

seca 101

Instructions for Use for Doctors and Assistants

from software version 1.2

CONTENTS

1. System description	3	5. Operation	10
1.1 Intended use	3	5.1 Starting/exiting the PC software	10
1.2 Description of function.	3	Starting the PC software	10
Transmission of data by seca scales and stadiometers	3	Opening a software window	11
Printing	3	Exiting the PC software	11
Transmitting data to a PDMS	4	5.2 Selecting measuring devices	11
Managing patient data	4	5.3 Measuring operation with the seca directprint module	13
Access rights	4	5.4 Measuring operation with the HL7 or GDT protocol	14
1.3 User qualification	4	Retrieving patient data from the PDMS	14
Installation and administration	4	Performing a measurement	14
Measuring mode	4	Saving the measured results	16
2.1 Safety rules in the instructions for use	5	5.5 Measuring operation with the seca keyboard module	17
2.2 Basic safety information	5	5.6 Working in the software window	18
Using the software	5	Adjusting window size	18
Using measured results	6	Navigating in a down-sized window	19
3. Overview	7	Minimizing/restoring window	20
3.1 Main window	7	Editing data	20
3.2 Identification on the packaging	8	6. Warranty	21
4. Installation	9		
4.1 General	9		
4.2 Obtaining version information	9		

1. SYSTEM DESCRIPTION

1.1 Intended use

The **seca 101** PC software is mainly used at hospitals, medical practices and inpatient care facilities in accordance with national regulations.

The **seca 101** PC software is for managing weight and height measurements and for automatically calculating parameters which can be deduced from them, for example body mass index (BMI).

Measured results can be transmitted to a patient data management system or printed out on a standard PC printer.

The results support the attending physician with the following medical issues:

- monitoring of growth processes and weight changes
- determining energy expenditure and energy reserves

The **seca 101** PC software is **not** diagnostic software.

1.2 Description of function

Transmission of data by **seca scales and stadiometers**

seca scales and stadiometers from the **seca 360° wireless** system enable wireless transmission of data to the **seca 101** PC software. The PC software must be installed on a PC for this purpose. The **seca 360° wireless USB adapter 456** must be connected to the same PC.

seca scales with an RS232 interface can transmit data to the **seca 101** PC software via the COM ports of the PC.

Printing

The **seca 101** PC software is supplied with a print module pre-installed. This module enables the **seca 101** PC software to compile detailed results reports and send them to a local or a network printer. Printing of the results reports is started directly from the connected **seca 360° wireless** devices.

The print function is not available for scales with an RS232 interface.

Transmitting data to a PDMS

The following EMR modules for data transmission to a patient data management system (PDMS) (file ending: "*.sem" = seca EMR Integration Module) are available for downloading from www.seca.com:

- seca GDT module
- seca HL7 module
- seca keyboard module

EMR modules for other protocols are in preparation and will continuously be made available for download on the seca website.

Managing patient data

The **seca 101** PC software does not contain its own patient database. If data transmission to a PDMS is used instead of the print function, access can be had to the patient data in the PDMS. An interface to the **seca 101** PC software has to be set up in the PDMS for this purpose.

Access rights

The **seca 101** PC software does not administer user accounts. The primary functions are freely accessible. System settings can be protected with a password.

1.3 User qualification

Installation and administration

The **seca 101** PC software may only be installed and administered by experienced administrators or hospital technicians.

Measuring mode

The **seca 101** 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.

NOTICE!

Identifies possibility of incorrect operation of 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.
- ▶ Use the **seca 101** PC software only for the specified intended use.
- ▶ Use only seca scales and stadiometers in conjunction with the **seca 101 PC software**.
- ▶ Keep HF devices such as cellphones and televisions a minimum distance of approx. 1 meter away in order to prevent faulty measurements or wireless transmission faults.
- ▶ The actual transmit power of HF devices can require minimum distances of more than 1 metre. For details, visit www.seca.com.

Using measured results



WARNING!

Hazard to patient

The **seca 101** PC software is **not** diagnostic software. The PC software 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 101** PC software.
- ▶ The responsibility for diagnoses and the therapies derived from them lies with the attending physician.



CAUTION!

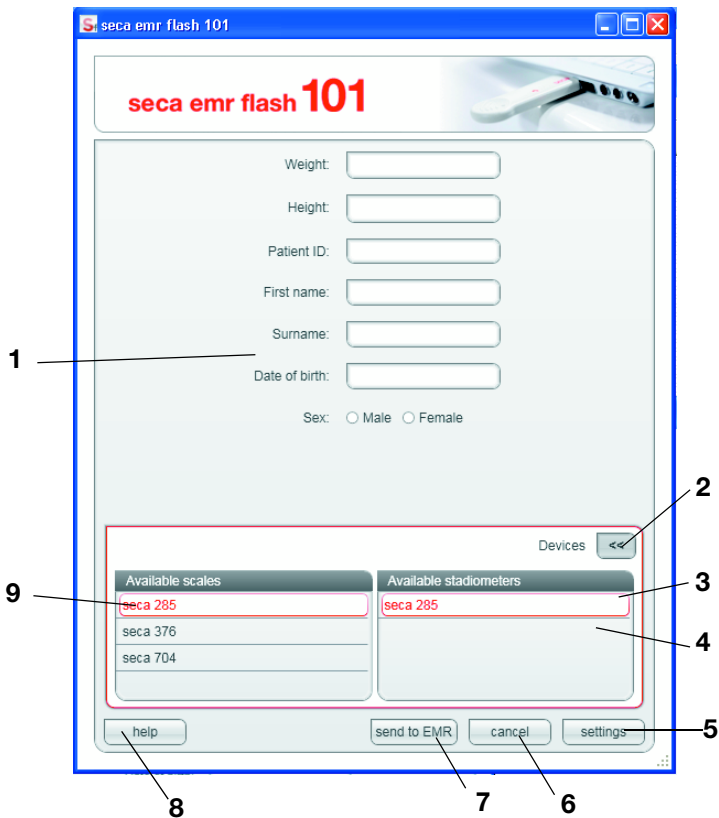
Hazard to patient

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.
- ▶ Before storing and using measurements acquired with the **seca 101** PC software (e. g. in a patient data management system), check that these measurements are plausible and correspond to the display on the measuring device.
- ▶ Once measurements have been transmitted from the **seca 101** PC software to a patient data management system, check that these measurements are plausible and have been assigned to the correct patient before using them.

3. OVERVIEW





3.1 Main window



No.	Control	Function
1	Patient data	<p>Values are entered on measurement:</p> <ul style="list-style-type: none">• Weight• Height <p>Data are transmitted from the PDMS to the seca 101 PC software:</p> <ul style="list-style-type: none">• Patient ID• First name• Surname• Date of birth• Gender <p>Fields containing data transmitted by the PDMS can be displayed or hidden. Contact your administrator.</p>

No.	Control	Function
2	Devices	Show/hide list of devices <ul style="list-style-type: none"> • « : hide list of devices • » : show list of devices
3	Available stadiometers	Shows which seca stadiometers and seca scales with a BMI function are connected to the seca 101 PC software.
4	Selection bar	Shows which devices are selected for measurements.
5	settings	Configuration options for administrators, password-protected
6	cancel	<ul style="list-style-type: none"> • Clears patient data from measuring window • Minimizes the software window
7	send to EMR	Transmit measured results to an Electronic Medical Record (EMR) in the PDMS
8	help	Access to: instructions for use for doctors and assistants
9	Available scales	Shows which seca 360° wireless scales are connected to the seca 101 PC software.

3.2 Identification on the packaging

Text/symbol	Meaning
	Follow instructions for use
	Device complies with EC directives
	Manufacturer's address and date of manufacture
	Packaging material can be disposed of through recycling programs

4. INSTALLATION

4.1 General

The **seca 101** PC software should only be installed by experienced administrators.

Information about configuration options can be found in the Administrator's manual. If you have any queries or requests for changes, please contact your administrator or hospital technician.



WARNING!

Misdiagnosis through loss of data

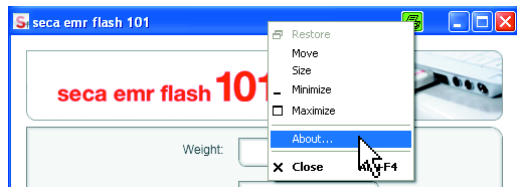
Improper installation or incorrect changes to installation may cause loss of data and result in misdiagnosis.

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

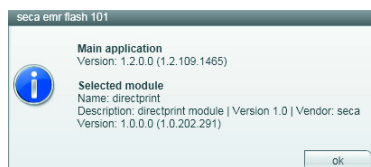
4.2 Obtaining version information

You can have information displayed about the version of the PC software installed and about the EMR module selected. To do so, proceed as outlined below.

1. Start the PC software.
2. Right-click in the header of the software window. A context menu appears.



3. In the context menu, click on **About ...**. The **About ...** box appears.



4. To close the **About ...** box, click on **ok**.

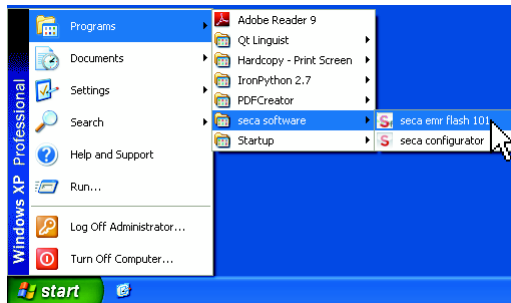
5. OPERATION

5.1 Starting/exiting the PC software

Starting the PC software

- Click on "start\Programme\seca\seca emr flash 101".

The PC software starts.



NOTE:

- The **seca 101** PC software can be set up so that it starts automatically whenever a user logs on in Windows. Contact your administrator for this.
- Some PDMS can be set up so that they start the **seca 101** PC software automatically as soon as patient data in the PDMS start being transmitted to the **seca 101** interface. Contact your administrator for this.

Opening a software window



If the **seca 101** PC software is set up to start automatically, it appears in the notification area of the taskbar in the form of a program icon.

- Right-click on the program icon in the notification area of the taskbar and select the item **Open**.

Exiting the PC software



- Click on the cross symbol at the top right. The PC software will close.

5.2 Selecting measuring devices


1. In the **seca 101** PC software, click on the » symbol next to the **Devices** entry. The device list opens.

The screenshot shows the 'seca emr flash 101' software window. At the top, there's a header with the software name and a small image of a scale. Below this, there are several input fields for patient information: Weight, Height, Patient ID, First name, Surname, Date of birth, and Sex (with radio buttons for Male and Female). At the bottom, there's a 'Devices' section that is currently expanded. It contains two side-by-side lists: 'Available scales' and 'Available stadiometers'. In both lists, 'seca 285' is highlighted. Below these lists are four buttons: 'help', 'send to EMR', 'cancel', and 'settings'.

2. Click on the desired devices.

NOTE:

- Measuring devices which appear in both the **Available scales** and the **Available stadiometers** fields are seca scales with a BMI function or seca measuring stations.
- If you want to receive both weight and height from a measuring device, click on the device in both the **Available scales** and **Available stadiometers** fields.

3. Click on the “” symbol.

The device list closes.

NOTE:

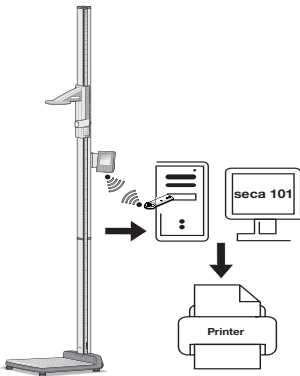
You cannot edit the device list. If devices need adding or removing, contact your administrator.

4. Perform the measuring process as appropriate for the EMR module in use:
 - "Measuring operation with the seca directprint module" from page 13
 - "Measuring operation with the HL7 or GDT protocol" from page 14
 - "Measuring operation with the seca keyboard module" from page 17

NOTE:

The information about which EMR module your system uses can be found in the **Selected module** field of the **About ...** box (see "Obtaining version information" on page 9).

5.3 Measuring operation with the seca directprint module



```
print
```

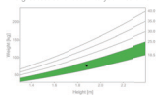


send
print



Seca | Your BMI printout

Dear Patient,
The greatest contribution to your health is made by YOU



Remember: you make an active contribution to a healthy life when you follow the basic rules: a healthy diet, adequate exercise and maintaining your normal weight. Energy consumption should always match your energy requirements. If it does, your weight will generally fall within the normal range. Your body will be grateful for years to come, since a healthy lifestyle reduces the risks of coronary heart disease, high blood pressure, stroke and Type 2 diabetes.

Ask me about your personal Bioelectrical Impedance Analysis (BIA) with the seca mBCA if you would like to have your body composition measured. The analysis gives you information about the proportions of fat and muscle mass.

[illegible]

If you are interested in your health, please talk to me.

Weight (kg)	77.00
Height (m)	1.68
BMI (kg/m ²)	27.79

Your BMI is in the normal range.

Health Tip

A good balance between weight and physical activity helps keep you healthy and mobile well into old age. Even if your success is not immediately obvious on the scale, you will feel like it.

Did you know?

One hot meal *per day* is not essential, since hot food cools down in the mouth. One hot meal reaches the stomach, it is practically the same temperature as cold food, which is warmed when consumed.

True or false? Many vegetables are better for you than seafood. *False!* All types of vegetables are difficult to digest in the same form, so your body can make better use of many valuable nutrients when they come in cooked vegetables.



Fuel, sports & nutrition
You can find more information at www.adaa.org

or simply scan the QR code.

NOTE:

The seca directprint function is not available for devices with an RS232 interface.

1. Check that the **seca 360° wireless USB adapter 456** is inserted in a USB port of the PC and that the LED on the USB adapter is red.
2. Ensure that all the measuring devices you have selected in the **seca 101** PC software (see "Selecting measuring devices" on page 11) are selected.

NOTICE!

Incorrect measurement if wrong devices selected

If the wrong devices are selected, measured results may be assigned to the wrong patient or measurements may not be received at all.

- Use the name of each device to check you have selected the right devices.

3. Perform the measurement(s) on the patient.
4. On the measuring devices, press the **print** button (if button has two functions, press and hold).

The measurements are transmitted to the **seca 101** PC software.

Printing out of the results report on the default PC printer starts automatically.

NOTICE!

Loss of data

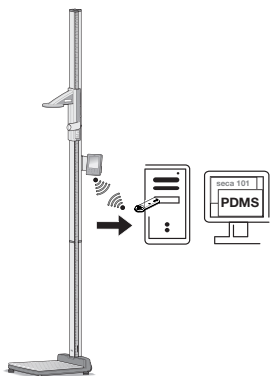
If there is no input for approx. 10 minutes, partial results are discarded.

- Measure one patient's weight and height immediately consecutively.

NOTE:

The measurements will be displayed in the units selected as defaults in the **seca 101** PC software, regardless of the settings used on the measuring devices.

5.4 Measuring operation with the HL7 or GDT protocol



NOTICE!

Faulty data transmission

The operation described in this section applies only to PDMS connected to the **seca 101** PC software via standardized protocols (e. g. HL7 or GTD).

- ▶ If the seca keyboard module is set up for data transmission to the PDMS, proceed as described in the section entitled "5.5 Measuring operation with the seca keyboard module".
- ▶ If you are uncertain what kind of connection has been set up between your PDMS and the **seca 101** PC software, contact your administrator.

Retrieving patient data from the PDMS

Before a measurement is taken, the patient data must first be transmitted from the PDMS to the **seca 101** PC software. This allows you to transmit the results straight to the patient record in your PDMS following the measurement.

An interface configured for the PDMS by your administrator is used to transmit the patient data.

The sequence of data transmission depends on the PDMS used and on how your administrator has configured the interface between the PDMS and the **seca 101** PC software. Contact your administrator for further information about this.

Performing a measurement

1. Make sure that the data connection has been made between the measuring device and the PC.
 - **seca 360° wireless** network:
seca 360° wireless USB adapter 456 is plugged into a USB port of the PC and the LED on the USB adapter is red
 - RS232 interface: there is an intact cable connection between the measuring device and the PC
2. Check that the correct patient data are shown in the **seca 101** PC software.
3. Make sure that all the measuring devices you have selected in the **seca 101** PC software (see "Selecting measuring devices" on page 11) are switched on.

NOTICE!**Incorrect measurement if wrong devices selected**

If the wrong devices are selected, measured results may be assigned to the wrong patient or measurements may not be received at all.

- Use the name of each device to check you have selected the correct devices.

▲
send

send
print
←

4. Perform the measurement(s) on the patient.
5. On the measuring devices, press the **send** button (if button has two functions, press button briefly). The measurements are transmitted to the **seca 101** PC software.

NOTICE!**Loss of data**

If there is no input for approx. 10 minutes, partial results are discarded.

- Measure one patient's weight and height immediately consecutively.

NOTE:

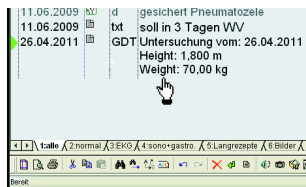
On **seca 360° wireless** devices with activated Autosend function, measurements are transmitted to the PC software automatically as soon as a hold value is available.

6. Check that the measured values are displayed in the **Weight/Height** fields of the PC software:

**NOTE:**

- If you are not sure whether automatic data transfer is activated on your **seca 360° wireless** devices, contact your administrator.
- Measurements will be displayed in the units selected as defaults in the PC software, regardless of the settings used on the measuring devices.

Saving the measured results



1. Click on **send to EMR**.

The measured results are transmitted to the patient record in the PDMS.

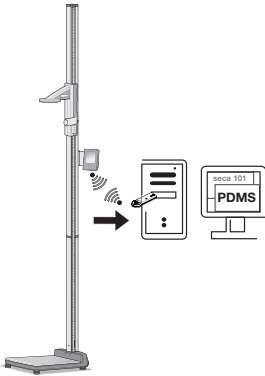
2. Check in the PDMS that the measurements have been correctly transmitted and assigned to the right patient record.

NOTE:

- Some PDMS can be set up so that the measurements are transmitted straight to the PDMS when transmitted via the interface without this being displayed in the main window of the seca 101 PC software (Autosend to PDMS/suppress GUI).
- Contact your administrator if you have any queries about the PDMS used at your institution.

5.5 Measuring operation with the seca keyboard module

The seca keyboard module allows measured results to be inserted directly at the cursor position in any target software, e.g. a word-processing program or a PDMS, which does not support common transmission protocols (HL7, GDT).



Notice!

Software malfunction in measuring mode

Transmitted data are converted into keyboard input, so in measuring mode, this may cause the **seca 101** PC software or the target software to behave unexpectedly.

- ▶ Check at the start of measuring that the target software, **not** the **seca 101** PC software is the active window.
- ▶ When the seca keyboard module is activated, **never** press the **send to EMR** button.
- ▶ If you are uncertain what kind of connection has been set up between your target software and the **seca 101** PC software, contact your administrator.

NOTE:

The seca keyboard module is not available for devices with an RS232 interface.

1. Check that the **seca 360° wireless USB adapter 456** is inserted in a USB port of the PC and that the LED on the USB adapter is red.
2. Ensure that all the measuring devices you have selected in the **seca 101** PC software (see "Selecting measuring devices" on page 11) are selected.

NOTICE!

Incorrect measurement if wrong devices selected

If the wrong devices are selected, measured results may be assigned to the wrong patient or measurements may not be received at all.

- ▶ Use the name of each device to check you have selected the right devices.
3. Perform the measurement(s) on the patient.

▲
send

send
print
↩

4. On the measuring devices, press the **send** button (if button has two functions, press button briefly).
The measurements are transmitted to the target software and inserted directly at the cursor position.

The measurements are **not** displayed in the software window of the **seca 101** PC software.

NOTICE!

Loss of data

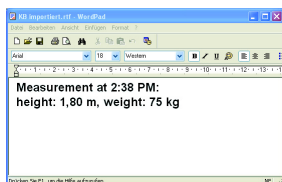
If there is no input for approx. 10 minutes, partial results are discarded.

- Measure one patient's weight and height immediately consecutively.

5. Check in the target software that the measurements have been correctly transmitted and assigned to the right patient record.

NOTE:

Measurements will be displayed in the units selected as defaults in the PC software, regardless of the settings used on the measuring devices.

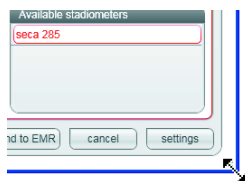


5.6 Working in the software window

Adjusting window size

As you are used to from other graphical program interfaces, you can also adjust window size for the **seca 101** software. To do so, proceed as outlined below.

- To adjust the size of the window individually, "drag" on one corner of the software window.

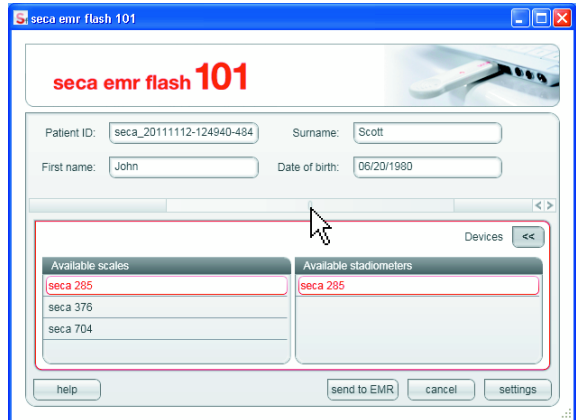


- To maximize the software window to fill the screen, click on the **Maximize** icon.
- To reduce the software window to the window size individually set, click on the **Down-size** icon.

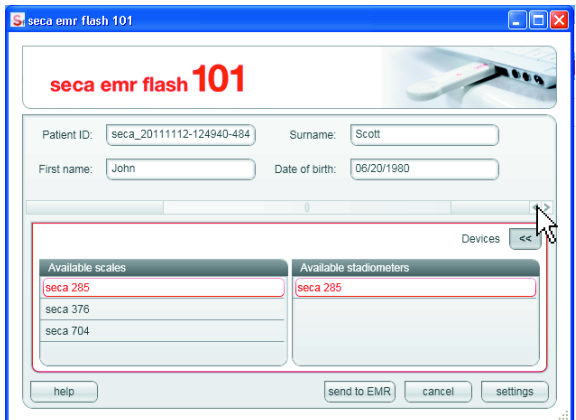
Navigating in a down-sized window

If you have significantly down-sized the software window, it will no longer be possible to show all the patient data in the software window. A scroll bar will be shown instead. To view all the patient data, proceed as outlined below.

- Move the scrollbar thumb to the left or right. The patient data will appear depending on the direction of movement.



- Click on one of the arrow keys of the scrollbar. The patient data will appear depending on the direction of the arrow.



Minimizing/restoring window



If you wish to close the software window without exiting the PC software, proceed as outlined below.

- Click on the **Minimize** icon.

The PC software will behave differently depending on the default settings made by the administrator:

- : the PC software appears in the taskbar in the form of a button.
- the PC software appears in the notification area of the taskbar in the form of a program icon

To restore the software window, proceed as outlined below depending on the default setting.

- Click on the button in the taskbar.
- Right-click on the program icon in the notification area of the taskbar and select the item **Open**.

Editing data

As you are used to from other graphical software interfaces, you can also edit entries in the **seca 101** PC software. To do so, proceed as outlined below.

- Supplement data manually.
- Select data and use the functions **Cut**, **Copy** and **Paste**.

NOTE:

- The functions **Cut**, **Copy** and **Paste** can be accessed as a context menu if you right-click.
- Once the **seca 101**PC software has received measurements, the entry fields for weight and height can no longer be edited.

6. 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
Överensstemmelsesattest
Försäkran om överensstämmelse
Konformitetserklæring
Vaatimuksenmukaisuusvakuutus
Verklaring van overeenkomst
Declaração de conformidade
Δήλωση Συμβατότητας
Prohlášení o shodě
Vastavusdeklaratsioon
Megfelelőségi nyilatkozat
Atitikties patvirtinimas
Atbilstības apliecinājums
Deklaracja zgodności
Izjava o skladnosti
Vyhlasenie 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 101

- D** ... erfüllt die geltenden Anforderungen folgender Richtlinien:
93/42/EEG über Medizinprodukte.
- GB** ... complies with the requirements of the following standard:
93/42/EEC on medical products.
- F** ... satisfait les exigences en vigueur de la norme suivante :
93/42/CEE sur les produits et appareils médicaux
- I** ... soddisfa i requisiti vigenti della seguente norma:
93/42/CEE sui prodotti medicali.
- E** ... cumple las exigencias vigentes de la siguiente norma:
93/42/CEE sobre productos médicos.
- DK** ... opfylder gældende krav iht. følgende standard:
93/42/EF om medicinprodukter.
- CZ** ... splňuje platné požadavky směrnice:
93/42/EHS o zdravotnických prostředcích.
- EST** ... täidab järgneva normi kehtivad nõudeid:
93/42/EMÜ meditsiinitoodete kohta.
- HU** ... megfelel a következő szabvány érvényben lévő előírásainak:
93/42/EGK irányelv az orvostechnikai eszközökről.
- LT** ... atitinka taikomas reikalavimus pagal standartą:
medicinos prietaisų direktyvos 93/42/EEB.
- LV** ... atbilst šāda standarta spēkā esošajām prasībām:
93/42/EWG par medicīnas produkciju.
- S** ... uppfyller gällande krav enligt norm:
93/42/EEG över medicinska produkter.
- N** ... oppfyller gjeldende krav i følgende standard:
93/42/EEC om medisinske produkter.
- FIN** ... täyttää seuraavan standardin voimassa olevat määräykset:
93/42/ETY lääketieteellisistä tuotteista.
- NL** ... voldoet aan de geldende eisen van de volgende norm:
93/42/EEG inzake medische hulpmiddelen.
- P** ... cumpre os requisitos em vigor da seguinte norma:
93/42/CEE sobre artigos médicos do Conselho.
- GR** ... εκπληρώνει τις ισχύουσες απαιτήσεις του ακόλουθου προτύπου:
DIN EN 62304 περί λογισμικού ιατρικών βοηθημάτων.
- PL** ... spełnia obowiązujące wymogi następującej normy:
93/42/EWG na temat wyrobów medycznych.
- SLO** ... izpolnjuje veljavne zahteve naslednjega standarda:
93/42/EGS za medicinske izdelke.
- SK** ... spĺňa platné požiadavky nasledovnej normy:
93/42/EWG o zdravotníckych výrobkoch.
- TR** ... şu normların geçerli gerekliliklerini sağlamaktadır:
tibbi ürünler hakkında 93/42/EWG.

Hamburg, August 2014

Frederik Vogel



CEO Development and Manufacturing
seca gmbh & co. kg
Hammer Steindamm 9-25
22089 Hamburg
Germany
Telefon: +4940 20 00 00-0
Telefax: +49 40 20 00 00-50
i: www.seca.com

Medical Measuring Systems and Scales since 1840

17-10-01-252-002a/08-2014G

seca gmbh & co. kg
Hammer Steindamm 9-25
22089 Hamburg • Germany
Telephone +49 40 20 00 00 0
Fax +49 40 20 00 00 50
info@seca.com

seca operates worldwide with headquarters
in Germany and branches in:

seca france

seca united kingdom

seca north america

seca schweiz

seca zhong guo

seca nihon

seca mexico

seca austria

seca polska

seca middle east

and with exclusive partners in
more than 110 countries.

All contact data under www.seca.com