



i-limb™ digits User Manual

Part number: MA01063: Issue No. 1, December 2012



This document provides information for **i-limb digits** users and should be used in conjunction with advice from a qualified clinical team with experience of **i-limb digits**.



This symbol signifies important information and is used throughout the manual.

Refer to www.touchbionics.com to ensure the latest copy of this document.

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1.0 i-limb digits

1.1 Product Description

i-limb digits is a customized prosthetic device designed to fit and function with your residual hand. **i-limb digits** is a tool to enhance function for individuals with partial hand loss or deficiency.

Each digit in the system has its own motor, which allows the **i-limb digits** to take the shape of whatever object is being held. This also allows you to stop a digit or multiple digits from moving by putting pressure against the digit to stop its motion. Additionally, different grasp patterns can then be programmed into the hand using a software system called biosim.

These various grasping patterns will be discussed in more detail later in this manual as well as how the **i-limb digits** can assist you in completing your daily activities, work tasks, and even some hobbies.



1.2 Know Your Prosthesis

Your **i-limb digits** device is a mechanical device to assist with everyday tasks. Although the device may look similar to a natural hand, there are some things that a normal hand can do that are not possible with the **i-limb digits** device.

To get the most out of the device do not use the **i-limb digits** device where you would not use a natural hand. The **i-limb digits** device will limit sensation and so you may not be aware if the hand is being stressed by excessive weight, temperature or moisture, or has been struck by an object that would cause pain in a natural hand. A natural hand and forearm absorb shock, the **i-limb digits** device is less able to do this. The **i-limb digits** device will not dampen vibration as much as the soft tissues of a natural hand.

The **i-limb digits** device will be damaged if the joints are moved in a way in which they were not designed. Do not apply forces to the side of the digits, or move the joints in directions which they are not intended to move.

When carrying a bag or other object protect the hand by resting the handle or strap toward the center of the hand and away from the tips of the digits.

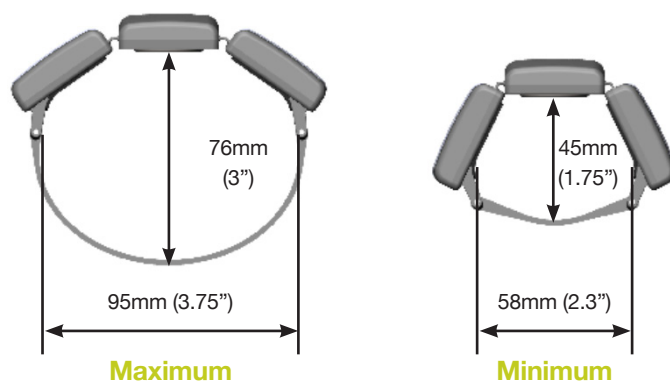
For further information contact your prosthetist.

Your device should be treated like any electrical device, it is important to avoid contact with water or moisture. Wipe your prosthesis dry quickly if there is any contact (review Warnings and Precautions for a comprehensive overview).

1.3 Wristband

The **i-limb digits** Wristband has a circumference range of 155mm (6") to 270mm (10.5").

The **i-limb digits** Wristband contains the PCB and two removable 3.7V batteries. It is connected to the main socket by a flexible sheath which protects the cabling.



2.0 Socket Interface

2.1 Socket Interface and Electrodes

Your **i-limb digits** device has been designed with a socket interface which has been specially created by your prosthetist team. The socket interface should fit comfortably and directly to your residual hand. Some minor redness on your residual hand may be normal when you first remove the device. However if this redness does not go away within 20 minutes or if you have any skin breakdown from your device, contact your prosthetist directly.

As part of the fitting process, your prosthetist selected the best

method for you to provide control of your device. This tells the processor (the brains of the hand) whether you want the hand to open or close. One option is an electrode. Electrodes pick up on the electrical activity that your body gives off when you contract a muscle. Another option is called a Force Sensing Resistor (FSR). These allow you to put pressure against a pad inside your device using movement from your residual hand. While gaining good control may take time and practice, your method of input should not cause pain. Talk with your prosthetist if you do not understand how your input control is working or if it is causing discomfort.

2.2 Battery

i-limb digits is powered by 800mAh, 3.7 Volt batteries which have been specifically designed to meet the power requirements of **i-limb digits** devices. Four batteries are provided, two for the Wristband and two spares.

Two 3.7v batteries will be needed with the Wristband (the Wristband will not work with only one battery).



The Wristband is switched on and off via the grey button on the central panel. The light sequence is as follows:

On : Red light appears for 8 seconds

Off : Red light brief flashes

Low power: Green light flashes continually when the charge level falls below 5%



Batteries are fitted into the Wristband battery housing and secured by the holding catch at the wrist side of the Wristband. Release the holding catch to remove the battery.



The batteries provided are designed to work specifically with the Touch Bionics **i-limb digits** Wristband and are not to be used with any other device.



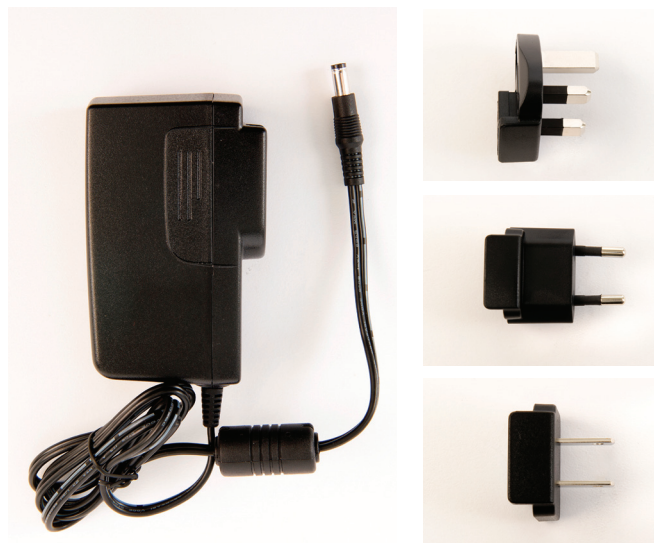
Only Touch Bionics batteries are approved for use with **i-limb digits**, use of alternative batteries will invalidate the warranty.



2.3 Battery Charging

Batteries for **i-limb digits** should only be charged using the Touch Bionics powerpack and battery charger supplied (UK, European and US style plugs are available). Place the batteries in the charger as illustrated. Insert the charger lead from the battery powerpack into the charge port. Insert the charger into the power outlet.

Charging time from full discharge is approximately 2 hours.



A continual blue light indicates that the battery is charging. When the battery is fully charged the light will go out.



If a continual red light appears for more than 10 minutes then the battery should be replaced.



Only use the plug to disconnect the charger, never pull the cable to remove the lead.

As an alternative to charging directly from domestic power, a car charger (PL069380A) is also available.



2.4 Storage and Maintenance

Always turn off the hand when not in use.

Aim to charge the battery each day after use.

Replace the battery every 12 months.

3.0 biosim

3.1 biosim Overview

The **i-limb digits** device contains a Bluetooth® receiver enabling it to work with software package known as **biosim**. Your prosthetist will also have a version of **biosim** to make changes to how your prosthesis functions. Using **biosim** it is possible to make changes to the functionality of the **i-limb digits** device. It will be important for you to understand what these changes mean to your device before changing any settings. Your **biosim** software provides access to training and games, along with the option to make changes to settings.

The **biosim** software, working through the Bluetooth® wireless connection, provides access to a range of control options, training features, real time display of impulses, battery status and a Hand Health Check

To use the **biosim** software with the **i-limb digits** device you

will need either an iPod Touch supplied by Touch Bionics and preloaded with the biosim App, or a PC loaded with the **biosim** software and used with the **biosim** Bluetooth® receiver (the system requires either Window XP, Windows Vista or Windows 7; Microsoft.NET framework v3.5; USB port for Bluetooth® connector and administrative rights to install the software and connector). Users of **biosim** via an iPod touch are directed to iPod Touch with biosim App: Quick Start Guide, provided with your iPod touch (also downloadable from www.touchbionics.com).

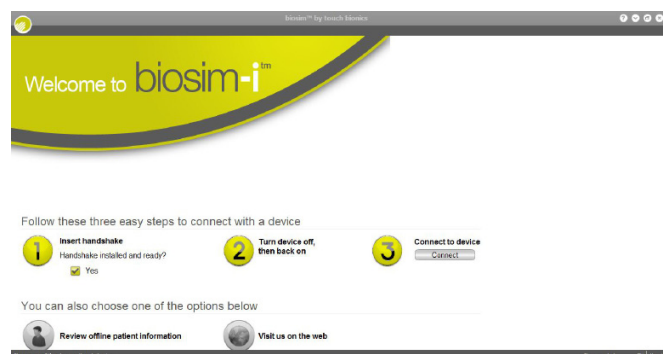
Occasionally updates to the **biosim** software will be provided. An automated notification will advise you when this is needed. Follow the steps as advised in the notification.

N.B. As all **i-limb digits** device are individually, custom designed products, accurate illustrations of your device is not possible. All illustrations show a full hand and are for guidance purposes only.

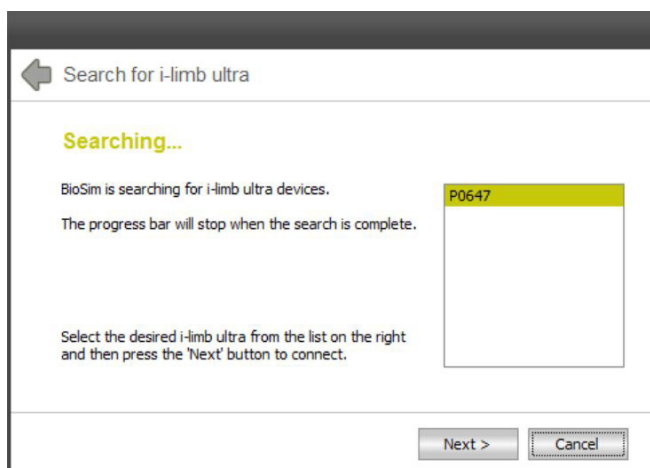
3.2 biosim Connecting

biosim can be downloaded and access rights set up via <http://www.touchbionics.com/Biosimdownload>. Load **biosim** by clicking on the **biosim** icon which should be clearly visible on the screen. The **biosim Handshake** dongle must also be inserted into a USB port to allow the Bluetooth® signal to be received by the **i-limb digits** prosthesis. The Handshake Bluetooth® receiver will pick up signals within a 10 meter range.

The opening welcome screen will load and the first numerical icon “insert handshake” request will flash. On insertion of the Bluetooth receiver (biosim dongle) the icon will be constantly lit, the “handshake installed and ready” box will then self-tick and the second icon “Turn device off, then back on” will begin to flash. At this point the **i-limb digits** device should be turned off and then on. The third icon “Connecting to device” will be constantly lit. The tab marked “connect” must now be selected for the connection to be made, this may take up to 24 seconds.

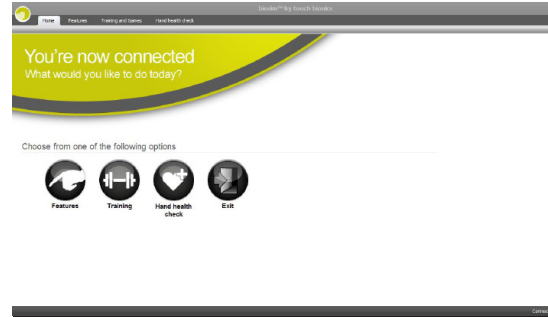


If there is more than one device (either **i-limb digits**, **i-limb ultra** or **virtu limb**) within range of the Bluetooth® receiver then a box will appear listing all devices by serial number. In the illustration only one device is listed. The correct **i-limb digits** device can then be selected from the list. For devices using the Wristband, the serial number is located in the battery housing on the main body of the Wristband, as illustrated. For devices using the full forearm socket, your prosthetist will be able to let you know where to find the serial number.



3.3 Navigating biosim

The *You're now connected* home screen will now be displayed, with seven options as illustrated. This is the homepage and can be accessed at any time from subsequent pages.



Features allows the set-up of the **i-limb digits** and is where triggers are linked with with grip patterns and gestures.

Training provides access to the training suite and a selection of games to improve overall control.

Hand health check icon provides a quick and easy diagnostic check of the hand.

Exit icon draws the session to a close, exiting the program.



Features



Training



Hand health
check



Exit

3.3.1 Features



Features

Click on the features icon to enter the features suite. The feature page provides access to all available features and associated changes. Features are the actual movements of the hand and triggers are the muscle action used to create the movements.

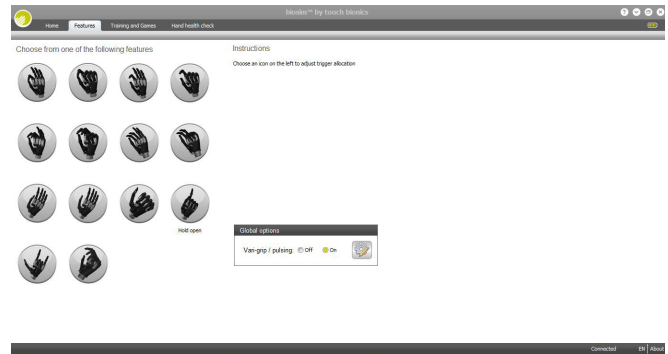
The grip patterns illustrated are:

First row – 4 precision pinch options

Second row – 4 tripod grip options

Third row – 2 thumb park options, lateral grip and index point options

Fourth row – custom gesture and custom grip options



Features Catalogue

Precision Pinch Grip Options

Standard Precision Pinch Opened

middle, ring and little finger remain fully opened and switch off. Index finger and thumb provide grip.



Standard Precision Pinch Closed

middle, ring and little finger automatically close and switch off. Index finger and thumb provide grip.



Thumb Precision Pinch Opened

middle, ring and little finger remain fully opened and switch off. Thumb automatically moves to a partially closed position. Index finger will move to provide grip against a fixed thumb.



Thumb Precision Pinch Closed

middle, ring and little finger automatically close and switch off. Thumb automatically moves to a partially closed position. Index finger will move to provide grip against a fixed thumb.



Tripod Grip Options

Standard 3 Jaw Chuck (Tripod) Opened

ring and little finger remain fully opened and switch off. Thumb, index and middle fingers move to provide grip.



Standard 3 Jaw Chuck (Tripod) Closed

ring and little finger move to terminal close. Thumb, index and middle fingers move to provide grip.



Thumb 3 Jaw Chuck (Tripod) Opened

ring and little finger remain fully opened and switch off. Thumb automatically moves to a partially closed position. Index and middle fingers move to provide grip against a fixed thumb.



Thumb 3 Jaw Chuck (Tripod) Closed

ring and little finger move to terminal close. Thumb automatically moves to a partially closed position. Index and middle fingers move to provide grip against a fixed thumb.



Additional Grip and Gesture Options

Thumb Park Continuous

all four fingers remain open and switch off, only the thumb will move.



Thumb Park Quick

all four fingers remain open and switch off, for 1.5 seconds the thumb will close and then automatically return to an open position.



Lateral Grip

all four fingers fully close and switch off. Only thumb will move.



Index Point

thumb, little, ring and middle fingers close and switch off. Only the index finger will move.



Customer Gesture

all fingers automatically move to a fully opened or fully closed position, as preset by the user.



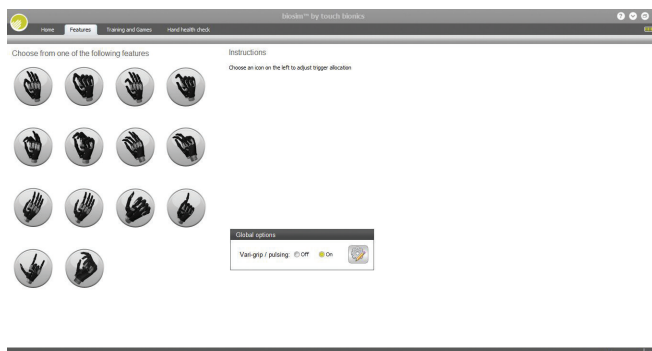
Custom Grip

all fingers automatically move to a user defined position.

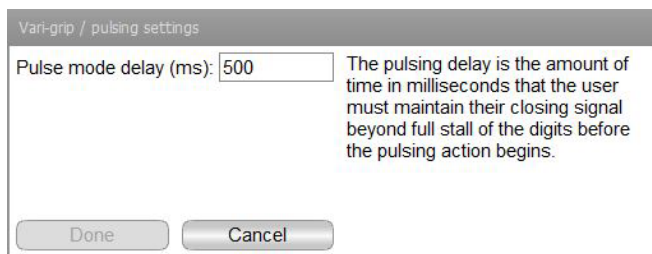


Additional Functioning

Toward the bottom right of the screen the additional Global Options box can be used to give access to Vari-grip / pulsating.



- Vari-grip / pulsating:** this mode provides additional grip force with subsequent activation of the closed signal. The default setting for activation is 500ms (0.5 seconds) which can be customized between 250 (0.25 seconds) to 3,000ms (3 seconds).



Triggers

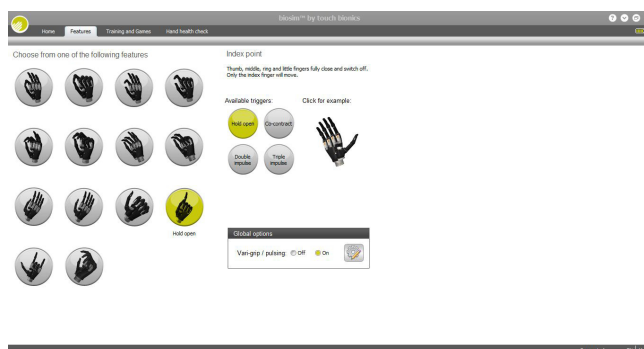
Four potential triggers are available to activate features: Hold open, Co-contraction, Double impulse and Triple impulse.

- 1 **Hold open** (a prolonged open signal)
- 2 **Co-contraction** (both open and closed signals activated simultaneously) may have already been customized by your prosthetist to be suited to your own unique signals.
- 3 **Double impulse** (two rapid open signals, separated by relaxation below the threshold). Your prosthetist will have pre-set this at the time of fitting. To activate a double impulse the device needs to be fully opened prior to attempting activation.
- 4 **Triple impulse** (three rapid open signals, separated by relaxation below the threshold). Your prosthetist will have pre-set this at the time of fitting. To activate a triple impulse the device needs to be fully opened prior to attempting activation.

Any of the above four potential triggers can be linked with any of the above features. Some users are able to perform activities of daily life (ADL's) without the use of any triggers. In many cases users initially set one or two triggers while familiarity and control is gained.

Linking Triggers with Features

In order to link a trigger with a feature simply click on to the desired feature, the feature will now be highlighted. Select and click the desired trigger which has been selected to link with the highlighted feature. Both feature and trigger should now be highlighted and the descriptive label will now appear under the feature icon. The illustration indicates the Index Point Feature linked to the Hold Open Trigger.



By clicking on any of the features on the features page the available triggers and example sections will also appear. In order to preview a feature simply highlight the feature and click on example to the right of the screen. The section will then enlarge and provide a demonstration of the feature. The hand image can be rotated to improve visualization by holding the left mouse key and moving the cursor in the direction of the intended rotation.

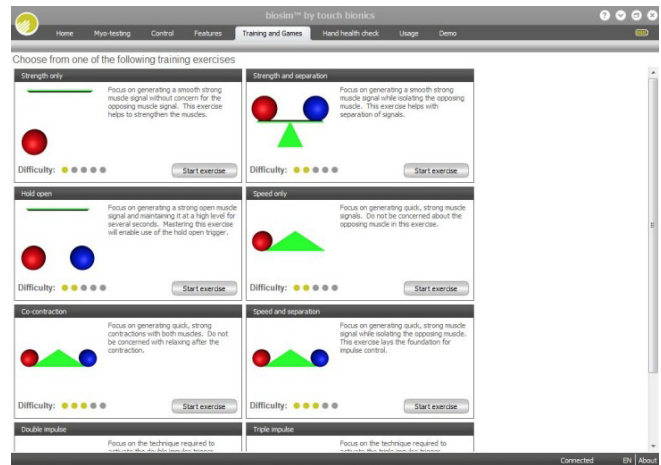


3.3.2 Training

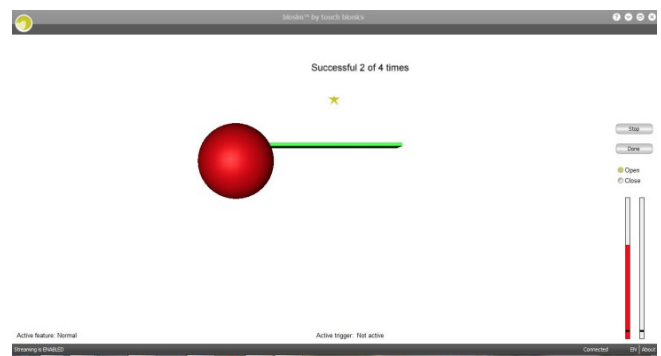


The training suite contains a variety of short training exercises aimed at developing control of the **i-limb digits** device. The opening screen highlights the series of exercises which can be selected individually and in any order. Both open and closed signals can be practiced by selecting the appropriate box to the right. Click on “Start” to start the exercise and “Done” when the exercise is complete. An indication of difficulty is provided by the 5 point scale on each module.

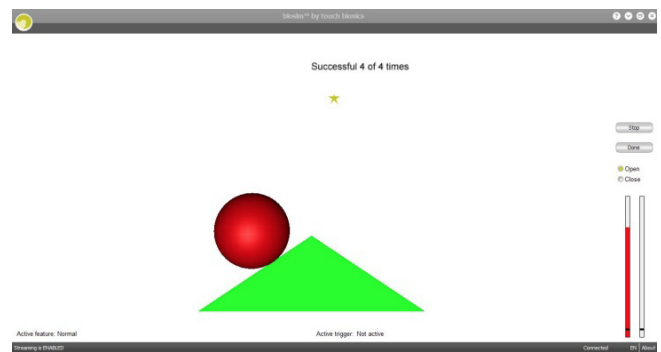
the right. Click on “Start” to start the exercise and “Done” when the exercise is complete. An indication of difficulty is provided by the 5 point scale on each module.



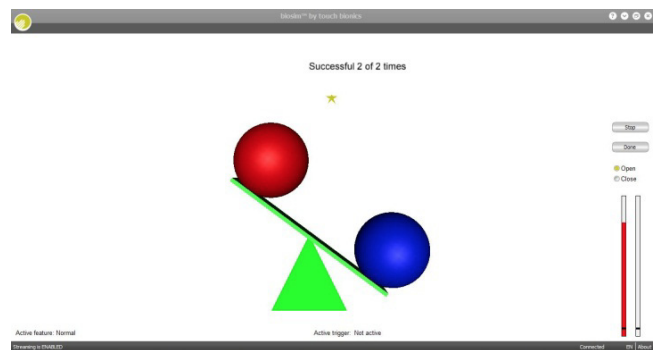
Strength Only focuses on generating a smooth strong muscle signal without concern for the opposing muscle signal. This exercise helps to strengthen the muscles.



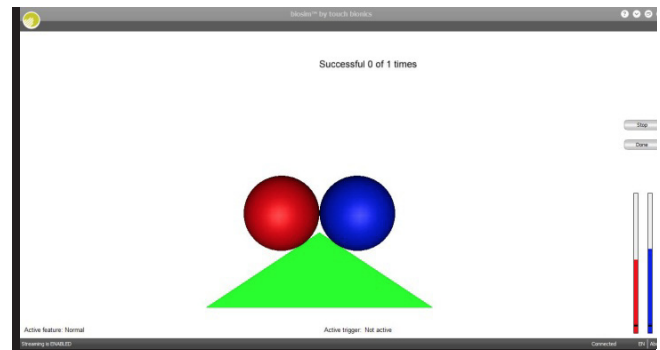
Speed Only focuses on generating quick, strong muscle signals. Do not be concerned about the opposing muscle in this exercise.



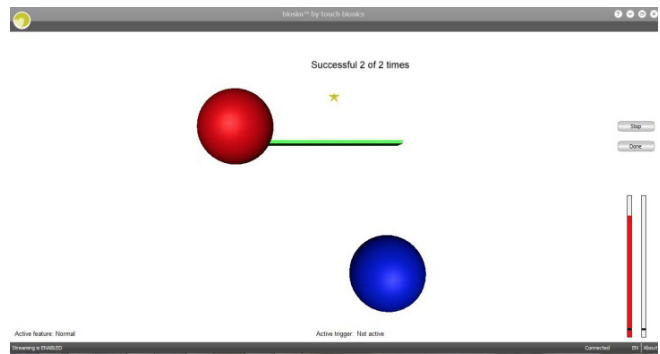
Strength and Separation focuses on generating a smooth, strong muscle signal while isolating the opposing muscle. This exercise helps with separation of signals.



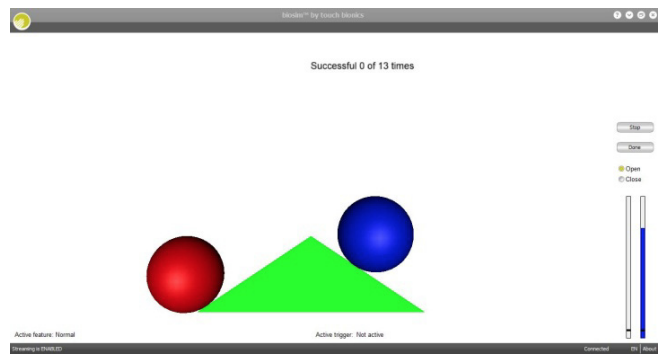
Co-contraction focuses on generating quick, strong simultaneous contractions with both muscles. Do not be concerned with relaxing after the contraction.



Hold Open focuses on generating a strong open muscle signal and maintaining it at a high level for several seconds. Mastering this exercise will enable use of the hold open trigger.



Speed and Separation focuses on generating quick, strong muscle signals while isolating the opposing muscle. This exercise lays the foundation for impulse control.



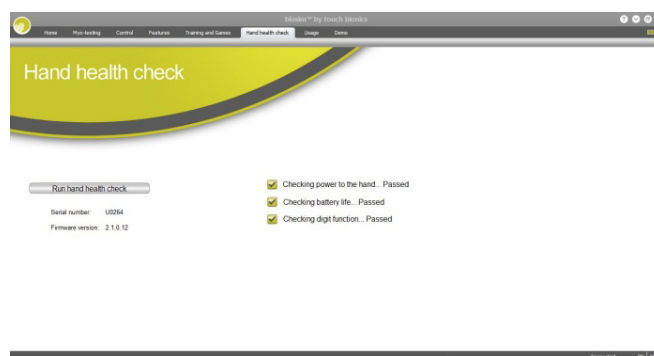
3.3.3 Hand Health Check



Hand Health Check screen provides a quick and easy check of the hand. Click on the “Run Hand Health Check” icon and the health check will begin. There must be an internet connection to run the Hand Health Check.



The **i-limb digits** device will then go through a series of movements as each digit is checked, the process will run for approximately 8 seconds and provide basic feedback on each step.



3.3.4 Exit



Use the Exit icon to fully exit **biosim**.

4.0 i-limb digits Coverings

4.1 Cover Options

Silicone digit covers will be provided for the **i-limb digits** device. Digit covers will be ready to fit and designed to cover each digit.

Touch Bionics' approved digit covers must be used with each digit of the device. The warranty will become void if the device is used without an approved cover.



General Precautions

- The **i-limb digits** device must be used with approved Touch Bionics' digits covers.
- Never put more than one cover on each digit of the **i-limb digits** device.
- Always use the digits cover designed for the **i-limb digits** device.
- Ensure covers are fitted properly.

i-limb digits covers do not provide full protection from moisture, oil, dust and dirt ingress. Caution should be observed.

5.0 Support Information

5.1 Troubleshooting

Problem	Action
Prosthesis does not operate	Ensure the prosthesis is switched on Ensure the battery is connected Ensure the battery is charged
Prosthesis stops midway through an action	Check the battery cable is not damaged Check that the i-limb digits device is connected correctly
Prosthesis is difficult to operate	Ensure the battery has good charge
Battery charge does not last a full day	Fully charge the battery, this may take up to 2 hours Check the battery connection Ensure that you are not holding a sustained signal to the device Replace the battery
Digits open when a closed signal is actioned	Contact your prosthetist
Battery is not working	Check the battery is connected Ensure the battery charger is working correctly Check the battery is charged

5.2 Warnings and Precautions

i-limb digits device

Do not use without an approved cover

Do not use under water

Do not use to operate heavy / industrial machinery

Do not use with machinery with moving parts that may cause personal injury or damage

Users must comply with local regulations on the operation of automobiles, aircraft, sailing vessels of any kind and any other motorized vehicle or device

Do not use for extreme activities that may cause injury to a natural hand

Do not expose to excessive moisture, liquid, dust, vibration or shock

Do not expose to high temperatures

Do not expose to naked flames

Do not use or expose to explosive atmospheres

Do not disassemble componentry or modify in any way

Maintenance, repairs and upgrades may only be performed by qualified Touch Bionics technicians and technical partners

Do not use with a damaged cover

Damaged covers must be replaced or repaired by a qualified Touch Bionics technician or technical partner

Only approved Touch Bionics accessories and tooling may be used with the **i-limb digits** device

Failure to comply with the above guidelines will invalidate the warranty.

Batteries

Do not bend or exert excessive pressure on the battery

Do not pierce the battery

Do not disassemble

Do not expose to high temperatures

Do not incinerate batteries

Do not alter battery terminal wires

Do not short circuit the battery

Do not store batteries inside a vehicle

Dispose of batteries in accordance with US, European or local regulations

Only use the appropriate Touch Bionics charger to charge Touch Bionics batteries

If the battery has visibly ballooned or swelled:

- discontinue the charging process immediately
- disconnect the battery
- remove to a safe area
- leave and observe for 15 minutes
- replace the battery
- do not re-use
- dispose of any leaking batteries in an appropriate manner

A list of frequently asked questions can be found on the Touch Bionics website.



If you experience technical problems with the **i-limb digits** device call your prosthetist or Touch Bionics as follows:

**North American Customers
(Canada, Mexico & US)**
Tel: +1 855 MYiLIMB (694 5462)
UK & Non-North American Customers
Tel: +44 1506 438 556

Driving of Motor Vehicles

The i-limb device has the functional capability to assist a patient with driving a motor vehicle however due to factors including the differences in world-wide driving regulations and the variations in the level of ability between patients Touch Bionics is unable to provide definitive advice in respect of a patient with an i-limb device driving a motor vehicle.

Touch Bionics is aware that patients have used the i-limb to drive a motor vehicle and our recommendations prior to a patient doing so would include the following:-

- contacting the driving authority in your home location to obtain and understand the local regulations;
- working with the appropriate authorities to have your car modified to meet the local regulations for your respective disabilities as required;
- re-taking any mandatory driving test using your i-limb device to demonstrate your ability to operate a motor vehicle safely if required by local regulations;
- contacting your insurance provider and advise them that you will be using the i-limb device to drive a motor vehicle;
- ensuring that the device has a fully charged battery. Please note that the i-limb device will emit a low battery signal which will alert you if the battery requires to be charged;
- switching off the i-limb device. This is due to the possibility of involuntary muscle signals being generated; and
- moving the thumb into the lateral position to allow the i-limb to be removed from the steering wheel without opening the hand.

It is entirely the patient's responsibility to seek confirmation that they are physically and legally able to drive using the device and to the fullest extent permitted by law Touch Bionics shall under no circumstances whatsoever be liable to the patient or any other party as a result of or in connection with a patient with an i-limb device driving a motor vehicle.

6.0 User Information

6.1 User Details

Provision of the following basic information will enable easy identification if the prosthesis is returned to Touch Bionics customer service. Please forward details to Touch Bionics as per the contact information on the back page of the manual.

User Name:

.....

Fitting Date:

.....

Hand Purchase Date:

.....

Hand Serial Number:

.....

7.0 Appendix

7.1 Technical Information

Activity	i-limb digits
Push up from wheelchair: full hand	80Kg/176lbs
Push up with one digit	20Kg/44lbs
Carry heavy bag full hand	100Kg/220lbs
Carry heavy bag one digit	25Kg/55lbs
Carry heavy bag on thumb	25Kg/55lbs

7.2 Component Compatibility

1. General Safety

1.1 The **i-limb digits** device is an electrical device, which under certain circumstances could present an electrical shock hazard to the user. Please read the accompanying user manual thoroughly and follow directions stated in the manual to assure maximum safety during charging and operation.

1.2 EN 60601-1:2006

1.2.1 Protection against electrical shock – Class II

1.2.2 Degree of protection against electrical shock – Type BF provides additional protection against electric shock

1.2.3 Degree of protection against ingress of water (IEC 60529:2001) – IP40

1.2.4 Not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide

1.3 EMI/EMC

1.3.1 Compliance against standard EN 60601-1-2:2007

1.4 Radio Spectrum Matters (ERM)/Bluetooth

1.4.1 Compliance against standard EN 301 489-1 V1.8.1

1.5 EN 301 489-3 Clause 7.1

1.5.1 EN55022: 2006








1.6 Radiation emissions, Enclosure

1.6.1 EN 301-489-1 Clause 8.2 - Pass (30MHz to 6,000MHz)

1.7 Zones of Use

1.7.1 Not recommended in zones 0, 1, 20 and 21

N.B. See www.touchbionics.com for further information on EMC testing carried out on products within this manual.

	Refer to operating instructions
	Class II equipment – provides double Isolation to protect against electric shock
IP40	Degree of protection – IP40 Protection against penetration by solid particles with diameters larger than 1 mm. No special protection against penetration by water
	Batch/Lot/ID Number
	For i-limb digits devices: Each device has a guaranteed unique id number example: 0001:2012 The unique serial number for i-limb digits devices is a D with a 4 digit alpha / numeric number. The year of manufacture of the device is then added.
	WEEE Compliance
	Catalogue number
	Manufacturer
	Keep Dry

1. Customer Service/Contact Information:

Touch Bionics, Unit 3 Ashwood Court,
Oakbank Park Way, Livingston EH53 0TH, UK

Tel: Customer Service: +44 (0) 1506 445 415
Tel: General Enquiries: +44 (0) 1506 438 556

www.touchbionics.com

Touch Bionics, 35 Hampden Road
Mansfield MA 02048, USA

Tel: +1 855 MY iLIMB (694 5462)

www.touchbionics.com

7.3 Warranty

Limited Warranty for i-limb digits

Touch Bionics warrants that the **i-limb digits** components will conform to its specifications and be free of defects in material and/or workmanship for a period of thirty-six (36) months from the date of Touch Bionics invoice for **i-limb digits** components. This Limited Warranty applies only to **i-limb digits** components provided by Touch Bionics or an accredited Touch Bionics provider. This Limited Warranty applies to all components including but not limited to fixtures, motors, bearings, and electronics for the same thirty-six (36) month period. This Limited Warranty is governed by UK law and is not transferrable.

Warranty:

Touch Bionics reserves the right to credit, repair or replace “in-warranty” **i-limb digits** components as its option. If required, replacements will be new products. The wearer shall report any defect claim to Touch Bionics directly or to the facility that provided **i-limb digits** components immediately upon discovering the defect, and, in any event, within the warranty period. The defective **i-limb digits** component must be returned to Touch Bionics or any other Touch Bionics provider. To find the nearest location, please search online at www.touchbionics.com or call +1-855-MY-iLIMB (US & Canada) or +44 (0) 1506 438 556 (International). Wristband, digits, electrodes and wiring loom components must be returned as originally shipped.

The warranty is void if the **i-limb digits** component is subjected to abuse, neglect, alteration, modification, improper repair and/or maintenance performed by anyone other than Touch Bionics or an accredited Touch Bionics provider. Damage as the result of normal wear and tear including the result of fatigue is not covered during the warranty period. Damage resulting from installation of parts and accessories not compatible with **i-limb digits** by anyone other than Touch Bionics or an accredited Touch Bionics facility is not covered, including use of non-Touch Bionics batteries.

This is the exclusive remedy under this warranty, any and all other remedies that may otherwise be applicable are excluded, including, but not limited to, incidental or consequential damages or punitive damages to the maximum extent permitted by law. This is the only warranty made by Touch Bionics on **i-limb digits** components, and there are no warranties which extend beyond the description herein. Any warranties that may otherwise be implied by law including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose are excluded.

This Limited Warranty gives the consumer specific legal rights. The consumer may also have other legal rights which vary from country to country, from state to state in the U.S., from province to province in Canada and from state to state in Mexico. Some countries and states may not allow the exclusion or limitation of incidental or consequential damages or warranties, so the above limitations or exclusions may not apply to you. If it is determined by a court of competent jurisdiction that a certain provision of this limited warranty does not apply, such determination shall not affect any other provision of this limited warranty and all other provisions shall remain in effect.



North American Customers

(Canada, Mexico & US)

Touch Bionics

35 Hampden Road

Mansfield MA 02048

USA

Tel: +1 855 MY iLIMB (694 5462)



International Customers

Touch Bionics

Unit 3, Ashwood Court

Oakbank Park Way

Livingston EH53 0TH

Scotland

Tel: +44 1506 438 556

Email: info@touchbionics.com

For address details and further information
please visit **www.touchbionics.com**

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