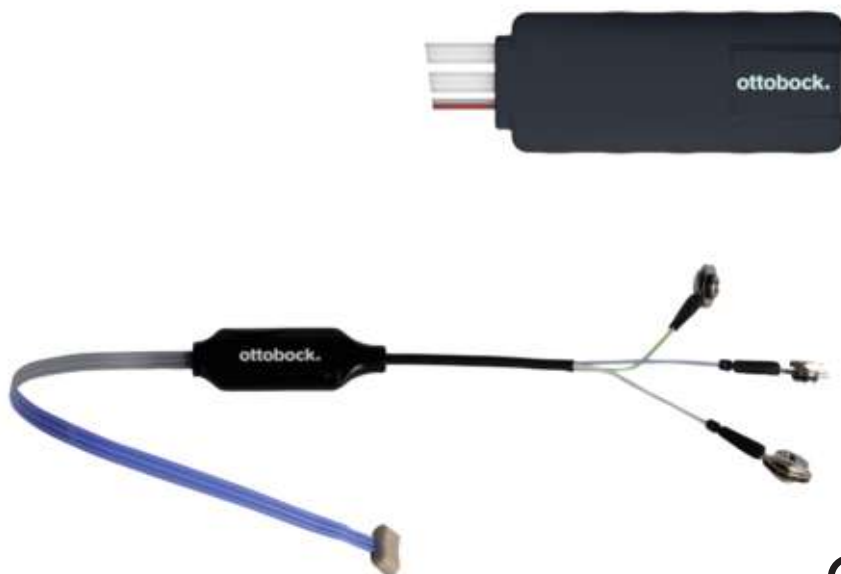




## myosmart 13E522=1

 Instructions for use (qualified personnel) .....

**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.

|           |                                                              |           |
|-----------|--------------------------------------------------------------|-----------|
| <b>1</b>  | <b>General .....</b>                                         | <b>5</b>  |
| <b>2</b>  | <b>Product description .....</b>                             | <b>5</b>  |
| 2.1       | Function.....                                                | 5         |
| 2.2       | Design .....                                                 | 5         |
| 2.3       | Product combinations .....                                   | 6         |
| <b>3</b>  | <b>Intended use .....</b>                                    | <b>7</b>  |
| 3.1       | Indications for use .....                                    | 7         |
| 3.2       | Conditions of use .....                                      | 7         |
| 3.3       | Environmental conditions .....                               | 7         |
| 3.4       | Indications.....                                             | 7         |
| 3.5       | Contraindications .....                                      | 7         |
| 3.6       | Qualification .....                                          | 7         |
| <b>4</b>  | <b>Safety-related information .....</b>                      | <b>8</b>  |
| 4.1       | Meaning of warning levels .....                              | 8         |
| 4.2       | Safety instructions .....                                    | 8         |
| <b>5</b>  | <b>Scope of delivery .....</b>                               | <b>9</b>  |
| <b>6</b>  | <b>Accessories.....</b>                                      | <b>9</b>  |
| <b>7</b>  | <b>Preparing the product for use.....</b>                    | <b>10</b> |
| 7.1       | Laminating instructions .....                                | 10        |
| 7.2       | Installing electrodes and external control elements .....    | 10        |
| 7.2.1     | 13E200*, 13E202* electrodes .....                            | 10        |
| 7.2.2     | 13E400*, 13E401* remote electrodes.....                      | 10        |
| 7.2.2.1   | Positioning the electrodes.....                              | 11        |
| 7.2.2.2   | Inserting electrodes .....                                   | 12        |
| 7.3       | Installing the control unit .....                            | 13        |
| 7.4       | Connecting the beeper.....                                   | 14        |
| 7.5       | Establishing a connection .....                              | 15        |
| 7.5.1     | Transradial treatment .....                                  | 15        |
| 7.5.1.1   | Connecting the coaxial plug .....                            | 15        |
| 7.5.1.2   | Connecting the electric wrist rotator .....                  | 16        |
| 7.5.1.3   | Connecting the hand cable.....                               | 16        |
| 7.5.2     | Transhumeral treatment.....                                  | 17        |
| 7.5.2.1   | Connecting the DynamicArm .....                              | 17        |
| 7.5.2.1.1 | Connecting the control unit to the Easy Plug .....           | 17        |
| 7.5.2.1.2 | Connecting the coaxial plug .....                            | 17        |
| 7.5.2.1.3 | Connecting the electric wrist rotator .....                  | 18        |
| 7.5.2.1.4 | Adjusting the elbow joint with ElbowSoft .....               | 18        |
| 7.5.2.2   | Connecting the ErgoArm Electronic plus .....                 | 19        |
| 7.5.2.2.1 | Connecting the coaxial plug.....                             | 19        |
| 7.5.2.2.2 | Connecting the MyoRotronic with electric wrist rotator ..... | 20        |
| 7.5.2.2.3 | Connecting the control unit to the Easy Plug .....           | 21        |

|           |                                                              |           |
|-----------|--------------------------------------------------------------|-----------|
| 7.5.2.3   | Connecting the ErgoArm Hybrid plus.....                      | 21        |
| 7.5.2.3.1 | Connecting the control unit to the Easy Plug .....           | 21        |
| 7.5.2.3.2 | Connecting the coaxial plug .....                            | 22        |
| 7.5.2.3.3 | Connecting the MyoRotronic with electric wrist rotator ..... | 22        |
| 7.6       | Connecting the power supply.....                             | 23        |
| 7.7       | Overview of adjustment possibilities.....                    | 23        |
| <b>8</b>  | <b>Adjustment app .....</b>                                  | <b>24</b> |
| 8.1       | System Requirements .....                                    | 25        |
| 8.2       | First time connection between app and product .....          | 25        |
| 8.3       | Starting the app for the first time.....                     | 25        |
| <b>9</b>  | <b>Use .....</b>                                             | <b>25</b> |
| 9.1       | Charging the battery .....                                   | 25        |
| 9.2       | Display of the current charge level .....                    | 25        |
| 9.3       | Safety Shutoff .....                                         | 25        |
| <b>10</b> | <b>Cleaning .....</b>                                        | <b>26</b> |
| <b>11</b> | <b>Legal information .....</b>                               | <b>26</b> |
| 11.1      | Liability .....                                              | 26        |
| 11.2      | Trademarks .....                                             | 26        |
| 11.3      | CE conformity .....                                          | 26        |
| 11.4      | Local Legal Information .....                                | 26        |
| <b>12</b> | <b>Technical data .....</b>                                  | <b>27</b> |
| <b>13</b> | <b>Appendices .....</b>                                      | <b>28</b> |
| 13.1      | Symbols Used.....                                            | 28        |
| 13.2      | Operating States .....                                       | 28        |
| 13.2.1    | Status signals .....                                         | 28        |
| 13.2.2    | Beep signals.....                                            | 28        |
| 13.3      | Troubleshooting .....                                        | 29        |
| 13.4      | Directives and manufacturer's declaration .....              | 29        |
| 13.4.1    | Electromagnetic environment .....                            | 29        |

# 1 General

## INFORMATION

Date of last update: 2026-05-11

- ▶ Please read this document carefully before using the product and observe the safety notes.
- ▶ Instruct the user how to use the product safely.
- ▶ 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 adjustment app in the following.

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.

## 2 Product description

### 2.1 Function

The product is used to control a myoelectric prosthesis.

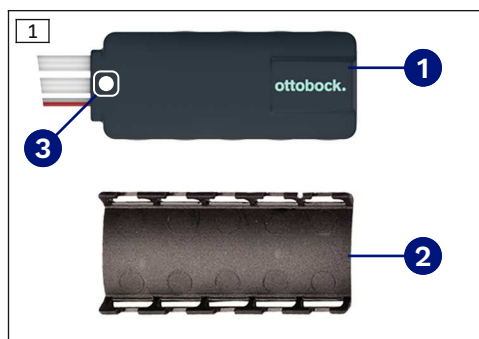
During a guided recording process in the adjustment app, the control unit records the user's control signals and then assigns them to the various movements. If necessary, the user can independently add, overwrite or delete recordings and thus adapt the prosthesis control.

### Essential performance of the product

- No essential performance according to IEC 60601-1

### 2.2 Design

#### Control unit



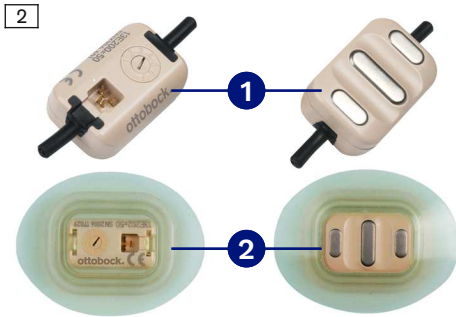
The control unit (1) receives the signals from the control elements and converts them into control signals for the prosthetic components (hand, rotation, elbow).

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.

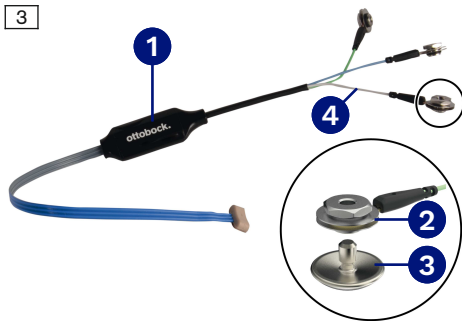
Up to 4 different control elements can be connected to this control unit.

### 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
4. For 13E401=\*: earth contact

## 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.

This product can be combined with the following Ottobock components.

#### Terminal devices

- 8E2=\* speed.hand
- bebionic hand EQD 8E70=\*
- 8E71=\* bebionic hand Short Wrist
- bebionic hand Flex 8E72=\*
- System Electric Greifer DMC VariPlus 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
- Transcarpal Hand DMC plus 8E44=6

#### 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

myosmart 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, etc.) or extreme sports (free climbing, paragliding, etc.). Furthermore, the product must not be used to operate personal vehicles, heavy equipment (such as construction machines), industrial machines or motor-driven equipment.

The product is intended **exclusively** for treatment of **one** user. Use of the product by a further person is prohibited by the manufacturer.

#### 3.3 Environmental conditions

|                                        |                                                                                                                                                                    |
|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Storage (with and without packaging)   | +5 °C to +40 °C<br>Max. 90 % relative humidity, non-condensing                                                                                                     |
| Transport (with and without packaging) | -20 °C to +60 °C<br>Max. 90 % relative humidity, non-condensing                                                                                                    |
| Operation                              | -5 °C/+23 °F to +45 °C/+113 °F<br>15% to 90% relative humidity, non-condensing<br>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
- Age: users aged 12 years and up and adults

#### 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**

### **4.1 Meaning of warning levels**

**WARNING!** Failure to follow instructions labelled in this way can lead to serious accidents and injuries.

**CAUTION!** Failure to follow instructions labelled in this way can lead to accidents and injuries.

### **4.2 Safety instructions**

**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.
- ▶ Observe the specifications for thread locks and tightening torques.
- ▶ 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**

- ▶ Whether and to what extent operating a motor vehicle with a prosthesis is permitted depends on the degree of impairment and the prosthesis being used (for example, the amputation level, unilateral or bilateral and the type of prosthesis) as well as the individual abilities of the prosthesis user and the respective applicable national legal regulations.
- ▶ It is essential to contact the respective responsible authorities and to obtain the required permits, inspections and adaptations or have them approved before operating a vehicle.
- ▶ Operating a motor vehicle therefore does not constitute an intended use of the product.
- ▶ The manufacturer accepts no liability whatsoever for damage, regardless of the legal grounds and claims of any kind arising from other than intended use are excluded.
- ▶ 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 must not be used to operate heavy machinery (such as 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.
- ▶ Observe the instructions for cleaning and care (see page 26).
- ▶ 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.

### **Danger of product damage and restricted functionality**

- ▶ Take off the product before entering a room or area with strong magnetic fields and store the product outside this room or area.
- ▶ Damage to the product caused by exposure to strong magnetic fields cannot be repaired.

## **5 Scope of delivery**

### **Control units**

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

## **6 Accessories**

### **Electrodes**

- |                                                                           |                                                                    |
|---------------------------------------------------------------------------|--------------------------------------------------------------------|
| • Electrode cable 13E129=* (only in combination with 13E200, 13E202)      | • Electrode dome, low 13Z161 (for electrode 13E400=*, 13E401=*)    |
| • Electrode 13E200=*, suction socket electrode 13E202=*                   | • Electrode dome, medium 13Z162 (for electrode 13E400=*, 13E401=*) |
| • Electrodes 13E400=*, 13E401=* (only in combination with a control unit) | • 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 (only in combination with 13E522=1 myosmart)**

- 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 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.

### **7.1 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.

### **7.2 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-step control element can be used in combination with 13E522=1 myosmart as additional external control elements.

#### **7.2.1 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.

#### **7.2.2 13E400\*, 13E401\* remote electrodes**

For a treatment with a control unit and remote electrodes, at least 2 13E401=\* electrodes have to be 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.

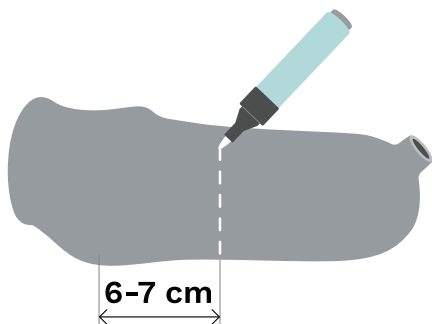
### 7.2.2.1 Positioning the electrodes

#### Required tools

- Drill; twist drill  $\varnothing$  5 mm

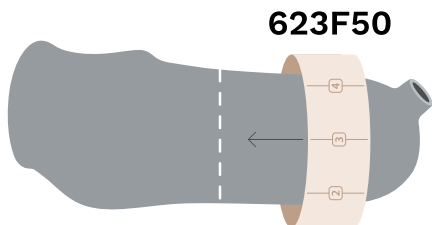
#### Transradial treatment

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



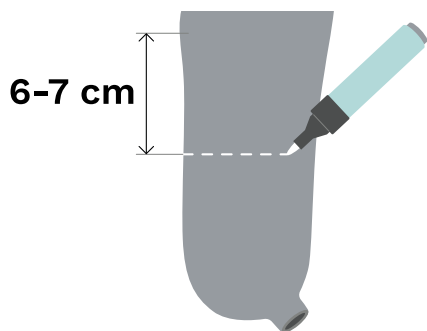
Pull the included elastic positioning gauge over the prosthetic socket and align it with this mark depending on the amputation side. The indicator must be located between positions 1 and 8 above the ulna.

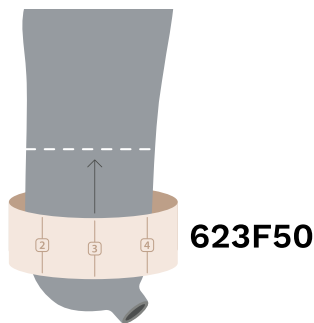
The numbers run in ascending order, depending on the side, from the inside to the outside.



#### Transhumeral treatment

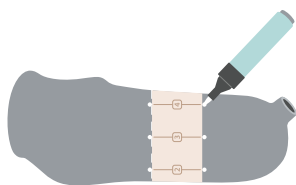
Depending on the residual limb length, draw the mark in the proximal third below the armpit. In the case of short residual limbs in particular, ensure that there is no loss of contact with the skin.



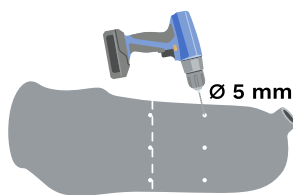


Pull the included elastic positioning gauge over the prosthetic socket and align it with this mark depending on the amputation side. The white indicator must be centred between positions 1 and 8 towards the armpit. The numbers run in ascending order, depending on the side, from the inside to the outside.

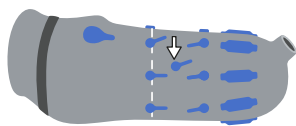
## Transradial and transhumeral treatment



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.

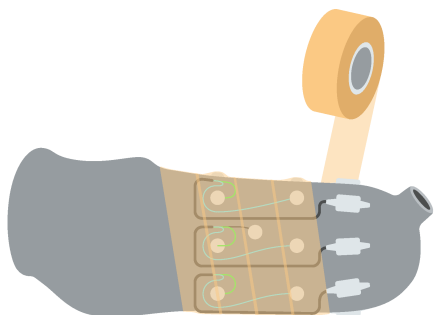
### 7.2.2.2 Inserting electrodes

#### **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.

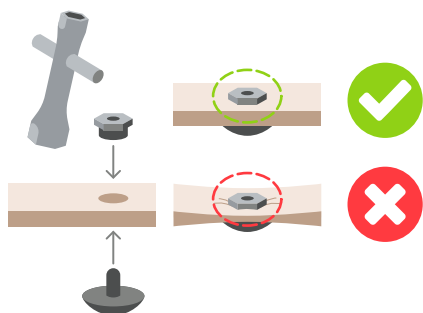


The remote electrode cables can be covered with film or adhesive tape to protect them against dirt and damage when disassembling the prosthesis.

### 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.

**NOTICE! If the dome nut is over-tightened, the dome tears off at the pre-determined breaking point. Use the supplied tools.**

- 6) Snap the black cover caps onto the dome nuts. **NOTICE! The cover caps prevent signal interference**

### 7.3 Installing the control unit

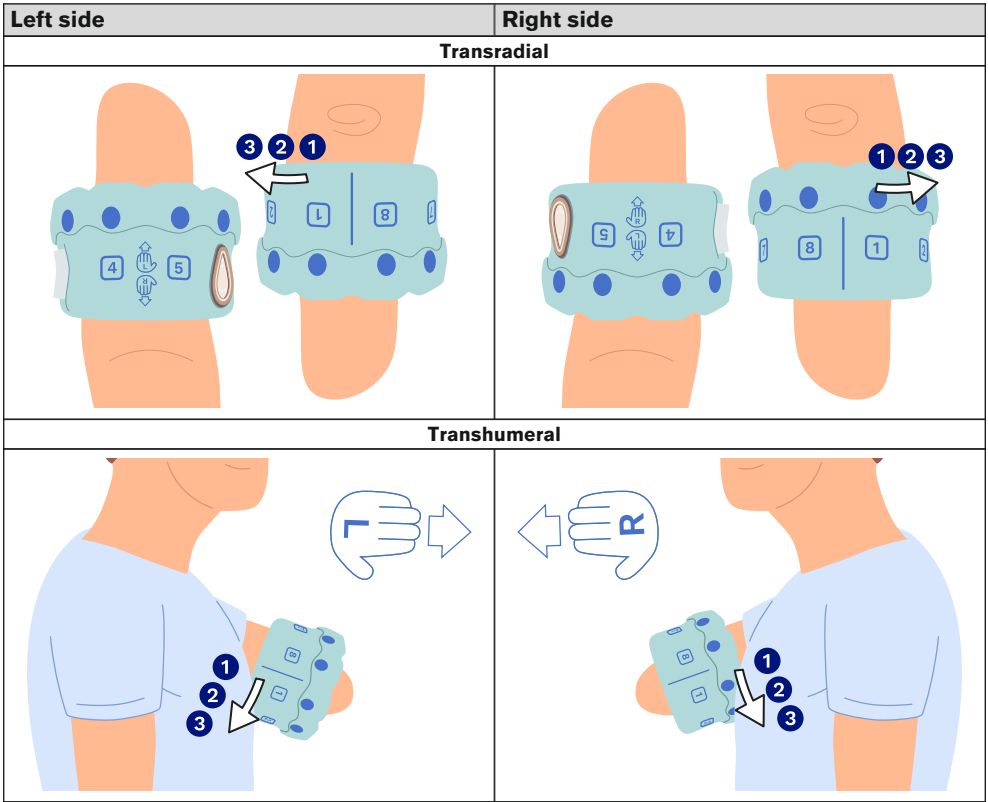
Secure the control unit on the inner socket with adhesive tape or hook-and-loop strap. To protect against damage while disassembling the prosthesis, the control unit and cables can be protected with film or adhesive tape.

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 starting with slot 1.  
Observe the correct assignment of the slots and that the electrodes are numbered in ascending order (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 14.
- 3) Close unused connections with the cover caps.
- 4) Secure the cables with the plug retention guard, see fig. 1 (2).



## 7.4 Connecting the beeper

The beeper generates an acoustic signal in case of system events.  
The beeper can be configured 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).

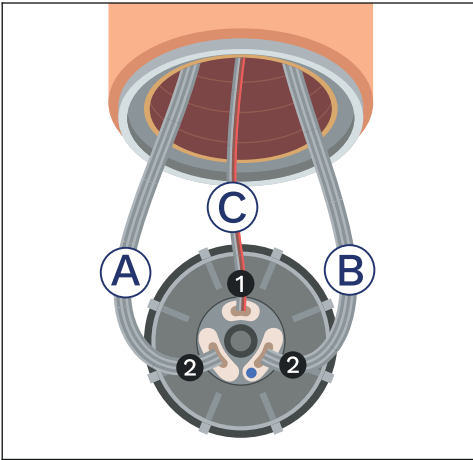


## 7.5 Establishing a connection

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.

### 7.5.1 Transradial treatment

#### 7.5.1.1 Connecting the coaxial plug

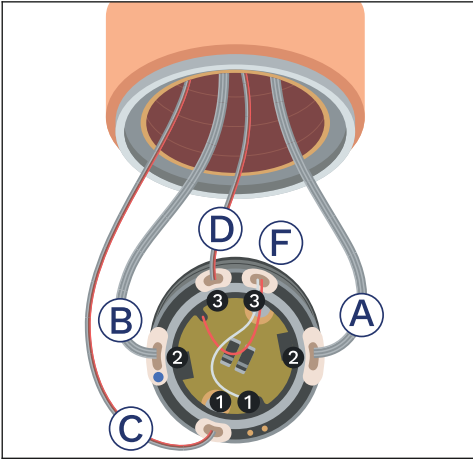


Ⓐ Connect the 3-pin cable without the blue dot to the left contact (2).

Ⓑ Connect the 3-pin cable with the blue dot to the right contact (2).

Ⓒ Connect the 2-pin cable of the MyoEnergy Integral to the contact (1).

### 7.5.1.2 Connecting the electric wrist rotator

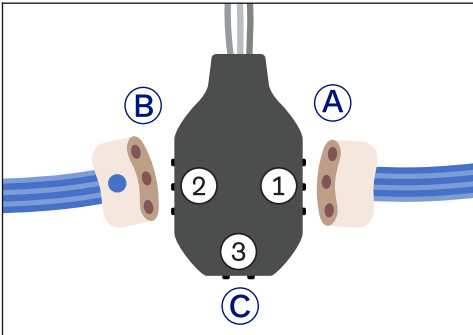


- Ⓐ Connect the 3-pin cable without the blue dot to the right contact (2).
- Ⓑ Connect the 3-pin cable with the blue dot to the left contact (2).
- Ⓒ Connect the 2-pin cable of the MyoEnergy Integral to the left contact (1).
- Ⓓ Connect the 2-pin cable to the left contact (3).
- Ⓕ Connect the motor cable of the electric wrist rotator to the right contact (3).

**NOTICE:** No cable may be connected to the right contact (1).

### 7.5.1.3 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.

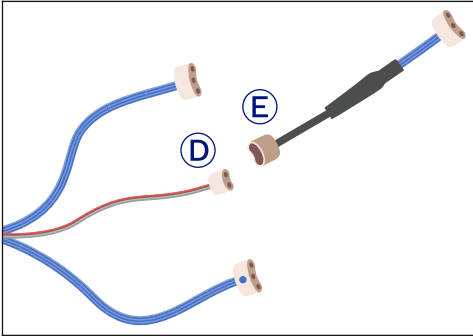


- Ⓐ Connect the 3-pin cable without the blue dot to the contact (1).
- Ⓑ Connect the 3-pin cable with the blue dot to the contact (2).
- Ⓒ Connect the cable of the MyoEnergy Integral to contact the (3).

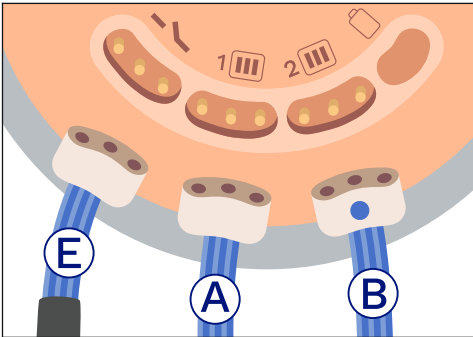
## 7.5.2 Transhumeral treatment

### 7.5.2.1 Connecting the DynamicArm

#### 7.5.2.1.1 Connecting the control unit to the Easy Plug



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

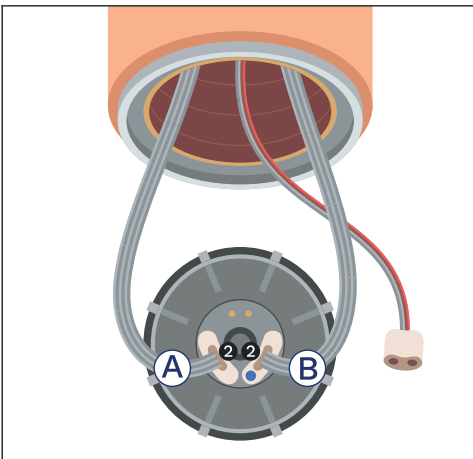


Ⓐ Connect the 3-pin cable without the blue dot to the contact (1).

Ⓑ Connect the 3-pin cable with the blue dot to the contact (2).

Ⓔ Connect the elbow adapter cable to the contact with the switch symbol.

#### 7.5.2.1.2 Connecting the coaxial plug

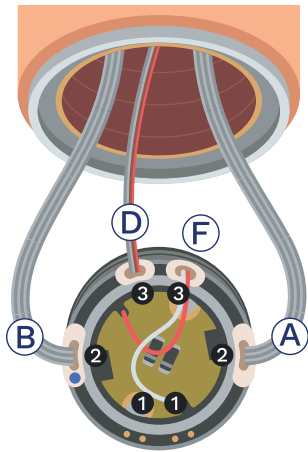


Ⓐ Connect the 3-pin cable without the blue dot to the left contact (2).

Ⓑ Connect the 3-pin cable with the blue dot to the right contact (2).

**NOTICE:** Do **not** connect the 2-pin cable.

7.5.2.1.3 Connecting the electric wrist rotator



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

7.5.2.1.4 Adjusting the elbow joint with ElbowSoft

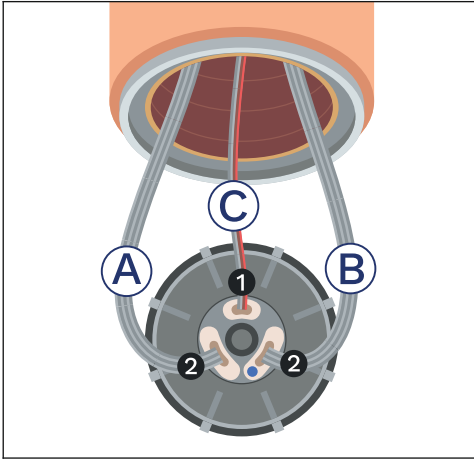
The following adjustments must be made in the ElbowSoft adjustment software to ensure correct prosthesis control functionality.  
See the elbow joint instructions for use and the corresponding training documentation from the Ottobock Academy.

|                     |                                     |                                     |                                     |
|---------------------|-------------------------------------|-------------------------------------|-------------------------------------|
|                     |                                     |                                     |                                     |
|                     | Elbow                               | Rotator                             | Hand                                |
| LT Step 1           | <input type="checkbox"/>            | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| LT Step 2           | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| LT Step3/<br>Switch | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |
| Timer: 0.5 s        |                                     |                                     |                                     |
| Automatic           | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/>            |

- 1) Calibrate the elbow joint.
- 2) Set control program 5.
- 3) Set the 100 % speed of the elbow joint.
- 4) In the 'Customizing' tab, clear all checkboxes in the 'Automatic' line.
- 5) Select the checkbox for 'LT Step 1' next to 'Hand'.
- 6) Select the checkbox for 'LT Step 2' next to 'Rotator'.
- 7) Select the checkbox 'LT Step 3/Switch' next to 'Elbow'.
- 8) Set the 'Timer' to 0.5 seconds.
- 9) Deactivate all feedback signals.
- 10) Set the input signal gain to a factor of 1.

## 7.5.2.2 Connecting the ErgoArm Electronic plus

### 7.5.2.2.1 Connecting the coaxial plug



Ⓐ Connect the 3-pin cable without the blue dot to the left contact (2).

Ⓑ Connect the 3-pin cable with the blue dot to the right contact (2).

Ⓒ Connect the 2-pin cable of the MyoEnergy Integral to the contact (1).

Connect the MyoSelect to the coaxial plug.  
Set program 1 with the MyoSelect.

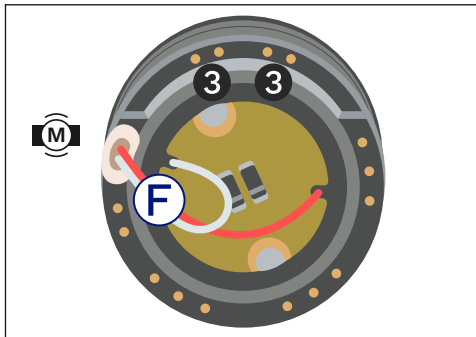
**INFORMATION:** Program 1 is configured at the factory.

#### 7.5.2.2.2 Connecting the MyoRotronic with electric wrist rotator

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



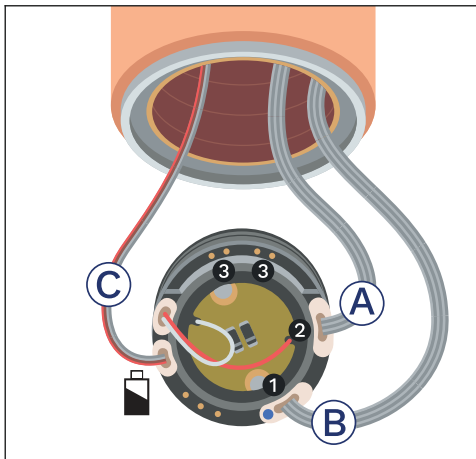
- 1) Connect the coaxial plug to the elbow joint.
- 2) Connect the MyoSelect to the coaxial plug.
- 3) Set program 1 in the elbow joint.  
**INFORMATION:** Program 1 is configured at the factory.
- 4) Disassemble the coaxial plug.



Disconnect the motor cable from the electric wrist rotator.  
Attach the MyoRotronic to the electric wrist rotator so that the two contacts (3) 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.

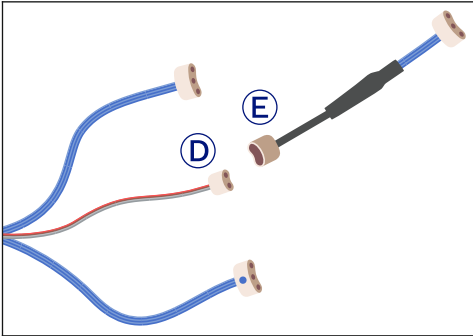


- Ⓐ Connect the 3-pin cable without the blue dot to the right contact (2).

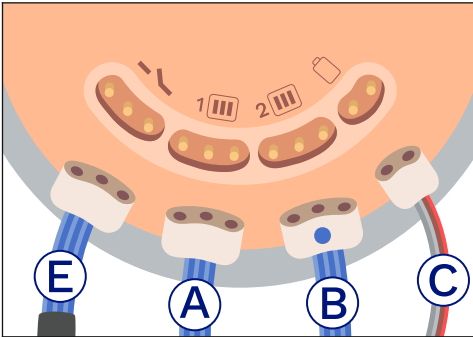
- Ⓑ Connect the 3-pin cable with the blue dot to the right contact (1).

- Ⓒ Connect the 2-pin cable of the MyoEnergy Integral to the contact with the battery symbol.

### 7.5.2.2.3 Connecting the control unit to the Easy Plug



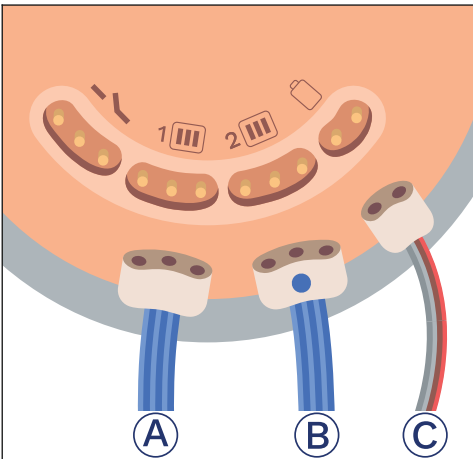
Ⓓ Connect the cable to the 13E102=1 elbow adapter cable Ⓔ.



Ⓐ Connect the 3-pin cable without the blue dot to the contact (1).  
Ⓑ Connect the 3-pin cable with the blue dot to the contact (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.

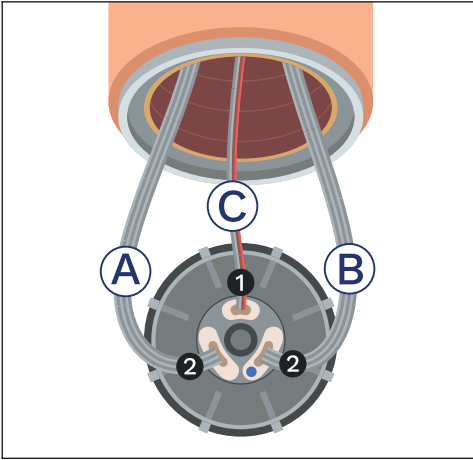
### 7.5.2.3 Connecting the ErgoArm Hybrid plus

#### 7.5.2.3.1 Connecting the control unit to the Easy Plug



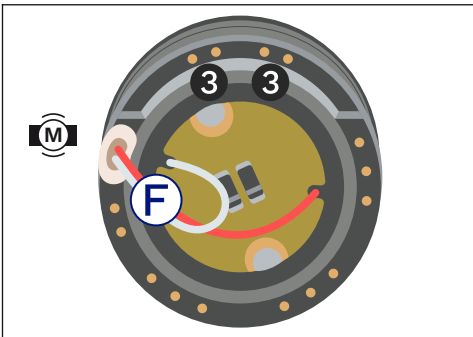
Ⓐ Connect the 3-pin cable without the blue dot to the contact (1).  
Ⓑ Connect the 3-pin cable with the blue dot to the contact (2).  
Ⓒ Connect the MyoEnergy Integral to the contact with the battery symbol.

### 7.5.2.3.2 Connecting the coaxial plug

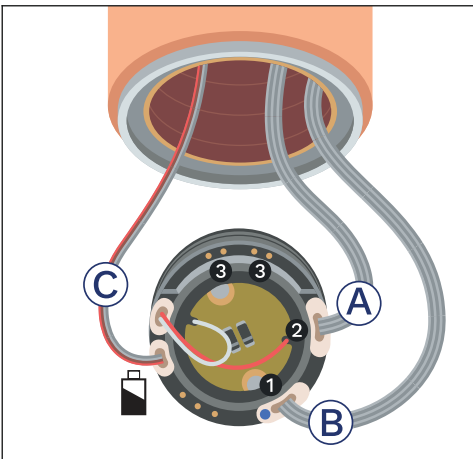


- Ⓐ Connect the 3-pin cable without the blue dot to the left contact (2).
- Ⓑ Connect the 3-pin cable with the blue dot to the right contact (2).
- Ⓒ Connect the 2-pin cable of the MyoEnergy Integral to the contact (1).

### 7.5.2.3.3 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 contacts (3) 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 (2).
- Ⓑ Connect the 3-pin cable with the blue dot to the right contact (1).
- Ⓒ Connect the 2-pin cable of the MyoEnergy Integral to the contact with the battery symbol.

## 7.6 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

When combining the control unit with a terminal device, certain battery types are recommended for the specific terminal device. For more information, please see the IFU for the terminal device.

## 7.7 Overview of adjustment possibilities

The following settings are required to connect the prosthesis to the myosmart control unit.

### Prerequisites

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

| Prosthesis                                                                                                 | Programming with | Setting/program                                                                                                                                                                         |
|------------------------------------------------------------------------------------------------------------|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8E70/71/72=* bebionic hand                                                                                 | connectgrip      | Reset to factory settings                                                                                                                                                               |
| 12K50 ErgoArm<br>The 10S17 MyoRotronic must be used in combination with the 13E205 electric wrist rotator. | MyoSelect        | Program 1                                                                                                                                                                               |
| 12K100N DynamicArm                                                                                         | ElbowSoft        | For prostheses with analogue terminal devices use 13E100 analogue adapter<br>Configure the settings in ElbowSoft. See section "Adjusting the elbow joint with ElbowSoft" (see page 18). |

### Fitting without elbow joint

The following functions can be activated, deactivated and adjusted in combination with the myosmart or myosmart plus control unit.

| Prosthesis                   | Settings with the connectgrip adjustment app                                                                                                                                                              | Prosthesis settings                               |
|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| 8E5=* michelangelo           | <ul style="list-style-type: none"><li>• Neutral position</li><li>• Standard grip</li><li>• Automatic switch-back to the standard grip</li><li>• Automatic opening of the hand when switching on</li></ul> | -                                                 |
| 8E2=* speed.hand             | <ul style="list-style-type: none"><li>• Neutral position</li><li>• Activating/deactivating the SUVA sensor</li></ul>                                                                                      | Switch on/off with button                         |
| 8E70, 71, 72=* bebionic hand | <ul style="list-style-type: none"><li>• Donning mode</li><li>• Primary, secondary grips for Open/Open mode</li></ul>                                                                                      | Activate with button for primary, secondary grips |

| Prosthesis                                     | Settings with the connect-grip adjustment app                                                          | Prosthesis settings                                                                                                                   |
|------------------------------------------------|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| Combination: bebionic with myosmart.plus       | <ul style="list-style-type: none"> <li>Choice between direct grip control or Open/Open mode</li> </ul> | Only activate in Open/Open mode with button for primary, secondary grips                                                              |
| 8E33/34/3 8/39/41/44=* MyoBock terminal device | -                                                                                                      | <ul style="list-style-type: none"> <li>Switch on/off with button</li> <li>Pressure on the SUVA sensor thumb: switch on/off</li> </ul> |

### Fitting with elbow joint

| Prosthesis                           | Settings with the connect-grip adjustment app | Prosthesis settings                                                                                                                                                                                                      |
|--------------------------------------|-----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8E5=* michelangelo                   | Standard grip                                 | Activating/deactivating the neutral position<br>In the open hand position, hold a strong "open" signal for at least 2 seconds.<br>While continuously holding the "open" signal, pull the thumb back with a medium force. |
| 8E2=* speed.hand                     | -                                             | <ul style="list-style-type: none"> <li>Switch on/off with button</li> <li>Pressure on SUVA sensor: switch on/off</li> </ul>                                                                                              |
| 8E70=*, 72=* bebionic hand           | -                                             | <ul style="list-style-type: none"> <li>Donning mode</li> <li>Activate with button for primary, secondary grips</li> </ul>                                                                                                |
| 8E33/38/44=* MyoBock terminal device | -                                             | <ul style="list-style-type: none"> <li>Switch on/off with button</li> <li>SUVA sensor (active yes/no)</li> </ul>                                                                                                         |

The combination of the control unit and adjustment app only supports Ottobock terminal devices and analogue signal processing. Please see the respective instructions for use for information on adjusting other products.

## 8 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**.

## 8.1 System Requirements

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

## 8.2 First time connection between app and product

**The following points should be observed before the initial connection:**

- Bluetooth of 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".

## 8.3 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 **Connect product**).  
→ An error message is displayed in the adjustment app and the product has been deleted from the list of available prostheses for safety reasons.

## 9 Use

### 9.1 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.

### 9.2 Display of the current charge level

The charge level can be queried at any time.

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

### 9.3 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.

## 10 Cleaning

### 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.

## 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.

The full text of the EU Declaration of Conformity 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.

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.**

12 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<br>or<br>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                                                                |

| Remote electrode    |           |
|---------------------|-----------|
| Frequency bandwidth | 80–500 Hz |
| Sensitivity range   | 1800x     |

## 13 Appendices

### 13.1 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)                                                                                                                                                                                                                                                                  |
|  | Declaration of conformity according to the applicable European directives                                                                                                                                                                                                                                                            |

|                                                                                   |                                                                                                                                                          |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Medical device                                                                                                                                           |
|  | Lot number<br>(10)PPPPYYYYWW<br>PPPP – plant<br>YYYY – year of manufacture<br>WW – week of manufacture                                                   |
|  | UDI number (Unique Device Identifier)                                                                                                                    |
|  | Article number                                                                                                                                           |
|  | 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° |
|  | MR unsafe                                                                                                                                                |

### 13.2 Operating States

#### 13.2.1 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         |

#### 13.2.2 Beep signals

The following beep signals are set by default:

| Beep signal | Additional display                           | Event                                                                                                                                                                                                                                            |
|-------------|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 x long    | -                                            | <ul style="list-style-type: none"> <li>Turn off product on charging receptacle</li> <li>Charging begins (charging plug connected to charging receptacle)</li> <li>Charging ends (charging plug disconnected from charging receptacle)</li> </ul> |
| 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                                                                                                                                                                                         |

### 13.3 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. | <ul style="list-style-type: none"> <li>Note arm position during calibration</li> <li>Take the weight into account during calibration</li> <li>Adjust the values in the app under the menu item <b>Control &gt; User &gt; Prosthesis Settings</b>.</li> </ul> |
| 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                                                                                                   | <ul style="list-style-type: none"> <li>Use mechanical overload protection: Pull fingers open with great force</li> <li>Rotate hand with great force</li> </ul>                                                                                               |
| Hand cannot be rotated any more                                                                                           |                                                                                                                  |                                                                                                                                                                                                                                                              |
| -                                                                                                                         | General fault                                                                                                    | <ul style="list-style-type: none"> <li>Switch the prosthesis off and on again</li> <li>Consult O&amp;P professional</li> </ul>                                                                                                                               |

### 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 notes in section "Safety-related information" (see page 8).

#### 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<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air, |
| High-frequency electromagnetic fields | IEC 61000-4-3                        | 10 V/m<br>80 MHz to 2.7 GHz<br>80 % AM at 1 kHz   |

| Phenomenon                                              | EMC basic standard<br>or<br>Test procedure | Interference immunity test level                                                                                    |
|---------------------------------------------------------|--------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| Magnetic fields with rated power frequencies            | IEC 61000-4-8                              | 30 A/m<br>50 Hz or 60 Hz                                                                                            |
| Electrical fast transients/bursts                       | IEC 61000-4-4                              | ±2 kV<br>100 kHz repetition rate                                                                                    |
| Surges<br>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<br>0.15 MHz to 80 MHz<br>6 V in ISM and amateur frequency bands between 0.15 MHz and 80 MHz<br>80 % AM at 1 kHz |
| Voltage drops                                           | IEC 61000-4-11                             | 0 % U <sub>T</sub> ; 1/2 period<br>At 0, 45, 90, 135, 180, 225, 270 and 315 degrees                                 |
|                                                         |                                            | 0 % U <sub>T</sub> ; 1 period<br>and<br>70 % U <sub>T</sub> ; 25/30 periods<br>Single phase: at 0degrees            |
| Voltage interruptions                                   | IEC 61000-4-11                             | 0 % U <sub>T</sub> ; 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<br>18 Hz             | 1.8               | 0.3          | 27                                     |
| 450                  | 430 to 470           | GMRS 460,<br>FRS 460                                                               | FM<br>± 5 kHz deviation<br>1 kHz sine | 1.8               | 0.3          | 28                                     |
| 710                  | 704 to 787           | LTE band 13,<br>17                                                                 | Pulse modulation<br>217 Hz            | 0.2               | 0.3          | 9                                      |
| 745                  |                      |                                                                                    |                                       |                   |              |                                        |
| 780                  |                      |                                                                                    |                                       |                   |              |                                        |
| 810                  | 800 to 960           | GSM 800/900,<br>TETRA 800,<br>iDEN 820,<br>CDMA 850,<br>GSM 800/900,<br>LTE band 5 | Pulse modulation<br>18 Hz             | 2                 | 0.3          | 28                                     |
| 870                  |                      |                                                                                    |                                       |                   |              |                                        |
| 930                  |                      |                                                                                    |                                       |                   |              |                                        |

| Test frequency [MHz] | Frequency band [MHz] | Radio service                                                                  | Modulation                 | Maximum power [W] | Distance [m] | Interference immunity test level [V/m] |
|----------------------|----------------------|--------------------------------------------------------------------------------|----------------------------|-------------------|--------------|----------------------------------------|
| 1,720                | 1,700 to 1,990       | GSM 1800;<br>CDMA 1900;<br>GSM 1900;<br>DECT;<br>LTE band 1, 3, 4, 25;<br>UMTS | Pulse modulation<br>217 Hz | 2                 | 0.3          | 28                                     |
| 1,845                |                      |                                                                                |                            |                   |              |                                        |
| 1,970                |                      |                                                                                |                            |                   |              |                                        |
| 2,450                | 2,400 to 2,570       | Bluetooth<br>WLAN 802.11 b/g/n,<br>RFID 2450<br>LTE band 7                     | Pulse modulation<br>217 Hz | 2                 | 0.3          | 28                                     |
| 5,240                | 5,100 to 5,800       | WLAN 802.11 a/n                                                                | Pulse modulation<br>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<br>2.1 kHz | 65                                     |
| 13.56 MHz      | Pulse modulation<br>50 kHz  | 7.5                                    |



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