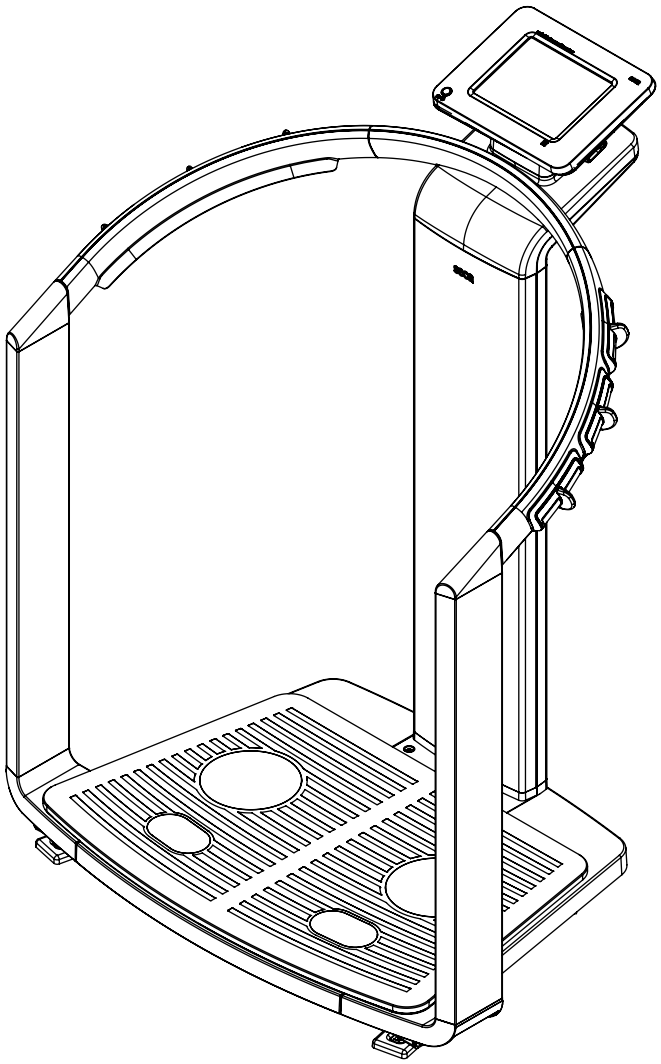
seca 515/514

Instructions for Use
for
Doctors and Assistants



seca®
Precision for health

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1. SEALS OF QUALITY (515)

With seca products, you are not only purchasing technology that has been perfected for more than 100 years, but a quality that has been officially and legally certified that also bears the quality seals from many institutions. seca products meet European directives, standards and national laws. When you buy seca, you buy the future.

M

Scales that bear this symbol conform to the European Directive 2009/23/EC on non-automatic weighing instruments. seca scales with this symbol meet the high quality and technical requirements that are demanded of calibratable scales.

III

Scales that bear this symbol meet the strict requirements of Calibration Class III and can be used for medical measurements subject to legal control.

CE 11 0109 0123

Products bearing this symbol fulfill the applicable regulatory requirements of the European Community, especially the following:

- Directive 2009/23/EC on non-automatic weighing instruments
- Directive 93/42/EEC on medical products
- DIN EN 45501 on metrological aspects of non-automatic weighing instruments

ISO 9001 ISO 13485

seca's professionalism is also recognized by official testing agencies. With this certificate, TÜV Süd Product Service, the agency responsible for medical products, confirms that seca adheres consistently to the strict legal requirements as a medical product manufacturer. seca's quality assurance system includes the areas of design and development, production, sales, and service of medical scales and height measurement systems as well as software and measurement systems for the assessment of the state of health and nutrition.

DER GRÜNE PUNKT

seca helps preserve the environment. Saving natural resources is very important to us. We therefore make every effort to save on packaging materials wherever it makes sense and whatever is leftover can be conveniently disposed of on site via the dual system.

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3. DEVICE DESCRIPTION

3.1 Congratulations!

With the Medical Body Composition Analyzer **seca 515/514**, you have just purchased a highly precise and simultaneously robust weighing instrument.

For more than 170 years, seca has used its experience in the service of health care and, as a market leader, it has always set standards in many countries of the world with innovative developments for weighing and measuring.

3.2 Application

Medical Body Composition Analyzer **seca 515/514** is mainly used in hospitals, medical practices and inpatient care facilities in accordance with national regulations. The **seca 515/514** device records weight, length and bioelectric impedance measurements and derivable parameters for automatic calculation, e.g. fat-free mass (FFM). The results are displayed graphically and assist the attending physician with the following medical aspects:

- Determining energy consumption and energy reserves as a basis for nutrition advising
- Assessing metabolic activity and success for a training program e.g. within the framework of rehabilitation or physiotherapy
- Determining the fluids status of a patient
- Determining the general state of health or, in the case of a previously known disease, assessing the severity

The **seca 515/514** is **not** a diagnostic device. To make an accurate diagnosis, in addition to the results of the **seca 515/514**, targeted examinations have to be ordered by the physician and their results taken into account.

3.3 Functional description

Calculating weight and height

The device uses an electronic scale. The weight calculation is made across 4 weighing cells. The height is calculated via manual entry or via wireless transmission from a **seca 360°** length measuring device.

Bioelectric impedance analysis

The bioelectric impedance analysis is performed according to the 8-point method. The flow of the low alternating current and the measurement of the impedance are performed for each half of the body using a pair of foot electrodes and three pairs of hand electrodes. The hand electrodes are attached at different heights so that persons with a body size of between 1.60 m and 2.0 m can take up an optimal position on the device for a BIA measurement.

Patient data management

Patient data can be created directly on the device and saved on a PC using the supplied software **seca analytics mBCA 115**. Alternatively, patient data can also be saved on the USB memory stick provided. It is only possible to edit patient data with the PC software **seca analytics mBCA 115**.

Analysis

The analysis of BIA measurements takes place in graphic form and is based on scientifically established formulas. An in-house study by seca has established formulas for determining the parameters of total body water (TBW), extracellular water (ECW), fat-free mass (FFM), and lean soft tissue (LST) for arms and legs. In the same study, in-house reference values were determined for the the following parameters, in order to be able to show normal ranges: Bioelectric impedance analysis (BIVA), mass indices (FMI, FMMI), phase angle (Φ). Further information is available in section „Medical basis“ from page 44.

User data management

Access data for users of the devices are managed in the supplied PC software **seca 115**. As part of the creation of user accounts for the **seca 115**, a user PIN for the **seca 515/514** is automatically generated.

The device can only be configured with administrator rights. An initial administrator PIN for the device is provided. It can only be changed on the device.

The creation and management of user data is thus only necessary if the seca patient database of the PC software **seca analytics mBCA 115** is to be accessed using the device.

Data transmission and network functions

The device can exchange data wirelessly with the PC software **seca analytics mBCA 115**. For this purpose, the PC software must be installed on a PC and the **seca 360° Wireless USB Adapter 456** (contained in the scope of delivery) must be connected to the same PC.

As an alternative to wireless transmission, a network cable (contained in the scope of delivery) can be used to connect the device to the PC (recommended for fast data transmission).

The device can wirelessly transmit measurement results and patient data to a **seca 360°** wireless printer.

seca 360° length measuring devices can wirelessly transmit measured results to the device.

The device has the following interfaces:

- On the weighing platform
  - Network connection (Ethernet)
- On the touchscreen display
  - Internal seca wireless module
  - USB interface for connecting a USB memory stick (contained in the scope of delivery)

3.4 User qualification

Administration/network connection

The device may only be set up and connected to a network by experienced PC administrators.

Operation

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

3.5 Contraindications

Impedance measurements may **not** be performed on patients who exhibit the following characteristics:

- Electronic implants, e.g. cardiac pacemaker
- Active prostheses

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

- Life-support electronic systems, e.g. artificial heart, artificial lungs
- Portable electronic medical devices, e.g. ECG

4. SAFETY INFORMATION

4.1 Safety rules in these instructions for use

DANGER!
Identifies an exceptionally hazardous situation. If you fail to take note of this information, serious irreversible or fatal injury will result.

WARNING!
Identifies an exceptionally hazardous situation. If you fail to take note of this information, serious irreversible or fatal injury may result.

CAUTION!
Identifies a hazardous situation. If you fail to take note of this information, minor to moderate injury may result.

ATTENTION!
Indicates that the product may have been operated incorrectly. If you fail to take note of this information, the device may be damaged or the measured results may be incorrect.

NOTE:
Contains additional information on how to use this device.

4.2 Basic safety rules

Handling the device

- Please take note of the information included in these instructions for use.
- Keep the instructions for use in a safe place.

DANGER!
Danger of explosion
Do not use the device in an environment enriched with one of the following gases:
- Oxygen
- Flammable anesthetics
- Other flammable substances/air mixtures

CAUTION!
Patient hazard, damage to device
- Additional devices that are connected to medical electrical devices must be demonstrably in accordance with their corresponding IEC or ISO standards (e.g. IEC 60950 for data-processing devices). Furthermore, all configurations must correspond to the normative requirements for medical systems (see IEC 60601-1-1 or section 16 of the 3rd edition of IEC 60601-1, respectively). The person who connects additional devices to medical electrical devices is the system configurator and is therefore responsible for ensuring that the system matches the normative requirements for systems. We would like to point out that local laws regarding normative requirements take precedence. Please direct any queries to your local specialist dealer or Technical Service.
- Please have maintenance, recalibration and BIA measuring technology checks performed every two years.
- The device does not contain any parts to be maintained by the user. Please only have maintenance, technical checks and repairs performed 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.
- Only use original seca accessories and spare parts. Otherwise, seca will not grant any warranty.

CAUTION!
Patient hazard, malfunction

- Keep other medical devices, e.g. high-frequency surgical devices, at a minimum distance of approx. 1 meter to prevent incorrect measurement or faults with wireless transmission.
- Keep HF devices such as cell phones at a minimum distance of approx. 1 meter to prevent incorrect measurement or faults with wireless transmission.

Preventing electric shock

WARNING!
Electric shock

- Never touch the power supply with wet hands.
- Do not use an extension cable and multiple outlets. This also applies for the USB connection on the touchscreen display.
- Make sure that the power cable is not crimped and cannot be damaged by sharp edges.
- Do not operate the device above a height of 3000 m.

Preventing injuries and infections

WARNING!
Patient hazard

- Prepare the device hygienically after each measurement (see “Hygienic preparation” on page 64).
- Ensure that the patient does not have any contagious diseases.
- Ensure that the patient does not have any wounds on the palms on their hands or the soles of their feet.
- Ensure that the positioning of the device is steady and even.
- The device is not designed to be a stand assist. Assist people with limited mobility, e.g. when they are sitting up from a wheelchair.
- Ensure that the weighing platform is dry before the patient steps onto it.
- Ensure that the patient has dry feet before they step onto the weighing platform.
- Ensure that the patient does not step directly onto the edges of the weighing platform.
- Ensure that the patient steps onto the weighing platform slowly and safely.
- Route the network and power cable such that no one can trip over them.

Preventing device damage

ATTENTION!
Damage to device

- Make sure that fluids never get inside the device. These can destroy the electronics.
- Switch off the device before you disconnect the power pack from the power supply.
- If device is not be used for a longer period of time, disconnect the power pack from the power supply. Only then is the device out of operation.
- Do not let the device fall.
- Do not subject the device to heavy jolts or vibrations.
- Do not place the device in direct sunlight and make sure that it is not placed in direct proximity of a heat source. High temperatures could damage the electronics.
- Avoid rapid temperature fluctuations. If the device is transported where a temperature difference of more than 20 °C occurs, the device must be left alone for two hours before it is switched back on. Otherwise, condensate may form; this can damage the electronics.

- Strong cleaning agents can ruin the scale's surfaces. Use only a soft cloth that you can dip in ethyl alcohol, if necessary.

Use of measured results

WARNING!
Patient hazard
The **seca 515/514** is **not** a diagnostic device. The device assists the attending physician with creating a diagnosis.

– For the creation of a precise diagnosis and for the initiation of therapies, in addition to the use of the **seca 515/514**, careful examinations must be conducted by the attending physician and the results of these taken into consideration.

– The responsibility for diagnoses and the therapies derived from them lies with the attending physician.

ATTENTION!
Data loss
- Before you save and re-use values measured with the **seca 515/514** (e.g. in the PC software **seca 115** or in a hospital information system), make sure that the measured values are plausible.
- If measured values have been transmitted from the software **seca 515/514** to the PC software **seca 115** or to a hospital information system, make sure before re-use that the measured values are plausible and assigned to the correct patient.

Handling packaging material

WARNING!
Danger of suffocation
Packaging material made of plastic film (bags) presents a danger of suffocation.

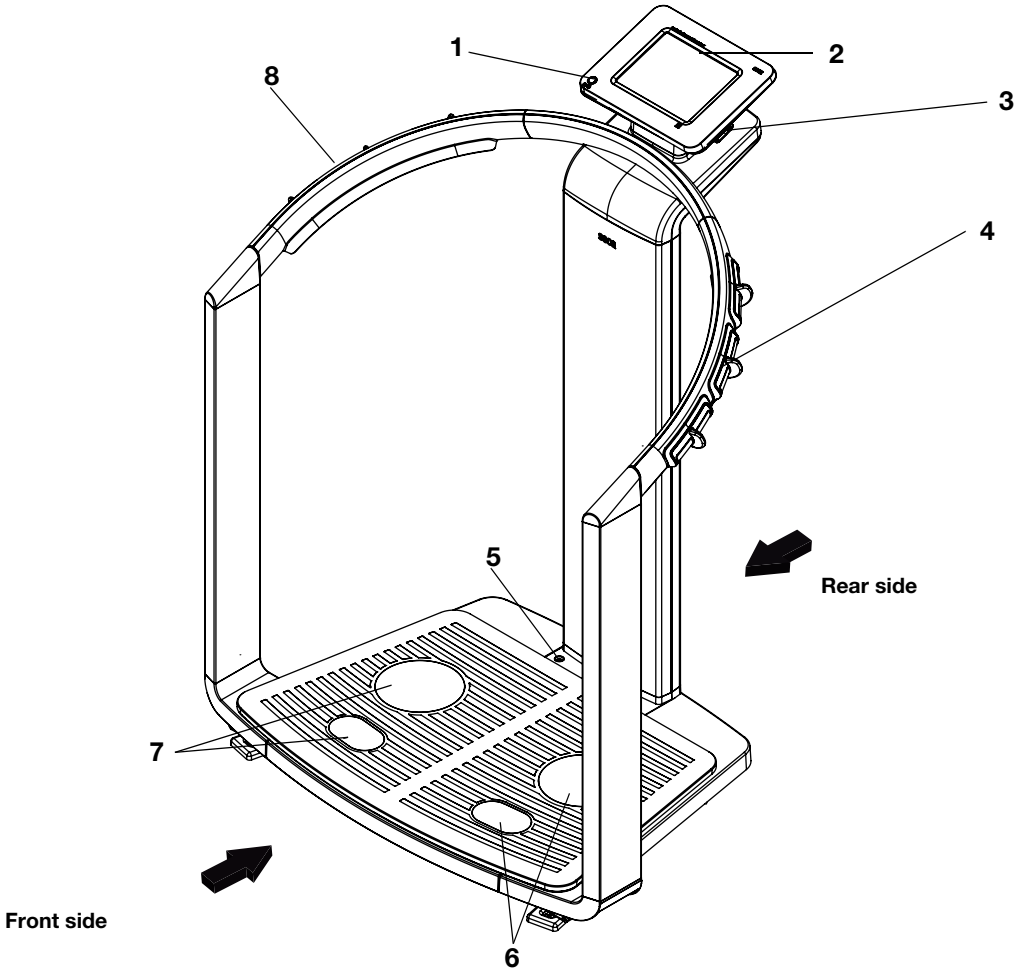
– Store packaging material out of the reach of children.

– If the original packaging material is no longer available, only use plastic bags with safety holes in order to reduce the danger of suffocation.

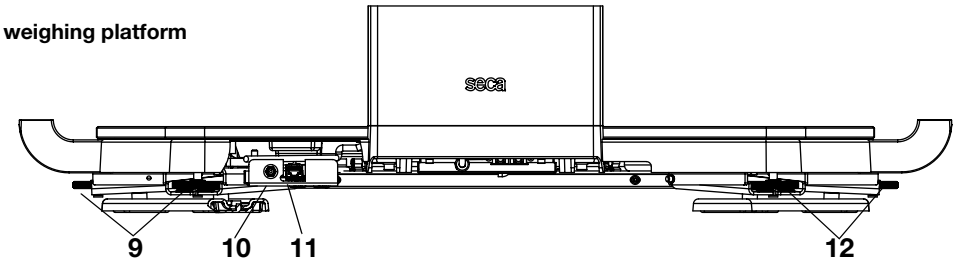
NOTE:
Store the original packaging material for future use (e.g. returning for maintenance).

5. OVERVIEW

5.1 Operating elements



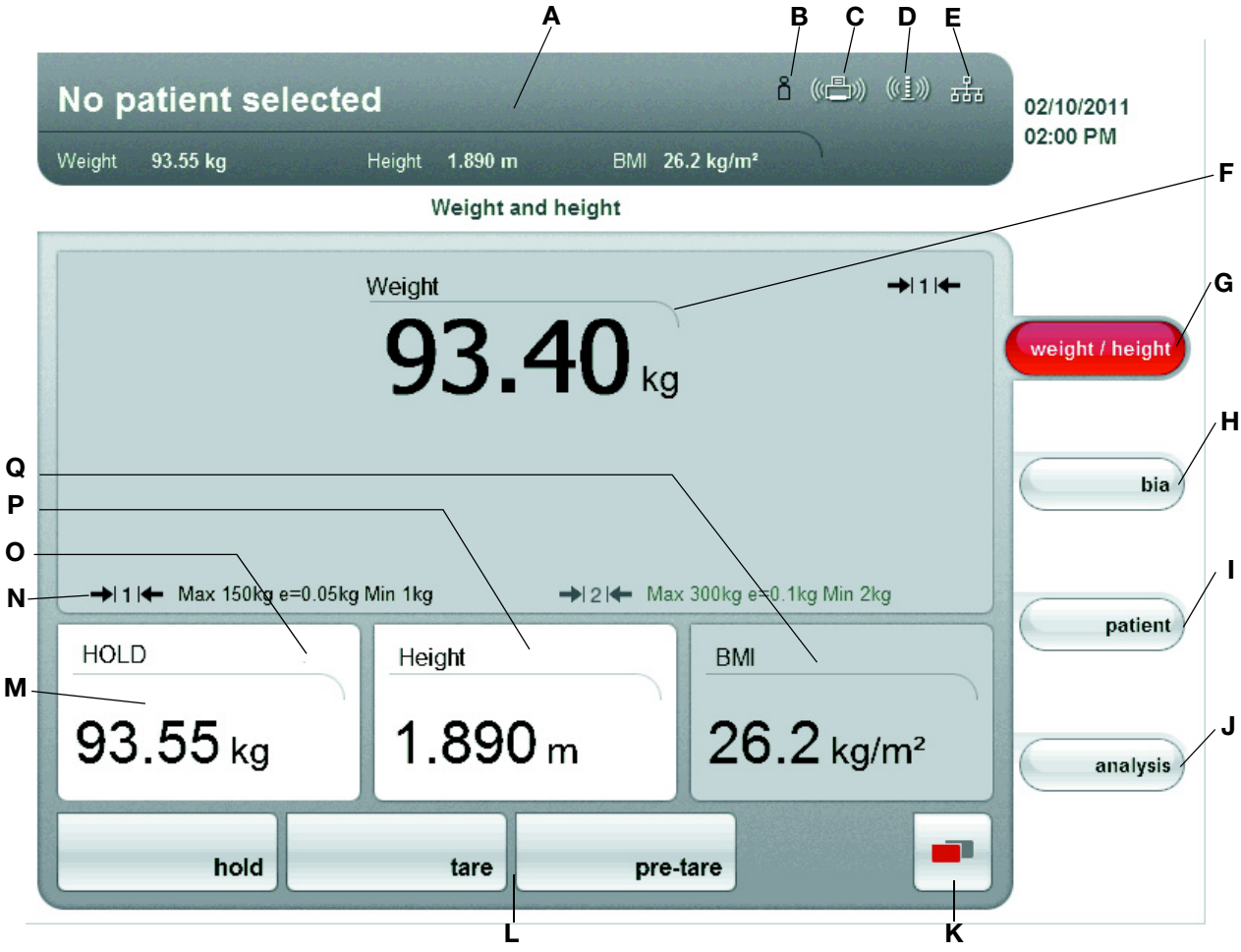
Rear side of weighing platform

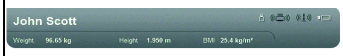


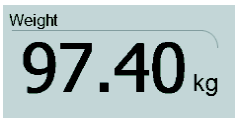
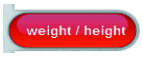
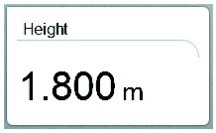
No.	Operating element	Function
1	ON/OFF switch	To switch on the device: Give button a brief press To switch the device into standby: Give button a brief press To switch off the device: Give button a long press
2	Touchscreen display	Central control and display element, can be swiveled 180° to left and right

No.	Operating element	Function
3	USB interface	For connecting a USB memory stick (contained in the scope of delivery) for managing the following data: • Creating patient data on the device • Load patient data from the supplied PC software **seca 115** onto the memory stick; call up data on device • Save measured results on the memory stick • Reading log files from the device (administrator function)
4	Pair of hand electrodes, right	3 pcs. with finger spacers, for BIA measurement The patient selects an electrode pair according to body size
5	Spirit level	Shows whether the device is positioned horizontally
6	Pair of foot electrodes, right	For heels and balls of feet, for BIA measurement
7	Pair of foot electrodes, left	For heels and balls of feet, for BIA measurement
8	Pair of hand electrodes, left	3 pcs. with finger spacers, for BIA measurement The patient selects an electrode pair according to body size
9	Foot screws, right	2 pcs, for precise adjustment
10	Power pack connection	For connecting the power pack
11	Ethernet interface	For integrating the device in a PC network
12	Foot screws, left	2 pcs, for precise adjustment

5.2 Symbols in the Start display

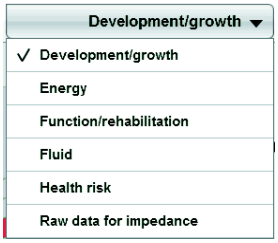


	Symbol	Meaning
A		Header, remains unchanged in all menu levels and tabs. The following data are displayed: • Patient data - Name - Weight - Height - BMI • Data connections • Date/time
B		Login symbol: Shows whether the user is logged in to a seca patient database (user PIN required)
C		Printer symbol: Shows whether there is a connection to a **seca 360°** wireless printer
D		Length measuring device symbol: Shows whether there is a connection to a **seca 360°** length measuring device

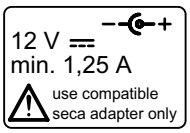
	Symbol	Meaning
E		Data connection symbol: Shows the current connection type to the seca patient database (here: Ethernet connection to PC using **seca 115**. Additional possible connection types: •  **seca 360°** Wireless connection to PC using **seca 115** •  USB memory stick connected to device
F		Weight display
G		**weight/height** tab Automatically active after switching on device For determining weight and height of a patient
H		**bia** tab For performing a bioelectric impedance analysis
I		**patient** tab For assigning the measured results to a patient file
J		**analysis** tab For analyzing measured results and analysis results and for saving data
K		**change menu** button Appears if secondary menu is available • Primary menu: Contains the functions commonly used in the current context • Secondary menu, contains the following functions: - **settings** - **print** - **save**
L		Menu bars with context-dependent buttons and change menu button
M		Hold value display
N		Weighing range currently used: • 1: Finer divisions of the weight display at a lower capacity • 2: Maximum capacity
O		Non-calibratable function is active (only for calibrated models)
P		Patient body size display • can be entered manually • can be received by a **seca 360°** length measuring device
Q		Patient body mass index (BMI) display. Automatically calculated as soon as a weight is available and a height value has been received or entered

5.3 Color symbols and additional operating elements

Operating element/ display	Symbol	Meaning
ON/OFF switch		LED white: Device on
		LED green: Device in standby
		LED off: Device off
Data connection symbol, here: **seca 360°** Wireless connection to a PC with **seca 115**		White: Connection available
		Red: Data being transmitted via the available connection
		Gray: Connection not available
Login symbol: Login to a seca patient database		White: User is logged in
		Gray: No user logged in
Tab		White: Tab not selected
		Red: Tab selected
Buttons		Light gray: Function available
		Gray: Button pressed, function selected
		Dark gray: Function not available
Electrode indicator (for BIA measurement)		Red: Contact poor
		Green: Contact good
Drop-down triangles		Gray: Function available
		Light gray: Function not available
Checkbox		Function deactivated
		Function activated

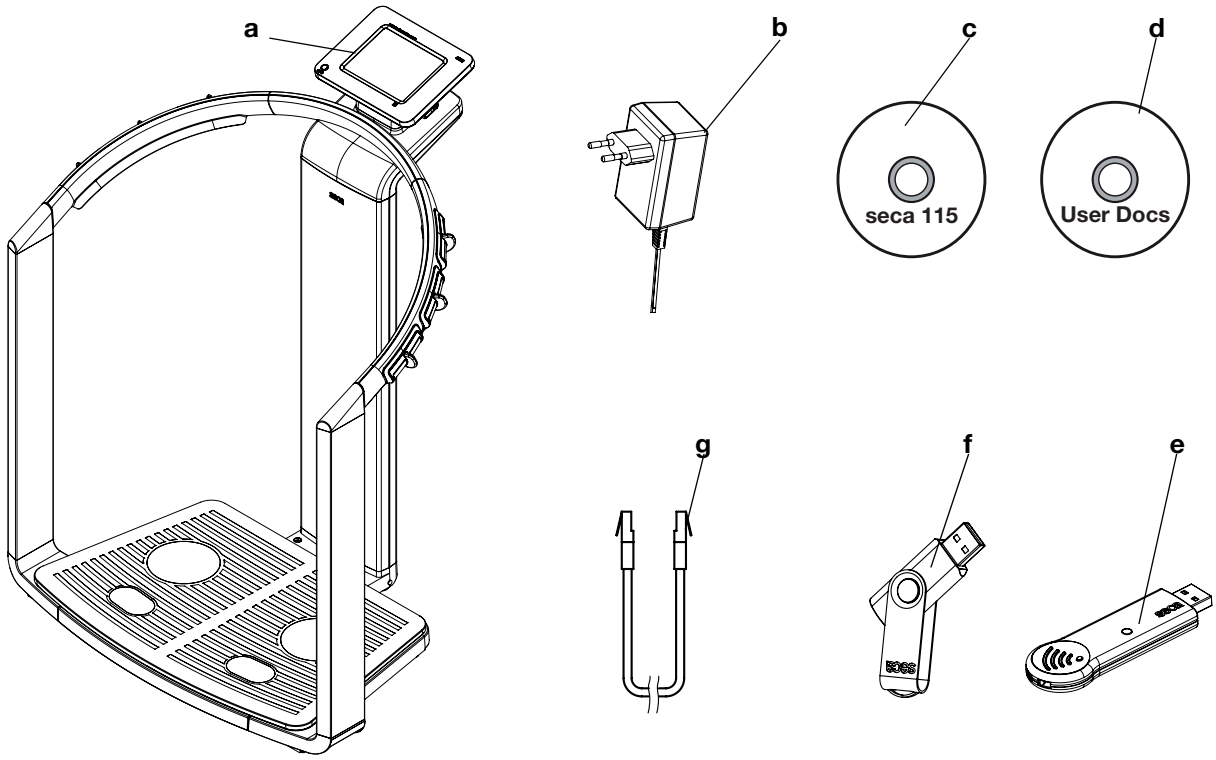
Operating element/ display	Symbol	Meaning
Drop-down menu		Selected function
		Drop-down menu opened
Text color	26.3 kg/m²	Red text: Value outside normal range
	23.6 kg/m²	Gray text: Value within normal range

5.4 Identification on the device and the type plate

Text/symbol	Meaning
Model	Model number
Approval type	Type designation of design approval (only **seca 515**)
Ser. no.	Serial number, consecutive
Product ID	Product identification number, consecutive
	Follow these instructions for use
	Electric medical device, type BF
	Insulated device, protection class II
FCC ID	For USA: Device approval number from the Federal Communications Commission (FCC)
IC	For Canada: Device approval number from Industry Canada
	Device conforms with the standards and guidelines of the EU
	FCC symbol (USA)
	Only operate device with compatible original seca power pack
	USB interface
	Do not dispose of this device with household waste

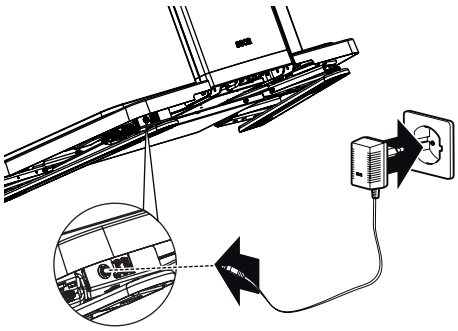
6. BEFORE YOU REALLY GET STARTED...

6.1 Scope of delivery



No.	Components	Pcs.
a	Medical Body Composition Analyzer	1
b	Power pack	1
c	DVD with PC software **seca 115** and license for a specific workplace	1
d	DVD “User Documentation” with user documentation in PDF format: • Instructions for use for doctors and assistants • Administrator manual • Quick guide • Additional information material	1
e	**seca 360° Wireless USB Adapter 456**	1
f	seca USB memory stick, 2 GB, initialized (USB PIN: 0000)	1
g	Ethernet cable (1.5 m) for connecting to a TCP/IP network	1
	Instructions for use for doctors and assistants, printed (not shown)	1

6.2 Establishing power supply



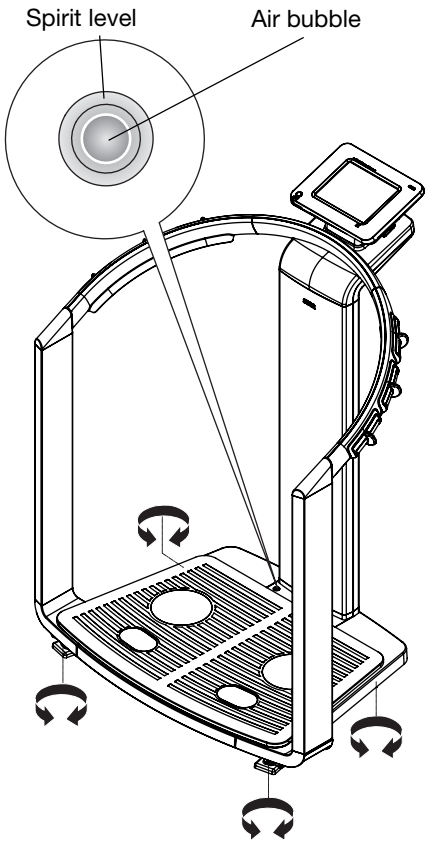
WARNING!
Using the wrong power supply may cause bodily injury or damage to the equipment
Conventional power supplies may provide a higher voltage than is indicated on them. The device may overheat, catch fire, melt, or short circuit.

– Use only the original seca plug-in power supply as contained in the scope of delivery and listed in section ”Spare parts” on page 73.

The connection for the power pack is located on the underside of the weighing platform. To establish the power supply, proceed as follows:

1. Insert the the mains plug required for your power supply into the power pack.
2. Tilt the device forward.
3. Insert the device plug of the power pack into the connector socket of the device.
4. Carefully return the device to an upright position.
5. Plug the power pack into a mains socket.

6.3 Setting up device



The device is fully assembled upon delivery.

ATTENTION!
Incorrect measurement due to force shunts
If the device with the housing is placed on top of something, e.g. due to an uneven or soft floor covering, the weight will not be correctly measured.

– Set the device up so that only its foot screws are in contact with the ground.

1. Place the device on firm and even ground.

ATTENTION!
Incorrect set-up may cause incorrect measurements
The spirit level is very sensitive. Additional weights, such as hand towels, can result in incorrect scale calibration.

– Make sure the scale is calibrated without any additional weight.

2. Calibrate the device by turning the foot screws.
   The air bubble in the spirit level must be located in the center of the circle.

6.4 Configuring device

Sections 6.5 to 6.7 show the data transmission options provided by the device. Your administrator or hospital technician decides which data connection types are set up for your device. Additional configuration options can be found in the administrator manual on the supplied DVD “User Documentation”. If you have any requests for changes, please contact your administrator.

ATTENTION!
Data loss
The improper installation of or improper changes to the installation can cause data loss and, as a result, misdiagnoses.
– Make sure installation or changes to installation are carried out by an experienced PC administrator or hospital technician.

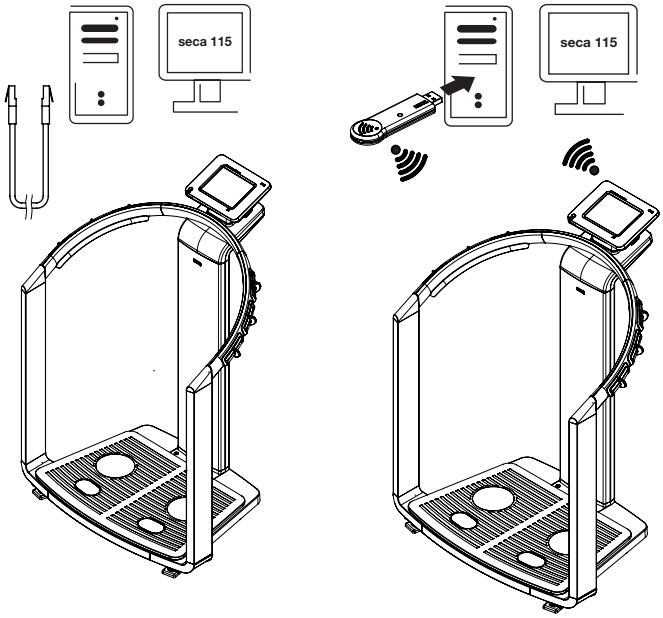
6.5 Operating the device in a PC network

The device does not have “on-board” patient and user management. If you wish to manage electronic patient files and user accounts, the device must be connected to a PC on which the PC software **seca 115** is installed. You have the following possibilities:

- Network connection via seca wireless network or Ethernet
- Indirect connection via USB memory stick

Network connection via Ethernet or seca wireless network

If the device is connected via seca wireless network or Ethernet to a PC on which the PC software **seca 115** is installed, you can directly access patient files on the PC software and directly transmit newly created patient files to the PC software.



NOTE:
- Information on creating and saving patient data can be found in section „Assigning patient“ from page 35.
- Observe the instructions for use for doctors and assistants for the PC software **seca 115**. If you have any queries regarding data connections, contact your administrator.

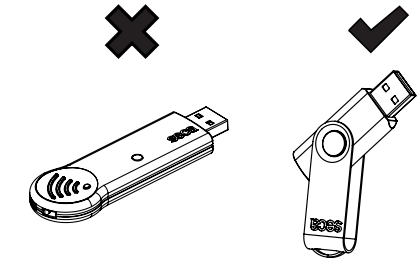
Indirect connection via USB memory stick

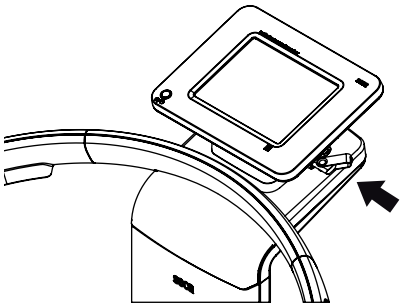
If the device is not to be directly integrated in a PC network, you can create patient data and save measurements on the supplied seca USB memory stick.

The seca USB memory stick is supplied in an initialized state, meaning it contains a seca patient database and is secured with an initial USB PIN (0000).

If you wish to use additional USB memory sticks (seca original accessories recommended), these must also be initialized before patient data can be saved on them. For this purpose, contact your administrator.

You can synchronize the seca patient database on the USB memory stick with the seca patient database of the PC software **seca 115**.

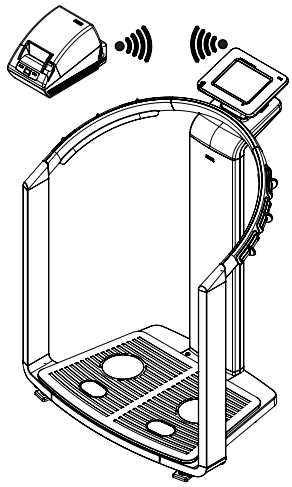




NOTE:

- Information on creating and saving patient data can be found in section „Assigning patient“ from page 35.
- Observe the instructions for use for doctors and assistants for the PC software **seca 115**. If you have any queries regarding data connections, contact your administrator.

6.6 Operation using a seca 360° wireless printer



If the device is not to be used to access patient data and user accounts, the connection to a PC is not required.

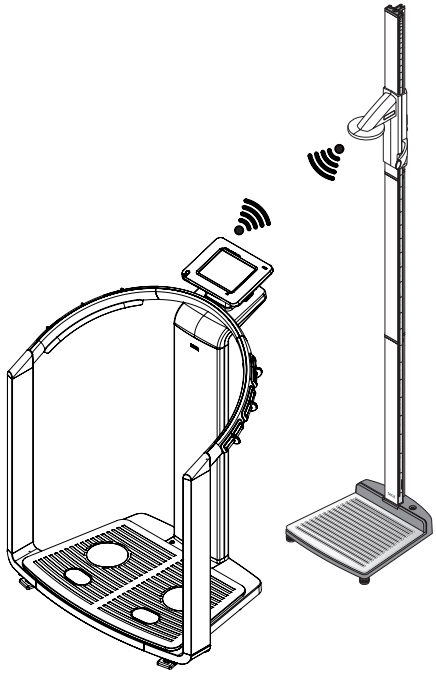
You can operate the device together with a **seca 360°** wireless printer and print out measured results and analyses.

If you operate the device in connection with a **seca 360°** wireless printer, you can create patient data in the **patient** tab. The patient data then appears on the results printout. In this configuration, you cannot save any data.

NOTE:

- Information on creating and saving patient data can be found in section „Assigning patient“ from page 35.
- Observe the instructions for use for the **seca 360°** wireless printer.
- If you have any queries regarding data connections, contact your administrator.

6.7 Operation using a seca 360° length measuring device



As an alternative to manual entry, you can use a **seca 360**° length measuring device to determine the height and transfer this to the **seca 515/ 514** via the seca wireless network.

The **seca 360**° length measuring device can be used as a supplement to the following accessories:

- **seca 360**° wireless printer
- PC with PC software **seca 115**

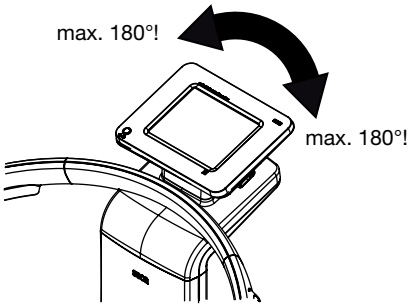
NOTE:

- Information on creating and saving patient data can be found in section „Assigning patient“ from page 35.
- Also observe the instructions for use of the **seca 360**° length measuring device. If you have any queries regarding data connections, contact your administrator.

7. OPERATION

7.1 Operating concept

Swiveling the touchscreen display



The touchscreen display of the device can be swiveled. As a result, it can be optimally positioned for every application.

♦ Swivel the touchscreen display for comfortable operation and reading.

ATTENTION!
Damage to device
The swivel mechanism of the touchscreen display has an end stop. Do not attempt to swivel the touchscreen display by more than 180°. This leads to mechanical damage to the housing and the internal cabling.

– In every direction, only rotate the touchscreen display as far as the end stop.

Switching on the device

The device is switched on using the ON/OFF button. During the switch-on procedure, the device performs a self-test. The self-test may take several seconds.

1. Give the ON/OFF button a brief press.
   The LED of the button turns white.
   The internal PC of the device boots up. This takes several seconds.
   The weighing function is available if the LED of the button turns white continuously and the **weight/height** tab is shown in the display.
2. In the display, press the **bia** tab.
   The bioelectric impedance analysis function is available if the message **self-test running** is no longer displayed and the dialog window **module selection** appears.
   The device is ready for operation.

Selecting functions

Functions can be selected using the following elements of the touchscreen display:

- Tab
- Buttons
- Drop-down menus
- Checkboxes

♦ In order to select a function, press directly on the corresponding display element (here: tab, button).

Selecting extended functions

Functions that are commonly used in a certain context are accessible in the primary menu. Additional functions are accessible in the secondary menu.

NOTE:
The assignment of functions into the primary and secondary menu is specified at the factory and cannot be changed.

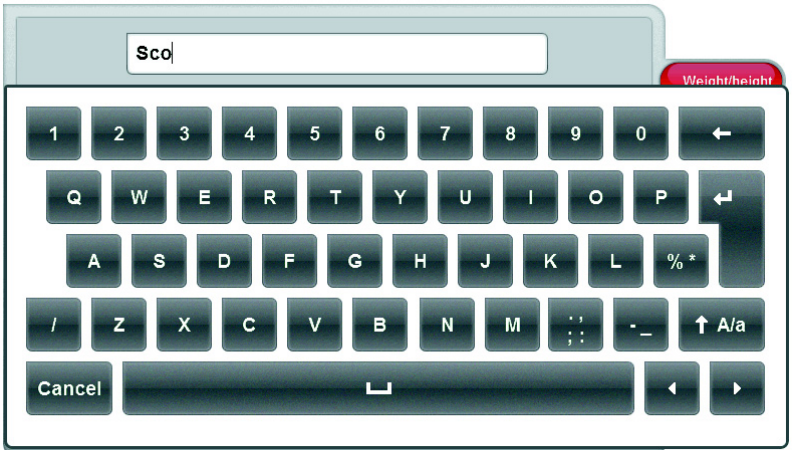
1. Press the **change menu** button.

The secondary menu is displayed.

2. Press the **change menu** button.
The functions in the primary menu are shown again.

Entering text

Text is entered via a computer keyboard that is shown on the touchscreen display.



1. Press an input field.
If a field requires a text entry, a computer keyboard appears in the display.
2. Type in the desired text.

3. On the keyboard, press the Enter key.
The entry is accepted.

Displaying special characters

With the computer keyboard, special characters can also be displayed.

1. Press and hold a button on the computer keyboard.

   All special characters are displayed in a context menu that is accessible via the selected key.
2. In the context menu, press the desired special character.
   The special character appears in the input field.
3. Enter further text as usual.

Entering numbers

Numbers are entered via a computer number keypad that is shown on the touchscreen display.

1. Press an input field.
   If a field requires a numerical entry, a numerical keypad appears in the display.
2. Press the desired number.
3. In the number keypad, press the Enter key.
   The entry is accepted.

Measurement procedure

The operating concept is based on the following typical measurement procedure:

- Measure weight and height
- Perform bioelectric impedance analysis
- Assign measurements to a patient
- Evaluate measured results
- Save measurement procedure

The order of the tabs on the touchscreen display follows this sequence. It is possible to operate in a different order.

ATTENTION!
Data loss
If there is no new entry for approx. 5 minutes, the current measurement is discarded. In this case, the complete measurement procedure must be repeated.

– Save or print the measured results immediately after the conclusion of the measurement procedure (see “Closing the measurement procedure” on page 42).

Automatic standby

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

- Measured results and settings that have not been saved are lost.
- The LED of the ON/OFF button turns green.
- The touchscreen display goes out.

Switching off the device

WARNING!
Electric shock
The device cannot be put out of operation by pressing the ON/OFF button.

– Always pull out the mains plug if the device is to be put out of operation, e.g. for hygienic preparation.

♦ Give the ON/OFF button a brief press.
The LED of the ON/OFF button turns green. The touchscreen display goes out. The device is in standby.

♦ Give the ON/OFF button a long press
The LED of the ON/OFF button goes out. The touchscreen display goes out. The device is switched off.

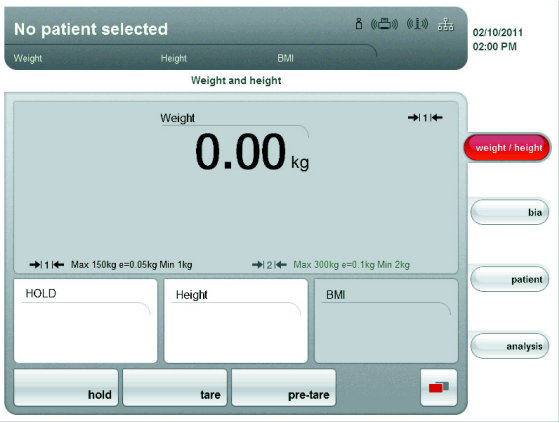
NOTE:
When switching on from standby, the device starts in the **weight/ height** tab. When switching on a device that is switched off, the internal PC boots up again. This takes several seconds.

7.2 Determining the weight and height

ATTENTION!
Incorrect measurement due to force shunts
All operating elements of the device are in the so-called weight-sensitive area. If you touch or support yourself on the device when measuring a patient, this influences the measured results.
– During the measurement process, ensure that the device is only touched by the patient who is currently being measured.

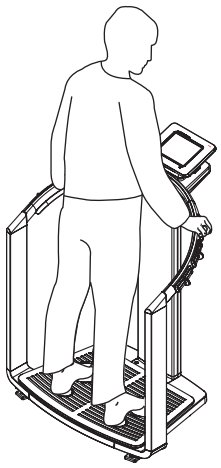
Starting the weighing procedure

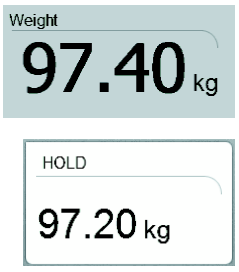
1. Ensure that the device has no load.
2. Switch on the device.
   The LED of the ON/OFF button turns white
3. Wait until the **weight/height** tab is active.



WARNING!
Injury due to falling
The device is not designed to be a stand assist.
– Assist persons with limited mobility when they are sitting up e.g. from a wheelchair.

NOTE:
If you wish to perform a bioelectric impedance analysis directly thereafter, ensure that the patient steps on the scale with bare feet (see “Performing bioelectric impedance analysis (BIA)” on page 31).





4. Ask the patient to position themselves on the device.
   The weight display flashes.
   The hold value is determined automatically.
5. Wait until the weight display and the hold value no longer flash.
6. Read the measurement result.

ATTENTION!
Data loss
If there is no new entry for approx. 5 minutes, the current measurement is discarded. The complete measurement procedure must be repeated.

NOTE:
When the patient steps off the device, the hold value will continue to be displayed. As a result, you can attend to the patient before recording the weight. To delete the hold value, press the **hold** button.

Manually determining the hold value (hold)

The device is equipped with an autohold function. During the measurement procedure, the weight is automatically frozen and displayed in the HOLD window. It is possible that you will have to manually determine the hold value, e.g. if the patient removes an item of clothing after the initial weighing without stepping off the scale. For this purpose, proceed as follows:

1. Press the **hold** button.
   The display flashes until a stable weight is measured. The weight is then continuously displayed. The ⚠ symbol is displayed (only for calibrated models).

2. Read the measurement result.

NOTE:
When the patient steps off the device, the hold value will continue to be displayed. As a result, you can attend to the patient before recording the weight. To delete the hold value, press the **hold** button.

Balancing additional weight (tare)

Using the **tare** function, you can prevent additional weight (e.g. a hand towel or a support on the weighing platform) from influencing the weight result.

1. Switch on the device.
2. Place the additional weight on the device.

3. Press the **tare** button.
   The message “NET” appears on the display.
4. Ask the patient to position themselves on the device.
5. Read the measurement result.
   The additional weight is automatically deducted.
6. To deactivate the TARE function, press the **tare** button again.
   The message “NET” is no longer displayed.

NOTE:
The maximum displayable weight is reduced by the weight of the objects already placed on the scale.

Permanently saving the additional weight (pre-tare)

Using the **pre-tare** function, you can permanently save an additional weight and automatically subtract this from a measurement result. For example, you can save a flat-rate figure for clothing and then always deduct this if a patient is weighed when fully clothed. The pre-tare value continues to be saved even after the device has been switched off.

1. Ensure that the device has no load.
2. Switch on the device.

3. Press the **pre-tare** button.
   The number keypad appears.
   The last additional weight saved is displayed.
4. Enter a different pre-tare value if desired.

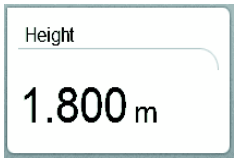
5. In the number keypad, press the Enter key.
   The entry is accepted.
   The message “PT” appears on the display.
   The value entered is saved and automatically subtracted from the measurement result during the next weighing procedure.
   The number keypad is no longer displayed.

Activating/deactivating the pre-tare function

If you wish to have a permanently saved additional weight automatically subtracted from the measurement result during the current weighing procedure, proceed as follows.

1. Switch on the device.
2. Ask the patient to position themselves on the device.
3. Press the **pre-tare** button.
   The number keypad appears.
   The last additional weight saved is displayed.
4. In the number keypad, press the Enter key.
   The entry is accepted.
   The message “PT” appears on the display
   The displayed value is automatically subtracted from the measurement result.
   The number keypad is no longer displayed.
5. Read the measurement result.
6. To deactivate the **pre-tare** function, press the **pre-tare** button again.
   The additional weight is added to the measurement result once more.

Manually entering body size



To manually enter the body size, e.g. to determine the BMI, proceed as follows:

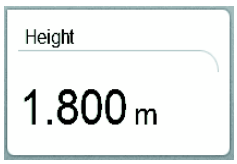
1. Ensure that the **weight/height** tab is active.
2. Press the **Height** field.
   The number keypad appears.
3. Enter the patient's height.
4. In the number keypad, press the Enter key.
   The entry is accepted.

Transmitting body size via seca wireless network

If the device is connected to a **seca 360°** length measuring device, you can transmit the body size, e.g. for determining the BMI, via the seca wireless network to the **seca 515/514**. To do so, proceed as follows:

1. Ensure that there is a **seca 360°** wireless connection.
   The radio symbol for the length measuring device is white.

   NOTE:
   If you uncertain of whether there is a **seca 360°** wireless connection, contact your administrator or hospital technician.
2. Switch on the length measuring device.
3. Perform the length measurement.
4. Ensure that the **weight/height** tab is active in the touchscreen display of the **seca 515/514**.
5. Press the **send/print** button on the length measuring device.
   The measured value appears in the body size field.



Automatic BMI calculation

To determine the BMI, you have to record the patient's height and weight.

- After weighing, manually enter the height of the patient.
  - Manually (see “Manually entering body size” on page 29)
  - Via the seca wireless network (see “Transmitting body size via seca wireless network” on page 29)

  The BMI is automatically calculated and displayed.

Automatic switchover of weighing range

The scale has 2 weighing ranges. In weighing range 1, there is a low maximum capacity and a more precise division of the weight display. In weighing range 2, you can use the maximum capacity of the scale.

After switching the scale on, weighing range 1 is active. If a particular weight is exceeded, the scale switches automatically to weighing range 2.

To return to weighing range 1, proceed as follows:

- Completely remove the load from the scale.
  The weighing range 1 is active again.

Printing partial results

If the device is connected to a **seca 360°** wireless printer, you can print the measured results directly.

1. Ensure that the **seca 360°** wireless printer is switched on and that there is a **seca 360°** wireless connection.
   The **seca 360°** wireless printer symbol on the touchscreen display turns white.

   NOTE:
   If you uncertain of whether there is a **seca 360°** wireless connection, contact your administrator or hospital technician.

2. Press the **change menu** button.
   The secondary menu appears.
3. Press the **print** button.
   All measured results and entries available at this point are printed.

7.3 Performing bioelectric impedance analysis (BIA)

Switching on the device

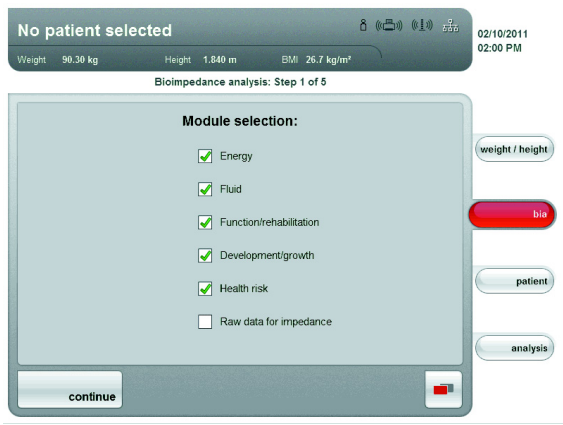
1. Ensure that the device has no load.
2. Press the ON/OFF button.
   The start screen appears.
   The **weight/height** tab is active.

Determining the weight and height

♦ Determine the weight and height as described in section „Determining the weight and height“ from page 27.

Checking the module selection

1. Activate the **bia** tab.
   The bioelectric impedance analysis is available when the message “Self-test running” is no longer displayed.



The **module selection** dialog window appears. All modules are activated in the factory (except raw data for impedance).

NOTE:
If the module selection does not appear, the function “Show the module selection at the start of the measurement procedure” is deactivated in the **settings** menu. You can reactivate this function or check the module selection directly in the **settings** menu (see “Configuring device” on page 61).

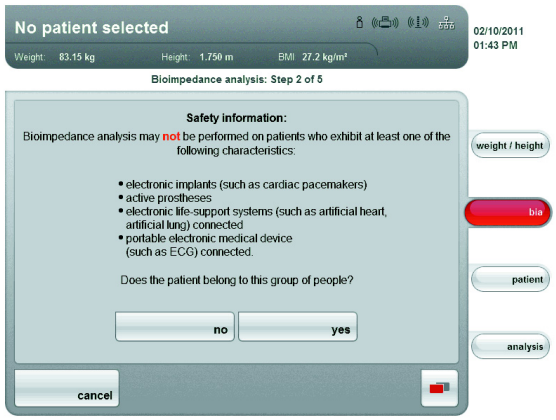
2. Check the module selection.
3. Deactivate modules for which no measurements are to be performed.

NOTE:
- If you activate the **Raw data for impedance** module, the duration of the BIA measurement is extended. Activate the **Raw data for impedance** module if you wish to use the measured results for scientific studies. The impedance data for up to 19 frequencies are available in the **analysis** tab.
- If you deactivate the **Energy** evaluation module, there is no request for the Physical Activity Level (PAL) following a BIA measurement.

4. Press the **continue** button.

Starting measurement

1. Make an entry stating whether the patient belongs to a group of people for whom a BIA measurement may not be performed.

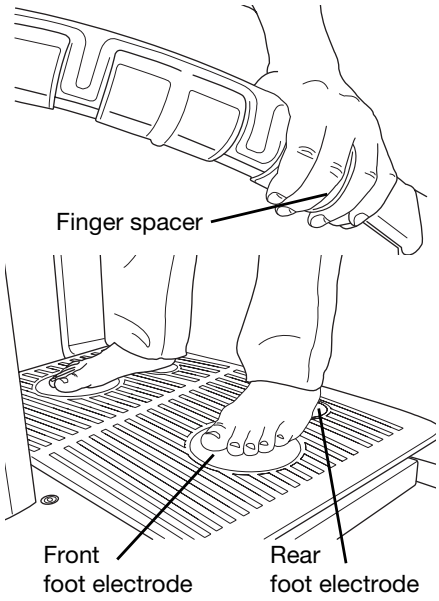


   – **yes**: The measurement is not performed. The **weight/height** tab is active again.
   – **no:** The procedure starts. A dialog window for positioning the patient appears.

WARNING!
Patient hazard
Illnesses can be transmitted due to poor hygiene.
   – Ensure that the patient does not have any contagious diseases.
   – Ensure that the patient's hands and feet are clean.
   – Ensure that the patient does not have any open wounds on the palms of their hands or the soles of their feet.
   – Disinfect the electrode surfaces after every measurement.

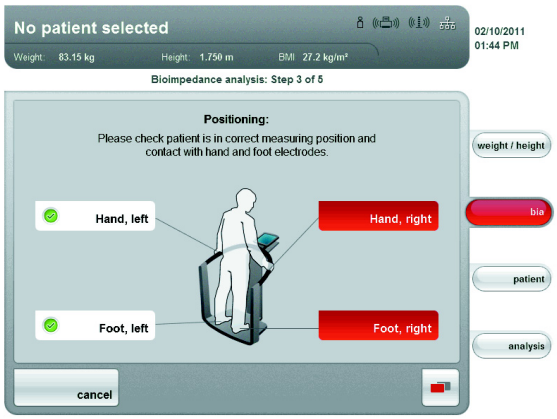
WARNING!
Injury due to falling
The device is not designed to be a stand assist.
   – Assist persons with limited mobility when they are sitting up e.g. from a wheelchair.

2. Ask the patient to position themselves on the device.
3. Make sure that the patient is standing on the scale correctly:



Test point	Characteristics
Hands	• Hands must be clean • Same pair of hand electrodes on left and right • Select the pair of hand electrodes such that arms are stretched out but not strained • Finger spacers of the hand electrodes between the middle finger and ring finger on both sides
Feet	• Stand on device with bare feet • Feet must be clean • Heels on the rear foot electrodes • Balls of feet on the front foot electrodes
Position	• Upright position • Knee slightly bent • Do not move during the measurement

4. Make sure that the patient is in correct contact with the hand and foot electrodes.



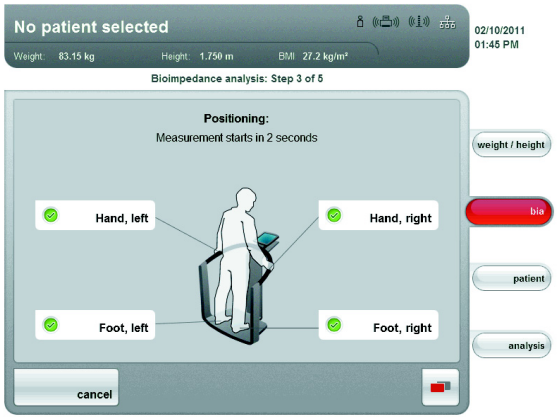
If the patient is not in correct contact with an electrode pair, the corresponding electrode indicator on the touchscreen display is red.

If the patient is in correct contact with an electrode pair, the corresponding electrode indicator on the touchscreen display is green.

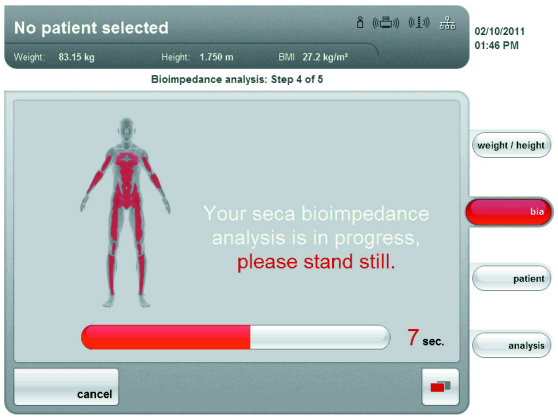
Note:

- The hand electrode selection influences the measurement result. Note the pair of hand electrodes selected by the patient. This means you can ensure that the patient can use the same pair of hand electrodes for future measurements.
- The electric current that is passed through the body during the measurement is very low and does not present any health risk. However, in isolated cases, very sensitive persons may feel a slight tingling sensation.

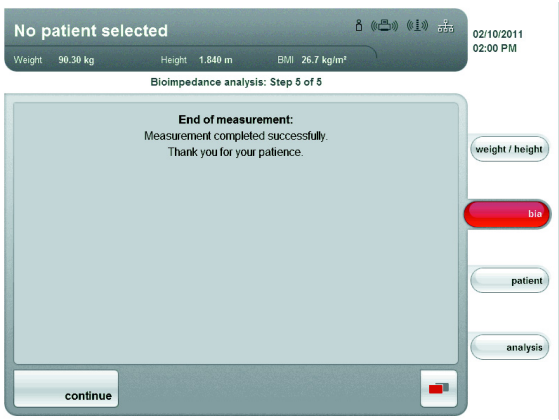
As soon as all electrode indicators on the touchscreen display are green, a countdown to the start of the measurement appears. The measurement starts automatically.



The remaining time of the measurement is displayed.



As soon as the measurement ends, the message **End of measurement** appears.



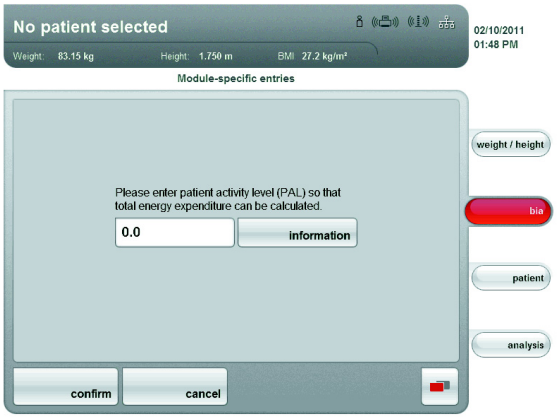
5. Press the **continue** button.

Entering the PAL value

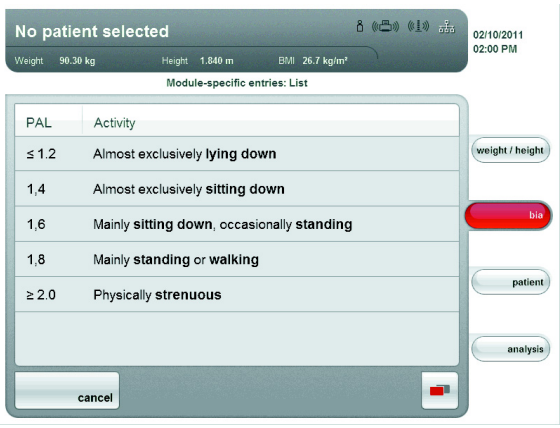
The **Module-specific entries** dialog window appears following a completed BIA measurement. Enter the PAL value (PAL = Physical Activity Level) here. Proceed as follows:

> **NOTE:**
> The **Module-specific entries** dialog window does not appear if the **Energy** evaluation module was deactivated in the module selection (see “Checking the module selection” on page 31) or in the standard module selection (see “Creating standard module selection” on page 62).

1. Press the **information** button next to the PAL input field.



A list with typical PAL values and brief descriptions appears.



2. Press the suitable PAL value for your patient.
   The list is closed.
   The value appears in the input field.
3. Press the **confirm** button.
   - If you have not yet measured the weight and height, the **weight/ height** tab is active.
   - If you have not yet assigned a patient, the **patient** tab is active.
   - If all data are available, the **analysis** tab is active.

   ATTENTION!
   Data loss
   If there is no new entry for approx. 5 minutes, the current measurement is discarded. The complete measurement procedure must be repeated.

Printing partial results

If the device is connected to a **seca 360°** wireless printer, you can print the measured results directly.

1. Ensure that the **seca 360°** wireless printer is switched on and that there is a **seca 360°** wireless connection.
   The printer symbol on the touchscreen display turns white.

   NOTE:
   If you uncertain of whether there is a **seca 360°** wireless connection, contact your administrator or hospital technician.

2. Press the **change menu** button.
   The secondary menu appears.
3. Press the **print** button.
   All measured results and entries available to this point are printed.

7.4 Assigning patient

Checking data connection

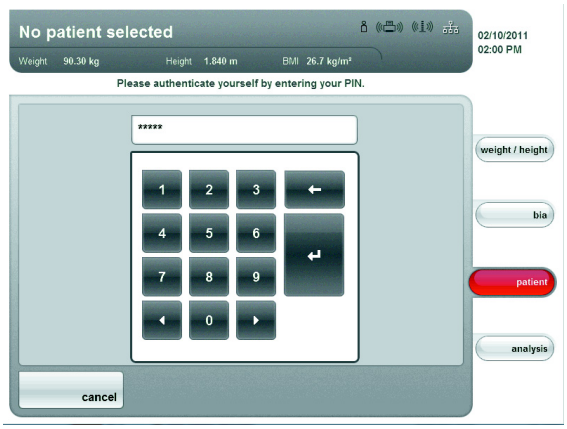
♦ Ensure that you can access the seca patient database in one of the following ways:
- The PC with PC software **seca 115** is switched on and connected to the device via seca wireless network or Ethernet. The corresponding data connection symbol turns white.
- The USB memory stick with seca patient database is connected to the touchscreen display USB interface. The corresponding data connection symbol turns white.

NOTE:

- If you have connected a USB memory stick containing a seca patient database to the device, you will not be able to access the seca patient database of the PC software **seca 115** via Ethernet or seca wireless network.
- If you are uncertain as to how a seca patient database can be accessed, contact your administrator or hospital technician.

Logging in to a seca patient database

If you wish to search or create patient data after switching on the device for the first time, the device will require you to use your user PIN for authentication. For this purpose, proceed as follows:



1. Enter your user PIN using the number keypad.

   NOTE:
   If you do not have your user PIN to hand, or if you have questions regarding access rights, contact your administrator or hospital technician.

2. In the number keypad, press the Enter key.
   The entry is accepted.
   The device now accesses the seca patient database.

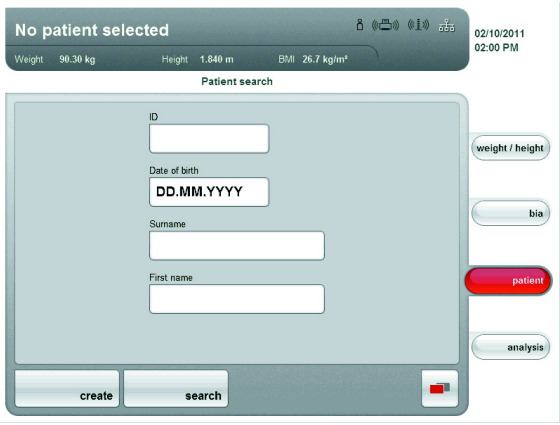
   The login symbol turns white. You are logged in to the seca patient database.

   ATTENTION!
   Data access by unauthorized persons
   If you are logged in to a patient database, unauthorized persons can also access patient data as long as the device is switched on.
   – Do not leave the device unsupervised if you are logged in to a patient database.
   – Log off from the patient database if you need to leave the device unsupervised (see “Logging off from a seca patient database” on page 43).
   – Switch off the device if you do not wish to use it for some time.

Searching for patient data

To search patient data, proceed as follows:

1. Press the **patient** tab.



The input screen for the patient search appears.

2. Enter at least the one of the following items of data:
   - Patient ID
   - Date of birth
   - Name

   NOTE:
   It is possible to perform a wildcard search for patient names (e.g. Br* for Brown).

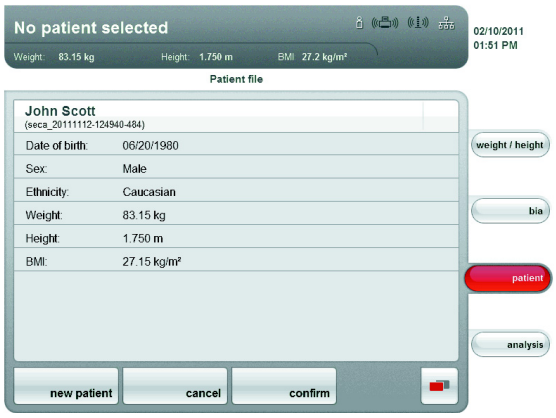
3. Press the **search** button.

   NOTE:
   If you are not logged in to a seca patient database, a dialog window appears for user PIN entry. Enter your user PIN as described in section ”Logging in to a seca patient database” on page 36.

   The device accesses the seca patient database (here: In the PC software **seca 115** via Ethernet). The search may take a few seconds.

All patients who meet the search criteria are displayed.

4. Press the desired entry.



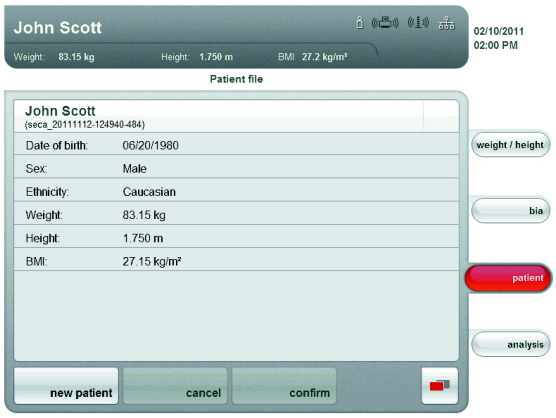
The patient details are displayed.

5. Make sure that you have selected the correct patient.

NOTE:

- If you wish to perform a new patient search, press the **new patient** button.
- If you wish to return to the results list, press the **cancel** button. If the results list has only one entry, the search screen appears.

6. Press the **confirm** button.



The current measurement is assigned to the selected patient.

The name of the patient appears in the header of the touchscreen display.

The **analysis** tab is active again

ATTENTION!

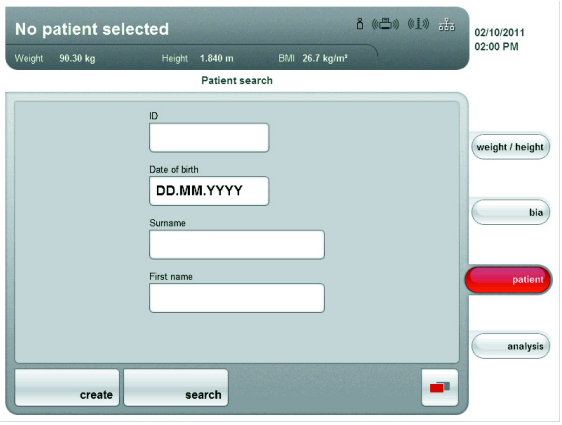
Data loss

The measurement has now been assigned to a patient, but has not yet been saved. If there is no new entry for approx. 5 minutes, the device switches to standby. The current measurement is discarded. The complete measurement procedure must be repeated.

– Save the measurement as described in section „Closing the measurement procedure“ from page 42.

Creating new patients

1. Press the **patient** tab.

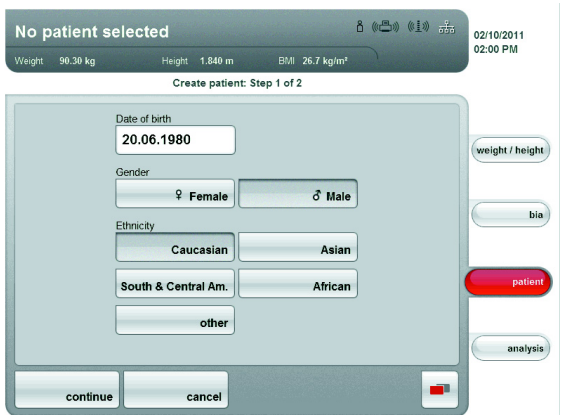


The input screen for the patient search appears.

2. Press the **create** button.

   NOTE:
   If you are not logged in to a seca patient database, a dialog window appears for user PIN entry. Enter your user PIN as described in section ”Logging in to a seca patient database” on page 36.

   The device accesses the seca patient database (here: In the PC software **seca 115** via Ethernet)

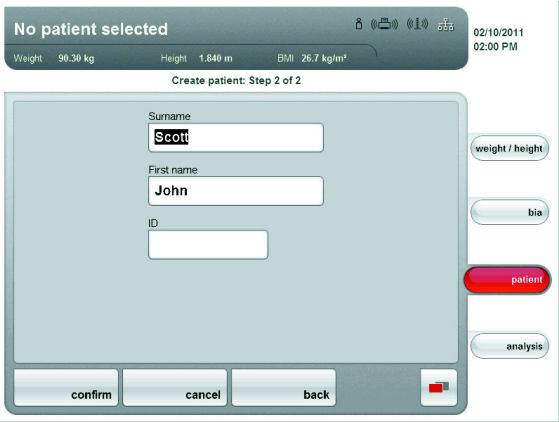


The initial input screen for patient data (mandatory fields) appears.

3. Enter the following patient data:
   - Date of birth
   - Gender
   - Ethnicity

   NOTE:
   You can find information regarding the influence of ethnicity on the evaluation of a bioelectric impedance analysis in section „Medical basis“ from page 44.

4. Press the **continue** button.

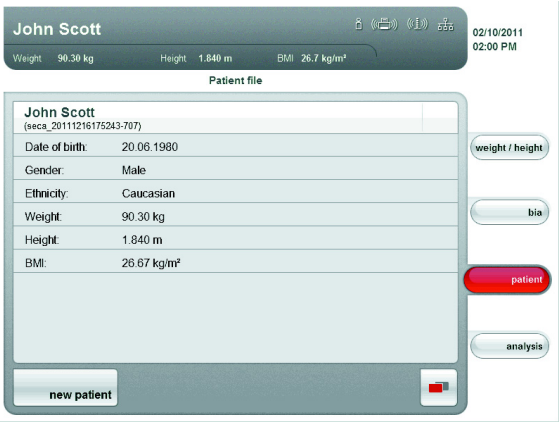


The second input screen for patient data (optional fields) appears.

5. Enter the following patient data:
   - First name
   - Name
   - Patient ID

   NOTE:
   You only need to enter a patient ID if this has to follow a specific structure in your institution. If you do not enter an ID, then an ID is assigned automatically when the data are saved.

6. Press the **confirm** button.



A summary of the patient data is shown.
The patient data are stored.

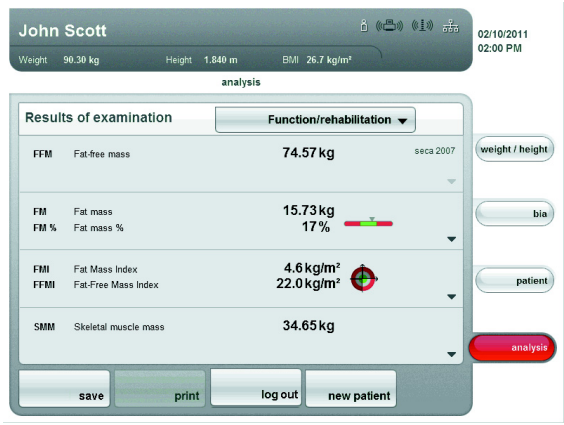
Editing patient data

You cannot make changes to patient data directly on the device. If you discover that patient data need to be changed, make the changes using the PC software **seca 115**. For further information, see the user documentation for the PC software.

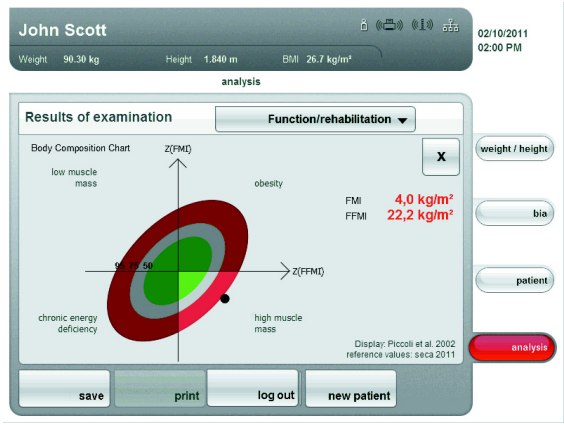
7.5 Viewing analyses

NOTE:
This section describes the navigation in the **analysis** tab. For information about the medical content of the evaluation modules, see chapter „Medical basis“ from page 44.

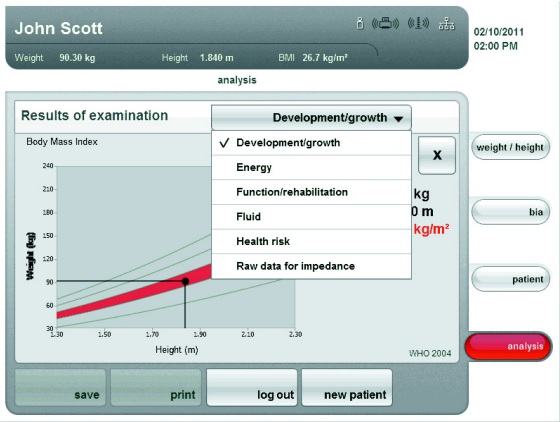
1. Press the **analysis** tab.
   The **Examination results** dialog window appears.
   The results for the first evaluation module (here: **Function/ rehabilitation**) are displayed.



2. For graphic analysis of individual results, press the drop-down triangle in the corresponding line.
   The graphic analysis appears:



3. To close the graphic analysis, press the **x** button.
4. To see the results of the other selected modules, press the drop-down menu.

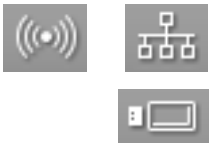


The drop-down menu is opened.

5. Select the evaluation module that you wish to view.

7.6 Closing the measurement procedure

Saving the measured results



1. Ensure that you can access the seca patient database in one of the following ways:
   - The PC with PC software **seca 115** is switched on and connected to the device via the seca wireless network or Ethernet. The corresponding data connection symbol turns white.
   - The USB memory stick with the seca patient database is connected to the touchscreen display USB interface. The corresponding data connection symbol turns white.

   NOTE:
   - If you have connected a USB memory stick to the device, you will not be able access the data of the PC software **seca 115** via Ethernet or the seca wireless network.
   - If you are uncertain as to how a seca patient database can be accessed, contact your administrator or hospital technician.

2. Press the **change menu** button.
   The secondary menu appears.
3. Press the **save** button.
   - If you are logged in to a seca patient database, the measured results will be saved. The corresponding data connection symbol turns red.
   - If you are not logged in to a seca patient database, a dialog window appears for PIN entry. Enter your user PIN as described in section ”Logging in to a seca patient database” on page 36. The measurement is assigned to the patient and saved. The corresponding data connection symbol turns red.
4. Log off from the seca patient database as described in section ”Logging off from a seca patient database” on page 43.
   The measurement procedure is complete.

Logging off from a seca patient database

In order to log off from a seca patient database, proceed as follows:

ATTENTION!
Data loss
If you log off without saving the measurement procedure, all data in the current measurement procedure will be lost.
– Save the current measurement procedure before logging off from a patient database (see “Saving the measured results” on page 42).

1. Press the **change menu** button.
   The secondary menu appears.
2. Press the **log out** button.

The login symbol is grayed out. You have been logged off from the seca patient database.

Printing measured results

If the device is connected to a **seca 360**° wireless printer, you can print the measured results directly.

1. Ensure that the **seca 360**° wireless printer is switched on and that there is a **seca 360**° wireless connection to the device.
   The printer symbol on the touchscreen display turns white.

NOTE:
If you are uncertain of whether a there is a **seca 360**° wireless connection, contact your administrator or hospital technician.

2. Press the **change menu** button.
   The secondary menu appears.
3. Press the **print** button.
   The measured results are printed.
   The printer symbol turns red.
   The measurement procedure is complete.

8. MEDICAL BASIS

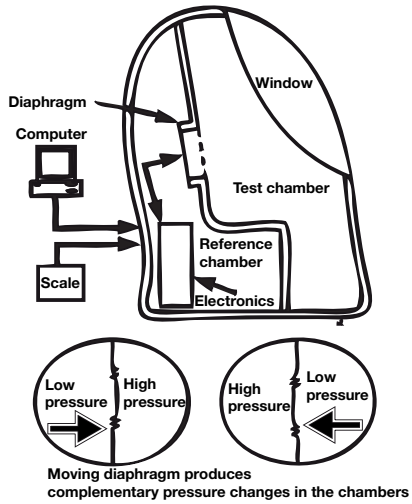
This section briefly describes the basis for bioelectric impedance analysis, as well as the contents and medical goals of the evaluation modules that have been pre-set in this device. The references on which the evaluations rest will also be presented.

For additional information, we refer to the appropriate professional literature.

8.1 Bioelectric impedance analysis (BIA)

Classic analysis of body composition

The current "gold standard" for analyzing body composition involves a combination of methods for calculating individual parameters, some of which are technically complex and all of which are time-consuming. The parameters are considered in combination with the weight and body size of the patient. This way, the nutritional condition and health risk of the patient can be individually assessed. The following table offers an overview of the gold standard parameters and the corresponding calculation methods.



Air Displacement Plethysmography (ADP)

Dual Energy X-ray Absorbtiometry (DEXA)

Parameters	Method
Total body water (TBW)	Dilatation method, tracer: Deuterium
Extracellular water (ECW)	Dilatation method, tracer: Sodium bromide
Fat mass (FM)	Calculation based on the four component model [a] of the quantities: body volume, bone minerals, weight, and total body water.
Fat-free mass (FFM)	Difference between weight and fat-free mass
Lean soft tissue (LST)	Dual Energy X-ray Absorbtiometry (DEXA)

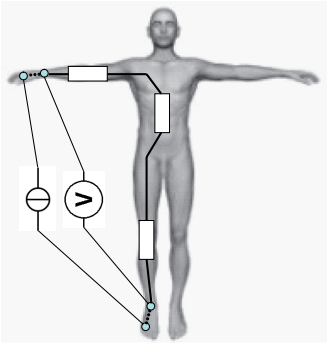
a. Fuller NJ, Jebb SA, Laskey MA, Coward WA, Elia M. Four-component model for the assessment of body composition in humans: comparison with alternative methods, and evaluation of the density and hydration of fat-free mass. Clin Sci 1992; 82: 687-693.

In order to determine the fat mass, a high degree of technical complexity is required. The following tables serves as an overview in this regard:

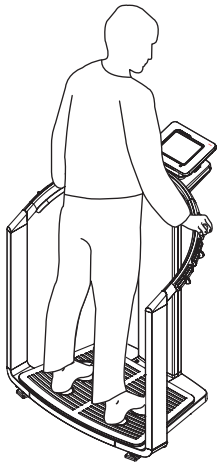
Height for calculating the FM	Method
Total body water (TBW)	Dilatation method, tracer: Deuterium
Body volume	Densitometry e.g. Air Displacement Plethysmography (ADP)
Bone minerals	Dual Energy X-ray Absorbtiometry (DEXA)

The high technical and financial input, combined with considerable time and space requirements, means that the “gold standard” is unsuitable for day-to-day operations in clinics and doctor’s practices.

Functional principle of bioelectric impedance analysis



Equivalent circuit diagram:
Measurement of total body impedance



seca 515/514:
Measurement of total body impedance

Bioelectric impedance analysis (BIA) is a method for rapid, simple, and non-invasive assessment of body composition. Only one measurement procedure is required on an individual device.

In the BIA method, the human body is regarded as an electrical conductor in an alternating current circuit and its alternating current resistance (impedance) is measured.

The following properties of an electrical conductor have an impact on its impedance:

Property	Correspondence in humans
Length	Body size
Cross-section	e.g. waist circumference
Material	Body water, cell tissue

When it comes to the human body, age, gender, bodily fitness, and ethnicity have an impact on the impedance.

In the event that a low alternating current is conducted to the arms and legs via electrodes and the voltage drop is measured via a second electrode pair, the following components of body impedance can be calculated:

Impedance components	Cause
Resistance (R), ohmic resistance	Body water is a good electrical conductor
Reactance (X_C), capacitive resistance	Cell tissue acts as a capacitor
Phase angle (Φ)	Phase shift between the maximum current and maximum voltage by the capacitor effect of the cell tissue

If the alternating current is applied with different frequencies, individual parameters can be specifically determined. In doing so, the proportion of extracellular water can be determined directly, for example, if lower frequencies of between 2 and 5 kHz are used. Alternating current with these frequencies is hardly able to penetrate cell walls. Cell walls and intracellular water therefore have a very minor impact on the impedance.

The body composition of the patient can be calculated and then assessed using the measured variables in combination with the patient's weight, height, age and gender. The pre-requisite in this case consists of formulas calculated according to scientific criteria.

Pioneering achievement: seca formulas

A number of formulas are already available form a number of sources, with the help of which the body composition can be calculated based on the R, X_C, weight, height, age, and gender of a patient. The formulas are based on results of what are referred to as validation studies of reference methods of gold standards, such as the Air Displacement Plethysmography (ADP) or the Dual-Energy X-ray Absorptiometry (DEXA).

However, the comparability and accuracy of these formulas must be regarded with a critical eye as the validation studies were performed with differing reference methods and, in all respects, heterogeneous reference populations. In addition, the study results cannot necessarily be transferred to other manufacturers' devices for technical reasons.

Therefore, seca has developed in-house prediction formulas for calculating the following parameters for the arms and legs:

- Total body water (TBW)
- Extracellular water (ECW)
- Fat-free mass (FFM)
- Lean soft tissue (LST) for the arms and legs

In-house reference values were determined for the following parameters in order to be able to show normal ranges:

- Bioelectric impedance vector analysis (BIVA)
- Mass indices (FMI, FMMI)
- Phase angle (Φ)

In order to calculate the formulas and reference values, there was close collaboration with the Institute for Human Nutrition and Food Studies at the University of Kiel and a joint representative study was performed.

In contrast to all formulas published so far, the seca in-house formulas are population-specific. The formulas developed in Kiel are valid for Caucasian population groups only.

Representative surveys were also performed in the USA in collaboration with the New York Obesity Nutrition Research Center at the St. Luke's Roosevelt Hospital. seca in-house formulas for African, South and Central American, and Asiatic population groups were developed on the basis of this study.

The seca in-house formulas are implemented for seca mbca devices andseca PC software only. As such, seca is a pioneer in the well-founded scientific and medically significant determination of the body composition by means of bioelectric impedance analysis.

8.2 Evaluation modules

Summary of the evaluation modules

At seca, we call all the variables required to assess body composition "evaluation modules". The following table offers an overview of the evaluation modules of the **seca 515/514**:

Evaluation module	Display	Diagnostic relevance
Bioelectric impedance vector analysis (BIVA)	• Normal range display of R and X_C in coordinate system in relation to body size • 50%, 75%, 95% percentiles as tolerance ellipses	• Assessment of the quantity of total body water and body cell mass • Monitoring of changes in both quantities
Body Mass Index (BMI)	• Absolute in kg/m^2 • Display for children in percentile curves • For adults: Graphic display of WHO reference values	• Classification option into normal, overweight, underweight, and obese • This is dependent on age and gender in children
Extracellular water (ECW)	Absolute in l	Differentiated view of changes in total body water Possible cause of increase in ECW: Storage of fluid in extracellular area
Fat-free mass (FFM)	Absolute in kg	A decrease in fat-free mass indicates a decline in the health of seriously ill and overweight people.
Fat mass (FM)	• Absolute in kg • Relative in % • For adults: Normal range display	• Determination of energy resources in underweight and heavily overweight patients • Study of change in fat mass whilst undergoing medical treatment or as a disease progresses

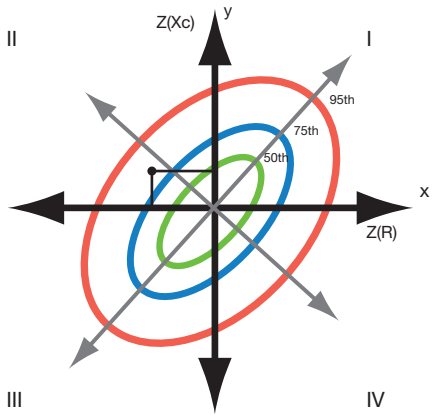
Evaluation module	Display	Diagnostic relevance
Total energy expenditure (TEE)	Absolut in MJ/d or kcal/d	• Energy balancing within the context of nutrition advising • Using the **seca 115** software therapy planner
Total body water (TBW)	Absolute in l	Study of changes in the quantity of fluid in the human body. Possible causes: Tumors, cardiac, liver, or kidney insufficiency
Weight (W)	• Absolute in kg • For children: Display in percentile curves	• Rough assessment of health • Weight change in intensive care and dialysis patients • Growth and development in children
Height (H)	• Absolute in m • For children: Display in percentile curves	• Differentiated view of weight • Differentiated view of growth and development in children • For BIA measurement: Length of the electrical conductor
Hydration (Hyd)	Relative in %	Assessment of fluid shifting between the intracellular and extracellular area. Fluid shifting occurs, for example, before the decrease in weight or FFM.
Energy stored in body (E_{body})	Absolute in MJ or kcal	Energy balancing within the context of nutrition advising
Mass indices Fat-free mass index (FMMI) Fat mass index (FMI)	• Absolute in kg/m^2 • Normal range display in coordinate system in relation to body size • 50%, 75%, 95% percentiles as tolerance ellipses	• Assessment of the nutrition and fitness level • Differentiated assessment of the BMI: In the case of a change in BMI, a change in FFM or FM may be the cause
Phase angle (Φ)	• Absolute in degrees • Normal range display according to seca in-house reference values	• Assessment of nutrition and health • A small phase angle is an indicator for a decline in health
Physical Activity Level (PAL)	Absolute as a figure without unit	• Calculation of the TEE • Determining the energy expenditure
Reactance (X_C)	Absolute in ohms	Indicator for cell quantity and cell quality
Resistance (R)	Absolute in ohms	Represents the quantity of total body water
Resting energy expenditure (REE)	Absolute in MJ/d or kcal/d	• Energy balancing within the context of nutrition advising • Using the **seca 115** software therapy planner
Skeletal muscle mass (SMM)	Absolute in kg	Assessment of physiological and metabolic processes in the human body
Waist circumference:	Absolute in cm	• Determination of the fat tissue stored in the abdominal cavity • Assessment of the cardio metabolic risk
Lean soft tissue mass (LST)	Absolute in kg	Displays the fat-free mass without bone mass

seca specialty: Coordinate system with tolerance ellipses

In addition to the classic display of evaluation modules in numerical values, bar graphs, and percentile curves, the **seca 515/514** uses coordinate systems with tolerance ellipses for the graphic display of body impedance and fat-mass indices.

This form of graphic display was developed by Professor A. Piccoli for the interpretation of body impedance under the name Bioelectric Impedance Vector Analysis (BIVA).

The transfer of this principle to the display and interpretation of the fat-mass indices is a new development from seca in collaboration with the Institute for Human Nutrition and Food Studies at the University of Kiel.



Biolelectric impedance analysis (BIVA)

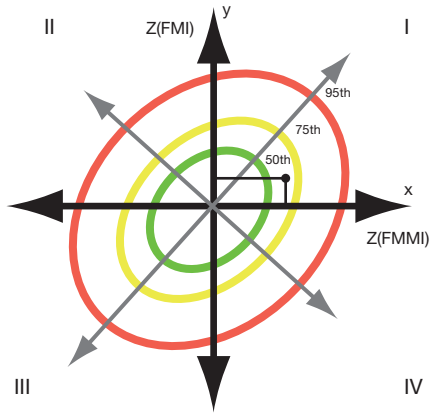
According to Professor A. Piccoli, the BIVA is a graphical display of the electrical resistances of the body. To this end, the impedance of the patient is displayed as a measurement point in a coordinate system: Capacitive resistance (X_C) on the ordinate, ohmic resistance (R) on the X-axis. Both sizes X_C and R are considered relative to body size (length of the electrical conductor).

With vector display, a proband can be investigated simultaneously with regard to his/her total body water – R – and his/her body cell mass – X_C. Changes to the measurement point (R, Xc) parallel to the X axis indicate changes to the fluid volume, while changes on the Y axis indicate an increase or decrease in the body cell mass.

The quadrants in the coordinate system are named correspondingly:

- I: X_C high, R high = lower proportion of water
- II: X_C low, R high = higher proportion of cells
- III: X_C low, R low = lower proportion of cells
- IV: X_C high, R low = higher proportion of water

An additional advantage of the BIVA is the comparison of an individual measured value with reference values. The 50%, 75%, and 95% percentiles are entered into the coordinate system as tolerance ellipses.



Fat mass indices (FFMI and FMI)

The system developed by Professor A. Piccoli can be applied to the display of the fat-mass indices on the basis of the work carried out by Schutz et al., who describe four typical situations for the relationship of FFMI and FMI.

The quadrants in the coordinate system are named correspondingly:

- I: FFMI high, FMI high = high muscle mass
- II: IFFMI low, FMI high = obesity
- III: FFMI low, FMI low = chronic energy deficiency
- IV: FFMI high, FMI low = low muscle mass

In addition, the FFMI (X axis) and the FMI (ordinate) are also plotted on the axes of the coordinate system for FFMI and FMI. The 50%, 75%, and 95% percentiles for the fat mass indices are displayed as tolerance ellipses.

8.3 Evaluation modules

The evaluation modules described below are pre-set in this device and assist you in assessing your patients' state of health.

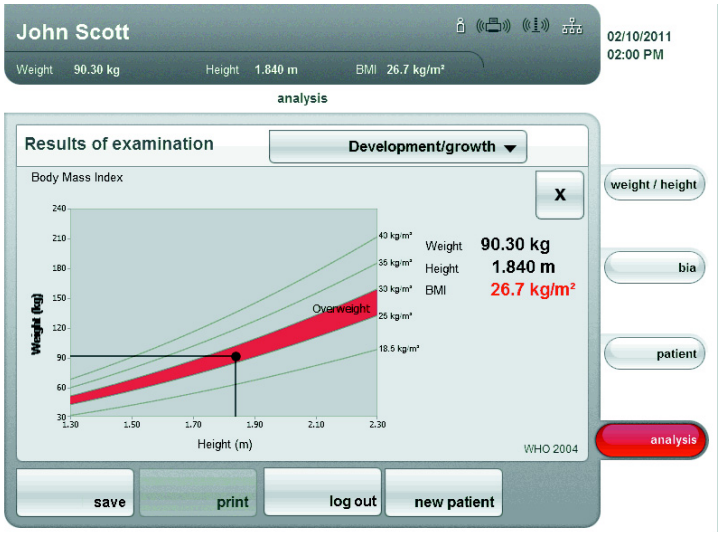
The evaluation modules offer the option of only viewing those evaluation modules (see “Evaluation modules” on page 46) that are relevant to a specific objective.

For information about how you can access the evaluation modules and navigate within them, see „Viewing analyses“ from page 41.

Development/growth

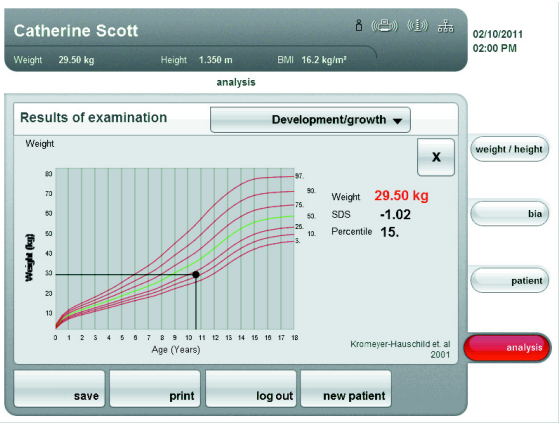
The goal of this module is the monitoring of growth processes and weight changes over the course of a hospital stay or medical treatment. This module assists with regular control examinations for the assessment of growth and development, especially in children. The following parameters are displayed:

- Weight
- Height
- Body mass index (BMI)

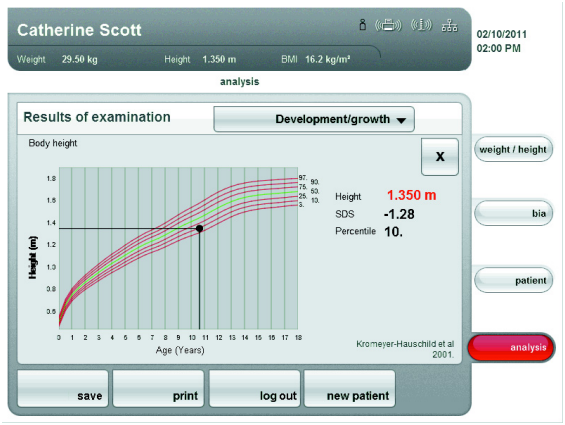


The following detail views are available for this module:

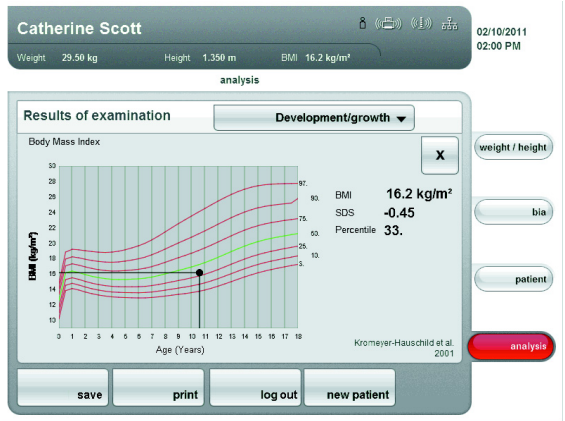
Weight percentile curves for children



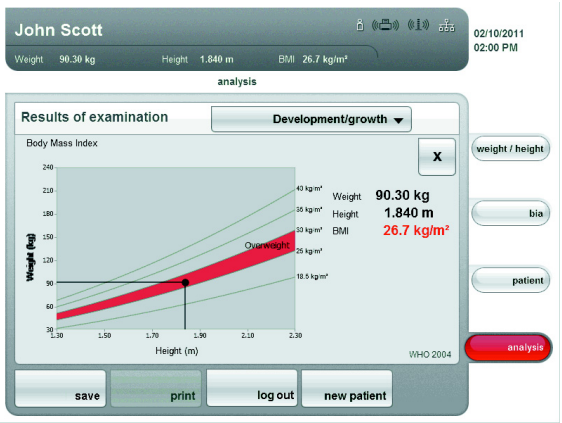
Height percentile curves for children



BMI percentile curves for children



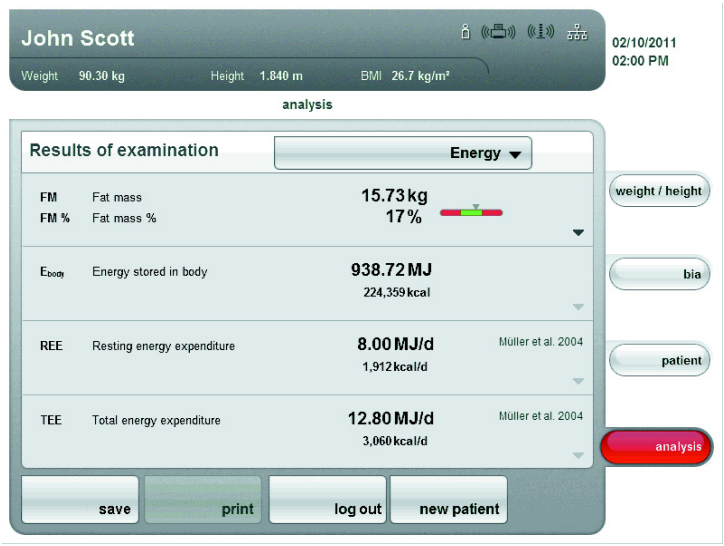
WHO reference values for adults



Energy

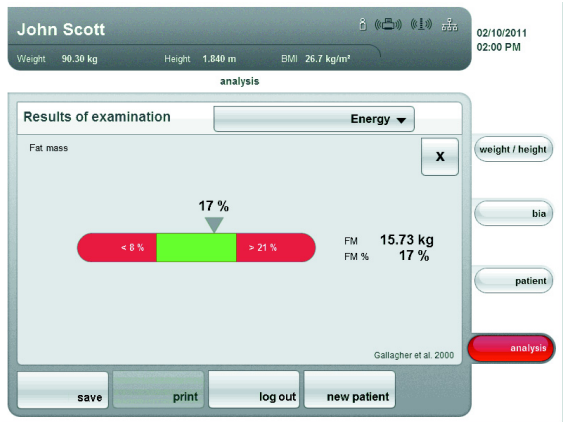
The goal of this module is the quantitative determination of energy expenditure and energy reserves of the body for the assessment of weight changes, the course of illnesses, and of the general nutritional state of a patient. The following parameters are displayed:

- Fat mass (FM) in kg
- Fat mass (FM) in %
- Energy stored in body (E_{body})
- Resting energy expenditure (REE)
- Total energy expenditure (TEE)



The energy module serves as the basis of nutrition advising. The following detail view is available in this module:

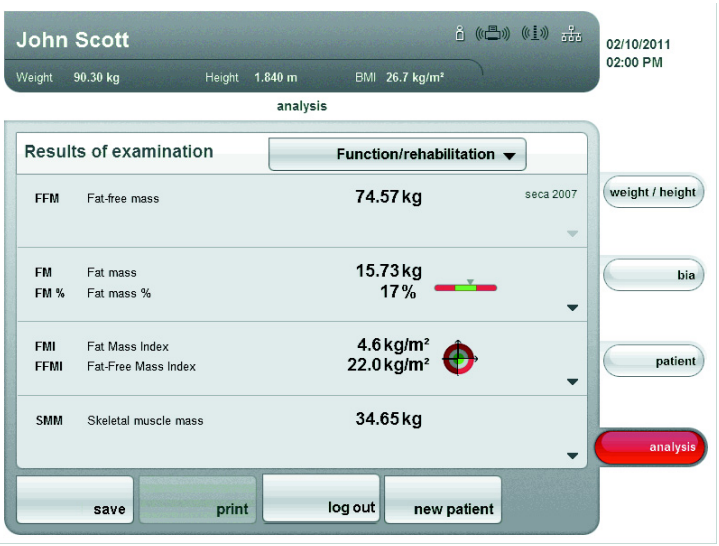
Normal data range display of the fat mass for adults



Function/rehabilitation

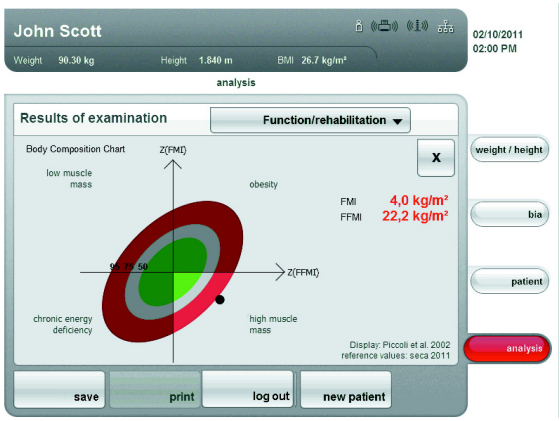
This module serves to determine the fitness level and to assess metabolic activity and success for a training program e.g. within the framework of rehabilitation or physiotherapy. The following parameters are displayed:

- Fat-free mass (FFM)
- Fat mass (FM) in kg
- Fat mass (FM) in %
- Fat mass index (FMI)
- Fat-free mass index (FMMI)
- Skeletal muscle mass (SMM)
- Lean soft tissue (LST)

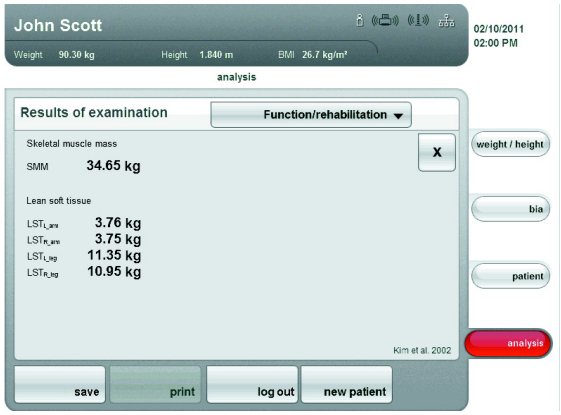


The following detail views are available for this module:

Fat mass index (body composition chart)



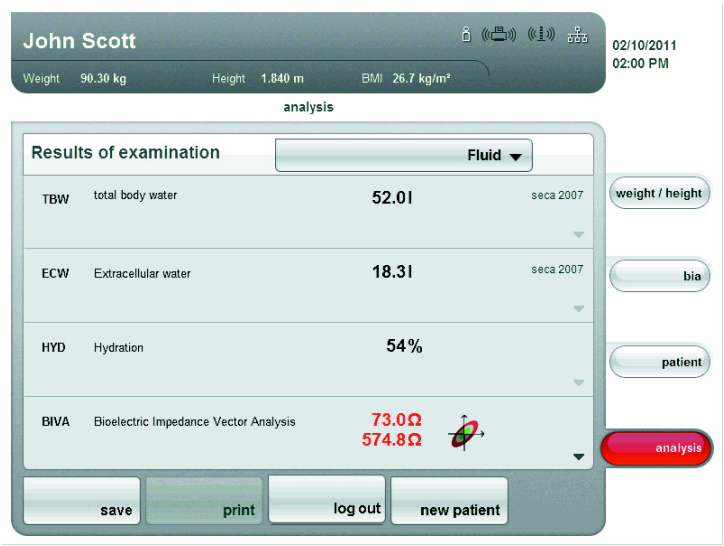
Skeletal muscle mass and lean soft tissue per extremity



Fluid

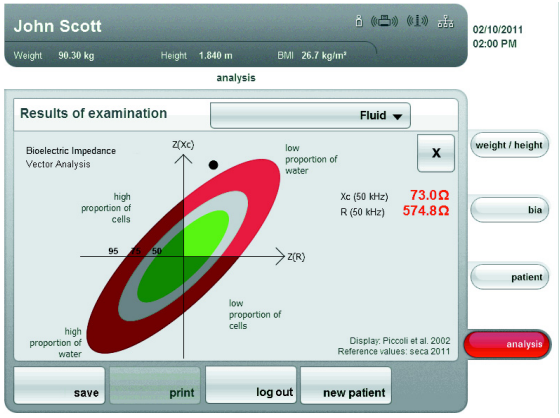
The fluid module makes it possible to determine the fluid status of a patient and to monitor changes in fluids as the result of medical treatment. The following parameters are displayed:

- Total body water (TBW)
- Extracellular water (ECW)
- Hydration (HYD)
- Bioelectric impedance vector analysis (BIVA)



The following detail view is available for this module:

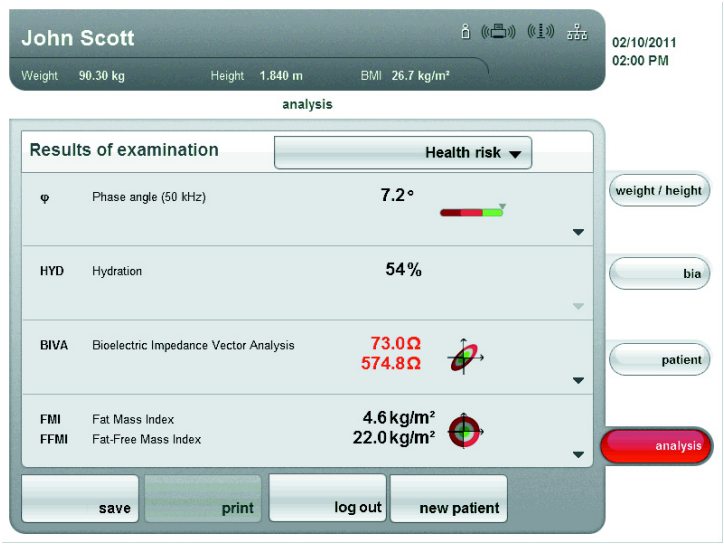
Bioelectric impedance vector analysis



Health risk

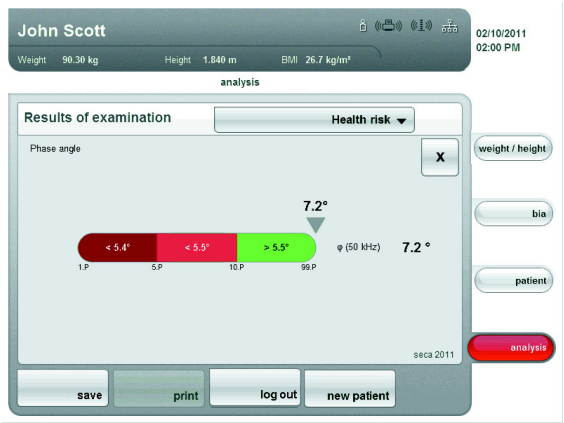
The goal is to determine the general state of health or, in the case of a previously known disease, assessing the severity. The following parameters are displayed:

- Phase angle Φ at 50Hz
- Hydration (HYD)
- Bioelectric impedance vector analysis (BIVA)
- Fat mass index (FMI)
- Fat-free mass index (FMMI)

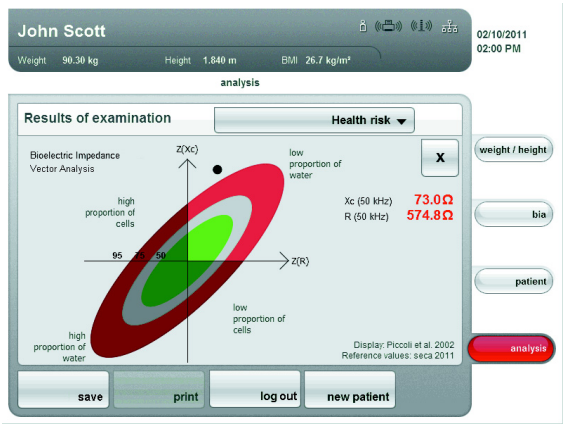


The following detail views are available for this module:

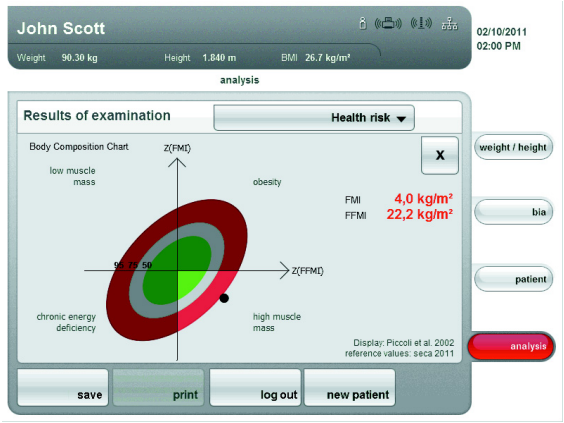
Normal range display for the phase angle



Bioelectric impedance vector analysis



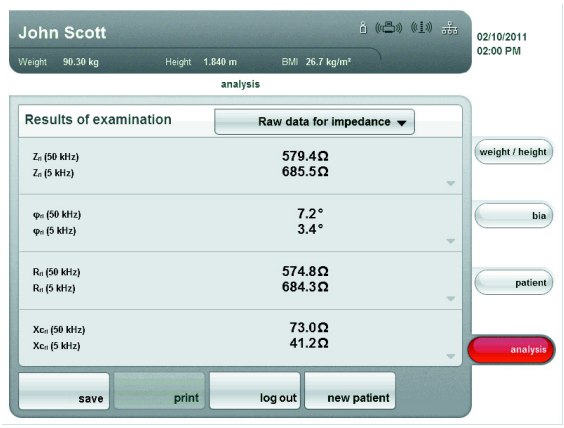
Fat mass index (body composition chart)



Raw data for impedance

The raw data for impedance module provides the results of the bioelectric impedance analysis as raw data so that it can be used for medical studies.

You can also view the impedance (Z), reactance (X_C), resistance (R), and phase angle (Φ) for the frequencies 50 Hz and 5 Hz.



NOTE:
In the PC software **seca 115**, you can view the raw data for impedance for individual body parts and for additional frequencies. For further information, see the user manuals for the PC software.

8.4 References

The following references constitute the scientific basis for bioelectric impedance analysis using the Medical Body Composition Analyzer **seca 515/514**. These references are stored in the device software and form the basis for the assessment of the state of health of your patient.

The references used by the device depend on the country in which you are active. For some evaluation modules (e.g. waist circumference for children), the reference used also depends on the patient's ethnicity.

As part of the device configuration, your administrator will enter your country as the setup location. The usual references for your country will be loaded automatically. The device automatically uses ethnicity-dependent references to suit the corresponding entry in the patient data (see “Creating new patients” on page 39).

Waist circumference for children

The following references are set depending on the setup location of the device:

Reference	Origin	Characteristics	Setup location
Fernandez et al. 2004[a]	USA	For children of the following ethnicities: • Caucasian • African • South and Central American	Germany Austria Switzerland USA Other
Inokuchi et al. 2007[b]	Japan	For Asian children	China Hong Kong

a. Fernández JR, Redden DT, Pietrobelli A, Allison DB. Waist circumference percentiles in nationally representative samples of African-American, European-American, and Mexican-American children and adolescents. J Pediatr 2004; 145(4):439-44.

b. Inokuchi M, Matsuo N, Anzo M, Takayama Hasegawa T. Age-dependent percentile for waist circumference for Japanese children based on the 1992-1994 cross-sectional national survey data. Eur J Pediatr 2007; 166:655-661.

Resting energy expenditure (REE) for children

The following references are set depending on the setup location of the device:

Reference	Origin	Setup location
Müller et al. 2004[a]	Germany	Germany
FAO/WHO/UNU 2004[b]	International	Austria Switzerland USA China Hong Kong Other

a. Müller MJ, Bosy-Westphal A, Klaus S,Kreymann G, Lührmann PM, Neuhäuser-Berthold M, Noack R, Pirke KM, Platte P, Selberg O, Steininger J. World Health Organization equations have shortcomings for predicting resting energy expenditure in persons from a modern, affluent population: generation of a new reference standard from a retrospective analysis of a German database of resting energy expenditure. AM J Clin Nutr 2004; 80:1379-90.

b. FAO Food and Nutrition Technical Report Series 1; Human energy requirements - Report of a Joint FAO/WHO/UNU Expert Consultation; Rome, 2004. http://www.fao.org/docrep/007/y5686e/y5686e00.HTM

Resting energy expenditure (REE) for adults

The following references are permanently set:

Reference	Origin	Setup location
Müller et. al. 2004[a]	Germany	Germany
Liu et al. 1995[b]	China	China
FAO/WHO/UNU 2004[c]	International	Austria Switzerland USA Hong Kong Other

a. Müller MJ, Bosy-Westphal A, Klaus S,Kreymann G, Lührmann PM, Neuhäuser-Berthold M, Noack R, Pirke KM, Platte P, Selberg O, Steininger J. World Health Organization equations have shortcomings for predicting resting energy expenditure in persons from a modern, affluent population: generation of a new reference standard from a retrospective analysis of a German database of resting energy expenditure. AM J Clin Nutr 2004; 80:1379-90.

b. Hsiu-Ying Liu, MS; Yi-Fa Lu, Phd; Wei-Jao Chen, MD, MPH. Predictive Equations for basal metabolic rate in Chinese adults: a cross-validation study. J Am Diet Assoc. 1995; 95:1403-1408

c. FAO Food and Nutrition Technical Report Series 1; Human energy requirements - Report of a Joint FAO/WHO/UNU Expert Consultation; Rome, 2004. http://www.fao.org/docrep/007/y5686e/y5686e00.HTM

Percentile curves for children

The following references are permanently set:

Reference	Origin
Centers for Disease Control and Prevention (CDC 2000)[a]	USA
World Health Organization (WHO 2007)[b]	International
Kromeyer-Hauschild et al. 2001[c]	Germany

a. Kuczmarski RJ, Ogden CL, Guo SS, et al. 2000 CDC growth charts for the United States: Methods and development. National Center for Health Statistics. Vital Health Stat 11(246). 2002.

b. De Onis M, Onyango AW, Borghi E, Siyam A, Nishidaa C, Siekmann J. Development of a WHO growth reference for school-aged children and adolescents. Bulletin of the World Health Organization 2007; 85:660–667.

c. Kromeyer- Hauschild K, Wabitsch M, Kunze D, Geller F, Geiß HC, Hesse V, von Hippel A, Jaeger U, Johnsen D, Korte W, Menner K, Müller G, Müller MJ, Niemann- Pilatus A, Remer T, Schaefer F, Wittchen HU, Zabransky S, Zellner K, Ziegler A, Hebebrand. Percentile for the body mass index for childhood and adolescence using a range of different German samples. Monatsschr Kinderheilkd 2001; 149:807-818.

Total body water (TBW)

The following reference is permanently set:

Reference	Origin	Characteristics
seca 2011[a]	Germany USA	• Considers 4 ethnicities: Caucasian, African, South/Central American, Asiatic • Age group 18 to 65 years • BMI range 18.5 to 35 kg/m^2

a..Reference values: seca gmbh & co. kg, Generation of normal ranges to analyze body composition of adults base on Bioelectrical Impedance Analysis (BIA), 2011

Extracellular water (ECW)

The following reference is permanently set:

Reference	Origin	Characteristics
seca 2011[a]	Germany USA	• Considers 4 ethnicities: Caucasian, African, South/Central American, Asiatic • Age group 18 to 65 years • BMI range 18.5 to 35 kg/m^2

a..Reference values: seca gmbh & co. kg, Generation of normal ranges to analyze body composition of adults base on Bioelectrical Impedance Analysis (BIA), 2011

Fat-free mass (FFM)

The following reference is permanently set:

Reference	Origin	Characteristics
seca 2011[a]	Germany USA	• Considers 4 ethnicities: Caucasian, African, South/Central American, Asiatic • Age group 18 to 65 years • BMI range 18.5 to 35 kg/m^2

a..Reference values: seca gmbh & co. kg, Generation of normal ranges to analyze body composition of adults base on Bioelectrical Impedance Analysis (BIA), 2011

Bioimpedance vector analysis (BIVA)

The following reference is permanently set:

Reference	Origin	Characteristics
seca 2011[ab]	Germany USA	Reference values for normal range display • Age group: 18 years and up

a.Definition of graphic display: Piccoli A, Rossi B, PillonL, Bucciante G. A new method for monitoring body fluid variation by bioimpedance analysis: the RXc graph. Kidney Int. 1994 Aug;46(2):534-9

b..Reference values: seca gmbh & co. kg, Generation of normal ranges to analyze body composition of adults base on Bioelectrical Impedance Analysis (BIA), 2011

Body Compostion Chart (Fat mass indices FMI, FFMI)

The following reference is permanently set:

Reference	Origin	Characteristics
seca 2011[ab]	Germany USA	• Reference values for normal range display • Body size: 1.6 to 2.0 m

a.Definition of graphic display: Piccoli A, Rossi B, PillonL, Bucciante G. A new method for monitoring body fluid variation by bioimpedance analysis: the RXc graph. Kidney Int. 1994 Aug;46(2):534-9

b..Reference values: seca gmbh & co. kg, Generation of normal ranges to analyze body composition of adults base on Bioelectrical Impedance Analysis (BIA), 2011

Phase angle (φ)

The following reference is permanently set:

Reference	Origin	Characteristics
seca 2011[a]	Germany USA	Reference values for normal range display • Age group: 18 years and up

a.Reference values: seca gmbh & co. kg, Generation of normal ranges to analyze body composition of adults base on Bioelectrical Impedance Analysis (BIA), 2011

Fat mass (FM)

The following reference is permanently set:

Reference	Origin	Characteristics
Gallagher et al. 2000[a]	USA	• Considers 3 ethnicities: Caucasian, Afro-American, Asiatic • Age group: 20+

a.Dympna Gallagher, Steven B Heymsfield, Moonseong Heo, Susan A Jebb, Peter R Murgatroyd, and Yoichi Sakamoto, Healthy percentage body fat ranges: an approach for developing guidelines based on body mass index1–3, Accepted for publication January 24, 2000.

Skeletal muscle mass (SMM)

The following reference is permanently set:

Reference	Origin	
Kim et al. 2002[a]	USA	• Age group: 18+ • BMI range: 15.9 to 34.8 kg/m^2

a.Kim J, Wang Z, Heymsfield SB, Baumgartner RN, Gallagher D. Total-body skeletal muscle mass: estimation by a new dual-energy X-ray absorptiometry method. Am J Clin Nutr. 2002 Aug;76(2):378-83. SourceObesity Research Center, St Luke's Roosevelt Hospital and the Institute of Human Nutrition, Columbia University, College of Physicians and Surgeons, New York, NY 10025, USA

Energy/energy equivalent stored in body

The following reference is permanently set:

Reference	Origin
Müller 2007[a]	Germany

a.Müller MJ. Nutritional medicine practice: Methods – prevention – treatment. 2nd edition. Springer Medizin Verlag 2007

9. CONFIGURING DEVICE

9.1 Adapting standard module selection for BIA

The standard module selection determines which evaluation modules are considered during a BIA.

The device is factory set, so that when activating the **bia** tab, the **standard module selection** dialog window appears and all evaluation modules are activated. This way, the module selection can be verified before each measurement and, if necessary, adapted for the individual measurement.

The device can be configured in such a way that the **standard module selection** dialog window does not appear if the **bia** tab is activated. Furthermore, an in-house standard module selection can be created.

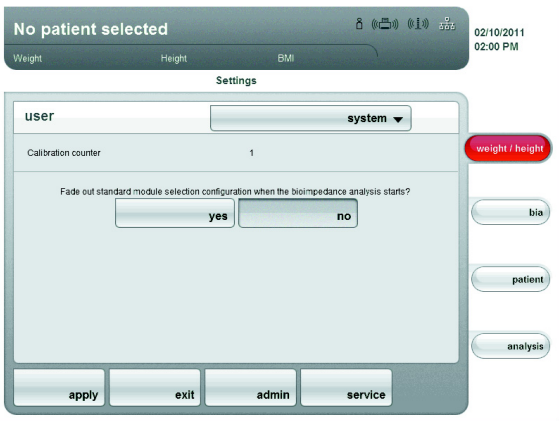
Showing/hiding standard module selection

In order to determine whether or not the **standard module selection** dialog window is displayed before each BIA, proceed as follows:

1. Press the **change menu** button.

   The secondary menu is displayed.

2. Press the **settings** button.
   The **user** menu appears.



   The current setting is displayed (button appears gray = pressed).

3. Enter the desired setting.
   - **on**: Standard module selection is active. It is displayed before every bioelectric impedance analysis and can be adapted for the corresponding measurement.
   - **off**: Standard module selection is active but is not displayed before the bioelectric impedance analysis. Adaptions to the standard module selection are only possible in the **settings** menu.

4. Press the **apply** button.
   The module selection is saved and available following the next bioelectric impedance analysis.

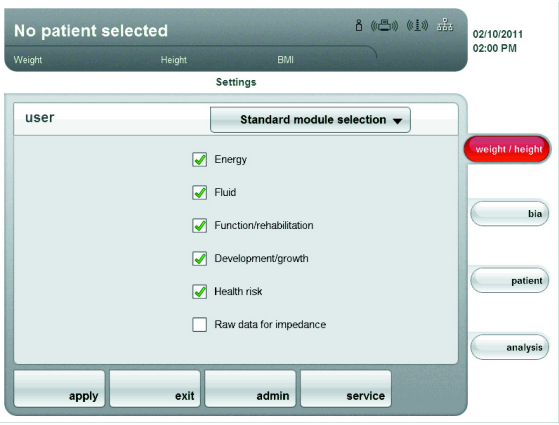
Creating standard module selection

In order to create an in-house standard module selection, proceed as follows:

1. Press the **change menu** button.

The secondary menu is displayed.

2. Press the **settings** button.
   The **user** menu appears.
3. Press the drop-down menu.
   The drop-down menu is opened.
4. Press the **standard module selection** menu element.



The current module selection is displayed.
Factory setting: All modules selected (exception: **Raw data for impedance**).

NOTE:

- Activating the **Raw data for impedance** module increases the duration of the BIA measurement. Activate the **Raw data for impedance** module if you wish to use the measured results for scientific studies. You can then evaluate raw data for impedance in the PC software **seca 115** for up to 18 frequencies.
- If you deactivate the **Energy** evaluation module, there is no request for the Physical Activity Level (PAL) following a BIA measurement.

5. Press all modules that you wish to deactivate.
   The checkmark in the checkbox is no longer displayed.

NOTE:
Press on the module again to reactivate it.

6. Press the **apply** button.
   The module selection is saved and available following the next bioelectric impedance analysis.

NOTE:
To exit the dialog window without saving, press the **cancel** button or the most recently active tab (red, here **bia**). The most recently active tab is active again.

9.2 Saving settings

Applying settings

1. Press the **apply** button.
   The **Save operation successful** dialog window appears.
2. Press the **continue** button.
   The **settings\user** menu appears on the display again.
   You can implement additional settings in the **settings\user** menu or exit the menu as described in the section “**Exit Settings\user menu**”.

Exit Settings\user menu

1. Press the **exit** button.
   The **Unsaved changes** dialog window appears.
2. Press the desired button **yes**.
   - **yes**: The changes are saved. The most recently active tab is active again. The device is ready for measurement.
   - **no**: The changes are not saved. The most recently active tab is active again. The device is ready for measurement

10. HYGIENIC PREPARATION

WARNING!
Electric shock
The device has not been put out of operation if the on/standby button is pressed and the touchscreen display goes out. The use of fluids on the device can lead to electric shock.

– Before each hygienic treatment, remove the mains cable to ensure that the device is out of operation.

10.1 Cleaning

Clean the surfaces of the device with a soft cloth as required, dipped in ethyl alcohol if necessary.

10.2 Disinfection

The device must be disinfected at regular intervals using commercially-available disinfectants. Observe the instructions for use of the disinfectant.

Observe the following intervals:

- Before each measurement:
  - Weighing platform and foot electrodes
  - Standing aid and pair of hand electrodes
- After each use:
  - Weighing platform and foot electrodes
  - Standing aid and pair of hand electrodes
- As required:
  - Touchscreen display

11. MAINTENANCE/RECALIBRATION (515)

11.1 Information on maintenance and recalibration

We recommend having your device maintained prior to recalibration.

The device's measurement technology for bioelectric impedance analysis (BIA) must be checked every two years.

ATTENTION!
Incorrect measurements may be taken as the result of improper maintenance

–Please only have maintenance and repairs performed 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.

Have an authorized technician perform a recalibration according to national standards and rules. The year of the first recalibration can be found behind the CE symbol on the type plate via the number of the stated office 0109 (Hessian Eichdirektion [Hessian calibration agency]) and 0123 (TÜV Süd Product Service).

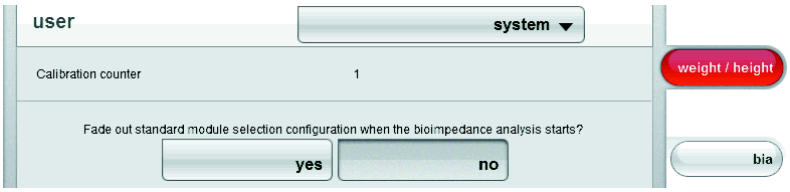
Recalibration is necessary where one or more calibration seals are damaged or the contents of the calibration counter no longer match the number on the valid calibration counter sticker.

11.2 Checking the content of the calibration counter

The scale has been calibrated. Calibrations may only be performed by authorized agencies. To guarantee this, the scale is equipped with a calibration counter that records each change in calibration-related data.
If you want to check whether the scale has been correctly calibrated, follow the instructions below:

1. Switch on the scale.
2. Press the **change menu** button.

3. Press the **settings** button.
   The **user** dialog window appears.



   The calibration counter reading (here: 6) is displayed.
4. Compare the content of the calibration counter issued with the number given on the calibration counter sticker.

Both numbers have to match for the calibration to be valid. If the sticker and the calibration counter do not match, the scale has to be recalibrated. Please contact your service partner or seca service.

Once the scale has been recalibrated, a new, updated calibration counter sticker is used to identify the calibration counter reader. This sticker is attached with an additional seal issued by the person authorized to perform the recalibration. The calibration counter sticker can be ordered from seca.

12. MAINTENANCE (514)

On leaving the factory, your seca device has an accuracy of ± 0.15 % or better. To preserve this level of accuracy, the product must be set up with care and maintained on a regular basis.

The device's measurement technology for bioelectric impedance analysis (BIA) must be checked every two years. We recommend performing maintenance of the whole device as part of this check.

ATTENTION!
Incorrect measurements may be taken as the result of improper maintenance

- Please only have maintenance and repairs performed 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.

13. TROUBLESHOOTING

13.1 Power supply and display

Problem	Cause	Remedy
Device cannot be switched on	The device has no power supply.	Check whether power is being supplied
	Power pack faulty	Replace power pack with original part
Touchscreen stays dark	Device in standby	• Touch the touchscreen display • Press the on/off switch • Place a load on the device
	Device not switched on	Switch on the device
	The device has no power supply.	Check whether power is being supplied
	Touchscreen display faulty	Inform seca service
Touchscreen no longer responds to entries or touches	Due to an implausible entry, the device is in an undefined state.	• Switch off the device (hold the on/off button for approx. 3 seconds) • Switch on the device again
Display on the touchscreen display is incomplete or incorrect	Touchscreen display faulty	Inform seca service

13.2 Height and weight

Problem	Cause	Remedy
0.00 does not appear before weighing	A load was already on the device before switching on.	• Remove the weight from the scale • Switch off the scale, then switch back on again
The message STOP appears	The maximum load has been exceeded.	Remove the weight from the scale
The message TEMP appears	The ambient temperature is too high or too low.	• Set up the device in an ambient temperature between +10 °C and +40 °C • Wait for around 15 minutes until the device has adapted to the ambient temperature
The message ER11 appears	The device has too high a load or too high a load in one corner.	• Remove the load or distribute the load evenly • Restart the device
The message ER12 appears	The device has been switched on with too high a load.	• Remove the load from the device • Restart the device
The message ER16 appears	The device was caused to oscillate, the zero point could not be determined.	• Restart the device • Restart measurement

13.3 Bioelectric impedance analysis

Problem	Cause	Remedy
The tab bia has been activated, but no module selection appears	Module selection has been deactivated.	Check setting and change if necessary (see “Adapting standard module selection for BIA” on page 61)
Not all modules are activated in the module selection	A standard module selection has been specified, whereby some modules have been deactivated.	• Activate missing modules in the module selection directly and perform the measurement • Adapt standard module selection (see “Creating standard module selection” on page 62)
The message: „Electrode detection could not be performed successfully.” appears	Patient’s skin too dry	Spray the skin on the contact points with electrode spray
	Patient’s skin too callous	Spray the skin on the contact points with electrode spray
	Electrodes faulty	Inform seca service
No PAL value can be entered after a BIA	The evaluation module **Energy** has been deactivated.	• If the evaluation module **Energy** is not required, continue and finish the measurement • If the evaluation module **Energy** is required, activate the evaluation module (see “Checking the module selection” on page 31) or (see “Creating standard module selection” on page 62)
The BIA results differ from the expected results	The patient moved during the measurement.	Request that the patient does not move during the measurement and repeat the measurement
	The patient has used different pairs of hand electrodes on the left and right.	Ensure that the patient uses the same hand electrodes on both sides and repeat the measurement
	Electrodes faulty	Inform seca service
The value of an evaluation module is displayed red in the tab evaluation	The value falls outside of the normal range calculated for the evaluation module.	• Repeat the measurement in order to exclude measurement errors • If the repeat measurement also produces a value outside of the normal range, take the value into account in further investigations
The assigned patient is no longer displayed in tab**patient** after temporarily calling another tab	The patient has been selected, but the selection is not confirmed.	Re-assign the patient and press the **confirm** button (see “Assigning patient” on page 35), only then can another tab be selected

13.4 Data connection

Problem	Cause	Remedy
A measurement procedure/ patient has been overwritten from the USB memory stick to the PC software seca 115 and the patient appears there as "not assigned"	For access to the seca patient database, the USB memory stick is used instead of the User PIN.	Manually assign the measurement procedure/patient in the **seca 115** to an attending physician.
Patient data when performing a patient search on the device cannot be found	Patient data not yet created	Create patient data (see "Creating new patients" on page 39)
	The patient is not assigned to you in the **seca 115**.	Check whether or not the patient can be assigned to you in the **seca 115**.
	Windows Firewall Port Block is active, the port used for communication with the device (standard 60767) is being blocked.	Administrator: Free the port used for communication with the device in Windows Firewall.
The seca patient database in the PC software seca 115 cannot be accessed	No seca wireless network has been established between the device and the PC on which the PC software **seca 115** is installed.	Administrator: Establish seca wireless network
	No Ethernet connection has been established between the device and the PC on which the PC software **seca 115** is installed.	Administrator: Establish Ethernet connection
	The device has been connected to a standalone PC via Ethernet cable. The PC's network card does not permit automatic crossover	Administrator: Use a crossover adapter (see "Accessories" on page 73)
	No USB memory stick is connected to the touchscreen display.	Connect USB memory stick to the touchscreen display
	The PC on which the PC software **seca 115** is installed has not been switched on.	Switch on the PC and start the PC software **seca 115**
	The PC software **seca 115** has not been started.	Start the PC software **seca 115**
The USB memory stick is connected to the touch screen but you are unable to access the seca patient database	An uninitialized USB memory stick is being used	• Use the supplied USB memory stick • Administrator: Initialize USB stick using the PC software **seca 115**
	The PIN has not been entered or has been entered incorrectly.	Use your user PIN or the PIN for the USB memory stuck.
	Unsuitable USB memory stick being used	• Use the supplied USB memory stick • Use a FAT16 USB memory stick
	Problem due to HF radiation from other devices (e.g. mobile phones)	Increase distance to HF devices

13.5 seca 360°wireless printer

Problem	Cause	Remedy
No printout	The **seca 360**°wireless printer is not switched on.	Switch on **seca 360**°wireless printer
	No seca wireless network has been established between the device and the **seca 360**° wireless printer.	Establish seca wireless network
No patient data on the printout	On repeat measurement: No patient assigned	Call up the **patient** tab and assign patient (see “Searching for patient data” on page 37)
	On initial measurement: Patient not yet created in database	Call up the **patient** tab and create the patient (see “Creating new patients” on page 39)
No BIA results on the printout	No BIA measurement was performed	Call up the **bia** tab and perform the measurement (see “Performing bioelectric impedance analysis (BIA)” on page 31)
No body size on the printout	No body size has been entered.	Call up the **weight/height** tab and enter the body size (see “Manually entering body size” on page 29)
	No body size has been sent from the **seca 360**° length measuring device.	Measure the body size of the patient again, then press the **send/print** button on the length measurement device (see “Transmitting body size via seca wireless network” on page 29)

14. TECHNICAL DATA

14.1 General technical data

General technical data	
Measurements • Depth • Width • Height	 828 mm 976 mm 1251 mm
Net weight	approx. 36 kg
Temperature range • Operation • Storage • Transport	 +10°C to +40°C (50 to 104°F) -10°C to +65°C (14 to 149°F) -10°C to +65°C (14 to 149°F)
Setup location, maximum height above mean sea level	3000 m
Air humidity • Operation • Storage • Transport	 30% - 80% non-condensing 0% - 95% non-condensing 0% - 95% non-condensing
Display type	8,4" touchscreen display, can be swiveled 180° to the left and right
Power supply	Power pack
Mains voltage	100 V - 240 V
Mains frequency	50 Hz - 60 Hz
Power consumption • Standby (touchscreen display off, on/off button green) • In operation (no BIA measurement, on/off button white) • In operation (ongoing BIA measurement, on/off button white)	 < 2,7 W < 6,6 W < 15 W
Medical device in accordance with Directive 93/42/EEC	Class IIa
EN 60601-1: • Insulated device, protection class II • Electric medical device, type BF	 
seca wireless network: • Frequency band • Transmitting power • Related standards	 2.433 MHz - 2.480 MHz < 10 mW EN 300 328, EN 301489-1 and 17
Interfaces: • Touchscreen display • Weighing platform	 USB 2.0 Ethernet (10/100 Base-T)
USB memory stick requirements: • Minimum disk space requirements • File system	 2 GB FAT 16
Compatible printer	**seca 360**° wireless printer Laser and ink-jet printer via PC software **seca 115**

14.2 Technical data of the bioelectric impedance analysis

BIA technical data	
Measuring method	8-point bioelectric impedance analysis
Electrode type	Stainless steel, 2 x 3 pairs of hand electrodes, 2 pairs of foot electrodes
Measuring frequencies	1; 1,5; 2; 3; 5; 7,5; 10; 15; 20; 30; 50; 75; 100; 150; 200; 300; 500; 750; 1000 kHz
Measured values	Impedance (Z), resistance (R), reactance (X_C), phase angle (Φ)
Phase angle measuring range	0° to 20°
Impedance measuring range	10 Ω to 1000 Ω
Measuring segments	Right arm, left arm, right leg, left leg, right side of body, left side of body, torso
Measuring current	100 µA
Measurement duration: Frequencies 5 kHz and 50 kHz All frequencies (only if module **Raw data for impedance** is active)	 max. 30 s max. 90 s
Accuracy at frequencies 5 kHz and 50 kHz Segments: Right side of body, left side of body • Impedance • Phase angle	 5 Ω 0,5°
Evaluation modules	See „Evaluation modules“ from page 46

14.3 Weighing data (calibrated model)

seca 515	
Accuracy class in accordance with Directive 2009/23/EC	III
Measuring method	4 load cells
Maximum load • Partial weighing range 1 • Partial weighing range 2	 150 kg 300 kg
Minimum load • Partial weighing range 1 • Partial weighing range 2	 1,0 kg 2,0 kg
Scale division • Partial weighing range 1 • Partial weighing range 2	 50 g 100 g
Tare range	to 300 kg
Accuracy on initial calibration • Weighing range 1: 0 to 25 kg • Weighing range 1: 25 kg to 100 kg • Weighing range 1: 100 kg to 150 kg • Weighing range 2: 0 to 50 kg • Weighing range 2: 50 kg to 200 kg • Weighing range 2: 200 kg to 300 kg	 ±25 g ±50 g ±75 g ±50 g ±100 g ±150 g

14.4 Weighing data (uncalibrated model)

seca 514	
Measuring method	4 load cells
Maximum load • Partial weighing range 1 • Partial weighing range 2	 150 kg / 330 lbs / 24 sts 300 kg / 660 lbs / 47 sts
Minimum load Partial weighing range 1 Partial weighing range 2	 1,0 kg 2,0 kg
Scale division • Partial weighing range 1 • Partial weighing range 2	 50 g / 0.1 lbs 100 g / 0.2 lbs
Tare range	300 kg
Accuracy • 0 to 35 kg • 35 kg to maximum load • 0 to 75 lbs • 75 lbs to maximum load • 0 to 5.5 sts • 5.5 sts to maximum load	 ±100 g ±0,3% ±0.2 lbs ±0,3% ±0.2 lbs ±0,3%

15. ACCESSORIES

Accessories	Article number
Measuring stations • **seca 285** • **seca 284** Height measuring rods • **seca 274** • **seca 264**	 Country-specific versions Country-specific versions Country-specific versions Country-specific versions
Wireless printer • **seca 360° Wireless Printer 465** • **seca 360° Wireless Printer Advanced 466**	 Country-specific versions Country-specific versions
PC software • **seca analytics mBCA 115**	 Application-specific license packages
USB wireless adapter **seca 360° Wireless USB Adapter 456**	456-00-00-009
Crossover adapter for Ethernet cable	68-32-10-265

16. SPARE PARTS

Spare parts	Article number
Power pack, Euro: 100-240V~ / 50-60Hz / 12V= / 1.2 A	68-32-10-268
Circumference measuring tape**seca 201**	201-17-17-009
DVD with PC software **seca analytics mBCA 115** and license for a specific workplace	Country-specific versions
seca 360° Wireless USB Adapter 456	456-00-00-009
Ethernet cable (1.5 m)	08-06-16-467

17. DISPOSAL

Do not dispose of the scale with your household waste. It must be properly disposed of as electronic waste. Follow your respective national regulations. For further information, please contact our service representative:

service@seca.com

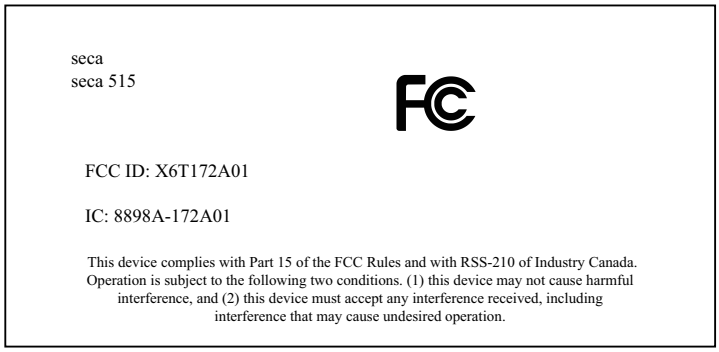
18. WARRANTY

There is a two-year warranty period from delivery for defects that are due to material or fabrication errors. All moving parts, including batteries, cables, network devices, rechargeable batteries, etc. are exempted from this. Defects that fall under the warranty will be repaired for the customer free of charge by presenting proof of purchase. Additional claims cannot be considered. Costs for transport back and forth are at the expense of the customer if the device is located somewhere other than the customer's headquarters. In case of transport damage, warranty claims can only be made if the complete original packaging was used for transport and the device was secured and fastened therein according to its originally-packaged condition. Therefore, keep all packaging parts.

Warranty is voided if the device is opened by persons not expressly authorized by seca to do so.

We ask customers overseas to contact the seller in their respective country directly in the event of warranty claims.

FOR USA AND CANADA:



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

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

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

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

CE

Konformitätserklärung
Declaration of conformity
Certificat de conformité
Dichiarazione di conformità
Declaración de conformidad
Overensstemmelsesattest
Försäkran om överensstämmelse
Konformitetserklæring
vaatimuksenmukaisuusvakuutus
Verklaring van overeenkomst
Declaração de conformidade
Δήλωση Συμβατότητας
Prohlášení o shodě
Vastavusdeklaratsioon
Megfelelőségi nyilatkozat
Atitikties patvirtinimas
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Oświadczenie o zgodności
Izjava o skladnosti
Vyhlásenie o zhode
Onay belgesi

Der medical Body Composition Analyzer
The medical Body Composition Analyzer
L'analyseur médical de composition corporelle
L'analizzatore di massa corporea medical Body Composition
El medical Body Composition Analyzer
Den medicinske Body Composition Analyzer
Den medicinska analysatorn för kroppssammansättning
Den medical Body Composition Analyzer
Ei-medical Body Composition Analyzer
De Medical Body Composition Analyzer
O medical Body Composition Analyzer
To medical Body Composition Analyzer
Diagnostický přístroj medical Body Composition Analyzer
Meditsiiniline kehaanalüsaator
Az orvosi testösszetétel-elemző készülék
Medicininis kūno sudėties analizatorius
Medicīniskais ķermeņa masas analizators
Urządzenie medical Body Composition Analyzer
Pripomoček za analizo telesne sestave
Zdravotnícky telesný analyzátor
medical Body Composition Analyzer

seca 515

Model: 5157021099

EG-Bauartzulassung D11-09-022
EC type approval D11-09-022
Homologation CE D11-09-022
Omologazione del tipo costruttivo CEE D11-09-022
Homologación CE D11-09-022
EF-typegodkendelse D11-09-022
EG-kontroll D11-09-022
EF-konstruksjonstype-godkjennelse D11-09-022
EY-tyyppihyväksyntä D11-09-022
EG-modelkeuring D11-09-022
Homologação CE de tipo de construção D11-09-022
Αδεια κατασκευαστικού τρόπου Ε.Κ. D11-09-022
ES schválení typu D11-09-022
EÜ-tüübikinnitus D11-09-022
A D11-09-022 EU-típusengedély
ES kvalifikacijos patvirtinimas Nr. D11-09-022
Izgatavošanas veida atļauja D11-09-022
Dopuszczenie na rynek UE nr D11-09-022
Odobritev vzorca EU D11-09-022
Schválenie konštrukcie EÚ D11-09-022
EG üretim türü izni D11-09-022

D … entspricht dem in der Bescheinigung über die Bauartzulassung beschriebenen Baumuster.
Die Waage erfüllt die geltenden Anforderungen folgender Richtlinien:

2009/23/EG über nichtselbsttätige Waagen, 93/42/EWG über Medizinprodukte.

Darüberhinaus sind unter anderem folgende Normen anwendbar:

EN 45501 über metrologische Aspekte nichtselbsttätiger Waagen;
EN 300 328, EN 301 489-1 und -17 über elektromagnetische Verträglichkeit und Funkspektrumangelegenheiten.

GB …corresponds to the type described in the certificate in respect of type approval permit.
The scales comply with the applicable requirements of the following directives:
2009/23/EC governing non-automatic weighing instruments, 93/42/EEC governing medical devices.

Furthermore the following directives are applicable among others:

EN 45501 governing metrological aspects of non-automatic weighing instruments; EN 300 328, EN 301 489-1 and -17 governing electromagnetic compatibility and radio spectrum matters.

F …conforme au modèle type décrit dans le certificat d'homologation.
Cette balance est conforme aux directives et normes suivantes:

2009/23/CE relative aux instruments de pesage à fonctionnement non automatique ; 93/42/CEE relatives aux dispositifs médicaux.

Par ailleurs, les normes suivantes peuvent être entre autres utilisées :

EN 45501 relative aux aspects métrologiques des instruments de pesage à fonctionnement non automatique ; EN 300 328, EN 301 489-1 et -17 relatives à la compatibilité électromagnétique et au spectre radioélectrique.

I …è conforme al campione descritto nel certificato di omologazione costruttiva.
La bilancia risponde alle vigenti esigenze poste dalle seguenti direttive:

2009/23/CE in materia di bilance a funzionamento non automatico; 93/42/CEE in materia di prodotti medicali.

Sono inoltre applicabili anche le seguenti norme:

EN 45501 sugli aspetti metrologici delle bilance a funzionamento non automatico; EN 300 328, EN 301 489-1 e -17 in materia di compatibilità elettromagnetica e di spettro radio.

E …corresponde a la muestra descrita en el certificado sobre el permiso de construcción.
La báscula cumple las exigencias vigentes de las siguientes directivas:
2009/23/CE relativa a los instrumentos de pesaje de funcionamiento no automático; 93/42/CEE sobre productos sanitarios.

Adicionalmente se aplicarán, entre otras, las normas siguientes:

EN 45501 sobre aspectos metrológicos de los instrumentos de pesaje de funcionamiento no automático; EN 300 328, EN 301 489-1 y -17 sobre compatibilidad electromagnética y cuestiones del espectro radioeléctrico.

DK ... svarer til det typemønster, som er beskrevet i attesten over typegodkendelsen.

Vægten opfylder de gældende krav fra følgende direktiver:
2009/23/EF om ikke automatiske vægte; 93/42/EØF om medicinprodukter.

Desuden er følgende standarder anvendelige:

EN 45501 om metrologiske aspekter for ikke automatiske vægte; EN 300 328, EN 301 489-1 og -17 om elektromagnetisk fordragelighed og radiospektrumanliggender.

S ...motsvarar bes krivningen enligt mönstertillståndet.

Vågen uppfyller gällande krav i följande direktiv och normer:
2009/23/EG om icke-automatiska vågar, 93/42/EEG om medicintekniska produkter.

Utöver detta kan följande normer användas:

EN 45501 om metrologiska bedömningsgrunder för icke automatiska vågar samt EN 300 328, EN 301 489-1 och EN 301 489-17 om elektromagnetisk kompatibilitet och gnistspektrumfrågor.

N ... er i samsvar med mønsteret som er beskrevet i sertifikatet over konstruksjonstype-godkjennelsen.
Vekten oppfyller gjeldende krav i følgende direktiver:

2009/23/EF om ikke-automatiske vekter; 93/42/EØF om medisinske produkter.

I tillegg kan blant annet følgende standarder anvendes:

EN 45501 om metrologiske aspekter ved ikke-automatiske vekter; EN 300 328, EN 301 489-1 og -17 om elektromagnetisk kompatibilitet og ting som angår spekteret av radiosignaler.

FIN ... on tyyppihyväksyntätodistuksessa kuvatun rakennemallin mukainen.
Vaaka täyttää seuraavien direktiivien voimassa olevat määräykset:
2009/23/EY, ei-itsetoimivat vaa'at; 93/42/ETY lääkinnälliset laitteet.

Tämän lisäksi sovelletaan mm. seuraavia standardeja:

EN 45501, manuaalisia vaakoja koskevat mittaus- ja toimintavaatimukset; EN 300 328, EN 301 489-1 ja -17, sähkömagneettinen yhteensopivuus ja radiospektriasiat.

NL ...komt overeen met de in de verklaring van over de modelkeuring beschreven constructie.
De weegschaal voldoet aan de geldende eisen van de volgende richtlijnen:
2009/23/EG betreffende niet-automatische weegwerktuigen; 93/42/EEG betreffende medische hulpmiddelen.

Daarnaast zijn onder meer de volgende normen van toepassing:

EN 45501 Metrologische aspecten van niet-automatische weeginstrumenten; EN 300 328, EN 301 489-1 en -17 betreffende elektromagnetische compatibiliteit en radiospectrumaangelegenheden.

P ... corresponde ao padrão de construção descrito no certificado de homologação de tipo de construção.
A balança cumpre os requisitos válidos das seguintes directivas:
2009/23/CE relativa a instrumentos de pesagem de funcionamento não automático; 93/42/CEE relativa a dispositivos médicos:

Para além destas aplicam-se, entre outras, as seguintes normas:

EN 45501 relativa a aspectos metrológicos dos instrumentos de pesagem de funcionamento não automático; EN 300 328, EN 301 489-1 e -17 relativa a compatibilidade electromagnética e assuntos de espectro radioeléctrico.

GR ... ανταποκρίνεται στο κατασκευαστικό πρότυπο που περιγράφεται στην εγκριτική βεβαίωση του κατασκευαστικού τρόπου.
Η ζυγαριά εκπληρώνει τις ισχύουσες απαιτήσεις των ακόλουθων Οδηγιών:
2009/23/ΕΚ περί οργάνων ζύγισης μη αυτόματης λειτουργίας, 93/42/ΕΟΚ περί ιατροτεχνολογικών προϊόντων.

Επιπλέον εφαρμόζονται μεταξύ άλλων τα ακόλουθα πρότυπα:

EN 45501 περί μετρολογικών απόψεων οργάνων ζύγισης μη αυτόματης λειτουργίας, EN 300 328, EN 301 489-1 και -17 περί ηλεκτρομαγνητικής συμβατότητας και περί θεμάτων ραδιοφάσματος.

CZ …odpovídá typu popsanému v certifikátu schválení typu.

Váha splňuje platné požadavky těchto směrnic:
2009/23/ES o vahách s neautomatickou činností, 93/42/EHS o zdravotnických prostředcích:

Dodatečně jsou aplikovatelné např. tyto normy:

EN 45501 o metrologických aspektech vah s neautomatickou činností, EN 300 328, EN 301 489-1 a -17 o elektromagnetické kompatibilitě a rádiovém spektru.

EST ...vastab tüübikinnitustunnistuses kirjeldatud tüübile.

Kaal täidab järgmiste direktiividega kehtestatud nõudeid:
2009/23/EÜ mitteautomaatkaalude kohta; 93/42/EMÜ meditsiinitoodete kohta.

Lisaks tuleb muu hulgas kohaldada järgmisi normatiive:

EN 45501 mitteautomaatkaalude metroloogiliste aspektide kohta; EN 300 328, EN 301 489-1 ja -17 elektromagnetilise ühilduvuse ning ringhäälinguga seonduva kohta.

HU ...megfelel a típusengedély megfelelőségigazolásában megadott típusnak.
A mérleg teljesíti a következő irányelvek érvényben lévő követelményeit:2009/23/EK a nem automatikus működésű mérlegekről; 93/42/EGK irányelv az orvostechnikai termékekről.

Ezen kívül többek között a következő normák alkalmazhatók:

EN 45501 a nem automatikus működésű mérlegek méréstechnikai követelményei és vizsgálata; EN 300 328, EN 301 489-1 és -17 az elektromágneses összeférhetőségi- és rádióspektrum ügyekről.

LT ...atitinka aprašytų gamybos pavyzdžių kvalifikacijos patvirtinimą.
Svarstyklės išpildo galiojančius tokių direktyvų reikalavimus:

2009/23/EB dėl neautomatinių svarstyklių; 93/42/EEB ir medicinos prietaisų.

Be to, taikomi šie standartai:

EN 45501 apie metrologinius neautomatinių svarstyklių aspektus; EN 300 328, EN 301 489-1 ir -17 dėl elektromagnetinio suderinamumo ir radijo dažnių spektro dalykų.

LV ... atbilst izgatavošanas veida atļaujas apliecībā norādītajam izgatavošanas paraugam.
Svari atbilst šādu direktīvu spēkā esošajām prasībām:
2009/23/EK par neautomātiskiem svariem; 93/42/EEK par medicīnas ierīcēm.

Bez tam ir piemērojami arī šādi standarti:

EN 45501 par neautomātisko svaru metroloģiskajiem aspektiem; EN 300 328, EN 301 489-1 un -17 par elektromagnētisko saderību un radiofrekvenču spektra jautājumiem.

PL ...odpowiada typowi konstrukcyjnemu opisanemu w świadectwie zgodności.
Waga spełnia obowiązujące wymagania następujących dyrektyw:
2009/23/WE w sprawie wag nieautomatycznych; 93/42/EWG o wyrobach medycznych.

Ponadto stosują się między innymi następujące normy:

normy EN 45501 dotyczącej zagadnień metrologicznych wag nieautomatycznych, EN 300 328, EN 301 489-1 i -17 dotyczących kompatybilności elektromagnetycznej i zagadnień widma radiowego.

SLO ...ustreza potrjenemu modelu vrste izdelave.

Tehtnica izpolnjuje veljavne zahteve naslednjih direktiv:

2009/23/ES o neavtomatskih tehtnicah; 93/42/EGS o medicinskih pripomočkih.

Poleg tega veljajo naslednje norme:

EN 45501 o metroloških vidikih neavtomatskih tehtnic; EN 300 328, EN 301 489-1 in -17 o elektromagnetni združljivosti in zadevah v zvezi z radijskim spektrom.

SK …zodpovedá typu popísanému v osvedčení o schválení konštrukcie.

Váha spĺňa platné požiadavky nasledovných smerníc:
2009/23/ES o váhach s neautomatickou činnosťou; 93/42/EHS o medicínskych výrobkoch.

Okrem toho sú použiteľné medzi iným tieto normy:

EN 45501 o metrologických aspektoch váh s neautomatickou činnosťou; EN 300 328, EN 301 489-1 a -17 o elektromagnetickej kompatibilite a záležitostiach rádiového spektra.

TR ...onay belgesinde ü retim türü ile ilgili açıklanan üretim örneğine uygundur.

Tartı, aşağıdaki yönergelerin geçerli talimatlarını yerini getirir:
Otomatik olmayan basküller hakkında 2009/23/AT; tıbbi ürünler hakkında 93/42/AET yönetmeliği.

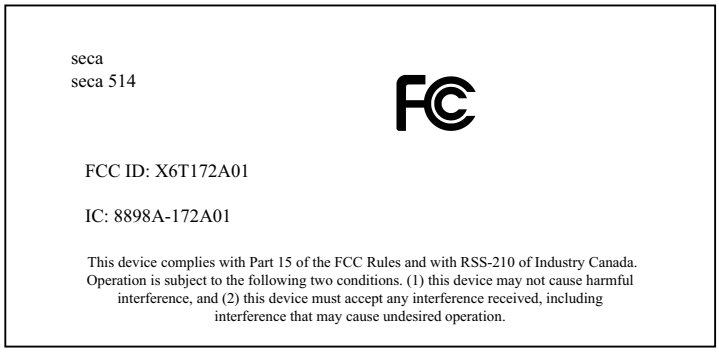
Bunun ötesinde aşağıdaki normlar da geçerlidir:

otomatik olmayan basküllerin metrolojik unsurları hakkında EN 45501; elektromanyetik uyumluluk ve radyo tayfi maddeleri hakkında EN 300 328, EN 301 489-1 ve -17.

Frederik Vogel
CEO Development and Manufacturing
seca gmbh & co. kg.
Hammer Steindamm 9-25
22089 Hamburg
Telefon: +49 40.200 000-0
Telefax: +49 40.200 000-50
ⓘ: www.seca.com

Hamburg, März 2012

FOR USA AND CANADA:



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

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

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

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

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Oświadczenie o zgodności
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Vyhlásenie o zhode
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Medicīniskais ķermeņa masas analizators
Urządzenie medical Body Composition Analyzer
Pripomoček za analizo telesne sestave
Zdravotnícky telesný analyzátor
medical Body Composition Analyzer

seca 514

Model: 5141321009

D Die Waage erfüllt die geltenden Anforderungen folgender Richtlinien:
93/42/EWG über Medizinprodukte.
Darüberhinaus sind unter anderem folgende Normen anwendbar:
EN 45501 über metrologische Aspekte nichtselbsttätiger Waagen;
EN 300 328, EN 301 489-1 und -17 über elektromagnetische Verträglichkeit und Funkspektrumangelegenheiten.

GB The scales comply with the applicable requirements of the following directives:
93/42/EEC governing medical devices.
Furthermore the following directives are applicable among others:
EN 45501 governing metrological aspects of non-automatic weighing instruments; EN 300 328, EN 301 489-1 and -17 governing electromagnetic compatibility and radio spectrum matters.

F Cette balance est conforme aux directives et normes suivantes:
93/42/CEE relatives aux dispositifs médicaux.
Par ailleurs, les normes suivantes peuvent être entre autres utilisées :
EN 45501 relative aux aspects métrologiques des instruments de pesage à fonctionnement non automatique ; EN 300 328, EN 301 489-1 et -17 relatives à la compatibilité électromagnétique et au spectre radioélectrique.

I La bilancia risponde alle vigenti esigenze poste dalle seguenti direttive:
93/42/CEE in materia di prodotti medicali.
Sono inoltre applicabili anche le seguenti norme:
EN 45501 sugli aspetti metrologici delle bilance a funzionamento non automatico; EN 300 328, EN 301 489-1 e -17 in materia di compatibilità elettromagnetica e di spettro radio.

E La báscula cumple las exigencias vigentes de las siguientes directivas:
93/42/CEE sobre productos sanitarios.
Adicionalmente se aplicarán, entre otras, las normas siguientes:
EN 45501 sobre aspectos metrológicos de los instrumentos de pesaje de funcionamiento no automático; EN 300 328, EN 301 489-1 y -17 sobre compatibilidad electromagnética y cuestiones del espectro radioeléctrico.

DK Vægten opfylder de gældende krav fra følgende direktiver:
93/42/EØF om medicinprodukter.
Desuden er følgende standarder anvendelige:
EN 45501 om metrologiske aspekter for ikke automatiske vægte; EN 300 328, EN 301 489-1 og -17 om elektromagnetisk fordragelighed og radiospektrumanliggender.

GR Η ζυγαριά εκπληρώνει τις ισχύουσες απαιτήσεις των ακόλουθων Οδηγιών:
93/42/ΕΟΚ περί ιατροτεχνολογικών προϊόντων.
Επιπλέον εφαρμόζονται μεταξύ άλλων τα ακόλουθα πρότυπα:
EN 45501 περί μετρολογικών απόψεων οργάνων ζύγισης μη αυτόματης λειτουργίας, EN 300 328, EN 301 489-1 και -17 περί ηλεκτρομαγνητικής συμβατότητας και περί θεμάτων ραδιοφάσματος.

CZ Váha splňuje platné požadavky těchto směrnic:
93/42/EHS o zdravotnických prostředcích:
Dodatečně jsou aplikovatelné např. tyto normy:
EN 45501 o metrologických aspektech vah s neautomatickou činností, EN 300 328, EN 301 489-1 a -17 o elektromagnetické kompatibilitě a rádiovém spektru.

EST Kaal täidab järgmiste direktiividega kehtestatud nõudeid:
93/42/EMÜ meditsiinitoodete kohta.
Lisaks tuleb muu hulgas kohaldada järgmisi normatiive:
EN 45501 mitteautomaatkaalude metroloogiliste aspektide kohta; EN 300 328, EN 301 489-1 ja -17 elektromagnetilise ühilduvuse ning ringhäälinguga seonduva kohta.

HU A mérleg teljesíti a következő irányelvek érvényben lévő köve93/42/EGK irányelv az orvostechnikai termékekről.
Ezen kívül többek között a következő normák alkalmazhatók:
EN 45501 a nem automatikus működésű mérlegek méréstechnikai követelményei és vizsgálata; EN 300 328, EN 301 489-1 és -17 az elektromágneses összeférhetőségi- és rádióspektrum ügyekről.

LT Svarstyklės išpildo galiojančius tokių direktyvų reikalavimus:
93/42/EEB ir medicinos prietaisų.
Be to, taikomi šie standartai:
EN 45501 apie metrologinius neautomatinių svarstyklių aspektus; EN 300 328, EN 301 489-1 ir -17 dėl elektromagnetinio suderinamumo ir radijo dažnių spektro dalykų.

LV Svari atbilst šādu direktīvu spēkā esošajām prasībām:
93/42/EEK par medicīnas ierīcēm.
Bez tam ir piemērojami arī šādi standarti:
EN 45501 par neautomātisko svaru metroloģiskajiem aspektiem; EN 300 328, EN 301 489-1 un -17 par elektromagnētisko saderību un radiofrekvenču spektra jautājumiem.

S Vågen uppfyller gällande krav i följande direktiv och normer:
93/42/EEG om medicintekniska produkter.
Utöver detta kan följande normer användas:
EN 45501 om metrologiska bedömningsgrunder för icke automatiska vågar samt EN 300 328, EN 301 489-1 och EN 301 489-17 om elektromagnetisk kompatibilitet och gnistspektrumfrågor.

N Vekten oppfyller gjeldende krav i følgende direktiver:
93/42/EØF om medisinske produkter.
I tillegg kan blant annet følgende standarder anvendes:
EN 45501 om metrologiske aspekter ved ikke-automatiske vekter; EN 300 328, EN 301 489-1 og -17 om elektromagnetisk kompatibilitet og ting som angår spekteret av radiosignaler.

FIN Vaaka täyttää seuraavien direktiivien voimassa olevat määräykset:
93/42/ETY lääkinnälliset laitteet.
Tämän lisäksi sovelletaan mm. seuraavia standardeja:
EN 45501, manuaalisia vaakoja koskevat mittaus- ja toimintavaatimukset; EN 300 328, EN 301 489-1 ja -17, sähkömagneettinen yhteensopivuus ja radiospektriasiat.

NL De weegschaal voldoet aan de geldende eisen van de volgende richtlijnen:
93/42/EEG betreffende medische hulpmiddelen.
Daarnaast zijn onder meer de volgende normen van toepassing:
EN 45501 Metrologische aspecten van niet-automatische weeginstrumenten; EN 300 328, EN 301 489-1 en -17 betreffende elektromagnetische compatibiliteit en radiospectrumaangelegenheden.

P A balança cumpre os requisitos válidos das seguintes directivas:
93/42/CEE relativa a dispositivos médicos:
Para além destas aplicam-se, entre outras, as seguintes normas:
EN 45501 relativa a aspectos metrológicos dos instrumentos de pesagem de funcionamento não automático; EN 300 328, EN 301 489-1 e -17 relativa a compatibilidade electromagnética e assuntos de espectro radioeléctrico.

PL Waga spełnia obowiązujące wymagania następujących dyrektyw:
93/42/EWG o wyrobach medycznych.
Ponadto stosują się między innymi następujące normy:
normy EN 45501 dotyczącej zagadnień metrologicznych wag nieautomatycznych, EN 300 328, EN 301 489-1 i -17 dotyczących kompatybilności elektromagnetycznej i zagadnień widma radiowego.

SLO Tehtnica izpolnjuje veljavne zahteve naslednjih direktiv:
93/42/EGS o medicinskih pripomočkih.
Poleg tega veljajo naslednje norme:
EN 45501 o metroloških vidikih neavtomatskih tehtnic; EN 300 328, EN 301 489-1 in -17 o elektromagnetni združljivosti in zadevah v zvezi z radijskim spektrom.

SK Váha spĺňa platné požiadavky nasledovných smerníc:
93/42/EHS o medicínskych výrobkoch.
Okrem toho sú použiteľné medzi iným tieto normy:
EN 45501 o metrologických aspektoch váh s neautomatickou činnosťou; EN 300 328, EN 301 489-1 a -17 o elektromagnetickej kompatibilite a záležitostiach rádiového spektra.

TR Tartı, aşağıdaki yönergelerin geçerli talimatlarını yerini getirir:
tıbbi ürünler hakkında 93/42/AET yönetmeliği.
Bunun ötesinde aşağıdaki normlar da geçerlidir:
otomatik olmayan basküllerin metrolojik unsurları hakkında EN 45501; elektromanyetik uyumluluk ve radyo tayfi maddeleri hakkında EN 300 328, EN 301 489-1 ve -17.

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