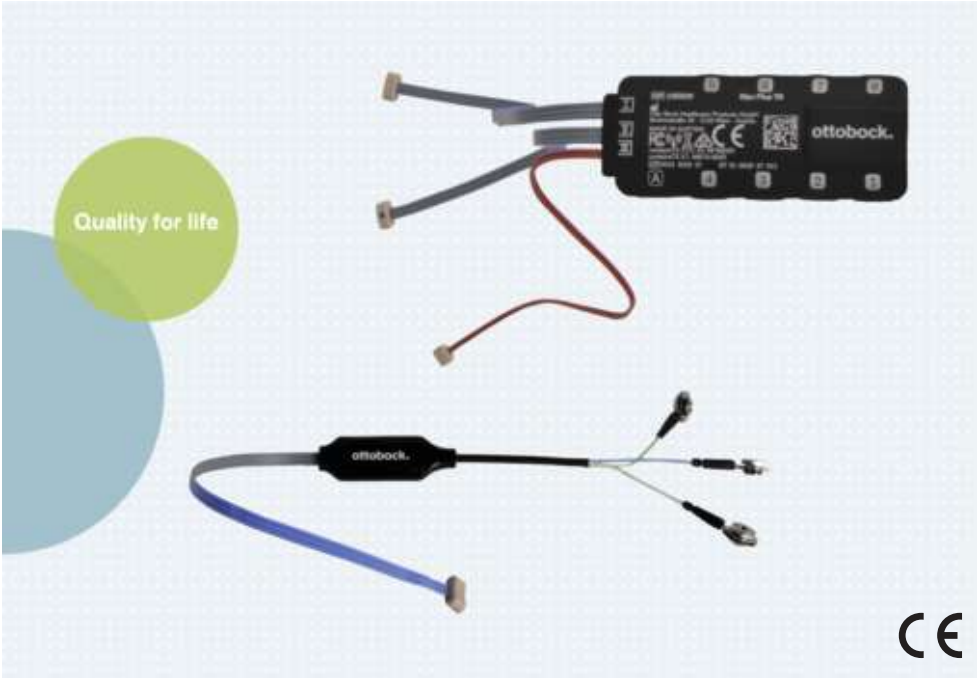
ottobock.



Myo Plus

Caution: Federal law (USA) restricts this device to sale by or on the order of a practitioner licensed by law of the State in which he/she practices to use or order the use of the device.

Quick Reference Guide

This "Quick Reference Guide" does not replace the instructions for use

Angewandte Symbole / Symbole Used / Symboles utilisés / Simboli utilizzati / Símbolos utilizados / Símbolos utilizados / Gebruikte symbolen / Symboler som används / Anvendte symboler / Benyttede symboler / Käytetyt symbolit / Stosowane symbole / Alkalmazott jelképek / Použité symboly / Rabljeni simboli / Uporabljeni simboli / Použité symboly / Kullanılan semboller / Применяемые символы / 本取扱説明書で使用している記号 **/** 使用的图标

Read the section in the instructions for use

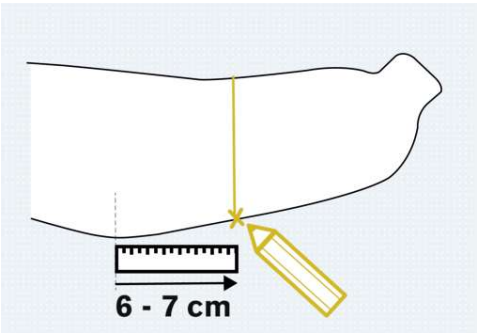
Right

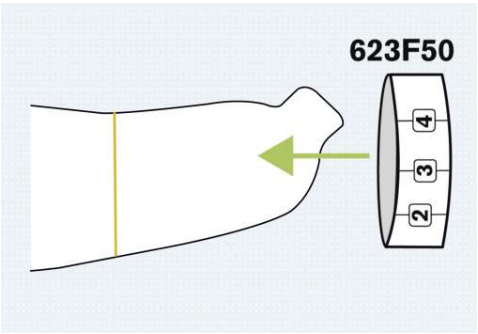
Wrong

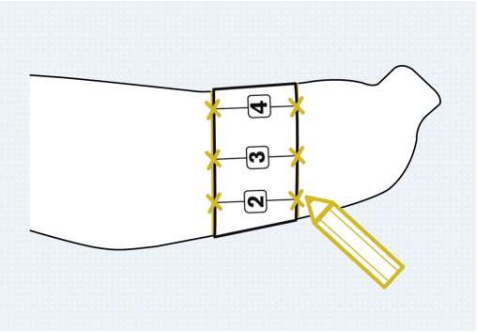
mark

use drilling machine

use tape



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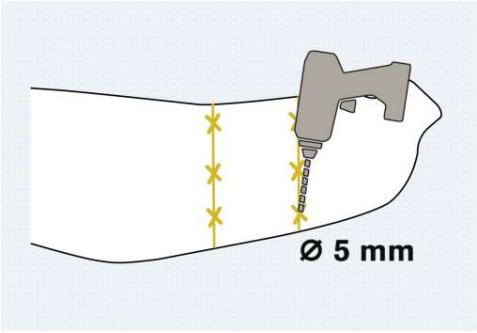
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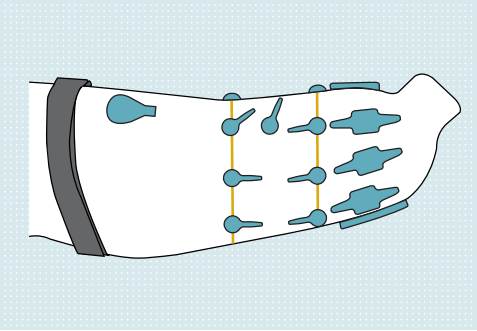


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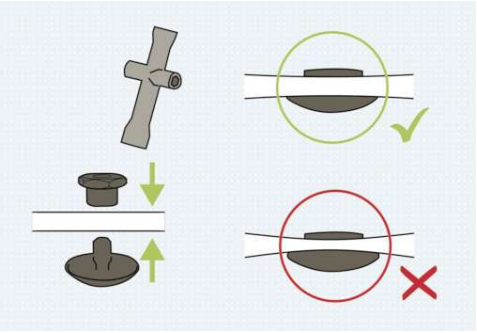

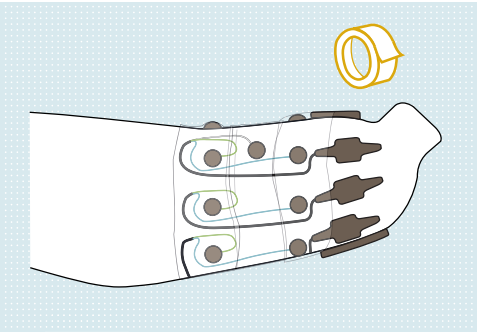

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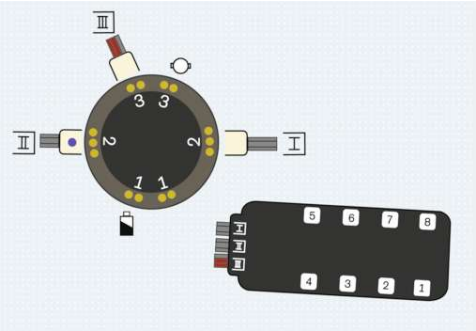
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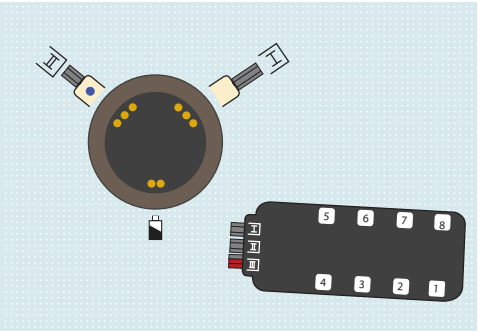
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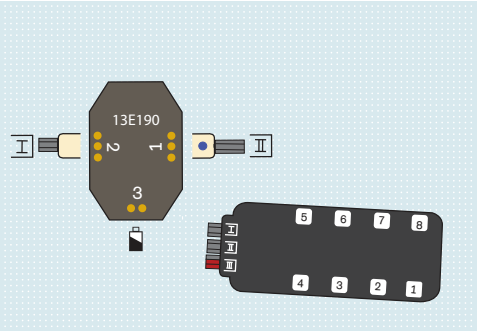
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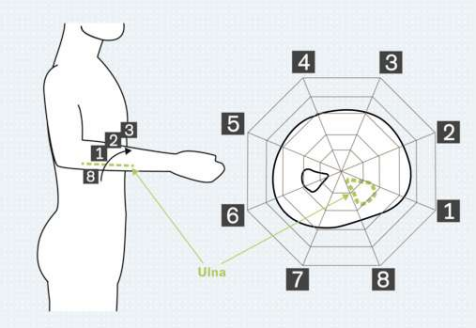
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Ulna

1 Foreword

INFORMATION

Date of last update: 2022-03-29

- ► Please read this document carefully before using the product and observe the safety notices.
- ► Instruct the user in the safe use of the product.
- ► 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 product "Myo Plus" is referred to as the product below.
These instructions for use provide you with important information on the use, adaptation and handling of the product.
Only put the product into use in accordance with the information contained in the accompanying documents supplied.
According to the manufacturer (Otto Bock Healthcare Products GmbH), the patient is the operator of the product according to the IEC 60601-1:2005/A1:2012 standard.

2 Product description

2.1 Function

The product is used to control a myoelectric prosthesis.
The product measures the patient's control signals and assigns them to the prosthesis movements.
By calibration via the Myo Plus app, the control unit learns to assign the sampled muscle signals to the various movement types. This calibration can be carried out directly by the user and repeated at regular intervals.

Essential performance of the product

- No essential performance according to IEC 60601-1

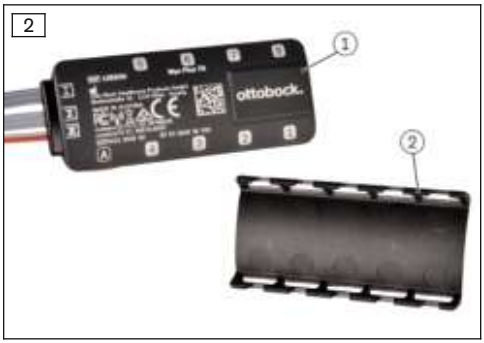
2.2 Design

The product consists of the following components:

Remote electrodes

1. Electronics housing
2. Dome nut and cable lug
3. Electrode dome

Myo Plus TR



The Myo Plus TR (1) receives the signals from the remote electrodes and converts them into control signals for the prosthesis components (hand, rotation). Up to 8 remote electrodes can be connected to the Myo Plus TR.
To secure the remote electrode plug connections, slide the cable protection cap (2) onto the Myo Plus TR.

2.3 Combination possibilities

This product can be combined with the following Ottobock components:

Terminal devices

INFORMATION

The 13E190=* switch block has to be used for combination with the 8E34=*, 8E39=*, 8E41=* and 8E71=* terminal devices.

- System Electric Hand DMC plus: 8E38=6, 8E39=6
- Sensor Hand Speed: 8E38=8, 8E39=8
- MyoHand VariPlus Speed: 8E38=9, 8E39=9, 8E41=9
- Transcarpal Hand DMC plus: 8E44=6
- System Electric Greifer DMC VariPlus: 8E33=9, 8E34=9
- DMC VariPlus System Electric Greifer: 8E33=9-1, 8E34=9-1
- bebionic hand EQD: 8E70=*
- bebionic hand Short Wrist: 8E71=*
- bebionic hand Flex: 8E72=*

INFORMATION

Connected terminal devices must be in a proportional 2-channel mode.

Active rotation
- 10S17 electric wrist rotator
- 10S1=* lamination ring

Passive rotation
- 9E169 coaxial plug
- 10S4 coupling piece
- 10S1=* lamination ring

Rechargeable battery
- 757B35=5 MyoEnergy Integral
- 757B35=3 MyoEnergy Integral
- 757B20 EnergyPack
- 757B21 EnergyPack

3 Intended use

3.1 Indications for use

Myo Plus is to be used exclusively for exoprosthetic fittings of the upper limbs.

3.2 Conditions of use

The product was developed for everyday use and must not be used for unusual activities such as extreme sports (free climbing, paragliding, etc.). Furthermore, the product must not be used for the operation of motor vehicles, heavy equipment (e.g. construction machines), industrial machines, firearms or motor-driven equipment.
The product is intended **exclusively** for use on **one** patient. Use of the product by another person is not approved by the manufacturer.

3.3 Indications

- For patients with unilateral and bilateral amputations.
- For patients with transcarpal and transradial amputation.

3.4 Contraindications

- For patients with transhumeral amputation.
- For patients with partial hand amputation.
- For patients with shoulder disarticulation.
- For patients who are not able to generate an adequately separable pattern.

3.5 Qualification

Fitting a patient with the product may only be carried out by O&P professionals who have been authorised by Ottobock after completion of a corresponding training course. The O&P professional also has to have the technical qualifications required for the alignment of a prosthesis with all required settings and adjustments.
The user must be instructed about the use of the product by authorised, qualified personnel.
The "O&P professional mode" of the adjustment app may only be used by qualified personnel, therapists and nursing staff after participating in the relevant product training and obtaining certification for the application. Additional product training courses may become necessary to qualify for app 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

Operating the product near medical devices critical for safety
Interference with life-sustaining medical devices (e.g., pacemaker, defibrillator, heart-lung machine, etc.) due to electromagnetic interference of the product.
- ► When operating the product in the immediate vicinity of life-sustaining medical devices, ensure that the minimum distances stipulated by the manufacturer are observed.
- ► Make sure to observe the operating conditions stipulated by the manufacturer and the safety notices.

⚠ WARNING

Use of inappropriate components
Injury due to malfunction of the product.
- ► Operate the product only with components prescribed by the manufacturer. You can find the list of components in the section "Combination possibilities".
- ► Operate the product only with accessories recommended by the manufacturer. You can find the list of components in the section "Scope of delivery and accessories".

⚠ WARNING

Changes or modifications to the product made independently
Injury due to faulty operation or malfunction of the product.
- ► Have any changes or modifications to the product carried out only by authorised, qualified Ottobock personnel.
- ► The battery may only be handled by authorised, qualified Ottobock personnel (replacement by the user is not permitted).
- ► The product and any damaged components may only be opened and repaired by authorised, qualified Ottobock personnel.

⚠ CAUTION

Penetration of dirt and humidity into the product
Injury due to faulty control or malfunction of the product.
- ► Ensure that neither solid particles nor liquids can penetrate into the product.
- ► Make sure that the plug connections are sealed with silicone grease.

⚠ CAUTION

Mechanical loads
Injury due to faulty control or malfunction of the product.
- ► Do not subject the product to mechanical vibrations or impacts.
- ► Check the product and its housing for visible damage (e.g. cracking or breakage). If the product is damaged or does not function properly, contact your Ottobock Service Centre.
- ► Watch for loosened electrode domes.
- ► Secure the remote electrodes and cables on the inner socket using suitable material (such as adhesive tape) to reduce cable movement.

⚠ CAUTION

Proximity to sources of strong magnetic or electrical interference (e.g. theft prevention systems, metal detectors)

Injury due to unexpected behaviour of the product caused by interference with internal data communication.

- ► Avoid remaining in the vicinity of visible or concealed theft prevention systems at the entrance/exit of stores, metal detectors/body scanners for persons (e.g. in airports) or other sources of strong magnetic and electrical interference (e.g. high-voltage lines, transmitters, transformer stations, computer tomographs, magnetic resonance tomographs, etc.).
- ► When walking through theft prevention systems, body scanners or metal detectors, watch for unexpected behaviour of the product.

⚠ CAUTION

Electrode lifting off

Injury due to unexpected product behaviour as a result of uncontrolled activation of the prosthesis component.

- ► Inform the patient that uncontrolled movement of the prosthesis component may occur if the electrode lifts off.

⚠ CAUTION

Skin irritation due to inadequate cleaning of the product

Skin irritation due to contact with soiled electrode domes.

- ► Clean the product only as described in the section "Cleaning and care" (see page 17).

⚠ CAUTION

Insufficient skin contact of the electrodes

Injury due to faulty control or malfunction of the product.

- ► The electrodes are to be placed on intact skin only and with as much electrode-skin contact as possible.
- ► Use the different electrode dome heights to improve the skin contact.
- ► Make sure that skin contact of the electrodes continues to be given when carrying heavy loads.

⚠ CAUTION

Insufficient space for electrode domes because distance is too small

Injury due to unexpected prosthesis behaviour.

- ► Make sure that the electrode domes do not touch each other. Reduce the number of electrode domes if necessary (e.g. if the arm is very thin).
- ► Watch the electrode contacts if the residual limb swings or moves.
- ► Use suitable dome heights according to the fit of the prosthetic socket.

⚠ CAUTION

Incorrect electrode settings due to muscle fatigue

Injury due to faulty control or malfunction of the product.

- ► The patient should take breaks during calibration.

⚠ CAUTION

Insufficient distance to HF communication devices (e.g. mobile phones, Bluetooth devices, WiFi devices)

Injury due to unexpected behaviour of the product caused by interference with internal data communication.

► Therefore, keeping a minimum distance of 30 cm from HF communication devices is recommended.

⚠ CAUTION

Operating the product in very close proximity to other electronic devices

Injury due to unexpected behaviour of the product caused by interference with internal data communication.

► Do not operate the product in the immediate vicinity of other electronic devices.
► Do not stack the product with other electronic devices during operation.
► If simultaneous operation cannot be avoided, monitor the product and verify proper use in the existing setup.

⚠ CAUTION

Improper securing of the electrode domes

Injury due to product malfunction.

► Do not use thread locking compound (Loctite) to secure the electrode domes. Applying thread locking compound forms an insulating layer that prevents transmission of the EMG signals.

NOTICE

Failure to observe the system requirements for the installation of the Myo Plus app

Malfunction of the device.

► Install the Myo Plus app only on the operating systems listed in the section "System requirements" (see page 14). The tested devices are listed in this section as well.

NOTICE

Mechanical damage to the product

Change in or loss of functionality due to damage.

► Use caution when working with the product.
► If the product is damaged, check it for proper function and readiness for use.
► Take any necessary measures (e.g. repair, replacement, inspection by the manufacturer's customer service, etc.).

5 Scope of Delivery and Accessories

Scope of Delivery

Items in the scope of delivery or accessories marked with ■ are application parts according to the IEC 60601-1:2005/A1:2012 standard.

- 1 pc. 13E520 Myo Plus TR
- 1 pc. 646C107 Bluetooth PIN card
- 1 pc. lug wrench
- 1 pc. lamination dummy for Myo Plus TR
- 1 pc. positioning gauge for O&P professional 623F50
- 3 pc. 13Z164 cable marking

- 1 pc. plug pull-off protection
- 1 pc. No Carbon Zone sticker
- 1 pc. Instructions for use (qualified personnel)
- 1 pc. Instructions for use (user)

Accessories
- 3 pc - 8 pc 13E400=*/13E401=* Remote electrodes

The remote electrodes can be combined with any of the following electrode domes:
- 13Z161 electrode dome, flat ■ (6 pc. per package)

or
- 13Z162 electrode dome, medium ■ (6 pc. per package)

or
- 13Z163 electrode dome, high ■ (6 pc. per package)
- Myo Plus app

6 Charging the battery

We recommend charging on a daily basis. If the device is not used for an extended period, the battery charge level should be checked regularly and the battery recharged.
See the respective instructions for use for information on correct battery charging.

7 Preparing the product for use

7.1 Laminating instructions

The product can be positioned in the forearm socket.

7.2 Determine electrode position

INFORMATION

Depending on the residual limb and socket structure, the electrode domes may leave impressions in the patient's skin. Use the flat electrode domes in case of deep impressions in the skin. Use the high electrode domes if there are no or only barely visible impressions in the patient's skin.

Required tools
- Drill; twist drill ø 5 mm

The remote electrodes have to be positioned as follows:
1) Mark the position of remote electrode 1 below the ulna and 6-7 cm distal of the olecranon.
2) Extend the marking around the entire circumference of the prosthetic socket.
   → This creates a circumferential line.
3) From the line, measure and mark 40 mm in the distal direction.
4) Extend the marking around the entire circumference of the prosthetic socket.
   → This creates a second circumferential line.
5) Determine the positions of the remaining remote electrodes using the positioning gauge for the O&P professional.
6) Mark the remote electrodes 2 - 8 on the proximal line (e.g. with an X).
7) Reflect the electrode positions to the distal line.
8) Drill through the prosthetic socket at the marked locations with a 5 mm bit.
9) For 2 of 8 electrodes, an additional hole has to be drilled for the reference potential contact.
   INFORMATION: The hole for the reference potential contact can either be drilled between the two electrode domes or in a position where little muscle activity is expected.

The electrode dummies must be used to fabricate the outer socket. The battery dummies and Myo Plus TR dummy must be positioned on the prosthetic socket according to the space requirements. If desired, the remote electrodes can also be attached in the cavity between the outer and

inner socket. Fabricate the outer socket using the familiar technique. The "No Carbon Zone" label can be applied to the Myo Plus TR dummy as an aid for the lamination of carbon sockets.

7.3 Inserting electrodes

⚠ CAUTION

Improper securing of the electrode domes
Injury due to product malfunction.
- ▶ Do not use thread locking compound (Loctite) to secure the electrode domes. Applying thread locking compound forms an insulating layer that prevents transmission of the EMG signals.

Required tools
- Lug wrench (7 mm)
  included in delivery

1) Insert the dome nut into the prepared hole in the prosthetic socket from the outside.
2) Insert the dome of the remote electrode into the prosthetic socket from the inside.
   The blue and green cables have to be positioned on the two marked lines.
3) Secure the remote electrodes and cables on the inner socket with adhesive tape or hook-and-loop fastening strap.
4) Screw on the dome with the dome nut.
5) Hand-tighten the dome nut with the wrench.
   INFORMATION: If the dome nut is over-tightened, the dome tears off at the predetermined breaking point. Use the supplied tools.
   INFORMATION: The remote electrodes and wiring can be protected against moisture and dirt with film or adhesive tape.

7.4 Installing the Myo Plus TR

The Myo Plus TR can be secured on the inner socket with adhesive tape or a hook-and-loop fastening strap. To protect it against moisture, the Myo Plus TR can be covered with film or adhesive tape.
Should the available space between the outer and inner socket be insufficient, a space must be reserved during lamination of the outer socket (lamination dummy). Different electrode cable lengths permit installation in the outer socket.
The following steps must be carried out to connect the electrode and Myo Plus TR:

1) Remove the cover caps from the required inputs.
2) Connect the remote electrodes to the Myo Plus TR.
   Observe the correct assignment of the plug connections.
   INFORMATION: Plug connection "A" must not be used.
   INFORMATION: If fewer than 8 remote electrodes are installed, the plug connections with the highest numbers are not used.
3) Secure the cables with the protection cap.

7.5 Establishing a connection

INFORMATION

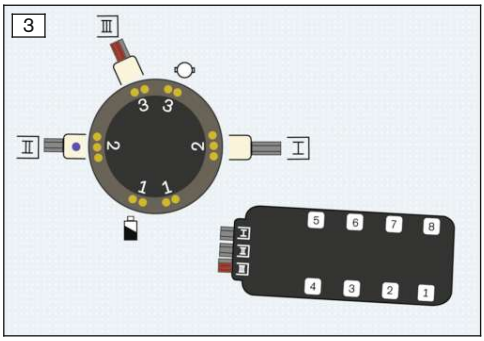
The numbers on the plastic housing serve as orientation for connecting the cables.

INFORMATION

The connection between the Myo Plus TR and the respective component is identical for a prosthesis on the right and left side. The prosthesis side and rotation direction are set in the Myo Plus app.

7.5.1 Establishing the connection to the electric wrist rotator

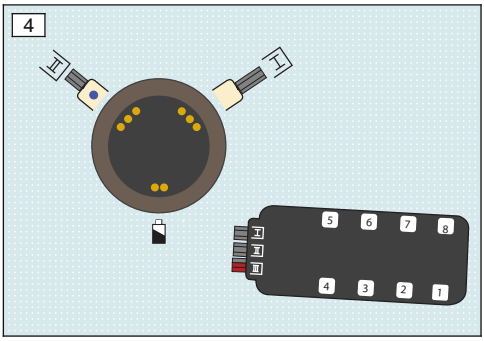
The following steps are required to connect the Myo Plus TR to the electric wrist rotator:



► Connect the cables of the Myo Plus TR to the rotation adapter (see fig. 3).

7.5.2 Establishing a connection to the coaxial plug

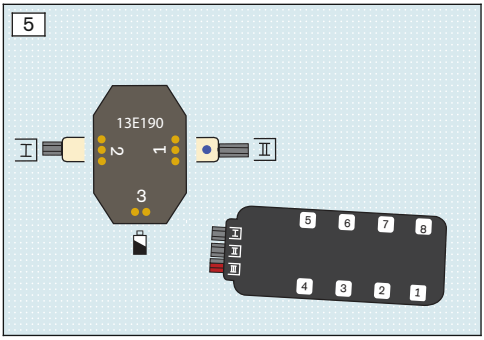
The following steps are required to connect the Myo Plus TR to a coaxial plug:



► Connect the cables of the Myo Plus TR to the coaxial plug (see fig. 4).

7.5.3 Establishing a connection to the 13E190 switch block

The following steps are required to connect the Myo Plus TR to the 13E190 switch block:



► Connect the cables of the Myo Plus TR to the switch block (see fig. 5).

7.6 Connecting the power supply

Power is supplied to the product and the prosthesis components by one of the following batteries:

- MyoEnergy Integral 757B35=1
- MyoEnergy Integral 757B35=3
- EnergyPack 757B20
- EnergyPack 757B21

INFORMATION

To supply power to the product in combination with the terminal devices 8E70=* bebionic hand EQD, 8E71=* bebionic hand Short Wrist and 8E72=* bebionic hand, only the 757B35=3, =5 MyoEnergy Integral batteries are recommended.

For information about charging the prosthesis, observe the battery instructions for use.

8 Myo Plus app

With the Myo Plus app, the user can change the behaviour of the product to a limited extent and is able to use the frequently used functions. The user can adapt the product to conditions on the current day and adjust the movements through calibration. A menu item in the app allows the user to train their muscle signal.

INFORMATION

The Myo Plus app can be downloaded free of charge from the respective online store. To download the Myo Plus app, the QR code on the supplied Bluetooth PIN card can be read with the mobile device (requirement: QR code reader and camera).

8.1 System Requirements

See the information in the Apple App Store or Google Play Store regarding compatibility with mobile devices and versions.

8.2 Initial connection between Myo Plus app and component

The following points should be observed before the initial connection:

- Bluetooth on the mobile device must be switched on.
- The Bluetooth ID and Bluetooth PIN of the component being connected must be known. They are found on the enclosed Bluetooth PIN card. The Bluetooth ID starts with the letters "BT ID".

8.2.1 Starting the Myo Plus app for the first time

- Keep the mobile app up to date at all times.
- Please contact the manufacturer if you suspect cybersecurity problems.

INFORMATION

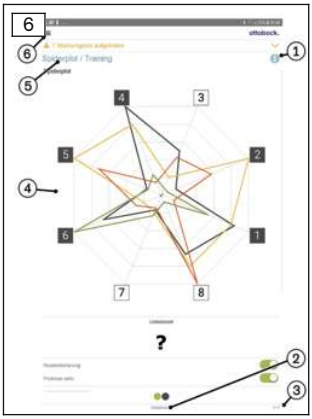
Bluetooth on the prosthesis must be turned on in order to use the MyoPlus app.
After turning on Bluetooth, it remains active for approx. 5 minutes. The app must be started and the connection established during this time.

1) Tap the icon for the Myo Plus app .
   → The end user licence agreement (EULA) is displayed.
2) If rights are requested the first time the app is started, these have to be granted. Otherwise, the app cannot be started.

3) Accept the end user licence agreement (EULA). If the end user license agreement (EULA) is not accepted, the Myo Plus app cannot be used.
4) The "Bluetooth connection" menu item is opened.
5) Tap + to establish a connection.
6) Select the desired component from the list.
7) Enter the Bluetooth PIN code and tap "Connect".
   → The (•) icon is displayed when the connection has been established.

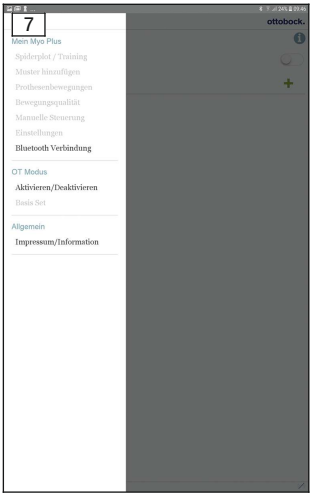
→ Once the connection has been established, the data are read from the component. Then the radar chart is displayed.

8.3 Control elements of the Myo Plus app



1. Access online help
2. Display and name of the currently selected motion sequence
3. (•) Connection to component has been established
4. Display of the selected screen
5. Display of the currently selected menu item
6. ☰ Access the navigation menu

8.3.1 Navigation menu



Tap the ☰ symbol in the menus to display the navigation menu. Additional settings for the connected component can be configured in this menu.
The navigation menu is divided into 3 main menu items:

1. My Myo Plus
2. O&P professional mode
3. General information

See the online help for further information about the respective submenus.

8.4 Performing basic calibration

The following steps have to be completed to start calibration:
1) Tap the navigation menu.

2) Tap the "Login" menu option.
3) Log in with the specialist user access data.
4) After logging in, select the desired and preferred parameters in "OT mode".
5) Enter all parameters (e.g. use of an electric wrist rotator, fitting side, number of installed electrodes...).
6) Confirm all parameters.
7) The "Basic set" page is displayed automatically.
8) Set the pause time between the movements.
   INFORMATION: The pause time should be adapted according to the patient (inexperienced patient – maximum, experienced patient or difficult arm position – minimum).
9) Tap " → " to start recording the calibration data.
10) Perform all six sets.
    INFORMATION: Perform all recordings in the illustrated arm position.
11) Save the classifier data.
    INFORMATION: The classifier data must be saved before the patient can go home.

INFORMATION

During the pause time, the patient has to relax their musculature without changing the arm position. For data recording, the muscle tension has to be increased up to the end. The maximum muscle tension should not be too high, since the patient has to be able to easily reach this tension again when using the prosthesis.

9 Use

All electrode signals are displayed in the Myo Plus app via the Myo Plus TR.
The product is set up and configured via the Myo Plus app.
All information on use is found in the menu texts of the app and in the online help.

9.1 Switching on the product

INFORMATION

Prior to use, make sure the terminal device is connected to the prosthetic socket before switching on. If the terminal device is connected to the prosthetic socket after switching on, rotation and the closing and opening function are active, but the various grip patterns cannot be recognised.

Perform the following steps to put the product into operation:
1) Put on the product.
2) Switch on the prosthesis.

→ Recalibrate the prosthesis if existing movements are to be adapted or new movements added.

Calibration procedure

The following steps have to be completed to start calibration:
1) Tap the navigation menu.
2) Tap the "Settings" menu option.
3) Set the pause time between the movements.
   INFORMATION: The pause time should be adapted according to previous experience with the product (inexperienced user – maximum, experienced user or difficult arm position – minimum).
4) Bring the arm to the selected arm position.
5) Tap " → " to start recording the calibration data.
6) Perform all 6 sets.
   INFORMATION: Perform all recordings in the illustrated arm position.

10 Cleaning and care

Cleaning the electrode domes

1) Clean the electrode domes with a cleaning cloth and 634A58 isopropyl alcohol after each application.
2) Dry the electrode domes with a cloth.

11 Legal information

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly.

11.1 Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorised modification of the product.

11.2 Trademarks

All product names mentioned in this document are subject without restriction to the respective applicable trademark laws and are the property of the respective owners.
All brands, trade names or company names may be registered trademarks and are the property of the respective owners.
Should trademarks used in this document fail to be explicitly identified as such, this does not justify the conclusion that the denotation in question is free of third-party rights.

11.3 CE conformity

Otto Bock Healthcare Products GmbH hereby declares that the product is in compliance with applicable European requirements for medical devices.
This product meets the requirements of the 2014/53/EU directive.
The product meets the requirements of the RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic devices.
The full text of the regulations and requirements is available at the following Internet address: http://www.ottobock.com/conformity

11.4 Local Legal Information

Legal information that applies **exclusively** to specific countries is written in the official language of the respective country of use in this chapter.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
1) This device may not cause harmful interference, and
2) This device must accept any interference received, including interference that may cause undesired operation.
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off

and on, the user is encouraged to try to correct the interference by one or more of the following measures:
—Reorient or relocate the receiving antenna.
—Increase the separation between the equipment and receiver.
—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
—Consult the dealer or an experienced radio/ TV technician for help.
Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
Caution: Exposure to Radio Frequency Radiation.
This device must not be co-located or operating in conjunction with any other antenna or transmitter.
Responsible party:
Otto Bock Health Care, LP
3820 West Great Lakes Drive
Salt Lake City, Utah 84120-7205 USA
Phone + 1-801-956-2400
Fax + 1-801-956-2401

This device complies with RSS 210 of Industry Canada.
Operation is subject to the following two conditions:
(1) this device may not cause interference, and
(2) this device must accept any interference, including interference that may cause undesired operation of this device.

L' utilisation de ce dispositif est autorisée seulement aux conditions suivantes:
(1) il ne doit pas produire d'interference et
(2) l' utilisateur du dispositif doit étre prêt à accepter toute interference radioélectrique reçu, même si celle-ci est susceptible de compromettre le fonctionnement du dispositif.
Caution: Exposure to Radio Frequency Radiation.
The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population; consult Safety Code 6, obtainable from Health Canada's website
http://www.hc-sc.gc.ca/rpb.
Responsible party:
Otto Bock Healthcare Canada Ltd.
5470 Harvester Road
L7L 5N5 Burlington, Ontario
Canada
Phone + 1-800-665-3327

Caution: Federal law (USA) restricts this device to sale by or on the order of a practitioner licensed by law of the State in which he/she practices to use or order the use of the device.

12 Technical data

Ambient conditions	
Storage in original packaging	+5 °C/41 °F to +40 °C/104 °F Max. 85% relative humidity, non-condensing

Ambient conditions	
Transport in original packaging	-25 °C/-13 °F to +35 °C/95 °F 15% to 90% relative humidity, non-condensing +35 °C/95 °F to +70 °C/158 °F Water vapour pressure up to 50 hPa
Storage between subsequent applications	-25 °C/-13 °F to +35 °C/95 °F 15% to 90% relative humidity, non-condensing +35 °C/95 °F to +70 °C/158 °F Water vapour pressure up to 50 hPa
Operation	+5 °C/41 °F to +40 °C/104 °F 15% to 90% relative humidity, non-condens-ing; air pressure 533 hPa to 1060 hPa

Myo Plus TR	
Reference number	13E520
Dimensions	67 x 27 x 9.2 mm/2.64 x 1.1 x 0.36 inch
Weight	15 g/0.53 oz
Operating voltage	6 V–11.1 V DC
Current draw	Max. 25 mA
Power supply	757B35=3, =5 MyoEnergy Integral or 757B20, 757B21 Energy Pack
Lifetime	5 years
Operating time	MyoBock hand: approx. 14 hours bebionic hand: approx. 8 hours

Myo Plus app	
Reference number	560X18-ANDR=V* / 560X18-IOS-V*
Supported operating system	See the information in the Apple App Store or Google Play Store regarding compatibility with mobile devices and versions.

Data transfer	
Wireless technology	Bluetooth Smart Ready
Range	min. 3 m/9.84 ft
Frequency range	2402 MHz to 2480 MHz
Modulation	GFSK, π/4 DQPSK, 8DPSK
Data rate (over the air)	2178 kbps (asymmetrical)
Maximum output power (EIRP):	+8.5 dBm

Remote electrode	
Reference number	13E400=*, 13E401=*
Product service life	5 years
Frequency bandwidth	80 - 500 Hz
Sensitivity range	1800x

13 Appendices

13.1 Operating States

13.1.1 Status signals

Charge level of the 757B35=* MyoEnergy Integral battery

Charging receptacle	Event
●	Battery fully charged (illuminated in green)
●	Battery 50% charged (illuminated in yellow)
●	Battery drained (illuminated in orange)

The battery charge level can be queried at any time.

1) With the prosthesis switched on, press the charging receptacle button and hold for less than one second.
2) The LED display on the charging receptacle provides information on the current battery charge level (Status signals).

Charge level of the 757B20/757B21 EnergyPack battery

The charge level is activated for a few seconds when the battery is inserted into the prosthetic socket.

LED indicator	Event
●	Charge level above 50% (illuminated in green)
● and ●	Charge level below 50% (flashing alternating green and orange)
●	Charge level below 5% (illuminated in orange)

13.1.2 Beep signals

The following beep signals are set by default:

Beep signal	Additional display	Event
1 x long	-	• Turn off product on charging receptacle • Charging begins (charging plug connected to charging receptacle) • Charging ends (charging plug disconnected from charging receptacle)
2 x short	LED on charging receptacle lights up briefly	Switching on the product
3 x short	-	Battery voltage too low, product shuts off automatically

13.2 Troubleshooting

Event	Cause	Required action
Unexpected prosthesis behaviour in various arm positions, e.g. during overhead use	Use in this arm position was not taken into account during calibration, or was incor-	• Note arm position during calibration • Take the weight into account during calibration

Event	Cause	Required action
Unexpected prosthesis behaviour in case of different weight settings, e.g. when loading the prosthesis with excess weight	rectly configured in the app.	• Adjust the values in the app under "Settings > Advanced Settings"
Hand cannot be opened any more	Faulty control	• Use mechanical overload protection: Pull fingers open with great force Rotate hand with great force
Hand cannot be rotated any more		
-	General fault	• Switch the prosthesis off and back on • Consult O&P professional

13.3 Symbols Used

Type BF applied part

Declaration of conformity according to the applicable European directives

In some jurisdictions it is not permissible to dispose of these products with unsorted household waste. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the instructions of your national authority pertaining to return and collection.

Manufacturer

Compliance with the requirements under "FCC Part 15" (USA)

Non-ionising radiation

Compliance with the requirements under the "Radiocommunications Act" (AUS)

Lot number (PPPP YYYY WW)
PPPP – plant
YYYY – year of manufacture
WW – week of manufacture

Article number

BT ID: YYWWNNN Bluetooth ID number

13.4 Directives and manufacturer's declaration

13.4.1 Electromagnetic environment

This product is designed for operation in the following electromagnetic environments:

- Operation in a professional healthcare facility (e.g. hospital, etc.)
- Operation in areas of home healthcare (e.g. use at home, use outdoors)

Observe the safety notices in the section "Information on proximity to certain areas" (Information on Proximity to Certain Areas).

Electromagnetic emissions

Interference measurements	Compliance	Electromagnetic environment directive
HF emissions according to CISPR 11	Group 1/class B	The product uses HF energy exclusively for its internal functioning. Its HF emissions are therefore very low, and interference with neighbouring electronic devices is unlikely.
Harmonics according to IEC 61000-3-2	Not applicable – power below 75 W	–
Voltage fluctuations/flicker according to IEC 61000-3-3	Product meets the requirements of the standard.	–

Electromagnetic interference immunity

Phenomenon	EMC basic standard or test procedure	Interference immunity test level
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air,
High-frequency electromagnetic fields	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz
Magnetic fields with rated power frequencies	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Electrical fast transients/bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition rate
Surges Line against line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Conducted interference induced by high-frequency fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur frequency bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage drops	IEC 61000-4-11	0% U_T; 1/2 period At 0, 45, 90, 135, 180, 225, 270 and 315 degrees

Phenomenon	EMC basic standard or test procedure	Interference immunity test level
Voltage drops	IEC 61000-4-11	0% U_T; 1 period and 70% U_T; 25/30 periods Single phase: at 0 degrees
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 periods

Interference resistance against wireless communication devices

Test frequency [MHz]	Frequency band [MHz]	Radio service	Modulation	Maximum power [W]	Distance [m]	Interference immunity test level [V/m]
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	1.8	0.3	28
710	704 to 787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, GSM 800/900, LTE band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1,720	1,700 to 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1,845						
1,970						
2,450	2,400 to 2,570	Bluetooth WLAN 802.11 b/g/n, RFID 2450 LTE band 7	Pulse modulation 217 Hz	2	0.3	28
5,240	5,100 to 5,800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5,500						
5,785						

The product is covered by the following patents:

Patents pending in Germany and USA.

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