



8E70=*, 8E71=*, 8E72=*

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1 Foreword

INFORMATION

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- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Instruct the user in the safe use of the product.
- ▶ Please contact the manufacturer if you have questions about the product or in case of problems.
- ▶ Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- ▶ Please keep this document for your records.

The products 8E70=* bebionic hand EQD, 8E71=* bebionic hand Short Wrist and 8E72=* bebionic hand Flex are referred to as product/terminal device/hand in the following.

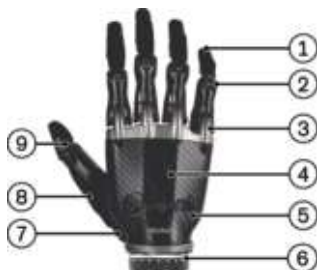
These instructions for use provide you with important information on the use, adaptation and handling of the product.

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

2 Product description

2.1 Design

The product consists of the following components:



1. Distal phalanx
2. Middle finger joint
3. Knuckles (finger chain behind (see page 25))
4. Program switch (see page 9)
5. Back of the hand
6. Wrist
7. CMC joint of the thumb
8. Gaiter
9. Distal thumb joint

2.2 Function

The product is a myoelectrically controlled and multiarticulating hand prosthesis.

The product enables objects to be gripped, pushed, pulled and carried with multiarticulating functionality. The product is designed to resemble the anatomical structure and weight of a human hand.

The thumb can be set to two different positions (opposition and lateral), allowing for 14 different grips (see page 5). Eight grips can be preconfigured using the adjustment software.

A finger chain that protects the drive serves as overload protection for the 4 actively powered fingers. In case of overloading, the corresponding finger cannot be flexed anymore since the connection to the drive was severed. The finger chain can be replaced without disassembling the terminal device (see page 25).

Essential performance of the product

- No essential performance according to IEC 60601-1

2.2.1 Grips

Moving the thumb from the lateral to the opposition position



- 1) Firmly grasp the base of the thumb with the free hand.
- 2) Apply controlled pressure to push the thumb inwards until it is opposite the palm.

Moving the thumb from the opposition to the lateral position



- 1) Firmly grasp the base of the thumb with the free hand.
- 2) Apply controlled pressure to push the thumb outwards until it is lateral to the palm.

Grips with opposed thumb (the thumb is opposite the palm)



Tripod grip

The index finger and middle finger are closed simultaneously with the thumb until the three fingers touch. Ring and little fingers continue to close until they meet resistance or the close signal stops. The thumb position has to be adjusted for this grip so it can be carried out precisely (see page 19).

Application examples: this grip can be used to grasp and hold objects (e.g. pens, coins).



Power grip

All fingers close until they encounter an object or the close signal stops. The thumb then moves towards the palm as well.

Application examples: this grip can be used to hold round objects (e.g. fruit, balls, glasses).



Finger adduction/abduction

By spreading the fingers, a flat, thin object ($< 3\text{ mm}/< 0.12\text{ inch}$) can be held between the finger joints when closing the hand. Spreading the fingers is most effective with the power grip. It can also be used with the key grip and finger point. This grip **cannot** be selected in the adjustment software. Application examples: makes it possible to hold thin objects effectively (e.g. magazine, cutlery, toothbrush).



Hook grip

This grip corresponds to a power grip with the fingers only partly closed. It makes it possible to engage objects with carrying loops and can also be initiated from the relaxed hand position. This grip **cannot** be selected in the adjustment software. Application examples: this grip makes it possible to carry bags.



Active index grip

All fingers close and can pick up an object while the index finger remains extended. Subsequently the index finger can be individually flexed or extended by the user. An open signal causes the index finger to extend first followed by the remaining fingers. The object is released from the hand. Application examples: this grip can be used for example to operate spray bottles.



Pinch grip

For this grip, only the index finger and thumb meet while the remaining fingers close. The thumb position has to be adjusted for this grip so it can be carried out precisely (see page 19). Application examples: this grip makes it possible to grasp small objects (e.g. house keys, coins, closures, pens).



Precision closed grip

The middle finger, ring finger and little finger are closed. The thumb moves to a half-closed position. Subsequently the index finger can be individually flexed or extended. The thumb position has to be adjusted for this grip so it can be carried out precisely (see page 19). Application examples: this grip makes it possible to grasp small objects and makes working at a table easier.



Precision open grip

The middle finger, ring finger and little finger remain open. The thumb moves to a half-closed position. Subsequently the index finger can be individually flexed or extended. The thumb has to be adjusted for this grip so it can be carried out precisely (see page 19). Application examples: this grip makes it possible to grasp small objects.

Grips with the thumb in the lateral position (the thumb is sideways to the palm)



Column grip

The thumb closes towards the palm, then the remaining fingers bend over the thumb. In doing so, the thumb blocks the closing movement of the index finger and lets it protrude beyond the other three fingers.

Application examples: this grip can be used to push large buttons (e.g. light switches) and for putting on clothes.



Finger point

The middle finger, ring finger, little finger and thumb move towards the palm. The index finger remains extended.

Application examples: small buttons can be operated with this grip (e.g. keyboard, remote control).



Key grip

The fingers close partway. In doing so, the thumb grasps the index finger sideways. This makes it possible to secure and release flat objects with the thumb, without movement of the remaining fingers.

Application examples: this grip can be used to hold thin objects without the remaining fingers moving (e.g. a spoon, paper, plate, credit card or key).



Mouse grip

The thumb and little finger close to grasp the computer mouse sideways. Only when the thumb encounters resistance can the index finger be flexed. The index finger extends automatically when no close signal is applied. An open signal loosens the grip.

Application examples: this grip makes it possible to operate a computer mouse.



Open palm grip

In the open hand position, the thumb is in the lateral position to achieve the largest possible flat palm. This grip **cannot** be selected in the adjustment software.

Application examples: this grip makes it possible to carry plates on the flat hand.



Relaxed hand position

The thumb is in the lateral position and closes partway towards the palm. All fingers assume a slightly flexed position. When the close signal is repeated, the fingers move to form the hook grip.

Application examples: this grip is recommended when the hand is not being actively used.

2.2.2 Program switch

A program switch is located on the back of the product (item 4). Both the program switch and flexion are not visible when using a prosthetic glove and have to be felt.

The switch incorporates various functions:

- Switching the terminal device on and off (see page 23)
- Switching the Bluetooth function on/off (see page 23)
- Switching between primary and secondary grips (see page 24)
- Activating donning mode (see page 24)

Depending on whether the terminal device is switched on or off and how long the program switch is pressed, the following functions can be carried out:

Terminal device switched on

Duration of pressing	Function	Beep signal	Vibration signal
Approx. 1 second	Switching between primary and secondary grips	1x short after releasing the program switch	1x short after releasing the program switch
Between 2 and 3 seconds	Switching the hand off	–	–
Longer than 4 seconds	Switching off the Bluetooth function	1x short	1x short
Longer than 4 seconds	Switching on the Bluetooth function	2x long	2x long

Terminal device switched off

Duration of pressing	Function	Beep signal	Vibration signal
Between 2 and 3 seconds	Switching the hand on	1x short after releasing the program switch	1x short after releasing the program switch
Approx. 3 seconds (until thumb opens)	Deactivating donning mode	–	–
Approx. 5 seconds (until thumb closes)	Activating donning mode	1x short	1x short

2.2.3 Switching modes

Switching between the default and alternative grip can be carried out as follows, depending on the selected mode:

- Mode 0: program switch
- Modes 1 through 4: with another open signal after fully opening the hand
- Mode 5: co-contraction signal after fully opening the hand

2.2.4 Factory settings

Mode 4 as the switching mode and the following grips are configured on delivery (factory settings):

Opposed primary grips

- Default: tripod grip
- Alternative: power grip

Lateral primary grips

- Default: key grip
- Alternative: finger point

2.2.5 Wrist joint versions

The products 8E70=*, 8E71=*, 8E72=* bebionic hand are differentiated by different variants of the wrist joint:



Opposed secondary grips

- Default: active index grip
- Alternative: tripod grip

Lateral secondary grips

- Default: column grip
- Alternative: mouse grip

8E70=* bebionic hand EQD (with quick-disconnect wrist unit)

Permits easy separation of the terminal device from the prosthetic socket. The terminal device can be removed quickly when needed via a 360° rotating movement and replaced by a different terminal device with the same quick-disconnect unit.



8E71=* bebionic hand Short Wrist

Low-profile connection for users with a long forearm or transcarpal amputation. The hand can be rotated against a constant friction, which can be adjusted during the fitting process. The required 9S110=* lamination ring is included in the scope of delivery.

The 13E190 or 13E190=150 switch block is required when this terminal device is used.



8E72=* bebionic hand Flex

The flexion joint with quick-disconnect wrist makes positioning possible for the user at 20° or 40° flexion, in the neutral position and at 20° or 40° extension. The terminal device can be removed quickly when needed via a 360° rotating movement and replaced by a different terminal device with the same quick-disconnect unit.

2.2.6 Unlocking/locking the wrist joint (8E72=*)



The individual flexion and extension of the wrist joint can be locked in five different positions (in 20° increments each).

- 1) Press the release button in the direction of the arrow.
- 2) Move the terminal device to the desired position while holding the release button. From the relaxed hand position, it engages at 20° and 40° in each direction.
- 3) Let go of the release button to lock the terminal device in the respective position.

2.3 Product combinations

This product can be combined with the following Ottobock components:

Control units

- 13E520=* Myo Plus TR
- myosmart 13E522=1

Power supply (rechargeable battery)

- 757B35=3 MyoEnergy Integral
- 757B35=4 MyoEnergy Integral
- 757B35=5 MyoEnergy Integral

Battery chargers

The following battery chargers can be used depending on the rechargeable battery:

- 757L35 MyoCharge Integral battery charger (including 757L16-4 power supply)
- 757L24 DynamicArm battery charger

Elbow components for the products 8E70=* and 8E72=*

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

Connection to the prosthetic socket

- 13E129=G* electrode cable with straight plug and plug connector (when using the 9X50/9X52 linear control elements or 13E200/13E202 electrodes)
- 13E190 or 13E190=150 switch block

Active rotation for the products 8E70=* and 8E72=*

- 13E205 MyoRotronic
- 10S17 Electric wrist rotator

Passive rotation for the 8E70=* and 8E72=* products

- 9E169 coaxial plug
- 10S4 coupling piece

Lamination rings

- 9S110=* lamination ring (included in the scope of delivery for the 8E71=*)
- 10S1=* lamination ring (for 8E70 and 8E72)

Switches and control elements

- Pressure switch 9X37
- Linear control element 9X50
- Cable pull switch 9X18
- Linear control element 9X52

Electrodes

- 13E200=* electrode
- 13E202=* suction socket electrode

3 Intended use

3.1 Indications for use

The product is intended **exclusively** for upper limb exoprosthetic fittings.

3.2 Conditions of use

The product is intended **exclusively** for use on **one** user. Use of the product by other persons is **prohibited** by the manufacturer.

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 should not be used to operate motor vehicles, heavy equipment (e.g. construction machines), industrial machines or motor-driven equipment.

See the technical data for the permissible environmental conditions (see page 33).

3.3 Indications

- Amputation level below-elbow, above-elbow and shoulder disarticulation
- For unilateral or bilateral amputation
- Dysmelia of the forearm or upper arm
- 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

INFORMATION

Increased maintenance requirements for bilateral users

In the day-to-day use of a bilateral user, the load on the prosthetic hands tends to be higher, as the user is dependent on the function of the prosthesis during all activities.

Therefore, please note there may be increased mechanical wear and tear and need for repairs when treating a bilateral amputation.

3.4 Contraindications

- All conditions which contradict or go beyond the specifications listed in the sections on "Safety" (see page 12) and "Intended use" (see page 12).

3.5 Qualification

Treatment may only be carried out by trained, qualified personnel.

4 Safety

4.1 Explanation of warning symbols

 **WARNING** Warning regarding possible serious risks of accident or injury.

 **CAUTION** Warning regarding possible risks of accident or injury.

 **NOTICE** Warning regarding possible technical damage.

4.2 Structure of the safety instructions

WARNING

The heading describes the source and/or the type of hazard

The introduction describes the consequences in case of failure to observe the safety instructions. Consequences are presented as follows if more than one consequence is possible:

> E.g.: Consequence 1 in the event of failure to observe the hazard

- > E.g.: Consequence 2 in the event of failure to observe the hazard
- ▶ This symbol identifies activities/actions that must be observed/carried out in order to avert the hazard.

4.3 General safety instructions

WARNING

Using the prosthesis while operating a vehicle

Accident due to unexpected prosthesis behaviour.

- ▶ The prosthesis should not be used for the operation of motor vehicles and heavy equipment (e.g. construction machines).

WARNING

Using the prosthesis while operating machines

Injury due to unexpected prosthesis behaviour.

- ▶ The prosthesis should not be used to operate industrial machines or motor-driven equipment.

WARNING

Use of damaged power supply unit, adapter plug or battery charger

Risk of electric shock due to contact with exposed, live components.

- ▶ Do not open the power supply unit, adapter plug or battery charger.
- ▶ Do not expose the power supply unit, adapter plug or battery charger to extreme loading conditions.
- ▶ Immediately replace damaged power supply units, adapter plugs or battery chargers.

WARNING

Use of the product while handling a firearm.

Injury due to unexpected product behaviour.

- ▶ The product may not be used for handling firearms.

WARNING

Skin contact with leaking lubricants due to mechanical defects

Injury due to skin irritation.

- ▶ Avoid contact between leaking lubricants and the mouth, nose and eyes.
- ▶ The product must be inspected by an authorised Ottobock Service Centre.

CAUTION

Signs of wear on the product

Injury due to faulty control or malfunction of the product

- ▶ In the interest of user safety and in order to maintain operating reliability, the terminal device has to be inspected by an authorised Ottobock Service Centre in case of noticeable restrictions of functionality.
- ▶ Note that the functionality of the terminal device may be limited if the battery charge level gets too low.

⚠ CAUTION

Use of a damaged product

Injury due to loss of product functionality.

- ▶ Prior to use, conduct an external visual inspection to verify that all parts of the product are undamaged.
- ▶ In case of damage, have the product repaired promptly.

⚠ CAUTION

Penetration of product with dirt and humidity

Injury due to unexpected product behaviour or malfunction.

- ▶ Ensure that neither solid particles nor liquids can penetrate into the product.

⚠ CAUTION

Independent manipulation of the product or product components

Injury due to faulty control or malfunction of the product due to manipulation

- ▶ Manipulations to the product other than the tasks described in these instructions for use are not permitted.
- ▶ Opening and repairing the product and any damaged components, and removing the back of the hand, is reserved exclusively for authorised, qualified Ottobock personnel.

⚠ CAUTION

Insufficient skin contact of the electrodes

Injury due to faulty control or malfunction of the product.

- ▶ The electrodes are to be placed on intact skin only and with as much electrode-skin contact as possible.
- ▶ In the case of strong interference from electronic devices, the position of the electrodes should be checked and changed if necessary.
- ▶ If the interference cannot be eliminated or if you do not achieve the expected results by adjustment or selection of the appropriate control programme, please contact the Ottobock branch responsible for your country.

⚠ CAUTION

Prosthesis use when battery charge level is too low

Injury due to unexpected prosthesis behaviour

- ▶ Check the current charge level before use and charge the prosthesis if required.
- ▶ Note that the operating time of the prosthesis may be reduced at low ambient temperatures or due to ageing of the battery.
- ▶ Note that the actions/reactions of the terminal device become slower when the battery voltage gets very low.
- ▶ Note that only a few grips or actions will still be possible with the terminal device when the battery voltage gets very low.
- ▶ A small opening width may indicate a low battery voltage.

4.4 Information on Alignment/Adjustment

⚠ CAUTION

Operator errors when adjusting settings using the adjustment software

Injury due to unexpected product behaviour.

- ▶ Participation in an Ottobock product training course is required prior to initial use. Additional product training courses may become necessary to qualify for software updates.
- ▶ Transfer the setting changes to the terminal device before you check the settings on the user.
- ▶ Use the online help function integrated into the software.

CAUTION

Use of unapproved accessories

- > Injury due to product malfunction as a result of reduced resistance to interference.
- > Interference of other electronic devices due to increased emissions.
- ▶ Only use the product in combination with the accessories, signal converters and cables listed in the sections "Combination possibilities" (see page 11), "Scope of delivery" (see page 17) and "Accessories" (see page 18).

CAUTION

Use of unsuitable prosthetic components

Injury due to unexpected product behaviour.

- ▶ Use the product only in combination with components listed in the section "Combination possibilities" (see page 11).

CAUTION

Failure to observe the instructions for use of all prosthesis components used

Injury due to unexpected product behaviour.

- ▶ Observe the instructions for use of the prosthesis components used.

CAUTION

Incorrect electrode settings/electrode assignment

Injury due to unexpected product behaviour.

- ▶ The electrodes are to be placed on intact skin only and with as much skin contact as possible. In the case of strong interference from electronic devices, the position of the electrodes should be checked and changed if necessary. If the interference cannot be eliminated or if you do not achieve the expected results by adjustment or selection of the appropriate control program, please contact the Ottobock branch responsible for your country.
- ▶ Set the electrode sensitivity as low as possible in order to reduce interference from powerful electromagnetic radiation (e.g. visible or concealed theft prevention systems at the entrance/exit of stores), metal detectors/body scanners for persons (e.g. in airports) or other sources of strong electromagnetic interference (e.g. high-voltage lines, transmitters, transformer stations, computer tomographs, magnetic resonance tomographs, etc.).
- ▶ Make sure that the electrode connection positions correspond to physiological opening and closing for the corresponding muscle groups.

4.5 Information on Proximity to Certain Areas

CAUTION

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

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

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

 CAUTION

Operating the product in very close proximity to other electronic devices

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

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

 CAUTION

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

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

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

4.6 Information on Use

 CAUTION

Mechanical stress on the product

Injury due to faulty control or malfunction of the product.

- ▶ Do not subject the product to mechanical vibrations or impacts.
- ▶ Check the product for visible damage before each use.

 CAUTION

Improper handling

Injury due to faulty operation or malfunction of the product.

- ▶ Instruct the user in the proper use of the product.

 CAUTION

Improper product care

- > Injuries due to faulty control/malfunction of the product or damage to the mechanical components.
- > Damage or breakage due to brittleness of plastics caused by the use of acetone or petrol, for example.
- ▶ Clean the product only as described in the section "Cleaning and care" (see page 25).
- ▶ Do not clean the product under running water.
- ▶ When using a prosthetic glove, also note the instructions for use of the glove.

 CAUTION

Grasping objects with incorrect gripping forces

Injury due to unexpected product behaviour.

- ▶ Note that the gripping has to be controlled manually depending on the consistency (soft/hard) of the object being grasped.

CAUTION

Overloading due to unusual activities

Risk of injury due to unexpected product behaviour as a result of a malfunction.

- ▶ 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.).
- ▶ Careful handling of the product and its components not only increases their service life but, above all, ensures the patient's personal safety!
- ▶ If the product and its components have been subjected to extreme loads (e.g. due to a fall, etc.), then the product must be inspected for damage immediately. If necessary, forward the product to an authorised Ottobock Service Centre.

CAUTION

Risk of pinching between the fingertips

Injury due to pinching parts of the body.

- ▶ Ensure that no body parts are between the fingertips when using the product.
- ▶ Ensure that no body parts are between the fingertips when closing the hand.
- ▶ When closing the hand, ensure that fingers and other body parts are not in the area of the finger joints.
- ▶ Make sure the product is switched off for cleaning.

CAUTION

Insufficient distance from sources of high heat

Inflammation of the product.

- ▶ Do not expose the product to sources of high heat (fire, stovetop, space heater, radiator, etc.).
- ▶ Do not grasp or hold burning objects with the product.

CAUTION

Unintentional unlocking of the terminal device

Risk of injury due to the terminal device disconnecting from the forearm (e.g. while carrying objects).

- ▶ Ensure that the connection is carried out correctly when connecting the hand to the prosthetic socket or components.

5 Scope of delivery, accessories, spare parts

5.1 Scope of delivery

- 1 pc. bebionic tool kit
- 1 pc. cosmetic case for battery charger and power supply
- 1 pc. prosthesis passport
- 1 pc. Instructions for use (qualified personnel)
- 1 pc. instructions for use (users)
- 1 pc. instructions for use (qualified personnel) for the bebalance+ adjustment software

Terminal devices

- 1 pc. 8E70=* bebionic hand EQD
- or
- 1 pc. 8E71=* bebionic hand Short Wrist

or

- 1 pc. 8E72=* bebionic hand Flex

5.2 Accessories

Adjustment app

- 560X12=V1.6 "bebalance+ 1.6" or higher adjustment software
- Bluetooth adapter "Bluetooth Long Range Dongle B33061"

or

- **560X27-*=* connectgrip adjustment app** for download from the app stores (Apple App Store, Google Play, etc.). Enter the following search terms: Ottobock, connectgrip or scan the QR code. Further information about the app and how it works can be found either in the link in the description of the app stores or in the installed app.



Battery chargers

- USB charging adapter: 757L43
To connect the 757L43 USB charging adapter to the respective charger, observe the information in the USB charging adapter instructions for use.

Prosthetic glove

- 8S710=* prosthetic glove
- 8S711=* prosthetic glove

5.3 Spare parts

A 501G16=M3X8 set screw with Allen head and a 509Y1=3 metal ball are supplied with each finger order number.

Finger/colour	Size S	Size M
Index finger (white)	9S317-2=1-6	-
Middle finger (white)	9S317-2=2-6	
Ring finger (white)	9S317-2=3-6	
Little finger (white)	9S317-2=4-6	
Index finger (black)	9S317-2=1-7	9S366-2=1-7
Middle finger (black)	9S317-2=2-7	9S367-2=1-7
Ring finger (black)	9S317-2=3-7	9S367-2=2-7
Little finger (black)	9S317-2=4-7	9S366-2=2-7

Spare part	Reference number
Finger chain	9S296-1=1
Bearing ball	509Y1=3

Spare part	Reference number
Set screw	501G16=M3X8

6 Preparing the product for use

6.1 Charging the battery

The following information can be found in the instructions for use of the respective batteries or the elbow components:

- Handling the battery
- Querying the charge level
- Feedback (beeps and vibration signals)

6.2 Adjusting the thumb position

The thumb of the terminal device is aligned for the tripod grip on delivery (see page 6).

The thumb position needs to be adjusted for certain grips. Two different adjustment options are provided on the thumb for this purpose:



Mediolateral thumb position:

This adjustment option allows the thumb to be repositioned so it contacts the index and middle fingers (tripod grip), or the index finger only (pinch grip). The thumb position is secured with a hexagon socket screw on the bebionic hand small and a number 2 slotted screw on the bebionic hand medium. The medial end stop can be adjusted with the screw when the thumb is in the opposed position.

The adjustment screw is perpendicular to the thumb axis and located under the gaiter. Perform the following steps to make the adjustments:

- 1) Turn off the energy supply to the terminal device (e.g. button in the charging receptacle on the prosthetic socket or switch on the elbow joint).
- 2) Separate the terminal device from the prosthetic socket.
- 3) Elevate the gaiter on the wrist and expose the adjustment screw.
- 4) Use a 3 mm Allen key for the bebionic hand small and a spanner bit for the bebionic hand medium on the mediolateral adjustment screw on the carpometacarpal joint of the thumb.
- 5) Loosen the screw by turning it completely counterclockwise twice.

Once the screw has been loosened, the thumb is freely moveable and can be repositioned manually.



- 6) Mount the terminal device on the socket, turn on the energy supply and set the new contact point of the thumb with the index finger (pinch grip) and the index and middle fingers (tripod grip).
- 7) By closing and opening the terminal device, check the new contact point of the thumb with the index finger (pinch grip) and the index and middle fingers (tripod grip).
Once the new thumb position has been set, close the hand and switch it off. Thus the closed grip secures the thumb position.
- 8) Switch the terminal device off with the thumb fixed.
- 9) Tighten the adjustment screw to 2 Nm by turning it clockwise and reposition the gaiter.
- 10) Switch the terminal device on and test it with the user.

Thumb contact point:

The adjustment option makes it possible to optimise the contact point of the thumb with the opposite index and middle fingers (for the tripod grip), or with the index finger only (pinch and precision grips). The adjustment screw is located below the CMC joint of the thumb. Perform the following steps to make the adjustments:

- 1) Turn off the energy supply to the terminal device (e.g. button in the charging receptacle on the prosthetic socket or switch on the elbow joint).
- 2) Separate the terminal device from the prosthetic socket.
- 3) Raise the gaiter on the wrist joint and expose the adjustment screw.
- 4) Use a 1.5 mm Allen key for the adjustment screw of the thumb contact point on the MCP joint of the thumb.





- 5) Turning the Allen key clockwise moves the thumb towards the palm (reducing the distance).

Turning the Allen key counterclockwise moves the thumb away from the palm (increasing the distance).

INFORMATION: The effect of the rotation movement applies for both the right and left bebionic hands.

The movement of the thumb cannot be observed while the adjustment is being made. An adjustment of one turn is sufficient.

- 6) Mount the terminal device on the prosthetic socket and, with the energy supply turned on, check the contact point by closing the terminal device. If the adjustment of the contact point was not sufficient, open the hand fully and perform the adjustment steps again.

6.3 Settings with the adjustment software

6.3.1 Introduction

The bebalance+ adjustment software or connectgrip adjustment app make it possible to optimise the product settings and grips for a patient. All settings have to be checked together with the user.

Please consult the integrated online help in the adjustment software/adjustment app for further information.

INFORMATION

See the instructions for use of the adjustment software for information about the adjustment software, installation and establishing a connection to the product.

INFORMATION

Cybersecurity

- ▶ Keep your operating system up to date and always install any available security updates.
- ▶ Protect your computer from unauthorised access (e.g. by using virus scans, password protection, etc.).
- ▶ Do not use unsecured networks.
- ▶ Please contact the manufacturer if you suspect cybersecurity problems.

6.3.2 Data transfer between the product and the PC

Product settings using the adjustment software can only be made via Bluetooth data transfer. For this purpose, a Bluetooth wireless connection must be established between the product and the PC using the B33061 Bluetooth adapter. To install the Bluetooth adapter for the first time, follow the procedure described in the instructions for use for the 560X12=V* bebalance+ adjustment software.

Optionally, the connectgrip adjustment app can be used to adjust the product.

6.3.3 Preparing the product to connect to the adjustment software

In order to activate the Bluetooth function of the terminal device, carry out the following steps:

- > The prosthesis is switched on.
- Hold the program switch on the back of the terminal device for at least 6 seconds until two long beeps are heard.
- The Bluetooth function of the terminal device is activated.

6.4 Donning the prosthetic glove

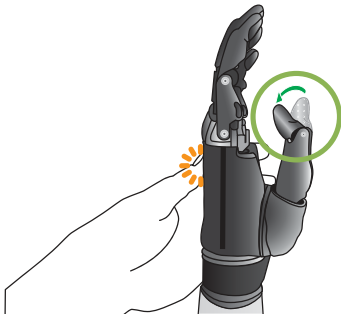
INFORMATION

Do not use silicone spray when putting on the prosthetic glove. This impairs the secure fit of the glove and can limit the functionality of the product (hand).
Observe the instructions for use provided for the prosthetic glove and the process for putting it on and taking it off described in the same.

INFORMATION

Avoid exposing the product without a prosthetic glove to direct sunlight or UV light (solarium) for extended periods.

Wearing the bebionic hand with the prosthetic glove is recommended for daily use. The glove protects the mechanism against environmental influences such as moisture, dirt and dust.



Donning mode for the terminal device must be activated before pulling on the prosthetic glove (see page 24). Donning mode is ideal for putting on clothes and jackets as this mode prevents the thumb from getting caught in clothing and therefore reduces breaking of the thumb.

For information about the use (putting on and taking off) and care of the prosthetic glove, please refer to the instructions for use included with the prosthetic glove.

7 Use

7.1 Applying/removing the terminal device

INFORMATION

Applying/removing the terminal device works only with the terminal devices 8E70=* bebionic hand EQD and 8E72=* bebionic hand Flex.

Separating the terminal device from the socket

⚠ CAUTION

Unintentional unlocking of the terminal device

Risk of injury due to the terminal device disconnecting from the forearm (e.g. while carrying objects).

- Ensure that the connection is carried out correctly when connecting the hand to the prosthetic socket or components.

- 1) Turn the prosthesis off with the button in the charging receptacle (prosthetic socket) or the switch on the elbow joint.
- 2) Rotate the terminal device once or twice around its own axis until a slight resistance is felt.
- 3) Overcome this resistance and pull the terminal device off the socket.

Attaching the terminal device to the socket

- 1) Insert the quick-disconnect wrist unit into the lamination ring and press it in firmly.
- 2) Turn the terminal device slightly to the left or right.
- 3) Verify proper attachment by pulling on the terminal device.

INFORMATION

Please see the 646T322 technical information for proper handling with the lamination ring.

7.2 Switching the Bluetooth function on/off

Switching on Bluetooth

The terminal device must be switched on in order to activate the Bluetooth function.

- Press and hold the program switch on the back of the hand for longer than 4 seconds until **two feedback signals** are generated (see page 35).

INFORMATION: If only one feedback signal is generated, the Bluetooth function has been deactivated.

→ Bluetooth is switched on.

Switching off Bluetooth

The terminal device must be switched on in order to deactivate the Bluetooth function.

- Press and hold the program switch on the back of the hand for longer than 4 seconds until **one feedback signal** is generated (see page 35).

INFORMATION: If two feedback signals are generated, the Bluetooth function has been activated.

→ Bluetooth is switched off.

Bluetooth also turns off automatically after two minutes when there is no active PC connection.

7.3 Terminal device on/off

Switching the hand on

- 1) Press and hold the program switch on the back of the hand for no longer than 2 to 3 seconds.
- 2) After releasing the program switch, a single short feedback signal is generated (see page 35).

INFORMATION: If a feedback signal was already generated in step 1, the Bluetooth function has been activated or deactivated.

→ The terminal device is switched on.

After the prosthesis has been switched on with the button in the charging receptacle or the switch on the elbow joint, the terminal device is switched on as well.

Switching the hand off

- Press and hold the program switch on the back of the hand for no longer than 2 to 3 seconds.
- If no feedback signal is generated after releasing the program switch, only the terminal device is switched off. Other prosthesis components, such as an elbow joint or electric rotator, can still be used.

INFORMATION: If a feedback signal is generated after releasing or while pressing the program switch, or if the thumb closes towards the palm, the program switch was not pressed long enough or pressed too long.

When the prosthesis is switched off with the button in the charging receptacle or the switch on the elbow joint, all other prosthesis components including the terminal device are switched off.

7.4 Switching between primary and secondary grips

- ▶ Briefly press the program switch. A short single feedback signal is generated after it is released (see page 35).
- The product has switched between the primary and secondary grips or vice versa.

7.5 Switching between default and alternative grips

Switching between the default and alternative grip can be carried out as follows, depending on the selected mode:

- Mode 0: program switch
- Modes 1 through 4: with another open signal after fully opening the hand
- Mode 5: co-contraction signal after fully opening the hand

The following switching mode is set on delivery of the terminal device (factory setting):

7.5.1 OPEN-OPEN/co-contraction

OPEN-OPEN

OPEN-OPEN switches between the default and alternative grips via the open electrode (pull switch, button or similar) (mode 4). OPEN-OPEN is produced by fully opening the hand (OPEN) followed by a brief open impulse (OPEN).

INFORMATION

When using the electric rotator with MyoRotronic 4-channel control, the musculature may only relax until it briefly falls below the on-threshold of the bebionic hand in order to then generate the open impulse. Fully relaxing the musculature or the elimination of the muscle signal leads to rotation control when generating an impulse.

Co-contraction

Co-contraction is used to switch between the default and alternative grips via two electrodes (mode 5). The co-contraction is the simultaneous and brief tensing of both muscle groups. This reliable control of the switching mode is only possible with two good myo-signals. However, the co-contraction cannot be used as the switching mode between the hand and hand rotation. The settings can be configured using the "Co-contraction" button in the adjustment software.

7.6 Donning mode

Activating donning mode

- 1) Move the thumb to the opposed position.
 - 2) With the terminal device switched off, press and hold the program switch on the back of the hand until the thumb automatically moves to donning mode.
- The thumb moves in towards the palm.
- or
- 1) Switch the prosthesis on with the button in the charging receptacle on the prosthetic socket or the switch in the elbow joint.
 - 2) During the initialisation phase of the terminal device, press and hold the program switch on the back of the hand until the thumb automatically moves to donning mode.
- The thumb moves in towards the palm.

INFORMATION

Sending the product to an authorised Ottobock Service Centre

Set the thumb to the lateral position and then activate donning mode on the terminal device.

Deactivating donning mode

- ▶ With the thumb pointing inward, press and hold the program switch on the back of the hand until the thumb opens.
- Donning mode is deactivated and the terminal device is switched on.

8 Cleaning and care

- 1) Switch off the product before cleaning.
- 2) Clean the product with a damp cloth and mild soap when needed.
Make sure that no liquids get into the product and product components.
- 3) Dry the product with a lint-free cloth and allow it to air dry fully.

INFORMATION

The hand can be cleaned three times per day on average.

INFORMATION

When using a prosthetic glove, note the cleaning information in the instructions for use for the prosthetic glove.

9 Maintenance and repair

Certified O&P professionals may carry out minor repairs themselves. These repairs include replacing the finger chain and fingers. All other repairs are carried out by an authorised Ottobock Service Centre.

INFORMATION

Replacement of the finger chain/finger by an authorised Ottobock Service Centre

If it is not possible to replace the finger chain or finger, the terminal device can also be sent to an authorised Ottobock Service Centre. The terminal device should be in donning mode prior to shipment (see page 24).

9.1 Replacing the finger chain

Tools/materials	
Designation	Reference number
Drift punch	Included in the tool kit
Hammer	General workshop supplies
Flat nose pliers	General workshop supplies
Finger chain	9S296-1=1 (included in tool kit)

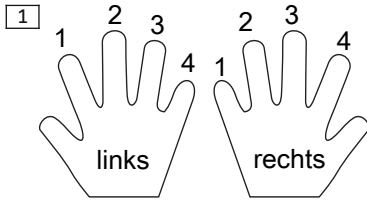
9.1.1 Sequence for “covered” fingers

INFORMATION

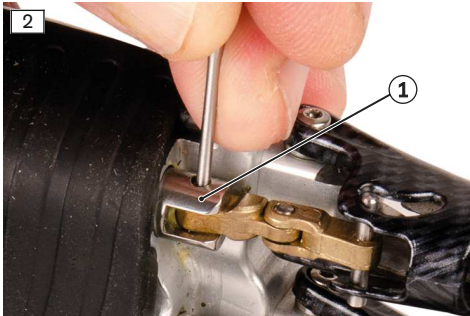
Manual blocking of the fingers when closing the terminal device

If a finger is manually blocked when closing the terminal device, only the non-blocked fingers close. This manual blocking does not cause damage to the terminal device since this blocking is recognised and the respective motor is switched off.

This is necessary, for example, to gain access to the locating pins.



9.1.2 Disassembling the finger chain



9.1.3 Assembling the finger chain

- 1) Take the replacement finger chain from the tool kit.
- 2) Insert the T-piece of the finger chain into the guide grooves of the finger.
NOTICE! Make sure that the flexion direction of the finger chain faces towards the MCP joint.
- 3) Flex the finger in the MCP joint to align the bores of the finger chain and spindle nut.

- 1) Since the conical fixation pin can only be tapped out from the LEFT, the sequence see fig. 1 of fingers 2, 3, 4 has to be followed when replacing the finger chains. Therefore, the finger chain of finger 1 has to be disassembled first to disassemble the finger chain of the finger 2.
- 2) To access the fixation pins on the fingers 2, 3, 4, manually block the respective finger while closing the terminal device.
- 1) Switch the terminal device on.
- 2) Bring the terminal device to the neutral position.
 → The spindle nuts (1) move out of the bores.
- 3) Switch the terminal device off.
- 4) Set the drift punch onto the left side of the fixation pin and tap out the fixation pin.
NOTICE! The fixation pin (conical) can only be tapped out/removed from the LEFT.
NOTICE! Avoid strong impacts on the spindle nuts and thus on the finger motors!
- 5) Take the finger chain out of the guide groove and remove it from the finger.



- 4) Insert the conical fixation pin from the right side.

NOTICE! The fixation pin can only be inserted from the RIGHT (conical design of the fixation pin).



- 5) Use flat nose pliers to press the fixation pin into the bore.

NOTICE! The fixation pin must be fully countersunk in the bore of the spindle nut and must not protrude from the spindle nut on either side.



- 6) Check the flexion of the finger.

9.2 Replacing fingers

Tools/materials	
Designation	Reference number
Hexagon key, size 1.5 mm	Included in the tool kit
50 Ncm torque wrench	General workshop supplies
Isopropyl alcohol	634A58
Fingers, set screw and ball	See section "Spare parts", see page 18

9.2.1 Disassembling the finger



- 1) Bring the terminal device to the neutral position.
→ The spindle nuts (1) move out of the bores.
- 2) Switch the terminal device off.



- 3) Disassemble the finger chain of the finger being replaced as described in the section "Disassembling the finger chain" (see page 26).
- 4) Switch the terminal device on.



- 5) Close the terminal device (e.g. key grip) to access the mounting screw (1).
→ The spindle nuts drive into the bores.
- 6) Switch the terminal device off.



- 7) Loosen the mounting screw (set screw) three turns using a hexagon key size 1.5.



- 8) Hold the terminal device with the fingers facing down.



- 9) Push the finger out of the guide towards the palm.

INFORMATION: Make sure the attachment ball does not fall out of the bore (see fig. 13).

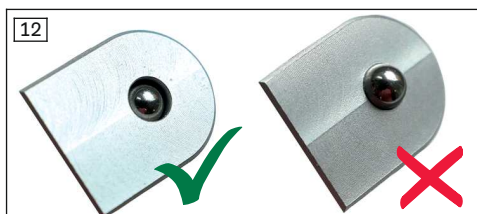
- 10) Clean the guide of the finger in the terminal device (e.g. with 634A58 isopropyl alcohol)

9.2.2 Preparing the finger for assembly

- 1) Take the finger, the set screw and the ball out of the packaging.
- 2) Insert the set screw into the bore with the tip facing forward and screw it in about four turns clockwise using an Allen key size 1.5.

INFORMATION: If the set screw is screwed in too far, the ball cannot be fully inserted into the bore in the next step.

- 3) Insert the ball into the bore.



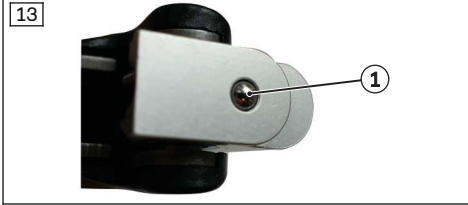
- 4) If the ball does not slide into the bore on its own, first check whether the set screw was not screwed in too far. If the set screw is not visible in the bore, push the ball into the bore using a suitable object until the ball is flush with the surface of the guide or is slightly lower.

The finger with the guide can also be placed on a tabletop to push it in.

9.2.3 Assembling the finger



- 1) Hold the terminal device with the fingers facing down.



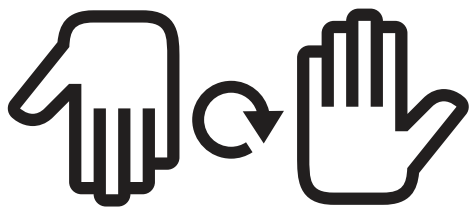
- 2) Before sliding the finger in, check whether the attachment ball (1) is in the bore.



- 3) Insert the finger into the guide of the terminal device and slide it in to the stop.



- 4) Tighten the mounting screw (set screw) to 50 ± 5 Ncm.
→ By pressing the knuckles of the finger towards the palm, check that the finger is correctly attached in the terminal device.



- 5) Hold the terminal device with the fingers facing up.
- 6) Switch the terminal device on.



- 7) Open the terminal device.
→ The spindle nuts move out of the bores.
- 8) Switch the terminal device off.



- 9) Assemble the finger chain as described in the section "Assembling the finger chain" (see page 26).
- 10) Perform a functional test of the terminal device.

INFORMATION: Ensure that the spindle nuts fully enter the respective bores when closing the terminal device.

10 Legal information

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

10.1 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.

10.2 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.

10.3 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>

10.4 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.

11 Technical data

Environmental conditions	
Storage in original packaging	+5 °C/+41 °F to +40 °C/+104 °F Max. 85 % humidity, non-condensing
Transport in original packaging	-25 °C/-13 °F to +70 °C/+158 °F Max. 90 % humidity, non-condensing
Storage and transport without packaging	-25 °C/-13 °F to +70 °C/+158 °F Max. 90 % humidity, non-condensing
Operation	-5 °C/+23 °F to +45 °C/+113 °F Max. 95 % humidity, non-condensing

General	bebionic hand EQD	bebionic hand Short Wrist	bebionic hand Flex
Reference number	8E70=*	8E71=*	8E72=*
Weight of the bebionic hand small	433 g/0.95 lbs	approx. 402 g/0.89 lbs	approx. 504 g/1.1 lbs
Weight of the bebionic hand medium	616 g/1.36 lbs	approx. 588 g/1.3 lbs	approx. 689 g/1.52 lbs
Opening width (between index finger and opposed thumb)	75 mm		
Extension/flexion of the wrist	–	–	-40° to +40° in 20° increments
Lifetime	6 years		
Behaviour of the terminal device during charging	The terminal device has no function		
Version of the terminal device	Hardware and firmware version accessible via the adjustment software		

Load limits	
Force on single finger (static)	32 N
Transverse force on single finger (static)	44 N
Force on chassis (static, supporting the hand)	500 N
Force with closed hand (static, carrying a bag)	152 N
Forces on thumb (static)	40 N

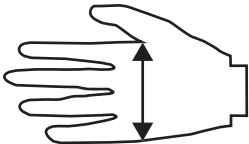
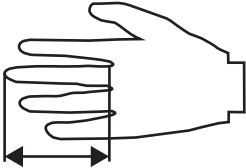
Data transfer	
Wireless technology	Bluetooth Smart/Low Energy
Range	min. 2 m / 6.7 ft
Frequency range	2402 MHz to 2480 MHz
Modulation	GFSK
Maximum output power	9.6 dBm

11.1 Torque values of the screw connections

Screw connection	Tightening torque
Adjustment screw for the mediolateral thumb position (see page 19)	2 Nm / 18 lbf. in.
Finger mounting screw (set screw) (see page 30)	50 Ncm / 3.54 lbf. in.

12 Appendix

12.1 Product dimensions

		bebionic hand small	bebionic hand medium
Palm of the hand		72 mm	85 mm
Max. hand width		122 mm	136 mm
Hand length including fingers		162 mm	188 mm
Finger length		75 mm	91 mm

12.2 Symbols Used

	Manufacturer		Non-ionising radiation
	Type BF applied part		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 nation-
	Compliance with the requirements of "FCC Part 15" (USA)		
	Complies with the requirements of the Radiocommunications Act (AUS)		

	al authority pertaining to return and collection procedures.
	Declaration of conformity according to the applicable European directives
	Serial number (21)YYYYWWNNNN YYYY – year of manufacture WW – week of manufacture NNN – sequential number

	Article number
	Medical device
	Protect from wetness
	UDI number (Unique Device Identifier)

12.3 Operating states/error signals

The prosthesis indicates operating states and error messages through beeps and vibration signals.

12.3.1 Beep and vibration signals

INFORMATION

Feedback signals can be turned off

When the feedback signals have been turned off in the adjustment software, the beeps and/or vibration signals are not generated in certain cases (see table). Signals in case of a product error are generated even when the feedback signals have been turned off.

Beep signal	Vibration signal	When	Signal can be deactivated	Function
1x short	1x short	After releasing the program switch	Yes	Switching between primary and secondary grips
1x short	1x short	After releasing the program switch	Yes	Hand is switched on
1x short	1x short	While pressing the program switch	No	Bluetooth function is deactivated
1x short	1x short	While pressing the program switch	Yes	Donning mode was activated
2x long	2x long	While pressing the program switch	No	Bluetooth function is activated
3x short	3x short	After successful data exchange with the PC	No	The configuration was transferred from the terminal device to the adjustment software
4x short	4x short	After successful data exchange with the PC	No	The configuration was transferred from the adjustment software to

Beep signal	Vibration signal	When	Signal can be deactivated	Function
				the terminal device
Long for 3 seconds	Long for 3 seconds	During product initialisation	No	Fault, the product must be inspected by an authorised Ottobock Service Centre.

12.4 Directives and manufacturer's declaration

12.4.1 Electromagnetic environment

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

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

Observe the safety notices in the section "Information on proximity to certain areas" (see page 15).

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.	–

Table 4 – casing

Phenomenon	EMC basic standard or test procedure	Interference immunity test level	
		Professional healthcare facility	Environments in areas of home healthcare *)
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	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	12 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz
High frequency electromagnetic fields in the immediate vicinity of wireless communication devices	IEC 61000-4-3	See Table 9	
Magnetic fields with rated power frequencies	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	

*) Tests conducted

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						

Test frequency [MHz]	Frequency band [MHz]	Radio service	Modulation	Maximum power [W]	Distance [m]	Interference immunity test level [V/m]
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						

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

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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