

seca 115

Instructions for Use for Physicians and Assistants

from software version 1.4

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1. SYSTEM DESCRIPTION

1.1 Congratulations!

With the seca **seca 115** PC software, you have acquired a product from the **seca 360°** system which will assist you with the analysis and interpretation of weight, height and bioimpedance measurements.

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.

1.2 Intended use

The **seca 115** PC software is mainly used in hospitals, medical practices and inpatient care facilities in accordance with national regulations.

The **seca 115** PC software is for administering weight, height and bioimpedance measurements and for calculating automatically parameters which can be derived from these measurements, e.g. FMI (fat mass index). Results are displayed in graphical form and assist the attending physician with the following medical issues:

- monitoring growth processes and weight changes
- determining energy expenditure and energy reserves in order to assess weight changes and the course of diseases as well as to provide dietary advice
- estimating cardiometabolic risk
- assessing metabolic activity and the success of a training program, e.g. within the framework of rehabilitation or physiotherapy
- determining the fluid status of a patient and observing changes in fluids as the result of medical treatment.
- determining general state of health or, in the case of a previously-known disease, assessing its severity.

The **seca 115** PC software is **not** diagnostic software.

1.3 Description of function

Installation options

The **seca 115** PC software can be installed in the form of a client/server solution or a standalone solution.

The **seca 115** PC software consists of the application software and a seca patient database, together with communication and evaluation modules.

For client/server operation, the application software is installed on PC workstations (clients). The seca patient database and the communication and evaluation modules are installed centrally on a server. All clients access the server and use the seca patient database and communication and evaluation modules there.

For standalone operation, the application software, the seca patient database and the communication and evaluation modules are installed on the same PC workstation.

seca mBCA data transmission

seca medical Body Composition Analyzers (mBCAs) have an Ethernet interface and can communicate with the **seca 115** PC software in a network.

The network connection allows a seca mBCA to use both the seca patient database and the special print function of the **seca 115** PC software.

The special print function of the **seca 115** PC software makes it possible to start printing a results report directly on a seca mBCA.

Alternatively to the Ethernet connection, seca mBCAs and the **seca 115** PC software can communicate wirelessly via **seca 360°** technology. For this to happen, the **seca 360° wireless USB adapter 456** must be connected to a PC on which at least the **seca 115** application software is installed.

Transmission of data by seca scales and stadiometers

seca scales and stadiometers from the **seca 360°** system can communicate with one another wirelessly and transmit data to the **seca 115** PC software. For this to happen, the **seca 360° wireless USB adapter 456** must be connected to a PC on which at least the **seca 115** application software is installed.

seca scales with an RS232 interface can transmit data to the PC software by wired connection.

Managing seca patient files

seca patient files can be created in the **seca 115** PC software or on a seca mBCA. seca patient files are saved in the seca patient database of the **seca 115** PC software. Alternatively, seca patient files can be saved on a USB memory stick. The USB memory stick has to be “initialized” for this purpose.

“Initializing” is a **seca 115** PC software function. This function allows the administrator to create an empty seca patient database on a USB memory stick.

seca patient files and seca patient databases contain exclusively data necessary for working with seca products or determined using seca products. seca patient files can only be managed and edited using the **seca 115** PC software.

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

Recording weight and height

On scales and stadiometers from the **seca 360°** system and on seca scales with an RS232 interface, it is possible to start recording weight and height directly from the **seca 115** PC software.

Measured results are sent from the **seca 360°** devices to the PC software. Alternatively, measured values can be entered manually in the **seca 115** PC software.

Determining body composition

Measurements with a seca mBCA (determines body composition by means of bioimpedance measurement) cannot be started from the **seca 115** PC software.

The results of a bioimpedance measurement are assigned to a seca patient file directly on the seca mBCA. The seca patient file is transmitted to the seca patient database of the **seca 115** PC software.

The **seca 115** PC software can only administer bioimpedance measurements determined using a seca mBCA.

Evaluation

Measured results are evaluated in graphical form based on scientifically-established formulas. In-house studies by seca established formulas for determining the parameters total body water (TBW), extracellular water (ECW), fat-free mass (FFM) and skeletal muscle mass (SMM) for arms, legs, torso and the whole body. In these studies, in-house reference values were determined for the following parameters to allow normal ranges to be shown: bioimpedance vector analysis (BIVA), mass indices (FMI, FMMI), phase angle (ϕ). Further information is available in the section entitled "Medical basis" from page 60.

Administration of user data

The following roles can be assigned to users of the **seca 115** PC software: physician, assistant or administrator. User accounts can only be set up or edited by an administrator. A user name and password are required for access to the **seca 115** PC software. If a user account is set up for the **seca 115** PC software, the **seca 115** PC software also generates a user PIN. The user PIN allows access from a seca mBCA to the seca patient database of the **seca 115** PC software.

Update of the PC software

When the PC software is updated, the seca patient database and its contents are retained. The seca patient database is adapted to suit the new version of the PC software. After the update is complete, it will no longer be possible to access the seca patient database with older versions of the PC software.

Compatibility with seca measuring devices

Version 1.4 of the **seca 115** PC software is compatible only with seca mBCAs on which device software version 1.1 is installed. There is no downward compatibility with seca mBCAs on which older versions of the device software are installed. For a summary of technical modifications, see the section entitled "Technical modifications" on page 78.

The **seca 115** PC software has unlimited compatibility with scales and stadiometers from the **seca 360°** system and with seca scales with an RS232 interface.

1.4 User qualification

Installation and administration

The **seca 115** PC software may only be installed and administered by experienced administrators or hospital technicians.

Measuring mode

The **seca 115** PC software may only be used by persons with sufficient expertise.

2. SAFETY INFORMATION

2.1 Safety rules in the 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!

Identifies possibility of incorrect operation of the product. If you fail to take note of this information, the device may be damaged or the measured results may be incorrect.

NOTE:

Includes additional information about use of the product.

2.2 Basic safety information

Using the software

- ▶ Please take note of the information in these instructions for use.
- ▶ Keep the instructions for use and the declaration of conformity they include in a safe place. The instructions for use are a component of the PC software and must be available at all times.

- ▶ Only install the **seca 115** PC software on PCs equipped with an antivirus program. Always keep your antivirus program up to date to protect your computer system from current and future malware. The **seca 115** PC software is protected from manipulation and was checked for malware at the time the software was created.
- ▶ Use the **seca 115** PC software only for the specified intended use.
- ▶ Use only seca mBCAs, scales and stadiometers in conjunction with the **seca 115** PC software.
- ▶ Keep other electrical medical devices, e.g. high-frequency surgical devices, a minimum distance of approx. 1 meter away to prevent incorrect measurements or wireless transmission interference.
- ▶ Keep high-frequency devices such as cell phones and televisions, for example, a minimum distance of approx. 1 meter away to prevent incorrect measurements or wireless transmission interference.
- ▶ The actual transmission output of high-frequency equipment may require minimum distances of more than 1 meter. For details, go to www.seca.com.

Using measured results



WARNING!

Hazard to patient

seca 115 is **not** diagnostic software. The device assists the attending physician in producing a diagnosis.

- ▶ To produce an accurate diagnosis and instigate therapies, the attending physician must commission specific examinations and take account of their results in addition to using the **seca 115** PC software.
- ▶ The responsibility for diagnoses and the therapies derived from them lies with the attending physician.



CAUTION!

Hazard to patient

To prevent misinterpretations, measured results for medical purposes may only be displayed and used in SI units (weight: kilograms, height: meters). Some devices and this PC software,

too, have the option of displaying measured results in different units. This is purely an additional function.

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

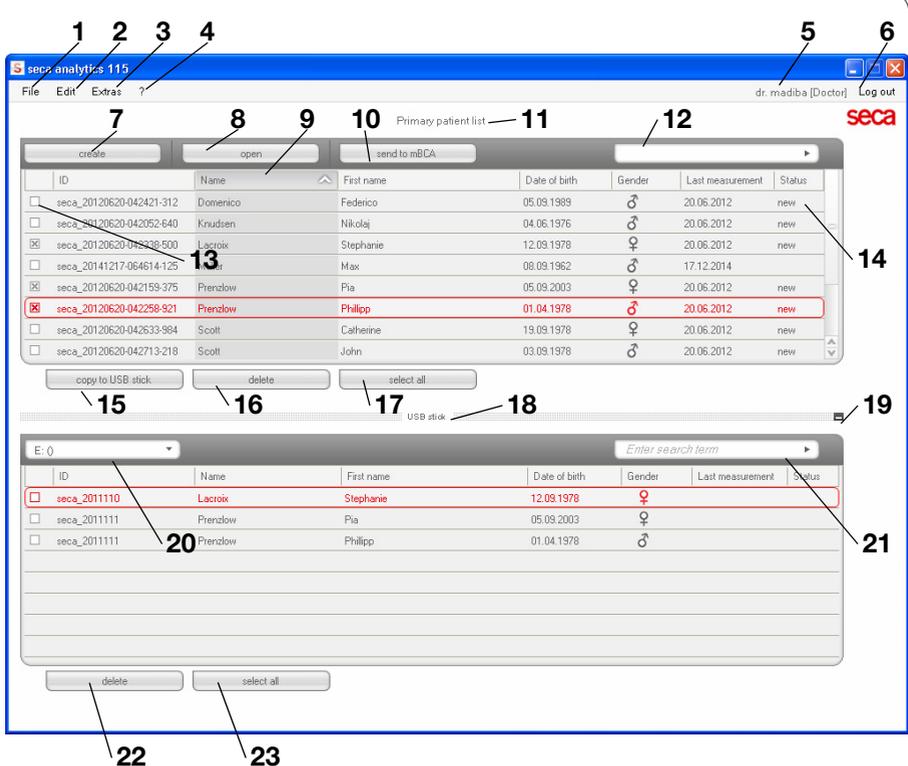
ATTENTION!

Loss of data

- Before you save and re-use measured results in the **seca 115** PC software (e.g. in a hospital information system), make sure that the measured values are plausible and that they correspond to the display on the measuring device.
- If measured values have been transmitted from the **seca 115** PC software to a hospital information system, make sure before re-use that the measured values are plausible and assigned to the correct patient.

3. OVERVIEW

3.1 seca patient list



No.	Control	Function
1	File	The following functions can be accessed using this menu element: <ul style="list-style-type: none"> • CSV export • Exit
2	Edit	The following functions can be accessed using this menu element (only with aseca patient file open): <ul style="list-style-type: none"> • Cut • Copy • Paste Also as a context menu - right-click
3	Extras	The following functions can be accessed using this menu element: <ul style="list-style-type: none"> • References • User-specific modules • Measuring device administration

No.	Control	Function
4	?	<p>The following functions can be accessed using this menu element:</p> <ul style="list-style-type: none"> • Product information • Instructions for Use • Administrator manual
5	Registered user [role]	<p>The following roles are provided:</p> <ul style="list-style-type: none"> • Administrator • Physician • Assistant <p>Changes can only be made by users with the Administrator role.</p>
6	Log off	Open the login dialog (enter user name and password) to log in another user
7	new	Create a new seca patient file in the main patient list
8	open	Open a seca patient file in the main patient list
9	Column sorting	<ul style="list-style-type: none"> • Up arrow: sort from A - Z • Down arrow: sort from Z - A
10	send to mBCA	Send seca patient file to a seca mBCA
11	Main patient list	<p>Displays seca patient files:</p> <ul style="list-style-type: none"> • data entered in the main patient list • data imported from the USB memory stick
12	Search window	<p>Search for seca patient files in the main patient list.</p> <ul style="list-style-type: none"> • “Asterisk search” - e.g. “Mi*” to find Miller • Back to the complete list with empty search
13	Checkbox	<ul style="list-style-type: none"> • Activates a seca patient file. • Clicking buttons in the seca patient list affects all “activated” seca patient files.
14	Selection bar	Indicates which seca patient file is currently selected. Clicking buttons has no effect on the selected file (cf. “Checkbox”)
15	copy to USB stick	Copy seca patient files selected in the main patient list to a USB memory stick, e.g. for use on an mBCA
16	delete	Delete “activated” seca patient file (seca patient file can be restored by users with the Administrator role)
17	select all deselect all	<ul style="list-style-type: none"> • Select all seca patient files in the main patient list in order to carry out actions for all • Deselect all seca patient files in the main patient list if action for all has been carried out or if no action is to be carried out
18	Patient list on USB memory stick	<p>Displays seca patient files saved on a USB memory stick</p> <ul style="list-style-type: none"> • seca patient files copied from the main patient list • seca patient files newly created on an mBCA

No.	Control	Function
19	Show/hide patient list from the USB memory stick	<ul style="list-style-type: none"> • seca patient list on the USB memory stick is automatically shown at system start • List can be hidden in order to display more entries in the main patient list
20	Drive selection window	For selecting the USB memory stick
21	Search window	Search seca patient files on the USB memory stick. <ul style="list-style-type: none"> • “Asterisk search” - e.g. “Mi*” to find Miller • Back to the complete list with empty search
22	delete	Delete seca patient file on the USB memory stick (seca patient file cannot be restored on the USB memory stick)
23	select all deselect all	<ul style="list-style-type: none"> • Select all seca patient files on the USB memory stick in order to carry out actions for all • Deselect all seca patient files on the USB memory stick if action for all has been carried out or if no action is to be carried out

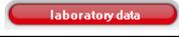
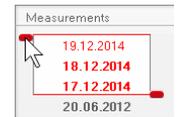
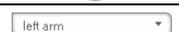
3.2 seca patient file

The screenshot shows the 'seca analytics 115' application window. At the top, there is a menu bar with 'File', 'Edit', and 'Extras'. Below the menu bar is a toolbar with buttons for 'measure', 'import', 'print', 'save', and 'close'. The main content area is titled 'Patient file' and displays the patient's name 'Prenzlou Philipp', gender '♂', and date of birth '01.04.1978 / Caucasian'. Below this, the patient's weight '98.80 kg', height '1.860 m', and BMI '28.56 kg/m²' are shown. The interface is divided into several sections: 'patient data' (highlighted in red), 'medical history', 'laboratory data', 'examination results', and 'comments'. The 'patient data' section includes fields for 'Name' (Title, Name, First name, Name suffix), 'Contact' (Street, House no., Postcode, Town, Country, Country, E-mail, Telephone 1, Telephone 2, Telephone 3), 'General data' (Date of birth, Gender, Ethnicity), 'Specific data' (Patient ID, Supervising doctor), and 'Comments'. The interface also features a status bar at the bottom right with 'dr. madiba [Doctor]', 'Log out', and the 'seca' logo.

	Symbol	Meaning
A	Patient info	Summary of the most important patient data
B	patient data	Enter, edit, and view the patient's master data
C	medical history	Enter, edit, and view the patient's medical history
D	laboratory data	Enter, edit, and view the patient's laboratory data Data can be imported if an interface to the hospital information system is programmed
E	examination results	View examination results
F	comments	Add and view comments about the seca patient file
G	measure	<ul style="list-style-type: none"> • Start measuring process for weight and height • Send seca patient file to a seca mBCA
H	import	Import patient data Note: Configuration or programming of an interface to the patient data management system (PDMS) required
I	print	Print results report or save as PDF

	Symbol	Meaning
J	save	Save changes and additions to the seca patient file
K	close	Close the seca patient file and return to the seca patient list
L	Date/time	Settings are adopted from the operating system

3.3 Color symbols and other controls

Control/display	Symbol	Meaning
Tab		White: tab not selected
		Red: tab selected
Typeface, evaluation modules		Red, with selection bar: module is active
	Function / rehabilitation	Bold: new data available
	Function / rehabilitation	Gray: module not available
Typeface, measurements		Red, with selection bar: measurement selected, details shown
	12.11.2011	Bold: new measurement
Typeface, evaluation parameters	28,6 kg/m²	Parameter red: value outside normal range
Handles		Selection of several measurements: <ul style="list-style-type: none"> • drag left handle upwards: add measurements of a more recent date. • drag right handle downwards: add measurements of an older date
Comments symbol		Comment for evaluation parameters present
Detail symbol		Detail view available for results graph
Drop-down triangles		Gray: function available
		Light gray: function not available
Data transmission		Data transmission in progress
		Data transmission successful
		Data transmission failed
Drop-down menu		Selected function
		Drop-down menu open

Control/display	Symbol	Meaning
Checkboxes	<input type="checkbox"/>	Empty: function deactivated
	<input checked="" type="checkbox"/>	Cross: function activated

3.4 Identification on the packaging

Text/symbol	Meaning
Mod	Model number
S/N	Serial number
	Follow instructions for use
	Product complies with EC directives
	Name of manufacturer
	Packaging material can be disposed of through recycling programs
	Protect from moisture
	Permitted min. and max. temperature for transport and storage
	Permitted min. and max. moisture for transport and storage

4. INSTALLATION/UPDATES

The PC software may only be installed and updated by experienced administrators or hospital technicians.

Information about the software version installed and about the availability of updates can be found in the menu line of the PC software at “**? → Product information**”.

For information about installation and configuration options, check the menu line of the software under “**? → Administrator manual**”.

In the event of questions about the system currently installed on your PC and if you want to make any changes, please contact your administrator.



ATTENTION! Loss of data

Incorrect installation or incorrect changes to the installation can lead to loss of data and, as a result, to misdiagnoses.

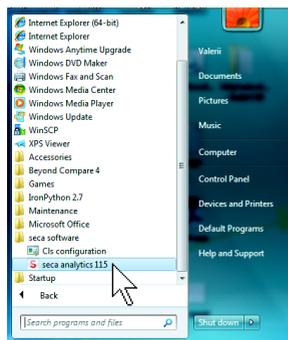
- ▶ Make sure the installation or changes to the installation are carried out by an experienced administrator or hospital technician.

5. OPERATION

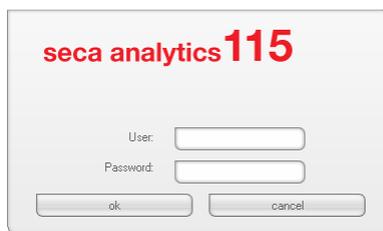
5.1 Starting/exiting program

Opening the program

1. Click “Start → Programs → seca → seca medical software”.



The login dialog opens.



2. Enter your user name.
3. Enter your password.

NOTE:

User name and password are created by the administrator. If you want to change the user name or password, please contact your administrator.

4. Confirm your entries with **ok**.
The **seca** patient list opens.

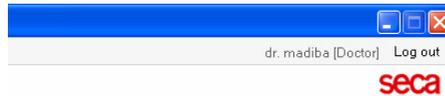
Logging off / switching user

- ▶ Click on **Log off**.
The login dialog opens.
Another user can log in.



Exiting program

- ▶ Click on the cross symbol.
The program will close.



5.2 “Extras” menu

Changing references

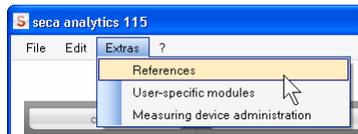
The **seca 115** PC software evaluates measured results using references. References are formulas and comparison values determined in clinical studies. During the installation and configuration of the **seca 115** PC software, your administrator sets in which country you are operating your **seca 115** PC software. With this setting, the references normally used in your country are preset automatically.

You can change the preset references to suit the regulations applying in your institution and your personal preferences. To do so, proceed as outlined below.

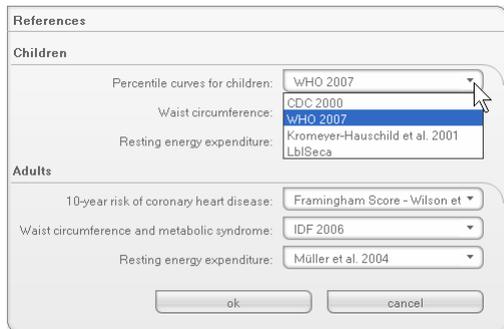
NOTE:

This section describes how to use the **seca 115** PC software. For information about the medical content, see the section entitled “Medical basis” from page 60.

1. From the **Extras** menu, select the **References** element.



The **References** dialog window opens.



2. Click on the arrow of the parameter for which you want to select the reference.
A pull-down menu with all the selection options for the reference opens.
3. Click the desired reference.
The pull-down menu closes.
The selected reference appears in the selection field.
4. Repeat steps 2. and 3. for all parameters whose references you would like to change.
5. To save the settings, click **ok**.
The dialog window closes.

NOTE:

If you click on “**Cancel**”, the settings are not saved.

Creating user-specific modules

A number of evaluation modules have already been set up to assess your patient's state of health (see "Evaluation modules" on page 60).

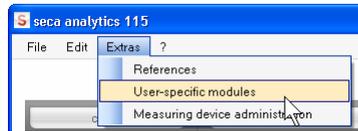
In the **User-specific modules** dialog, you can compile two further modules. You can view and evaluate these in the seca patient file under the **examination results** tab, just like the preset evaluation modules.

NOTE:

This section describes how to use the **seca 115** PC software. For information about the medical content, see the section entitled "Medical basis" from page 60.

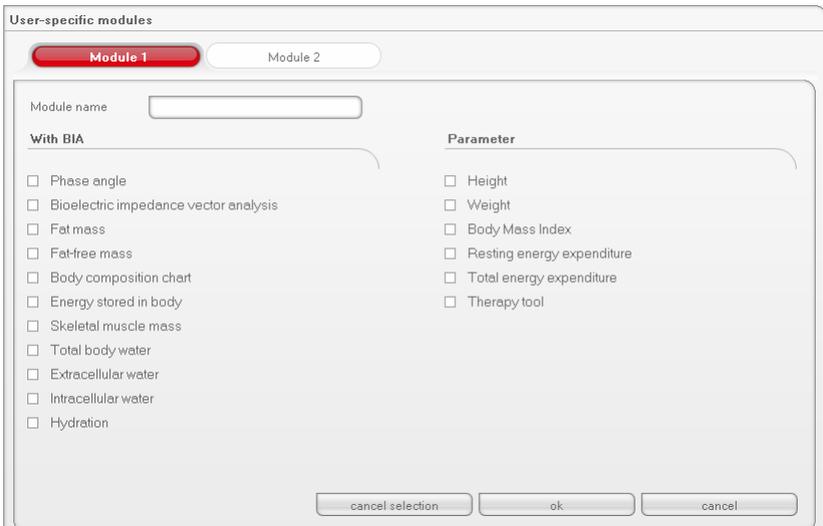
To compile a user-specific module, proceed as outlined below.

1. In the **Extras** menu, click on **User-specific modules**.



The **User-specific modules** dialog window appears.

Module 1 is preselected.

A screenshot of the 'User-specific modules' dialog window. The window has a title bar 'User-specific modules' and two tabs: 'Module 1' (selected) and 'Module 2'. Below the tabs is a 'Module name' input field. The main area is divided into two columns: 'With BIA' and 'Parameter'. Each column contains a list of checkboxes. The 'With BIA' column includes: Phase angle, Bioelectric impedance vector analysis, Fat mass, Fat-free mass, Body composition chart, Energy stored in body, Skeletal muscle mass, Total body water, Extracellular water, Intracellular water, and Hydration. The 'Parameter' column includes: Height, Weight, Body Mass Index, Resting energy expenditure, Total energy expenditure, and Therapy tool. At the bottom of the dialog are three buttons: 'cancel selection', 'ok', and 'cancel'.

2. In the **Module name** field, enter the name you want to give the module.
3. Click a maximum of 4 parameters you want displayed in your module.
4. Click on **ok**.
The user-specific module is saved.

NOTE:

- With **Cancel selection**, you can deselect all selected items with a mouse-click.
- With **Cancel**, you can exit the dialog window without saving settings.
- To delete a saved module, click on **Cancel selection**, delete the module name in the **Module name** field and click on **ok**.

5. If desired, repeat the process for **Module 2**.

Viewing measuring device administration

You can view which scales and stadiometers are connected to your PC.

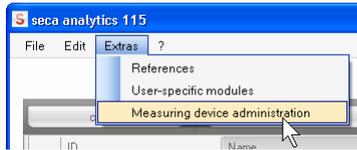
The following information is displayed for each seca measuring device connected:

- device name if entered by the administrator (recommended)
- model
- setup location if entered by the administrator (recommended)
- serial number
- connection properties:

Connection	Properties
Ethernet	[IP address]:[port]
seca 360°wireless network	[PC name : channel; device type]
RS232 devices	[PC name : COM port]

To have the measuring device configuration displayed, proceed as outlined below.

1. From the **Extras** menu, select the **Measuring device administration** element.



The **Measuring device administration** window appears.

Measuring device administration

Weight

Name	Model	Location	Serial number	Connection properties

Height

Name	Model	Location	Serial number	Connection properties
Längenmessgerät	Längenmessgerät		05704183104409	

BIA

Name	Model	Location	Serial number	Connection properties
mBCA	mBCA			0,5
mBCA	mBCA			1,5
mBCA	mBCA			127.0.0.1:192.168.2.12:60671

close

NOTE:

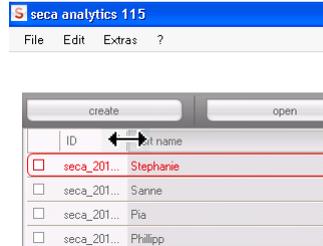
You cannot make any changes in this window. If changes are to be made, please contact your administrator.

2. To exit the **Measuring device administration** window, click on **close**.

5.3 Working with the seca patient list

Adjusting column width

1. Position the mouse pointer in the title line on the line between two columns.

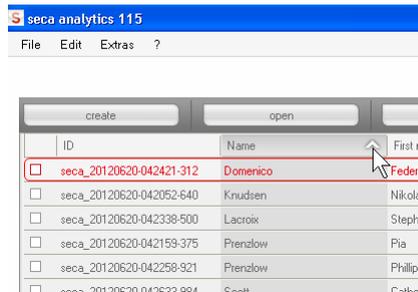


The pointer turns into a double arrow.

2. Hold down the left mouse button and drag to make the column wider or narrower.
3. Release the left mouse button once the required column width is reached.

Sorting column content in ascending or descending order

1. Click in the title line of the desired column.



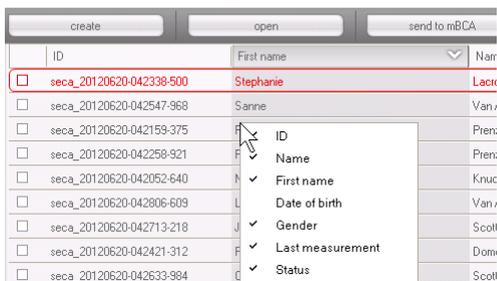
An arrow appears next to the column title, to indicate the current sorting direction.

2. Click the arrow to re-sort column content.
3. To reverse the sorting direction, click the arrow again.

Showing and hiding columns

1. Position the mouse pointer in the seca patient list.
2. Right-click.

A context menu with the titles of all columns appears.



The screenshot shows a table with columns: ID, First name, and Name. The first row is highlighted in red and contains the ID 'seca_20120620-042338-500' and the name 'Stephanie'. A context menu is open over the 'ID' column header, listing the following columns with checkmarks: ID, Name, First name, Date of birth, Gender, Last measurement, and Status. The table also has buttons for 'create', 'open', and 'send to mBCA' at the top.

	ID	First name	Name
<input type="checkbox"/>	seca_20120620-042338-500	Stephanie	Lac...
<input type="checkbox"/>	seca_20120620-042547-968	Sanne	Van...
<input type="checkbox"/>	seca_20120620-042159-375		Prent...
<input type="checkbox"/>	seca_20120620-042258-921		Prent...
<input type="checkbox"/>	seca_20120620-042052-640		Knuc...
<input type="checkbox"/>	seca_20120620-042806-609		Van...
<input type="checkbox"/>	seca_20120620-042713-218		Scot...
<input type="checkbox"/>	seca_20120620-042421-312		Dom...
<input type="checkbox"/>	seca_20120620-042633-984		Scot...

3. Click on the title of the column you want to hide.
The checkmark in front of the column title is no longer displayed.
The corresponding column is hidden in the seca patient list.
4. Click on the title of the column again to show it again.
The checkmark in front of the column title is displayed again.
The corresponding column is shown in the seca patient list again.

Showing and hiding the seca patient list from the USB memory stick

The patient list from the USB memory stick is shown each time the program starts. You can hide the patient list from the USB memory stick to obtain more space for the entries of the main patient list.

1. Click on the “-” symbol above the patient list from the USB memory stick.

04.06.1976	♂	20.06.2012	new
12.09.1978	♀	20.06.2012	new
05.09.2003	♀	20.06.2012	new
01.04.1978	♂	20.06.2012	new
19.09.1978	♀	20.06.2012	new
03.09.1978	♂	20.06.2012	new
06.09.1999	♀	20.06.2012	new

all



The patient list from the USB memory stick is no longer shown.

2. To show the patient list from the USB memory stick again, click on the “-” symbol again.



Searching for a seca patient file

1. Enter a search term in the search field.

The screenshot displays the 'seca analytics 115' application window. The main area shows a 'Primary patient list' table with columns for ID, Name, First name, Date of birth, Gender, Last measurement, and Status. The row for 'seca_201... Prenzlau Philipp' is highlighted in red. Below the table are buttons for 'copy to USB stick', 'delete', and 'select all'. A secondary window titled 'USB stick' is open, showing a search field with the text 'Enter search term' and a dropdown menu set to 'No USB stick found.'. Below this search window is another empty table with the same column headers as the main patient list, and 'delete' and 'select all' buttons.

ID	Name	First name	Date of birth	Gender	Last measurement	Status	
<input type="checkbox"/>	seca_201...	Domenico	Federico	05.09.1989	♂	20.06.2012	new
<input type="checkbox"/>	seca_201...	Knudsen	Nikolaj	04.06.1976	♂	20.06.2012	new
<input type="checkbox"/>	seca_201...	Lacroix	Stephanie	12.09.1978	♀	20.06.2012	new
<input type="checkbox"/>	seca_201...	Prenzlau	Pia	05.09.2003	♀	20.06.2012	new
<input checked="" type="checkbox"/>	seca_201...	Prenzlau	Philipp	01.04.1978	♂	20.06.2012	new
<input type="checkbox"/>	seca_201...	Scott	Catherine	19.09.1978	♀	20.06.2012	new
<input type="checkbox"/>	seca_201...	Scott	John	03.09.1978	♂	20.06.2012	new
<input type="checkbox"/>	seca_201...	Van Aelst	Sanne	06.09.1999	♀	20.06.2012	new

NOTE:

If you do not know exactly how to spell a name, you can carry out a so-called “asterisk search” - e.g. “Mi*” to find “Miller”.

2. Click the arrow next to the search field.
The search process starts.
The search results are displayed.
3. In order to return to the complete seca patient list, delete the search term in the search field.
4. Click the arrow next to the search field.
The complete seca patient list is shown again.

Creating a new seca patient file

If you create a new seca patient file, you must fill in at least the following fields (each marked “*” in the file):

- date of birth
- gender
- ethnicity
- attending physician (if the current user is a physician, this field will be filled in automatically)

If the patient ID has to comply with a specified structure in your institution, you can enter it manually. If you do not enter a “manual” ID, then an ID will be assigned automatically when the seca patient file is saved.

1. Click on **new**.

Primary patient list

create		open		send to mBCA	
ID	Name	First name	Date of birth		
<input type="checkbox"/>	seca_201... Domerico	Federico	05.09.1989		
<input type="checkbox"/>	seca_201... Knudsen	Nikolaj	04.06.1976		

An empty seca patient file appears.

The **patient data** tab is active.

The screenshot shows the 'seca analytics 115' application window. The title bar includes 'File Edit Extras ?' and 'dr. madiba [Doctor] Log out'. The main window displays a 'Patient file' form with the 'patient data' tab selected. The form is divided into several sections:

- Name:** Fields for Title, Name, First name, and Name suffix.
- General data:** Fields for Date of birth (08.09.1962), Gender (Male), and Ethnicity (Caucasian).
- Specific data:** Fields for Patient ID (seca_20141217-064614-125) and Supervising doctor (dr. madiba).
- Contact:** Fields for Street, House no., Postcode, Town, County, and Country (Germany). It also includes E-mail, Telephone 1, 2, and 3, each with a 'Private' dropdown menu.
- Comments:** A text area for entering patient comments.

At the top of the form, there are buttons for 'measure', 'input', 'print', 'save', and 'close'. The date and time '17.12.2014 18:46' are displayed in the top right corner.

2. Enter the patient data:

NOTE:

If you are logged in as a physician, you will automatically be entered in the **Attending physician** field. The field can be edited.

3. Click on **save**.

If no manual ID was assigned, the ID created automatically by the **seca 115** software is displayed.

4. Click on **close**.

The seca patient list is shown again.

Additional seca patient files can be created.

Sending seca patient file to a seca mBCA

Use this function to send a seca patient file to a seca mBCA to determine a patient's body composition on that device.

NOTE:

This function is only available if you have an Ethernet network connection available.

1. Ensure that the desired seca mBCA is switched on.
2. In the patient list of the PC software, select the desired seca patient file.
3. Click on **send to mBCA**.

Primary patient list

create		open		send to mBCA	
ID	Name	First name			
<input checked="" type="checkbox"/>	seca_20120620-042421-312	Domenico	Federico		0
<input type="checkbox"/>	seca_20120620-042052-640	Knudsen	Nikolaj		0

The **Measuring device selection** dialog window appears.

Measuring device selection

Weight:

Height:

Body composition:

4. In the **Measuring device selection** dialog window, select the desired seca mBCA in the **Body composition** line.
5. Click on **Send patient file**.

Measuring device selection

Weight:

Height:

Body composition:

The seca patient file is passed to the selected seca mBCA where it appears in the **patient** tab.

Copying seca patient files to USB memory stick

If you want to work with seca patient files on a seca mBCA and there is no wireless or Ethernet connection to this device, you can use an initialized USB memory stick.

NOTE:

If you are uncertain of whether the USB memory stick has been initialized, please contact your administrator.

In order to copy data to a USB memory stick, proceed as outlined below.

1. Insert the USB memory stick in a free USB port on the PC.
The message **USB stick detected** appears.
2. Click on **ok**.
The dialog window closes.
3. In the main patient list, select the seca patient files you want to copy to the USB memory stick.

The screenshot shows the 'seca analytics 115' application window. The main area displays a 'Primary patient list' table with columns for ID, Name, First name, Date of birth, Gender, Last measurement, and Status. The patient 'Prenzlou Pia' (ID: seca_20120620-042159-375) is selected. Below the table are buttons for 'copy to USB stick', 'delete', and 'select all'. A 'USB stick' dialog box is open at the bottom, showing a search field and an empty table with 'delete' and 'select all' buttons.

ID	Name	First name	Date of birth	Gender	Last measurement	Status	
<input type="checkbox"/>	seca_20120620-042421-312	Domenico	Federico	05.09.1989	♂	20.06.2012	new
<input type="checkbox"/>	seca_20120620-042052-640	Knuudsen	Nikolaj	04.06.1976	♂	20.06.2012	new
<input checked="" type="checkbox"/>	seca_20120620-042338-500	Lacroix	Stephanie	12.09.1978	♀	20.06.2012	new
<input type="checkbox"/>	seca_20141217-064614-125	Müller	Max	08.09.1962	♂	17.12.2014	
<input checked="" type="checkbox"/>	seca_20120620-042159-375	Prenzlou	Pia	05.09.2003	♀	20.06.2012	new
<input type="checkbox"/>	seca_20120620-042258-921	Prenzlou	Philipp	01.04.1978	♂	20.06.2012	new
<input type="checkbox"/>	seca_20120620-042633-984	Scott	Catherine	19.09.1978	♀	20.06.2012	new
<input type="checkbox"/>	seca_20120620-042713-218	Scott	John	03.09.1978	♂	20.06.2012	new

4. Click on **copy to USB stick**.
The copied entries are shown in the patient list of the USB memory stick.

The screenshot shows the 'seca analytics 115' application window. The main area displays a 'Primary patient list' table with columns for ID, Name, First name, Date of birth, Gender, Last measurement, and Status. The row for ID 'seca_20120620-042159-375' (Name: Prenzlow, First name: Pia, Date of birth: 05.09.2003, Gender: ♀, Last measurement: 20.06.2012, Status: new) is highlighted in red. Below the table are buttons for 'copy to USB stick', 'delete', and 'select all'.

The 'USB stick' section at the bottom shows a search bar with 'E: 0' and a search input field. Below it is a table with columns for ID, Name, First name, Date of birth, Gender, Last measurement, and Status. The row for ID 'seca_2011110' (Name: Lacroix, First name: Stephanie, Date of birth: 12.09.1978, Gender: ♀) is highlighted in red. Below this table are buttons for 'delete' and 'select all'.

5. Eject the USB memory stick in accordance with the procedure of your PC's operating system.
6. Extract the USB memory stick from the USB port of the PC.

NOTE:

In order to be able to access seca patient files on a seca mBCA, you need your user PIN (generated automatically when your administrator sets up your user account for the **seca 115** PC software) or the USB PIN (generated when your administrator initializes the USB memory stick). If you do not have either of the PINs handy, contact your administrator.

Importing seca patient files from the USB memory stick

If you have created or updated seca patient files on a USB memory stick, e.g. during a measurement on a seca mBCA, you can import these data to the patient database of the **seca 115** PC software. To do so, proceed as outlined below.

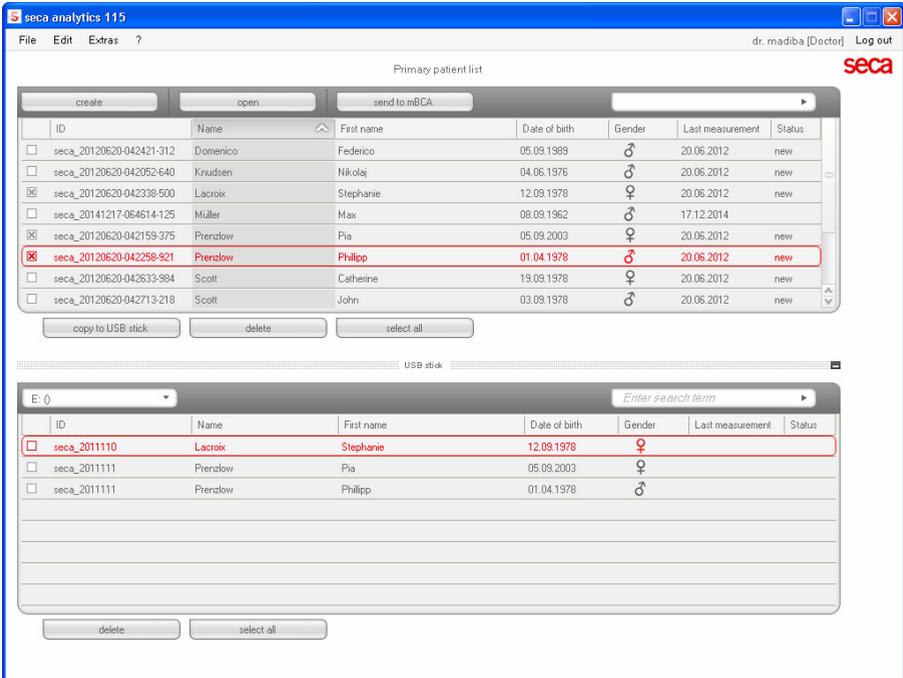
1. Insert the USB memory stick in a free USB port on the PC.

The message **USB stick detected** appears.

2. Click on **ok**.

The dialog window closes.

The patient files on the USB memory stick are shown in the patient list of the USB memory stick.



Data import starts automatically.

Imported entries are shown in the main patient list.

NOTE:

If you accidentally assign a patient ID which already exists in the **seca 115** PC software, the corresponding seca patient file will be copied from the USB memory stick to the patient buffer

of the **seca 115** PC software. Your administrator can provide the seca patient file with a unique ID and transfer it to the main patient list.

3. Eject the USB memory stick in accordance with the procedure of your PC's operating system.
4. Extract the USB memory stick from the USB port of the PC.

Exporting seca patient files to .csv format

If you would like to re-use a patient's examination results outside this program, you can export them to the .csv format. This data format can be imported into common spreadsheet programs.

NOTE:

Personal data such as the name and address of the patient will not be exported.

1. Position the red selection bar on the seca patient file to be exported.
2. Click the appropriate checkbox.
A cross appears in the checkbox.
The seca patient file is selected.
3. Repeat steps 1. and 2. for all seca patient files to be exported.

NOTE:

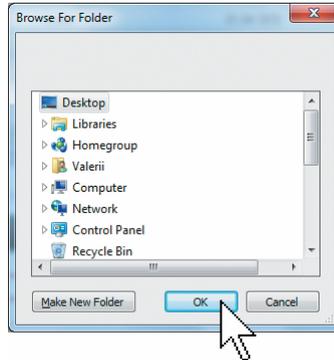
If you want to export all the seca patient files, use the **select all** function.

4. In the **File** menu, click on **Export**.
The export window appears.

CSV export

<input type="checkbox"/> Fat mass	<input type="checkbox"/> Total body water
<input type="checkbox"/> Fat-free mass	<input type="checkbox"/> Extracellular water
<input type="checkbox"/> Body composition chart	<input type="checkbox"/> Intracellular water
<input type="checkbox"/> Skeletal muscle mass	<input type="checkbox"/> Hydration
<input type="checkbox"/> BMI	<input type="checkbox"/> Resting energy expenditure
<input type="checkbox"/> Height	<input type="checkbox"/> Total energy expenditure
<input type="checkbox"/> Weight	<input type="checkbox"/> Energy stored in body
<input type="checkbox"/> Raw data for impedance left arm	<input type="checkbox"/> 10-year risk of coronary heart disease
<input type="checkbox"/> Raw data for impedance right arm	<input type="checkbox"/> Metabolic syndrome
<input type="checkbox"/> Raw data for impedance left leg	<input type="checkbox"/> Waist circumference
<input type="checkbox"/> Raw data for impedance right leg	<input type="checkbox"/> Phase angle
<input type="checkbox"/> Raw data for impedance left half of body	<input type="checkbox"/> Bioelectric impedance vector analysis
<input type="checkbox"/> Raw data for impedance right half of body	
<input type="checkbox"/> Raw data for impedance Torso	

5. Select the parameters you want to export.
6. To confirm the settings, click **ok**.
The **Save as** dialog window appears.



7. Select the directory to which you want to export the patient data.
8. Click on **save**.
The data is exported.

NOTE:

If an interface to your PDMS is configured, then weight and height, as well as a PDF document with all the measured results and evaluations, will be exported to the PDMS automatically. If you are uncertain of whether an interface has been configured, please contact your administrator.

Deleting individual seca patient files

You can delete seca patient files both in the main patient list and in the patient list of the USB memory stick. To do so, proceed as outlined below.

1. Select the seca patient file to be deleted (in this case, in the main patient list).

Primary patient list

ID	Name	First name	Date of birth	Gender	Last measurement	Status
<input type="checkbox"/>	seca_201...	Domenico	Federico	05.09.1989	♂	20.06.2012 new
<input type="checkbox"/>	seca_201...	Knudsen	Nikolaj	04.06.1976	♂	20.06.2012 new
<input type="checkbox"/>	seca_201...	Lacroix	Stephanie	12.09.1978	♀	20.06.2012 new
<input type="checkbox"/>	seca_201...	Prenzlow	Pia	05.09.2003	♀	20.06.2012 new
<input checked="" type="checkbox"/>	seca_201...	Prenzlow	Philipp	01.04.1978	♂	20.06.2012 new
<input type="checkbox"/>	seca_201...	Scott	Catherine	19.09.1978	♀	20.06.2012 new
<input type="checkbox"/>	seca_201...	Scott	John	03.09.1978	♂	20.06.2012 new
<input type="checkbox"/>	seca_201...	Van Aelst	Sanne	06.09.1999	♀	20.06.2012 new

2. Click the appropriate checkbox.
A cross appears in the checkbox.
The seca patient file is selected.
3. Repeat steps 1. and 2. for all seca patient files to be deleted.
4. Click on **delete**.
The seca patient file is deleted.

ATTENTION!

Loss of data

If you delete data on the USB memory stick, you cannot restore them.

- Before deleting data on the USB memory stick, make sure that the data have been imported into the main patient list (see “Importing seca patient files from the USB memory stick” on page 32).

NOTE:

If you have inadvertently deleted data in the main patient list, your administrator can restore the data using the **Restore patient data** function. The entire patient data set will be restored. Entries and measurements which have not been saved will be lost.

Deleting all seca patient files

You can delete seca patient files both in the main patient list and in the patient list of the USB memory stick. To do so, proceed as outlined below.

1. Click on **select all** (in this case, in the main patient list).



The screenshot shows a software interface for managing patient data. At the top, there are buttons for 'create', 'open', and 'send to mBCA', along with a search bar labeled 'Enter search term'. Below this is a table with columns for ID, Name, First name, Date of birth, Gender, Last measurement, and Status. The first row is highlighted in red and has a checkbox selected. Below the table are three buttons: 'copy to USB stick', 'delete', and 'select all'. A mouse cursor is pointing at the 'select all' button.

ID	Name	First name	Date of birth	Gender	Last measurement	Status	
<input checked="" type="checkbox"/>	seca_201...	Domenico	Federico	05.09.1989	♂	20.06.2012	new
<input type="checkbox"/>	seca_201...	Knudsen	Nikolej	04.06.1976	♂	20.06.2012	new
<input type="checkbox"/>	seca_201...	Lacroix	Stephanie	12.09.1978	♀	20.06.2012	new
<input type="checkbox"/>	seca_201...	Prenzlów	Pia	05.09.2003	♀	20.06.2012	new
<input type="checkbox"/>	seca_201...	Prenzlów	Phillipp	01.04.1978	♂	20.06.2012	new
<input type="checkbox"/>	seca_201...	Scott	Catherine	19.09.1978	♀	20.06.2012	new
<input type="checkbox"/>	seca_201...	Scott	John	03.09.1978	♂	20.06.2012	new
<input type="checkbox"/>	seca_201...	Van Aelst	Sanne	06.09.1999	♀	20.06.2012	new

NOTE:

If you want to undo the selection, click on **deselect all**.

2. Click on **delete**.

All seca patient files are deleted.

ATTENTION!

Loss of data

If you delete data on the USB memory stick, you cannot restore them.

- Before deleting data on the USB memory stick, make sure that the data have been imported into the main patient list (see "Importing seca patient files from the USB memory stick" on page 32).

NOTE:

If you have inadvertently deleted data in the main patient list, your administrator can restore the data using the **Restore patient data** function. The entire patient data set will be restored. Entries and measurements which have not been saved will be lost.

5.4 Working with the seca patient file

Opening the seca patient file

1. Click on the checkbox of the seca patient file you want to open.
A cross appears in the checkbox.
The seca patient file is selected.

Primary patient list

	ID	Name	First Name	Date of Birth
<input checked="" type="checkbox"/>	seca_201...	Domenico	Federico	05.09.1961
<input type="checkbox"/>	seca_201...	Knudsen	Nikolaj	04.06.1961
<input type="checkbox"/>	seca_201...	Lacroix	Stephanie	12.09.1961
<input type="checkbox"/>	seca_201...	Frenzlow	Pia	05.09.1962
<input type="checkbox"/>	seca_201...	Frenzlow	Phillipp	01.04.1964
<input type="checkbox"/>	seca_201...	Frank	Christian	19.09.1964

2. Click on **open** or double-click on the entry in the seca patient list.
The seca patient file opens.

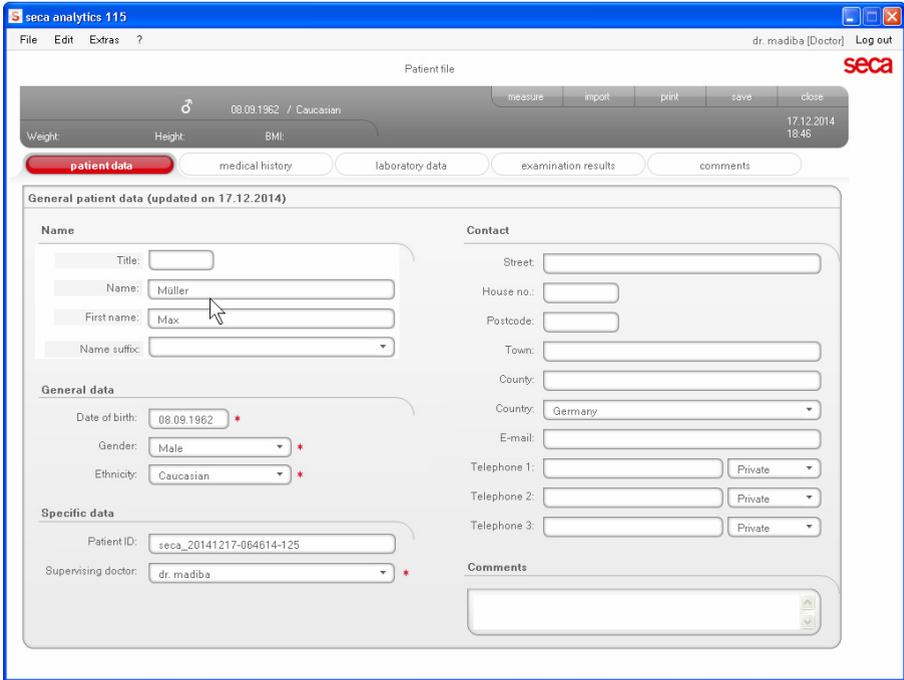
Editing patient data

When you have opened an existing seca patient file, the following fields are filled in as a minimum:

- date of birth
- gender
- ethnicity
- patient ID
- attending physician

You can change and add to patient data at any time.

1. Open a seca patient file (see “Opening the seca patient file” on page 37).
The **patient data** tab is active.
2. Select the tab on which you would like to change data.



3. Change or add to the patient data where necessary:
 - supplement data manually.
 - mark entries and use the **Cut**, **Copy** and **Paste** functions. These functions are accessible via the **Edit** menu element or by right-clicking on the context menu.

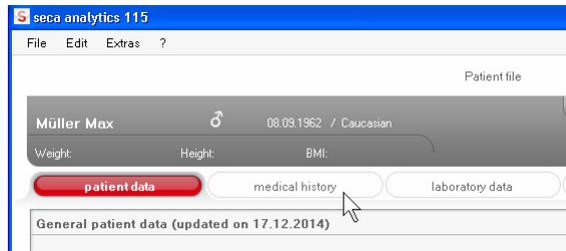


4. Click on **save**.
5. To close the seca patient file, click **close**.
The seca patient list is shown again.

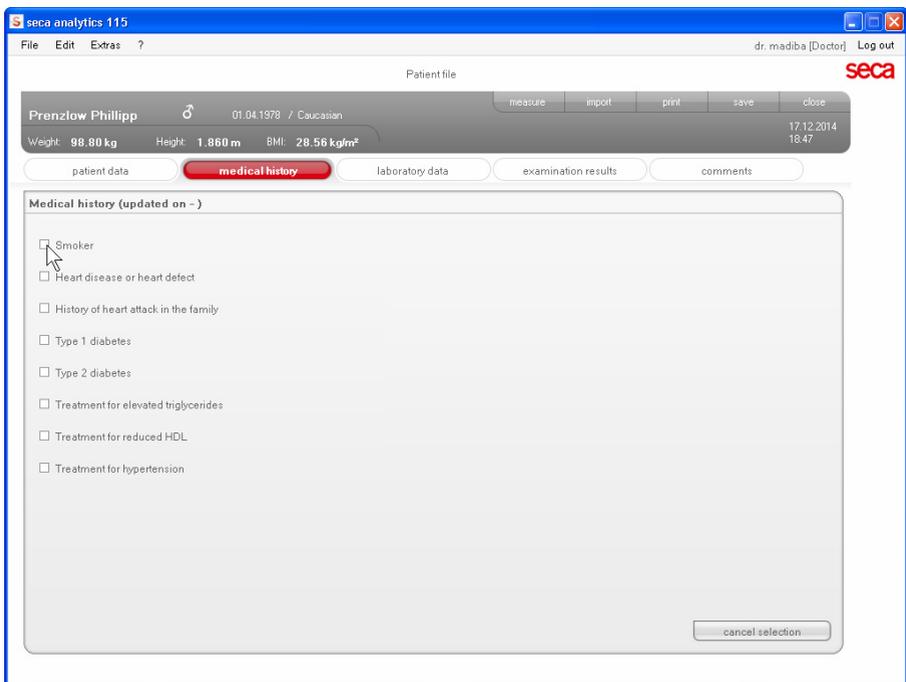
Entering a medical history

On the **medical history** tab, you can enter previous illnesses or therapies already started. This information is included in the evaluation of the measured results (see “Assessing the examination results” on page 47).

1. Click on **medical history**.
The **medical history** tab is active.



2. Click on the checkboxes for the relevant previous illnesses and therapies.
A cross appears in the corresponding checkboxes.



3. Click on **save**.

NOTE:

Use **Cancel selection** to undo the entire selection. Then click on **save** again.

Entering laboratory data

In the **laboratory data** tab, you can enter the patient's current laboratory data and waist circumference and track the history.

If an interface to your patient data management system (PDMS) has been configured for this program, patient and laboratory data can be transferred from the PDMS.

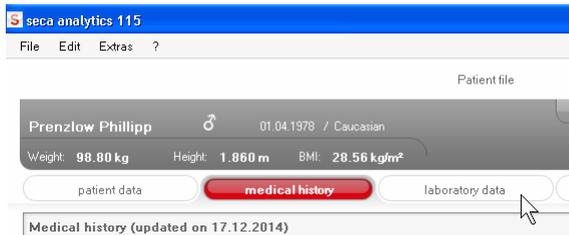
NOTE:

If you are uncertain of whether an interface has been configured, please contact your administrator.

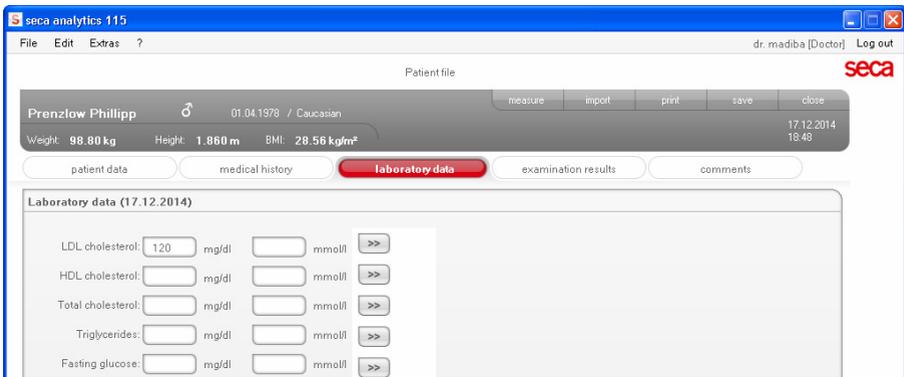
To enter laboratory data manually, proceed as outlined below.

1. Click on **laboratory data**.

The **laboratory data** tab is active.



2. Click in a value field.
3. Enter the value.



NOTE:

You can specify the value in mg/dl or in mmol/l. The conversion to the other value takes place automatically as soon as you click on the empty field.

seca analytics 115

File Edit Extras ?

Patient file dr. madiba [Doctor] Log out

Prenzlöw Philipp 01.04.1978 / Caucasian

Weight: 98.80 kg Height: 1.860 m BMI: 28.56 kg/m²

patient data medical history **laboratory data** examination results comments

Laboratory data (17.12.2014)

LDL cholesterol: 120 mg/dl 3.10 mmol/l

HDL cholesterol: mg/dl mmol/l

Total cholesterol: mg/dl mmol/l

Triglycerides: mg/dl mmol/l

Fasting glucose: mg/dl mmol/l

- Repeat steps 2. and 3. for all values you want to enter.
- Click on **save**.

Viewing history for individual values

You can view the history for individual values. To do so, proceed as outlined below.

- Click on the » symbol next to the desired value.

seca analytics 115

File Edit Extras ?

Patient file dr. madiba [Doctor] Log out

Prenzlöw Philipp 01.04.1978 / Caucasian

Weight: 98.80 kg Height: 1.860 m BMI: 28.56 kg/m²

patient data medical history **laboratory data** examination results comments

Laboratory data (17.12.2014)

LDL cholesterol: 138 mg/dl 3.57 mmol/l

HDL cholesterol: 38 mg/dl 0.98 mmol/l

Total cholesterol: 167 mg/dl 4.32 mmol/l

Triglycerides: 112 mg/dl 1.26 mmol/l

Fasting glucose: 88 mg/dl 4.88 mmol/l

History

Date	Time	Value in mg/dl	Value in mmol/l
17.12.2014	18:48:58	138	3.57
17.12.2014	18:48:35	120	3.10

The history field for that value opens.

- To close the history view, click «.
- To return to the seca patient list, click **close**.

Deleting values in the history field

You can delete individual values in the history field. To do so, proceed as outlined below.

1. Right-click on the value you want to delete.
The **delete** button appears.
2. Left-click on the **delete** button.
The value is deleted
3. To return to the seca patient list, click **close**.



Date	Time	Value in mg/dl	Value in
17.12.2014	18:49:23	138	3.57
17.12.2014	18:48:58	138	
17.12.2014	18:48:35	120	3.10

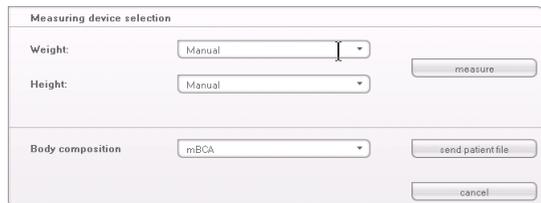
Determining weight and height

To determine a patient's weight and height, proceed as outlined below.

1. Open the seca patient file (see “Opening the seca patient file” on page 37) or create a seca patient file if necessary (see “Creating a new seca patient file” on page 27).
2. In the title bar of the seca patient file, click on **measure**.



The **Measuring device selection** dialog window appears.



Measuring device selection

Weight:

Height:

Body composition:

3. In the **Weight** and **Height** lines, click on the devices you want to use to perform the measurement.

ATTENTION!**Incorrect measurement if incorrect device selected**

If the incorrect device is selected, measured results may be assigned to an incorrect patient or no measurement may be performed at all.

- ▶ Use the name of each device to check you have selected the right devices.
- ▶ For selecting devices logged on to the same USB wireless adapter: make sure that the selected measuring devices are logged on to the same wireless group.
- ▶ If devices in the network have to be renamed or the configuration of wireless groups changed, contact your administrator.

NOTE:

Select the **Manual** setting if your scales and stadiometers are not networked with the PC. In the next dialog window, you can then enter the measured values directly.

4. In the **Measuring device selection** dialog window, click on **measure**.

The screenshot shows a dialog window titled "Measuring device selection". It has three rows of dropdown menus. The first row is labeled "Weight:" and has "Personenwaage" selected. The second row is labeled "Height:" and has "Langenmessgerät" selected. The third row is labeled "Body composition" and has "mBCA" selected. To the right of the first two rows is a button labeled "measure" with a mouse cursor pointing to it. Below the third row are two buttons: "send patient file" and "cancel".

The **Measured values** dialog window appears.

The selected measuring devices are displayed next to the corresponding value windows.

Measured values

Weight (kg) seca 285, Raum 1

Height (m)

Please enter the patient's waist circumference to determine cardiometabolic risk:

Waist circumf. (m)

Please enter the patient's activity level (PAL) to determine total energy expenditure:

PAL ?

5. Perform the measurements as described in the instructions for use for the selected devices.
6. Ensure that the measured values are shown in the **Measured values** dialog window:
 - If you are using **seca 360°** devices on which automatic data transmission is activated, the measured values are automatically sent to the PC.
 - If you are using **seca 360°** devices on which automatic data transmission is **not** activated or is not provided, press the Enter key (**Send/print**) on the measuring devices to send the measured values to the PC.
 - If you are working with scales which are connected to the PC via RS232 interface, the measured values are transmitted to the PC automatically.
 - If your scales and stadiometers are not networked with the PC, enter the measured values manually.

NOTE:

- If you are unsure whether automatic data transmission is activated or available on your **seca 360°** devices, contact your administrator.
 - Regardless of the setting on the measuring devices, measured values will be displayed in the units preset for the **seca 115** PC software.
7. If you want to assess the patient's cardiometabolic risk, enter the **Waist circumference** in the **Measured values** dialog window.

Measured values

Weight (kg) seca 285, Raum 1

Height (m) seca 285, Raum 1

Please enter the patient's waist circumference to determine cardiometabolic risk:

Waist circumf. (m)

Please enter the patient's activity level (PAL) to determine total energy expenditure:

PAL ?

8. If you want to determine the patient's total energy expenditure (TEE), enter the patient's **Physical Activity Level (PAL)** in the **Measured values** dialog window.

NOTE:

- If you do not enter waist circumference and PAL, the following modules will not be displayed in the **examination results** tab:
Cardiometabolic risk, Energy.
- If waist circumference is not yet available, you have the option of entering waist circumference in the **laboratory data** tab later. This must be done the same day as the weight and height measurement (see "Entering laboratory data" on page 40).
- If you click on the ? symbol next to the **Physical Activity Level (PAL)** line, a table of PAL values appears. If you click on a value, it will be adopted in the **Measured values** window.

Please enter the patient's activity level (PAL) to determine total energy expenditure:

PAL ?

ok cancel

PAL	Activity
≤ 1.2	almost exclusively lying down
1.4	almost exclusively sitting down
1.6	mainly sitting , occasionally standing
1.8	primarily standing or walking
≥ 2.0	physically demanding

cancel

- In the measured values window, click on **ok**.
The measuring procedure is complete.
The **examination results** tab is active.
The results of the examination can be evaluated.

Determining body composition with a seca mBCA

If you would like to determine a patient's body composition using a seca mBCA (bioimpedance measurement), you can send an open seca patient file to the desired seca mBCA. To do so, proceed as outlined below.

NOTE:

This function is only available if you have an Ethernet network connection available.

- Ensure that the desired seca mBCA is switched on.
- Open the seca patient file (see "Opening the seca patient file" on page 37) or create a seca patient file if necessary (see "Creating a new seca patient file" on page 27).
- In the title bar of the seca patient file, click on **measure**.



The **Measuring device selection** dialog window appears.

The screenshot shows a dialog box titled "Measuring device selection". It has two rows of input fields. The first row has "Weight:" and "Height:" labels, each followed by a dropdown menu currently set to "Manual". To the right of these are "measure" and "send patient file" buttons. The second row has a "Body composition" label followed by a dropdown menu that is open, showing "mBCA" selected. Below the dropdown are "send patient file" and "cancel" buttons.

4. In the **Measuring device selection** dialog window, select the desired seca mBCA in the **Body composition** line.
5. In the **Measuring device selection** dialog window, click on **Send patient file**.

This screenshot is similar to the previous one, but the "Body composition" dropdown menu is now closed and shows "mBCA". A mouse cursor is pointing at the "send patient file" button.

The seca patient file is passed to the selected seca mBCA where it appears in the **patient** tab.

6. Perform the bioimpedance measurement as described in the "Instructions for Use for Physicians and Assistants" for the seca mBCA.
7. Save the bioimpedance measurement on the seca mBCA as described in the "Instructions for Use for Physicians and Assistants" for the seca mBCA.

The seca patient file in the **seca 115** PC software is updated automatically.

The results can be assessed in the **examination results** tab of the **seca 115** PC software.

Assessing the examination results

On the **examination results** tab, you can view the evaluations of all measurements performed for the patient. In addition to weight and height, the evaluation also includes waist circumference and physical activity level, as well as medical history and laboratory data. If the values for a bioimpedance measurement are available, these are also taken into account. The results are displayed in evaluation modules.

NOTE:

This section describes how to use the **seca 115** PC software. For basic information about the medical content of the evaluation modules, see the section entitled “Medical basis” from page 60.

The following evaluation modules can be considered if weight, height, PAL and waist circumference are available for a patient.

- **Cardiometabolic risk**
- **Development/growth**
- **Energy**

The following evaluation modules can be considered in addition if data from a bioimpedance measurement are available:

- **Function/rehabilitation**
- **Fluid**
- **Health risk**
- **Raw data for impedance**

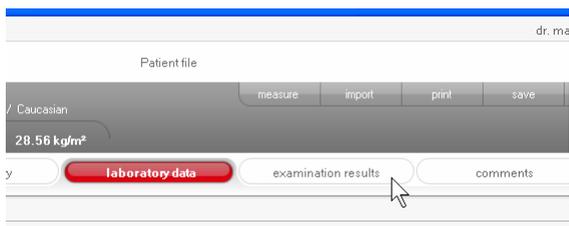
The principles behind bioimpedance measurement can be found in the “Medical basis” section of the “Instructions for Use for Physicians and Assistants” for the seca mBCA.

On the **examination results** tab you can also view the results for **User-specific modules**.

Viewing examination results

To view the evaluation modules, proceed as outlined below.

1. Click on **examination results**.
The **examination results** tab is active.



2. Click on the module you want displayed.

Cardiometabolic risk

Development / growth

Energy

Function / rehabilitation

- Click on the measurement you want displayed.



The evaluation of the measurement is displayed.
For some evaluations, a graphical display is provided.

The screenshot shows the 'seca analytics 115' application window. The patient file for Phillip Prenzlow (DOB: 01.04.1978, Caucasian) is open. The 'examination results' tab is selected, showing results for an examination on 19.12.2014 at 18:53. The 'Cardiometabolic risk' section is highlighted in red. The 'Body Mass Index' is 29.32 kg/m², accompanied by a weight-height graph. The 'Visceral adipose tissue (VAT)' section notes that no calculation is possible. The 'Metabolic syndrome' section states it is not present based on the 19.12.2014 data. The '10-year risk of coronary heart disease' is 4%.

seca analytics 115 | dr. madiba [Doctor] | Log out

Patient file

Prenzlow Philipp | 01.04.1978 / Caucasian | measure | import | print | save | close

Weight: 95.00 kg | Height: 1.800 m | BMI: 29.32 kg/m² | 19.12.2014 18:53

patient data | medical history | laboratory data | **examination results** | comments

Cardiometabolic risk

Development / growth

Energy

Function / rehabilitation

Fluid

Health risk

Raw data for impedance

Measurements

- 19.12.2014
- 18.12.2014
- 17.12.2014
- 20.06.2012

Results of examination dated 19.12.2014 18:53

Body Mass Index:
29.32 kg/m²

Weight (kg) vs Height (m) graph showing a red line for the patient's weight and a shaded area for the reference range.

Visceral adipose tissue (VAT)
No calculation possible. Please perform bioimpedance measurement.

Metabolic syndrome
Based on the examination data of 19.12.2014, metabolic syndrome is not present.

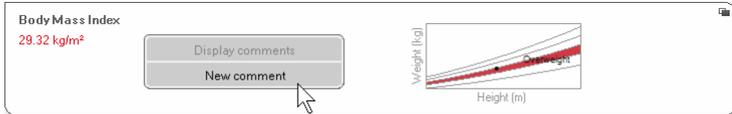
10-year risk of coronary heart disease
4%

Wilson et al. 1998

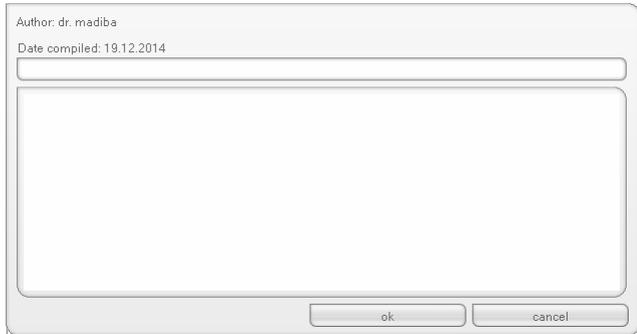
Adding a comment to an evaluation parameter

You can add a comment to every evaluation parameter shown.

1. Right-click in a results graph.
A context menu appears.



2. Click on **New comment**.
The comments window opens.



The date and time are entered automatically.

3. Enter a **subject**.
4. Enter your comment in the comments field.
5. Click on **ok** in the comments field.
The comments field closes.



The comment symbol appears in the results graph.

Viewing comments on an evaluation parameter



If the comment symbol is shown in the results graph of an evaluation parameter, there is at least one comment.

1. Right-click in a results graph.
A context menu appears.



2. Click on **Display comments**.
The comments list opens.

Body Mass Index

Measurement from:	Date compiled:	Author:	Comment:
19.12.2014	19.12.2014 18:54:01	dr. madiba	Kommentar 2 Kommentar 2
19.12.2014	19.12.2014 18:54:00	dr. madiba	Kommentar 1 Kommentar 1

close

All the comments on that evaluation parameter are displayed.

3. To exit the comments list, click on **close**.

Deleting comments on evaluation parameters

You can delete comments on the evaluation parameters.

1. Open the comments list as described in the section entitled “Viewing comments on an evaluation parameter” on page 51.
2. Right-click on the comment you want to delete.

Body Mass Index

Measurement from:	Date compiled:	Author:	Comment:
19.12.2014	19.12.2014 18:54:01	dr. madiba	Kommentar 2 Kommentar 2
19.12.2014	19.12.2014 18:54:00	dr. madiba	Kommentar 1 Kommentar 1

delete

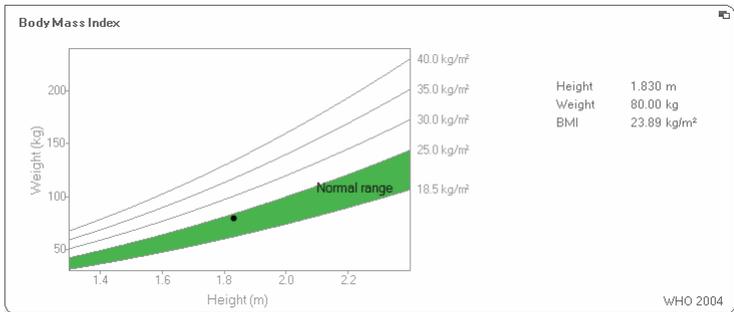
- The **delete** button appears.
- Click on the **delete** button.
The measurement is deleted.

Displaying results graphs enlarged



The results graphs can be displayed enlarged if the window symbol appears in the graph. The enlarged displays contain additional details which enable you to assess your patient's state of health better.

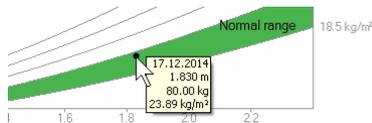
- Click on a graph to have it displayed enlarged and with details (in this case, BMI).



- Click on the graph again to shrink it back to its original size.

NOTE:

If you position the mouse pointer on a measurement point in the graph, the associated measured values will be displayed.



Viewing the history

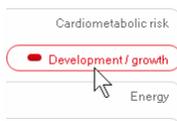
You can view a patient's history by selecting several measurements. Measured results and evaluations are then displayed in progression graphs.

NOTE:

This function is not available in the **Cardiometabolic risk** and **Raw data for impedance** modules, as in these modules, a progression display is not relevant for assessing a patient's state of health.

Proceed as outlined below to select measurements for the history.

1. Click on the **examination results** tab.
2. Click on the module you want displayed.
The module is displayed in a selection bar.



3. Click on a measurement you wish to select.
The measurement is displayed on a selection bar.



4. While holding down the left mouse button, drag the selection bar across all the other measurements you want to view as a history (in this case, left handle upwards).



The individual parameters of the module will be displayed as progression graphs.

seca analytics 115

File Edit Extras ?

dr. madiba [Doctor] Log out

seca

Patient file

measure input print save close

Prenzlow Philipp ♂ 01.04.1978 / Caucasian

Weight: 95.00 kg Height: 1.800 m BMI: 29.32 kg/m² 19.12.2014 18:54

patient data medical history laboratory data **examination results** comments

Cardiometabolic risk

Development/growth

Energy

Function / rehabilitation

Fluid

Health risk

Raw data for impedance

Measurements

19.12.2014

18.12.2014

17.12.2014

20.06.2012

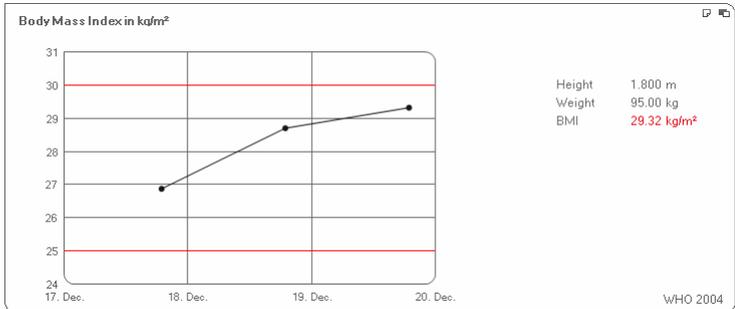
Results of examination dated 17.12.2014 18:53 to 19.12.2014 18:53

Weight in kg
95.00 kg

Height in m
1.800 m

Body Mass Index in kg/m²
29.32 kg/m²

- Click on a graph to have it displayed enlarged and with details (in this case, BMI).



- Click on the graph again to shrink it back to its original size.

Using the therapy planner (Energy module only)

If the patient's resting energy expenditure and total energy expenditure are known, you can calculate the recommended daily energy intake for the patient in order to achieve a target weight within a defined time (duration of therapy).

The **seca 115** PC software can calculate resting energy expenditure (REE) if the following parameters are entered or have been measured: age, gender, weight and height. Total energy expenditure (TEE) can be calculated if the physical activity level (PAL) has also been entered.

1. In the **Energy** module, click on **Therapy planner**.

Therapy tool

Treatment objective: BMI in kg/m² ▼

Duration of treatment in days:

Recommended energy intake in [kcal/day]:

close

2. Enter the value and type of the therapy objective.
3. Enter the therapy duration in days.
The recommended daily energy intake is calculated.

Therapy tool

Treatment objective: BMI in kg/m² ▼

Duration of treatment in days:

Recommended energy intake in [kcal/day]:

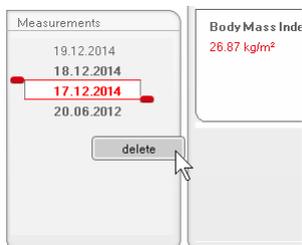
close

4. To save settings in the **Therapy planner**, click on **close**.

Deleting measurements

You can delete individual measurements. To do so, proceed as outlined below.

1. Right-click on the measurement you want to delete.
The **delete** button appears.
2. Left-click on the **delete** button.
The measurement is deleted.



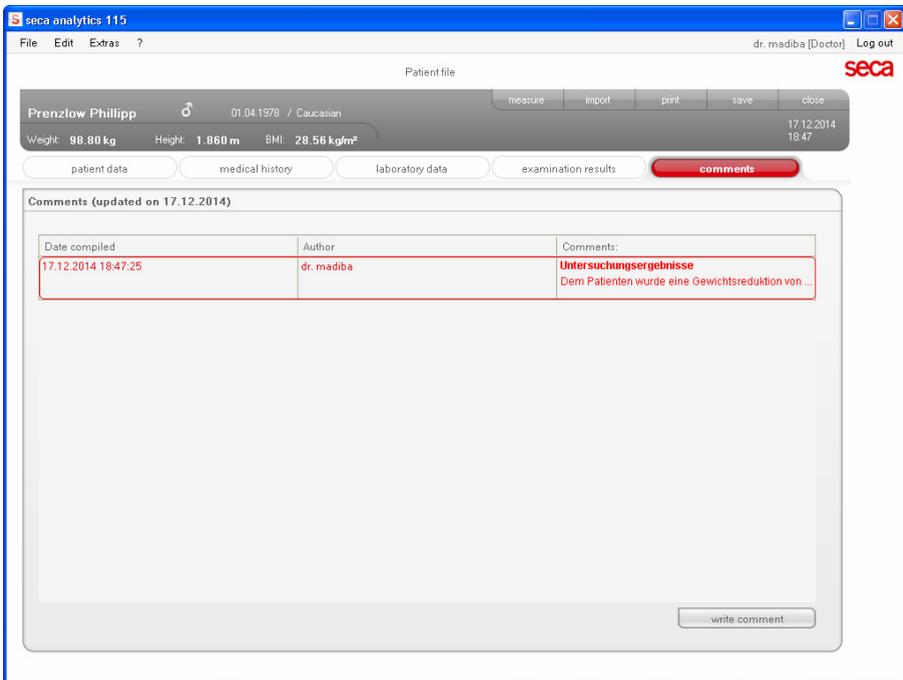
Writing comments

On the **comments** tab, you can add comments to the seca patient file.

1. Click on **comments**.



The **comments** tab is active.



2. Click on **Writing comments**.
The comments window opens.



The date and time are entered automatically.

NOTE:

Comments can be neither deleted nor subsequently edited in the **comments** tab.

3. Enter a **subject**.
4. Enter your comment in the comments field.
5. Click on **ok** in the comments field.
The comments field closes.
The comment appears as the top entry in the comments list.

5.5 Managing a seca patient file

Printing a seca patient file

In the **print** dialog, you can save all the results of a measurement in the form of a PDF file. You can print out the PDF file using a PDF viewer such as Adobe Reader.

NOTE:

If you do not have a PDF viewer installed on your computer, contact your administrator.

1. Open the seca patient file.
2. In the seca patient file, click on **print**.
The **print** dialog window appears.





3. Specify the scope of the printout:
 - no selection: results graphs for all parameters without further explanations
 - **patient**: results graphs for all parameters with explanations for the patient
 - **table**: all parameters in tabular form
4. Click on **ok** to save the evaluation in the form of a PDF file.

The PDF file created is automatically displayed in the PDF viewer.
5. Use the print dialog of the PDF viewer to print out the PDF file.

Importing a patient file

If an interface to your patient data management system (PDMS) has been configured for the **seca 115** PC software, you can import patient files from the PDMS.

The import will work differently depending on the configuration of the interface. As an example, the import may run as described in this section.

NOTE:

If you are uncertain of whether an interface has been configured and how the import works on your system, please contact your administrator.

1. In the seca patient list, click on **new**.

An empty seca patient file appears.
The **patient data** tab is active.

seca analytics 11.5

File Edit Extras ?

dr. madiba [Doctor] Log out

seca

Patient file

measure import print save close

Weight: Height: BMI: 17.12.2014 18:46

patient data medical history laboratory data examination results comments

General patient data (updated on -)

Name

Title:

Name:

First name:

Name suffix:

General data

Date of birth: *

Gender: *

Ethnicity: *

Specific data

Patient ID: *

Supervising doctor:

Contact

Street:

House no.:

Postcode:

Town:

County:

Country:

E-mail:

Telephone 1:

Telephone 2:

Telephone 3:

Comments

- In the **Patient ID** field, enter the ID under which the patient file is managed in your PDMS.
- Click on **import**.
The patient data are imported.



6. MEDICAL BASIS

This section briefly describes the content of the preset evaluation modules in this **seca 115** PC software, together with their medical objectives. The references on which the evaluations are based will also be introduced.

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

6.1 Evaluation modules

The evaluation modules described below are preset in this **seca 115** PC software and will assist you in assessing your patients' state of health.

For information about how to access the evaluation modules and navigate within them, see “Assessing the examination results” from page 47.

The following evaluation modules can be considered if weight, height, PAL and waist circumference are available for a patient.

- **Cardiometabolic risk**
- **Development/growth**
- **Energy**

The following evaluation modules can be considered in addition if data from a bioimpedance analysis are available for the patient:

- **Function/rehabilitation**
- **Fluid**
- **Health risk**
- **Raw data for impedance**

The principles behind bioimpedance analysis can be found in the “Medical basis” section of the “Instructions for Use for Physicians and Assistants” for the seca mBCA.

Cardiometabolic risk

This module indicates whether metabolic syndrome is present and the level of the 10-year risk for coronary heart disease.

NOTE:

The **Cardiometabolic risk** module is only available if a seca patient file has been created for a patient and the laboratory data and waist circumference have been entered no later than the day weight and height were measured (see “Entering laboratory data” on page 40).

No bioimpedance analysis is required for this module. The following parameters are displayed:

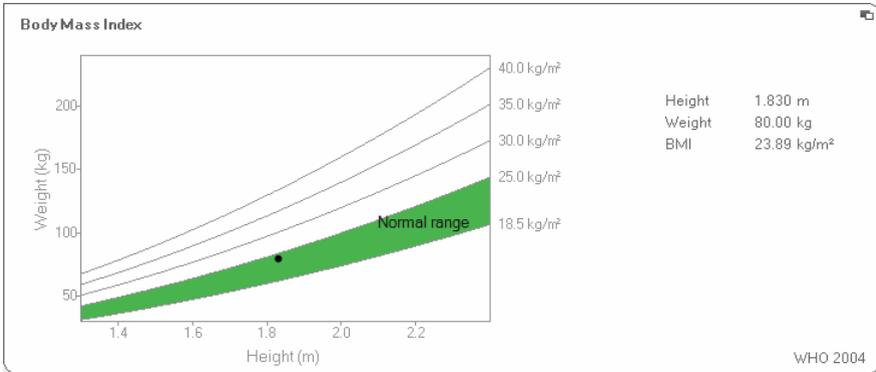
- body mass index (BMI)
- waist circumference (WC)
- metabolic syndrome (MSX)
- 10-year risk for coronary heart disease

The screenshot shows the 'seca analytics 115' software interface. At the top, it displays the patient name 'Prenzlöw Phillip', gender '♂', date of birth '01.04.1978', and ethnicity 'Caucasian'. The current examination date is '19.12.2014 18:53'. The patient's weight is '95.00 kg', height is '1.800 m', and BMI is '29.32 kg/m²'. The interface is divided into several sections:

- Navigation:** 'patient data', 'medical history', 'laboratory data', 'examination results' (highlighted), and 'comments'.
- Cardiometabolic risk:** A red indicator shows this module is active.
- Development / growth:** Includes 'Energy', 'Function / rehabilitation', 'Fluid', 'Health risk', and 'Raw data for impedance'.
- Measurements:** A list of dates with '19.12.2014' highlighted in red.
- Results of examination dated 19.12.2014 18:53:**
 - Body Mass Index:** 29.32 kg/m². Includes a graph of Weight (kg) vs Height (m) with a red trend line.
 - Visceral adipose tissue (VAT):** No calculation possible. Please perform bioimpedance measurement.
 - Metabolic syndrome:** Based on the examination data of 19.12.2014, metabolic syndrome is not present. Includes a grid with a red cell.
 - 10-year risk of coronary heart disease:** 4%. Includes a grid and the citation 'Wilson et al. 1998'.

Detail views are available for the following parameters:

Detail view, body mass index



Detail view, visceral adipose tissue (VAT)



Detail view, metabolic syndrome

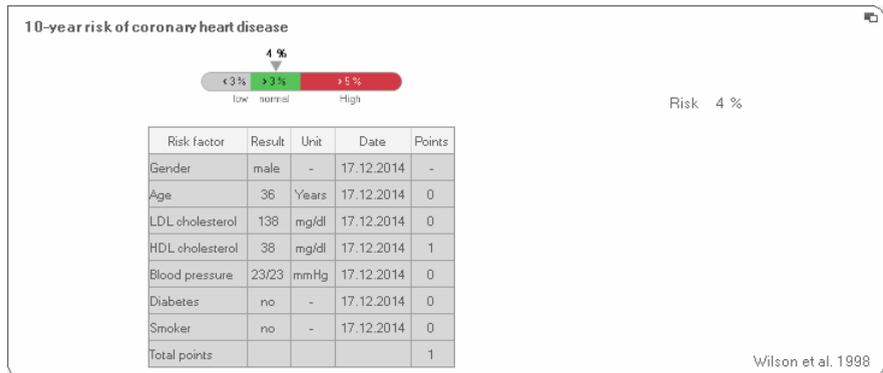
Síndrome metabólico

Sobre la base de los datos de exploración del 15.12.2014 no existe síndrome metabólico.

Factor de riesgo	Valor límite	Resultado	Unidad	Terapia específica	Fecha
Circunferencia de cintura	>=0.940	0.900	m		15.12.2014
Triglicéridos	>=150	112	mg/dl	no	15.12.2014
Colesterol HDL	<40	38	mg/dl	no	15.12.2014
Presión arterial	>=130 / >=85	23 / 23	mmHg	no	15.12.2014
Glucemia en ayunas	>=100	88	mg/dl		15.12.2014
Diabetes tipo 2		no			15.12.2014

IDF 2006

Detail view, 10-year risk of coronary heart disease for the age group 30-74 years



Development/growth

This module indicates both the weight and height of a person and automatically calculates the BMI. This allows weight changes to be monitored in both children and adults.

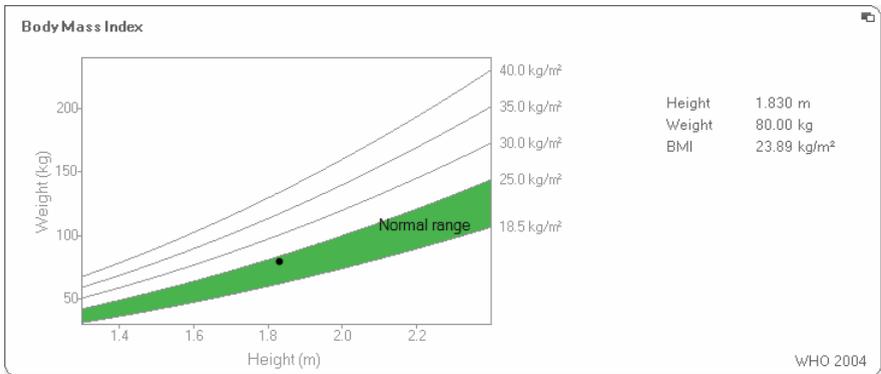
In children, this module assists with regular checks to assess growth and development.

No bioimpedance analysis is required for this module. The following parameters are displayed:

- weight
- height
- body mass index (BMI)

The screenshot displays the 'seca analytics 115' software interface. At the top, the patient name 'Prenzlau Philipp' and date of birth '01.04.1978 / Caucasian' are shown. The current examination date is '19.12.2014 18:53'. The patient's weight is 95.00 kg, height is 1.800 m, and BMI is 29.32 kg/m². The interface includes a sidebar with categories like 'Cardiometabolic risk', 'Energy', 'Function / rehabilitation', 'Fluid', 'Health risk', and 'Raw data for impedance'. The 'Development / growth' category is selected. The main area shows 'Results of examination dated 19.12.2014 18:53' with fields for Weight (95.00 kg), Height (1.800 m), and Body Mass Index (29.32 kg/m²). A graph plots Weight (kg) against Height (m) with a red line indicating the current weight and a shaded area representing the range.

A detail view is available for the BMI:



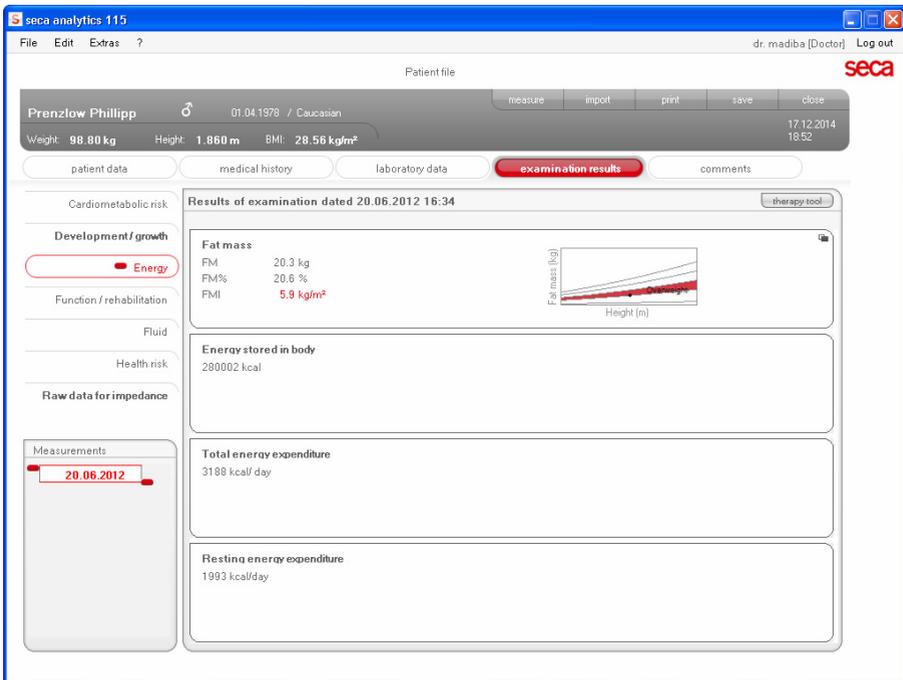
Energy

The aim of this module is to determine a person's energy expenditure and energy reserves. The following parameters are displayed:

- fat mass (FM)
- fat mass index (FMI)
- energy stored in the body (E_{body})
- resting energy expenditure (REE)
- total energy expenditure (TEE)

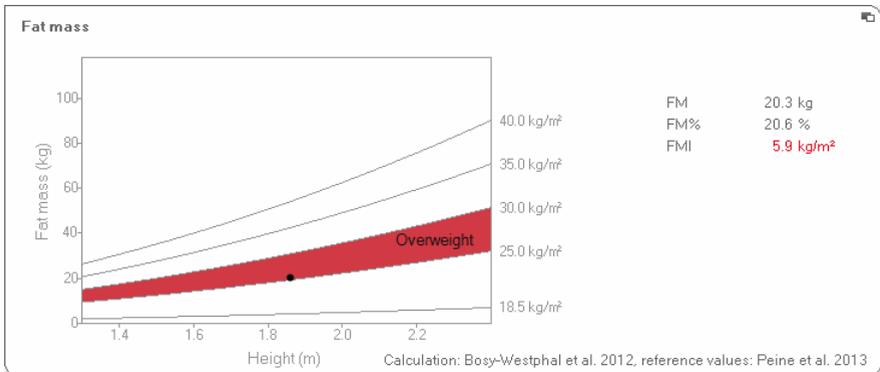
The parameter resting energy expenditure (REE) is available without bioimpedance analysis. REE is determined with the aid of the parameters height and weight, and with the aid of automatic BMI calculation.

For all other parameters in this module, a bioimpedance analysis is required in addition to height and weight.



A detail view and a therapy planner are available for this module:

Fat mass



Therapy planner

The **Energy** module serves as a basis for dietary advice. The therapy planner of the module assists you in this. You can use the therapy planner to specify the following values:

- treatment objective: weight change or BMI change
- duration of treatment in days

From these values, the planner calculates recommended daily energy intake.

Therapy tool

Treatment objective: BMI in kg/m² ▾

Duration of treatment in days:

Recommended energy intake in [kcal/day]:

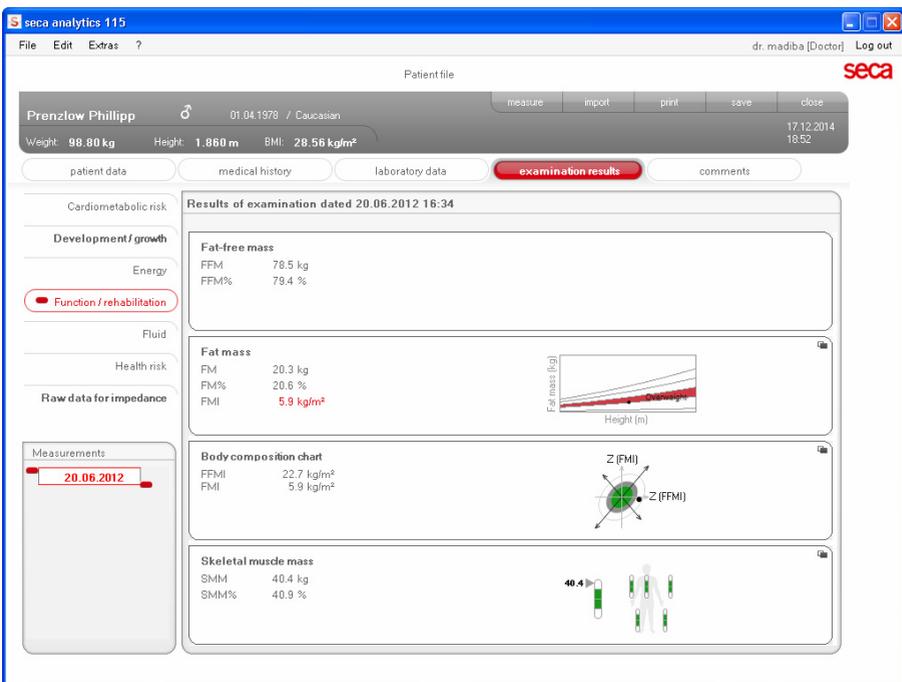
No detail views are available in this module.

Function/rehabilitation

This module is for determining a person's level of fitness. This allows the success of a training regime to be assessed.

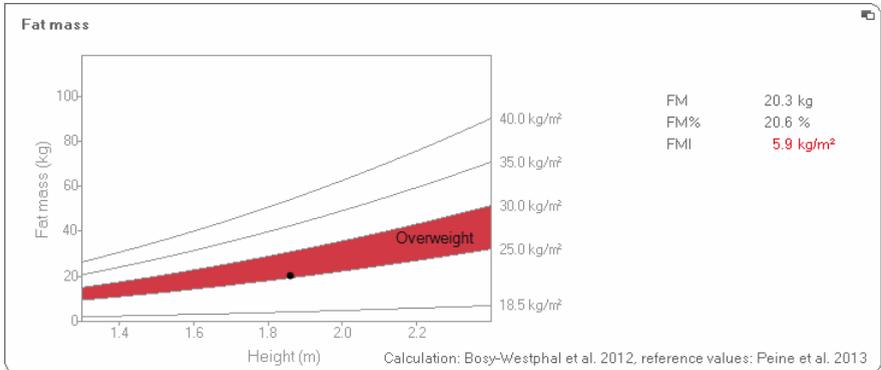
The parameters height and weight, as well as a bio-impedance analysis, are required for this module. The following parameters are displayed:

- fat-free mass (FFM)
- fat mass (FM) in kg
- fat mass (FM) in %
- fat mass index (FMI)
- fat-free mass index (FFMI)
- skeletal muscle mass (SMM)

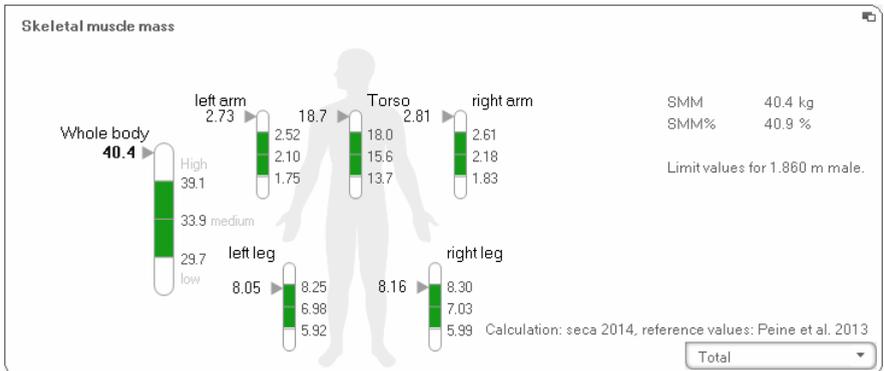


The following detail views are available for this module:

Display of normal fat mass range for adults



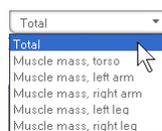
Skeletal muscle mass



For this parameter, you can have the following additional information displayed for each part of the body:

- skeletal muscle mass (SMM) in kg
- skeletal muscle mass (SMM) in percent
- height and gender as a reference for the limit values used

1. Click on the drop-down menu
The drop-down menu opens.



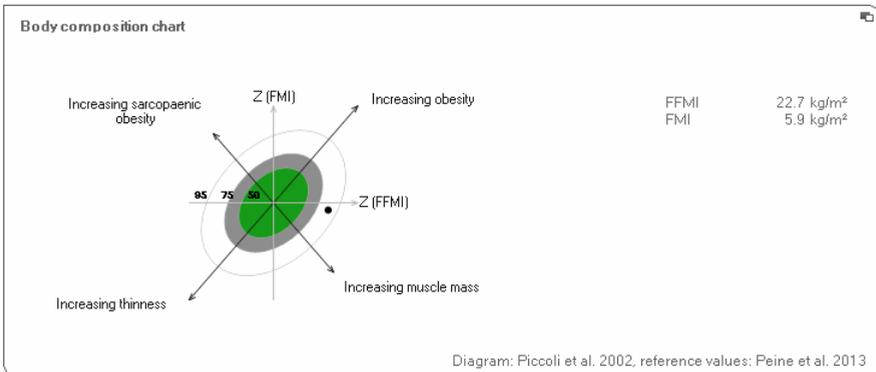
2. Click on the desired part of the body.

SMM 40.4 kg
SMM% 40.9 %

Limit values for 1.860 m male.

The additional information for the selected part of the body is displayed.

Body composition chart (mass indices)



Fluid This module allows a person's fluids status to be determined.

The parameters height and weight, as well as a bio-impedance analysis, are required for this module. The following parameters are displayed:

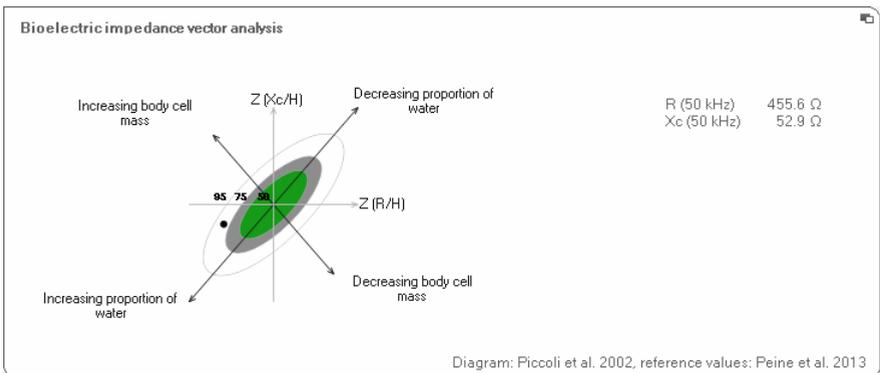
- total body water (TBW)
- extracellular water (ECW)
- hydration (HYD);
 $HYD = (100 \times ECW) / (TBW - ECW) [\%]$
- bioimpedance vector analysis (BIVA)

The screenshot shows the 'seca analytics 115' software interface. At the top, it displays 'Patient file' for 'Prenzlow Phillip' (DOB: 01.04.1978, Caucasion). Patient data includes Weight: 98.80 kg, Height: 1.860 m, and BMI: 28.56 kg/m². The interface is divided into several sections:

- Navigation:** patient data, medical history, laboratory data, **examination results** (highlighted), comments.
- Cardiometabolic risk:** A sidebar menu with options: Development/growth, Energy, Function/rehabilitation, **Fluid** (selected), Health risk, Raw data for impedance.
- Measurements:** A calendar view showing a measurement on 20.06.2012.
- Results of examination dated 20.06.2012 16:34:**
 - Total body water:** 58.2 l (59%), with a gauge showing a range from 23 to 35l.
 - Extracellular water:** 22.9 l (23%).
 - Hydration:** HYD = TBW / ECW = 22.9l / 35.3l = 65.0 %.
 - Bioelectric impedance vector analysis:** R (50 kHz) 455.6 Ω, Xc (50 kHz) 52.9 Ω. Includes a vector diagram with axes Z (Xc/H) and Z (R/H).

The following detail view is available for this module:

Bioimpedance vector analysis

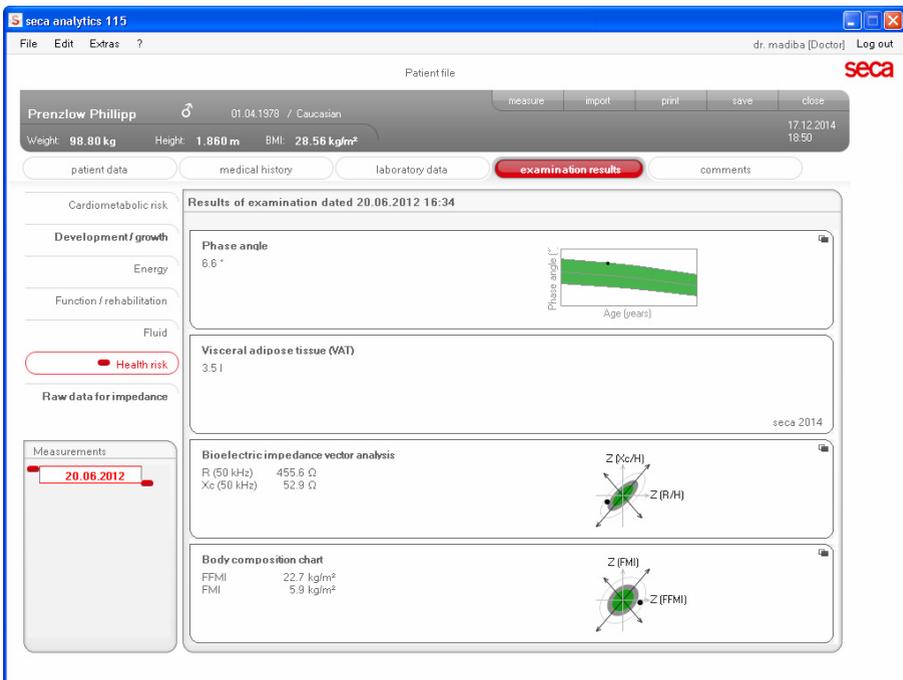


Health risk

The aim of this module is to provide an overview of body composition and to compare the results with values for healthy people. A body composition which deviates from the normal range is an indicator which can be used to assess the risk to health. The goal is to determine the general state of health or, in the case of a previously known disease, assess its severity.

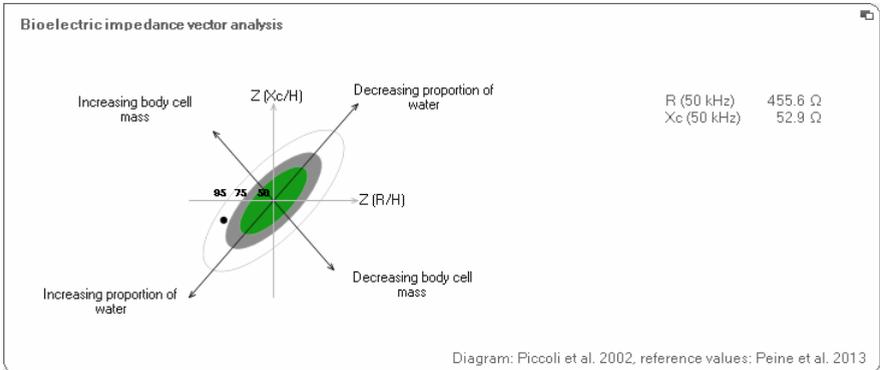
The parameters height and weight, as well as a bioimpedance analysis, are required for this module. The following parameters are displayed:

- phase angle (ϕ)
- visceral adipose tissue (VAT)
- bioimpedance vector analysis (BIVA)
- fat mass index (FMI)
- fat-free mass index (FFMI)

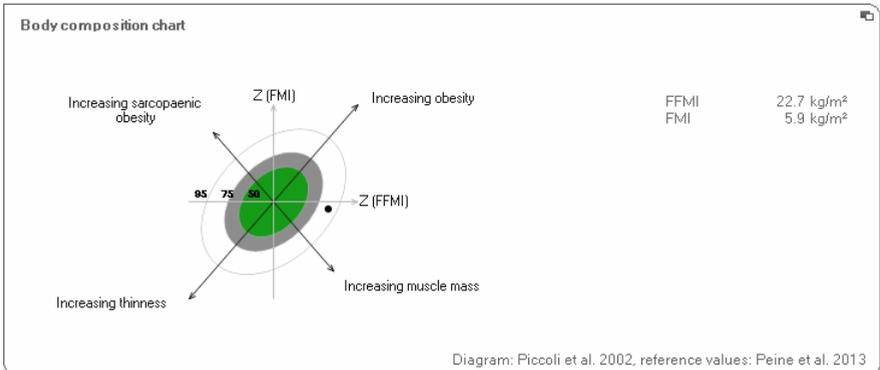


The following detail views are available for this module:

Bioimpedance vector analysis



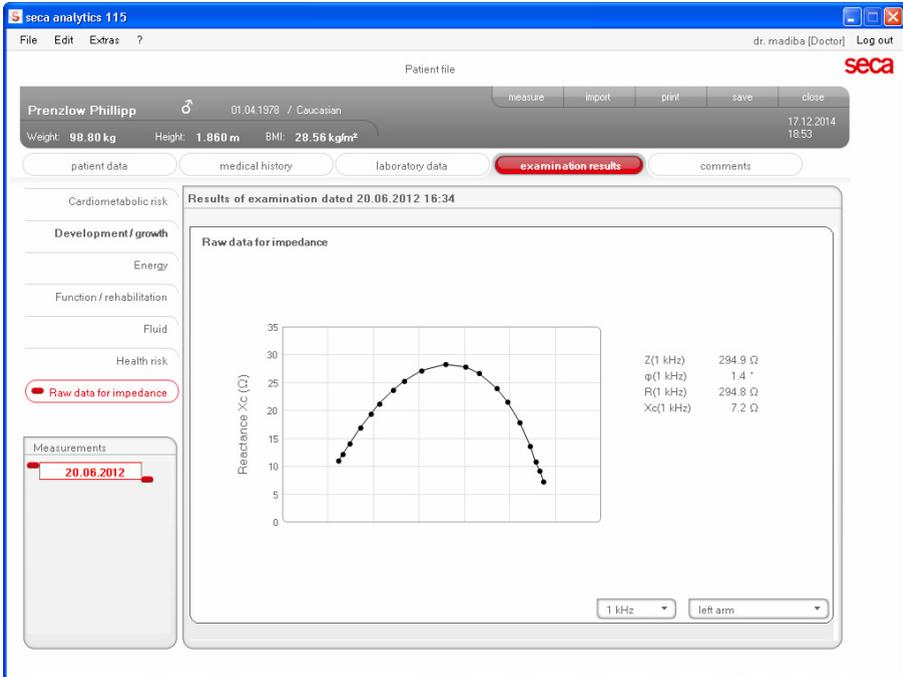
Body composition chart (mass indices)



Raw data for impedance

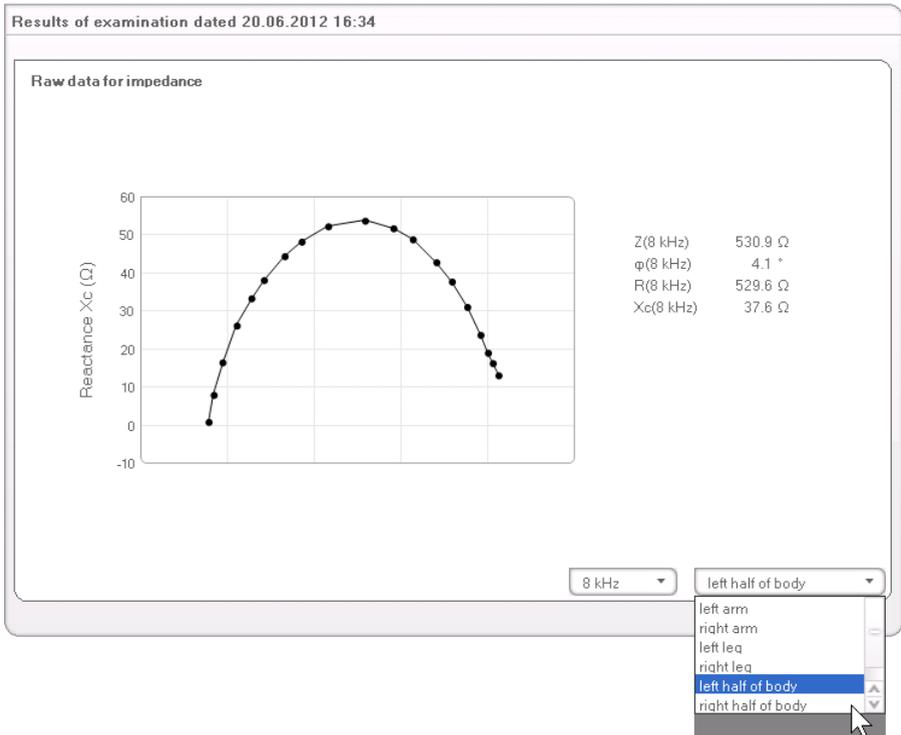
This module shows detailed raw data for resistance (R), reactance (X_c), impedance (Z) and phase angle (ϕ) for information purposes.

You can also view impedance (Z), reactance (X_c), resistance (R) and phase angle (ϕ) for individual parts of the body and frequencies.



Selecting the part of the body

1. Click on the drop-down menu to select the part of the body.

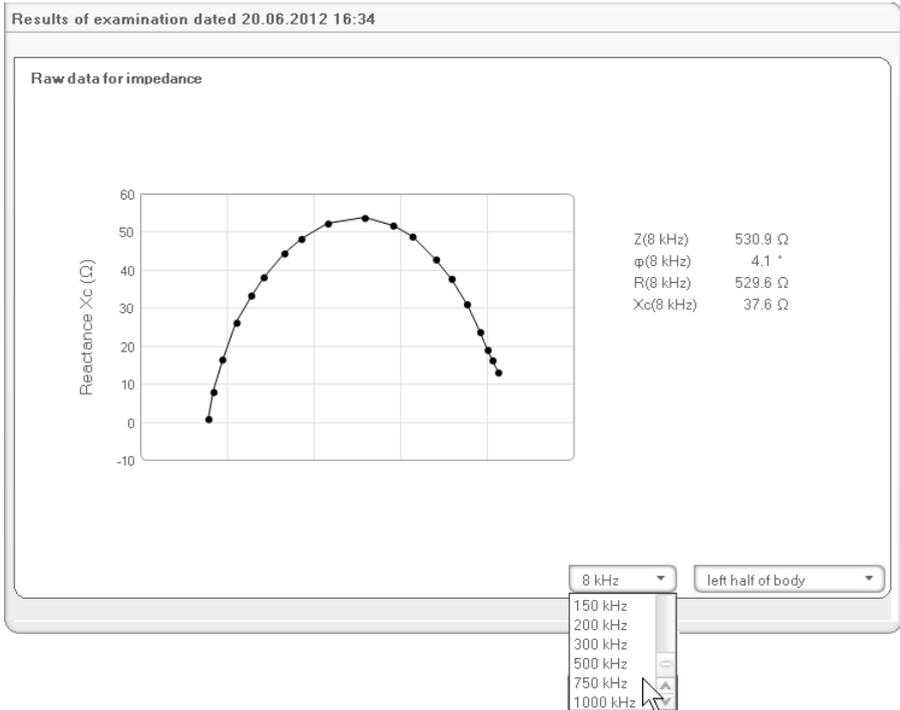


The drop-down menu opens.

2. Click on the desired part of the body.
3. The values for the selected part of the body are displayed.

Selecting frequency

1. Click on the drop-down menu to select the frequency.



- The drop-down menu opens.
2. Click on the desired frequency.

NOTE:

If the **Raw data for impedance** module on the mBCA was not activated, only four frequencies will be available to choose from.

3. The values for the selected frequency are displayed.

6.2 References

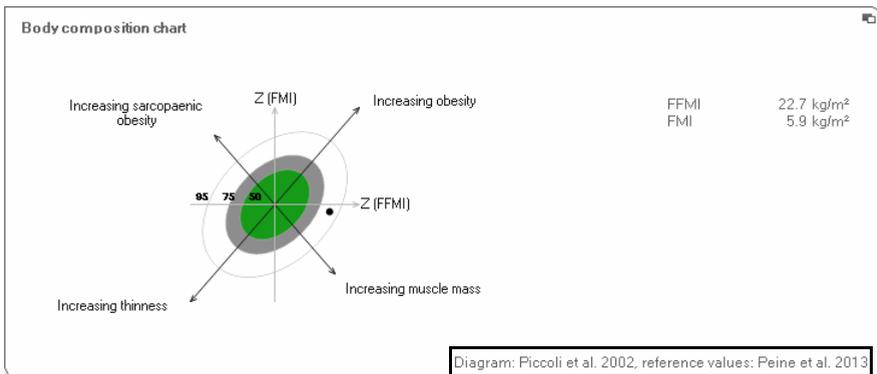
Bioimpedance analysis using a seca medical Body Composition Analyzer is scientifically based on clinical studies. The results of the clinical studies are stored as references in the seca mBCA and in the **seca 115 PC** software and form the basis for assessing your patients' state of health

For some evaluation parameters (e.g. waist circumference for children), the reference used depends on the patient's ethnicity. The device automatically uses ethnicity-dependent references to suit the corresponding entry in the seca patient file (see "Creating a new seca patient file" on page 27).

Which references you use depends on the country in which you are operating, the regulations applying in your institution and your personal preferences.

For information about how to set the references in this **seca 115 PC** software, see "Changing references" from page 18.

The evaluation module in question indicates which clinical study is being used as a reference for determining and assessing an evaluation parameter, e.g. "Peine et al. 2013".



Reference used

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

7. TECHNICAL INFORMATION

7.1 Technical modifications

Combination of seca mBCA seca 515/514 (SW version 1.1) and seca 115 (SW version 1.4)	
Downward-compatible?	No
seca patient database	Existing seca patient database is adopted in the current version of the PC software; no further access is then possible using older versions of the PC software
New	<ul style="list-style-type: none"> • Regional settings: “Name format” drop-down menu • Enter waist circumference with “Health risk” evaluation module activated (seca mBCA only) • Visceral fat (VAT) parameter in the “Health risk” evaluation module • Skeletal muscle mass (SMM) parameter in the “Function/ rehabilitation” evaluation module • In evaluation modules: comments function for every evaluation parameter • Send individual secaseca patient file from the seca 115 PC software to a seca mBCA • Initiate a printout of results reports directly on the seca mBCA
Modified	Graphical representation: phase angle (ϕ), bioimpedance vector analysis (BIVA), body composition chart (BCC), total body water (TBW)
No longer applicable	Lean soft tissue mass (LST) parameter in the “Function/ rehabilitation” evaluation module

7.2 Display of weight values

The **seca 115** PC software displays the weight values it receives only in the unit set in the PC software. If the setting on the transmitting device is different, the weight values will be converted automatically. Details are in the table below.

seca 115 PC software setting	seca device setting	seca 115 display	
		Weight ≤ 20 kg	Weight > 20 kg
kg	kg	kkk.ggg	kkk.gg
	lbs		
	sts		
	-	kkk.gg ¹⁾	
lbs	kg	ppp:oo.o	ppp.p
	lbs		
	sts		
	-	ppp.p ¹⁾	
sts	kg	s;pp:oo.o	ss;pp.p
	lbs		
	sts		
	-	ss;pp.p ¹⁾	

¹⁾ Manual entry of measured values directly in the PC software **seca 115**

8. WARRANTY

Please note that this PC software is subject to restrictions on the warranty which may arise in conjunction with the license, for example. The warranty restrictions can be called up at www.seca.com.



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
Atbilstības apliecinājums
Oświadczenie o zgodności
Izjava o skladnosti
Vyhlásenie o zhode
Onay belgesi

Die Software
The software
Le logiciel
Il software
El software
Softwaren
Programvaran
Programvaren
Ohjelmisto
De software
O software
Το λογισμικό
Software
Tarkvara
A szoftver
Programinè jřanga
Programatūra
Oprogramowanie
Programska oprema
Softvér
Yazılımı

seca 115

- D** ... erfüllt die geltenden Anforderungen folgender Richtlinien:
93/42/EWG über Medizinprodukte.
- GB** ... complies with the requirements of the following Directives:
93/42/EEC governing medical devices.
- F** ... satisfait aux exigences en vigueur figurant dans les directives suivantes :
93/42/CEE relatives aux dispositifs médicaux.
- I** ... risponde ai requisiti prescritti dalle direttive seguenti:
93/42/CEE in materia di prodotti medicali.
- E** ... cumple las exigencias vigentes de las siguientes directivas:
93/42/CEE sobre productos sanitarios.
- DK** ... opfylder de grundlæggende krav fra følgende direktiver:
93/42/EØF om medicinprodukter.
- GR** ... εκπληρώνει τις ισχύουσες απαιτήσεις των ακόλουθων οδηγιών:
93/42/EOK περί ιατροτεχνολογικών προϊόντων.
- CZ** ... splňuje platné požadavky těchto směrnic:
93/42/EHS o zdravotnických prostředcích:
- EST** ... vastab järgmiste direktiividega kehtestatud nõuetele:
meditsiinitoodete direktiivid 93/42/EMÜ
- HU** ... teljesíti a következő irányelvek érvényben lévő köve telményeit:
93/42/EGK irányelv az orvostechnikai termékekről.
- LT** ...atitinka tokias galiojančias direktyvas:
93/42/EEB ir medicinos prietaisų.
- LV** ... atbilst šādu direktīvu spēkā esošajām prasībām:
93/42/EEK par medicīnas ierīcēm.
- S** ... oppfyller gällande krav enligt följande direktiv:
93/42/EEG om medicintekniska produkter.
- N** ... oppfyller gjeldende krav i følgende direktiver:
93/42/EØF om medisinske produkter.
- FIN** ... täyttää seuraavien direktiivien voimassa olevat mää-
rökset:
93/42/EY lääkinnälliset laitteet.
- NL** ...is in overeenstemming met de geldende eisen van de
volgende richtlijnen:
93/42/EEG betreffende medische hulpmiddelen.
- P** ... cumpre os requisitos essenciais das seguintes
Directivas:
93/42/CEE relativa a dispositivos médicos:
- PL** ...spełnia obowiązujące wymagania następujących
dyrektyw:
93/42/EWG o wyrobach medycznych.
- SLO** ... izpolnjuje veljavne zahteve naslednjih direktiv:
93/42/EGS o medicinskih pripomočkih.
- SK** ...splňa platné požiadavky nasledujúcich smerníc:
smernice 93/42/EHS o medicínskych výrobkoch.
- TR** ... aşağıdaki yönergelerin geçerli talimatlarını yerine
getirir:
tıbbi ürünler hakkında 93/42/AET yönetmeliği.

Hamburg; February 2014



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