

# **seca 115**

**Instructions for use  
for Physicians  
and Assistants**

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# 1. SYSTEM DESCRIPTION

## 1.1 Congratulations!

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With the **seca 115** seca software you have acquired a product from the **seca 360° wireless** system that assists 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

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The **seca 115** software is used according to the national regulations, primarily in hospitals, physicians' practices, and inpatient care institutions.

The **seca 115** software is used to manage weight, height and bioelectric impedance measurements as well as for the automatic calculation of parameters derived from such measurements, e.g. FMI (fat mass index). Results are displayed graphically and assist the treating doctor with the following medical aspects:

- Monitoring of growth processes and weight changes
- Determination of the energy expenditure and energy reserves for the assessment of weight changes, the course of illnesses and the provision of advice about diet
- Estimation of the cardiometabolic risk
- Assessment of metabolic activity and the degree of success for a training programme, e.g. in the framework of rehabilitation or physiotherapy.
- Determination of the fluids status of a patient and the observation of changes in fluids as the result of medical treatment.
- Determination of the patient's general state of health or, in the case of a known disease, assessment of its severity.

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

## 1.3 User qualification

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The **seca 115** software may only be used by people with sufficient professional knowledge.

## 1.4 Data transmission measuring devices

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The seca medical body composition analyzer (mbca) allows data to be transmitted wirelessly to the PC. The **seca 360° wireless USB adapter 456** included in the mbca's scope of supply is required for this purpose. Alternatively, data can be transmitted to the PC via an Ethernet network connection (recommended for fast data transmission) or using a USB flash memory stick.

Weight and length measuring devices from the **seca 360° wireless** system can transmit measured results wirelessly to the PC. As an accessory, the **seca 360° wireless USB adapter 456** is required for this.

seca scales and height measuring equipment with RS232 interface can transmit measurements to the PC through a wire.

## 2. SAFETY INFORMATION

### 2.1 Basic safety information

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#### Handling of the software

- Note the warnings in the instructions for use.
- Keep these instructions for use and the declaration of conformity that they contain in a safe place.
- The **seca 115** software is **not** diagnostic software. The software assists the treating doctor with creating a diagnosis. For the creation of a precise diagnosis and for the initiation of therapies, in addition to the use of the **seca 115** software, careful examinations must be conducted by the treating doctor and the results of these taken into consideration. The responsibility for diagnoses and the therapies derived from them lies with the treating doctor.
- Use **seca 115** only for the prescribed purpose.
- Use only scales and length measuring devices from seca together with the **seca 115** software.
- Keep HF devices such as mobile telephones and TVs at least 1 meter away in order to prevent mistaken measurements and disturbances during the wireless transmission.

#### Handling measured results

- Before you save and re-use measured values in the **seca 115** 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** software to a hospital information system, make sure before re-use that the measured values are plausible and assigned to the correct patient.

## 2.2 Safety information in these instructions for use

---

**DANGER!**

Indicates an exceptionally dangerous situation. If you do not heed this warning, severe irreversible or life-threatening injuries may result.

**WARNING!**

Indicates an exceptionally dangerous situation. If you do not heed this warning, severe irreversible or life-threatening injuries may result.

**CAUTION!**

Indicates a dangerous situation. If you do not heed this warning, slight to medium injuries may result.

**WARNING!**

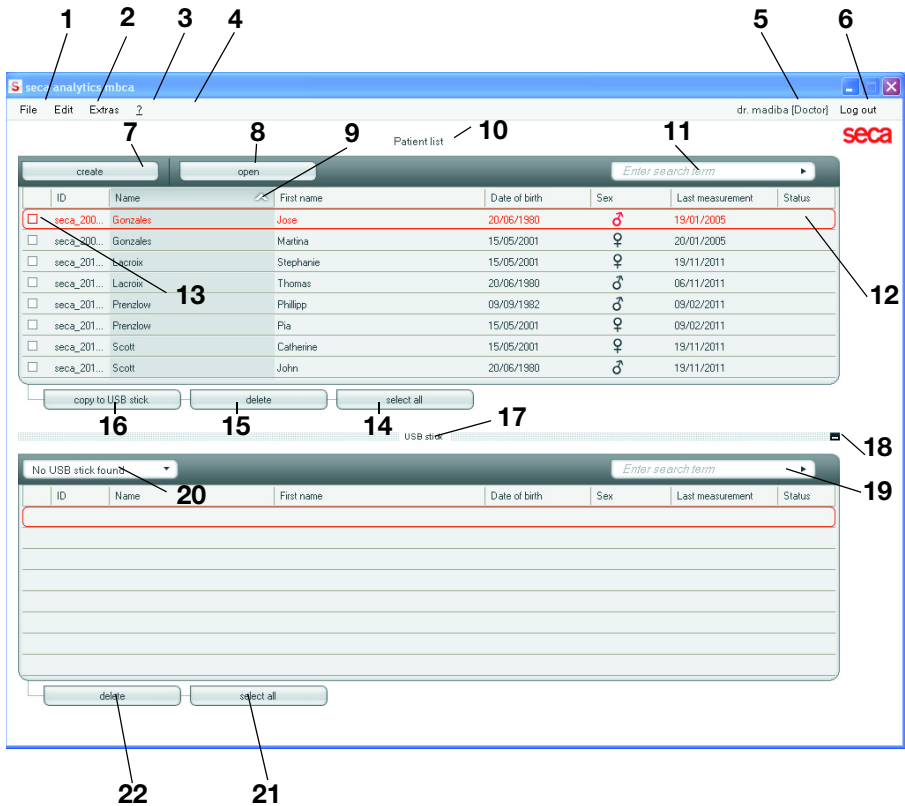
Indicates a possible mistaken operation of the product. If you do not heed this warning, device damage or incorrect measured results may result.

**NOTE:**

Contains additional information about the application of this product.

# 3. OVERVIEW

## 3.1 Patient list



No.	Operating element	Function
1	File	The following functions can be accessed using this menu element: <ul style="list-style-type: none"> <li>• CSV export</li> <li>• Exit</li> </ul>
2	Edit	The following functions can be accessed using this menu element (only with an open patient file): <ul style="list-style-type: none"> <li>• Cut</li> <li>• Copy</li> <li>• Paste</li> </ul> Also as a context menu via right mouse-click



No.	Operating element	Function
3	Extras	The following functions can be accessed using this menu element: <ul style="list-style-type: none"> <li>• <b>References</b></li> <li>• <b>User-specific modules</b></li> <li>• <b>Measuring device administration</b></li> </ul>
4	?	The following functions can be accessed using this menu element: <ul style="list-style-type: none"> <li>• <b>Product information</b></li> <li>• <b>Instructions for use</b></li> <li>• <b>Administrator manual</b></li> </ul>
5	Registered user [role]	The following roles are provided in the software: <ul style="list-style-type: none"> <li>• <b>Administrator</b></li> <li>• <b>Doctor</b></li> <li>• <b>Assistant</b></li> </ul>
6	Log off	<ul style="list-style-type: none"> <li>• Open the login dialog (input the user name and password) in order to log in another user</li> </ul>
7	Create	Create a new patient file
8	Open	Open an existing patient file in the main patient list
9	Column sorting	<ul style="list-style-type: none"> <li>• Up arrow: ascending sorting</li> <li>• Down arrow: descending sorting</li> </ul>
10	Main patient list	Displays patient files: <ul style="list-style-type: none"> <li>• Data created in the main patient list</li> <li>• Data imported from the USB stick</li> </ul>
11	Search window	Search for patient files in the main patient list. <ul style="list-style-type: none"> <li>• "Asterisk search," e.g. "Mi*" for Miller possible</li> <li>• Back to the complete list with empty search</li> </ul>
12	Selection bar	Indicates which patient file is currently selected.
13	Checkbox	Activate a patient file. Clicking buttons in the patient list affects all "activated" patient files.
14	Select all Unselect all	<ul style="list-style-type: none"> <li>• Select all patient files in the main patient list to perform actions for all of them.</li> <li>• Unselect all patient files in the main patient list when an action was performed for all of them or when an action is to be omitted.</li> </ul>
15	Delete	Delete patient file (patient files can be restored by users with the role <b>Administrator</b> .)
16	Copy to USB stick	Copy patient files selected in the main patient list to a USB stick, e.g. for use on an mbca.
17	Patient list, USB stick	Displays patient files: <ul style="list-style-type: none"> <li>• Data copied from the main patient list to the USB stick</li> <li>• Data created on the USB stick</li> </ul>

No.	Operating element	Function
18	Show/hide patient list on USB stick	<ul style="list-style-type: none"> <li>• Any patient list stored on the USB stick is automatically displayed when the system starts up.</li> <li>• Lists can be hidden to display more entries in the main patient list.</li> </ul>
19	Search window	Search patient files on USB stick. <ul style="list-style-type: none"> <li>• 'wildcard' search (with asterisk), e.g. "Sa*" for Sampleman</li> <li>• Back to complete list if search unsuccessful</li> </ul>
20	Drive selection window	Used to select USB stick.
21	<b>Select all</b> <b>Unselect all</b>	<ul style="list-style-type: none"> <li>• Select all patient files on the USB stick to perform actions for all of them.</li> <li>• Unselect all patient files on the USB stick when an action was performed for all of them or when an action is to be omitted.</li> </ul>
22	<b>Delete</b>	Delete patient file on USB stick (Patient file cannot be restored on USB stick)



## 3.2 Patient file

The screenshot shows the 'seca analytics' patient file interface. The top bar displays the patient's name 'Louis da Gaule', sex '♂', date of birth '12/05/1965', and ethnicity 'Caucasian'. Below this, a navigation bar includes tabs for 'patient data', 'medical history', 'laboratory data', 'results of examination', and 'comments'. The main content area is titled 'General patient data (updated on 24/10/2010)' and contains two columns of form fields: 'Name' (Title, First name, Surname, Name suffix), 'Contact' (Street, House no., Postcode, Town, County, Country, E-mail, Telephone 1-3), 'General data' (Date of birth, Sex, Ethnicity), and 'Specific data' (Patient ID, Doctor supervising). A 'Comments' section is at the bottom right. The interface is annotated with letters A through L pointing to various elements.

	Symbol	Meaning
<b>A</b>	Patient info	Summary of the most important patient data
<b>B</b>	<b>Patient data</b>	Enter, edit, and view the patient's main data
<b>C</b>	<b>Medical history</b>	Enter, edit, and view the patient's medical history
<b>D</b>	<b>Laboratory data</b>	Enter, edit, and view the patient's laboratory data Data can be imported if an interface to the hospital information system is programmed.
<b>E</b>	<b>Results of examination</b>	View results of examination.
<b>F</b>	<b>Comments</b>	Add and view comments about the patient file
<b>G</b>	<b>Measure</b>	Start measurement procedure
<b>H</b>	<b>Import</b>	Import patient data <b>Note:</b> Configuration or programming of an interface to the patient data management system (PDMS) required
<b>I</b>	<b>Print</b>	Print patient data or save as PDF

	<b>Symbol</b>	<b>Meaning</b>
<b>J</b>	<b>Save</b>	Save changes and additions to the patient file
<b>K</b>	<b>Close</b>	Close the patient file and return to the patient list
<b>L</b>	Date/time	Settings are taken over from the operating system

### 3.3 Identification on the packaging

<b>Text/symbol</b>	<b>Meaning</b>
Model	Model number
Ser. no.	Serial number
	Heed instructions for use
	Product conforms to the standards and guidelines of the EC

## 4. INSTALLATION

The **seca 115** software may only be installed by experienced PC administrators.

For information about installation and configuration options, check the menu bar of the software under "**?→Administrator manual**". In case of questions and requests for changes to the system currently installed on your PC, please contact your administrator.



### **ATTENTION!**

#### **Data loss**

The improper installation of or improper changes to the installation can cause data loss and, as a result, misdiagnoses.

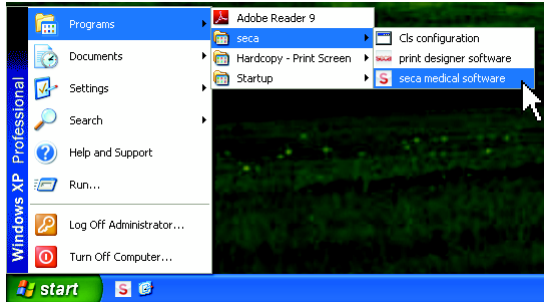
- Have the installation or changes to the installation made by an experienced PC administrator.

# 5. OPERATION

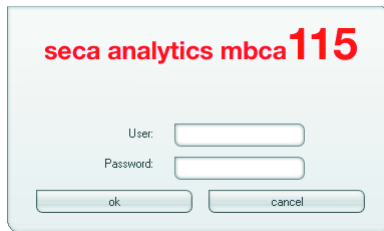
## 5.1 Starting/exiting the program

### Opening the program

1. Click "Start→Programs→seca→seca medical software.



The login dialog is opened.



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

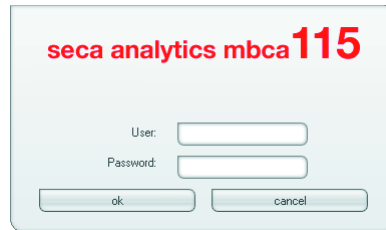
#### NOTE:

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 patient list is opened.

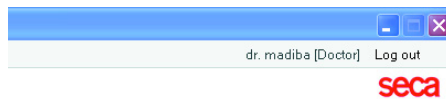
### Logging off/changing the user

- ◆ Click on **Log off**.  
The login dialog is opened.  
Another user can log on.



### Exiting the program

- ◆ Click the "x" symbol.  
The program exits.



## 5.2 "Extras" menu

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### Changing references

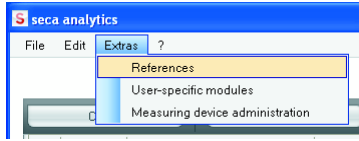
The **seca 115** software evaluates measured results using references. During the installation and configuration of the software, your administrator sets in which country you are operating your software. With this setting, the references that are normally used in your country are pre-set automatically.

According to the regulations that apply in your institution and your personal preferences, you can change the pre-set references. To do this, proceed as follows:

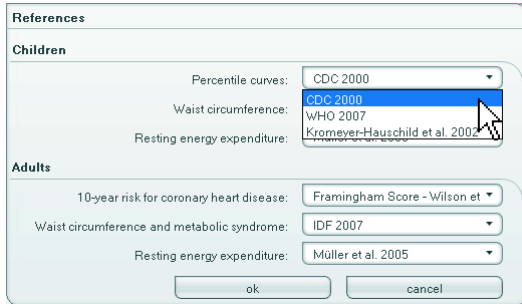
#### **NOTE:**

This section describes the handling of the software. For basic information about the medical content, see chapter "Medical basis" starting on page 51.

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 selection possibilities for the reference opens.
3. Click the desired reference.  
The pull-down menu closes.  
The selected reference appears in the selection field.
4. Repeat the steps 2. and 3. for all parameters whose references you would like to change.
5. In order 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 created to evaluate your patient's state of health (see "Evaluation modules" on page 51).

On the **User-specific modules** dialog, you can compile two additional modules. You can view and evaluate these in the patient file under **Results of examination**, just like the pre-set evaluation modules.

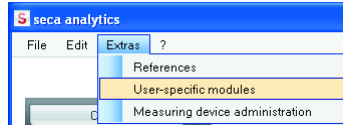


**NOTE:**

This section describes the handling of the software. For basic information about the medical content, see chapter “Medical basis” starting on page 51.

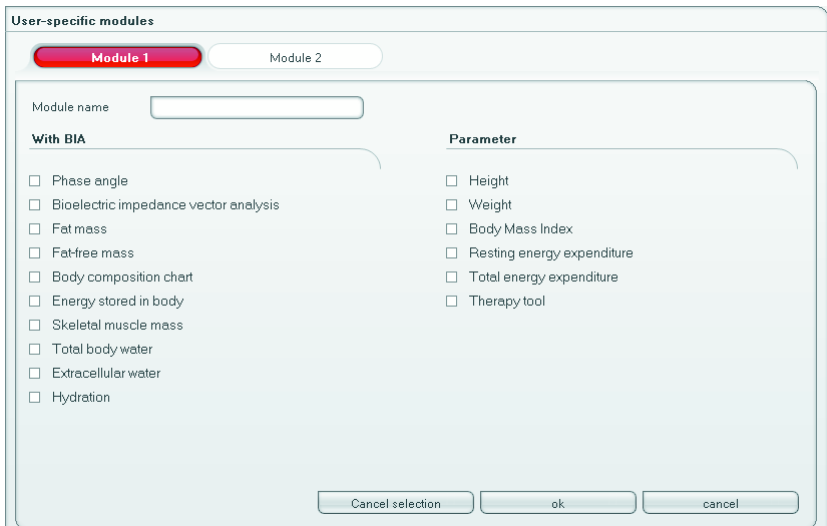
In order to compile a user-specific module, proceed as follows:

1. Click in the **Extras** menu on **User-specific modules**.



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

The **Module 1** is pre-selected.



2. In the **Module name** field, enter the name that you want to assign the module.
3. Click a maximum of 4 parameters that you want to display in your module.

4. Click on **OK**.

The user-specific module is saved.

**NOTE:**

- With **Cancel selection** you can de-select all selected points with a mouse-click.
- With **Cancel** you can exit the dialog window without saving settings.
- In order 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 the **Module 2**.

## Viewing measuring device administration

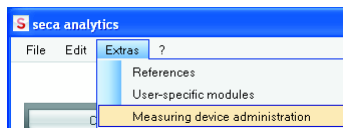
You can see which scales and length measuring devices are connected to your PC.

The following information is displayed for each connected measuring device:

- Device name if entered by the administrator (recommended)
- Model
- Setup location if entered by the administrator (recommended)
- Serial number
- Connection properties:
  - **seca 360° wireless**: [PC name : channel; device type]
  - RS232 devices: [PC name : COM port]

In order to display the measuring device configuration, proceed as follows:

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	Length measuri...		05704183104409	192.168.2.12:2:2

BIA

Name	Model	Location	Serial number	Connection properties
mbca	mbca			1.5
mbca	mbca			2.5
mbca	mbca			0.5

close

**NOTE:**

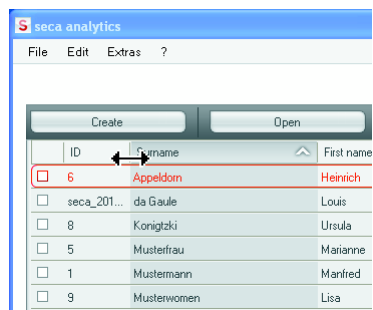
You cannot make any changes on this window. If changes should be made, please contact your administrator.

2. In order to exit the **Measuring device administration** window, click on **Close**.

## 5.3 Working with the patient list

### Setting the column width

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

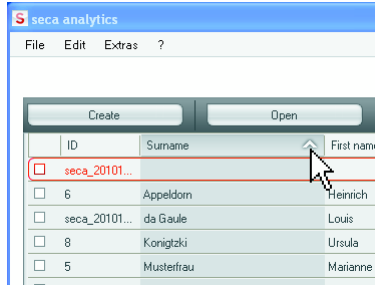


The mouse pointer becomes a double arrow.

2. Hold the left mouse button down and drag the column wider or narrower with the mouse.
3. Release the left mouse button when the desired column width has been reached.

## Sorting the column content in ascending or descending order

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



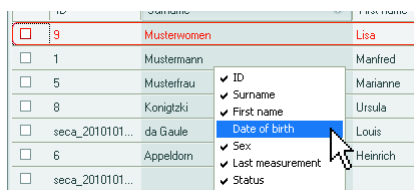
An arrow appears next to the column title, which shows the current sorting direction.

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

## Showing and hiding columns

1. Position the mouse pointer in the patient list.
2. Click the right mouse button.

A context menu with the titles of all columns appears.



3. Click on the title of the column that you want to hide.

The checkmark in front of the column title is no longer displayed.

The corresponding column is hidden in the patient list.



## Searching a patient file

1. Enter a search term in the search field.

The screenshot shows the 'seca analytics mbca' application window. The title bar includes 'seca analytics mbca', 'File Edit Extras 2', 'admin [Administrator]', and 'Log out'. The main area is titled 'Patient list' and contains a search bar with 'Sc\*' and a table of patients. The table has columns: ID, Name, First name, Date of birth, Sex, Last measurement, and Status. The data rows are as follows:

ID	Name	First name	Date of birth	Sex	Last measurement	Status	
<input type="checkbox"/>	seca_200...	Gonzales	Jose	20/06/1980	♂	19/01/2005	new
<input type="checkbox"/>	seca_200...	Gonzales	Martina	15/05/2001	♀	20/01/2005	new
<input type="checkbox"/>	seca_201...	Lacroix	Stephanie	15/05/2001	♀	19/11/2011	new
<input type="checkbox"/>	seca_201...	Lacroix	Thomas	20/06/1980	♂	06/11/2011	new
<input type="checkbox"/>	seca_201...	Prenzlou	Phillipp	09/09/1982	♂	09/02/2011	new
<input type="checkbox"/>	seca_201...	Prenzlou	Fia	15/05/2001	♀	09/02/2011	new
<input checked="" type="checkbox"/>	seca_201...	Scott	Catherine	15/05/2001	♀	19/11/2011	new
<input type="checkbox"/>	seca_201...	Scott	John	20/06/1980	♂	19/11/2011	new

Buttons below the table: 'copy to USB stick', 'delete', 'select all'. A secondary window titled 'USB stick' is open below, showing 'No USB stick found', a search field with 'Enter search term', and an empty table with columns: ID, Name, First name, Date of birth, Sex, Last measurement, Status. Buttons below: 'delete', 'select all'.

### NOTE:

If you do not know exactly how to write a name, you can carry out a so-called "asterisk search," e.g. "Mi\*" for "Miller."

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

## Creating a patient file

If you create a new patient file, you must fill out at least the following fields (in the file, each marked with "\*"):

- Date of birth
- Gender
- Ethnicity
- Doctor supervising treatment (if the current user is a doctor, this field is filled out automatically)

If the patient ID must fulfill a prescribed structure in your institution, you can enter it manually. If you do not enter a "manual" ID, then an ID is assigned automatically when the patient file is saved.

1. Click on **Create**.

	create	open		
ID	Name	First name	Date of b	
<input type="checkbox"/>	seca_200...	Gonzales	Jose	06/20/19
<input type="checkbox"/>	seca_200...	Gonzales	Martina	05/15/20
<input type="checkbox"/>	seca_201...	Lacroix	Stephanie	05/15/20
<input type="checkbox"/>	seca_201...	Lacroix	Thomas	06/20/19
<input type="checkbox"/>	seca_201...	Prenzlou	Phillipp	09/09/19

An empty patient file appears.

The **Patient data** tab is active.

The screenshot shows the 'seca analytics' application window. The title bar includes 'seca analytics', 'File Edit Extras ?', 'Dr.Grey [Doctor]', and 'Log off'. The main window title is 'Patient file'. Below the title bar are buttons for 'Measure', 'Import', 'Print', 'Save', and 'Close'. A status bar at the top right shows '28.10.2010 09:00'. The 'Patient data' tab is selected, showing a form with the following sections:

- Name:** Title, First name, Surname, Name suffix (dropdown).
- General data:** Date of birth, Sex (Male), Ethnicity (Caucasian).
- Specific data:** Patient ID, Attending physician (Dr.Grey).
- Contact:** Street, House no., Zip code, City/town, County, Country (United States), E-mail, Telephone 1, 2, 3 (each with a Private dropdown).
- Comments:** A text area for notes.

2. Enter the patient data:

**NOTE:**

If you are logged in as a doctor, you are entered automatically in the **Doctor supervising** field. The field can be edited.

3. Click on **Save**.

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

**WARNING!****Data loss due to incomplete saving**

If you do not close a patient file after saving it and you enter another patient file, the data of the first patient will be overwritten.

- Close a newly-created patient file before you create another patient file.

4. Click on **Close**.

The patient list is shown again.

Additional patient files can be created.

**Copying patient files to a USB stick**

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

**NOTE:**

If you are not sure whether the available USB stick has been initialised, contact your administrator.

To copy data to a USB stick, proceed as follows:

1. Plug the USB stick into a free USB port on your PC.  
The message **USB stick detected** will appear.
2. Click **OK**.  
The dialog window closes.
3. In the main patient list select the patient files you wish to copy to the USB stick.



The screenshot shows the 'seca analytics mbca' application window. The main area displays a 'Patient list' table with columns for ID, Name, First name, Date of birth, Sex, Last measurement, and Status. A red box highlights the row for 'seca\_201... Scott' with first name 'Catherine', date of birth '05/15/2001', sex '♀', last measurement '11/19/2011', and status 'new'. Below the table are buttons for 'copy to USB stick', 'delete', and 'select all'. A mouse cursor is pointing at the 'copy to USB stick' button. Below the patient list is a section for a 'USB stick' with a search bar and an empty table with the same columns as the patient list. Below this table are 'delete' and 'select all' buttons.

ID	Name	First name	Date of birth	Sex	Last measurement	Status	
<input type="checkbox"/>	seca_200...	Gonzales	Jose	06/20/1980	♂	01/19/2005	
<input type="checkbox"/>	seca_200...	Gonzales	Martina	05/15/2001	♀	01/20/2005	new
<input checked="" type="checkbox"/>	seca_201...	Lacroix	Stephanie	05/15/2001	♀	11/19/2011	new
<input type="checkbox"/>	seca_201...	Lacroix	Thomas	06/20/1980	♂	11/06/2011	
<input type="checkbox"/>	seca_201...	Prenzlowl	Phillipp	09/09/1982	♂	02/09/2011	
<input type="checkbox"/>	seca_201...	Prenzlowl	Pia	05/15/2001	♀	02/09/2011	new
<input checked="" type="checkbox"/>	seca_201...	Scott	Catherine	05/15/2001	♀	11/19/2011	
<input type="checkbox"/>	seca_201...	Scott	John	06/20/1980	♂	11/19/2011	

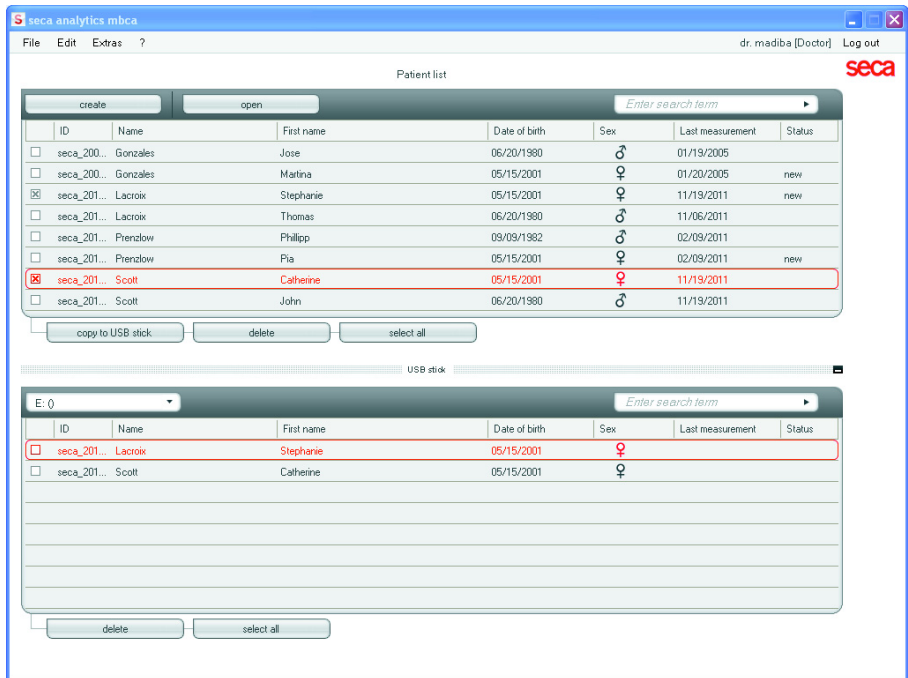
copy to USB stick   delete   select all

USB stick

ID	Name	First name	Date of birth	Sex	Last measurement	Status

delete   select all

4. Click **Copy to USB stick**.  
The entries copied are displayed in the patient list of the USB stick.



5. Select the USB stick for ejection as provided by your PC's operating system.
6. Remove the USB stick from the USB port of your PC.

**NOTE:**

To access patient files on a seca mbca, you will require your user PIN (generated automatically when your administrator creates your user account for the PC software) or the USB PIN (generated when your administrator initialises the USB stick). If you have none of the PINs to hand, contact your administrator.

**Importing patient files from the USB stick**

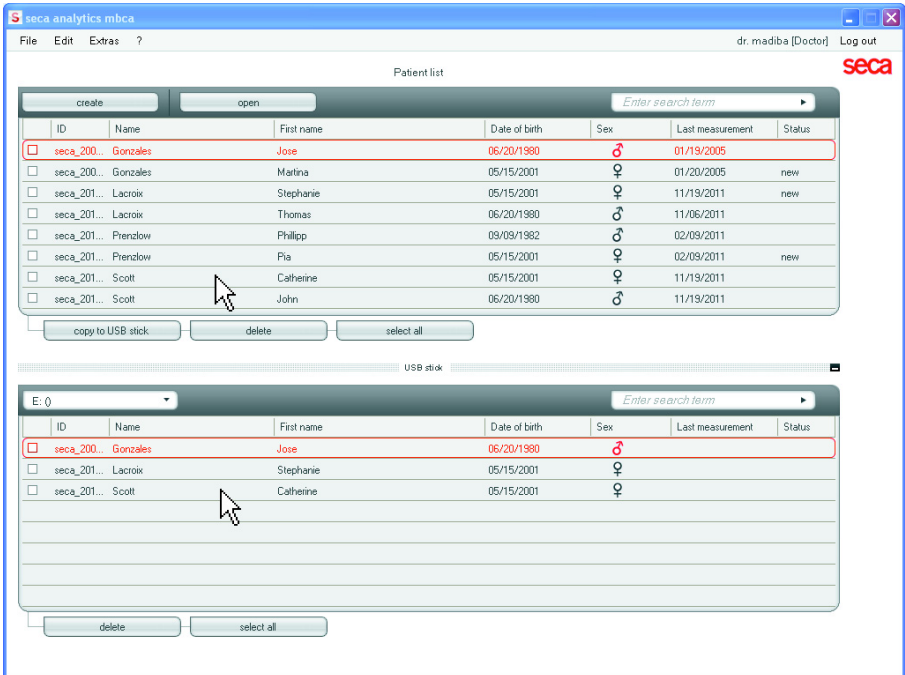
If you have created or updated patient files on a USB stick, e.g. during measurement on a seca mbca, you can import this data to the patient database of the software. To do so, proceed as follows:

1. Plug the USB stick into a free USB port on your PC. The message **USB stick detected** will appear.

2. Click **OK**.

The dialog window closes.

The patient files available on the USB stick are displayed in the patient list of the USB stick.



Import of the data starts automatically.

Imported entries are displayed in the main patient list.

**NOTE:**

If you have accidentally assigned a patient ID which already exists in the PC software, the relevant patient file is copied from the USB stick to the temporary patient buffer of the PC software. Your administrator can allocate a unique ID to the patient file and transfer it to the main patient list.

3. Select the USB stick for ejection as provided by your PC's operating system.
4. Remove the USB stick from the USB port of your PC.

## Exporting patient files in CSV format

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

### NOTE:

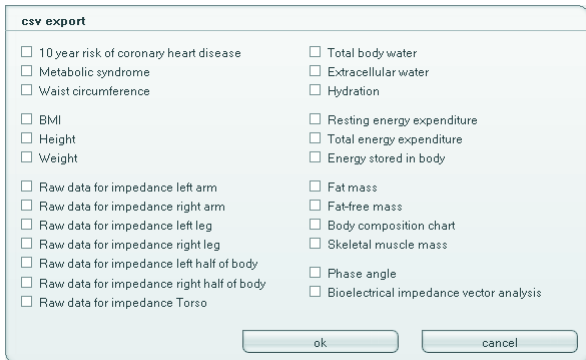
Person-related data such as name and address of the patient will not be exported.

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

### NOTE:

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

4. Click in the "**File**" menu on "**Export.**"  
The export window appears.

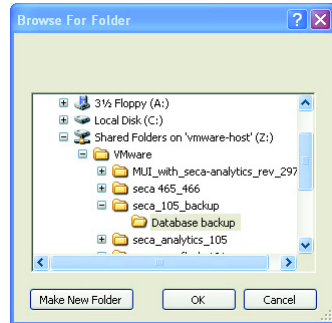


The screenshot shows a dialog box titled "csv export" with a list of checkboxes for selecting parameters to export. The parameters are arranged in two columns. At the bottom right, there are two buttons: "ok" and "cancel".

Parameter	Parameter
<input type="checkbox"/> 10 year risk of coronary heart disease	<input type="checkbox"/> Total body water
<input type="checkbox"/> Metabolic syndrome	<input type="checkbox"/> Extracellular water
<input type="checkbox"/> Waist circumference	<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"/> Fat mass
<input type="checkbox"/> Raw data for impedance right arm	<input type="checkbox"/> Fat-free mass
<input type="checkbox"/> Raw data for impedance left leg	<input type="checkbox"/> Body composition chart
<input type="checkbox"/> Raw data for impedance right leg	<input type="checkbox"/> Skeletal muscle mass
<input type="checkbox"/> Raw data for impedance left half of body	<input type="checkbox"/> Phase angle
<input type="checkbox"/> Raw data for impedance right half of body	<input type="checkbox"/> Bioelectrical impedance vector analysis
<input type="checkbox"/> Raw data for impedance Torso	

5. Select the parameters that you want to export.

- In order to confirm the settings, click **OK**.  
The **Save as** dialog window appears.



- Select the directory into which you want to export the patient data.
- Click on **Save**.  
The data is exported.

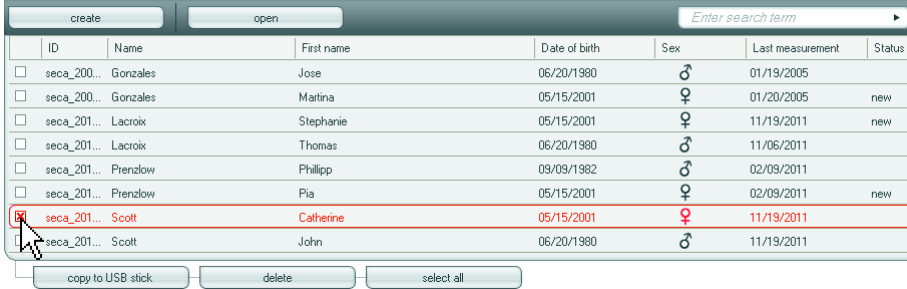
**NOTE:**

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

## Deleting individual patient files

You can delete patient files in both the main patient list and the patient list of the USB stick. To do so, proceed as follows:

1. Select the patient file that should be deleted (here: in main patient list).



	ID	Name	First name	Date of birth	Sex	Last measurement	Status
<input type="checkbox"/>	seca_200...	Gonzales	Jose	06/20/1980	♂	01/19/2005	
<input type="checkbox"/>	seca_200...	Gonzales	Martina	05/15/2001	♀	01/20/2005	new
<input type="checkbox"/>	seca_201...	Lacroix	Stephanie	05/15/2001	♀	11/19/2011	new
<input type="checkbox"/>	seca_201...	Lacroix	Thomas	06/20/1980	♂	11/06/2011	
<input type="checkbox"/>	seca_201...	Prenzlow	Phillipp	09/09/1982	♂	02/09/2011	
<input type="checkbox"/>	seca_201...	Prenzlow	Pia	05/15/2001	♀	02/09/2011	new
<input checked="" type="checkbox"/>	seca_201...	Scott	Catherine	05/15/2001	♀	11/19/2011	
<input type="checkbox"/>	seca_201...	Scott	John	06/20/1980	♂	11/19/2011	

Buttons: copy to USB stick, delete, select all

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

### ATTENTION!

#### Loss of data

If you delete data from the USB stick, it cannot be restored.

- Before deleting data from the USB stick, check that the data has been imported to the main patient list (see “Importing patient files from the USB stick” on page 26).

### NOTE:

Should you unintentionally delete data in the main patient list, your administrator can restore the data with the function **Restore patient data**. The entire patient data record will be restored. Entries and measurements that were not saved are lost.

## Deleting all patient files

You can delete patient files in both the main patient list and the patient list of the USB stick. To do so, proceed as follows:

1. Click on **Select all** (here: in main patient list).

Patient list

ID	Name	First name	Date of birth	Sex	Last measurement	Status
<input checked="" type="checkbox"/>	seca_200...	Gonzales	Jose	06/20/1980	♂	01/19/2005
<input type="checkbox"/>	seca_200...	Gonzales	Martina	05/15/2001	♀	01/20/2005 new
<input type="checkbox"/>	seca_201...	Lacroix	Stephanie	05/15/2001	♀	11/19/2011 new
<input type="checkbox"/>	seca_201...	Lacroix	Thomas	06/20/1980	♂	11/06/2011
<input type="checkbox"/>	seca_201...	Prenzlow	Phillipp	09/09/1982	♂	02/09/2011
<input type="checkbox"/>	seca_201...	Prenzlow	Pia	05/15/2001	♀	02/09/2011 new
<input type="checkbox"/>	seca_201...	Scott	Catherine	05/15/2001	♀	11/19/2011
<input type="checkbox"/>	seca_201...	Scott	John	06/20/1980	♂	11/19/2011

copy to USB stick    delete    select all

### NOTE:

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

2. Click on **Delete**.  
All patient files are deleted.

### ATTENTION!

#### Loss of data

If you delete data from the USB stick, it cannot be restored.

- Before deleting data from the USB stick, check that the data has been imported to the main patient list (see “Importing patient files from the USB stick” on page 26).

### NOTE:

Should you unintentionally delete data in the main patient list, your administrator can restore the data with the function **Restore patient data**. The entire patient data record will be restored. Entries and measurements that were not saved are lost.

## 5.4 Working with the patient file

### Opening the patient file

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



ID	Name	First name
<input checked="" type="checkbox"/> seca_200...	Gonzales	Jose
<input type="checkbox"/> seca_200...	Gonzales	Martina
<input type="checkbox"/> seca_201...	Lacroix	Stephanie
<input type="checkbox"/> seca_201...	Lacroix	Thomas
<input type="checkbox"/> seca_201...	Prenzlow	Phillipp
<input type="checkbox"/> seca_201...	Prenzlow	Fia
<input type="checkbox"/> seca_201...	Scott	Catherine

2. Click on **Open** or double-click on the entries in the patient list.  
The patient file is opened.

### Editing patient data

If you have opened an existing patient file, the following fields are usually filled out:

- Date of birth
- Gender
- Ethnicity
- Patient ID
- Doctor supervising treatment

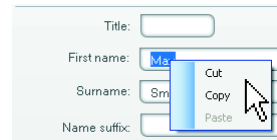
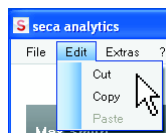
You can change and add to patient data at any time.

1. Open a patient file (see “Opening the patient file” on page 32).  
The **Patient data** tab is active.
2. Select the tab on which you would like to change data.



The screenshot shows the 'seca analytics' application window. At the top, there is a menu bar with 'File', 'Edit', and 'Extras'. The patient file header displays 'Max Smith' with a male symbol, date of birth '08/09/1962', and ethnicity 'Caucasian'. Below this, physical attributes are listed: Weight: 152.1 lbs, Height: 5'10 7/8", BMI: 21.3 kg/m². The main form area has several tabs: 'patient data' (highlighted in red), 'medical history', 'laboratory data', 'results of examination', and 'comments'. The 'patient data' tab is expanded to show four sections: 'Name' (Title, First name: Max, Surname: Smith, Name suffix), 'Contact' (Street, House no., Postcode, Town, County: Germany, E-mail, Telephone 1-3 with privacy dropdowns), 'General data' (Date of birth: 08/09/1962, Sex: Male, Ethnicity: Caucasian), and 'Specific data' (Patient ID: seca\_20101015-125423-812, Doctor supervising: Dr. Grey). A 'Comments' text area is at the bottom right.

3. Change or add to the patient data insofar as necessary:
  - Add data manually
  - Mark the entries and use the functions **Cut**, **Copy**, and **Paste**. These functions are accessible via the **Edit** menu element or via the context menu with a right mouse-click.



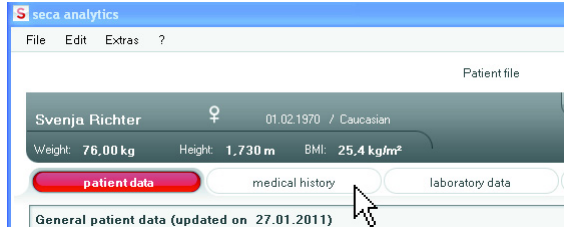
4. Click on **Save**.
5. In order to close the patient file, click **Close**.  
The patient list is shown again.

## Entering a medical history

On this tab you can enter previous illnesses or therapies already started. This information flows into the evaluation of the measured results (see “Evaluating results” on page 40).

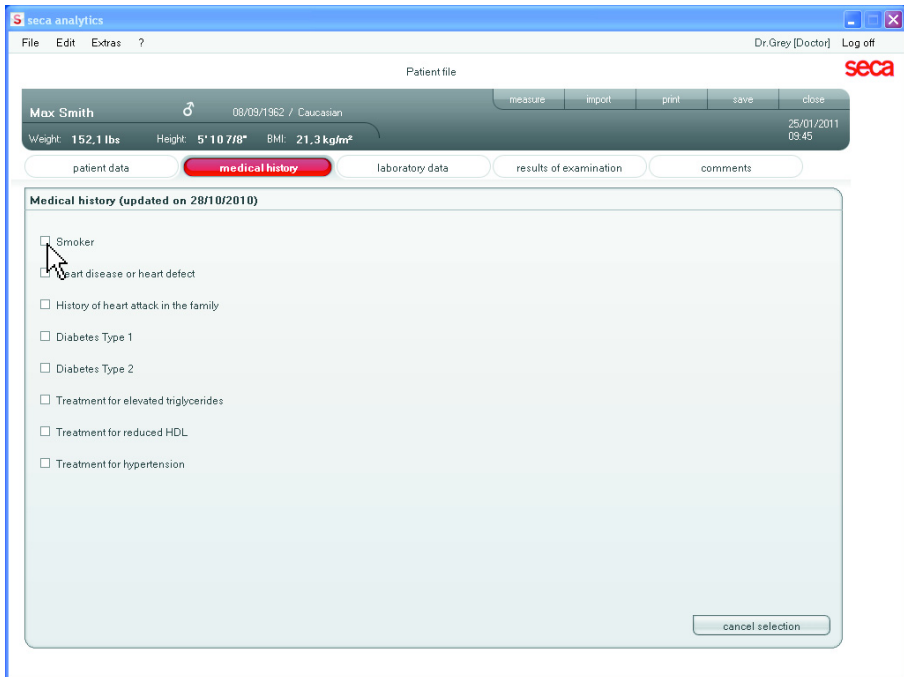
1. Click on **Medical history**.

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:

With **Cancel selection** you can 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 for this program an interface to your patient data management system (PDMS) has been configured, 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.

In order to enter laboratory data manually, proceed as follows:

1. Click on **Laboratory data**.  
The **Laboratory data** tab is active

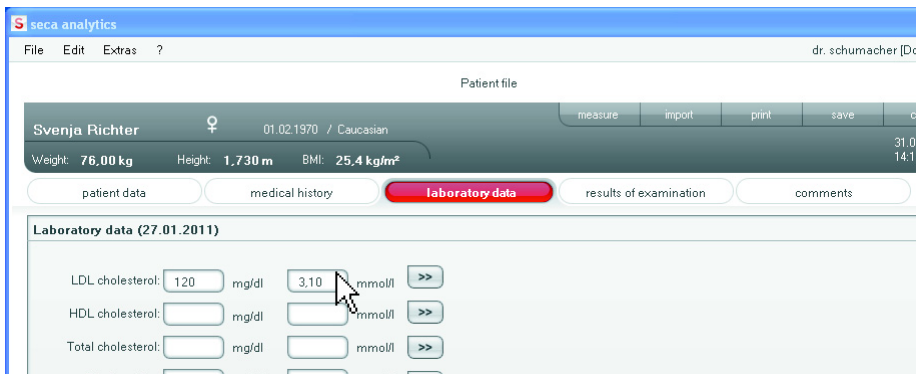
The screenshot shows the 'seca analytics' application window. At the top, there is a menu bar with 'File', 'Edit', 'Extras', and '?'. The patient name 'Svenja Richter' and gender '♀' are displayed. Below this, patient statistics are shown: Weight: 76,00 kg, Height: 1,730 m, BMI: 25,4 kg/m<sup>2</sup>. The 'laboratory data' tab is selected and highlighted in red. Other tabs include 'patient data', 'medical history', 'results of examination', and 'comments'. A mouse cursor is hovering over the 'laboratory data' tab.

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

The screenshot shows the 'seca analytics' application window with the 'Laboratory data' tab active. The patient information is the same as in the previous screenshot. The 'Laboratory data (27.01.2011)' section is visible, containing input fields for cholesterol and triglycerides. The 'LDL cholesterol' field has the value '120' entered in the 'mg/dl' unit. A mouse cursor is pointing at the '120' value. There are also empty fields for 'mmol/l' and a '>>' button for conversion.

### NOTE:

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

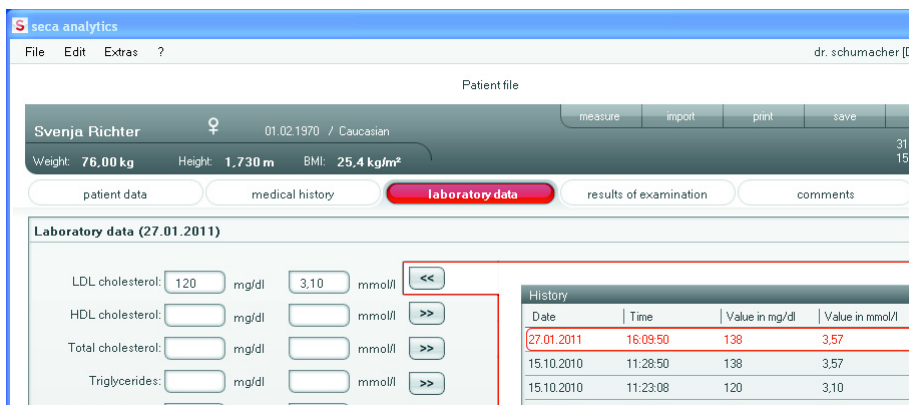


4. Repeat the steps 2. and 3. for all values that you want to enter.
5. Click on **Save**.

### View history for individual values

You can view the history for individual values. To do so, proceed as follows:

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



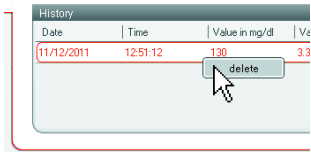
The history field for that value is opened.

2. To close the history view, click «.
3. To return to the patient list, click **Close**.

## Delete values in the history field

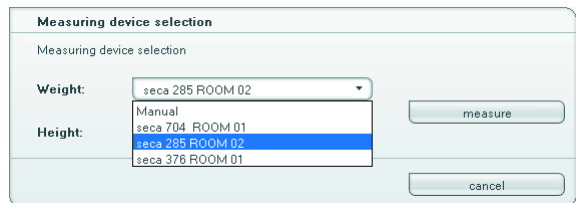
You can delete individual values in the history field. To do so, proceed as follows:

1. Click the right mouse button on the value you want to delete.  
The **Delete** button appears.
2. Click the left mouse button on the **Delete** button.  
The value is deleted.
3. To return to the patient list, click **Close**.



## Measuring

1. Open the patient file (see “Opening the patient file” on page 32) or create a patient file if necessary (see “Creating a patient file” on page 22).
2. Click on **Measure**.  
The **Measuring device selection** dialog window appears.



3. Select the devices with which you want to determine the patient's weight and height.

### WARNING!

#### Mistaken measurements with incorrect device selection

In case of incorrect device selection, it can happen that measured results are assigned to the incorrect patients or no measurement at all is performed.

- Use the device names to ensure that you have selected the correct devices.
- For the selection of devices that are connected to the same USB adapter: Make sure that the selected measuring device is logged onto the same wireless group.
- If devices on the network must be renamed or the composition of wireless groups must be changed, please contact your administrator.

**NOTE:**

- Select the **Manual** setting if your scales and length measuring devices are not networked with the PC. On the next dialog window, you can enter the measurement values directly.
- You cannot use the PC software to start BIA measurements on a seca mbca. Start BIA measurements from the device itself and transmit the measured results to the PC software either wirelessly, via Ethernet or using a USB stick.

4. Click on **Measure**.

The **Measured values** dialog window opens.

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

The screenshot shows a dialog box titled "Measured values". It has a light blue background and rounded corners. At the top, it says "Measured values". Below that, there are two rows of input fields. The first row is for "Weight (kg)" with a text box containing "76" and "seca 285" to its right. The second row is for "Height (m)" with an empty text box and "seca 285" to its right. Below these is a section with the text "Please enter the patient's waist circumference to determine cardiometabolic risk:" followed by a "Waist circumf. (m)" label and an empty text box. Below that is another section with the text "Please enter the patient's activity level (PAL) to determine total energy expenditure:" followed by a "PAL" label, an empty text box, and a question mark icon in a circle. At the bottom, there are two buttons: "OK" and "cancel".

5. Perform the measurements on the patient.

6. Make sure that the measured value is entered on the **Measured values** dialog window:

- If you are working with **seca 360° wireless** devices for which the automatic data transmission is activated, the measured values will be transmitted automatically to the PC.
- If you are working with **seca 360° wireless** devices for which the automatic data transmission is **not** activated, press the

(**send/print**) Enter key on the measuring devices in order to transmit the measured values to the PC.

- If your scales and length measuring devices are not networked with the PC, enter the measured values manually.
- If you are working with scales that are connected to the PC via RS232 interface, the measured values are transmitted automatically to the PC.

**NOTE:**

- If you are uncertain whether the automatic data transmission is activated for your **seca 360° wireless** devices, please contact your administrator.
- Regardless of the setting on the measuring devices, measured values will be displayed in the units pre-set for the software.

7. If you want to assess the patient's cardiometabolic risk, enter the **Waist circumference:** in the **Measured values** dialog window.

8. If you want to determine the patient's total energy expenditure, 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 on the **Results of examination** 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 35).

- If you click on the question mark next to the **Physical Activity Level (PAL)** line, a table appears with PAL values. If you click a value, it is taken over into the **Measured values** window.

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

PAL  ?

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

9. On the measured values window, click on **OK**.  
The measurement procedure is complete.  
The **Results of examination** tab is active.  
The results of the examination can be evaluated.

## Evaluating results

On this tab, you can view the evaluations of all measurements performed for the patient. In addition to the measured values for weight and height, waist circumference and physical activity level, as well as medical history and the laboratory data also flow into the evaluation. The results are displayed in evaluation modules.

### NOTE:

This section describes the handling of the software. For basic information about the medical content of the evaluation modules, see chapter “Medical basis” starting on page 51.

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



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

The following evaluation modules can also be viewed if data from a bioelectric impedance analysis (BIA) is available:

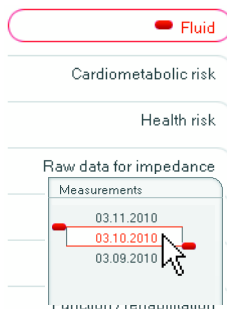
- **Function/rehabilitation**
- **Fluid**
- **Health risk**
- **Raw data for impedance**

The principles of bioelectric impedance analysis are described in the chapter "Medical basis" in the user manual of the seca mbca.

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

### Display conventions

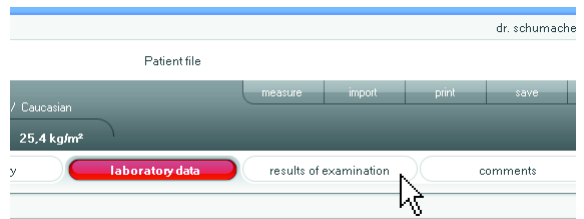
- Bold:
  - module: new, not-yet-regarded measurements/evaluations present
  - measurement: new, not yet regarded
- Red border:
  - module is active
  - details are displayed
- Grayed out (modules only):
  - module cannot be displayed since not all parameters are present



### Viewing results of examination

In order to view the evaluation modules, proceed as follows:

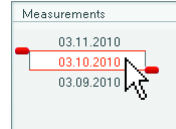
1. Click on **Results of examination**.  
The **Results of examination** tab is active.



2. Click on the module that you want to display.

- Fluid
- Cardiometabolic risk
- Health risk
- Raw data for impedance

3. Click on the measurement that you want to display.



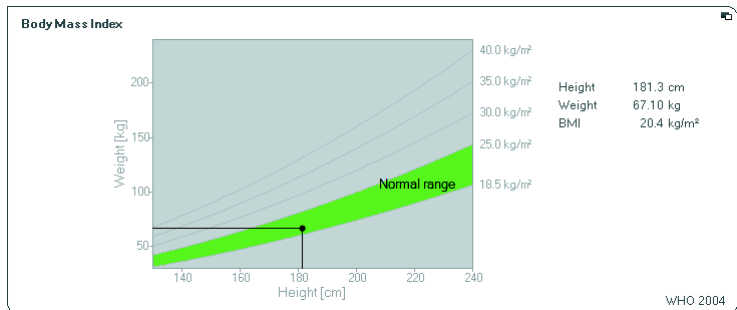
The evaluation of the measurements is displayed. For some evaluations, a graphic display is provided.

### Displaying results graphics enlarged



You can display the results graphics enlarged if the window symbol appears in the graphics. The enlarged displays contain additional details that enable you to better assess the state of health of your patient.

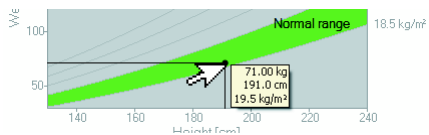
1. Click on a graphic in order to display it enlarged and with details (here: BMI).



2. Click on the graphic again in order to shrink it back to its original size.

**NOTE:**

If you position the mouse pointer on a measurement point in the graphic, the associated measurement 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.

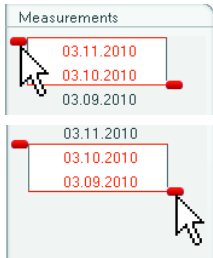
**NOTE:**

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

Proceed as follows to select measurements for the history:

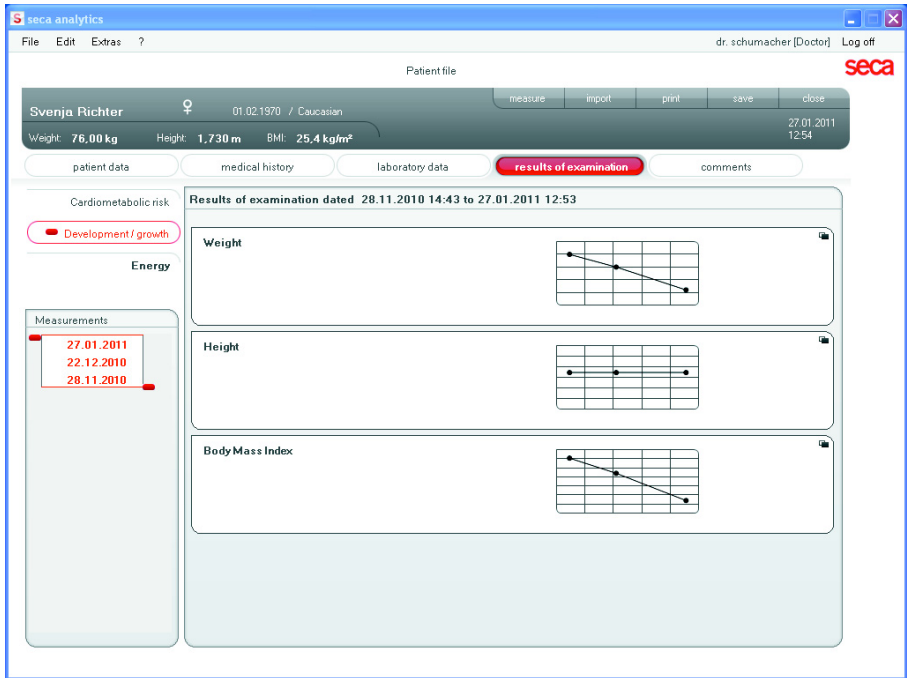
1. Click the **Results of examination** tab.
2. Click on the module that you want to display.  
The module is displayed in a selection bar.
3. Click on the one of the measurements you wish to select.  
The measurement is displayed on a selection bar.

4. While holding down the left mouse button, drag the selection bar across all the other measurements you want to view as a history.

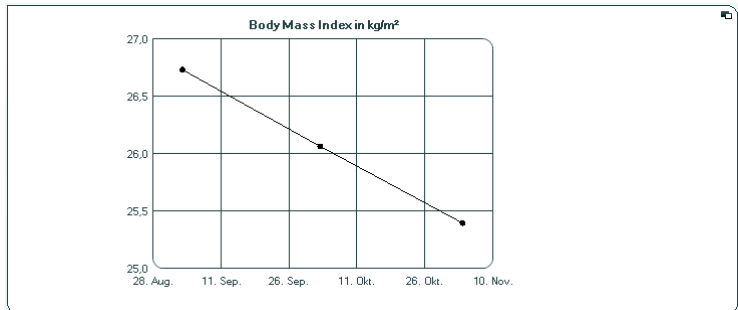


- Left handle upwards: more recent measurements will be added to the selection.
- Right handle downwards: older measurements will be added to the selection

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



5. Click on a graphic in order to display it enlarged and with details (here: BMI).



- Click on the graphic again in order to shrink it back to its original size.

### Using the therapy planner (only Energy module)

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

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

- Click in the **Energy** module on **Therapy tool**.

**Therapy tool**

Treatment objective:  BMI in kg/m² ▾

Duration of treatment in days:

Recommended energy intake in [kcal/d]:

- Enter the value and type of the therapeutic goal.
- Enter the therapy duration in days.  
The recommended daily energy intake is calculated.

**Therapy tool**

Treatment objective:  BMI in kg/m<sup>2</sup> ▾

Duration of treatment in days:

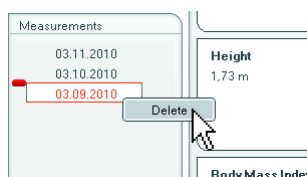
Recommended energy intake in [kcal/d]:

- In order to save the settings in the **Therapy tool**, click **Close**.

## Deleting measurements

You can delete individual measurements. Proceed as follows:

- Click the right mouse button on the measurement that you want to delete.  
The **Delete** button appears.
- Click with the left mouse button on the **Delete** button.  
The measurement is deleted.



## Writing comments

On the **Comments** tab you can add comments about the patient file.

- Click on **Comments**.  
The **Comments** tab is active.



- Click on **Write comment**.  
The comments window opens.  
The date and time are entered automatically.

### NOTE:

Comments can be neither deleted nor subsequently edited.

The screenshot shows the 'seca analytics' application window. At the top, there is a menu bar with 'File', 'Edit', and 'Extras'. The user is logged in as 'dr. schumacher [Doctor]' and can click 'Log off'. The patient's name is 'Svenja Richter', female, born '01.02.1970 / Caucasian'. Physical data includes 'Weight: 76,00 kg', 'Height: 1,730 m', and 'BMI: 25,4 kg/m²'. The date and time are '31.01.2011 15:39'. Navigation buttons include 'measure', 'import', 'print', 'save', and 'close'. Below this, there are tabs for 'patient data', 'medical history', 'laboratory data', 'results of examination', and 'comments' (which is highlighted in red). The 'Comments' section contains a table with columns 'Date compiled', 'Author', and 'Comments'. A 'write comment' button is located at the bottom right of the comments area.

3. Enter a **Subject**.
4. Enter your comment in the comments field.

The dialog box shows the following information: 'Author: Dr. Schumacher' and 'Date compiled: 04.11.2010'. There is a text input field containing 'Result of an investigation' and a larger text area containing 'Recommended weight reduction - 5kg'. At the bottom, there are 'OK' and 'Cancel' buttons.

5. Click in the comment field on **OK**.  
The comment field closes.  
The comment appears as the uppermost entry in the comment list.

## 5.5 Managing patient files

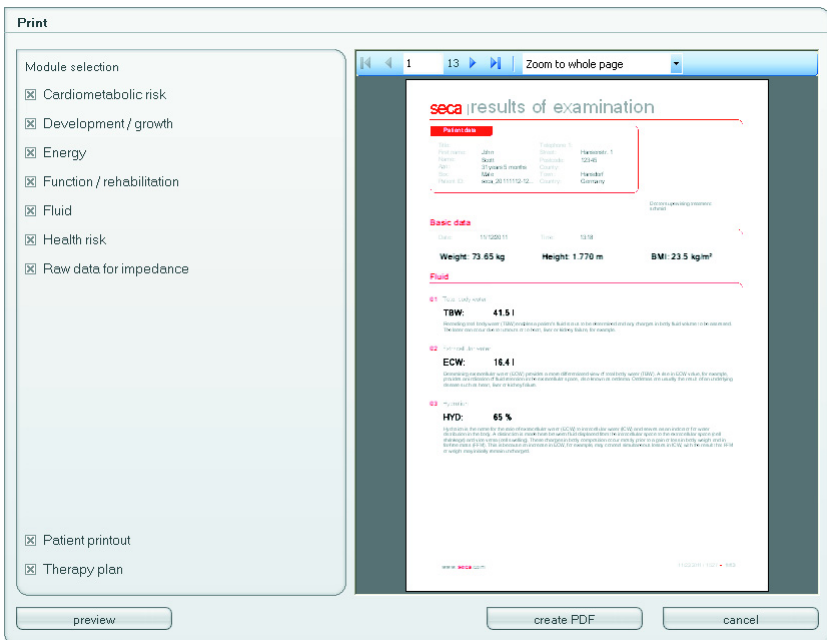
### Printing patient files

In the **Print** dialogue, you can save all the results of a measurement or just individual evaluation modules in the form of a PDF file. You can print out the PDF file using PDF display software such as Adobe Reader.

#### NOTE:

If there is no PDF display software installed on your computer, contact your administrator.

1. Open the patient file.
2. Click on **Print** in the patient file.  
The **Print** dialog appears.



3. Select the desired evaluation modules and if present, the therapy plan.
4. Specify whether the printout for the patient (**Patient printout**) should be printed.

#### NOTE:

The **Patient printout** includes explanations of parameters and measured results.



5. Click on **Create PDF** to save the evaluation as a PDF file.

The PDF file created is automatically displayed in the PDF display software.

**NOTE:**

Press **Cancel** to exit the Print dialogue of the **seca 115** software without creating a PDF file.

6. Use the Print dialogue of the PDF display software to print out the PDF file.

## Importing patient files

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

Depending on the configuration of the interface, the import will function differently. The import can run in exemplary fashion, 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.
- Use the **Preview** button to get a preview of the PDF files. In this case, the printing process takes a little longer.

1. Click in the patient list on **Create**.

An empty patient file appears.

The **Patient data** tab is active.

seca analytics

File Edit Extras ? Dr. Grey [Doctor] Log off

Patient file

measure import print save close

Weight: Height: BMI: 25/01/2011 09:40

patient data medical history laboratory data results of examination comments

**General patient data (updated on -)**

**Name**

Title:

First name:

Surname:

Name suffix:

**General data**

Date of birth:  \*

Sex:  \*

Ethnicity:  \*

**Specific data**

Patient ID:

Doctor supervising:  \*

**Contact**

Street:

House no.:

Postcode:

Town:

County:

Country:

E-mail:

Telephone 1:

Telephone 2:

Telephone 3:

**Comments**

2. In the **Patient ID** field, enter the ID under which the patient file is kept in your PDMS.
3. Click on **Import**.  
The patient data is imported.



## 6. MEDICAL BASIS

This section describes in short form the contents of the evaluation modules pre-set in this software and their medical goals. The references on which the evaluations rest will also be presented.

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

### 6.1 Evaluation modules

---

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

For information about how you can access the evaluation modules and navigate within them, see "Evaluating results" starting on page 40.

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

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

The following evaluation modules can also be viewed if data from a bioelectric impedance analysis (BIA) is available for the patient:

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

The principles of bioelectric impedance analysis are described in the chapter "Medical basis" in the user manual of the seca mbca.

## Cardiometabolic risk

The goal of this module is to check whether there is a metabolic syndrome as well as the assessment of the 10-year risk for coronary heart diseases.

### NOTE:

The **Cardiometabolic risk** module is only available if a patient file has been created for a patient and the laboratory data and waist circumference have been entered no later than the day that weight and height were entered (see "Entering laboratory data" on page 35).

The following parameters are displayed:

- Body Mass Index (BMI)
- Waist circumference (WC)
- Metabolic syndrome (MSX)
- 10-year risk for coronary heart diseases

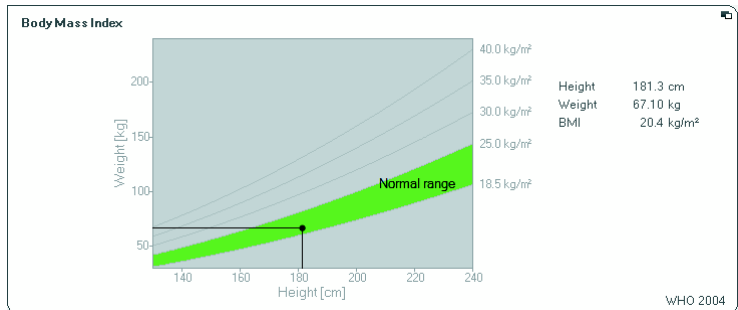
The screenshot shows the 'seca analytics mbca' software interface. At the top, the patient file for 'John Scott' is displayed, including his date of birth (06/20/1980), gender (male), and ethnicity (Caucasian). His current weight is 90.00 kg, height is 1.850 m, and BMI is 26.3 kg/m². The interface includes navigation tabs for 'patient data', 'medical history', 'laboratory data', 'examination results' (which is highlighted), and 'comments'. A sidebar on the left lists various measurement categories: 'Development / growth', 'Energy', 'Function / rehabilitation', 'Fluid', 'Health risk', and 'Raw data for impedance'. The main content area shows 'Results of examination dated 11/12/2011 13:18'. It displays the following results:

- Body Mass Index:** 23.5 kg/m². A graph shows weight (kg) on the y-axis and height (m) on the x-axis, with a green shaded area representing the BMI range.
- Waist circumference:** 0.960 m. A red bar indicates the current value, with a range of < 0.940 m to > 0.940 m.
- Metabolic syndrome:** Based on the examination data of 11/12/2011, metabolic syndrome is not present. A grid shows a red bar for the date 11/12/2011.
- 10 year risk of coronary heart disease:** 2%. A grid shows a red bar for the date 11/12/2011.

A 'Measurements' sidebar on the left shows a list of dates: 11/19/2011, 11/12/2011 (highlighted with a red bar), 11/12/2011, and 11/12/2011.

Detailed views are available for the following parameters:

### Detail view body mass index



### Detail view waist circumference



### Detail view metabolic syndrome

**Metabolic syndrome**

Based on the examination data of 03.11.2010, metabolic syndrome is not present.

Risk factor	Limit value	Result	Unit	Specific treatment	Date
Waist circumference:	>0,80	0,81	m		03.11.2010
Triglycerides	>=150	112	mg/dl	No	03.11.2010
HDL cholesterol	<50	38	mg/dl	No	03.11.2010
Blood pressure	>=130 / >=85	120 / 80	mmHg	No	03.11.2010
Fasting blood sugar	>=100	88	mg/dl		03.11.2010
Diabetes Type 2		No			03.11.2010

IDF 2006

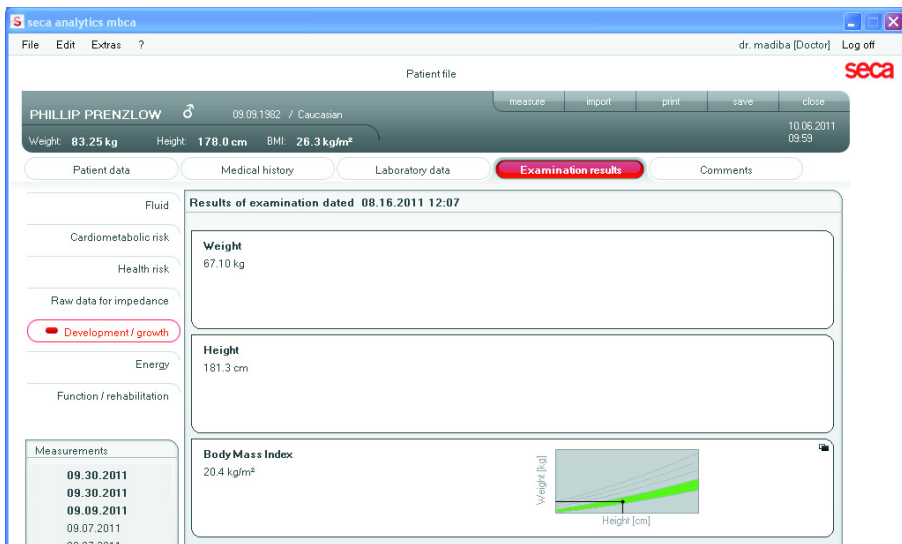
## Detail view 10-year risk of coronary heart disease for the age group 30-74 years



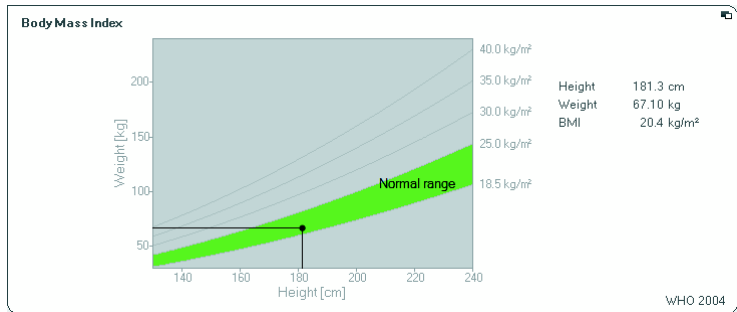
## Development / growth

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

- Weight
- Height
- Body Mass Index (BMI)



A detail view is available for the BMI:



## Energy

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

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

seca analytics mbca

File Edit Extras ? dr. madiba [Doctor] Log out

Patient file

John Scott 06/20/1980 / Caucasian measure import print save close

Weight: 90.00 kg Height: 1.850 m BMI: 26.3 kg/m<sup>2</sup> 11/22/2011 15:28

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

Cardiometabolic risk

Development / growth

Energy

Function / rehabilitation

Fluid

Health risk

Raw data for impedance

Measurements

11/12/2011

Results of examination dated 11/12/2011 13:18 therapy tool

**Fat mass**

15.9 kg  
22 %

8 % > 8 % > 21 %

**Energy stored in body**

873.30 MJ  
208725 kcal

**Resting energy expenditure**

7.13 MJ/day  
1704 kcal/day

Müller et al. 2004

**Total energy expenditure**

14.26 MJ/day  
3409 kcal/day

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

### Fat mass

**Fat mass**

5.7 kg  
8 %

8 %

< 8 % > 8 % > 21 %

Gallagher et al. 2000

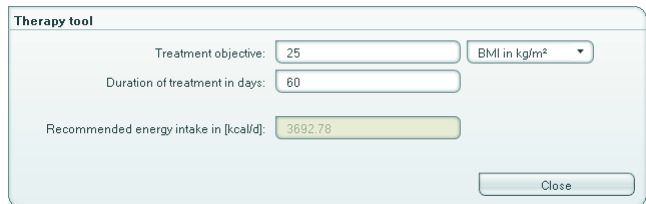


## Therapy planner

The energy module serves as the basis of energy advising. Here, the therapy planner of the module assists you. With the therapy planner, you can specify the following values:

- Treatment objective: weight change or BMI change
- Duration of treatment in days

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



The screenshot shows a window titled "Therapy tool" with the following fields and values:

Field	Value
Treatment objective:	25
Duration of treatment in days:	60
BMI in kg/m <sup>2</sup>	(dropdown menu)
Recommended energy intake in [kcal/d]:	3692.78

A "Close" button is located at the bottom right of the window.

No detail views are available in this module.

## Function/rehabilitation

This module is used to determine the fitness level and to assess metabolic activity and the degree of success for a training programme, e.g. in the framework of rehabilitation or physiotherapy. The following parameters are displayed:

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

seca analytics mbca

File Edit Extras ? dr. madiba [Doctor] Log out

Patient file

John Scott 06/20/1980 / Caucasian measure import print save close

Weight: 86.35 kg Height: 1.750 m BMI: 28.2 kg/m<sup>2</sup> 02/24/2012 12:04 PM

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

Cardiometabolic risk

Development / growth

Energy

Function / rehabilitation

Fluid

Health risk

Raw data for impedance

Measurements

02/24/2012

**Results of examination dated 02/24/2012 11:41 AM**

**Fat-free mass**  
68.1 kg  
seca 2011

**Fat mass**  
18.2 kg  
21 %

< 8 % > 8 % > 21 %

**Body Composition Chart**

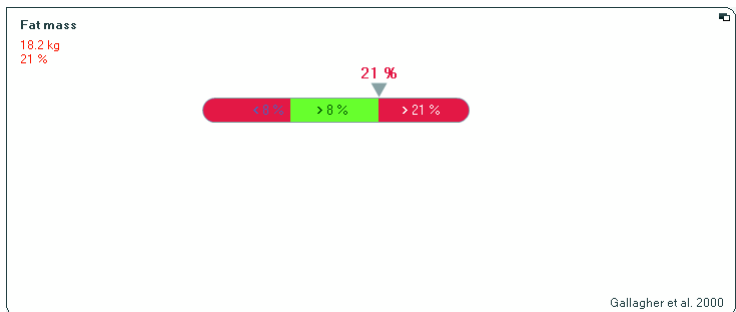
FFMI 22.3 kg/m<sup>2</sup>  
FMI 5.9 kg/m<sup>2</sup>

Z (FMI)  
-Z (FFMI)

**Skeletal muscle mass**  
34.5 kg

The following detail views are available for this module:

### Fat mass

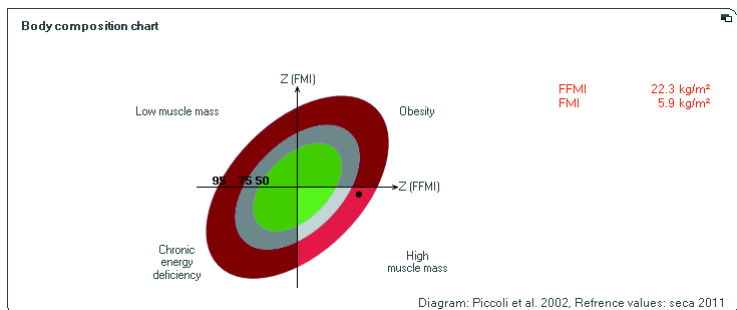


## Skeletal muscle mass and Lean soft tissue per extremity

Skeletal muscle mass	
SMM	34.5 kg
Lean soft tissue	
LST(R_leg)	11.2 kg
LST(L_leg)	10.8 kg
LST(R_arm)	3.9 kg
LST(L_arm)	3.7 kg

Kim et al. 2002

## Body composition chart (Fat mass index)



## Fluid

The Fluid module allows the fluids status of a patient to be determined and to observe changes in fluids as the result of medical treatment. The following parameters are displayed:

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

seca analytics mbca

File Edit Extras ? dr. madiba [Doctor] Log out

Patient file

**John Scott** 06/20/1980 / Caucasian

measure import print save close

Weight: **90.00 kg** Height: **1.850 m** BMI: **26.3 kg/m<sup>2</sup>** 11/22/2011 15:29

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

Cardiometabolic risk

Development / growth

Energy

Function / rehabilitation

**Fluid**

Health risk

Raw data for impedance

Measurements

11/12/2011

**Results of examination dated 11/12/2011 13:18**


**Total body water**  
41.5 l  
seca 2011

**Extracellular water**  
16.4 l  
seca 2011

**Hydration**  
65 %

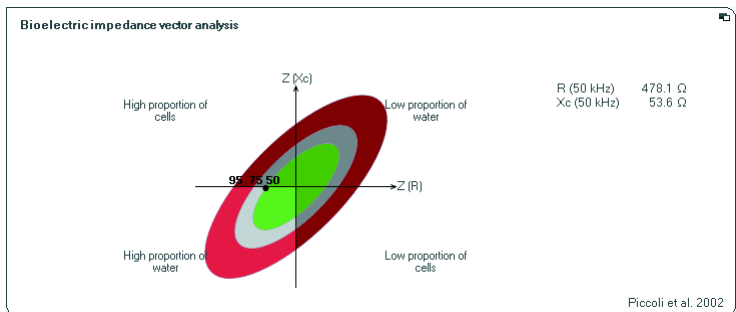
**Bioelectric impedance vector analysis**

R (50 kHz) 579.7 Ω  
Xc (50 kHz) 63.3 Ω



The following detail view is available for this module:

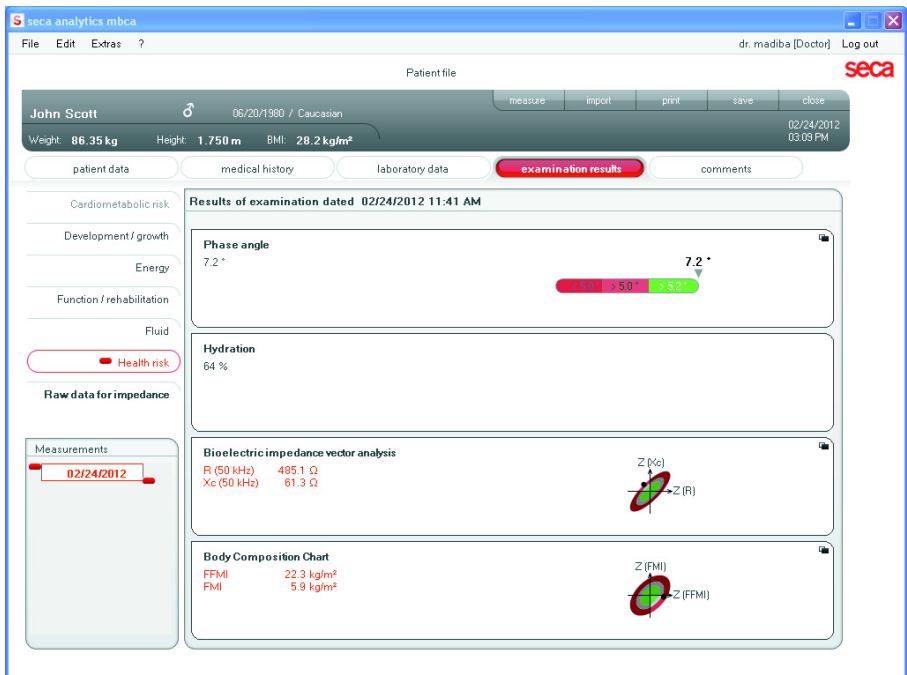
### Bioelectric impedance vector analysis



## Health risk

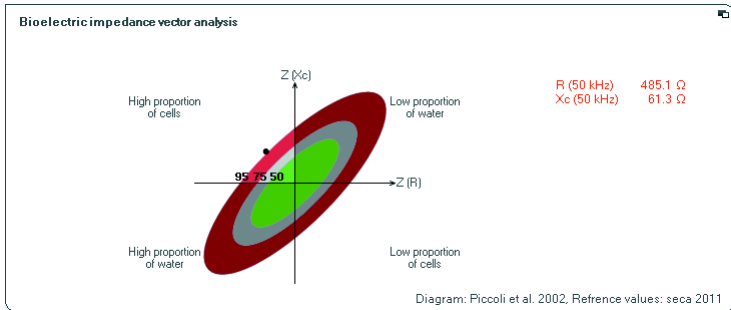
The goal here is to determine the patient's general state of health or, in the case of a known disease, to assess its severity. The following parameters are displayed:

- Phase angle  $\phi$  at 50Hz
- Hydration (HYD)
- Bioelectric impedance vector analysis (BIVA)
- Fat mass index (FMI)
- Fat-free mass index (FFMI)

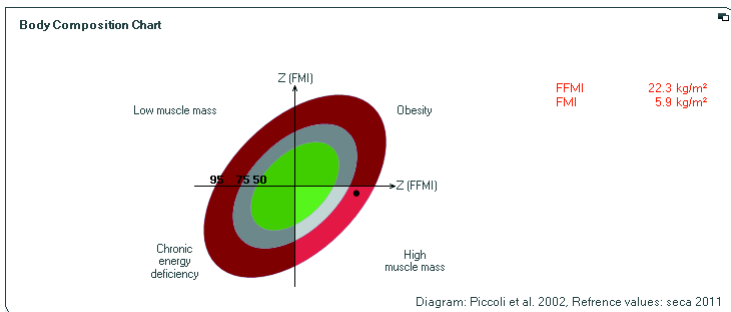


The following detail views are available for this module:

### Bioelectric impedance vector analysis



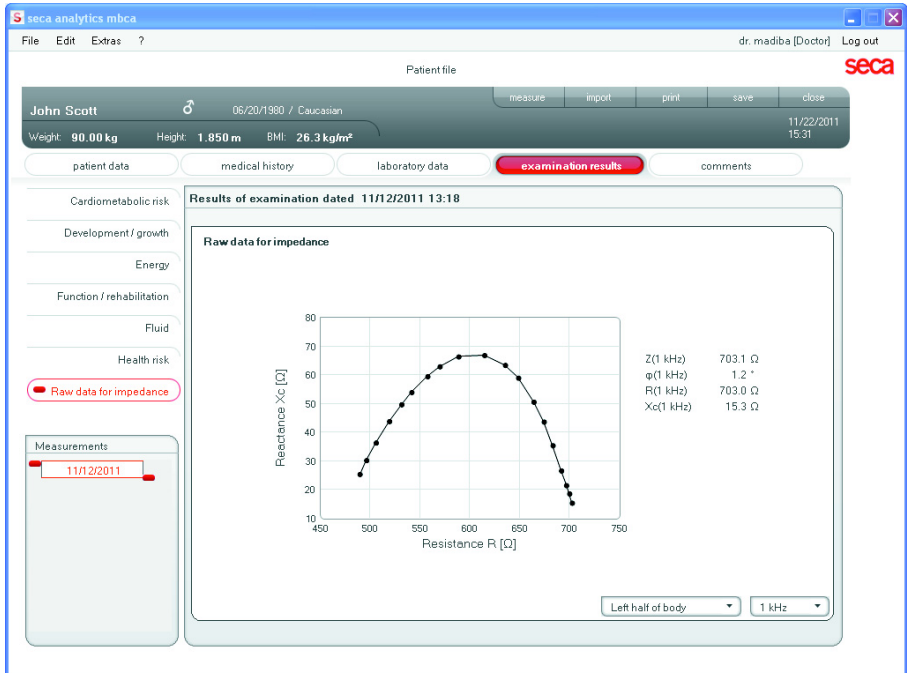
### Body composition chart (Fat mass index)



## Raw data for impedance

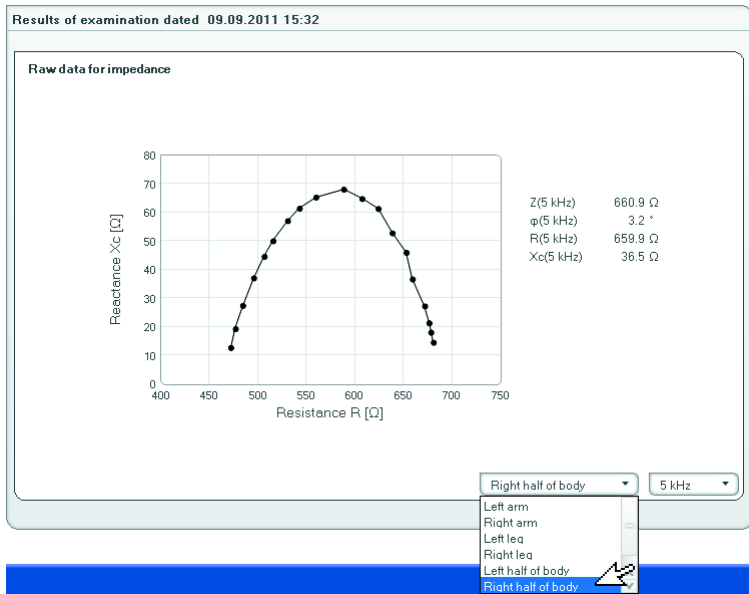
The Bioimpedance module outputs the results of the bioelectric impedance analysis in the form of raw data so it can be used for medical studies.

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



## Selecting parts of the body

1. Click on the dropdown menu to select a part of the body.



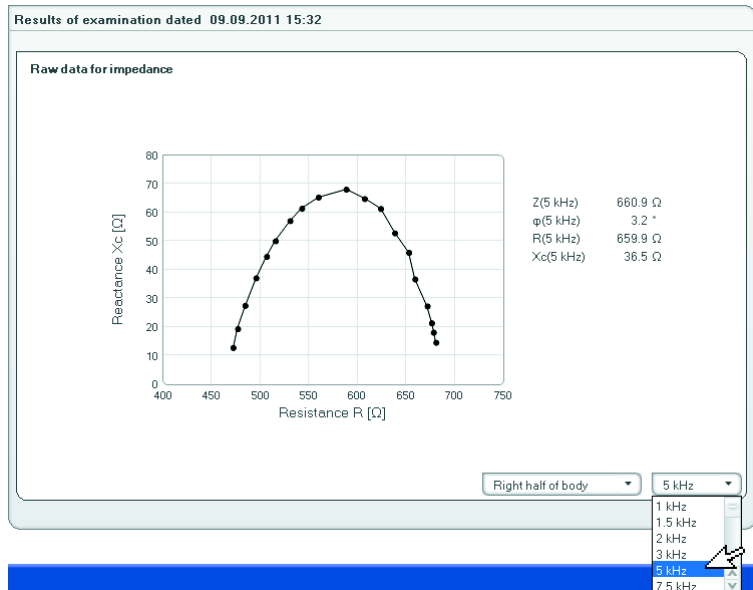
The dropdown menu opens.

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



## Selecting the frequency

1. Click on the dropdown menu to select the frequency.



The dropdown menu opens.

2. Click on the required frequency.

### NOTE:

If the **Raw data for impedance** module was not activated on the mbca, only four frequencies will be available for selection.

3. The values for the frequency selected are displayed.

## 6.2 References

The references listed below are stored in the software and form the basis for the assessment of the state of health of your patient. Some evaluation modules allow you to select which references you wish to use.

Which references you use depends on the country in which you are active, the regulations that apply in your institution, and your personal preferences.

For information about how you set the references in this software, see “Changing references” starting on page 15.

### Percentile curves for children

The following references can be selected:

Reference	Origin
Centers for Disease Control and Prevention (CDC 2000) <sup>a)</sup>	USA
World Health Organisation (WHO 2007) <sup>b)</sup>	International
Kromeyer-Hauschild et al. 2001 <sup>c)</sup>	Germany

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

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

<sup>c)</sup> Kromeyer-Hauschild K, Wabitsch M, Kunze D, Geller F, Geiß HC, Hesse V, von Hippel A, Jaeger U, Johnsen D, Korte W, Menner K, Müller G, Müller MJ, Niemann-Pilatus A, Remer T, Schaefer F, Wittchen HU, Zabransky S, Zellner K, Ziegler A, Hebebrand. Percentile für den Body-mass-Index für das Kindes- und Jugendalter unter Heranziehung verschiedener deutscher Stichproben. Monatsschr Kinderheilkd 2001; 149:807-818.

### Waist circumference for children

The following references can be selected:

Reference	Origin	Characteristics
Fernandez et al. 2004 <sup>a)</sup>	USA	For children of the following ethnicities: <ul style="list-style-type: none"> <li>• Caucasian</li> <li>• African</li> <li>• South and Central American</li> </ul>

Reference	Origin	Characteristics
Inokuchi et al. 2007 <sup>b)</sup>	Japan	For Asian children

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

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

**Resting energy expenditure children** The following reference is permanently fixed:

Reference	Origin
Müller et al. 2004 <sup>a)</sup>	Germany

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

**10-year risk for coronary heart disease** The following references can be selected:

Reference	Origin	Characteristics
Framingham score Wilson et al. 1998 <sup>a)</sup>	USA	Age group: 30-74 years
Prospective Cardiovascular Münster (PROCAM) Assmann et al. 2002 <sup>b)</sup>	Germany	Age group: 35-65 years, male
SCORE Conroy et al. 2003 <sup>c)</sup>	Europe	<ul style="list-style-type: none"> <li>• Age group: 18 years and up</li> <li>• Three tables are stored: <ul style="list-style-type: none"> <li>- Germany</li> <li>- High-risk countries<sup>d)</sup></li> <li>- Low-risk countries<sup>e)</sup></li> </ul> </li> </ul> <p>Depending on the country setting that the administrator uses during installation, the corresponding table is loaded.</p>

a) Wilson PWF, D'Agostino RB, Levy D, Belanger AM, Silbershatz H, Kannel WB. Prediction of Coronary Heart Disease Using Risk Factor Categories. *Circulation* 1998; 97:1837-1847.

- b) Assmann G, Cullen P, Schulte P. Simple Scoring Scheme for Calculating the Risk of Acute Coronary Events Based on the 10-Year Follow-Up of the Prospective Cardiovascular Münster (PROCAM) Study. *Circulation* 2002; 105:310-315.
- c) Conroy RM, Pyörälä K, Fitzgerald AP, Sans S, Menotti A, De Baquer D, Ducimetière P, Jousilahti P, Keil U, Njølstad I, Oganov RG, Thomson T, Tunstall-Pedoe H, Tverdal A, Wedel H, Whincup P, Wilhelmsen L, Graham IM. Estimation of ten-year risk of fatal cardiovascular disease in Europe: the SCORE project. *European Heart Journal* 2003; 24:987-1003.
- d) **European high-risk countries:** Albania (AL), Andorra (AND), Armenia (ARM), Azerbaijan (AZ), Bosnia and Herzegovina (BiH), Bulgaria (BG), Denmark (DK), Estonia (EE), Finland (FI), Georgia (GE), Ireland (IE), Iceland (IS), Croatia (HR), Liechtenstein (FL), Latvia (LV), Lithuania (LT), Malta (MT), Macedonia (MK), Moldova (MD), Monaco (MC), Montenegro (MNE), Kingdom of Norway (N) Austria (AT), Romania(RO), Russia (RUS), San Marino (RSM), Serbia (SRB), Slovakia (SK), Slovenia (SI), Czech Republic (CZ), Turkey (TR), Hungary (HU), Republic of Cypress (CY), Ukraine (UA), Vatican (V), United Kingdom (UK), Belarus (BY)
- e) **European low-risk countries:** all European countries not listed under 4)

**Resting energy expenditure, adults** The following references can be selected:

Reference	Origin
Müller et. al. 2004 <sup>a)</sup>	Germany
Liu et al. 1995 <sup>b)</sup>	China
FAO/WHO/UNU 2004 <sup>c)</sup>	International

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

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

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

**Metabolic syndrome** The following references can be selected:

Reference	Origin	Characteristics
IDF 2006 IDF 2006 <sup>a)</sup>	International International	Age group: 10-16 years Age group: 16 years and up
NCEP-ATP III 2001 <sup>b)</sup>	USA	Age group: 18 years and up

a) The IDF consensus worldwide definition of the Metabolic Syndrome. International Diabetes Federation 2006.

- b) National Cholesterol Education Program – Adult Treatment Panel III (NCEP – ATP III).  
Clinical Identification of the Metabolic Syndrome. National Institutes of Health;  
Publication No. 01-3305, May 2001

**Total body water (TBW)** The following reference is permanently selected:

Reference	Origin	Characteristics
seca 2011 <sup>a)</sup>	Germany USA	<ul style="list-style-type: none"> <li>• Takes 4 ethnicities into account: Caucasian, African, South &amp; Central American, Asian</li> <li>• Age group 18 to 65 years</li> <li>• BMI range 18.5 to 35 kg/m<sup>2</sup></li> </ul>

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

**Extracellular water (ECW)** The following reference is permanently selected:

Reference	Origin	Characteristics
seca 2011 <sup>a)</sup>	Germany USA	<ul style="list-style-type: none"> <li>• Takes 4 ethnicities into account: Caucasian, African, South &amp; Central American, Asian</li> <li>• Age group 18 to 65 years</li> <li>• BMI range 18.5 to 35 kg/m<sup>2</sup></li> </ul>

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

**Fat-free mass (FFM)** The following reference is permanently selected:

Reference	Origin	Characteristics
seca 2011 <sup>a)</sup>	Germany USA	<ul style="list-style-type: none"> <li>• Takes 4 ethnicities into account: Caucasian, African, South &amp; Central American, Asian</li> <li>• Age group 18 to 65 years</li> <li>• BMI range 18.5 to 35 kg/m<sup>2</sup></li> </ul>

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

**Bioimpedance vector analysis (BIVA)** The following reference is permanently selected:

Reference	Origin	Characteristics
seca 2011 <sup>a) b)</sup>	Germany USA	Reference values for normal range display • Age group: 18 and upwards

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

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

**Body Composition Chart (Fat mass indices FMI, FFM)** The following reference is permanently selected:

Reference	Origin	Characteristics
seca 2011 <sup>a) b)</sup>	Germany USA	Reference values for normal range display • Age group: 18 and upwards

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

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

**Phase angle ( $\phi$ )** The following reference is permanently selected:

Reference	Origin	Characteristics
seca 2011 <sup>a)</sup>	Germany USA	Reference values for normal range display • Age group: 18 and upwards

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

**Fat mass (FM)** The following reference is permanently selected:

Reference	Origin	Characteristics
Gallagher et al. 2000 <sup>a)</sup>	USA	<ul style="list-style-type: none"> <li>• Takes 3 ethnicities into account: Caucasian, Afro-American, South &amp; Central American, Asian</li> <li>• Age group: 20 and upwards</li> </ul>

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

**Skeletal muscle mass (SMM)** The following reference is permanently selected:

Reference	Origin	Characteristics
Kim et al. 2002 <sup>a)</sup>	USA	<ul style="list-style-type: none"> <li>• Age group: 18 and upwards</li> <li>• BMI range: 15.9 to 34.8 kg/m<sup>2</sup></li> </ul>

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

## 7. DISPLAY OF WEIGHTS

Weights are displayed in the software as follows:

Display scale	Setting BW <sup>a)</sup>	Display software
kkk.gg <sup>b)</sup>	kg	kkk.ggg if weight $\leq 20\text{kg}$ kkk.gg if weight $> 20\text{kg}$
kkk.g	kg	kkk.ggg if weight $\leq 20\text{kg}$ kkk.gg if weight $> 20\text{kg}$
kkk.ggg	kg	kkk.ggg if weight $\leq 20\text{kg}$ kkk.gg if weight $> 20\text{kg}$
ppp.p <sup>c)</sup>	kg	kkk.ggg if weight $\leq 20\text{kg}$ kkk.gg if weight $> 20\text{kg}$
ppp	kg	kkk.ggg if weight $\leq 20\text{kg}$ kkk.gg if weight $> 20\text{kg}$
ppp:oo <sup>d)</sup>	kg	kkk.ggg if weight $\leq 20\text{kg}$ kkk.gg if weight $> 20\text{kg}$
ss:pp.p <sup>e)</sup>	kg	kkk.ggg if weight $\leq 20\text{kg}$ kkk.gg if weight $> 20\text{kg}$
pp:oo.o	kg	kkk.ggg if weight $\leq 20\text{kg}$ kkk.gg if weight $> 20\text{kg}$
kkk.gg	lbs	ppp:oo.o if weight $\leq 20\text{kg}$ ppp.p if weight $> 20\text{kg}$
kkk.g	lbs	ppp:oo.o if weight $\leq 20\text{kg}$ ppp.p if weight $> 20\text{kg}$ ;
kkk.ggg	lbs	ppp:oo.o if weight $\leq 20\text{kg}$ ppp.p if weight $> 20\text{kg}$
ppp.p	lbs	ppp:oo.o if weight $\leq 20\text{kg}$ ppp.p if weight $> 20\text{kg}$
ppp	lbs	ppp:oo.o if weight $\leq 20\text{kg}$ ppp.p if weight $> 20\text{kg}$
ppp:oo	lbs	ppp:oo.o if weight $\leq 20\text{kg}$ ppp.p if weight $> 20\text{kg}$
ss:pp.p	lbs	ppp:oo.o if weight $\leq 20\text{kg}$ ppp.p if weight $> 20\text{kg}$
pp:oo.o	lbs	ppp:oo.o if weight $\leq 20\text{kg}$ ppp.p if weight $> 20\text{kg}$
kkk.gg	sts	s:pp:oo.o if weight $\leq 20\text{kg}$ ss:pp.p if weight $> 20\text{kg}$
kkk.g	sts	s:pp:oo.o if weight $\leq 20\text{kg}$ ss:pp.p if weight $> 20\text{kg}$



Display scale	Setting BW <sup>a)</sup>	Display software
kkk.ggg	sts	s:pp:oo.o if weight ≤20kg ss:pp.p if weight >20kg
ppp.p	sts	s:pp:oo.o if weight ≤20kg ss:pp.p if weight >20kg
ppp	sts	s:pp:oo.o if weight ≤20kg ss:pp.p if weight >20kg
ppp:oo	sts	s:pp:oo.o if weight ≤20kg ss:pp.p if weight >20kg
ss:pp.p	sts	s:pp:oo.o if weight ≤20kg ss:pp.p if weight >20kg
pp:oo.o	sts	s:pp:oo.o if weight ≤20kg ss:pp.p if weight >20kg

a) "kg": kilograms, "lbs": pounds, "sts": stones

b) "k§": figure indicates kilograms, "g": figure indicates grams

c) "p": figure indicates pounds

d) "p": figure indicates pounds, "o": figure indicates ounces

e) "s": figure indicates stones, "p": figure indicates pounds

#### NOTE:

- For manual entry of measured values, the display takes place exclusively in the format "ppp.p" if the unit "lbs" is set in the software.
- For manual entry of measured values, the display takes place exclusively in the format "ss:pp.p" if the unit "sts" is set in the software.

## 8. WARRANTY

Please note that warranty limitations which, among other things, can arise from the license, apply to this software. The warranty limitations can be called up at [www.seca.com](http://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  
Deklaracija 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  
Programinė įranga  
Programmatūra  
Oprogramowanie  
Programska oprema  
Softvér  
Yazılım

**seca 115**

**D** ... erfüllt die geltenden Anforderungen folgender Richtlinien:  
Richtlinien 93/42/EWG und 2007/47/EG über Medizinprodukte.

**GB** ...complies with the requirements of the following Directives:  
Directives 93/42/EEC and 2007/47/EC for medical products.

**F** ...satisfait aux exigences en vigueur figurant dans les directives suivantes :  
Directives 93/42/CEE et 2007/47/CE relatives aux dispositifs médicaux

**I** ...risponde ai requisiti prescritti dalle direttive seguenti:  
direttive 93/42/CEE e 2007/47/CEE sui dispositivi medici.

**E** ...cumple las exigencias vigentes de las siguientes directivas:  
Directivas 93/42/CEE y 2007/47/CE sobre productos sanitarios.

**DK** ... opfylder de grundlæggende krav fra følgende direktiver:  
direktiverne 93/42/EØF og 2007/47/EF om medicinprodukter.

**S** ...uppfyller gällande krav enligt följande direktiv:  
Direktiv 93/42/EEG och 2007/47/EG om medicinska produkter.

**N** ... oppfyller gjeldende krav i følgende direktiver:  
direktiv 93/42/EØF og 2007/47/EF om medisinske produkter.

**FIN** ... täyttää seuraavien direktiivien voimassa olevat määräykset:  
lääkinnällisiä laitteita koskevat direktiivit 93/42/ETY ja 2007/47/EY.

**NL** ...is in overeenstemming met de geldende eisen van de volgende richtlijnen:  
richtlijnen 93/42/EEG en 2007/47/EG betreffende medische hulpmiddelen.

**P** ... cumpre os requisitos essenciais das seguintes Directivas:  
Directivas 93/42/CEE e 2007/47/CE relativas a dispositivos médicos.

**GR** ... εκπληρώνει τις ισχύουσες απαιτήσεις των ακόλουθων οδηγιών:  
Οδηγίες 93/42/EOK και 2007/47/EK περί ιατρικών βοηθημάτων.

**CZ** ...splňuje platné požadavky těchto směrnic: směrnice 93/42/EHS a 2007/47/ES o zdravotnických prostředcích.

**EST** ...vastab järgmiste direktiividega kehtestatud nõuetele: meditsiinivahetite direktiivid 93/42/EMÜ ja 2007/47/EÜs.

**HU** ...teljesíti a következı irányelvek érvényben lévı követelményeit: 93/42/EGK és 2007/47/EK irányelv az orvostechnikai termékekrıl.

**LT** ...atitinka tokias galiojančias direktyvas: direktyvą 93/42/EEB ir 2007/47/EB dėl medicinos produktų.

**LV** ... atbilst šādu direktīvu spēkā esošajām prasībām: direktīvas 93/42/EEK un 2007/47/EK par medicīniskām ierīcēm.

**PL** ...spełnia obowiązujące wymagania następujących dyrektyw: dyrektywy 93/42/EWG i 2007/47/WE o wyrobach medycznych.


**SLO** ...izpolnjuje veljavne zahteve naslednjih direktiv: direktiv 93/42/EGS in 2007/47/ES o medicinskih pripomočkih.

**SK** ...spĺňa platné požiadavky nasledujúcich smerníc: smernice 93/42/EHS a 2007/47/ES o medicínskych výrobkoch.

**TR** ...aşağıdaki yönergelerin geçerli talimatlarını yerine getirir: Tibbi ürünler hakkında 93/42/AET ve 2007/47/AT yönetmeliđi.



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