ottobock.

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

1 Foreword

INFORMATION

Date of last update: 2022-02-09

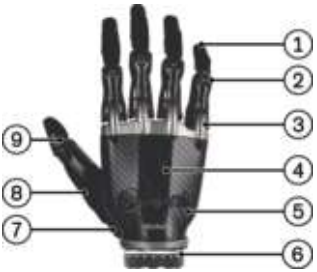
- ► Please read this document carefully before using the product and observe the safety notices.
- ► Instruct the user in the safe use of the product.
- ► Please contact the manufacturer if you have questions about the product or in case of problems.
- ► Report each serious incident related to the product 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 the 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.
According to the manufacturer (Otto Bock Healthcare Products GmbH), the patient is the operator of the product according to the IEC 60601-1:2005/A1:2012 standard.

2 Product description

2.1 Design

The product consists of the following components:



1. Distal phalanx
2. Middle finger joint
3. Finger chain
4. Program switch (see page 7)
5. Back of the hand
6. Wrist joint
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 3). 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 22).

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 16).
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
By spreading the fingers, a flat, thin object (< 3 mm/< 0.12 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 16).
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 16).
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 16).
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 20)
- Switching the Bluetooth function on/off (see page 20)
- Switching between primary and secondary grips (see page 20)
- Activating donning mode (see page 21)

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

Opposed secondary grips
- Default: active index grip
- Alternative: tripod grip

Lateral secondary grips
- Default: column grip
- Alternative: mouse grip

2.2.5 Wrist joint versions

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

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 unit makes positioning possible for the user at 20° or 40° of flexion, in the neutral position and at 20° or 40° of 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 Combination possibilities

This product can be combined with the following Ottobock components:

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

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

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

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 another person is not approved 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 joint (pushups, downhill racing, mountain biking, ...) 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.

Permissible ambient conditions are described in the technical data (see page 25).

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 patient must be able to understand usage and safety messages and put them into practice.
- The patient must fulfil the physical and mental requirements for perceiving visual/acoustic signals and/or mechanical vibrations.

3.4 Contraindications

- All conditions which contradict or go beyond the specifications listed in the section on "Safety" and "Indications for use".

3.5 Qualification

The fitting of a patient with the product may only be carried out by O&P professionals who have been authorised with the corresponding Ottobock training.

4 Safety

4.1 Explanation of warning symbols

⚠ WARNING	Warning regarding possible serious risks of accident or injury.
⚠ CAUTION	Warning regarding possible risks of accident or injury.
NOTICE	Warning regarding possible technical damage.

4.2 Structure of the safety instructions

⚠ WARNING

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

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

> E.g.: Consequence 1 in the event of failure to observe the hazard
> E.g.: Consequence 2 in the event of failure to observe the hazard

► This symbol identifies activities/actions that must be observed/carried out in order to avert the hazard.

4.3 General safety instructions

⚠ WARNING

Non-observance of safety notices

Personal injury/damage to the product due to using the product in certain situations.

► Observe the safety notices and the stated precautions in this accompanying document.

⚠ WARNING

Operating a vehicle with the prosthesis

Accidents due to unexpected actions of the prosthesis.

► 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 actions of the prosthesis.

► 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 Center.

⚠ CAUTION

Signs of wear on the product
Injury due to faulty control or malfunction of the product
► In the interest of patient 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 during the adjustment process with 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 patient.
► Use the online help which is 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 9), "Scope of delivery" (see page 15) and "Accessories" (see page 15).

⚠ 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 9).

⚠ 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 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.
- ► 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 proper 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 use
Injury due to faulty operation or malfunction of the product.
► Instruct the patient 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 embrittlement of plastics caused by the use of acetone, petrol or similar solvents.
► Clean the product only as described in the section "Cleaning and care" (see page 21).
► 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
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 with excessive strain and/or shocks to the wrist joint (pushups, downhill mountain biking, ...) 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 of body parts.
► 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 any red-hot objects with the product.

⚠ CAUTION

Unintentional unlocking of the terminal device

Injury due to releasing the terminal device from the forearm (e.g. while carrying objects).

► When connecting the hand to the prosthetic socket or components, ensure that the connection is carried out correctly.

5 Scope of Delivery and Accessories

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 (user)
- 1 pc. 647G1392 instructions for use (qualified personnel) | 560X12=V1.4 bebalance+ 1.4 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

The following components are not included in the scope of delivery and must be supplied for operation:

- "bebalance+ 1.4 560X12=V1.4" or higher adjustment software
- Bluetooth adapter "Bluetooth Long Range Dongle B33061"
- 757B35=3 MyoEnergy Integral (from LOT no. 2018 22 XXX)
- 757B35=5 MyoEnergy Integral
- 757L35 MyoCharge Integral battery charger (including 757L16-4 power supply)
- 757L24 DynamicArm battery charger (already included in the scope of delivery for the 12K100* elbow component)

Connection to the prosthetic socket

- 9E169 coaxial plug (only with 8E70=* and 8E72=*)
- 10S4 coupling piece (only with 8E70=* and 8E72=*)
- 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

Lamination rings

- 9S110=* lamination ring (included in the scope of delivery for the 8E71=*)
- 10S1=* lamination ring (for 8E70 and 8E72)
- 706Z10 pliers (to unscrew the 8E71=* bebionic hand Short Wrist)

Switches and control elements

- Pressure switch: 9X37
- Cable pull switch: 9X18
- Linear control element: 9X50
- Linear control element: 9X52
- 13E200=* electrode
- 13E202=* suction socket electrode

- 13E520=* Myo Plus TR

Prosthetic glove

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

6 Preparing the product for use

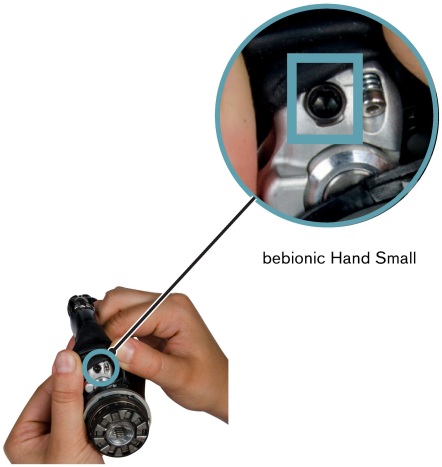
6.1 Charging the battery

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

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

6.2 Adjusting the thumb position

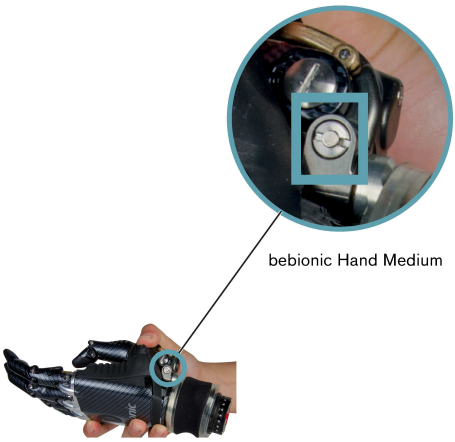
The thumb of the terminal device is aligned for the tripod grip on delivery (see page 4).
The thumb position needs to be adjusted for certain grips. Two different adjustment options are provided on the thumb for this purpose:



bebionic Hand Small

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 an Allen 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) Raise the gaiter on the wrist joint and expose the adjustment screw.
4) Use a 3 mm Allen key for the bebionic hand small and the spanner bit for the bebionic hand medium on the mediolateral adjustment screw on the CMC 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.



bebionic Hand Medium

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) Retighten the adjustment screw by turning it clockwise, and reposition the gaiter.
10) Switch the terminal device on and test it with the user.

bebionic Hand Small

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 Configuring with the "bebalance+" adjustment software

6.3.1 Introduction

The "bebalance+" adjustment software makes it possible to optimise the product settings and grips for a patient. All settings have to be checked together with the patient.
Please consult the integrated online help in the adjustment software 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.

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

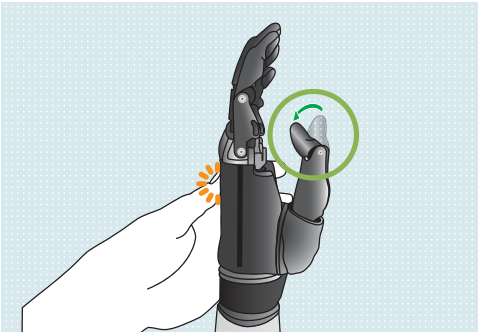
INFORMATION

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 21). 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

Injury due to releasing the terminal device from the forearm (e.g. while carrying objects).

► When connecting the hand to the prosthetic socket or components, ensure that the connection is carried out correctly.

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 around its own axis until a slight resistance is felt (about 360°).
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 646T332 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 28).
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 28).
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 28).
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 28).

→ 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 or the switch on 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. All other repairs are carried out by an authorised Ottobock Service Centre.

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 (Included in the tool kit)

Proceed as follows to replace the finger chain:

1) Open the terminal device and bring the thumb into opposition.
2) Switch off the product.
3) 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 side.
   NOTICE! Avoid strong impacts to the product and finger motors!

4) Take the finger chain out of the guide groove, remove it from the product and dispose of it.
5) Take the replacement finger chain from the tool kit.
6) Insert the T-piece of the finger chain into the guide groove of the finger.
   NOTICE! Make sure that the flexion direction of the finger chain faces towards the MCP joint.
7) Flex the finger in the MCP joint to align the bores of the finger chain and the lead-screw.

8) Insert the conical fixation pin from the right side.
NOTICE! The fixation pin can only be inserted from the RIGHT side (due to the conical shape of the fixation pin).

9) Use flat nose pliers to press the fixation pin into the bore.
NOTICE! Avoid strong impacts to the product and finger motors!
NOTICE! The fixation pin must be fully recessed in the bore and must not project from the bore on either side.

10) Check the flexion of the finger.
→ The finger chain has been replaced and the product can be used again.

INFORMATION

Replacement of the finger chain by an authorised Ottobock Service Centre
If the finger chain cannot be replaced, 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 21).

10 Legal information

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.
This product meets the requirements of the 2014/53/EU directive.
The product meets the requirements of the RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic devices.
The full text of the regulations and requirements is available at the following Internet address: http://www.ottobock.com/conformity

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.
Responsible party:
Otto Bock Health Care, LP

3820 West Great Lakes Drive
Salt Lake City, Utah 84120-7205 USA
Phone + 1-801-956-2400
Fax + 1-801-956-2401

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

L' utilisation de ce dispositif est autorisée seulement aux conditions suivantes:
(1) il ne doit pas produire d'interference et
(2) l' utilisateur du dispositif doit étre prêt à accepter toute interference radioélectrique reçu, même si celle-ci est susceptible de compromettre le fonctionnement du dispositif.

Caution: Exposure to Radio Frequency Radiation.
The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population; consult Safety Code 6, obtainable from Health Canada's website
http://www.hc-sc.gc.ca/rpb.
Responsible party:
Otto Bock Healthcare Canada Ltd.
5470 Harvester Road
L7L 5N5 Burlington, Ontario
Canada
Phone + 1-800-665-3327

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

11 Technical data

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

General information	**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

General information	bebionic hand EQD	bebionic hand Short Wrist	bebionic hand Flex
Opening width (between index finger and opposed thumb)	75 mm		
Extension/flexion of the wrist	–	–	-40° to +40° in 20° increments
Service life	5 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

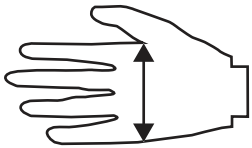
Data transfer	
Wireless technology	Bluetooth Smart/Low Energy
Range	min. 2 m / 6.7 ft
Frequency range	2402 MHz to 2480 MHz
Modulation	GFSK
Maximum output power	9.6 dBm

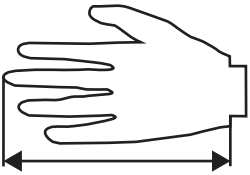
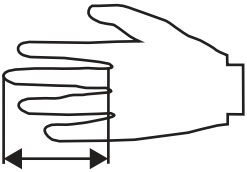
11.1 Torque values of the screw connections

Screw connection	Tightening torque	
	bebionic hand small	bebionic hand medium
Adjustment screw for the mediolateral thumb position (see page 16)	2 Nm/18 lbf. In.	1 Nm/9 lbf. In.

12 Appendix

12.1 Product dimensions

		bebionic hand small	bebionic hand medium
Palm of the hand		72 mm	85 mm

		bebionic hand small	bebionic hand medium
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

Type BF applied part

Compliance with the requirements according to "FCC Part 15" (USA)

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

Non-ionising radiation

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

Declaration of conformity according to the applicable European directives

SN

Serial number (YYYY WW NNN)
YYYY – year of manufacture
WW – week of manufacture
NNN – sequential number

REF

Article number

MD

Medical device

Protect from moisture

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

Beep signal	Vibration signal	When	Signal can be deactivated	Function
4x short	4x short	After successful data exchange with the PC	No	The configuration was transferred from the adjustment software to 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 13).

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

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

The product is covered by the following patents:

Canada:	CA 2 767 121
USA:	US 9 101 499; US 9 592 134
European Patent	EP 2510906 in AT, CH, DE, FR, GB, IT, SE
Patents pending in:	Canada and EPA
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.

Otto Bock Healthcare Products GmbH
Brehmstraße 16 · 1110 Wien · Austria
T +43-1 523 37 86 · F +43-1 523 22 64
info.austria@ottobock.com · www.ottobock.com