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  6.6 Disposal
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1.0 Introduction

This document contains important information for the correct use and set up of the bebionic hand. Read this document thoroughly before fitting a bebionic hand.

These manual has been updated last on: 2017-04-03.

A bebionic system is completed by adding from a selection of compatible system components including electrodes (or other input devices), battery systems, wrists and cables.

The bebionic hand is designed for mild to moderate activities. Avoid use in situations with heavy loads, vibrations or impacts.

1.1 In the case

1. bebalance Radio Frequency (RF) Dongle
2. bebionic3 hand
3. bebionic tool kit
4. bebionic3 user guide
5. bebionic3 technical manual
6. bebalance software CD

⚠️ WARNING
Text with this symbol contain important safety information.

⚠️ CAUTION
Text with this symbol highlights potential sources of damage to the hand.

⚠️ WARNING
The bebionic hand contains Electrostatic Sensitive Devices. Any disassembly on this hand must be carried out by Steeper authorised personnel in an Electrostatic Protected Area (EPA). Failure to do this could cause ESD damage which will affect the reliability of the product and could impact product warranty.

⚠️ WARNING
We do not recommend the use of carbon fibre materials in fabricating a prosthetic arm due to electrical conductivity. If however it is used then it is important to ground the carbon fibre lamination.
## 1.2 Principal Dimensions and Specifications

### Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Medium / Large</th>
</tr>
</thead>
<tbody>
<tr>
<td>maximum power grip force</td>
<td>140.1N</td>
</tr>
<tr>
<td>maximum tripod grip force</td>
<td>36.6N</td>
</tr>
<tr>
<td>maximum key grip force</td>
<td>26.5N</td>
</tr>
<tr>
<td>maximum time to open or close - tripod grip</td>
<td>1.0 seconds</td>
</tr>
<tr>
<td>maximum time to open or close - power grip</td>
<td>0.5 seconds</td>
</tr>
<tr>
<td>maximum time to open or close - key grip</td>
<td>1.0 seconds</td>
</tr>
<tr>
<td>maximum static load - hook grip</td>
<td>99lb 3oz (45kg)</td>
</tr>
<tr>
<td>maximum load individual finger - hook grip</td>
<td>55lb 2oz (25kg)</td>
</tr>
<tr>
<td>maximum finger tip extension load</td>
<td>13lb 3oz (6kg)</td>
</tr>
<tr>
<td>maximum safe vertical load taken through knuckles</td>
<td>198lb 6oz (90kg)</td>
</tr>
</tbody>
</table>

### Principal Dimensions

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Medium</th>
<th>Large</th>
</tr>
</thead>
<tbody>
<tr>
<td>A middle finger tip to hand base</td>
<td>6 ½&quot; (165mm)</td>
<td>6 ½&quot; (165mm)</td>
</tr>
<tr>
<td>B thumb tip to hand base</td>
<td>4 ½&quot; (105mm)</td>
<td>4 ½&quot; (105mm)</td>
</tr>
<tr>
<td>C max chassis width (no glove)</td>
<td>2 ⅞&quot; (72mm)</td>
<td>2 ⅞&quot; (72mm)</td>
</tr>
<tr>
<td>D diameter of chassis at wrist</td>
<td>1 ⅝&quot; (45mm)</td>
<td>1 ⅝&quot; (45mm)</td>
</tr>
<tr>
<td>palm circumference (no glove)</td>
<td>7&quot; (179mm)</td>
<td>7&quot; (179mm)</td>
</tr>
<tr>
<td>maximum opening width - tripod grip</td>
<td>3 ⅞&quot; (90mm)</td>
<td>3 ⅛&quot; (90mm)</td>
</tr>
<tr>
<td>thumb swing through angle</td>
<td>68°</td>
<td>68°</td>
</tr>
<tr>
<td>X EQD only</td>
<td>¼&quot; (2mm)</td>
<td>¼&quot; (2mm)</td>
</tr>
</tbody>
</table>

### General

<table>
<thead>
<tr>
<th>Description</th>
<th>Medium</th>
<th>Large</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product service life</td>
<td>5 years</td>
<td>5 years</td>
</tr>
</tbody>
</table>

### Part Number

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Build Height †</th>
<th>Weight</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BBHMD*QD</td>
<td>121mm + 25mm</td>
<td>591g</td>
<td>bebionic medium hand with EQD Wrist</td>
</tr>
<tr>
<td>BBHMD*SW</td>
<td>121mm + 25mm</td>
<td>570g</td>
<td>bebionic medium hand with Short Wrist</td>
</tr>
<tr>
<td>BBHMD*QD-MF</td>
<td>151mm + 25mm</td>
<td>691g</td>
<td>bebionic medium hand with Multi-Flex Wrist</td>
</tr>
<tr>
<td>BBHMD*QD-F</td>
<td>149mm + 25mm</td>
<td>661g</td>
<td>bebionic medium hand with Flex Wrist</td>
</tr>
<tr>
<td>BBHLG*QD</td>
<td>125mm + 25mm</td>
<td>598g</td>
<td>bebionic large hand with EQD Wrist</td>
</tr>
<tr>
<td>BBHLG*SW</td>
<td>125mm + 25mm</td>
<td>577g</td>
<td>bebionic large hand with Short Wrist</td>
</tr>
<tr>
<td>BBHLG*QD-MF</td>
<td>155mm + 25mm</td>
<td>698g</td>
<td>bebionic large hand with Multi-Flex Wrist</td>
</tr>
<tr>
<td>BBHLG*QD-F</td>
<td>155mm + 25mm</td>
<td>668g</td>
<td>bebionic large hand with Flex Wrist</td>
</tr>
</tbody>
</table>

† Build height comprises of thumb tip to base of hand measurement, followed by the build height for each wrist option. The second number refers to the minimum allowance for the mating wrist unit.

*Denotes side of hand, Insert L for a left hand, or R for a right hand.
2.0 bebionic Grips

The bebionic hand provides 14 different grip patterns, allowing the user to have a more complete device to assist them in their day to day life. The hand has two selectable thumb positions: opposed and non-opposed.

Opposed places the thumb in opposition to the fingers on the hand, allowing grips like Tripod and Power.

Non-Opposed places the thumb parallel with the fingers of the hand and allows grips like Key and Finger Point.

Opposed Non-Opposed

2.1 Factory Settings

The hand is supplied preset in Mode 4. This provides two input operation with proportional control of grip and speed. Speed and grip force are set to maximum.

To alternate between the default and alternative grip pattern, an OPEN OPEN signal must be applied (i.e. the hand must be fully opened, the signal relaxed and then a second open signal supplied). To alternate between the primary grip pattern table and secondary grip pattern table, press the Program Switch for less than two seconds. The Auto Grip feature is turned off.

Factory setting grips -

if your hand has been reprogrammed prior to delivery individual settings will vary.

<table>
<thead>
<tr>
<th>Primary Opposed</th>
<th>Primary Non-Opposed</th>
<th>Secondary Opposed</th>
<th>Secondary Non-Opposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Default - Tripod</td>
<td>Default - Key</td>
<td>Default - Active Index</td>
<td>Default - Column</td>
</tr>
<tr>
<td>Alternative - Power</td>
<td>Alternative - Finger Point</td>
<td>Alternative - Tripod</td>
<td>Alternative - Mouse</td>
</tr>
</tbody>
</table>
2.2 Program Switch

A Program Switch is provided on the back of the hand. This has four functions;

1. Switch the hand ON and OFF

A single press for approximately three seconds will switch the hand OFF. A single press for more than two seconds will switch the hand ON.

2. Alternate between the primary and secondary grip patterns

When the hand is switched ON, a single press of less than two seconds will alternate between the primary and secondary grip patterns. This will be accompanied by a short bleep and vibration (if activated on bebalance).

3. Enable / disable the in-hand bluetooth module

With the hand switched ON, a single press for more than six seconds will enable the bluetooth module. A double beep/vibrate will indicate connection has been made. Pressing the switch again for more than two seconds or disconnecting the power to the hand will disable the bluetooth module.

4. Enter / exit glove mode as follows

With the hand switched OFF, press the switch until the thumb begins to drive in. Then release the switch. For more information please see page 20.

2.3 Thumb Adjustment

To achieve certain grips it is necessary to adjust the thumb position. There are two different planes to move the thumb in, as detailed below.

An adjuster is provided to allow repositioning of the thumb for contact with either the index and middle fingers, as in Tripod Grip, or with index finger only, as in Pinch and Precision Grips. The thumb pivot assembly is fitted with a slotted screw as shown above. This acts to adjust the friction on an internal clamp and is loosened by making two complete turns and pushing the screw inward. With the clamp slackened the thumb position can be manually repositioned. The assembly must be retightened before electrically driving the thumb.

An adjuster has also been provided to alter the baseline position of the thumb, in order to optimize the contact point of the thumb tip against the opposing finger(s) for Tripod, Pinch and Precision Grips. This is done by moving the thumb either towards the palm or away from the palm. This adjuster is located under the thumb bracket as shown above. Using a hex drive the adjuster should be turned clockwise to move the thumb towards the palm and counterclockwise to move the thumb away from the palm. The effect will not be observed while making the adjustment and can only be observed by resetting the hand i.e. switching the hand OFF and ON again.

CAUTION

Thumb adjustment MUST be completed by a qualified technician or practitioner
Grips

2.4 Opposed - Thumb in opposition to the fingers

Tripod

When the thumb is opposed, the hand closes into Tripod Grip with index and middle fingers meeting the thumb. Ring and little fingers continue to close until they meet resistance or the close signal stops. This type of grip allows users to pick up, hold and manipulate a variety of everyday objects such as car keys, coins, jar lids and pens.

Power

With the thumb opposed, all four fingers close into the palm until they meet resistance or the close signal stops. When fingers are approaching a fully closed position, the thumb drives in to cover the fingers for additional grip security. This pattern allows round objects such as a ball or a piece of fruit to be held securely. This grip can also provide a handshake. Cylindrical shaped objects such as bottles, home and garden utensil handles are also held easily and securely.

Finger Adduction

The fingers of the bebionic hand move together naturally as the fingers close. This allows the user to securely grip thin objects, such as cutlery or a toothbrush, between the fingers to achieve function in a different plane. Finger Adduction is most functional with the hand in Power Grip but can also be achieved with the hand in Key Grip and Pinch Grip.

Hook

With the thumb in opposed position, a partially closed Power Grip provides Hook Grip. This is ideal for carrying a shopping bag or briefcase. Hook Grip can also be achieved by closing the fingers from the relaxed hand position.
\textbf{SERIOUS WARNING}

The bebionic hand **MUST NOT be used to operate a firearm.**

**Active Index**

With the thumb opposed Active Index Grip will grasp the handle of an object with the middle, ring and little fingers and secure the grip with the thumb. The index finger will then close – this may be positioned over the lever of the device held such as a spray bottle, it also offers the ideal finger position for typing. The index finger is under independent user control and may be positioned accordingly. To exit Active Index, an open signal will fully open the index finger before the other fingers and thumb release their grip.

**Pinch**

The thumb only contacts index finger and is used for the fine manipulation of objects. To achieve this grip it is necessary for the thumb to be manually repositioned by the practitioner/technician so that the thumb only contacts the index finger (See section 2.3).

**Precision Closed**

This grip can be used in situations similar to the Precision Open Grip, but where extended fingers would be obstructive, such as working at a desk. Initially the middle, ring and little fingers close into the palm. The thumb moves to the midpoint of its range and pauses. The Index is then active and under user control.

(To achieve this grip it is necessary for the thumb to be manually repositioned by the practitioner/technician so that the thumb only contacts the index finger.)

**Precision Open**

With the thumb opposed, the index finger meets the static thumb allowing the user to pick up and manipulate small objects. When this grip is selected and a close signal is applied, the thumb closes to the midpoint of its range and pauses. The index is then active and under user control. The middle, ring and little fingers remain extended. (To achieve this grip it is necessary for the thumb to be manually repositioned by the practitioner/technician so that the thumb only contacts the index finger.)
Grips

2.5 Non-Opposed - Thumb is parallel with the fingers

Key

In the non-opposed thumb position, the four fingers partially close. The thumb then closes onto the side of the index finger. The thumb position may be raised and lowered without moving the other four fingers allowing for release, capture or reposition of the object being gripped. This pattern is ideal for carrying paper or letters, using a spoon and for holding a thin flat object such as a plate, a credit card or a key.

Finger Point

With the thumb in the non-opposed setting, the user can move to Finger Point position. The middle, ring, and little fingers close against the palm and the thumb moves against the middle finger. With this grip, typing on a keyboard or input pad, pressing a bell or a button can be achieved.

Open Palm

With the thumb in the non-opposed position the hand may be fully opened to provide a flat palm suitable for carrying a tray or a plate.
Relaxed Hand

The thumb is set to the non-opposed position and partially driven in toward the palm. All the fingers are driven to a slightly flexed position. Applying a further signal will drive the fingers into Hook Grip for a carrying position.

Column

This grip moves the thumb into the palm from a non-opposed position. The fingers then close over the thumb to provide a fixed column that can be used as a way to push heavier objects or larger buttons and switches. Column is also the recommended grip for dressing, as the thumb is kept out of the way.

Mouse

The thumb and little finger close to hold the side of the mouse, with the middle and ring fingers providing stability. The index finger closes on to the mouse button and then backs off to provide the button press. Each close signal will give a mouse click whilst an open signal will release the mouse.
The bebionic glove is made from a multi-layered, variable hardness, silicone-based material, lined with fabric mesh. This construction resists soiling, wear and puncture damage.

Bebionic gloves provide high compliance with gripped objects. The fabric liner allows the glove to slide over the joints during motion, this reduces the amount of power need to drive the hand and conserves battery life.

The standard glove is supplied in 19 skin tones and in a solid black color. Bebionic gloves provide an additional barrier to dirt, dust and moisture ingress to the hand. Direct exposure to water, or situations where dirt and dust are prevalent should be avoided as these have the potential to interfere with or damage the hands performance.

CAUTION
The bebionic glove has been designed specifically for use with the bebionic hand. The use of other gloves may damage the hand and will void the warranty.

3.1 Care Instructions

Care
Take care when fitting and using the bebionic glove. Try to avoid contact with sharp or pointed objects.

High Definition Nails
Silicone gloves have nails painted by hand following the manufacturing process.

We do not recommend the use of polystyrene nails attached with Cyano-acrylic glue as attempts to remove the nails bonded with this adhesive will permanently damage the glove.

Cleaning
General soiling can be removed with soap and water. After cleaning remove all traces of the cleaner and wipe the surface dry. Most dyes will be fully removed by this process. A liquid domestic fabric softener can be diluted to reduce the ‘tackiness’ of the surface. The material used will resist most staining media.

For any other enquiries please contact your local supplier.
1. Move the thumb into the opposed position.

⚠️ **CAUTION**

Do not attempt to fit the glove unless the hand is in glove donning mode.

2. Switch the hand OFF by pressing down the program switch on the back of the hand for approximately three seconds.

3. Press and hold the program switch for six seconds. The hand will automatically drive into glove mode.

⚠️ **CAUTION**

Do not use talcum powder or lubricant when fitting the glove.

4. The thumb will be in the position shown above when the hand is in glove mode.

5. Fold up the base of the glove.

6. Pull the glove over the hand.
7. Ensure the fingers and thumb of the hand align correctly with the fingers and thumb of the glove.

8. Hold down the program switch for four seconds to exit glove donning mode and begin using the hand.

3.3 Removing the bebionic glove

1. Firstly oppose the thumb. Then turn the hand OFF by pressing the program switch for approximately three seconds. Next put the hand into glove donning mode by pressing the program switch for 4 seconds.

2. Roll up the base of the glove and pull the whole glove off from the back of the hand.

3. Do not pull the fingers individually as this can damage the glove and the hand.

4. Exit glove donning mode by pressing and holding the program switch for four seconds, the hand will automatically drive out of glove donning mode and will be active in the default grip.
4.0 Connections and Compatibility

A bebionic system is very versatile and allows a number of different power and connectivity options. Most options are detailed in the following section of this document. However if you have a question regarding a specific build not outlined in this document please contact your local supplier.

4.1 Wrist Options

There are currently four wrist options for the bebionic hand.

- **Electric Quick Disconnect (EQD)**
  Allows the hand to be removed with a rotating action. The EQD wrist allows the patient to quickly rotate and remove or attach terminal devices as required.

- **Short Wrist**
  Low profile connector for applications where there is a long residual limb. A short wrist lamination assembly is supplied attached to these hands. The hand can be rotated against a constant friction, which can be adjusted by the patient.

- **Multi-Flex Wrist**
  The Flexion Wrist from Motion Control is a simple flexion device that allows the wearer to easily lock or unlock the wrist position and reposition the wrist in either a flexion or extension position. The mechanism allows the wrist to be flexed or extended to 30 degrees in either direction and locked in each of the three positions.

- **Flexion Wrist**
  A versatile flexion device that allows the wearer to easily lock or unlock the wrist position and reposition the wrist either a flexion or extension position. With 30 degrees in either direction and locked in each of the three positions.

4.2 Battery Option

**WARNING**

Only the following battery option should be used with the bebionic. Use of other battery systems is not recommended.

**BBI=2200S**

Supplied with a removable shrink fit coating, allowing the cells to be split for easier fitting in the prosthesis.

- Typical Capacity: 2200mAh
- Voltage (Nominal): 7.4V
- Size: 18.5 x 36.5 x 70 mm
  
- or 18.5 x 18.5 x 70 mm (x2 when split)
  
- (3⁄4" x 3⁄4" x 2 3⁄4")
4.3 Power Information

⚠️ WARNING
System cables **MUST NOT** be cut while power is ON.
This will short the battery and damage the system.
Any damage caused in this way will void the bebionic warranty.

Power Cables

A bebionic hand uses five actuators and therefore requires a higher current supply than single motor devices. This can be accommodated safely using bebionic power cables. Other power cable types may not be efficient or safe. However, cables from other manufacturers may be adequate for signaling application.

Low Power Condition

When the battery capacity approaches its lower limit the hand operation will slow down and begin to respond only to OPEN signals. This occurs to ensure the hand stops in an open position to prevent the hand becoming locked onto an object when the power has been completely drained from the battery. The battery must be recharged for further use.

⚠️ CAUTION
When attaching or detaching a bebionic hand to/from a prosthesis, it is important to first disconnect power by moving the battery switch to the OFF position.
This is to avoid a potential current surge to the hand when it connects/disconnects with the power source.

⚠️ WARNING
The prosthesis **MUST NOT** be worn whilst the batteries are charging.

Battery Switch / Charging Module

An ON/OFF switch is integrated into the charge module. The switch disconnects power completely, and has two positions. When the switch is positioned closest to the charge port, power is OFF and the battery can be charged by connecting the lead from the bebionic charger. When the switch is furthest away from the charge point, power is switched ON. The battery cannot be charged in this position.

The ON/OFF switch / charge module is fitted to the battery and requires an additional connector cable to link to the hand.

The connector cable for EQD hands, as shown on page 19, is supplied with each battery. For short wrist or friction wrist options a different connector cable (13E190=150), as shown on page 20, will need to be ordered separately and connected to the battery pack in place of the EQD connector cable.

A small laminating dummy is included in the kit. Prior to lamination this should be placed in a suitable location and orientation on the forearm model. The position chosen should allow sufficient space between the inner and outer sockets to allow easy access to the switch and plug point by the user.

⚠️ WARNING
It is **NOT** recommended to route the power supply to the hand without passing through the switch.
4.3 System Connections

The system detailed below is suitable for a bebionic hand with an Electronic Quick Disconnect, Multi-Flex and Flex Wrist

Please note: Part B27804 is supplied with each battery pack and will not need to be ordered separately.
Components not to scale.
The system detailed below is suitable for a bebionic hand with a Short Wrist.

Please note: Part B27804 is supplied with each battery pack and will not need to be ordered separately, however part 13E190=150 will need to be ordered separately for hands with Short Wrist.

Components not to scale.
4.5 System Compatibility

⚠️ CAUTION

Use of unsuitable prosthetic components
Injury due to unexpected product behaviour.
- Use the product only in combination with components listed below.

Electrodes
Both are available to purchase and are optimized for use with bebionic.

Inputs

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Part Number</th>
<th>Type of Input</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otto Bock™</td>
<td>9X18, 9X37</td>
<td>Switch</td>
</tr>
<tr>
<td>Otto Bock™</td>
<td>13E200, 13E202</td>
<td>MyoBock Electrode</td>
</tr>
<tr>
<td>Otto Bock™</td>
<td>9X50, 9X52</td>
<td>Linear Transducer</td>
</tr>
</tbody>
</table>

Elbows

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Part Number</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otto Bock™</td>
<td>12K44=</td>
<td>ErgoArm Hybrid Plus™</td>
</tr>
<tr>
<td>Otto Bock™</td>
<td>12K50=</td>
<td>ErgoArm Electronic Plus™</td>
</tr>
<tr>
<td>Otto Bock™</td>
<td>12K100N=</td>
<td>DynamicArm</td>
</tr>
<tr>
<td>Otto Bock™</td>
<td>12K110N=</td>
<td>DynamicArm Plus</td>
</tr>
</tbody>
</table>

Wrist

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Part Number</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otto Bock™</td>
<td>10S17 + 13E205</td>
<td>Wrist Rotator and MyoRotronic</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wrist Rotator Mode</th>
<th>Type</th>
<th>Compatibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program 1</td>
<td>Two Electrodes - Fast Rise</td>
<td>bebionic Mode 4</td>
</tr>
<tr>
<td>Program 2</td>
<td>Two Electrodes - Co-Contraction</td>
<td>bebionic Mode 4</td>
</tr>
<tr>
<td>Program 3</td>
<td>Two Electrodes - Safety Co-Contraction</td>
<td>bebionic Mode 4</td>
</tr>
<tr>
<td>Program 4</td>
<td>Two Electrodes + One Switch - Actuate and Hold</td>
<td>bebionic Mode 4 and Mode 5</td>
</tr>
<tr>
<td>Program 5</td>
<td>One Electrode - or One Linear Transducer - Quick Pull</td>
<td>bebionic Mode 0 and Mode 3</td>
</tr>
</tbody>
</table>

Please note: Devices or components not listed above are not recommended.
5.0 bebalance+

bebalance+ has been designed to give you optimum control over the new bebionic small hand. It features many new tools which will help you and your patients optimize and customize the function of the hand. Language selection, electrode configuration with a simulation preview, and simplified menu systems are all included in bebalance+.

⚠️ CAUTION

Please DO NOT program or control a bebionic system with unapproved, alternative software or hardware systems. Doing so will void the warranty.

5.1 Introduction

Out of the box, the bebionic hand is preconfigured with two site threshold Myo Electric control (Mode 4), where an OPEN-OPEN signal is used to change grip patterns. This mode has been chosen to provide a standard solution that works well for the majority of users who demonstrate two well-controlled muscle signals.

However, bebalance+ is particularly useful if muscles produce limited or difficult to control signals, as is often the case with higher-level amputation. With bebalance+ the practitioner may adjust the operation of the electrode, reset co-contraction signals, change signal timing features, choose between one or two electrode or transducer control and enable the Auto Grip feature. All are able to enhance the users’ natural control capability.

bebalance+ software also provides the ability to record patient information, and to record a history of configuration settings for each hand.

The programming of the hand requires a USB Bluetooth dongle (supplied) to be plugged into the hosting computer. When activated, the dongle will link to the Bluetooth module in the bebionic small hand.

It is also possible to read the current configuration back from the hand and store it against the user record.

⚠️ CAUTION

This software is not intended for patient use. Alterations should be made by the practitioner ONLY.

Only bebionic bluetooth compatible hands can be programmed using bebalance+.
5.2 Installation

1. Close all open applications
2. Insert the bebalance+ CD
3. Wait for Autorun
4. Follow instructions on screen

The default target directory is C:\users\<user>\bebbalance+. An alternative installation directory can also be specified, however it is essential that the application directory and sub-directories have read and write permissions.

If setup fails to automatically open, run it manually by doubling clicking on the installation program setup.exe on the CD.

When reinstalling bebalance, the existing version MUST first be uninstalled. Although the existing database will be retained, it is advisable to back up the previous version before proceeding.

The bebalance software used for bebionic3 and bebionic V2 hands does not need to be un-installed as this will run separately from bebalance+. Note: Only one version of the bebalance+ software can run at any one time.

The bebalance+ software requires the .Net Framework 4.0 to operate. If not already installed it can be installed from the CD by opening the dotNet Framework folder and double clicking on ‘dotNetFx40_Full_x86_x64.exe’ Similarly, the Bluetooth and RF USB Dongles both require software to be installed to operate. Specific versions can be found in the Windows Driver Folder.

The latest version of the software can be found at www.bebionic.com/downloads/bebalance
A password is required to download bebalance+, please contact your local supplier to access this.
5.3 Start up Screen

Upon opening the application, the screen shown below will appear. The red highlighted areas show the following:

1) bebalance+ version, Steeper Group information and links to company websites for further information and downloads.

2) Language selection for the following languages: English, French, German, Spanish, Portuguese, Italian, Turkish, Russian.

3) To access the help files click on the hyperlink in the top right corner or press the F1 button. This will bring up the help files in the language that the software is currently set for.

4) The bebionic Main button provides access to the bebionic main window to enable configuration of any hand shown in the image below.

The images of the hands show the user how each hand interfaces to the bebalance+ software.

1) The small hand uses the orange and white Bluetooth Long Range Dongle.

2) The medium & large hands use either a red or black RF Dongle.

5.4 Communications

5.4.1 Introduction

To configure any bebionic hand for patient use, the communications must first be enabled between the hand and its corresponding communications dongle. This is due to the bebalance+ software now supporting the small, medium & large hands, and therefore the user must know which USB dongle connects to which hand.

5.4.2 bebionic Small Hand

The latest version of the bebionic hand uses Bluetooth technology for communications and uses the orange and white Bluetooth USB Dongle. This dongle must be selected in the communications form as the choice interface device.

5.4.3 bebionic Medium and Large Hands

Both of these hands, although different in size, use the same hardware and software and communicate using an RF USB Dongle. This dongle must be selected in the communications form as the choice interface device.

Note: The black RF USB dongles can be used, but these have been discontinued by the manufacturer and have been replaced by the Red USB dongle.
5.4.4 Communications Form
A user can access the communications form by clicking on the communications button in the top right in the bebionic main form as shown below.

Before any of the USB dongles can function correctly, each device driver file must first be installed. If the device drivers are not installed, please go to section 5.2 for installation information.

5.4.5 Bluetooth Communications
The communications form is the default, and should appear automatically as shown below. The last device used will be selected as default.

To use the Bluetooth dongle, simply click the button ‘Use Bluetooth’ and the form should expand to show a section which lists available communications ports and available bebionic devices.

Virtual Comports
When a Bluetooth dongle is inserted, it creates a port that will become visible as shown opposite. We recommend that only one dongle is inserted at any one time.

bebionic Devices
Note: Only bebionic devices will be listed here.

If the port is correct, click the ‘Device Scan’ button to start scanning for all bebionic devices that are currently transmitting (this button will show as ‘stop scanning’ once device scanning is in progress).

If no devices are being listed then make sure that the bebionic hand has the communications turned on. This can be done by holding down the button on the back of the hand until the user hears the hand beep twice (usually after 4 seconds). This is a very distinct sounds and the hand will only beep twice when the communications have been activated.

A bebionic device should now appear in the devices box below. The devices signal strength is also displayed along with a signal strength indication bar.

5.4.6 RF Communications
If attempting to connect to a medium or a large hand, the RF dongle must be selected as shown below. The button will change from ‘Use Bluetooth’ to ‘Use RF Dongle’.

Clicking the ‘Use RF Dongle’ button will expand the form showing only the available virtual comports. The user can decide to switch between Bluetooth and the RF communications dongles by clicking the ‘Change Interface’ button.

Clicking the ‘Connect’ button will display the progress form showing the status of the connection as it is attempted. If the connection is successful, the form will close automatically. If the connection is unsuccessful, another attempt can be made until the connection is achieved.
5.4.7 Hand Configuration
When the hand has been successfully connected, the buttons ‘Send to Hand’ and ‘Read from Hand’ will be enabled to allow the hand configuration to be read.

To read the current hand configuration, click the ‘Read from Hand’ button and a progress form should appear, indicating the status of the communications. This will only take a few seconds, and the form will automatically close if it is successful.

Once the hand has been read successfully, the bebionic main form will change to highlight its current configuration.

5.4.8 Troubleshooting
If a connection cannot be made after several attempts, there may be interference from other sources.

The following can be tried for successful connection using all types of dongle:

1) Turn off all other bebionic devices that use dongles as they work on the same frequency and will disrupt communications if activated.

2) Move the hand closer to the dongle, avoiding any obstacles in between to make the direct line of sight link shorter.

3) Turn the hand off, close the bebalance+ program and remove the dongle. Then, restart bebalance+, re-insert the dongle and turn the hand on.

5.5 Operating Modes

5.5.1 Overview
The main screen below is where the configuration of the bebionic hands takes place. It is advised that the user understands each of the available functions before the hand is configured.

To read the current hand configuration, click the ‘Read from Hand’ button and a progress form should appear, indicating the status of the communications. This will only take a few seconds, and the form will automatically close if it is successful.

5.5.2 Control Strategy
The hands can be controlled by either using one or two electrodes, this is dependent on the user’s ability to use their muscles to produce the required signals. The number of electrodes used has an effect on which operating modes can be used. The following clarifies this:

Dual (Site) Electrodes
Modes 4 & 5

Single (Site) Electrode
Modes 0, 1, 2 & 3

5.5.3 Open / Close Strategy
The signals to open and close the hands can be reversed if the user requires.

Single Site Control
Select either Electrode A or Electrode B to control the hand.

Dual Site Control
Electrodes A, B:
Electrode A opens the hand
Electrode B closes the hand

Electrodes B, A:
Electrode B opens the hand
Electrode A closes the hand
5.5.4 Control Options
The hand can be controlled not just by electrodes, but by other transducers, such as force sensitive resistors and linear transducers interfaced with a hand.

5.5.5 Control Response
The user can utilise either Proportional or Threshold control of the hands.

Proportional Control
The speed and strength of the hand is proportional to the electrode signal produced by the user.

Threshold Control
The speed and strength of the hand is constant but can be altered in the Advanced Options section.

5.5.6 Change Indication
The hardware inside the hands provides audible and vibration indicators for specific actions such as changing grip patterns, activating wireless communications, etc. These options can be disabled if the user requires.

5.5.7 Grip Selection
Grip patterns can be selected as desired by the user by selecting the options in the relevant tables.

Opposed Primary / Secondary
This refers to selection of the grip patterns available with the thumb in the opposed position as shown below. The default grip is automatically available, and the user can switch to the alternate grip by applying the appropriate change signal, e.g. in mode 4, an OPEN/OPEN signal.

Press the button on the back of the hand to switch between the primary and secondary grip patterns.

Non-Opposed Primary / Secondary
These options allow selection of the grip patterns as described above, but with the thumb in the non-opposed position as shown below.
5.5.8 Operating Modes
Certain modes only allow the use of a specific range of grip patterns that the user can have in their configuration.

<table>
<thead>
<tr>
<th>Operating Mode</th>
<th>Interface</th>
<th>Open and Close Strategy</th>
<th>Control Options</th>
<th>Control Response</th>
<th>Grip Switch</th>
</tr>
</thead>
</table>
| Mode 0         | Single Site Electrode 1 x Transducer | • Open – Apply a signal  
• Close – Remove the signal | Invert Electrode Signal | Threshold | • Thumb Position Change  
• Palm Switch |
| Mode 1         | Single Site Electrode 1 x Transducer | • Open – Apply a short burst signal  
• Close – Apply a sustained /long signal | • Default Switch Back Time  
• Grip Switch Time  
• Open Dwell Time  
• Close Dwell Time | Threshold | • Thumb Position Change  
• Palm Switch  
• Open / Open Signal |
| Mode 2         | Single Site Electrode 1 x Transducer | • Open – Apply a quick rising signal  
• Close – Apply a slow rising signal | • Default Switch Back Time  
• Grip Switch Time  
• Dwell Threshold  
• Dwell Time | Proportional | • Thumb Position Change  
• Palm Switch  
• Open / Open Signal |
| Mode 3         | Single Site Electrode 1 x Transducer | The first signal applied will close the hand; a delay of between 50ms and 2s will allow a repeat close if required.  
A signal applied outside of the delay will open the hand; a delay of between 50ms and 2s will allow a repeat close if required. | • Default Switch Back Time  
• Grip Switch Time  
• Direction Change Time | Proportional & Threshold | • Thumb Position Change  
• Palm Switch  
• Open / Open Signal |
| Mode 4*        | Dual Site Electrode 2 x Transducers | • Open – Apply signals from the Open electrode  
• Close – Apply signals from the Close electrode | • Default Switch Back Time  
• Grip Switch Time  
• Auto Grip | Proportional & Threshold | • Thumb Position Change  
• Palm Switch  
• Open / Open Signal |
| Mode 5*        | Dual Site Electrode 2 x Transducers | • Open – Apply signals from the Open electrode  
• Close – Apply signals from the Close electrode | • Default Switch Back Time  
• Auto Grip | Proportional & Threshold | • Thumb Position Change  
• Palm Switch  
• Co-contraction Signal |

*In modes 4 and 5, the hand operates on the first signal that exceeds the ON THRESHOLD.

If an opposing signal is received and exceeds the initial signal by a pre-set amount, then the larger signal will become the dominant signal.

The hand will be delivered pre-set to Mode 4 with default values set to provide an operational hand straight out of the box. Therefore, configuration via bebalance+ may not be essential pre-fitting.

Please see overleaf for advanced options for each mode.
5.5.9 Advanced Options
In bebalance+, adjustment of further specific features can be accessed by clicking on ‘Advanced’, which will open a dialog box. The features displayed will be appropriate to the mode selected, and are detailed in the following sections.

Grip Strength (All Modes)
It is possible to either select High, Medium or Low grip strength. This setting provides adjustment of the grip strength and battery consumption; if a lower setting is selected, this will result in a lower grip strength and a prolonged battery life.

Note: This has minimal effect on operation speed.

Speed Control (All Modes)
This option is the adjustable maximum speed for both open and close. The numeric up/down controls provide independent hand opening and closing speeds; 100% (default) being the maximum.

Deferred Reset (All Modes)
When enabled, each time the hand resets, the automated calibration sequence is paused until the user gives an open signal.

This feature has been added for patients using elbow systems and prevents held objects from being dropped when the elbow power is cycled.

Invert Electrode Signal (Mode 0)
The action of the signal is inverted.

Default Switch Back Time (Modes 1, 2, 3, 4 & 5)
The time, in seconds, in which the hand will revert back from the alternate to the default grip pattern.

Note: A zero disables the parameter.

Grip Switch Time (Modes 1, 2, 3, & 4)
The time, in seconds, in which the user can switch between the alternate grip patterns and the default grip patterns (and vice-versa).

Open Dwell Time (Mode 1)
The maximum time in milliseconds the control signal has to be asserted before being recognised as an Open signal.

Close Dwell Time (Mode 1)
The minimum time in milliseconds the control signal has to be asserted before being recognised as a Close signal.

Direction Change Time (Mode 3)
The time, in milliseconds, in which an applied signal will repeat the last action.

Auto Grip (Modes 4 & 5)
The Auto Grip functions in Tripod grip only and is activated by providing three consecutive close signals. Deactivation occurs when the hand is given an Open signal.

If movement / slippage of an object is detected, the finger position / grip force is automatically altered to provide a more secure grip.

5.5.10 bebalance+ Button Bar
The buttons on the top of the ‘bebionic main’ window, enables Load, Save, Read & Update Hand Configurations as required.

Restore Defaults
To restart configuration, clicking the ‘Restore Defaults’ button reverts all the controls to the default settings for the current mode.

Save
The hand configuration can be stored by clicking the ‘Save’ button. Before data is saved, a patient name or identifier must be entered. There is a description field for recording specific information as necessary.

Clicking the ‘Save Record’ button will trigger a prompt, asking if the settings are correct.

Once a configuration is saved, the time and date is also saved automatically as shown below.
History
Clicking the ‘History’ button opens a list of saved configurations for the user. By entering a patient identifier and clicking the ‘Find’ button, the records can be filtered. This feature enables the recovery of previous settings for resending to the hand or providing a base template to work from.

There are 6 default configurations to choose from. None of these default configurations can be deleted.

Read from Hand
This feature enables the current configuration to be read from the hand which can then be modified as required and stored in a history file if necessary. Following a reading, the patient identifier must be entered. This enables retrieval of the specific patient configuration, if desired.

Send to Hand
When connected to a bebionic hand it can be updated with the current configuration as set by the user. Whilst updating, another window will appear showing the status of the update. The hand will stay connected after the update if another configuration is required or if the user wants to verify or modify the settings.

Communications
This button gives us access to the communications form for connecting to all hands for both Bluetooth and RF USB dongles. When a connection is made, the communications status box will turn green as shown below. See section 5.4.

To resolve any connection issues, please first refer to section 5.4.8 Troubleshooting for assistance.

5.6 Device Information

Once a hand has been connected, the 'Device Information' button becomes active. In this form, specific manufacturing information is available that is required for diagnostic purposes.

5.6.1 Device Information Sample Configuration
The example below shows a sample configuration read from a bebionic small hand. This section provides information that can be used by the customer services team to trace the hand’s history and current status should a problem with the hand occur.

If a problem with the hand does occur, please convey this information to customer services for support.

5.6.2 External Control Activation
This feature allows the hand to be controlled by an external device through the communications port on the hands EQD. To activate the external control, a license key must be procured from customer services and then entered in the license key form.
To request a license key, click the ‘Request License Key’ button. An information form will appear with the details required by the customer services team, along with contact details.

This information can be copied to the clipboard by clicking on the hyperlink. A notification message will appear at the bottom right of the screen. These details can then be copied directly into an email ready for sending to customer services.

Once a license key has been procured and entered into the form, the ‘Enable’ button will become active.

Upon entering a valid license key, another form will appear to inform the user that the protocol has been enabled.

To make this change permanent, the user must still re-program the hand on the bebionic main form by pressing the ‘Send to Hand’ button. See section 5.5.10 for details on this function.

To disable an active External Control Protocol, the same steps can be used to do so. No key is required to disable this feature.

5.7 Electrodes

To monitor, review and adjust the electrode signals, select the ‘Electrode Screen’ button, to view the Myo Configuration / Trainer window as shown below.

5.7.1 Threshold Levels
The sliders highlighted on the screen are used to independently adjust on-threshold and maximum levels of the individual channels on the hand.

The Blue line shows the current ON threshold level.

The Red line shows the current MAX threshold level.

The electrode threshold and maximum levels can be adjusted using the relevant sliders. The strength of the signal is displayed as a green vertical bar with the peak signal indicated as single green line.

The animation enables modification of the threshold settings to be simulated without the need to keep sending data to the hand. The hand animation will open and close in the response to the electrode signals.

These can then be sent to the hand once the user is comfortable with the settings. On closing the form, the settings are retained for configuring the hand using the ‘Send to Hand’ option.
5.7.2 Co-contraction
Ensure the ‘bebalance Electrodes’ window has been closed. Selecting ‘Co-contraction’ opens the form to monitor and set the co-contraction signals. This option is only available when Mode 5 is achieved.

In Mode 5, co-contraction is used to move between default and alternate grip patterns. The blue horizontal lines show the on-threshold level set during the myo configuration process, and can be adjusted from this screen if necessary.

The slider items highlighted on the image are used to set the required characteristics of co-contraction signals. Clicking ‘Start’ (this button will show as ‘Start’ upon opening the window) will initiate tracing of the electrode signal.

One channel will be displayed with signals moving upwards, and the second channel generating signals moving downwards. When the trace reaches the right hand side of the display, it will automatically stop. To remove the previous trace, click the ‘Clear’ button, this will then automatically start a new one. If you wish to stop the trace before it reaches the right hand side of the display, click ‘Stop’.

The trace period can be changed by selecting the 10, 20 or 30 seconds from the ‘Display Period’ drop down menu.

The black horizontal lines identify the co-contraction threshold level and can be adjusted as necessary.

The ‘Co-contraction Window (ms)’ button can be used to set the co-contraction time window. A co-contraction signal is active when signals from both channels 1 and 2 pass through both the on-threshold and co-contraction within a designated time frame.

With the bebionic hand, there is a ‘soft’ co-contraction option where the co-contraction threshold can be set lower than the on-threshold level. Providing that the peak signal does not exceed the on-threshold level, a co-contraction signal is active.
6.0 Additional Information, Warranty, Returns and Repairs

There are a number of field repairs and replacement parts that are available for the bebionic. Instructions are set out in this section.

For further advice on any repairs please contact the manufacturer’s customer service.

For both parts and service, include details on date of purchase, size (medium, large) and side (left or right).

6.1 Repairs

1. The clevis link has been designed to bend, should the hand be excessively loaded during use. If this should occur the part will need to be replaced so that the finger can be driven again.

2. Firstly ensure the thumb is in the non-opposed position and that all of the fingers are fully driven open. Then remove the pivot pin between the clevis and leadscrew with the bebionic pivot removal pliers (Part:B27430*). Alternatively the pivot can be removed with the pin punch provided in the tool kit.

*available for purchase separately.
3. Using a spare clevis link assembly from the tool kit. Place it into the slot in the proximal. Ensure that the curve of the clevis link curves away from the finger towards the palm.

5. Keeping the finger flexed, use needle point pliers to insert the pivot pin through both parts of the link.

   Note: The pin is tapered and can be inserted & removed from one side only.

4. Bend finger forward to align the holes for the pivot pin.

6. Using a pair of standard pliers ensure that the pivot pin sits flush with the surface on both sides of the leadscrew.

7. Ensure that the finger flexes fully forward and springs back to the upright position as shown in the two images above.

8. Finished.
6.1.1 Gaitor Removal

1. Pull the rear strap down and over the EQD to reveal the serial number on the back of the hand.

2. Tilt the hand backward and stretch the strap over the bottom of the EQD.

3. Using the screwdriver with the 1.50mm hex bit contained within the toolkit, loosen the screws in the rear cover. Note: Do not completely remove.

4. Slide gaiter flaps out from under the rear cover.

5. Pull the gaiter away from the palm of the hand, making sure that the thumb cable stays in position.

6. Taking care to avoid the thumb cable, pull the gaiter over the thumb and off the bebionic3 hand.
7. Completely remove the gaiter from the hand.

8. Note the thumb cable position, as this is key when refitting a new gaiter.

6.1.2 Gaitor Refitting

1. Slide the thumb section of the gaiter over the thumb. Ensure the gaiter strap is under the thumb. Pay special attention to the thumb cable position.

2. Ensure the thumb section of the gaiter is pushed all the way to the gap shown in the image above.

3. Pull the gaiter strap around to the rear of the hand and up over the EQD.

4. Line up the sections of the hand highlighted with the sections of the gaiter when pushing the gaiter flaps under the rear cover. Pay special attention to the thumb cable position.
5. Carefully push the flap all the way home under the rear cover.

6. Ensure there is as small a gap as possible between the gaiter and the rear cover.

7. Retighten both of the screws in the rear cover. 
   Note: Do NOT overtighten.

8. Finished.
6.2 Quality Assurance

Steeper operate a UKAS approved quality management system and fully complies with the requirements of BS EN ISO 9001:2008, ISO27001:2005 & TickIT Issue 5. This certifies that Steeper meet the appropriate international quality standards for design, manufacture and supply of prosthetic products and user software.

Steeper is registered with both the Medicines and Healthcare Regulatory Authority in the UK and the Food and Drugs Administration of the United States Government for the manufacture and supply of prosthetics and orthotics products.

MHRA Registration N°: CA001031  
FDA Registration N° : 9612243

FCC Registration N° : QOQBLE113  
IC : 5123A-BGTABLE113

Model N°: RSL-RP608

Continued compliance with the standard is monitored by a programme of internal and external audits.

All individual products are marked indicating that they comply with the requirements of the Medical Devices Directive 93/42/EEC (MDD).

The C mark may be applied on packaging, accompanying literature or an enclosure, rather than the product itself.

The bebionic hand and its associated components listed in this document are covered by test certificates for:-

- **BS EN 60601-1-2:2007** Electromagnetic Compatibility for Electronic Hand (EMC)
- **BS EN 60601-1-2006** Medical Electrical Essential requirements for Safety
- **BS EN 60950-1-2006** Information Technology Equipment for Safety
- **ETSI 300 440-2 V1.3.1 (2009-03)** Electromagnetic Compatibility for RF Module
- **ETSI 301 489-3 V1.4.1 (2002-08)** Electromagnetic Compatibility for RF Module

Additional internal and external test results and associated project documentation can be found in the Technical File RP609.
FCC Warning Statement

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 complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.
- The bebionic Hand, Model: RSL-RP608, complies with Part 18 of the FCC Rules (Section 18.212).
- The antenna(s) used for this transmitter must be installed to provide a separation distance of at least 20cm from all persons.
- The End product must have a label stating ‘Contains FCC ID:QOQBLE113’ place on it inline with FCC labelling regulations.

The FCC and IC information is located on the wrist lock ring.

INDUSTRY CANADA STATEMENTS

This device complies with Industry Canada licence-exempt RSS standard(s). 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 the device.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This radio transmitter (IC:5123A-BGTLBLE113) has been approved by Industry Canada to operate with the antenna types listed below with the maximum permissible gain and required antenna impedance for each antenna type indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

<table>
<thead>
<tr>
<th>Name / Model</th>
<th>Gain</th>
<th>Impedance</th>
</tr>
</thead>
<tbody>
<tr>
<td>7488910245/Wurth</td>
<td>1,0</td>
<td>50 Ohm</td>
</tr>
</tbody>
</table>

OEM Responsibilities

The BLE113 Module has been certified for integration into products only by OEM integrators under the following conditions:

1. The antenna(s) must be installed such that a minimum separation distance of 20cm is maintained between the radiator (antenna) and all persons at all times.
2. The transmitter module must not be co-located or operating in conjunction with any other antenna or transmitter.

As long as the two conditions above are met, further transmitter testing will not be required. However, the OEM integrator is still responsible for testing their end-product for any additional compliance requirements required with this module installed (for example, digital device emissions, PC peripheral requirements, etc.).
IMPORTANT NOTE

In the event that these conditions can not be met (for certain configurations or co-location with another transmitter), then Industry Canada certification is no longer considered valid and the IC Certification Number can not be used on the final product. In these circumstances, the OEM integrator will be responsible for re-evaluating the end product (including the transmitter) and obtaining a separate Industry Canada authorization.

End Product Labeling

The BLE113 Module is labeled with its own IC Certification Number. If the IC Certification Number is not visible when the module is installed inside another device, then the outside of the device into which the module is installed must also display a label referring to the enclosed module. In that case, the final end product must be labeled in a visible area with the following:

“Contains Transmitter Module IC 5123A-BGTABLE113” or “Contains IC 5123A-BGTABLE113”

The OEM of the BLE113 Module must only use the approved antenna(s) listed above, which have been certified with this module. The OEM integrator has to be aware not to provide information to the end user regarding how to install or remove this RF module or change RF related parameters in the user’s manual of the end product. The user’s manual for the end product must include the following information in a prominent location:

“To comply with Industry Canada RF radiation exposure limits for general population, the antenna(s) used for this transmitter must be installed such that a minimum separation distance of 20cm is maintained between the radiator (antenna) and all persons at all times and must not be co-located or operating in conjunction with any other antenna or transmitter.”

Radio Equipment - Canadian Warning Statements

"Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication." "This device complies with Industry Canada licence-exempt RSS standard(s). 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 the device."

"Conformément à la réglementation d’Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d’un type et d’un gain maximal (ou inférieur) approuvé pour l’émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l’intention des autres utilisateurs, il faut choisir le type d’antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l’intensité nécessaire à l’établissement d’une communication satisfaisante.** Le présent appareil est conforme aux CNR d’Industrie 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, et
(2) l’utilisateur de l’appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d’en compromettre le fonctionnement."

“To comply with industry Canada RF radiation exposure limits for general population, the antenna(s) used for this transmitter must be installed such that a minimum separation distance of 20cm is maintained between the radiator (antenna) and all persons at all times and must not be co-located or operating in conjunction with any other antenna or transmitter.”
6.3 Warranty

Warranty Terms

The bebionic hand comes with a 2-year-standard warranty from Otto Bock Healthcare Products GmbH.

In addition, the following warranty packages are available at the date of purchase:

- 3-year-product warranty
- 5-year-product warranty
- Warranty extension from a 3- to 5-year-product warranty. The 2-year warranty extension can also be purchased subsequently. But, it must be purchased no later than prior to the end of the 36th month following the delivery date.

The warranty includes:

- Free of charge repair* of the prosthesis hand
- Free of charge replacement unit for the period of repair and maintenance in case of warranty

*Superficial damage and damage resulting from negligence or improper use are not included.

The warranty does not include wear and tear parts, such as gloves and batteries. An exception is the “Minor repair package”. This package includes a separate exchange of the gaiter, the clevis links and the finger pulps.

With the 3- (with or without warranty extension) and the 5-year-warranty package you will get:

- Free of charge maintenance in the 24th month and for a warranty period of 5 years an additional free of charge maintenance in the 48th month
- Free of charge “Minor repair package”

Further information on the warranty coverage can be found in the warranty terms and conditions.

Hand Policy

Hands returned to the bebionic authorized service center will be assessed and where deemed beyond repair will be replaced. Where a claim is made under warranty, this claim must be supported by appropriate documentation. The warranty will be void on all system components if any components have been subject to abuse, repair or maintenance by an uncertified person, deliberate damage, loads beyond those for which the product was designed, or by modification or neglect. You must state that you wish us to supply a replacement.

To identify the hand serial number, see outer edge of locking ring above the wrist unit.

Glove Policy

Cosmetic gloves are only replaceable under warranty where the failure is due to a manufacturing fault as we have no control over the environment in which they are used. Please inspect the glove at first fitting to identify any faults so that we can provide a replacement where necessary.

Please note: Each bebionic hand is fitted with a passive Radio Frequency Identity Device to allow identification and trace during manufacture and in case of return to our bebionic service centres.

6.4 Returns

If bebionic components are to be returned for servicing please contact us or your local distributor stating the hand’s serial number. We will issue a returns number and returns form that will need completing in full so your request can be dealt with promptly.

Spare Parts Policy

Some components of a bebionic system are replaceable by bebionic accredited practitioners.

For further advice on any repairs please contact your bebionic distributor or email us.

For both parts and service, please mention that the hand is a bebionic small hand; include details on date of purchase, size (medium or large) and side (left or right).
6.5 Environmental conditions

<table>
<thead>
<tr>
<th>Environmental conditions</th>
<th>Temperature</th>
<th>Humidity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage and transport in original packaging</td>
<td>-20°C/-4°F to +40°C/104°F</td>
<td></td>
</tr>
<tr>
<td>Storage and transport without packaging</td>
<td>-20°C/-4°F to +40°C/104°F</td>
<td>max. 80% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Operation</td>
<td>-20°C/-4°F to +40°C/104°F</td>
<td>max. 80% relative humidity, non-condensing</td>
</tr>
</tbody>
</table>

6.6 Disposal

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.

6.7 Symbols Used

- Declaration of conformity according to the applicable European directives
- Legal manufacturer
- Serial number
- Compliance with the requirements under the “Radiocommunications Act” (AUS)
- Non-ionising radiation