ottobock.

Quality for life

$C\epsilon$

bebalance+ 1.4 560X12=V1.4

1 Foreword

INFORMATION

Date of last update: 2021-12-23
► 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 "560X12=V.14 bebalance+ 1.4" adjustment software is referred to simply as bebalance+, software or adjustment software below.

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

2 Product description

2.1 Function

The software is used to adjust the bebionic hand EQD, bebionic hand Short Wrist and bebionic hand Flex.

Various control programmes and switching methods are available for optimum adaptation to the patient.

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

2.2 Combination possibilities

Supported Bluetooth adapter
• Bluetooth adapter "Bluetooth Long Range Dongle B33061"

Products that can be adjusted
• 8E70=*, 8E71=*, 8E72=*

3 Intended use

3.1 Indications for use

The software allows for patient-specific adaptation of the bebionic hand control device.

3.2 Conditions of use

The software is intended exclusively for adjusting the bebionic hand in the course of unilateral or bilateral fittings of the upper limbs.

The B33061 Bluetooth Long Range Dongle is the only permissible method of data transfer between the system components. It can be purchased from Ottobock.

An existing RF dongle can be used only for older bebionic hands of the M and L models.

4 Safety

4.1 Explanation of warning symbols

⚠ CAUTION	Warning regarding possible risks of accident or injury.

4.2 Structure of the safety instructions

> ⚠ **CAUTION**
>
> **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 case of failure to observe the hazard
> > E.g.: Consequence 2 in case 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

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

> ⚠ **CAUTION**
>
> **Operator errors during the adjustment process**
> Injury 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.
> ► The prosthesis must not remain unattended during the adjustment process while connected to the adjustment software and when being worn by the patient.
> ► Observe the maximum range of the Bluetooth connection and note that obstacles may limit this range.
> ► The Bluetooth dongle must not be unplugged from the computer during data transfer.
> ► 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.
> ► Participation in an Ottobock product training course is recommended.
> ► Use the online help which is integrated into the software.

> ⚠ **CAUTION**
>
> **Errors while establishing a connection with the prosthesis**
> Injury resulting from connection with more than one or the wrong prosthesis.
> ► When establishing a connection using the RF dongle, make sure only one RF device is activated in the immediate vicinity.

> **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 software CD "560X12=V1.4 bebalance+ 1.4"
- 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.

For 32-bit platforms
- PC with an Intel Pentium IV processor
- 1 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 (higher settings can lead to display problems, depending on the resolution selected)
- 32-bit colour depth (16.7 million colours)
- CD-ROM drive or DVD-ROM drive
- 1 free USB connection 2.0 or higher
- Mouse and keyboard

For 64-bit platforms
- 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 (higher settings can lead to display problems, depending on the resolution selected)
- 32-bit colour depth (16.7 million colours)
- CD-ROM drive or DVD-ROM drive
- 1 free USB connection 2.0 or higher
- Mouse and keyboard

6.2 Supported operating systems

INFORMATION

Please note that the latest bebalance+ USB driver version must always be installed for establishing the Bluetooth connection. You can download the latest driver version from the following site: www.ottobock.com.

- Microsoft Windows 7, SP1 or higher, all editions except Microsoft Windows 7 Starter
- Microsoft Windows 8
- Microsoft Windows 10

6.3 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 4.0

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.

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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

To run the setup program, start Microsoft Windows and insert the software CD into the PC's CD/DVD drive. The installation program starts automatically when the CD is inserted.

INFORMATION

If the installation does not start after the CD is inserted:
Windows 7/Windows 8: open "Computer" (key combination [Windows logo key ⊞+E]).
Right-click on the **CD drive** in the **right window**. Click the menu item "Install or run program from your media" with the **left mouse button**.

Windows 10: Press the key combination [Windows logo key ⊞+E]. **Right-click** on the **CD drive** in the **left window**. Click the menu item "Install or run program from your media" with the **left mouse button**.

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

8 Data Transfer between the Prosthesis and PC

⚠ CAUTION

Errors while establishing a connection with the prosthesis
Injury resulting from connection with more than one or the wrong prosthesis.
► When establishing a connection using the RF dongle, make sure only one RF device is activated in the immediate vicinity.

Product 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 product and the PC.

8.1 Establishing a Bluetooth Connection to the Prosthesis

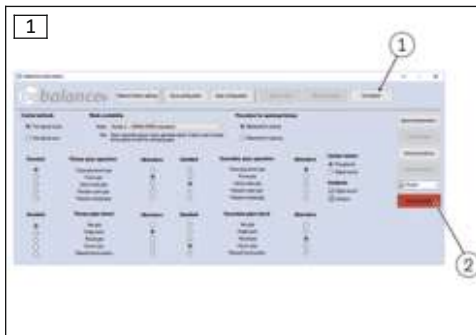Carry out the following steps to activate the Bluetooth function of the prosthesis:
> The prosthesis is switched on.
► Press and hold the program switch of the prosthesis for at least six seconds.
→ Two beeps/vibration signals indicate that the Bluetooth function of the prosthesis has been activated successfully.

9 Starting the Program

► Double-click the 🔧 icon on the desktop.
→ The program starts.

1) Click the "Connection" button (see fig. 1, item 1) in the main menu.
   → Another window appears (see fig. 2).
2) Select the appropriate adapter under "Wireless interface".
   INFORMATION: Ottobock bebionic: Use the Bluetooth adapter (B33061 Bluetooth Long Range Dongle).
   INFORMATION: Steeper bebionic: Use the Bluetooth adapter (B33061 Bluetooth Long Range Dongle) for the size "Small". Use the RF dongle for the size "Medium/Large".
3) Depending on the adapter used, click the "Use Bluetooth" or "Use RF adapter" button.
   → The sub-items "Ports" and "bebionic components" are added to the window.
   → When the RF adapter is used, the component is searched automatically and displayed in the list.
4) Click the "Search" button.
   → This starts a search for bebionic components.
5) The bebionic hand to be used appears in the "bebionic components" sub-item.
6) Select the hand to be used in the list.
7) Click the "Connect" button.
   → The main menu displays [Connected] (see fig. 1, item 2).

10 Closing the Program

The following options are available for closing the program:
- 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.

12 Further Information

12.1 Information Regarding the Online Help

The online help can be accessed via the **F1** button or the homepage.

12.2 Obtaining Program Version Information

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

12.3 Software Updates

Software and driver updates will be made available for free at regular intervals.
1) Make sure you are connected to the internet and go to the "http://ottobock.com/en/datastation/" website.
   → The webpage for the "Data Station" software will open.
2) Search for the description of the software that is to be updated under "Application/Patch".
3) Search for the applicable version.
4) Click "Download" in the column on the right in order to download the update.
5) Extract the "ZIP file" and execute it.

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14 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

15 Symbols Used

Manufacturer

Article number

Licence Agreement

Manufacturer: Otto Bock Healthcare Products GmbH, Brehmstraße 16, 1110 Vienna, Austria.

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The permanent assignment of the usage rights granted to you is only possible when:
- the third party to whom the rights are to be assigned accepts the terms and conditions of this licence agreement,
- the entire Ottobock software, and not just parts thereof, is assigned, and
- you do not retain any copies of the Ottobock software, not even in the main memory or cache of your computer.

4. Liability

Ottobock is liable to you according to the provisions of the Product Liability Act; in case of intent or gross negligence; for the loss of life, physical injury or the impairment of health; where Ottobock issues any guarantees; and in other cases of mandatory legal liability – respectively pursuant to the applicable legal regulations. Damages shall be limited to an amount representing typically foreseeable damages. Damage compensation claims against Ottobock in case of slight negligence are excluded.

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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.

Ottobock is not liable for specific fitness or specific characteristics of the Ottobock software.

All claims shall be excluded if you fail to use and operate or modify the software expertly and properly and/or if you combine or operate the software with unsuitable components.

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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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