weight

▶ Specify the unit for height

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

# 3. DATA CONNECTION

## 3.1 Setting up LAN connection (stationary operation)

**Introduction**

If the device is to be used on a stationary basis, e.g. in a treatment room in your practice, you can integrate the monitor in your LAN using a network cable and set up a connection to the **seca 115** PC software.
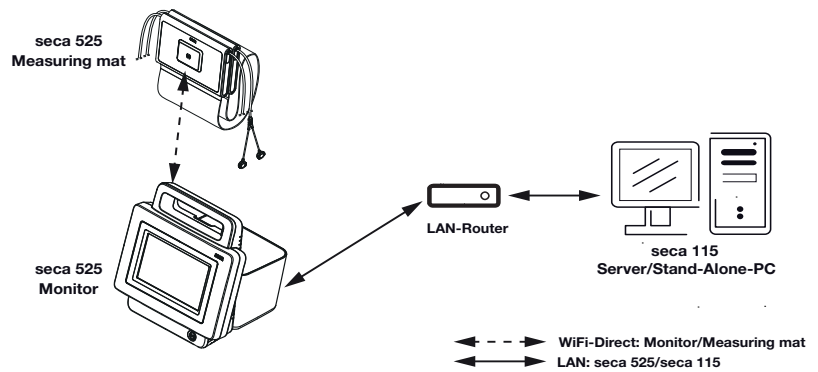


The monitor and the PC software communicate via the LAN connection. The monitor and the measuring mat communicate with one another via a direct WiFi connection (WiFi direct). It is not possible for the measuring mat and the PC software to communicate directly.

**Setting up LAN connection**

1. Press the **LAN** tab.
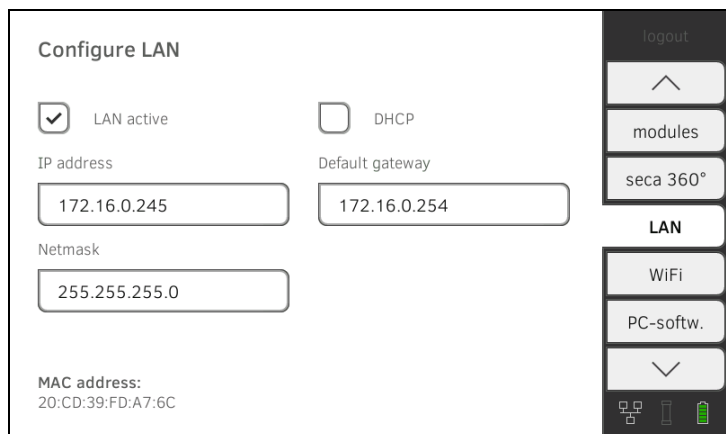


2. Make the applicable setting for your network.

   ► To set up connection on automated basis: press the **DHCP** button

   ► To set up connection manually, continue at Step 3.

3. Make the relevant settings for your network.

   ► Enter IP address

   ► Enter netmask

   ► Enter default gateway

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

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

**Checking direct WiFi connection to measuring mat**

1. Ensure that the measuring mat is correctly suspended in the storage compartment of the monitor.

2. Press the **WiFi** tab.

3. Ensure that the following settings are in place:

| Function | Setting |
|----------|---------|
| **WiFi** | activated |
| **WiFi Direct** | activated |

The ▯ symbol is displayed on the monitor.
The direct connection between the monitor and the measuring mat is set up.

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

**Deactivating/activating LAN**

1. Press the **LAN** tab.
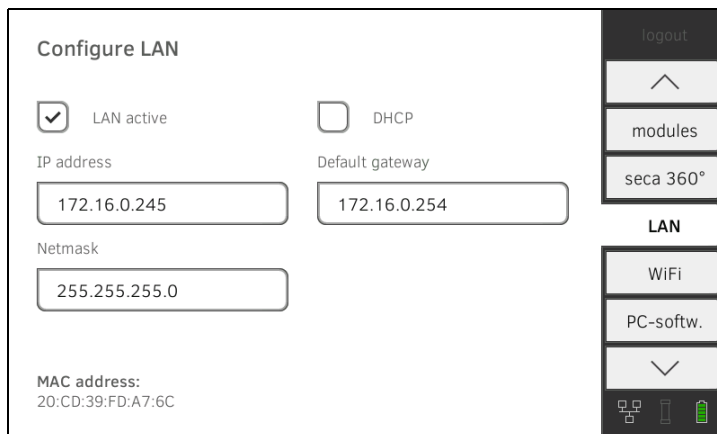


2. Press the **LAN active** checkbox.
   The LAN function is deactivated.
   The connection data are retained.

3. To reactivate the LAN function, press the **LAN active** checkbox again.

## 3.2 Setting up WiFi connection (mobile operation)

**Introduction**

If the device is to be used on a mobile basis, e.g. on a hospital ward, you can integrate the device in your WiFi network and set up a connection to the **seca 115** PC software.
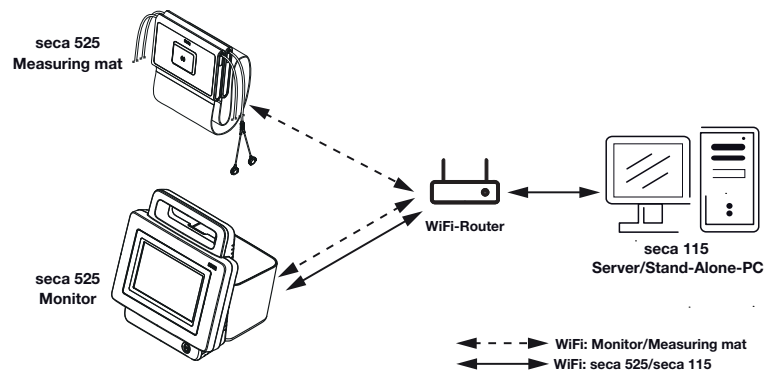


The monitor and the PC software communicate via the WiFi connection. The monitor and the measuring mat likewise communicate via the WiFi connection. It is not possible for the measuring mat and the PC software to communicate directly.

> **NOTE:**
> If you and the device leave the reception range of the WiFi router, the monitor and the measuring mat will automatically switch to a direct WiFi connection.

**Setting up a WiFi connection**

1. Ensure that the measuring mat is correctly suspended in the storage compartment of the monitor.

2. Press the **WiFi** tab.
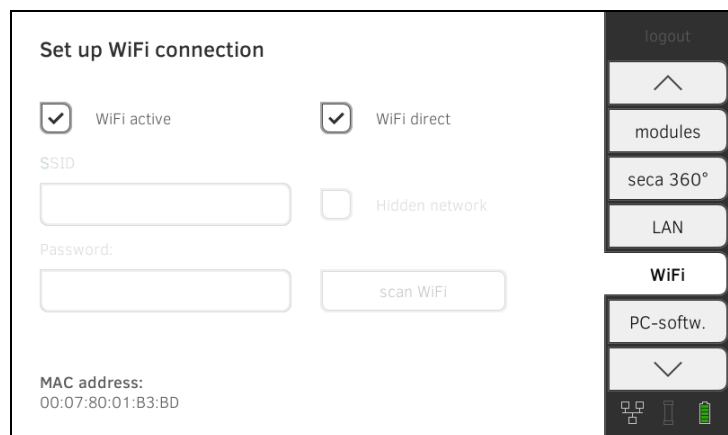


3. Ensure that the following functions are active:

| Function | Setting |
|---|---|
| **WiFi** | activated |
| **WiFi Direct** | activated |

4. Make the applicable setting for your WiFi network.
   ► Visible network: press the **scan WiFi** button.
   ► Hidden network: press the **Hidden Network** button

5. Enter the SSID for your network.
   ► Visible network: select SSID from dropdown menu
   ► Hidden network: enter SSID manually

6. Enter the password for your network.
   The settings will be transmitted to the measuring mat.
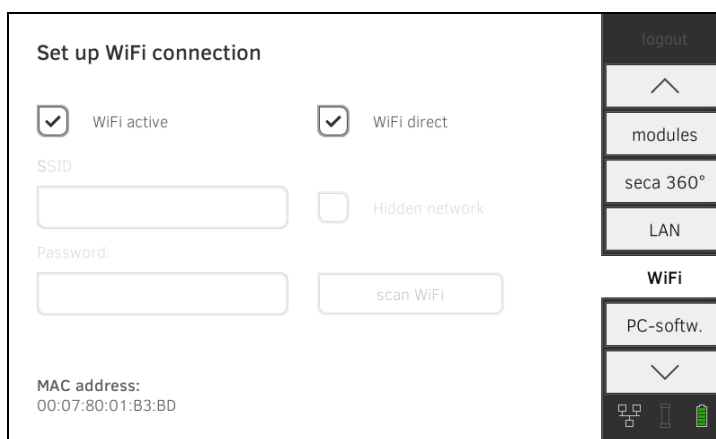
   The symbols ![wifi icon] and ![mat icon] are displayed on the monitor.

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

**Deactivating/activating WiFi**

1. Press the **WiFi** tab.



2. Press the **WiFi active** checkbox.
   The WiFi function is deactivated.
   The connection data are retained.

3. To reactivate the WiFi function, press the **WiFi active** checkbox again.

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

**Introduction**

On the **PC softw.** tab, you can connect the device to the **seca 115** PC software either via UDP or manually. The functions below are then available.

- Synchronize patient and user data automatically➔ Activating automatic synchronization.

- **seca directprint**: issue results reports directly from the device on a network printer ➔ Viewing the evaluation.



seca 525     seca 115 Server/Stand-Alone-PC (seca mediator service)     Network-Printer
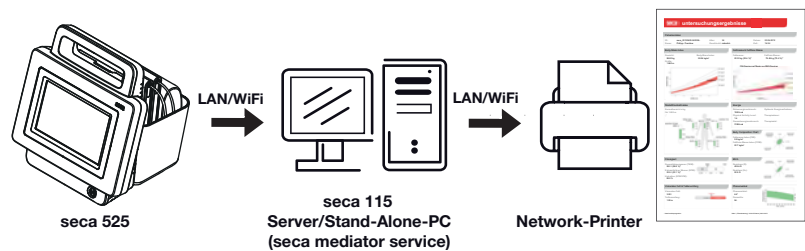
**NOTE:**
- You specify the network printer for the **seca directprint** function directly in the **seca 115** PC software

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

- Also observe the Administrator Manual for the **seca 115** PC software.

**Setting up PC connection on an automated basis (UDP)**

1. Press the **PC softw.** tab.
   The **Connect via UDP** checkbox is activated at the factory.
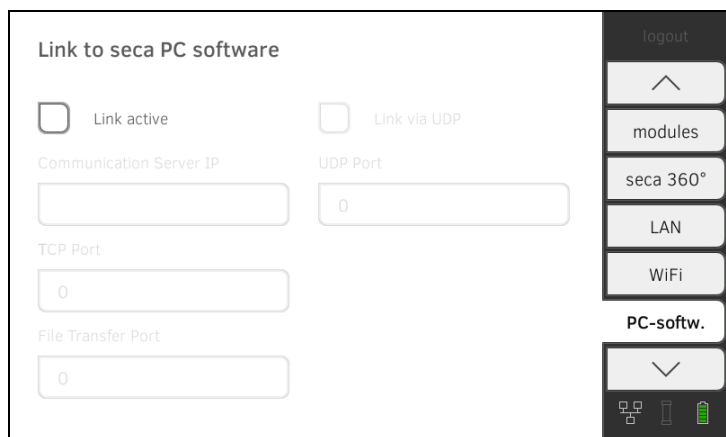


2. Press the **Link active** checkbox.
   The function is activated.

3. Adapt default settings if necessary.

| Input field | Default setting |
|---|---|
| **UDP Port** | 20011 |
| **File Transfer Port** | 20012 |

**Setting up PC connection manually**

1. Press the **PC softw.** tab.



2. Press the **Link active** checkbox.
   The function is activated.

3. Deactivate the **Connect via UDP** checkbox.

4. In the **Communication Server IP** line, enter the appropriate IP address.

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

5. In the **TCP Port** line enter the value of the PC selected under 4., (Default: 20010).

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

## 3.4 Setting up the seca 360° wireless network

**Introduction**

If you use devices from the **seca 360° wireless** system in your institution, e.g. a measuring station, you can link them to the **seca 525**. You can transmit the parameters height and weight directly to the **seca 525** and adopt them in a seca patient file.
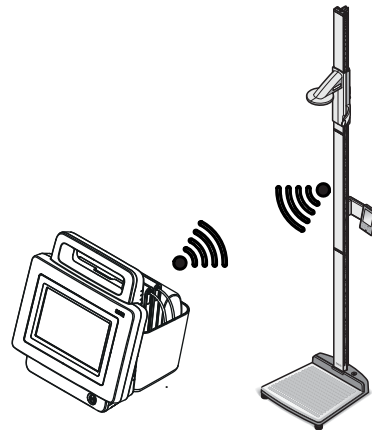


In order to be able to communicate with devices from the **seca 360° wireless** system, the **seca 360° wireless** module of the **seca 525** must be activated and a wireless group set up.

> **NOTE:**
> You should also follow the Instructions for Use for the devices from the **seca 360° wireless** system being used.

**Activating/deactivating the seca 360° wireless module**

1. Press the **seca 360° wireless network** tab.
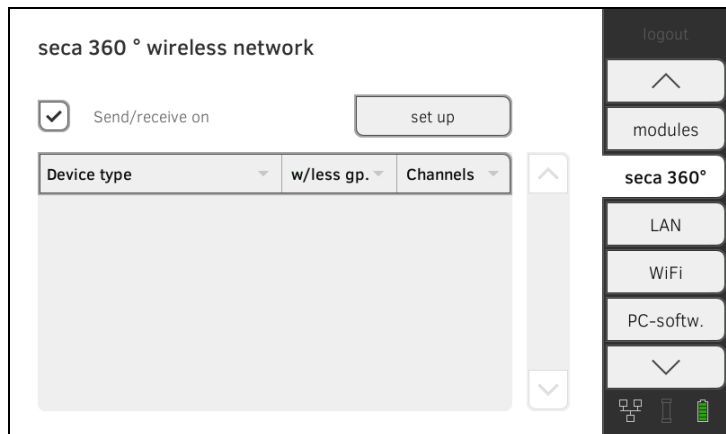


2. Press the **Send/receive on** checkbox.
   The **seca 360° wireless** module is activated.

3. To deactivate the **seca 360° wireless** module, press the **Send/receive on** checkbox again.

**Setting up a seca 360° wireless connection**

1. Ensure that the **seca 360° wireless** modules of the **seca 525** and all the devices you want to connect to the **seca 525** are activated.

2. Switch off all the devices you want to connect to the **seca 525**.

3. Press the **seca 360° wireless network** tab.
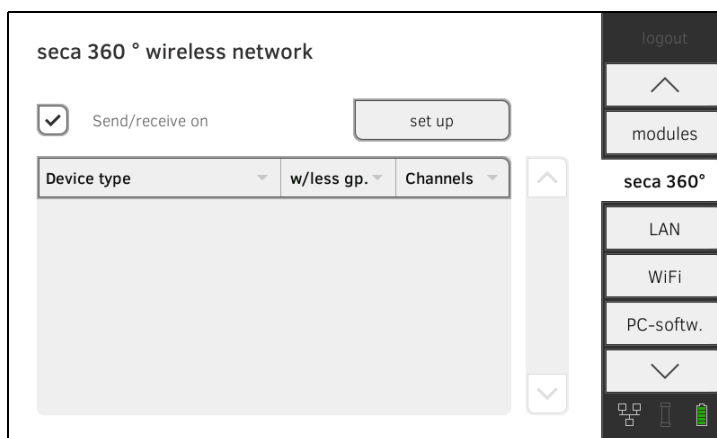


4. Press the **set up** button.

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

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

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

6. Switch on all **seca 360° wireless** devices you wish to incorporate in the wireless group.
   When devices are detected, a beep will be heard.
   Detected devices will be displayed on the monitor.

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

# 4. SYSTEM DATA

## 4.1 Synchronization and backup

**Activating automatic synchronization**

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

- seca patient files
- user accounts and passwords
- automatic export settings

> **ATTENTION!**
> **Malfunction**
> In order to be able to use automatic synchronization, a connection to the PC software must be set up ➔ Setting up a connection to the seca analytics 115 PC software.
> ► Ensure that the connection to the PC software is set up before you activate automatic synchronization.

1. Press the **synchr.** tab.
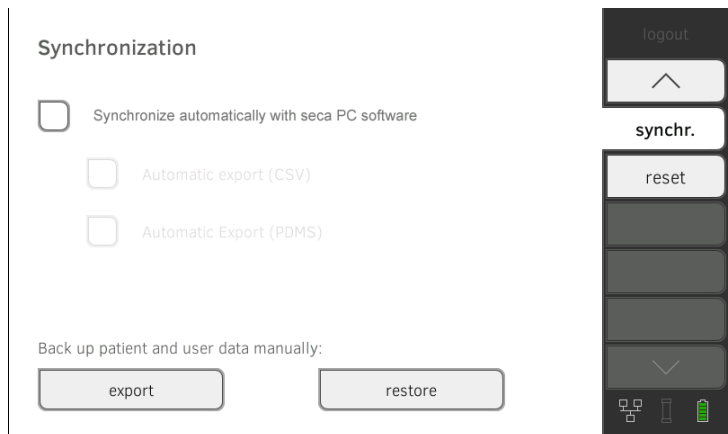


2. Press the **Synchronize automatically with seca PC software** checkbox. Automatic synchronization is activated.

> **NOTE:**
> • The data are synchronized as soon as they are changed either on the device or in the PC software. No further settings are required.
>
> • In the event of conflicts during synchronization, the data of the **seca 115** PC software take priority. The data of the **seca 525** will be overwritten.

**Setting up automatic export**

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

1. Establish which data format your practice or hospital information system accepts.

2. Press the **synchr.** tab.
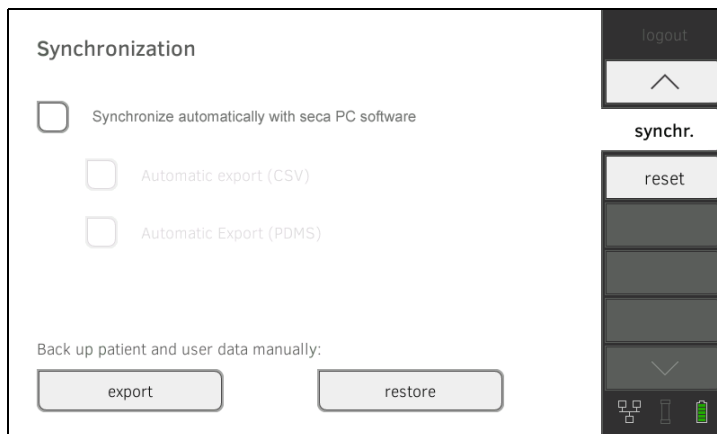


3. Ensure that the **Synchronize automatically with seca PC software** checkbox is activated.

4. Press the desired export format.
   - **Automatic export CSV**
   - **Automatic export PDMS**

5. Set up an interface to the **seca 115** PC software in your practice or hospital information system.

   **NOTE:**
   - Settings you make in this dialog window are transmitted to the **seca 115** PC software ➔ Activating automatic synchronization.

   - Note the user documentation for the practice or hospital information system used.

   - seca service would be pleased to help you if you have any questions relating to "interface configuration".

**Exporting patient and user data manually**

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

1. Press the **synchr.** tab.
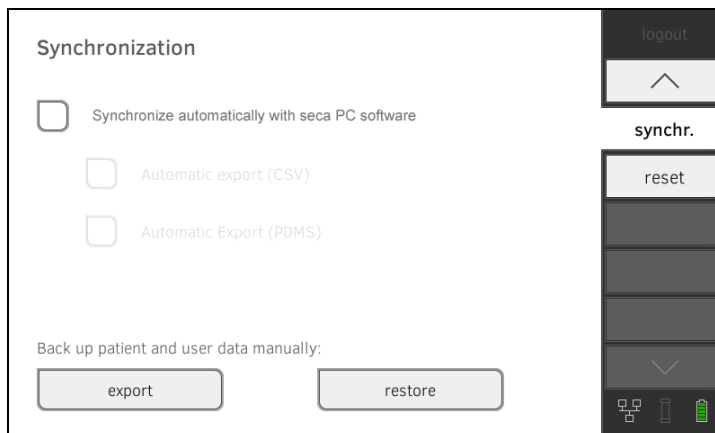


2. Connect a USB memory stick to the monitor.

3. Press the **export** button.
   The data are exported to the USB memory stick.

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

**Restoring patient and user data manually**

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

> **ATTENTION!**
> **Loss of data**
> When you restore externally backed-up data, the current data on the device will be overwritten.
> ► Export seca patient files and user accounts manually **before** restoring older data manually (operate without **seca 115** PC software).
> ► **Before** restoring manually, ensure that all the data on the device have been synchronized with the **seca 115** PC software (operate with **seca 115** PC software).

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

2. Press the **synchr.** tab.
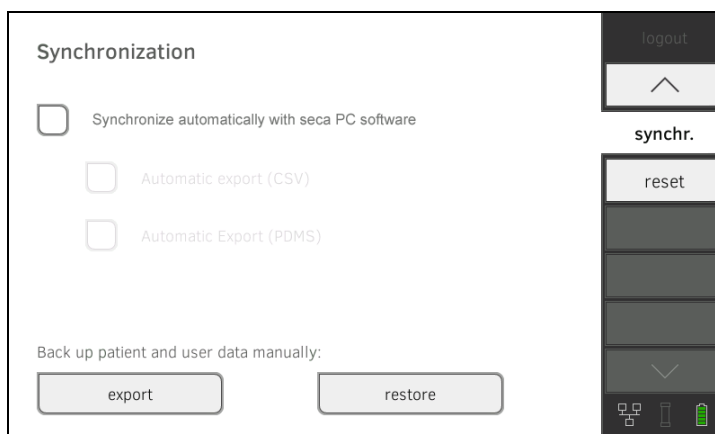


3. Connect the USB memory stick to the monitor.

4. Press the **restore** button.
   The data will be imported.

## 4.2   System information

**Viewing software versions**

1. Press the **system** tab.
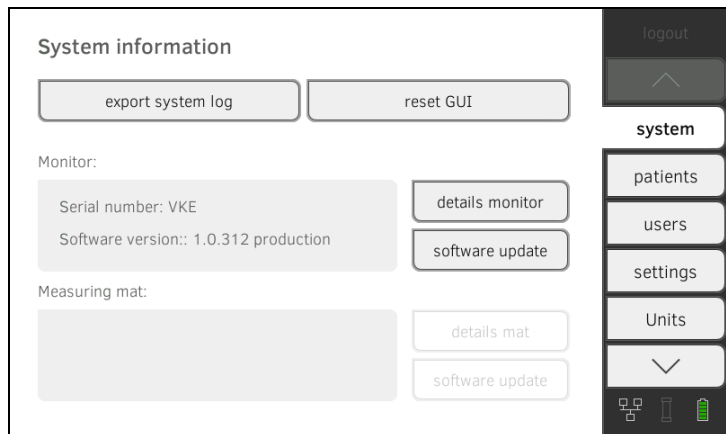


The serial number and software version are now displayed for both the monitor and the measuring mat.

2. You have the following options for displaying details.

   ► Press the **monitor details** button

   ► Press the **details mat** button

**Updating software**

This function allows you to update the software of the monitor and the measuring mat.

> **ATTENTION!**
> **Loss of data**
> The device will be reset to factory settings. seca patient files and user accounts will be deleted.
> ► Export seca patient files and user accounts manually **before** updating the software (operate without **seca 115** PC software).
> ► **Before** updating the software, ensure that all the data on the device have been synchronized with the **seca 115** PC software (operate with **seca 115** PC software).

1. Press the **system** tab.
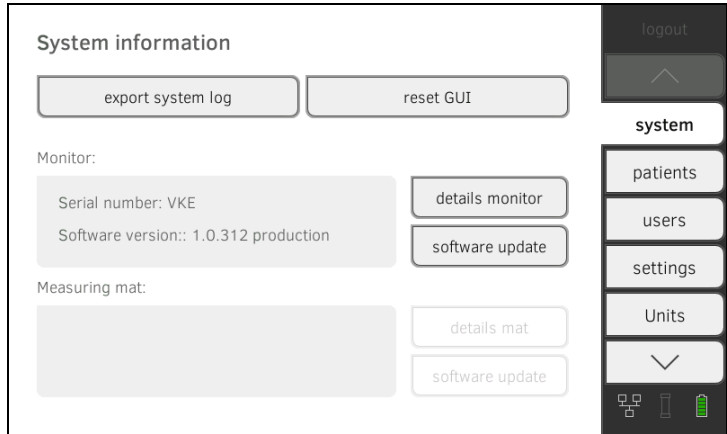


2. Press the **software update** button.
3. Select the source for the software update.
   - ► USB memory stick: continue with Step 4.
   - ► Network: continue with Step 5.
4. Connect the USB memory stick to the monitor.
5. Press the **start software update** button.
   The software package will be loaded.
   If the software package includes an update for the measuring mat, the **update mat** button will be active.
6. Follow the on-screen instructions.
7. Press the **update mat** button.
8. Follow the on-screen instructions.

**Exporting the system log**

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

1. Press the **system** tab.
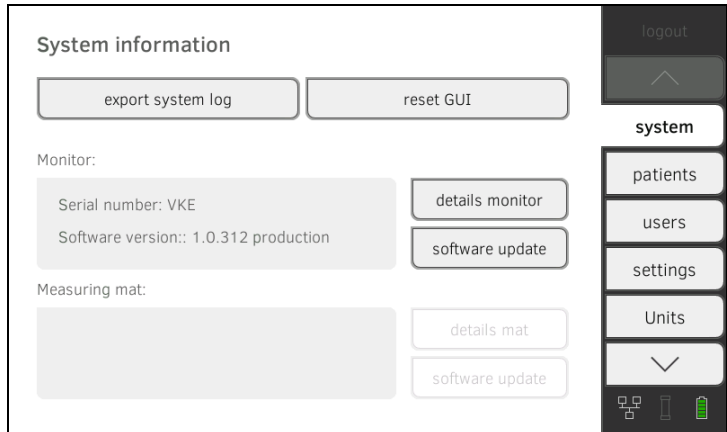


2. Press the **export system log** button.
3. Select the export destination.
   - ► USB memory stick: continue with Step 4.
   - ► Network: continue with Step 5.
4. Connect a USB memory stick to the monitor.
5. Press the **start export** button.
   The system log will be exported.

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

**Resetting GUI**

In the **system** tab, you can reset the graphical user interface (GUI) to factory settings ➜ Factory settings.

> **NOTE:**
> This function retains seca patient files and user accounts. If you want to reset the device completely, proceed as described in the section entitled ➜ Resetting device.

1. Press the **system** tab.

System information

| export system log | reset GUI |

Monitor:

Serial number: VKE

Software version:: 1.0.312 production

details monitor

software update

Measuring mat:

details mat

software update

logout

system
patients
users
settings
Units
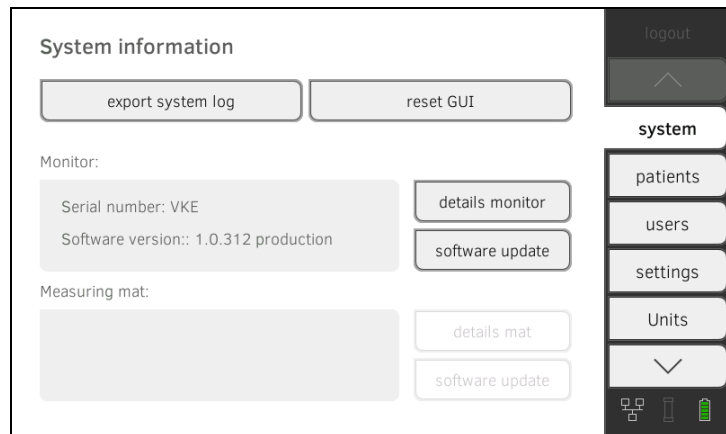
2. Press the **reset GUI** button.
   The user interface will be reset.
   seca patient files and user accounts will be retained.

## 4.3 Factory settings

→ Resetting device

→ Enabling VNC access

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

| Function | Setting |
|---|---|
| Administrator password | 1357 |
| Dialog language | English |
| Date format: International North America | mm.dd.yyyy mm/dd/yyyy |
| Time format: International North America | 24 h 12 h |
| Naming convention | Surname, first name |
| Name separator | Comma |
| Display brightness | 100 % |
| Volume for warning and information sounds Volume for button sounds | 50 % 50 % |
| Weight: International North America | kg lbs |
| Height: International North America | m ft |
| Decimal separator: International North America | Comma Decimal point |
| Energy | MJ |
| Reference resting energy expenditure | FAO/WHO/UNU |
| LAN Connection data | On None |
| WiFi Direct WiFi Connection data | On On None |
| **seca 360° wireless** Connection data | Off None |
| **PC softw.** Communication Server IP TCP Port UDP Port File Transfer Port | Off 0.0.0.0 20010 20011 20012 |
| Active evaluation modules | All |

**Resetting device**

**ATTENTION!**
**Loss of data**
seca patient files and user accounts will be deleted if you reset the device to factory settings.
► Export seca patient files and user accounts **before** resetting (operate without **seca 115** PC software).
► Synchronize the data **before** resetting (operate with **seca 115** PC software).
► If you want to retain the seca patient files and user accounts, simply reset the GUI ➜ Resetting GUI.

1. Press the **reset** tab.
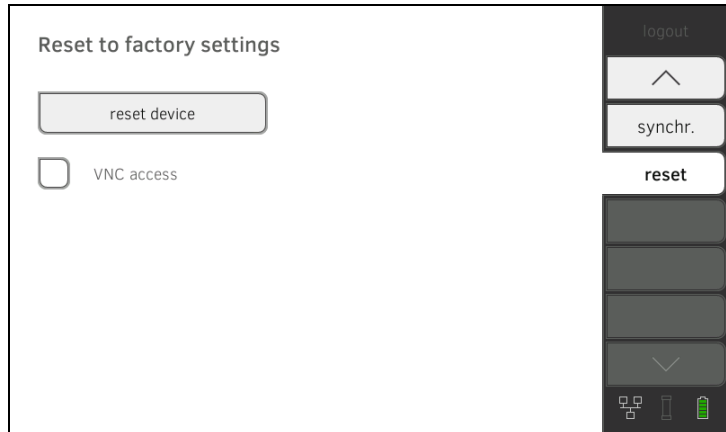


2. Ensure that seca patient files and user accounts have been exported or synchronized using the **seca 115** PC software.
3. Press the **reset device** button.
   The device will be reset to factory settings ➜ Factory settings.

**Enabling VNC access**

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

1. Press the **reset** tab.
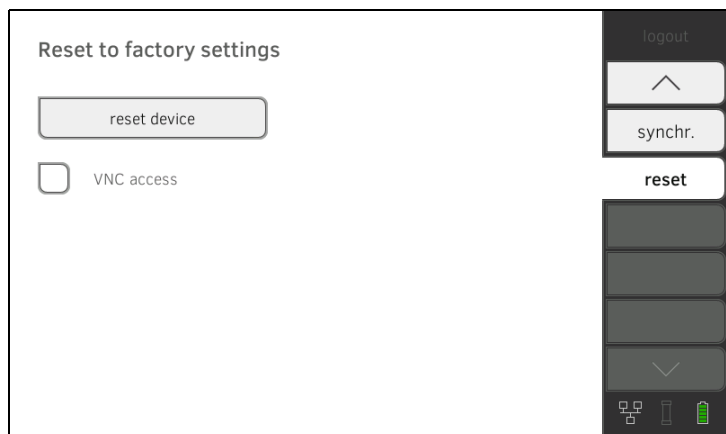


2. Press the **VNC access** checkbox.
3. Restart the device.
   The VNC service of the device will be started.
4. Set up the VNC connection using the VNC viewer of your PC.

# DECLARATIONS OF CONFORMITY

**For USA and Canada:**

seca
seca 525
seca 360 wireless Modules:
FCC ID: X6T172A01
IC: 8898A-172A01
WiFi Module Monitor:
FCC QOQWF111
IC 5123A-BGTWF111
WiFi Module Measuring Mat:
FCC QOQWF121
IC 5123A-BGTWF121

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

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

- This device may not cause harmful interference.

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

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

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

**For Europe**

# C E

Konformitätserklärung
Declaration of conformity
Certificat de conformité
Dichiarazione di conformità
Declratión de conformidad
Overensstemmelsesattest
Försäkran om överensstämmelse
Konformitetserklæring
Vaatimuksenmukaisuusvakuutus
Verklaring van overeenkomst
Declaração de conformidade
Δήλωση Συμβατότητας
Prohlášení o shodě
Vastavusdeklaratsioon
Megfelelőségi nyilatkozat
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**D** ... erfüllt die geltenden Anforderungen folgender Richtlinien:
93/42/EWG über Medizinprodukte, 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten, 1999/5/EG über Funkanlagen und Telekommunikationssendeinrichtungen und die gegenseitige Anerkennung ihrer Konformität.

Darüber hinaus sind unter anderem folgende Normen anwendbar:
EN 300 328, EN 301 489-1 und -17 über elektromagnetische Verträglichkeit und Funkspektrumangelegenheiten.

**GB** ...complies with the applicable requirements of the following directives:
93/42/EEC governing medical devices, 2011/65/EU governing the restriction of the use of certain hazardous substances in electrical and electronic equipment, 1999/5/EC governing radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity.

Furthermore the following directives are applicable among others:
EN 300 328, EN 301 489-1 and -17 governing electromagnetic compatibility and radio spectrum matters.

**F** ... est conforme aux directives et normes suivantes:
93/42/CEE relatives aux dispositifs médicaux, 2011/65/UE relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques, 1999/5/CE concernant les équipements hertziens et les équipements terminaux de télécommunications et la reconnaissance mutuelle de leur conformité.

Par ailleurs, les normes suivantes peuvent être entre autres utilisées :
EN 300 328, EN 301 489-1 et -17 relatives à la compatibilité électromagnétique et au spectre radioélectrique.

**I** ... risponde alle vigenti esigenze poste dalle seguenti direttive:
93/42/CEE in materia di prodotti medicali, 2011/65/CEE sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche, 1999/5/CEE concernente le apparecchiature radio, le apparecchiature terminali di telecomunicazioni e il reciproco riconoscimento della loro conformità.

Sono inoltre applicabili anche le seguenti norme:
EN 300 328, EN 301 489-1 e -17 in materia di compatibilità elettromagnetica e di spettro radio.

**E** ... cumple las exigencias vigentes de las siguientes directivas:
93/42/CEE sobre productos sanitarios, 2011/65/EU sobre las restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos, 1999/5/CE sobre equipos radioeléctricos y equipos terminales de telecomunicación y el mutuo acuerdo de su conformidad.

Adicionalmente se aplicarán, entre otras, las normas siguientes:
EN 300 328, EN 301 489-1 y -17 sobre compatibilidad electromagnética y cuestiones del espectro radioeléctrico.

**DK** opfylder de gældende krav fra følgende direktiver:
93/42/EØF om medicinprodukter, 2011/65/EU om begrænsning af anvendelsen af visse farlige stoffer i elektrisk og elektronisk udstyr, 1999/5/EF om radio- og teleterminaludstyr samt gensidig anerkendelse af udstyrets overensstemmelse.

Desuden er følgende standarder anvendelige:
EN 300 328, EN 301 489-1 og -17 om elektromagnetisk fordragelighed og radiospektrumanliggender.

**GR** ... εκπληρώνει τις ισχύουσες απαιτήσεις των ακόλουθων Οδηγιών:
93/42/EOK περί ιατροτεχνολογικών προϊόντων, Οδηγία 2011/65/EE για τον περιορισμό χρήσης συγκεκριμένων ουσιών σε ηλεκτρονικές και ηλεκτρικές συσκευές, 1999/5/EK σχετικά με τον ραδιοεξοπλισμό και τον τηλεπικοινωνιακό τερματικό εξοπλισμό και την αμοιβαία αναγνώριση της συμβατότητάς τους.

Επιπλέον εφαρμόζονται μεταξύ άλλων τα ακόλουθα πρότυπα:
EN 300 328, EN 301 489-1 και -17 περί ηλεκρομαγνητικής συμβατότητας και περί θεμάτων ραδιοφάσματος.

**CZ** ... splňuje platné požadavky těchto směrnic:
93/42/EHS o zdravotnických prostředcích, Směrnice 2011/65/ES o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních, směrnice 1999/5/ES o rádiových zařízeních a telekomunikačních koncových zařízeních a vzájemném uznávání jejich shody.

Dodatečně jsou aplikovatelné např. tyto normy:
EN 300 328, EN 301 489-1 a -17 o elektromagnetické kompatibilitě a rádiovém spektru.

**EST** ... täidab järgmiste direktiividega kehtestatud nõudeid:
93/42/EMÜ meditsiinitoodete kohta, 2011/65/EL teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes, 1999/5/EÜ raadioseadmete ja telekommunikatsioonivõrgu lõppseadmete ning nende nõuetekohasuse vastastikuse tunnustamise kohta.

Lisaks tuleb muu hulgas kohaldada järgmisi normatiive:
EN 300 328, EN 301 489-1 ja -17 elektromagnetilise ühilduvuse ning ringhäälinguga seonduva kohta.

**HU** ... teljesíti a következő irányelvek érvényben lévő köve 93/42/EGK irányelv az orvostechnikai termékekről, 2011/65/EU egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról, 1999/5/EK a rádióberendezésekről és a távközlő végberendezésekről, valamint megfelelőségük kölcsönös elismeréséről.

Ezen kívül többek között a következő normák alkalmazhatók:
EN 300 328, EN 301 489-1 és -17 az elektromágneses összeférhetőségi- és rádióspektrum ügyekről.

**LT** ... išpildo galiojančius tokių direktyvų reikalavimus:
93/42/EEB ir medicinos prietaisų, 2011/65/ES dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo, 1999/5/EB dėl radijo ryšio įrenginių ir telekomunikacijų galinių įrenginių bei abipusio jų atitikties pripažinimo.

Be to, taikomi šie standartai:
EN 300 328, EN 301 489-1 ir -17 dėl elektromagnetinio suderinamumo ir radijo dažnių spektro dalykų.

**LV** ... atbilst šādu direktīvu spēkā esošajām prasībām:
93/42/EEK par medicīnas ierīcēm, 2011/65/ES par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās, 1999/5/EK par radioiekārtām un telekomunikāciju termināla iekārtām un to atbilstības savstarpējo atzīšanu.

Bez tam ir piemērojami arī šādi standarti:
EN 300 328, EN 301 489-1 un -17 par elektromagnētisko saderību un radiofrekvenču spektra jautājumiem.

**S** ... uppfyller gällande krav i följande direktiv och normer:
93/42/EEG om medicintekniska produkter, 2011/65/EU om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning, 1999/5/EG om radioutrustning och teleterminalutrustning och om ömsesidigt erkännande av utrustningens överensstämmelse.

Utöver detta kan följande normer användas:
EN 300 328, EN 301 489-1 och EN 301 489-17 om elektromagnetisk kompatibilitet och gnistspektrumfrågor.

**N** ... oppfyller gjeldende krav i følgende direktiver:
93/42/EØF om medisinske produkter, 2011/65/EU om begrensning av bruk av visse farlige stoffer i elektrisk og elektronisk utstyr, 1999/5/EF om radioutstyr og teleterminalutstyr og gjensidig godkjenning av utstyrets samsvar.

I tillegg kan blant annet følgende standarder anvendes:
EN 300 328, EN 301 489-1 og -17 om elektromagnetisk kompatibilitet og ting som angår spekteret av radiosignaler.

**FIN** ... täyttää seuraavien direktiivien voimassa olevat määräykset:
93/42/ETY lääkinnälliset laitteet, 2011/65/EU tiettyjen vaarallisten aineiden käytön rajoittamisesta sähkö- ja elektroniikkalaitteissa, 1999/5/EY radio- ja telepäätelaitteista ja niiden vaatimustenmukaisuuden vastavuoroisesta tunnustamisesta.

Tämän lisäksi sovelletaan mm. seuraavia standardeja:
EN 300 328, EN 301 489-1 ja -17, sähkömagneettinen yhteensopivuus ja radiospektriasiat.

**NL** ... voldoet aan de geldende eisen van de volgende richtlijnen:
93/42/EEG betreffende medische hulpmiddelen, 2011/65/EU betreffende beperking van het gebruik van gevaarlijke stoffen in elektrische und elektronische apparatuur, 1999/5/EG betreffende radioapparatuur en telecommunicatie-eindapparatuur en de wederzijdse erkenning van hun conformiteit.

Daarnaast zijn onder meer de volgende normen van toepassing:
EN 300 328, EN 301 489-1 en -17 betreffende elektromagnetische compatibiliteit en radiospectrumaangelegenheden.

**P** ... cumpre os requisitos válidos das seguintes directivas:
93/42/CEE relativa a dispositivos médicos, 2011/65/UE relativa à restrição do uso de determinadas substâncias perigosas em dispositivos eléctricos e electrónicos, 1999/5/CE relativa aos equipamentos de rádio e equipamentos terminais de telecomunicações e ao reconhecimento mútuo da sua conformidade.

Para além destas aplicam-se, entre outras, as seguintes normas:
EN 300 328, EN 301 489-1 e -17 relativa a compatibilidade electromagnética e assuntos de espectro radioeléctrico.

**PL** ... spełnia obowiązujące wymagania następujących dyrektyw:
93/42/EWG o wyrobach medycznych, 2011/65/UE w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym, 1999/5/WE w sprawie urządzeń radiowych i i końcowych urządzeń telekomunikacyjnych oraz wzajemnego uznawania ich zgodności.

Ponadto stosują się między innymi następujące normy:
EN 300 328, EN 301 489-1 i -17 dotyczących kompatybilności elektromagnetycznej i zagadnień widma radiowego.

**SLO** ... izpolnjuje veljavne zahteve naslednjih direktiv:
93/42/EGS o medicinskih pripomočkih, 2011/65/EU o omejevanju uporabe nekaterih nevarnih snovi v električni in elektronski opremi, 1999/5/ES o radijski opremi in telekomunikacijski terminalski opremi ter medsebojnem priznavanju skladnosti te opreme.

Poleg tega veljajo naslednje norme:
EN 300 328, EN 301 489-1 in -17 o elektromagnetni združljivosti in zadevah v zvezi z radijskim spektrom.

**SK** ... spĺňa platné požiadavky nasledovných smerníc:
93/42/EHS o medicínskych výrobkoch, 2011/65/EÚ na obmedzení používa-
nia určitých nebezpečných látok v elektrických a elektronických zariade-
niach, 1999/5/ES o rádiových zariadeniach a koncových telekomunikačných
zariadeniach a vzájomnom uznávaní ich zhody.

Okrem toho sú použiteľné medzi iným tieto normy:

EN 300 328, EN 301 489-1 a -17 o elektromagnetickej kompatibilite a záleži-
tostiach rádiového spektra.

**TR** ... aşağıdaki yönergelerin geçerli talimatlarını yerini getirir:
tıbbi ürünler hakkında 93/42/AET yönetmeliği, Elektrik ve elektronik cihaz-
larda tehlikeli maddelerin kullanılmasına ilişkin kısıtlama konusunda 2011/65/
AB direktifi. Telsiz tesisleri ve iletişim uç düzenekleri ile bunların uyum-
luluğunun karşılıklı kabul edilmesine ilişkin 1999/5/AT direktifi.

Bunun ötesinde aşağıdaki normlar da geçerlidir:

 elektromanyetik uyumluluk ve radyo tayfi maddeleri hakkında EN 300 328,
EN 301 489-1 ve -17.

Hamburg, December 2015

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