




bebionic  **RSLSTEEPER**
Improving people's lives

technical information

bebionic3

technical information

Contents

| | |
|--|-------|
| 1.0 Introduction..... | 04-07 |
| 1.1 In the Box | |
| 1.2 Principal Dimensions | |
| 1.3 Specifications | |
| 2.0 bebionic Grips..... | 09-19 |
| 2.1 Factory Settings | |
| 2.2 Programme Switch | |
| 2.3 Thumb Adjustment | |
| 2.4 Opposed Grips | |
| 2.5 Non-opposed Grips | |
| 2.6 Further Grips and Hand Positions | |
| 3.0 bebionic Glove..... | 21-25 |
| 3.1 How to fit a bebionic Glove | |
| 3.2 Removing a bebionic Glove | |
| 3.3 Care Instructions for bebionic Glove | |
| 4.0 Connections & Compatibility..... | 27-35 |
| 4.1 Wrist Options | |
| 4.2 Battery Options | |
| 4.3 Power Information | |
| 4.4 System Connections | |
| 4.5 System Compatibility | |
| 5.0 bebalance | 37-49 |
| 5.1 Introduction | |
| 5.2 Installation | |
| 5.3 Start up | |
| 5.4 Language Selection | |
| 5.5 Radio Frequency Module Configuration | |
| 5.6 Operating Modes | |
| 5.7 Hand Configuration | |
| 5.8 Grip Selection | |
| 5.9 Advanced | |
| 6.0 Additional Information, Warranty, Repairs and Returns..... | 51-63 |
| 6.1 Gaiter Removal | |
| 6.2 Gaiter Refitting | |
| 6.3 Clevis Link Replacement | |
| 6.4 Quality Assurance | |
| 6.5 Warranty | |
| 6.6 Returns | |

1.0 Introduction

This document contains important information for the correct use and set up of the bebionic3 hand. Please note some of the images may differ as this document applies to both the medium and large size of hands. Read this document thoroughly before fitting a bebionic3 hand.

A bebionic system is completed by adding from a selection of compatible system components including myo electrodes (or other input devices), battery systems, wrists and cables. We recommend RSLSteeper components for all of these requirements.

The bebionic3 hand is designed for mild to moderate activities. Its use in situations where heavy loads, vibrations or impacts may be encountered must be avoided.

Key:



WARNING

Texts with this symbol need special attention. They contain information to do with safety.



Caution

Texts with this symbol draw your attention to potential sources of damage to the hand.

1.1 What's in the box



-
1. bebionic radio frequency (RF) module
 2. bebionic3 hand
 3. bebionic tool kit
 4. bebionic in car charger
 5. bebalance3 programming software
 6. bebionic3 user guide
 7. bebionic3 technical information

1.2 Principal Dimensions



| Principal Dimensions | Large | Medium |
|-------------------------------------|--------------------|--------------------|
| A Middle Finger Tip to Hand Base | 200mm | 190mm |
| B Thumb Tip to Hand Base | 125mm | 121mm |
| C Max Chassis Width (no glove) | 92mm | 84mm |
| D Diameter of Chassis at Wrist | 50mm | 50mm |
| Palm Circumference (no glove) | 220mm | 204mm |
| Maximum Opening Width - Tripod Grip | 105mm (with glove) | 105mm (with glove) |
| Thumb Swing Through Angle | 68° | 68° |
| X EQD Only | 5mm | 5mm |

1.3 Specifications

| Part Number | Build Height † | Weight | Description |
|-------------|----------------|--------|--|
| BBHLG*QD | 125mm + 25mm | 598g | bebionic3 Large Hand with EQD Wrist |
| BBHLG*FW | 125mm + 37mm | 557g | bebionic3 Large Hand with RSLSteeper Friction Wrist |
| BBHLG*SW | 125mm + 12mm | 577g | bebionic3 Large Hand with Short Wrist |
| BBHLG*EU | 125mm + 16mm | 574g | bebionic3 Large Hand with M12 Thread Stud |
| BBHLG*NA | 125mm + 16mm | 572g | bebionic3 Large Hand with 1/2 x 20 UNF Stud |
| BBHMD*QD | 121mm + 25mm | 591g | bebionic3 Medium Hand with EQD Wrist |
| BBHMD*FW | 121mm + 37mm | 550g | bebionic3 Medium Hand with RSLSteeper Friction Wrist |
| BBHMD*SW | 121mm + 12mm | 570g | bebionic3 Medium Hand with Short Wrist |
| BBHMD*EU | 121mm + 16mm | 567g | bebionic3 Medium Hand with M12 Thread Stud |
| BBHMD*NA | 121mm + 16mm | 565g | bebionic3 Medium Hand with 1/2 x 20 UNF Stud |

† Build height comprises of thumb tip to base of hand measure, 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, i.e. insert L for a left hand, or R for a right hand.

| | Large | Medium |
|---|-------------|-------------|
| Maximum Power Grip Force | 140.1N | 140.1N |
| Maximum Tripod Grip Force | 36.6N | 36.6N |
| Maximum Key Grip Force | 26.5N | 26.5N |
| Maximum Time to Open or Close - Tripod Grip | 0.5 Seconds | 0.5 Seconds |
| Maximum Time to Open or Close - Power Grip | 1.0 Seconds | 1.0 Seconds |
| Maximum Time to Open or Close - Key Grip | 1.0 Seconds | 1.0 Seconds |
| Maximum Static Load - Hook Grip | 45Kg | 45Kg |
| Maximum Load Individual Finger - Hook Grip | 25Kg | 25Kg |
| Maximum Finger Tip Extension Load | 6Kg | 6Kg |
| Maximum Safe Vertical Load Taken Through Knuckles | 90kg | 90kg |



2.0 bebionic grips

The *bebionic3* hand provides a number of grips, 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 & non-opposed.

Opposed is where the thumb is in opposition to the fingers on the hand, allowing grips like pinch and power.

Non-Opposed is where the thumb is parallel with the fingers of the hand and allows grips like key and finger point.

Opposed Non-opposed



Introduction

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 & grip force are set to maximum.

To alternate between 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 Programme Switch for less than 2 seconds. The Auto Grip feature is turned off.

Primary Opposed

Default - Tripod

Alternative - Power

Primary Non-Opposed

Default - Key

Alternative - Finger Point

Secondary Opposed

Default - Active Index

Alternative - Tripod

Secondary Non-Opposed

Default - Column

Alternative - Mouse

2.2 Programme Switch



A Programme 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 RF module

With the hand switched ON, a single press for more than four seconds will enable the RF module. Pressing the switch again for more than two seconds or disconnecting the power to the hand will disable the RF module.

4. Enter / exit glove mode as follows

With the hand switched OFF, press the button until the thumb begins to drive in. Then release the button.

! Caution

Thumb adjustment **MUST** be done by a qualified technician or practitioner.

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 and they are detailed below.



1. Thumb ML Adjuster



2. Thumb Contact Point Adjuster



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 in diagram 1. This acts to adjust the friction on an internal clamp and is loosened by turning two complete turns and pushing the screw inward. With the clamp slackened the thumb position can be manually re-positioned. 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 optimise 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 anticlockwise to move the thumb away from the palm. The effect will not be observed whilst making the adjustment and can only be observed by resetting the hand i.e. switching the hand OFF and ON again.

! WARNING

Please ensure screw is securely tightened before resuming use.

Grips

2.4 Opposed - Thumb is opposite 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.

Pinch

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). The thumb only contacts index finger and is used for the fine manipulation of objects.

SERIOUS WARNING

NEVER use a bebionic hand with firearms.



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 & garden utensil handles are also held easily and securely.

Active Index (Formerly Trigger)

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. 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.

Grips

2.5 Non-Opposed - Thumb is inline with the palm.



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 a 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.



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

With the thumb non-opposed, 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.

Grips

2.6 Further functions of the bebionic3 hand.



Precision Open

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. 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.



Precision Closed

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. This grip can be used in situations similar to the Precision Open Grip but where extended fingers would be obstructive, when working at a desk for instance.

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.



Hook

With the thumb in opposed, a partially closed Power Grip gives the Hook Grip. This is ideal for carrying a shopping bag or briefcase.



Finger Adduction

The fingers of the bionic 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 and Pinch.

Grips

2.6 Further functions of the bebionic3 hand.



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 a carrying position.

be yourself

bebionic3

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3.0 bebionic glove

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 also allows the glove to slide over the joints during motion, this reduces the amount of power need to drive the hand and increases battery life.

The standard glove is supplied in 19 skin tones and also in a solid black colour.

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 or damage the hands performance.

Caution

There is no alternative manufacturer of cosmetic gloves for the bebionic hand and wrist. The use of other gloves may damage the hand and will void the warranty.

bebionic glove

3.1 fitting the bebionic glove



1. Move the thumb into the opposed position.



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

! Caution

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



5. Fold up the base of the glove.



6. Pull the glove over the hand

⚠ Caution

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



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



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



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



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

bebionic glove

3.2 Removing the bebionic glove



1. Firstly oppose the thumb. Then turn the hand OFF by holding down the programme switch for approximately three seconds. Next put the hand into glove donning mode by holding down the programme 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 hand.



4. Exit glove donning mode by pressing and holding the programme switch for 4 seconds; the hand will automatically drive out of glove donning mode and will be active in the default grip.

bebionic glove

3.3 Care instructions and information

Care

Take care when fitting and using silicone cosmetic gloves. Try to avoid contact with sharp or pointed objects. The material used will resist most staining media.

High Definition Nails

Silicone gloves have nails painted by hand following the manufacturing process. Bonding to the base material is good.

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 used in solution to reduce the 'tackiness' of the surface.

For any other enquiries please use the contact details supplied on the inside cover of this document.





4.0 connections & compatibility

A bebionic system is very versatile and allows a number of different wrist, 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 RSLSteeper.

The bebionic hand may also be used with other manufacturers electrodes and wrists. This means the bebionic3 hand can be fitted into an existing system without having to change every single component of the system.

4.1 Wrist Options

There are currently 4 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/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.



Threaded Stem -

A hand plate with a threaded stud is pre-fitted. Two thread options can be supplied USA or European standards are available.



Friction Wrist -

Interfaces with a RSLSteeper 50mm, friction wrist (part C12810). These hands are supplied pre-fitted with a Friction Wrist hand plate. The wrist has user adjustable friction that can be adjusted at any time through a simple twist action. This option produces rotations through a range of 320 degrees.

4.2 Battery Options

WARNING

Only the following battery options should be used with the *bebionic3*. Use of other battery systems is not recommended.



BBI=2200

Typical Capacity:
2200mAh

Voltage (Nominal): 7.4V

Size: 18.5mm x 36.5mm
x 70mm

BBI=1300S

Typical Capacity:
1300mAh

Voltage (Nominal): 7.4V

Size: 8.6mm x 3mm x
66.5mm (x2)

BBI=2200S

Typical Capacity:
2200mAh

Voltage (Nominal): 7.4V

Size: 18.5mm x 18.5mm
x 70mm (x2)

4.3 Power Information



Battery Switch / Charging Module

⚠ WARNING
System cables **MUST NOT** be cut while power is ON. This will short the battery and will damage the system. Any damage caused is considered to be outside of 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 will begin to slow. With continuous use it will eventually stop. If the hand stops in a closed position the user can apply a series of open signals to fully open the hand. The hand will remain in an open position until the battery is recharged.

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

A ON/OFF switch is integrated into the charge module. The switch disconnects power completely, and has 2 positions. When the switch is positioned closest to the charge point, 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. Connecting the charger to the charge plug will have no effect on the battery.

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 32, is supplied with each battery. For short wrist, friction wrist, or threaded stud wrist options a different connector cable (CBBHA72), as shown on page 20, will need to be ordered separately and connected to the battery pack after removing B27804.

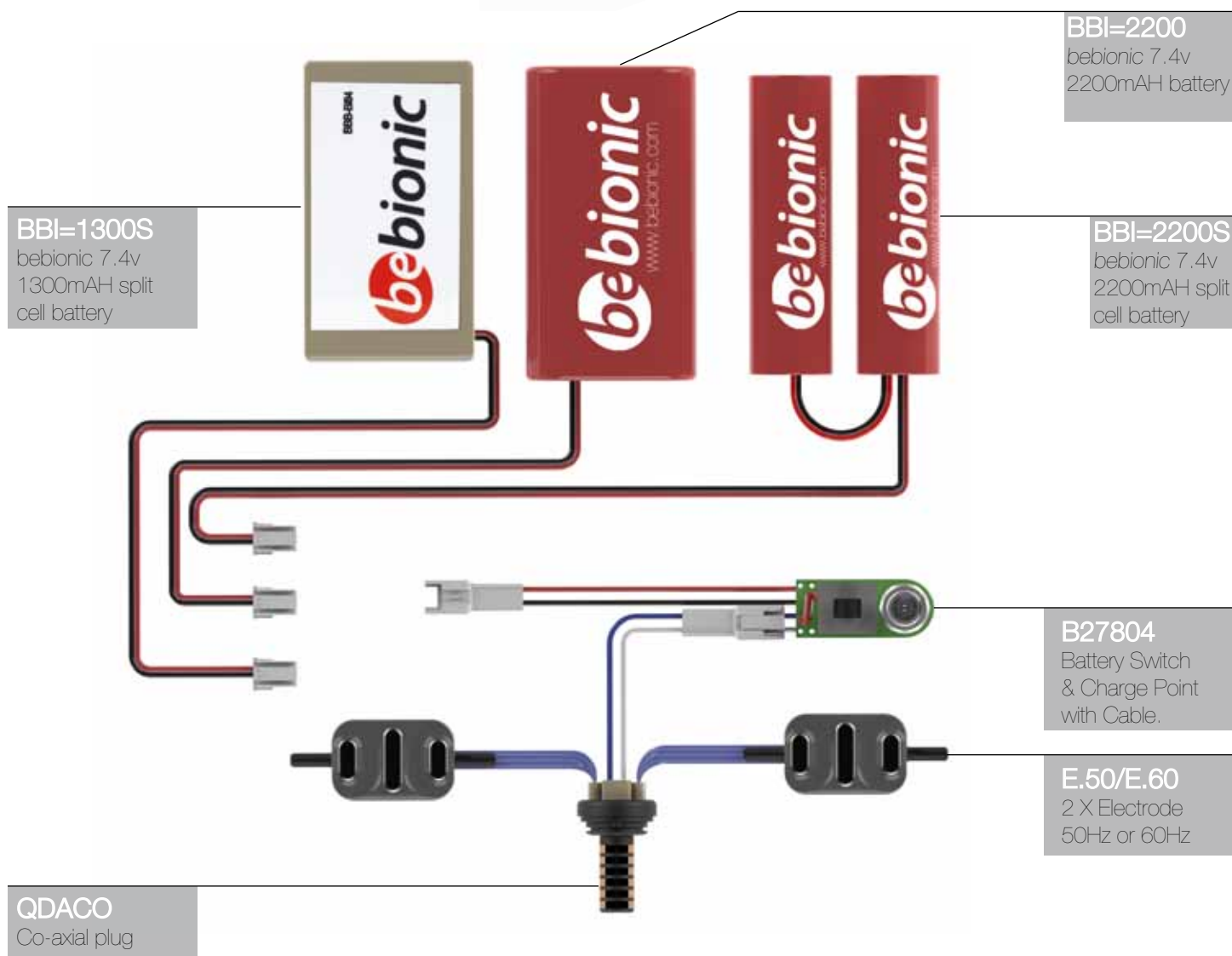
A small laminating dummy is included in the kit. Prior to lamination this is placed in a suitable location and orientation on the forearm model. The position is chosen to allow sufficient space between the inner and outer sockets and to allow easy access to the switch and plug point by the user.

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

4.4 System Connections

The system detailed below is suitable for a
bebionic hand with an

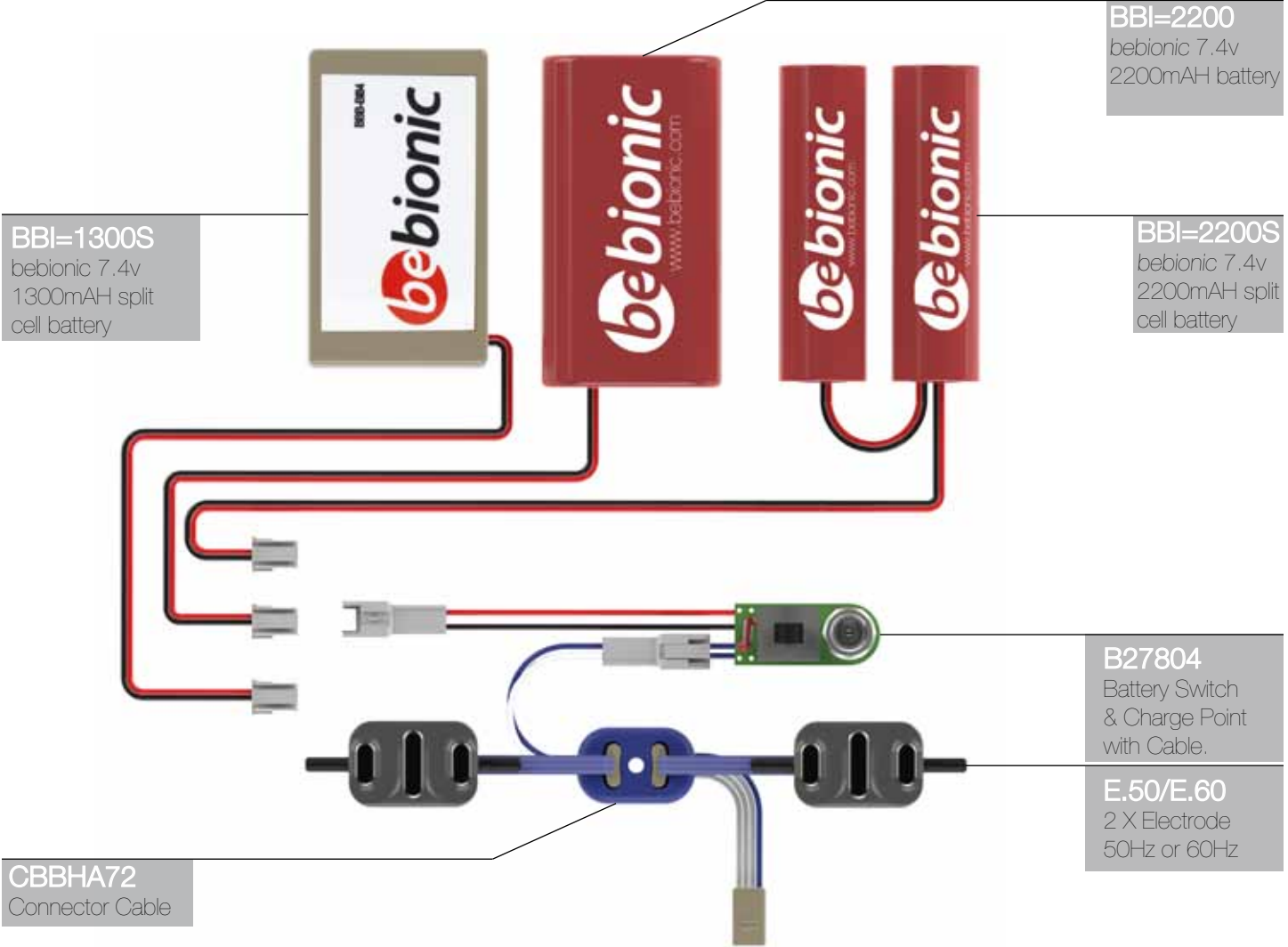
Electronic Quick Disconnect Wrist



Please note: Part **B27804** is supplied with each battery pack and do not need to be ordered separately.

Components not to scale.

The system detailed below is suitable for a
 bebionic hand with either a
**Short Wrist, a Friction Wrist or a
 Threaded Stem**



BBI=1300S
 bebionic 7.4v
 1300mAH split
 cell battery

BBI=2200
 bebionic 7.4v
 2200mAH battery

BBI=2200S
 bebionic 7.4v
 2200mAH split
 cell battery

B27804
 Battery Switch
 & Charge Point
 with Cable.

E.50/E.60
 2 X Electrode
 50Hz or 60Hz

CBBHA72
 Connector Cable

Please note: Part **B27804** is supplied with each battery pack and do not need to be ordered separately, however part **CBBHA72** will need to be ordered separately for hands with short wrist, friction wrist, or threaded stem wrist options. Components not to scale.

4.5 System Compatibility

The bebionic hand is potentially compatible with a number of different parts from other suppliers. A common list is shown on the page opposite. Please adhere to the advice given below.

Caution

The bebionic system has not been exhaustively tested with all alternative electrodes, wrists and control systems. Any damage caused will be held to be outside of the design parameters of our system.

The statements above do not imply that RSLSteeper recommend or warrant these combinations.

We believe that, on the basis of statements in the literature from these manufacturers that these combinations will work effectively but it is for the bebionic practitioner to test and warrant the combination. These combinations may invalidate warranties given by other manufacturers. The practitioner should confirm the warranty position with these manufacturers.

Electrodes

We recommend RSLSteeper E.50 or E.60. Both are available to purchase and are optimised for use with bebionic3



Inputs

| Supplier | Part Number | Type of Input |
|------------|------------------------|--------------------------|
| RSLSteeper | E.50 & E.60 | MyoElectrode |
| Otto Bock™ | 9X18, 9X37 | Switch |
| Otto Bock™ | 13E125, 13E200, 13E202 | MYOBOCK electrode |
| Otto Bock™ | 9X50, 9X52 | Linear Transducer |
| LTI | DC200B= | MyoElectrode |
| LTI | TP01, TP02 | Force Sensitive Resistor |

Elbows

| Supplier | Part Number | Name |
|----------------|-------------|--------------------------|
| Otto Bock™ | 12K44= | ErgoArm Hybrid plus™ |
| Otto Bock™ | 12K50= | ErgoArm Electronic plus™ |
| LTI | BE330 | Boston Elbow Digital |
| Motion Control | | Utah Arm™ 3 & 3+ |

Wrist

| Supplier | Part Number | Name |
|----------------|----------------|-------------------------------|
| Otto Bock™ | 10S17 + 13E205 | Wrist Rotator and MyoRotronic |
| Motion Control | | MC Wrist Rotator |

| Wrist Mode | Type | Compatibility |
|------------|---|--------------------------|
| Program 1 | 2 Electrodes - Fast Rise | bebionic Mode 4 |
| Program 2 | 2 Electrodes - Co-Contraction | bebionic Mode 4 |
| Program 3 | 2 Electrodes - Safety Co-Contraction | bebionic Mode 4 |
| Program 4 | 2 Electrodes + 1 Switch - Actuate & Hold | bebionic Mode 4 & Mode 5 |
| Program 5 | 1 Electrode - or 1 Linear Transducer - Quick Pull | bebionic Mode 0 & Mode 3 |

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



5.0 operating instructions

bebalance3 has been designed to give you optimum control over the new bebionic3 hand. It features many new tools which will help you and your patients optimise and customise the function of the hand.

Language selection, electrode configuration with a simulation preview and simplified menu systems are all included in bebalance3.

Note: Installation disc is affixed to the inside back cover.

Caution

Please **DO NOT** programme 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 pre-configured with two site proportional myoelectric 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, bebalance3 is particularly useful if muscles produce limited or difficult to control signals, as is often the case with the higher-level amputation.

With bebalance3 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.

bebalance3 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 radio dongle (supplied) to be plugged into the hosting computer, which when activated, links to the radio module in the bebionic3 hand.

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

Caution

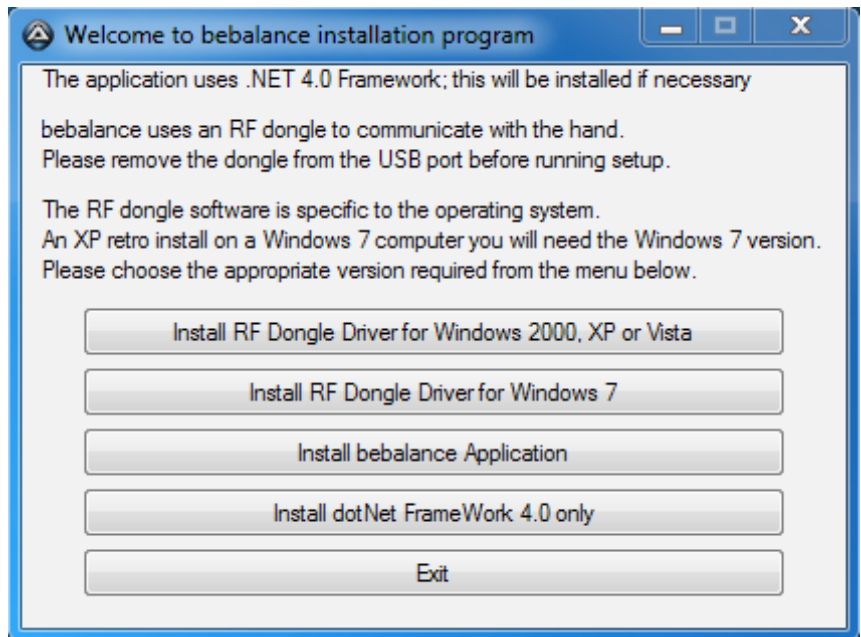
This software is not intended for patient use. Alterations should be made by the practitioner **ONLY**.

Caution

Only *bebionic v2* and *bebionic3* hands can be programmed using *bebalance3*

5.2 Installation

1. Close all open applications
2. Insert CD into your CD-ROM
3. Wait for Autorun
4. Follow instructions on screen



1. The default target directory is C:\users\USERNAME\bebalance3 You can choose an alternative should you wish; however it should be noted that it is essential that the bebalance application directory and sub-directories have read & write permission.

CP210_Win2K_XP_Vista or CP210_Win7 folder. If using a retro operating system it may be necessary to use software specific to the computer build.

The latest version of the software can be found at www.rslsteeper.com/downloads

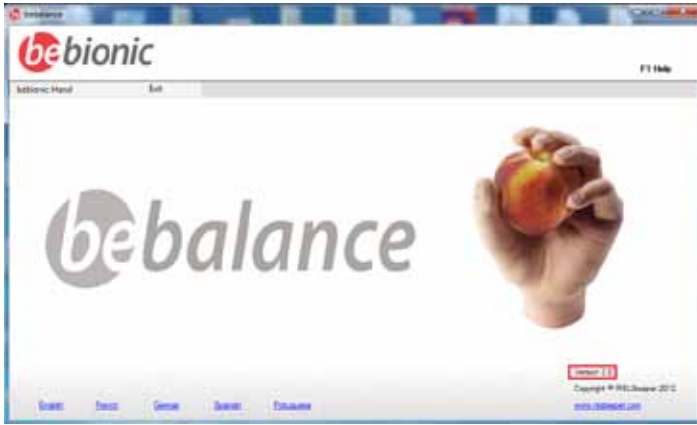
If setup fails to automatically open, run it manually from the BBsetup.exe

bebalance V2 can co-reside with bebalance3.

If you are re-installing bebalance3, the existing version **MUST** be uninstalled. Although the existing database will be retained, it is advised that the previous version is backed up before proceeding with this installation.

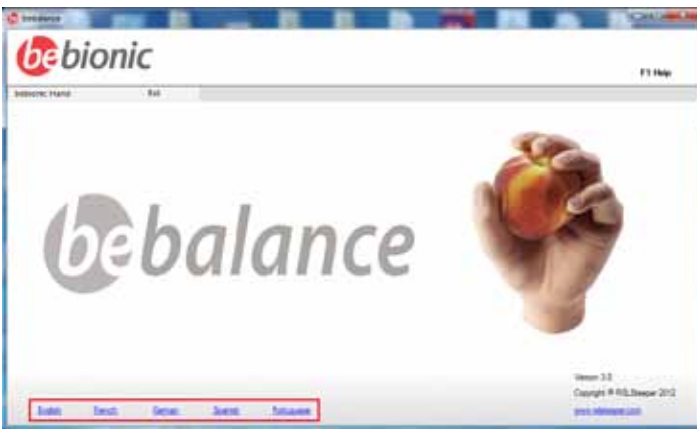
The bebalance3 application requires .Net Framework 4.0 to operate. If not installed it can be installed from the CD by opening dotNet Framework folder and double clicking on 'dotNetFx40_Full_x86_x64.exe' Similarly the radio dongle requires software to be installed to operate. Specific versions can be found in

5.3 Start up



On opening the application the main screen shown above will appear. Any greyed out options are currently not operational. The area highlighted in red identifies the bebalance version number.

5.4 Language Selection



At the bottom of the entry screen there are hyperlinks available to select the appropriate language. Those available are: English, French, German, Spanish and Portuguese.

5.5 Radio Frequency (RF) Module Configuration



bebalance now has an auto-detect feature for the radio. You are advised to insert the RF dongle into a USB port of the computer before starting the application as it will be detected on start-up.

However, if you forget, just insert the dongle and either return to the entry screen menu as highlighted above. Or, on the configuration screen, click on the button marked 'Radio'.

When the radio dongle has been found the message box will show 'RF Dongle Found' highlighted in green. If not found the message box will show 'No RF Dongle'

Enabling RF Module on the bebionic Hand

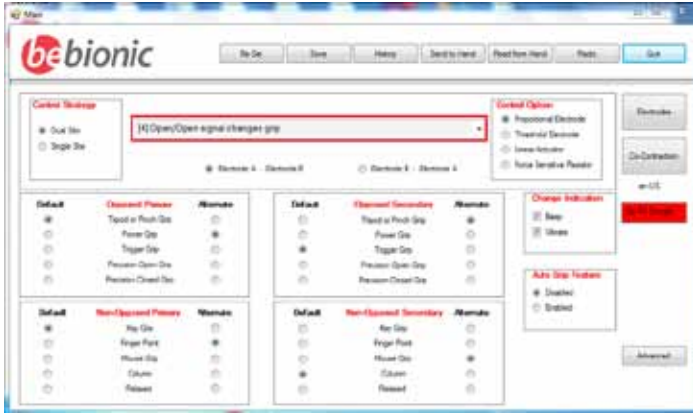
With the hand switched ON, press and hold the programme switch on the back of the hand for approximately three seconds until the RF dongle begins to flash continually.

Note: This function differs from the glove donning mode as to enable the RF Module the hand must be switched ON, whereas in glove donning mode the hand is first switched OFF. The RF Module can be disabled by pressing for more than 2 seconds. Alternatively you can disconnect the power to the hand by using the battery switch.

Operating Modes

There are six modes. These are selected from the highlighted box, along with the appropriate control strategy.

Note: Grip change will generate a bleep and / or vibration if this feature is enabled.



Mode 0

Control Strategy – Single Site Threshold

- To OPEN hand – apply signal
- To CLOSE hand – remove signal

Grip Patterns

Thumb Opposed – up to 4 grip patterns
 Thumb Non-opposed - up to 2 grip patterns

Mode 1

Control Strategy – Single Site Proportional / Threshold

- To OPEN hand – apply a short burst signal
- To CLOSE hand – apply a sustained signal
- To switch between default grip and alternative grip – apply a further OPEN signal within variable time (up to 2 seconds) of the hand fully opening.

Grip Patterns

Thumb Opposed – up to 4 grip patterns
 Thumb Non-opposed - up to 4 grip patterns

Mode 2

Control Strategy – Single Site Proportional / Threshold

- To OPEN hand – apply a quick rising stimulus
- To CLOSE hand – apply a slow rising stimulus
- To switch between default grip and alternative grip – apply a further OPEN signal within variable time (up to 2 seconds) of the hand fully opening.

Grip Patterns

Thumb Opposed - up to 4 grip patterns
 Thumb Non-opposed - up to 4 grip patterns

Mode 3

Control Strategy – Single Site Proportional / Threshold Alternating

-To OPEN hand – the first signal will OPEN the hand; a configurable delay of 50ms to 2.0s will allow repeat OPENS if required.

-To CLOSE hand – a signal applied outside of the delay will CLOSE the hand; a configurable delay of 50ms to 2.0s will allow repeat CLOSES if required

-To switch between default grip and alternative grip – apply a further OPEN signal within variable time (up to 2 seconds) of the hand fully opening

Grip Patterns

Thumb Opposed - up to 4 grip patterns
 Thumb Non-opposed - up to 4 grip patterns

Mode 4

Control Strategy – Dual Site Proportional / Threshold OPEN OPEN

- To OPEN hand – apply signal from OPEN electrode
- To CLOSE hand – apply signal from CLOSE electrode
- To switch between default grip and alternative grip – apply a further OPEN signal within variable time (up to 2 seconds) of the hand fully opening

Grip Patterns

Thumb Opposed – up to 4 grip patterns
 Thumb Non-opposed – up to 4 grip patterns

Mode 5

Control Strategy – Dual Site Proportional / Threshold Co-contrast

- To OPEN hand – apply signal from OPEN electrode
- To CLOSE hand – apply signal from CLOSE electrode
- To switch between default grip and alternative grip – apply a co-contraction signal

Grip Patterns

Thumb Opposed – up to 4 grip patterns
 Thumb Non-opposed – up to 4 grip patterns

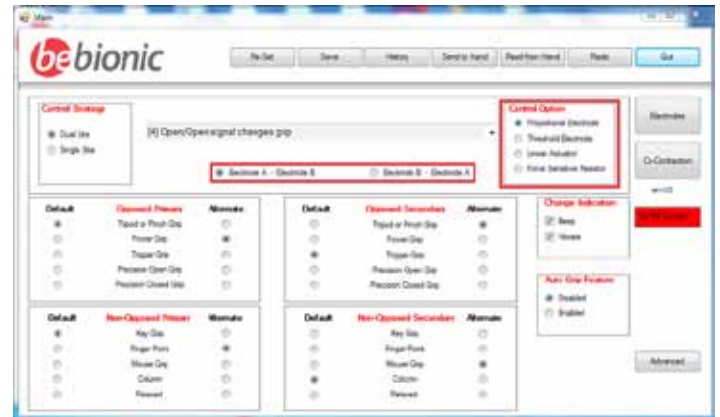
Please note: Where more than one grip pattern is available, the practitioner can select the default and alternative grips for both the primary and secondary grip patterns using bebalance programming software. Pressing the programme switch on the back of the hand allows the user to alternate between the primary and secondary set of grip patterns.

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

5.7 Hand Configuration Introduction

Hand Configuration

Select `bebionic` on the main menu to open the configuration screen as shown below. The 'No RF Found' message may be replaced with 'RF Dongle Found'.



For most patients, the factory settings on the bebionic hand will be adequate. However, for experienced practitioners bebalance software can be used to customise each hand to each individual through the bebionic menu option.

By default the configuration screen opens with dual-site control strategy. You can change to single-site by point & click on the single-site 'radio button' under Control Strategy.

Configuration essentially changes the way the bebionic hand operates. These changes are downloaded from the computer to the hand to allow the user to try them. Successful alterations can be loaded and saved in the hands memory. Details of individual iteration, once saved, are with the patient's ID in the History file.

Caution

Only bebionic v2 and bebionic3 hands can be programmed using bebalance3

Grip Selection

Grips can be selected and ordered as desired by the user by a simple point and click in the relevant tables.



Opposed Primary

This enables selection of the initial two grip patterns available with the thumb in the opposed position. The default grip is available immediately, the user can switch to the alternate grip by applying the appropriate change signal e.g. in mode 4, an OPEN OPEN signal will switch between the default and alternate grip patterns.

Non-opposed Primary

Allows selection of the grip patterns as described above, but with the thumb in the non-opposed position.

Opposed Secondary

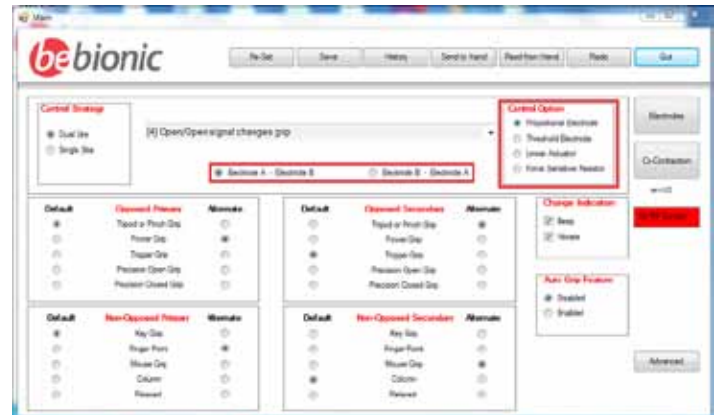
This enables selection of a further two grip patterns with the thumb in the opposed position. These grips are activated by pressing the programme switch on the back of the hand. As with the primary grip patterns, the user can switch between the default and the alternate grip by applying the appropriate change signal. The user can return to the primary grip patterns by pressing the programme switch.

Non-opposed Secondary

Allows selection of the grip patterns as described for Opposed Secondary but with the thumb in the non-opposed position.

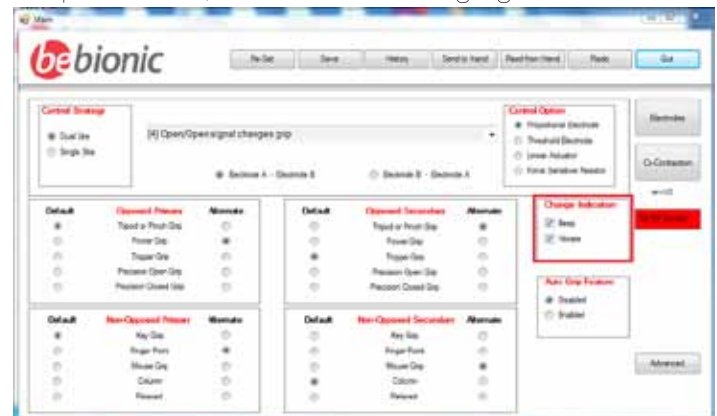
Control Option

The hand can be controlled by proportional or threshold electrodes or alternatively by linear transducers or force sensitive resistors. It is possible to reverse the electrode/transducer operation without the need to physically swap cables. By simply clicking on the electrode radio buttons highlighted below.



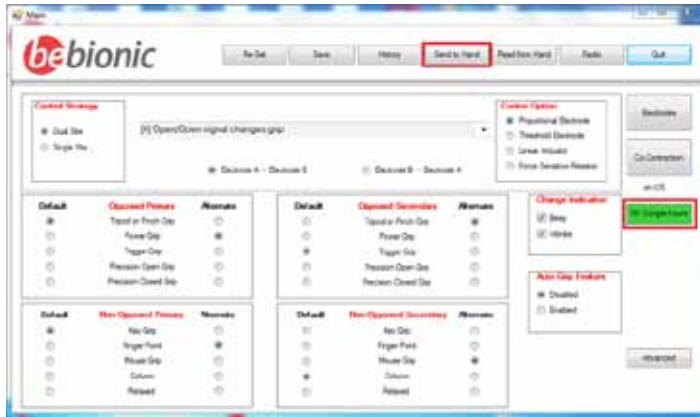
Change Indication

Function change indication is available by ticking either beep or vibrate, both or none as highlighted below.



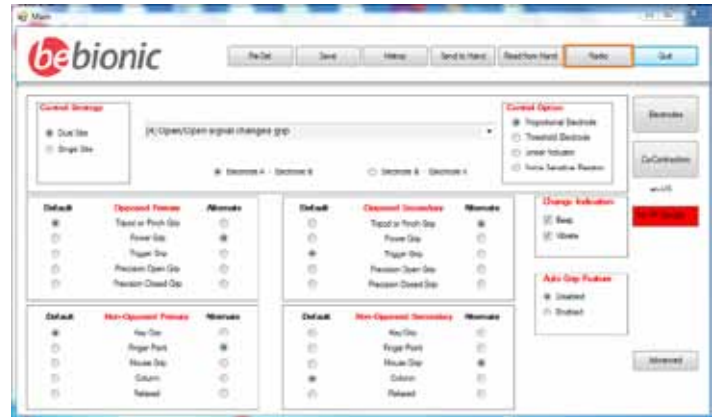
Send to Hand

With the radio dongle inserted and configured and the radio activated on the hand. It starts transmitting a stream of signals, which can be identified by the rapid flashing of the LED on the dongle. Clicking **Send to Hand** starts the transmission of the current configuration to the hand. On completion the message panel on the right will show success or in failure of the process.



Radio

This enables connection of the radio module should you forget to install the dongle before running the application. When the dongle is found the message box will 'RF Dongle Found' highlighted in green. If not found the message box will show 'No RF Dongle' highlighted in red. See section 8.1 for more information.



Read from Hand

This feature enables the current hand configuration to be read from the hand and stored in the history file. Following a read you are required to enter a patient identifier. This enables retrieval of the specific patient configuration, if desired.



Quit

This will close the configuration form and return to the main entry screen.



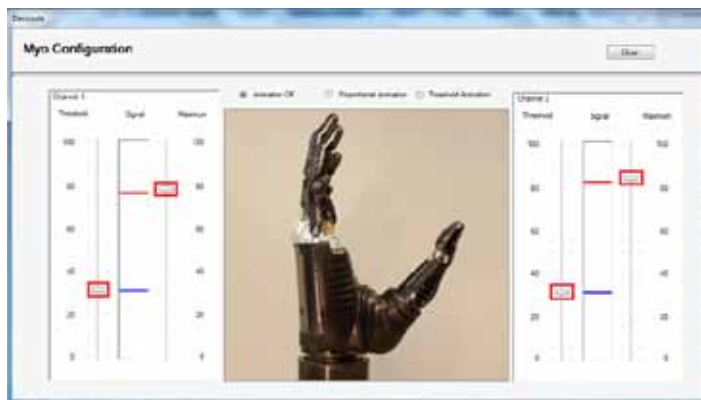
Vertical Buttons

Electrodes

Selecting **Electrodes** from the vertical button menu opens a form, shown second below. This allows electrode signals to be monitored, reviewed and adjusted.



The sliders identified are for independently adjusting on-threshold and maximum levels of the individual channels on the hand.

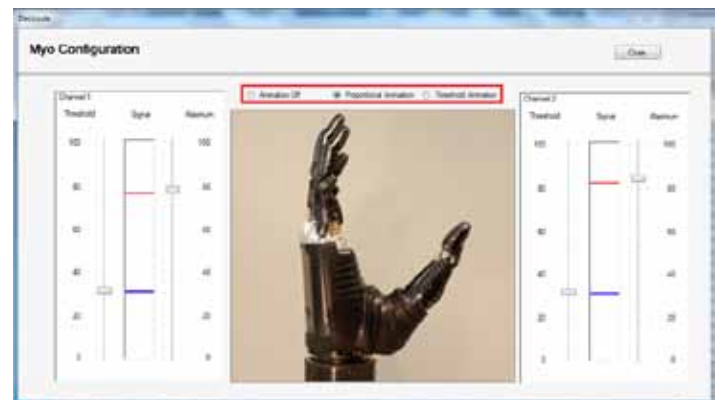


The off threshold is a predetermined offset from the on level. The on level (blue line) determines the level the electrode signal must reach before it is active. Once the signal reaches this level the hand operates until the signal drops below the predetermined off level. The maximum level (red line) sets the proportional range of the signal input.

With the signals displayed the electrode threshold and maximum levels can be adjusted with the relevant sliders, which reposition the blue and red horizontal lines in the associated display panels. The strength of the signal is displayed as a green vertical bar with the peak signal indicated as single green line. On closing the form the settings are retained for configuring the hand using the **Send to Hand** option. The embedded animation system enables modification of the threshold settings to be sampled without the need to keep sending data to the hand. These can then be sent to the hand once the user is comfortable with the settings.

The animation system can also be used as a pure training aid without the need for a bebionic hand. However a training tower (XXXXXXX) and radio module (XXXXXXX) will be required.

To turn on, point & click on **Proportional Animation** or **Threshold Animation** as highlighted below.

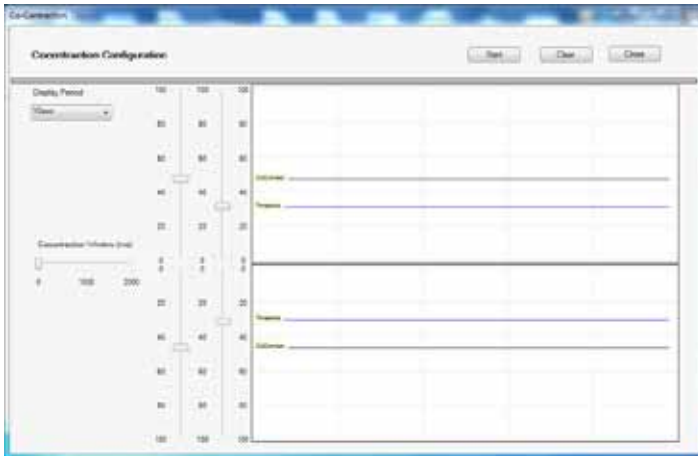


The animation shows Tripod Grip as the default which, will open and close in response to the electrode signals. By applying an OPEN OPEN signal within a definable period (default 1sec) the hand will change to / from a Power Grip.

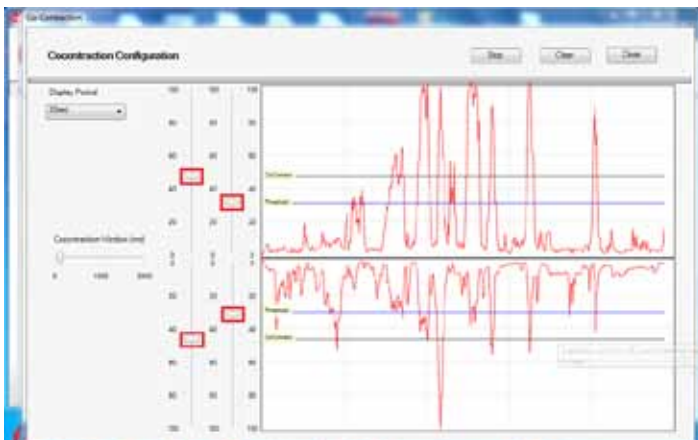
This system provides a useful 'myo' assessment tool for the upper extremity amputee and also provides an entertaining aid for use, both pre and post prescription.

Co-Contraction

Selecting **Co-Contraction** opens a form, shown below, to monitor and set the co-contraction signals.



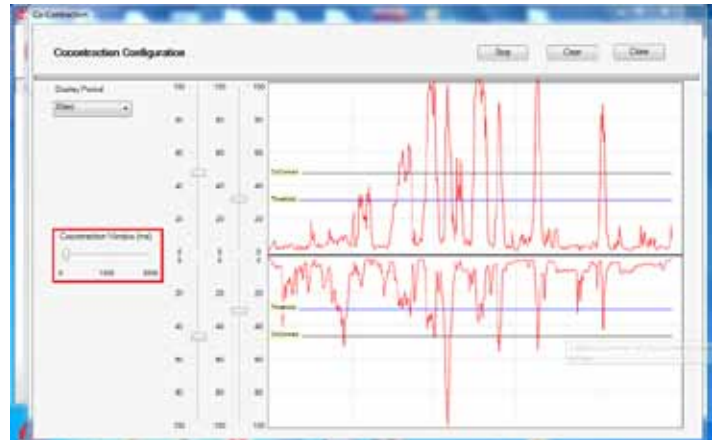
In Mode 5, co-contraction is used to move between default and alternate grip patterns. The blue horizontal lines show the on threshold level set during the myo configuration process and can be adjusted from this option if necessary.



The slider items highlighted on the image above are used to set the required characteristics of co-contraction signals. Clicking **Start** will initiate tracing of the electrode signal. One channel will be displayed with raising signals moving upward and the second channel raising signals moving downward. When the trace reaches the right hand side of the display it will stop. To continue click **Clear**, this will remove the previous trace and automatically start a new one. If you wish to stop the trace at any point, click **Stop**.

The display period can be changed by selecting the appropriate time period (10, 20 or 30 seconds) from the display period drop down (top left).

The black horizontal lines identify the co-contraction level and can be adjusted as necessary. The horizontal lines on the display area move simultaneously with the vertical slider.



The horizontal slider highlighted above (centre left) can be used to set the co-contraction time window.

A co-contraction signal is considered to exist when signals from both channel 1 and 2 pass through both the on threshold and co-contraction within a designated timeframe (co-contraction window).

With the bionic 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, a co-contraction signal will be considered to exist.

5.9 Advanced Features

In bebalance3 the basic features can be selected by simply clicking on the appropriate radio button or check box control. Adjustment of more specific features can be done by clicking **Advanced**.



This opens an overlay form similar to the screen highlighted below. The features displayed will be appropriate to the mode selected.



Grip Current

It is possible to select High, Medium or Low Grip Current. This setting provides adjustment of grip strength and battery consumption; the lower the setting the lower the grip and current draw. Note: This has minimal effect on operation speed.

Speed Control

Should you want to open or close the hand at less than maximum speed, the numeric up/down controls provide independent hand opening and closing speeds; 40 (default) being maximum.

Timer Control

For modes 1, 2, 3 & 4 there are two numeric up/down controls to change mode timings. The upper control **Mode Change Period** sets the window of time to search for a mode change signal. In these modes additional signals received will have no effect and will be considered to be the same signal.

The lower control **Mode Return Period** sets the period after which the mode reverts to default where there has been no activity. Setting the slider to zero deactivates the revert feature. For Mode 5 there is no upper control as mode change is activated by a co-contraction signal. Dwell Threshold (Upper & Lower) This feature is only used on Mode 1. The Upper control sets the time that the signal has to exist to be identified as a CLOSE signal. The Lower control sets the value for the period a signal has to be held once considered an OPEN signal.

Signal Select & Increase on Threshold

This feature offers **Open** & **First** protocols. The default is **Open** which means that the hand will move in response to receipt of the larger signal if both exceed the electrode on threshold. When the **First** option is selected, the hand will open on receipt of the first signal to exceed the threshold and remains with this signal even if a larger opposing signal is received.

The exception to the **First** signal protocol is when an opposite signal exceeds the value of the controlling signal by the amount set on the **Minimum Dwell Threshold** control. If this happens the larger signal becomes the dominant signal. If multiple signals are received to open and close, the hand will continue to open unless the close signal exceeds the amount set on the **Minimum Dwell Threshold** control, which is a value above the standard electrode level.

Dwell Threshold (Min & Max)

This feature is only used on Mode 2. The minimum control sets the level that the signal has to exceed within a time set by the maximum control.

Direction Change Timer

This control is used in Mode 3 only. It is used to set the additional time window when a second signal will be accepted as an additional same direction movement. If set to zero, hand movement will alternate with the next detected signal.

A man with a white beard and mustache, wearing a light-colored cowboy hat and a blue and purple plaid shirt, is looking down at a bundle of hay. He is standing in a field with trees in the background. The text "be confident" is overlaid on the image.

be confident

bebionic3

 **RSLSTEEPER**
Improving people's lives



6.0 additional information,
warranty, returns and
repairs

There are a number of field repairs and replacement parts that are available for the bebionic3. The instructions for how to do this are described in this section.

For further advice on any repairs please contact your bebionic distributor or email: enquiries@rslsteeper.com.

For both parts and service, please mention that the hand is a bebionic3 hand; including details as to whether it is Large or Medium, Left or Right and the date of purchase.

Repairs

6.1 Gaiter 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.



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 bionic3 hand.



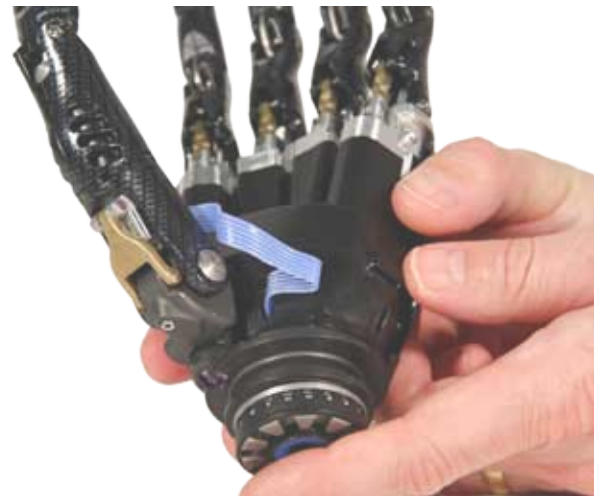
3. Using the screwdriver with the 1.50mm hex bit contained within the toolkit, loosen the screws in the rear cover.
Note: Do not completely remove.



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



7. Completely remove the gaiter from the hand.



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

Repairs

6.2 Gaiter 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.



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.



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 highlighted when pushing the gaiter flaps under the rear cover. Pay special attention to the thumb cable position.



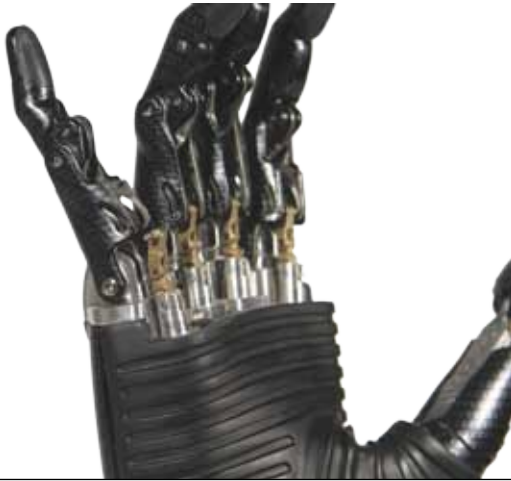
7. Retighten both of the screws in the rear cover. **Note:** Do NOT overtighten.



8. Finished!

Repairs

6.3 Clevis Link Replacement



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.

5.1



Circle indicates correct side for inserting pivot pin.



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 only be inserted from the side with the circle detailed in image 5.1.



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 with the bionic pivot removal pliers (Part:508-27430*). Alternatively the pivot can be removed with the pin punch provided in the tool kit.

*available for purchase separately.



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



3. Using a spare clevis link 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.



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

Note: Clevis curving towards the palm.



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



8. Finished!

6.4 Quality Assurance

RSLSteeper 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 RSLSteeper meet the appropriate international quality standards for design, manufacture and supply of prosthetic products and user software.

RSLSteeper 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° : PBBGC350616 IC:ID : 10634A-RSLRFBB

Model N°: RSL-RP609

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

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

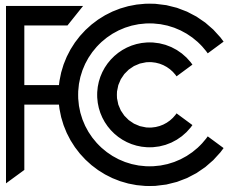
The **CE** mark may be applied on packaging, accompanying literature or an enclosure, rather than the product itself.

The bionic 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 RSLSteeper bebionic Medium Hand, Model: RSL-RP609, 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:PBBGC350616' place on it inline with FCC labelling regulations.

The FCC and IC information is located on the outside of the palm of each hand (left and right) underneath the gaitor.

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:ID : 10634A-RSLRFBB) 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.

| Name / Model | Gain | Impedance |
|-------------------------|-------------|------------------|
| 7488910245/Wurth | 1,0 | 50 Ohm |

OEM Responsibilities

The RSL-RP609 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 RSL-RP609 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 RSL-RP609

or

“Contains IC: RSL-RP609”

The OEM of the RSL-RP609 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

Radio Equipment - Canadian Warning Statements

English

"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."

French

"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."

6.5 Warranty

Warranty Terms

| Item | Warranty Period | Warranty Terms |
|----------------------|-----------------|---|
| bebionic Hand | 12 months | Design and Manufacture |
| Cables | 12 months | Design and Manufacture |
| Wrist | 12 months | Design and Manufacture |
| Batteries / Chargers | 12 months | Design and Manufacture, correct charging |
| Gloves | 3 months | Design and Manufacture, not wear and tear |

An extended warranty is available for the bebionic hand, providing additional cover for year 2 or years 2+3.

Hand Policy

Hands returned to the RSLSteeper bebionic service centres 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.

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 this is necessary.

To identify the hand serial number, lift the gaiter on the back of the hand. The serial number can be found underneath.

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.

6.6 Returns

If bebionic components are to be returned for servicing please contact us at: bebionic@rslsteeper.com stating the hand serial number. We will issue a returns number and returns form that will need completing in full so that 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: enquiries@steeperusa.com.

For both parts and service, please mention that the hand is a bebionic3 hand; including details as to whether it is Large or Medium, Left or Right and the date of purchase.



Installation Disc

Please refer to page 36 for installation instructions



www.bebionic.com

be confident



Technical Support
Manufacturing Centre, Unit 7,
Hunslet Trading Estate,
Severn Road,
Leeds, LS10 1BL, UK
Tel: +44 (0) 113 270 4841
e: enquiries@rslsteeper.com



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Shavano Center III, Suite 200,
San Antonio, 78231
Texas, USA
Tel: 210 481 4126
e: enquiries@steeperusa.com