ottobock.

Quality for life

Data Station

CE

C-Soft Plus 1.10 4X440=V1.10

Table of contents

1 Foreword

INFORMATION

Date of last update: 2021-12-21
- ► Please read this document carefully before using the product and observe the safety notices.
- ► Please contact the manufacturer if you have questions about the product or in case of problems.
- ► Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- ► Please keep this document for your records.

The "4X440=V1.10 C-Soft Plus 1.10" adjustment software is referred to below as C-Soft Plus, software or adjustment software.

Only put the product into use in accordance with the information contained in the accompanying documents supplied.

2 Product description

2.1 Function

The "C-Soft Plus" software is designed for the patient-specific adjustment of the products 3C98-3=*, 3C88-3=*. The integrated alignment recommendation supports optimum adaptation of the component to the patient.

Communication between the software and the prosthesis takes place exclusively via Bluetooth data transfer.

2.2 Combination possibilities

Supported Bluetooth adapter
- 60X5 BionicLink PC

Products that can be adjusted
- 3C88-3=*, 3C98-3=*

3 Intended use

3.1 Indications for use

The "C-Soft Plus" software is designed for the patient-specific adjustment of the products 3C88-3=*, 3C98-3=*.

3.2 Conditions of use
- For the software to be able to be used, the PC must fulfil the system requirements.
- The battery of the prosthesis must be charged.

3.3 Contraindications
- All conditions which contradict or go beyond the specifications listed in the section on "Safety" and "Indications for use".

3.4 Qualification

The adjustment software may only be used by qualified personnel that has participated in the relevant product training and has been certified for the application. Additional product training courses may become necessary to qualify for software updates.

4 Safety

4.1 Explanation of warning symbols

⚠ WARNING	Warning regarding possible serious risks of accident or injury.
⚠ CAUTION	Warning regarding possible risks of accident or injury.
NOTICE	Warning regarding possible technical damage.

4.2 Structure of the safety instructions

> **⚠ WARNING**
>
> **The heading describes the source and/or the type of hazard**
> The introduction describes the consequences in case of failure to observe the safety instructions. Consequences are presented as follows if more than one consequence is possible:
> > E.g.: Consequence 1 in the event of failure to observe the hazard
> > E.g.: Consequence 2 in the event of failure to observe the hazard
> ► This symbol identifies activities/actions that must be observed/carried out in order to avert the hazard.

4.3 General safety instructions

> **⚠ WARNING**
>
> **Non-observance of safety notices**
> Personal injury/damage to the product due to using the product in certain situations.
> ► Observe the safety notices and the stated precautions in this accompanying document.

> **⚠ WARNING**
>
> **Outdated version of the product information on the data carrier**
> Personal injury/damage to the product may result from insufficient information about product handling.
> ► Please note that the product information on the data carrier may not be current.
> ► Please refer to the product information included with each respective delivery or handed out during product training.
> ► To find out whether your product information is up to date, please contact an authorised Ottobock Service Centre.

> **⚠ CAUTION**
>
> **Operator errors when adjusting settings using the adjustment software**
> Falling due to unexpected prosthesis behaviour.
> ► Do not charge the prosthesis battery during the adjustment process since the prosthesis is not functional while the battery is being charged.
> ► During the adjustment process, the prosthesis must not remain unattended when connected to the adjustment software while being worn by the patient.
> ► Observe the maximum range of the Bluetooth connection and note that obstacles may limit this range.
> ► During the data transfer (PC to prosthesis), the prosthesis wearer should sit or stand still, and the BionicLink PC must not be removed from the computer.

- ► If you want to make only temporary changes to the settings while connected to the adjustment software, you must reverse these changes before disconnecting the adjustment software.
  You must also ensure the patient does not leave the range of the Bluetooth connection if settings have been changed temporarily.
- ► Inform the patient immediately if the data connection is accidentally interrupted during the adjustment process.
- ► The connection to the prosthesis must always be disconnected after adjustments have been completed.
- ► Successful participation in an Ottobock product training course is mandatory prior to initial use. Additional product training courses may be required to qualify for software updates.
- ► The correct input of the foot size, prosthesis dimensions, body weight and calibration are important criteria for achieving a quality fitting. If the values are too high, the prosthesis may not switch to the swing phase. If the values are too low, the prosthesis may trigger the swing phase at the wrong time.
- ► If the patient uses walking aids (e.g., crutches or walking canes) during the adjustment process, you will need to readjust the settings when the patient no longer requires these aids.
- ► Use the online help function integrated into the software.
- ► Do not disclose your personal access data.

NOTICE

Connecting the data carrier to a USB connection that is not easily accessible on the computer
In the event of a fault, you will not be able to disconnect the power supply to the data carrier immediately.
- ► Connect the data carrier only to USB connections that can be easily accessed on the computer.

INFORMATION
- ► Please note that observing the prescribed system requirements is mandatory.
- ► It is recommended that you do not run any other programs during installation and use of the adjustment software, since this can affect performance.
- ► If you require further information, contact the Ottobock office responsible for your country.

INFORMATION

Cybersecurity
- ► Keep your operating system up to date and always install any available security updates.
- ► Protect your computer from unauthorised access (e.g., by using virus scans, password protection etc.).
- ► Do not use unsecured networks.
- ► Please contact the manufacturer if you suspect cybersecurity problems.

5 Scope of delivery
- 1 pc. 4X440=V1.10 C-Soft Plus 1.10 USB data carrier
- 1 pc. Instructions for use (qualified personnel)

6 System Requirements

6.1 Minimum PC Hardware Requirements

The minimum hardware requirements for installation/use of the adjustment software apply independently of the operating system being used. If the minimum requirements for using the operating system are higher than the hardware requirements described here, the minimum requirements for the operating system apply.

- PC with an Intel Core2 processor (x64) or faster
- 2 GB RAM
- At least 5 GB free hard drive space
- Graphics card with Open GL support
- Resolution 1280 x 768
- Display scale 100% or 96 DPI (settings above 150% can cause display problems depending on the chosen resolution)
- 32-bit colour depth (16.7 million colours)
- 1 free USB connection 2.0 or higher
- Mouse and keyboard

6.2 Supported operating systems

The following 64-bit operating systems are supported:

> **INFORMATION**
>
> 32-bit operating systems are no longer supported.

- Microsoft Windows 7, SP1 or higher, all editions except Microsoft Windows 7 Starter
- Microsoft Windows 10

> **INFORMATION**
>
> Please note that the latest USB driver version must always be installed for the Bluetooth connection via the 60X5 BionicLink PC. You can download the latest driver version from the following site: http://ottobock.com/en/datastation/. The latest version can also be downloaded via the "software update" function (see page 12).

6.3 Additional Recommended Software Components

The following software components are recommended:
- Internet browser
- An installed program for sending e-mail (e.g. Microsoft Outlook, Mozilla Thunderbird…).

6.4 Additional Installed Software Components

The following additional software components are required and installed during installation of the software (if they are not already installed on the PC):
- Microsoft .NET Framework 4.5.2

> **INFORMATION**
>
> Before the installation is started, the installation program checks if there is sufficient free space on the hard drive and returns an error message if this is not the case. If this occurs, a corresponding amount of space must be freed up on the hard drive. All components required by the Ottobock software are copied to the hard drive automatically by the installation program.
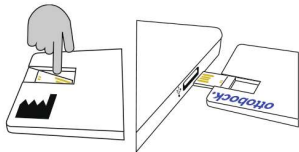
7 Installation

Installation information
- Please note that observing the prescribed system requirements is mandatory.

- It is recommended that you do not run any other programs during installation and use of the adjustment software, since this can affect performance.
- You must have administrator rights to install the software.

Carrying out the installation

1) Start Microsoft Windows.
2) If necessary, poke the USB data carrier out from the card.
   INFORMATION: The data carrier cannot be detached from the card.
3) Connect the data carrier to a freely accessible USB connection. The golden contacts should face upwards.
   → Microsoft Windows will automatically recognise the data carrier.
4) Follow the on-screen instructions to perform the installation.

INFORMATION

The installation does not start automatically
► Open "Computer" (key combination [Windows logo key ⊞+E])
► Click the folder with the Data Station symbol ⊞.
► Start the installation by double-clicking "**setup**" or "**setup.exe**".

After the installation program starts, follow the on-screen instructions.
Information: fields marked with an asterisk (*) are mandatory.

When the "**Registration result**" window is displayed, the following options are available to continue the installation:
• Continue installation without registration
• Continue installation with registration

7.1 Continue Installation Without Registration

If you do not want to register, click the "**Skip registration**" button and follow the further instructions of the installation wizard.

8

Data Station

Once installation is complete, an icon for starting the Ottobock Data Station is added to the Windows desktop. The "C-Soft Plus" software can be accessed after the Ottobock Data Station has been started.
The Ottobock Data Station is a superordinate software platform used to launch the corresponding programs. For this reason a separate icon for the "C-Soft Plus" software is not created during installation.

7.2 Continue Installation With Registration

In order to register, enter the company information and then click the "**Next**" button.

When the summary of the data already entered appears, the following possibilities (buttons) are available for registering the software:
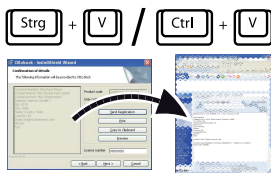
Standard e-mail program available ("Send registration" button)

If you are able to send emails using a standard email program (e.g. Microsoft Outlook, Mozilla Thunderbird), carry out the following steps:
1. Click the "Send registration" button.
   An email with the required registration data is sent automatically.

Webmail available ("Copy to Clipboard" button)

If you do not use a standard email program, but have access to the Internet from your PC, carry out the following steps:
1. Click the "**Copy to Clipboard**" button.
2. Paste the contents of the clipboard into the text field of your webmail email client (e.g. Gmail, Yahoo ...) with the key combination [Ctrl+V] or with the right mouse button.
   Information: automatic processing is only possible when this method is used.
3. Send the email to the following address:
   registration.austria@ottobock.com

Fax available ("Print" button)

If you do not have an Internet connection, carry out the following steps:
1. Click the "Print" button to make a printed copy.
2. Send the printout by fax to the following address:
   (+43-1) 526 79 85 • Otto Bock Healthcare Products GmbH • Brehmstraße 16 • 1110 Vienna • Austria.

Follow the subsequent instructions of the installation wizard.

Once installation is complete, an icon for starting the Ottobock Data Station is added to the Windows desktop. The "C-Soft Plus" software can be accessed after the Ottobock Data Station has been started.

The Ottobock Data Station is a superordinate software platform used to launch the corresponding programs. For this reason a separate icon for the "C-Soft Plus" software is not created during installation.

8 Data Transfer between the Prosthesis and PC

Prosthesis settings using the adjustment software can only be made via Bluetooth data transfer. In order to do so, a Bluetooth wireless connection must be established between the prosthesis and the PC with the help of the 60X5 BionicLink PC. To install the 60X5 BionicLink PC for the first time, follow the procedure described in the instructions for use supplied with this adapter.

> **INFORMATION**
>
> Do not disconnect the 60X5 BionicLink PC from the PC when there is an active Bluetooth connection.

> **INFORMATION**
>
> The adjustment software does not support the 60X4 (Anycom) BionicLink PC adapter.

8.1 Establishing a Bluetooth Connection to the Prosthesis

1) Note the serial number of the component you want to connect.
2) Connect/disconnect the battery charger, or
   Hold the prosthesis with the knee head down (turn it upside-down), keep it still and wait for feedback signals.
   Information: If no feedback signals are produced, this may have the following causes: Feedback signal volume reduced, prosthesis battery drained or prosthesis switched off.
3) Click the "**Connect**" button within 2 minutes and, in the window that opens, select the corresponding component from the list according to the serial number.
   Information: The Bluetooth function or Bluetooth recognition of the component is turned off after 2 minutes. When a connection with the PC is active (the —◯— icon is lit up), the Bluetooth function is not switched off automatically.
→ After successfully establishing a connection to the PC using the 60X5 BionicLink PC, the blue LED on the prosthesis and the blue LED of the BionicLink PC flash.
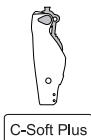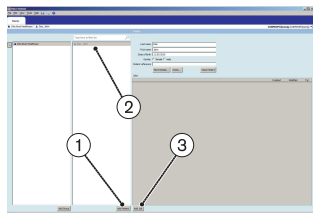
> **INFORMATION**
>
> If the connection is reestablished within a previously opened job after the connection was lost, no steps are required for recognition of the component.

9 Starting the Program

- Double-click the ⊞ icon (Ottobock Data Station) on the desktop. The program starts.

- After the Ottobock Data Station has been started the first step is to create a new patient record (click the "Add Patient" button) (item 1) or select an existing patient record (item 2).
  Information: fields marked with an asterisk (*) are mandatory.
- Click the "Add Job" button (item 3).

- Click the "C-Soft Plus" button. You will find this on the "Prosthetic Lower Extremity" tab.

- Prior to first use, the corresponding information has to be entered into the "Username" and "Unlock-PIN" fields.
  Information: Make sure to use correct spelling (upper/lower case) when entering the information.
- Click the "Log On" button.

- After entering the **unlock PIN** and clicking the "Log On" button you will be asked to enter and confirm a password of your own choice.
  Information: the password entry window only appears after you have entered the unlock PIN. If you have already entered a password in the previous step, the password entry screen will not appear.
- Click the "OK" button.

- Next, the screen for establishing the connection to the prosthesis appears.
  Information: The tube adapter configuration tool can be used without a connection to the prosthesis by clicking the ✎ symbol.
- Click the "Connect" button to establish a connection with the prosthesis.
  If there are several prostheses within range, compare the serial number shown with the serial number of the prosthesis with which you want to connect.
  Information: The serial number is found on the inside of the knee joint frame.
- Once the connection to the prosthesis has been established, the ─◯─ symbol appears in the top right corner.

INFORMATION

If the connection is disrupted during operation, see the section "Troubleshooting" (see page 13).

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10 Closing the Program

The following options are available for closing the program:
- Click "File > Exit" in the menu bar
- Click the "X" button in the top right corner of the program window
- Press the key combination [Alt+F4]

11 Uninstalling

To uninstall the Ottobock software, use the Windows uninstall function.

All components of the adjustment software are deleted during the uninstall. If another adjustment software is installed within the Data Station, the Data Station remains, otherwise it is deleted as well.

However, the entered patient data are not deleted.

12 Further Information

12.1 Information Regarding the Online Help

General Online Help

The online help can be accessed via the **F1** button or the "Help > Contents …" menu bar.

Online help for the currently displayed page

Information on the page currently being displayed in the adjustment software can be accessed by clicking the ⓘ symbol.

12.2 Obtaining Program Version Information

The current program version of the installed software can be obtained from the menu bar. You should have this information available whenever you contact the software support.

1) Click "Help > About" in the menu bar.
   → A window with the currently installed software will open.
2) Click on the desired entry to obtain further information.

12.3 Software Updates

1) Click "**Help > About**" in the menu bar of the Data Station when you are connected to the Internet.

→ The window opens with the versions of the previously installed programs and the manufacturer's address.
2) Click the "**Check for updates**" button in this window.
   → A search for updates of previously installed software products and components is performed via the Internet.
3) If updates are available, click "**Download**" in the column on the right in order to download and save the update.
4) Extract the "ZIP file" and execute it.

13 Troubleshooting

Causes of connection errors (–◐▯– symbol appears)
If the –◐▯– symbol appears in the software's user interface, the connection to the prosthesis was severed.
Verify operational readiness of the 60X5 BionicLink PC and the prosthesis using the table below. Eliminate any causes that apply.

Event	Cause/required action
The blue LED on the prosthesis is not lit up	Prosthesis switched off • Connect/disconnect the battery charger on the prosthesis to turn the prosthesis on.
	Bluetooth on the prosthesis is switched off • Rotate the prosthesis by 180° (the sole of the foot has to face up) or connect/disconnect the battery charger to turn on Bluetooth for approx. 2 minutes. You must attempt to connect again during this time.
	Prosthesis battery drained • Charge the prosthesis battery.
The blue LED on the prosthesis is lit up continuously	Connection to the PC disrupted because the distance to the prosthesis is too large • Reduce the distance between the prosthesis and the 60X5 BionicLink PC.
The green LED on the 60X5 BionicLink PC is not lit up	The 60X5 BionicLink PC is not operational • Check the connection of the BionicLink on the PC. • Connect the BionicLink to a different USB port on the PC. • If a hub is being used, connect the BionicLink directly to the USB port on the PC.
The blue LED on the 60X5 BionicLink PC is not lit up	Connection to the PC disrupted because the distance to the prosthesis is too large • Reduce the distance between the prosthesis and the 60X5 BionicLink PC.

Once the blue LED on the prosthesis and the green LED on the 60X5 BionicLink PC light up after eliminating the cause of the problem, start another connection attempt.
If a connection still cannot be established, contact the Ottobock branch responsible for your country.
When the connection has been restored, check the most recently configured settings.

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15 CE conformity

Otto Bock Healthcare Products GmbH hereby declares that the product is in compliance with applicable European requirements for medical devices.
The full text of the regulations and requirements is available at the following Internet address: http://www.ottobock.com/conformity

16 Symbols Used

▲▲	Manufacturer
CE	Declaration of conformity according to the applicable European directives
REF	Article number

Licence Agreement

Manufacturer: see back of this document
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1.2 The licence covers the Ottobock software, including any related documentation (referred to as "Ottobock Software" below). The terms and conditions of this licence agreement also apply to any updates to the Ottobock software that replace or amend the original software – where Ottobock provides them to you after the installation of the Ottobock software – unless such an update is the object of a separate licence agreement. Any possible maintenance of the Ottobock software or other Ottobock products is not covered by this agreement; a separate agreement is required.
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2.4 You are authorised to install the Ottobock Software on several computers at the same time, or to use it on a network where the software can be accessed on more than one computer simultaneously. Making the software accessible to the public is not permitted. For the purposes of these Terms of Use, "computers" shall also be understood to mean those Ottobock products using the software according to its intended function.

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•   you do not retain any copies of the Ottobock software, not even in the main memory or cache of your computer.

4. Liability

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Any other claims for compensation by you against Ottobock – no matter on what legal grounds and especially due to material defects, defective title and/or the breach of other obligations arising from the contract on the part of Ottobock, its legal representatives, employees, or assistants or due to illegal acts – are excluded.

To the extent that the liability of Ottobock is limited or excluded by the preceding provisions, the same applies to the personal liability of the legal representatives, employees or vicarious agents of Ottobock.

The preceding provisions do not affect the burden of proof to your detriment. Claims for compensation on your part expire within the legal period of limitation, starting at the beginning of said period as established by law.

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6. Severability clause

Should one or more provisions of this agreement be or become ineffective or unenforceable in whole or in part, the validity of the remaining provisions of the agreement shall not be affected.

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