ottobock.

CE

13E522=1 myosmart.

EN Instructions for use (qualified personnel) 3

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1 General

INFORMATION

Date of last update: 2025-05-05

- ► 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 any serious incident related to the product, in particular any deterioration of health, to the manufacturer and the competent authority in your country.

The product "myosmart." is referred to as the product/control unit below.
The “connectgrip.” app is referred to as the adjustment app in the following document.
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 standard.

2 Product description

2.1 Function

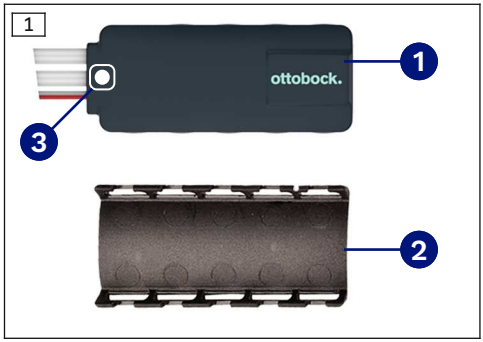
The product is used to control a myoelectric prosthesis.
During a guided recording process in the adjustment app, the control unit records the user’s control signals and then assigns them to the various movements. If necessary, the user can independently add, overwrite or delete recordings and thus adapt the prosthesis control.

Essential performance of the product

- No essential performance according to IEC 60601-1

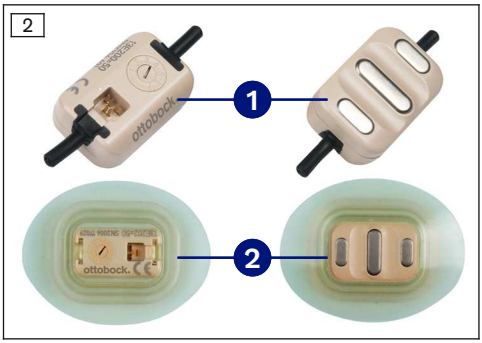
2.2 Design

Control unit



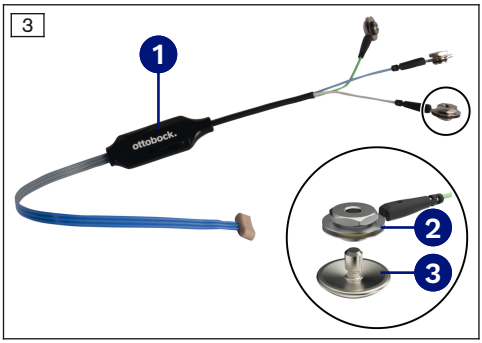
The control unit (1) receives the signals from the control elements and converts them into control signals for the prosthetic components (hand, rotation, elbow).
In order to secure the plug connection of the control elements, the plug holder (2) is plugged onto the control unit.
The cable at this mark (3) is marked with a blue dot on the plug.
Up to 4 different control elements can be connected to this control unit.

13E200=*, 13E202=* electrodes (optional)



1. 13E200=* electrode
2. 13E202=* suction shaft electrode

13E400=*, 13E401=* remote electrodes (optional)



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

2.3 Product combinations

INFORMATION

The 13E190=* switch block has to be used for combination with the 8E34=*, 8E39=*, 8E41=*, 8E44=* and 8E71=* terminal devices.

INFORMATION

Before connecting the bebionic hand to the control unit, the following settings must be selected in the bebalance+ adjustment software:
Select the **Mode 4 (Open-Open)** control program
Select the procedure for **opening/closing: Standard**
Control version: Select **proportional**
Set the Myo thresholds to the factory setting

This product can be combined with the following Ottobock components:

Terminal devices

- speed.hand: 8E2=*
- bebionic hand EQD 8E70=*
- bebionic hand Short Wrist: 8E71=*
- bebionic hand Flex 8E72=*
- System Electric Greifer DMC VariPlus: 8E33=9, 8E34=9
- DMC VariPlus System Electric Greifer: 8E33=9-1, 8E34=9-1

- System Electric Hand DMC plus: 8E38=6, 8E39=6
- System Electric Hand Digital Twin: 8E38=7, 8E39=7
- SensorHand Speed: 8E38=8, 8E39=8
- 8E38=9, 8E39=9, 8E41=9 MyoHand VariPlus Speed
- SensorHand Speed Flex: 8E43=8*
- Transcarpal Hand DMC plus: 8E44=6

INFORMATION

Connected terminal devices must be part of a 2-electrode program (proportional/digital).

Prerequisites:

	Programming	Program selection
8E70/71/72=* bebionic hand	bebalance+	Mode 4 – OPEN-OPEN standard
12K50 ErgoArm: 10S17 electric wrist rotator and 13E205 MyoRotronic	MyoSelect	Program 1
12K100N DynamicArm	ElbowSoft	For prostheses with analogue terminal devices use 13E100 analogue adapter and make the settings in ElbowSoft. See section “Adjusting the elbow joint with ElbowSoft” (see page 19).

Fitting without elbow joint			
	speedhand 8E2=*	**MyoBock terminal device 8E33/34/38/39/41/44-=***	**8E70/71/72=* bebionic hand**
connectgrip	Relaxed hand position	-	Donning mode
	8E2=*-1: thumb sensor		
Terminal device	On/off switch	On/off switch	Primary/secondary grips
		8E*=8: thumb sensor	

Fitting with elbow joint			
	speedhand 8E2=*	**MyoBock terminal device 8E33/38/44=***	**8E70/72=* bebionic hand**
connectgrip	-	-	-
Terminal device	On/off switch	On/off switch	Donning mode
	8E2=*-1: thumb sensor	8E*=8: thumb sensor	Primary/secondary grips

The combination of the “myosmart” product and the “connectgrip” adjustment app only supports Ottobock terminal devices and analogue signal processing. Please see the respective instructions for use for information on adjusting other products.

Elbow joints

- 12K44=* ErgoArm Hybrid Plus
- 12K50=* ErgoArm Electronic plus
- 12K100N=* DynamicArm

Rechargeable battery

- 757B35=3 MyoEnergy Integral
- 757B35=4 MyoEnergy Integral
- 757B35=5 MyoEnergy Integral
- 757B20 EnergyPack
- 757B21 EnergyPack

3 Intended use

3.1 Indications for use
The product 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. These unusual activities include, for example, sports which involve excessive strain and/or shocks to the wrist (pushups, downhill racing, mountain biking, ...) or 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 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 Environmental conditions

Storage (with and without packaging)	+5 °C to +40 °C Max. 90 % relative humidity, non-condensing
Transport (with and without packaging)	-20 °C to +60 °C Max. 90 % relative humidity, non-condensing
Operation	-5 °C/+23 °F to +45 °C/+113 °F 15% to 90% relative humidity, non-condensing Air pressure: 70 kPa to 106 kPa (-425 m to 3000 m without pressure equalisation)

3.4 Indications
- Transcarpal/carpal amputation
- Wrist disarticulation
- Transradial amputation (below-elbow amputation)
- Elbow disarticulation
- Transhumeral amputation (above-elbow amputation)
- Shoulder disarticulation
- Interthoracascapular amputation
- For unilateral or bilateral amputation
- Dysmelia with characteristics similar to that of an amputation mentioned
- The user must be able to understand usage instructions and safety notices and put them into practice.
- The user must fulfil the physical and mental requirements for perceiving optical/acoustic signals and/or mechanical vibrations

3.5 Contraindications
- Finger/thumb amputation or equivalent dysmelia
- Partial hand amputation and equivalent dysmelia
- Diseased or unhealed condition of skin areas that come into contact with the system in the area of the socket while the prosthesis is being used.

3.6 Qualification
The product may be fitted only by qualified personnel authorised by Ottobock after completing the corresponding training.
The user must be instructed about the use of the product by authorised, qualified personnel.
The “Qualified personnel mode” of the adjustment app may only be used by qualified personnel (O&P professionals, therapists) who have completed the relevant product training and have been certified for the application. Additional product training courses may become necessary to qualify for app updates.

4 Safety-related information

Meaning of warning levels
WARNING! Failure to follow the instructions can lead to serious accidents and injuries.
CAUTION! Failure to follow the instructions can lead to accidents and injuries.

WARNING!

Risk of injury due to product malfunction
- ► Before each use, check the product and all associated components for visible damage.
- ► Observe the alignment and assembly instructions.
- ► Do not make any changes to the product that have not been approved by the manufacturer.

WARNING!

Risk of injury due to malfunction of the product or interference with other electronic devices
- ► When operating the product in the immediate vicinity of life-sustaining medical devices, ensure that the minimum distances stipulated by the manufacturer are observed.
- ► Only combine the product with the accessories, signal converters and cables listed in the chapters "Product combinations", "Scope of delivery" and "Accessories".
  This prevents a malfunction of the product (reduced electromagnetic interference immunity) or interference with other electronic devices (increased emissions).

WARNING!

Risk of injury and accident due to improper use of the product
- ► The prosthesis must not be used for extreme sports (free climbing, downhill, mountain biking, paragliding, etc.).
- ► The prosthesis must not be used to operate firearms.
- ► The product may not be used to operate heavy machinery (e.g. construction machines), industrial machines or motor-driven equipment.

CAUTION!

Risk of injury due to product malfunction
- ► Use the different electrode dome heights to improve the skin contact.
- ► Make sure that the electrode domes do not touch each other. Reduce the number of electrode domes if necessary (e.g. with very thin arms).
- ► Use suitable dome heights according to the fit of the prosthetic socket.
- ► Inform the patient that uncontrolled movement of the prosthesis component may occur if the electrode is lifted off.
- ► The electrodes are to be placed on intact skin only and with as much skin contact as possible.
- ► Make sure that skin contact of the electrodes remains in place when carrying heavy loads.
- ► Pay attention to the electrode contact in case of residual limb fluctuations.
- ► Do not expose the product to mechanical vibrations and shocks.
- ► Clean the product only as described in the section “Cleaning and care”.
- ► Observe the calibration instructions.
- ► The patient should take breaks during calibration.
- ► Maintain the recommended minimum distance (30 cm) from HF communication devices (e.g. mobile phones, Bluetooth devices, WLAN devices). If the minimum distance is not met, the functionality of the product may be impaired.
- ► Avoid proximity to sources of strong magnetic or electrical interference (e.g. theft prevention systems, metal detectors).
- ► Only store and transport the product within the permissible temperature range (see the section “Environmental conditions”).
- ► Ensure that neither solid particles nor liquids penetrate the product.

CAUTION!

Risk of injury due to malfunction of the product or interference with other electronic devices

► 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 with other electronic devices cannot be avoided, monitor the product and verify its intended use in the existing setup.

NOTICE!

Possible data theft and data loss

► Do not leave your mobile phone unattended when the adjustment app is open.

5 Scope of delivery

myosmart scope of delivery.

- 1 pc. Instructions for use (qualified personnel)
- 1 pc. myosmart. 13E522=1
- 1 pc. 646C107=INT Bluetooth PIN card
- 1 pc. lug wrench
- 1 pc. lamination dummy for the control unit
- 1 pc. 623F50 electrode positioning jig
- 3 pcs. 13Z164 cable labels
- 1 pc. 13Z165 plug holder
- 1 pc. “No Carbon Zone” sticker

6 Accessories

Electrodes

- Electrode cable 13E129=* (only in combination with 13E200, 13E202)
- Electrode 13E200=*, suction socket electrode 13E202=*
- Electrodes 13E400=*, 13E401=* (only in combination with a control unit)
- Electrode dome, low 13Z161 (for electrode 13E400=*, 13E401=*)
- Electrode dome, medium 13Z162 (for electrode 13E400=*, 13E401=*)
- Electrode dome, high 13Z163 (for electrode 13E400=*, 13E401=*)

Active rotation

- 10S17 electric wrist rotator
- 10S1=* lamination ring
- 13E205 MyoRotronic (only in combination with 12K44=* ErgoArm Hybrid plus, 12K50=* ErgoArm Electronic plus)

Passive rotation

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

Switches and control elements

- Harness pull switch 9X14
- Cable pull switch 9X18
- 9X25 Rocker switch
- Pressure switch 9X37

Adapter cable

- Elbow adapter cable 13E102=* (for DynamicArm 12K100N=*, ErgoArm Electronic plus 12K50=*)

Adjustment app

- Android app “Connectgrip. 560X27-*=ANDR"
- iOS app "Connectgrip. 560X27-*=IOS"

Beeper

- 13E101=1 myosmart.beeper

7 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.

8 Preparing the product for use

Check the function of the assembled prosthesis with the adjustment app, or together with the user after creating a control device (recording).
Ensure that the prosthesis fittings can move freely.

8.1 Laminating instructions

Electrode dummies must be used to fabricate the outer socket. The battery dummies and the control unit dummy (optional) must be positioned on the model for the prosthetic socket according to the space requirements. Fabricate the outer socket using the familiar technique.
When laminating carbon sockets, the position of the control unit must not be shielded from the outside. Apply the “No Carbon Zone” sticker to the control unit dummy as an aid.

8.2 Installing electrodes and external control elements

The 13E200*, 13E202* electrodes and the 13E400*, 13E401* remote electrodes can be used. A mixture of electrode types in one treatment is not permitted.
Various switches and the linear or 4-stage control element can be used as additional external control elements.

8.2.1 13E200*, 13E202* electrodes

First set the electrodes to a gain of 5.

INFORMATION

If the gain is changed after recording movements, all recordings have to be repeated.

Please see the corresponding instructions for use for the procedure for installing the 13E200*, 13E202* electrodes.

8.2.2 13E400*, 13E401* remote electrodes

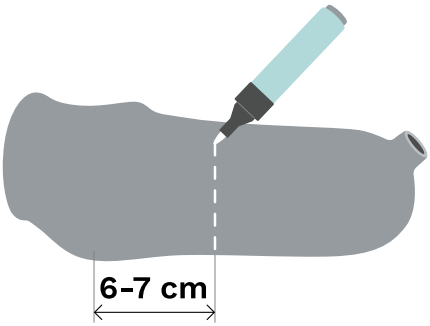
For a treatment with a control unit and 2 to 4 remote electrodes (13E400=*, 13E401=*), at least one type 13E401=* electrode must be used.
Recommendation: For secure ground contact, both electrodes should be of type 13E401=* when 2 remote electrodes are used.
The assignment of the control unit plug connections has to be configured in the adjustment app.
The elastic positioning gauge serves as an aid since an even radial arrangement achieves the best result in most cases. Nevertheless, the electrode position for each user must be selected so that the muscle signals are recognised and do not cause the user any pain.
Therefore, the electrodes must not be placed on highly scarred tissue or over a bone. Constant skin contact must be ensured.

8.2.2.1 Positioning the electrodes

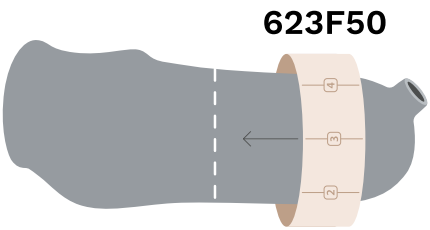
Required tools

- Drill; twist drill ø 5 mm

Transradial treatment

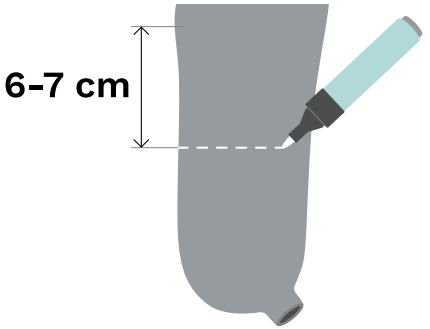


Make the mark below the ulna and approx. 6–7 cm distal from the olecranon.

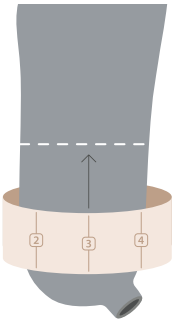


Pull the included elastic positioning gauge over the prosthetic socket and align it with this mark depending on the amputation side. The indicator must be located between positions 1 and 8 above the ulna.
The numbers run in ascending order, depending on the side, from the inside to the outside.

Transhumeral treatment



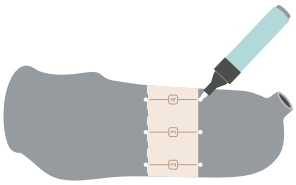
Depending on the residual limb length, draw the mark in the proximal third below the armpit. In the case of short residual limbs in particular, ensure that there is no loss of contact with the skin.



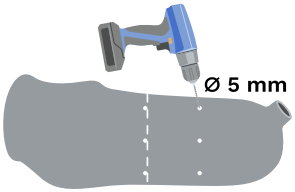
623F50

Pull the included elastic positioning gauge over the prosthetic socket and align it with this mark depending on the amputation side. The white indicator must be centred between positions 1 and 8 towards the armpit.
The numbers run in ascending order, depending on the side, from the inside to the outside.

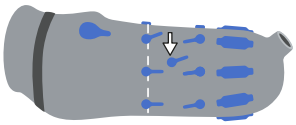
Transradial and transhumeral treatment



Mark and number the electrode numbers to the left and right of the elastic positioning gauge on the prosthetic socket.
For control unit "myosmart".: Only select those electrode positions that were selected based on the evaluation and the required number. (2 to 4 positions).



Drill through the prosthetic socket at the marked locations with a 5 mm drill bit.

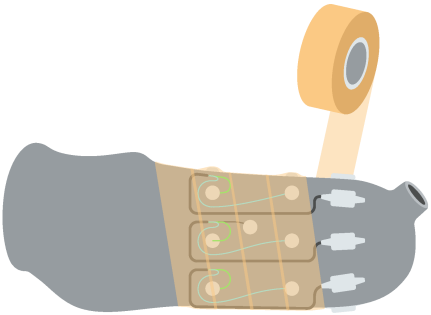


13E401=* remote electrode: Drill an additional hole for the ground contact (white cable).
INFORMATION: The position of the ground contact can generally be freely selected, but must always be in contact with the skin.
Recommendation: Place the ground contact between the two electrode contacts.
The electrode domes must not touch.

8.2.2.2 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.

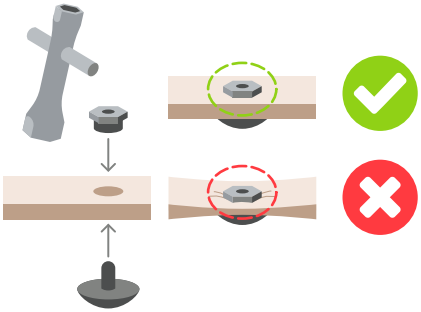


The remote electrode cables can be covered with film or adhesive tape to protect them against dirt and damage when disassembling the prosthesis.

Required tools

- Lug wrench (7 mm)
  Included in scope of delivery

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

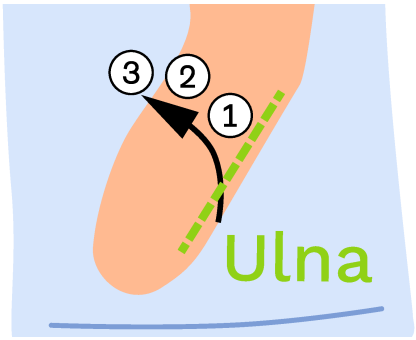
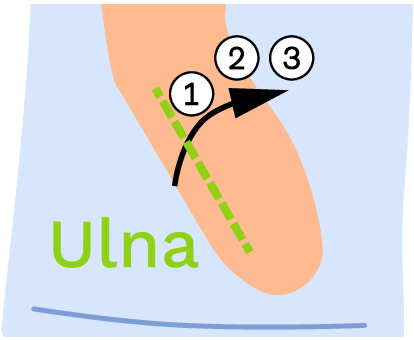
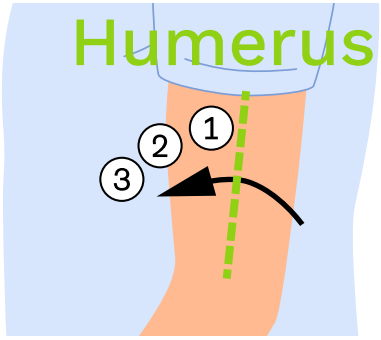
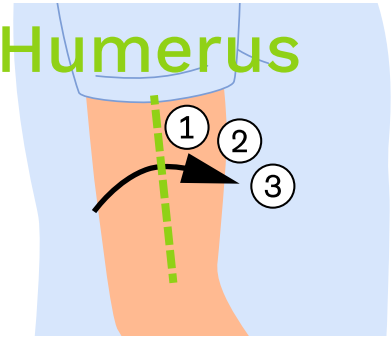


1) Insert the dome nut into the prepared hole in the prosthetic socket from the outside.
2) Insert the dome of the remote electrode into the prosthetic socket from the inside.
3) Secure the remote electrodes and cables on the inner socket with adhesive tape or a hook-and-loop strap.
4) Screw on the dome 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.

8.3 Installing the control unit

Secure the control unit on the inner socket with adhesive tape or hook-and-loop strap. To protect against damage while disassembling the prosthesis, the control unit and cables can be protected 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.
Complete the following steps to connect the control element (electrode, switch) and the control unit:
1) Remove the cover caps from the required inputs.

2) Connect the control elements to the control unit.
   Observe the correct assignment of the slots (see table below).
   INFORMATION: The slot with the data transfer symbol must not be used for control elements (electrodes, switches). Exception: 13E101=1 beeper, see page 15.
   If fewer than 4 control elements are installed in the control unit, the slots with the highest numbers are not used.
3) Close unused connections with the cover caps.
4) Secure the cables with the plug retention guard, see fig. 1.

Left side	Right side
Transradial	
	
Transhumeral	
	

8.4 Connecting the beeper

The beeper emits an acoustic signal when switching between the prosthetic components.
Several processes for switching can be configured, the volume of the beeper can be set and the beeper can be turned on or off in the adjustment app.

1) Install and secure the beeper in the prosthetic socket.
INFORMATION: The sound opening (1) of the beeper must not be taped over and must remain free.
2) Connect the cable of the beeper to the control unit at the input with the symbol (data transfer).

8.5 Establishing a connection

INFORMATION

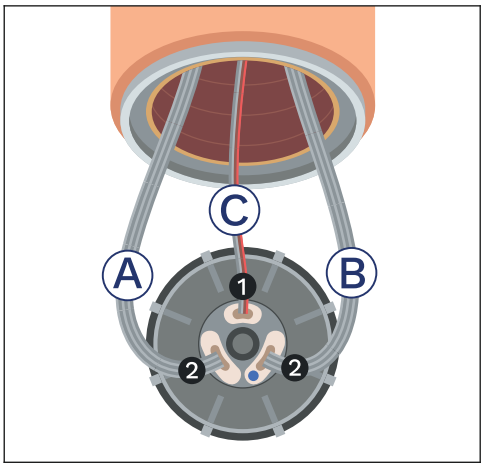
The numbers on the plastic housing serve as orientation for connecting the cables.

INFORMATION

The connections between the control unit and the respective component are the same for a prosthesis on the right and left side. The prosthesis side and rotation direction are set in the adjustment app.

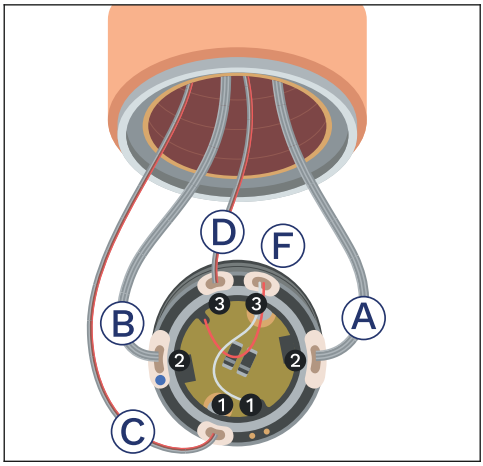
8.5.1 Transradial treatment

8.5.1.1 Connecting the coaxial plug



Ⓐ Connect the 3-pin cable without the blue dot to left contact no. 2.
Ⓑ Connect the 3-pin cable with the blue dot to the right contact no. 2.
Ⓒ Connect the 2-pin cable of the MyoEnergy Integral to contact no. 1.

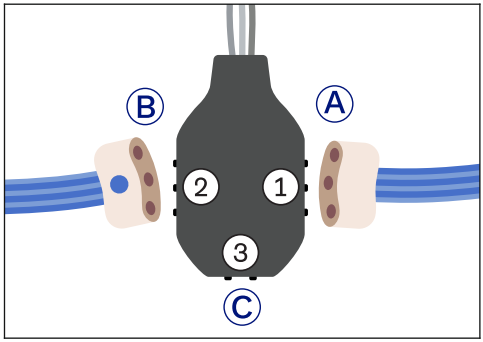
8.5.1.2 Connecting the electric wrist rotator



Ⓐ Connect the 3-pin cable without the blue dot to the right contact no. 2.
Ⓑ Connect the 3-pin cable with the blue dot to the left contact no. 2.
Ⓒ Connect the 2-pin cable of the MyoEnergy Integral to left contact no. 1.
Ⓓ Connect the 2-pin cable to left contact no. 3.
Ⓕ Connect the motor cable of the electric wrist rotator to the right contact no. 3.
No cable may be connected to the right contact no. 1.

8.5.1.3 Connecting the hand cable

For a prosthesis with the wrist.short or wrist.transcarpal wrists, the connection to the control unit is established using the hand cable of the wrist.

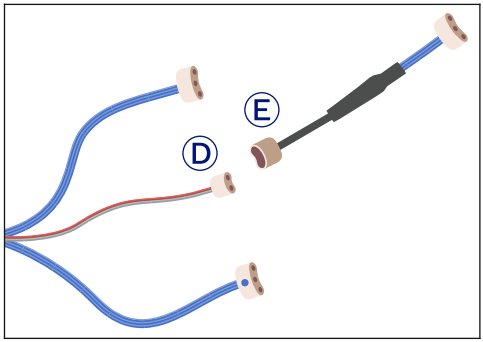


Ⓐ Connect the 3-pin cable without the blue dot to contact no. 1.
Ⓑ Connect the 3-pin cable with the blue dot to contact no. 2.
Ⓒ Connect the cable of the MyoEnergy Integral to contact no. 3.

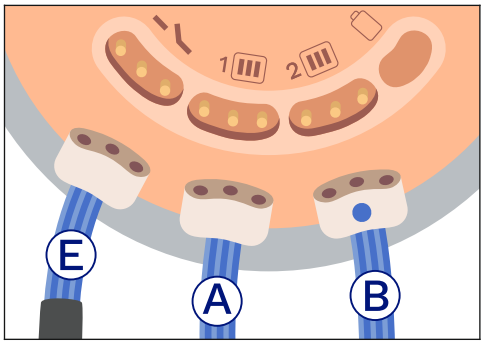
8.5.2 Transhumeral treatment

8.5.2.1 Connecting the DynamicArm

8.5.2.1.1 Connecting the control unit to the Easy Plug

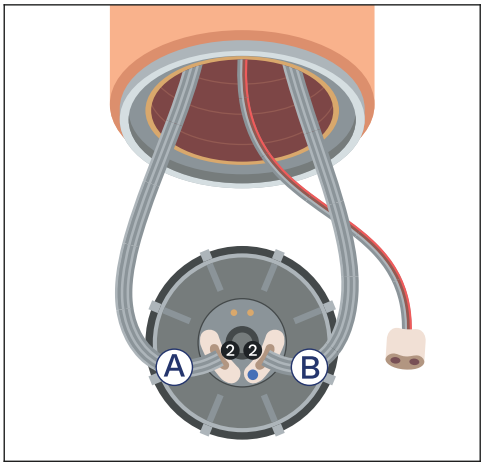


Ⓓ Connect the cable to the 13E102=1 elbow adapter cable Ⓔ.



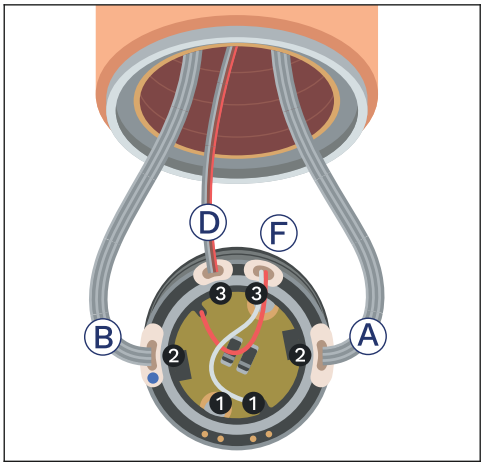
Ⓐ Connect the 3-pin cable without the blue dot to contact no. 1.
Ⓑ Connect the 3-pin cable with the blue dot to contact no. 2.
Ⓔ Connect the elbow adapter cable to the contact with the switch symbol.

8.5.2.1.2 Connecting the coaxial plug



Ⓐ Connect the 3-pin cable without the blue dot to left contact no. 2.
Ⓑ Connect the 3-pin cable with the blue dot to the right contact no. 2.
NOTICE: Do **not** connect the 2-pin cable.

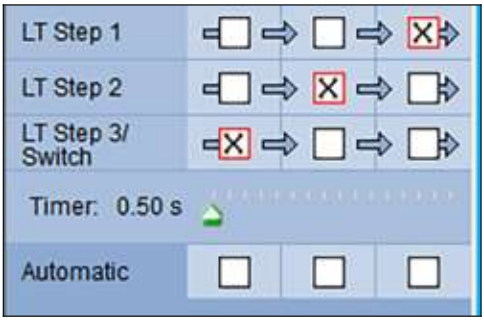
8.5.2.1.3 Connecting the electric wrist rotator



Ⓐ Connect the 3-pin cable without the blue dot to the right contact no. 2.
Ⓑ Connect the 3-pin cable with the blue dot to the left contact no. 2.
Ⓓ Connect the 2-pin cable to left contact no. 3.
Ⓕ Connect the motor cable of the electric wrist rotator to the right contact no. 3.
No cable may be connected to the two no. 1 contacts.

8.5.2.1.4 Adjusting the elbow joint with ElbowSoft

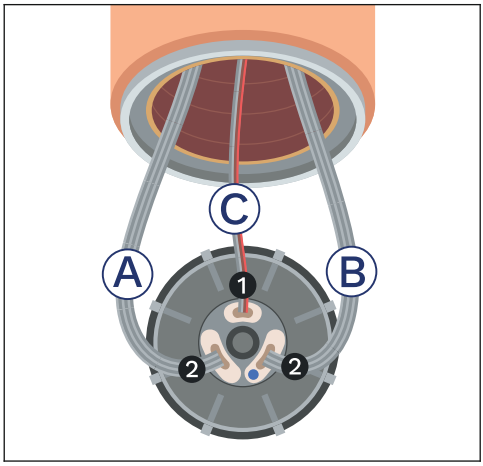
The following adjustments must be made in ElbowSoft to ensure correct prosthesis control functionality.
See the ElbowSoft instructions for use and the corresponding training documentation from the Ottobock Academy.



1) Calibrating the elbow joint.
2) Set control program 5.
3) Set the speed to 100 %.
4) Clear all check boxes next to “Automatic”.
5) Activate the checkbox Manual for “LT Step 1.”
6) Select the checkbox Wrist for “LT Step 2.”
7) Select the checkbox Elbow joint for “LT Step 3.”
8) Set “LT Timer” to 0.5 seconds.
9) Deactivate feedback signals.

8.5.2.2 Connecting the ErgoArm Electronic plus

8.5.2.2.1 Connecting the coaxial plug

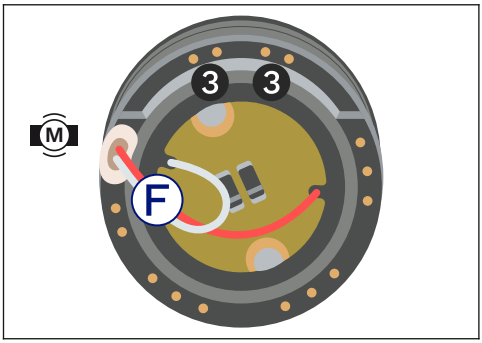


Ⓐ Connect the 3-pin cable without the blue dot to left contact no. 2.
Ⓑ Connect the 3-pin cable with the blue dot to the right contact no. 2.
Ⓒ Connect the 2-pin cable of the MyoEnergy Integral to contact no. 1.
Connect the MyoSelect to the coaxial plug.
Set program 1 with the MyoSelect.
INFORMATION: Program 1 is configured at the factory.

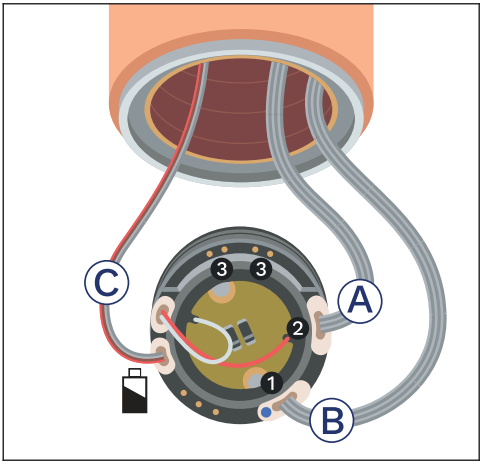
8.5.2.2.2 Connecting the MyoRotronic with electric wrist rotator

The coaxial plug is required to configure program 1 with the MyoSelect.

1) Connect the coaxial plug to the elbow joint.
2) Connect the MyoSelect to the coaxial plug.
3) Set program 1 in the elbow joint.
   INFORMATION: Program 1 is configured at the factory.
4) Disassemble the coaxial plug.

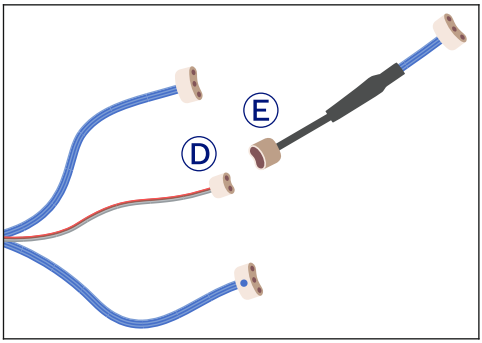


Disconnect the motor cable from the electric wrist rotator.
Attach the MyoRotronic to the electric wrist rotator so that the two no. 3 contacts remain free.
Connect the MyoSelect to the MyoRotronic.
Set program 1 in the MyoRotronic.
INFORMATION: Program 1 is configured at the factory.
Ⓕ Connect the motor cable to the MyoRotronic.

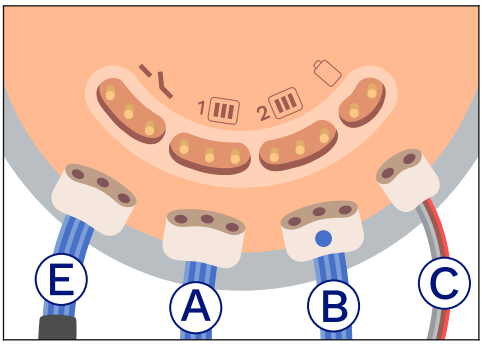


Ⓐ Connect the 3-pin cable without the blue dot to the right contact no. 2.
Ⓑ Connect the 3-pin cable with the blue dot to the right contact no. 1.
Ⓒ Connect the 2-pin cable of the MyoEnergy Integral to the contact with the battery symbol.

8.5.2.2.3 Connecting the control unit to the Easy Plug



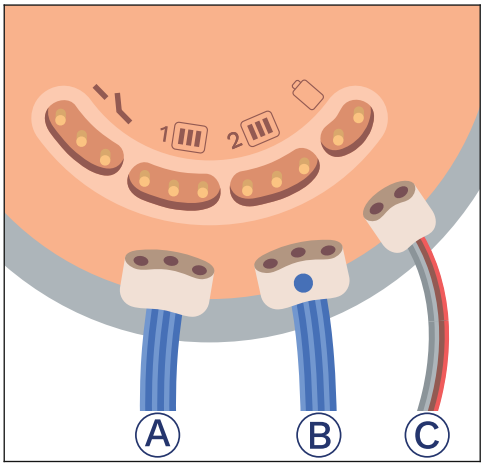
Ⓓ Connect the cable to the 13E102=1 elbow adapter cable Ⓔ.



Ⓐ Connect the 3-pin cable without the blue dot to contact no. 1.
Ⓑ Connect the 3-pin cable with the blue dot to contact no. 2.
Ⓒ Connect the 2-pin cable of the MyoEnergy Integral to the contact with the battery symbol.
Ⓔ Connect the elbow adapter cable to the contact with the switch symbol.

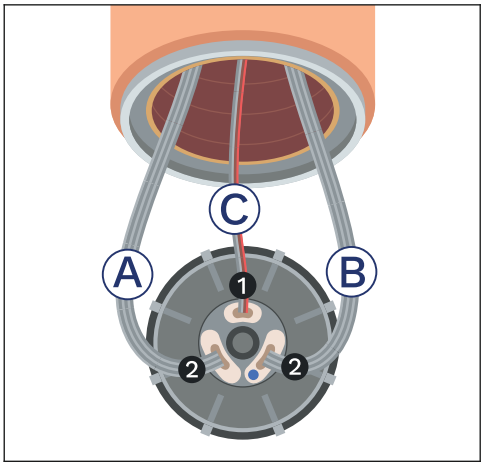
8.5.2.3 Connecting the ErgoArm Hybrid plus

8.5.2.3.1 Connecting the control unit to the Easy Plug



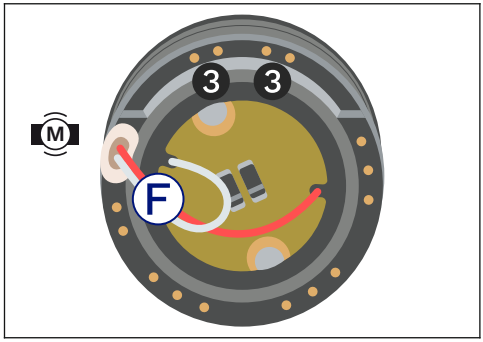
Ⓐ Connect the 3-pin cable without the blue dot to contact no. 1.
Ⓑ Connect the 3-pin cable with the blue dot to contact no. 2.
Ⓒ Connect the MyoEnergy Integral to the contact with the battery symbol.

8.5.2.3.2 Connecting the coaxial plug

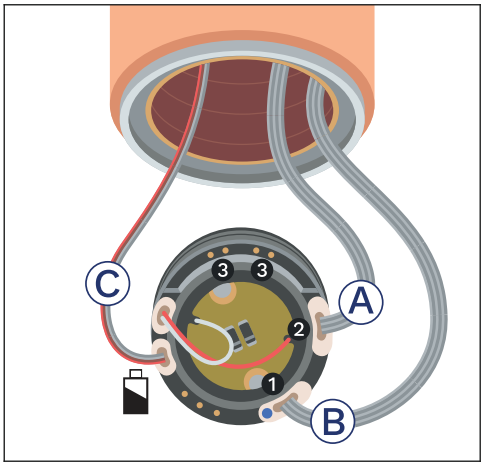


Ⓐ Connect the 3-pin cable without the blue dot to left contact no. 2.
Ⓑ Connect the 3-pin cable with the blue dot to the right contact no. 2.
Ⓒ Connect the 2-pin cable of the MyoEnergy Integral to contact no. 1.

8.5.2.3.3 Connecting the MyoRotronic with electric wrist rotator



Disconnect the motor cable from the electric wrist rotator.
Attach the MyoRotronic to the electric wrist rotator so that the two no. 3 contacts remain free.
Connect the MyoSelect to the MyoRotronic.
Set program 1 in the MyoRotronic.
INFORMATION: Program 1 is configured at the factory.
Ⓕ Connect the motor cable to the MyoRotronic.



Ⓐ Connect the 3-pin cable without the blue dot to the right contact no. 2.
Ⓑ Connect the 3-pin cable with the blue dot to the right contact no. 1.
Ⓒ Connect the 2-pin cable of the MyoEnergy Integral to the contact with the battery symbol.

8.6 Connecting the power supply

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

- 757B35=3 MyoEnergy Integral
- 757B35=4 MyoEnergy Integral
- 757B35=5 MyoEnergy Integral
- 757B20 EnergyPack
- 757B21 EnergyPack

If a DynamicArm is used, power is supplied by the rechargeable battery in the DynamicArm.

INFORMATION

Only the 757B35=3, =4, =5 MyoEnergy Integral batteries are recommended to supply power to the product in combination with the terminal devices 8E2=*.

9 Adjustment app

The qualified personnel can carry out the basic product settings using the adjustment app after a successful login in “qualified personnel mode”. These basic settings are part of treatment and can only be adjusted or deleted by qualified personnel.

INFORMATION

The adjustment app can be downloaded free of charge from the respective online store. Enter the search terms “ottobock” or “connectgrip”.
The instructions for use of the adjustment app can be opened as a PDF file in the adjustment app via **Menu** > **Instructions for use**.

9.1 System Requirements

For compatibility with mobile devices and versions, refer to the information in the Apple App Store or Google Play Store.

9.2 First time connection between app and product

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 product being connected must be known.
  The Bluetooth PIN and Bluetooth ID are found on the enclosed Bluetooth PIN card.
  The Bluetooth ID can be found on the control unit (see fig. 1, item 1) and starts with the letters “BT ID”.

9.3 Starting the app for the first time

INFORMATION

Keep mobile app up to date.

- Please contact the manufacturer if you suspect cybersecurity problems.

Establishing the Bluetooth connection

1) Switch on the product.
   → The LED lights up and two beeps are audible.
2) After it is switched on, a 2-minute time window starts in which the prosthesis is displayed in the list of available prostheses in the adjustment app.

3) If the connection is not established within 2 minutes: Reestablish the Bluetooth connection (menu item **Connecting prostheses**).
   → An error message is displayed in the adjustment app and the product has been deleted from the list of available prostheses for safety reasons.

10 Use

10.1 Display of the current charge level

The battery charge level can be queried at any time.

1) With the product switched on, press the button on the charging receptacle and hold for less than one second.
2) The LED display on the charging receptacle provides information on the current battery charge level (see page 28).

10.2 Safety Shutoff

The purpose of the safety shutoff is to protect the battery; it is triggered in case of:

- Excessively high or low temperature during the charging process
- Short circuit
- Overvoltage or undervoltage

INFORMATION

After a safety shutdown, the battery charger must be connected to reactivate the electronics.

11 Cleaning and Care

Cleaning electrode contacts

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

12 Legal information

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

12.1 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.

12.2 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.

12.3 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

12.4 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.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s)..

Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

(1) L'appareil ne doit pas produire de brouillage;

(2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

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.

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.

13 Technical data

Control unit	
Reference number	13E522
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	Approx. 6 V to approx. 8.2 V
Current draw	Max. 25 mA
Power supply	757B35=3 MyoEnergy Integral, =4, =5 or 757B20, 757B21 EnergyPack
Lifetime	6 years

Data communication	
Wireless technology	Bluetooth 5.0 (Bluetooth Low Energy)
Distance range	Approx. 10 m/32.8 ft
Frequency range	2402 MHz to 2480 MHz
Modulation	GFSK
Data rate (over the air)	Up to 2 Mbps
Maximum output power (EIRP):	+4 dBm (~2.5 mW)

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

14 Appendices

14.1 Symbols Used

BT ID	Bluetooth ID
	In some jurisdictions it is not permissible to dispose of these products with unsorted household waste. Disposal that is not in accordance with regulations in your country can be harmful to health and the environment. Please observe the instructions of your national authority pertaining to return and collection procedures.
	Manufacturer
	Type BF applied part
	Complies with the requirements of the Radiocommunications Act (AUS)

CE	Declaration of conformity according to the applicable European directives
MD	Medical device
LOT	Lot number (10)PPPPYYYYWW PPPP – plant YYYY – year of manufacture WW – week of manufacture
UDI	UDI number (Unique Device Identifier)
REF	Article number
GTIN	Global Trade Item Number

IP22	Protection against penetration of solid foreign objects with a diameter greater than 12.5 mm, protection against dripping water when tilted at up to 15°

14.2 Operating States

14.2.1 Status signals

Charging receptacle	Event
LED shows green light	Battery fully charged
LED shows yellow light	Battery 50 % charged
LED shows orange light	Battery empty

14.2.2 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

14.3 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 incorrectly configured in the app.	• Note arm position during calibration • Take the weight into account during calibration • Adjust the values in the app under the menu item **Control** > **User** > **Prosthesis Settings**.
Unexpected prosthesis behaviour in case of different weight settings, e.g. when loading the prosthesis with excess weight		
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 on again • Consult O&P professional

14.4 Directives and manufacturer's declaration

14.4.1 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 notes in section “Safety-related information” (see page 9).

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
		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						

Immunity to magnetic fields in close range

Test frequency	Modulation	Interference immunity test level [A/m]
30 kHz	CW	8
134.2 kHz	Pulse modulation 2.1 kHz	65
13.56 MHz	Pulse modulation 50 kHz	7.5

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.

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