ottobock.

PAULA 1.2 646C52=V1.2

1 Foreword

INFORMATION

Date of last update: 2021-12-27
► 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 "646C52=V1.2 PAULA 1.2" adjustment software is referred to simply as PAULA 1.2, software, adjustment software or product 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 PAULA 1.2 software is used in combination with the 757M11=X-Change MyoBoy and supports the O&P professional in the myo-signal evaluation, product selection, socket design and the ordering of components or complete test prostheses for upper limbs.

Communication between the software and the prosthesis takes place exclusively via the USB connection of the 757M11=X-Change MyoBoy hardware.

2.1.1 PAULA 1.2 software functions

• Selection of components to create myoelectric, cable-controlled and passive arm prostheses
• Evaluation of muscle signals and optimal electrode adjustment
• Playful training of the musculature by means of an integrated computer game. Patients learn quickly and effectively how to contract individual and specific muscle groups
• Video animations show how to measure correctly the limbs to be fitted
• The software suggests appropriate components based on the patient's information
• The product ensures the compatibility of the selected components throughout the entire process.
• Integrated free-space computations, indicator to help avoid excessive prosthesis lengths
• Realistic simulation of all current MyoBock systems
• Residual limb measurement/documentation via photo camera
• Computer-aided design (CAD) of test sockets
• Electronic ordering of fully prefabricated Ottobock test sockets or individual Ottobock components
• Documentation of all recorded patient data with printouts, e.g. for the sponsor
• Integrated online help to support the O&P professional's work

3 Intended use

3.1 Indications for use

PAULA 1.2 software is intended exclusively for prosthetic fittings of the upper limb with myoelectric Ottobock components.

PAULA 1.2 software can be used for unilateral or bilateral amputees or in case of dysmelia.

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

⚠ CAUTION	Caution indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.
NOTICE	Warning regarding possible technical damage.

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 procedure
Injury due to unexpected prosthesis behaviour.
► Do not charge the prosthesis battery during the configuration process since the prosthesis is not functional while the battery is being charged.
► The prosthesis must not remain unattended during the configuration process while connected to the adjustment software and being worn by the patient.
► Take note of 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 remain sitting still and the BionicLink PC must not be removed from the computer.
► Inform the patient immediately if the data connection is accidentally interrupted during the configuration process.
► The connection to the prosthesis must always be disconnected after adjustments have been completed.

> ► Ottobock product training for the prosthesis must be completed before the first fitting. Additional product training may be required in order to qualify for product updates.
> ► Use the online help which is integrated into the software.
> ► Do not share your unlock PIN.

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. "646C52=V1.2 PAULA 1.2" software CD
- 1 pc. Instructions for use (qualified personnel)

6 System Requirements

INFORMATION

Operating PAULA 1.2 and 757M11=X-Change MyoBoy can only be ensured if the USB driver has been installed and the MyoBoy connected to the PC. The USB driver of the MyoBoy must not be installed while the PAULA 1.2 software is running. For more information on the 757M11=X-Change MyoBoy, see the relevant instructions for use.

6.1 General information
- Important data should be backed up before installing the program.
- In most cases, a charger connected to a laptop interferes with the operation of the electrodes; that is, the values do not reach zero even when the electrodes are not activated. Therefore, disconnecting the charger and operating the laptop on battery power while recording myo data is recommended.

6.2 Minimum PC hardware requirements
The minimum hardware requirements depend on the operating system. The following requirements apply if they are higher:

For 32-bit platforms
- PC with an Intel Pentium IV processor
- 1 GB RAM
- At least 1.5 GB free hard drive space
- Graphics card with Open GL support
- Resolution 1024 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 1.5 GB free hard drive space
- Graphics card with Open GL support
- Resolution 1024 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

6.3 Supported operating systems
The following operating systems (32-bit and 64-bit) are supported:
- Microsoft Windows 7, SP1 or higher, all editions except Microsoft Windows 7 Starter
- Microsoft Windows 8
- Microsoft Windows 10

INFORMATION

Please note that the latest USB driver version must always be installed to connect to the 757M11=X-Change MyoBoy. 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 8).

6.4 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…).

6.5 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 3.5 (must be downloaded for Windows 8 & 10 at http://ottobock.com/windows8)
- 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.

INFORMATION

The functioning of the PAULA 1.2 software in combination with 757M10 MyoBoy via a serial connection is ensured with MyoBoy version 1.2 and higher. The version number of your MyoBoy is engraved on the rear of the device in the housing below the nameplate.

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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.

7.1 Registration

INFORMATION

The product code required for registration is printed on the inside of the CD cover.

When the summary of the data already entered appears, the following possibilities (buttons) for requesting the licence number are available:

Webmail available ("Copy to Clipboard" button)

If you do not use a standard e-mail 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 email client (e.g. Hotmail, Yahoo, ...) with the key combination [Ctrl+V] or with the right mouse button.
   Information: automatic processing is only possible in this way. If the contents of the clipboard are sent as a separate file, the processing cannot be automated and it will take longer to receive your licence number.
3. Send the e-mail 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.

| INFORMATION |

The installation can only continue once you have received the licence number. Please ensure you keep the licence and registration information in a safe place.

You will receive your personal licence number within the next 2 working days.

7.2 Continuing the Installation after Receiving the Licence Number

| Licence number | XXXXXXXX |

Enter the licence number in the "Licence number" field and click the "Next" button. Follow the subsequent instructions from the installation wizard.

Data Station

Once installation is complete, an icon for starting the Ottobock Data Station is added to the Windows desktop. The "PAULA 1.2" 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 "PAULA 1.2" software is not created during installation.
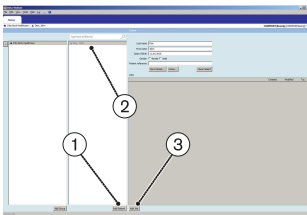
8 Starting the Program

| INFORMATION |

To run the software, ensure that the user is logged on to the PC with at least standard user rights.

Data Station

• 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 on the appropriate amputation level for the patient.
A window opens where different options for the new task can be selected.
A detailed description can be found in the online help of the Ottobock Data Station (see page 8).

> **INFORMATION**
>
> Fields highlighted in light blue indicate software applications that have not been installed yet. Contact the Ottobock branch responsible for your country in order to ask about the availability of these applications.

9 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]
- Select the Windows system menu and click "Close via Start Menu"

10 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.

11 Further Information

11.1 Information Regarding the Online Help

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

11.2 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.

11.3 Software Updates

Software and driver updates will be made available for free at regular intervals.
1) Click "Help > Otto Bock Support Website" in the menu bar when you are connected to the Internet.
    → 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.

12 Required tools

- 743R11 Case set
- 743L234 Digital camera
- 99B90=2 Residual limb sock
- 743S50 Black photo background
- 743S30 Calibration tool
- 623Z20 Loop attachment points

13 Process for creating patient photos

| **INFORMATION** |
| If you wish to use the computer-aided socket design, you will need the 743R11 case set with the 743L234 digital camera. |

To design a test socket using the software, digital photos of the patient's residual limb must be taken.

Process for creating digital images
1. Preparing the patient
2. Taking patient measurements
3. Attaching the calibration tool
4. Setting up the camera
5. Taking patient photos
6. Transmitting the photos from the camera to the PC

13.1 Preparing the patient

► Pull the white 99B90=2 residual limb sock over the residual limb as smoothly as possible. Flex and extend the residual limb as much as is possible. The sock adjusts to the residual limb. This reduces any shifting during subsequent marking.
INFORMATION: At any rate, the sock should not be pulled up too tight. This would distort the contour of the residual limb and thus render the photos useless. Any wrinkles, which may form in the case of very small or pointed residual limbs, can be touched up later in the software.

13.2 Taking patient measurements

► Measure the widest ML measurement directly on the condyles using the calliper supplied. This measurement will have to be adjusted for the patient for the subsequent socket processing in the software by adding approximately 10 mm.

► Mark with an X the position of the lateral electrode directly on the sock. The ML measurement can be noted laterally on the residual limb.
INFORMATION: The position of the medial electrode does not have to be marked; this is determined by a rule (directly opposite of the lateral electrode).

► Mark the position of the olecranon. Identify the olecranon protrusion with a horizontal line. The residual limb flexion must already be 15 degrees; otherwise, this would cause shifts in the bony protrusion below the sock and skin. Make sure that the markings are precise! The reference point is used by the software to check the socket length.
INFORMATION: The line towards the lateral side of the residual limb must be extended somewhat, so that it is well visible in the lateral photo. In addition, stress and relief points can be marked on the residual limb in order to position a patch later on, for example.

► Attach the 743S50 black photo background to the patient. It has an opening for the arm and can be attached easily to the shoulder. When taking photos, all of the white residual limb must be in front of the black background.
INFORMATION: If necessary, use the attachment belt supplied. This may be particularly helpful with posterior photos.
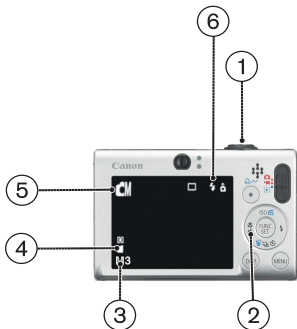
13.3 Attaching the calibration tool

► Attach the 743S30 calibration tool posteriorly to the residual limb along the residual limb's longitudinal axis. Use the 623Z20 loop attachment points for this purpose.
INFORMATION: Positioning in the case of short residual limbs is possible slightly above the olecranon (horizontal marking remains visible).

► The calibration tool must remain in the exact same position on the residual limb in both photos. If the calibration tool comes loose or shifts after the first photo, it will have to be re-attached, and **both** photos will have to be retaken.

13.4 Setting up the camera

1. Maximum optical zoom (3x)
2. Turn off macro or wide angle
3. Resolution 1600x1200 ("M3" for the Canon IXUS 95 model)
4. Very fine compression
5. Manual mode
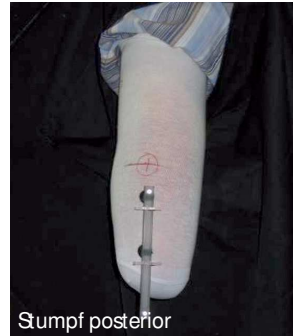6. Turn on flash, turn off redeye reduction

13.5 Taking patient photos
- A lateral-view and a posterior-view photo is required.
- Photograph the calibration tool with the residual limb orthogonally, so that only the white front of the fins can be seen. Only **two** of the white reflector points may be visible!
- Ensure that the recommended residual limb flexion of 15° is maintained for the lateral **and** posterior photo.

When creating the posterior photo, slightly set back the entire arm of the patient (shoulder rotation). Re-adjust the 15-degree residual limb flexion and ensure that the residual limb is not rotated (otherwise, pull down the arm a bit again).

Take the following steps to photograph the residual limb:

1) Keep residual limb rotation neutral
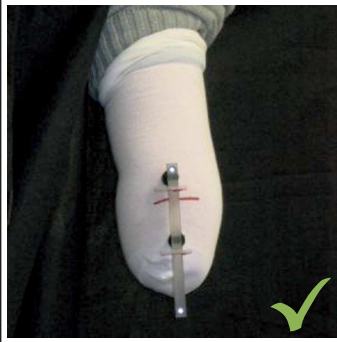2) Take photo at approximately 1 m from the residual limb

Stumpf lateral

Stumpf posterior

After taking the photos, check whether the specified residual limb flexion and appropriate number of reflector points have been maintained.
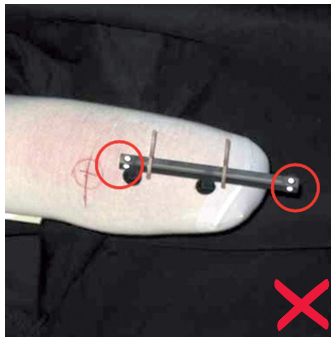
TIP: Focus on the calibration tool with one eye and move your head until only the white front sides of the fins are visible. Without moving your head, place the camera's viewfinder in front of your eye and photograph the residual limb.

13.6 Examples

CORRECT	INCORRECT	NOTES
		Lateral image: The camera was not orthogonal to the residual limb. The yellow colour of the fins is visible!
		Lateral image: • The arm was flexed too much at approximately 40 degrees. 15° flexion is ideal. • The camera was not orthogonal to the residual limb. • The zoom was not used, or the distance was > 1 m.
CORRECT	INCORRECT	NOTES

		Posterior image: For posterior photos, the 15-degree flexion in the elbow joint must be maintained at all times. Failure to do so would change the view of the contour.
		Posterior image: The camera is not above and orthogonal to the calibration tool, but to its side. When the camera is positioned perfectly, only the top reflectors of the calibration tools are visible, while the lateral ones are not.

13.7 Transmitting the photos from the camera to the PC

After taking the photos, check the digital photos in the camera's display, select the best images and transmit them to the PC.

Two options for transferring photos are available:

- Use a memory card reader to read the card
- Read the memory card using a USB interface cable

In both options, the images can be stored in a file folder using Windows Explorer and will then be available to the program for the socket design.

14 Trademarks

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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

Declaration of conformity according to the applicable European directives

REF Article number

17 Licence Agreement

Manufacturer: see back of this document
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1.1 By accepting these Terms of Use, you are entering into a contract between yourself and the named Ottobock company (hereinafter also "Ottobock"); however, if you are acting on behalf of a company when installing or using the Ottobock software (e.g. as an employee of said company), the contract is concluded between the company and Ottobock (in which case "you" refers to said company). In case of any doubt, you are a party to the contract.
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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1.4 To the extent that training requirements are specified for the use of the Ottobock software, the software may only be used by qualified personnel.

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2.3 You do not have the right to modify, edit, translate, rearrange, or otherwise alter the Ottobock Software nor to decompile, disassemble, or reverse engineer the Ottobock Software yourself or via third parties unless expressly permitted to do so by law.

2.4 The Ottobock Software may only be installed on a single computer unless a supplementary licence agreement is concluded. Simultaneous installation on several computers, installation on a network which permits the software to be used on more than one computer at one time, or making the software accessible to the public are all prohibited. Installing the Ottobock Software on a different single computer requires prior removal of the software from the previous computer. For the purposes of this EULA, "computers" shall also be understood to mean those Ottobock products using the software according to its intended function.

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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.

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.

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.

5. Applicable law and jurisdiction

This licence agreement shall be subject to the laws of the country in which the manufacturer is domiciled. The UN convention on contracts for the international sale of goods does not apply. The exclusive jurisdiction for all disputes arising from or in relation to this licence agreement is the registered office of the manufacturer.

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.

Any arrangement, change or addition (particularly commitments with respect to characteristics, features or the quality of the software product) in connection with these Terms of Use shall be deemed void unless made in writing and unless Ottobock's prior consent has been obtained.