

Training Protocol for Therapists i-limb™ ultra revolution and i-limb™ ultra





This manual should be read and used in conjunction with training from the Touch Bionics clinical team for the evaluation and training of users of the i-limb products. The material herein is designed to facilitate the authorization of patient services, enhance patient evaluation, support team-based rehabilitation services and to optimize outcomes.



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

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1.0 Introduction to Upper Limb Prosthetics

1.1 Upper Limb Amputee Training

Individuals with upper limb loss or deficiency are impacted in profound ways. The human hand functions in gross grasp and prehensile activities, as a sensory organ, and as a means of communication and social interaction. Any amount of loss or deficiency can interfere with an individual's productivity and alter one's interactions with the environment. In fact, it is estimated that the hand provides 90% of the overall function of the upper limb (Light, Chappell & Kyberd, 2002). Emotional impacts, such as a feeling of incompleteness, are also common.

Each person with an upper limb amputation is unique, and no two amputations are identical. Because we rely on our hands for engagement with the world around us, training an individual to use a prosthesis can be one of the most challenging and rewarding clinical opportunities a therapist can experience.

The goal of most people with upper limb loss or deficiency is to achieve independence in the functional activities they want or need to perform. For the majority of unilateral amputees, this goal is entirely possible. Individuals with bilateral transhumeral (above the elbow) or bilateral shoulder disarticulation limb loss, present with a significantly more challenging situation, typically requiring more adaptations and creative solutions to improve independence.

From the acute phase to community reintegration, the therapist has a critical role in every stage of the functional training process. In a survey of individuals one year post amputation, respondents indicated a strong desire for functional training with their prosthesis (van Lunteren, et al., 1983). By contributing to the successful integration of a prosthesis, the therapist helps reduce the risk of cumulative trauma disorders which are three times more likely for individuals with unilateral limb loss (McFarland, et al., 2010).

Various studies show that the type and amount of therapy received correlates to improved functional outcomes. Weeks, Anderson, and Wallace (2003), noted the importance of having variation in training, rather than purely rote practice. In another study, individuals were instructed to complete a list of functional tasks. One group was given formal training to complete the tasks while the other group was instructed to complete them independently. In a period of just four days, those who received formal training demonstrated significantly better efficiency in completing the tasks than those without training (Lake, 1997).



2.0 Overview of i-limb ultra revolution and i-limb ultra Prosthetic Devices

2.1 Device Overview

Touch Bionics offers two myolectric powered options for patients with upper limb loss at the wrist or more proximal: the i-limb ultra revolution and the i-limb ultra.

The i-limb ultra revolution and the i-limb ultra offer many customizable features, providing wearers with the flexibility to perform a wide range of daily activities with improved control, accuracy, and ease-of-use.

Multi-Articulating Digits

The i-limb ultra revolution and the i-limb ultra have five articulating digits powered by motors. Four motors power the index to small digits with articulations at the metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joints. The fifth motor powers thumb flexion and extension at the MCP joint. The i-limb ultra revolution has these same motors but also offers one additional motor for thumb rotation (Figure 1).

Manual Versus Powered Rotating Thumb

The one extra motor in the i-limb ultra revolution provides the wearer with a powered rotatable thumb, a distinguishing feature from the i-limb ultra since the i-limb ultra thumb must be manually (or passively) rotated and positioned to achieve certain grips and gestures.

The i-limb ultra revolution includes a powered rotating thumb allowing motion from the palmar position to a fully lateral position and anywhere in between. The thumb automatically moves to the position needed for the selected grip pattern, saving time and improving grasp accuracy. The thumb also has a manual override so it can be manually rotated, increasing the versatility to available positions along the full range of thumb rotation.

The i-limb ultra thumb can be manually positioned anywhere along the range of motion, but it must be pre-positioned by the user during specific grip patterns. Typically, a user can achieve manual rotation by pushing the thumb against the upper thigh or a hard object, or by reaching over with the contralateral side.



Figure 1. i-limb ultra revolution

Stall Out and Compliant Grip

For both the i-limb ultra revolution and the i-limb ultra, the motors can be stalled (or stopped) when they reach resistance or when pressure is put against them. This stalling mechanism allows the hand to conform to objects of various shapes and sizes (Figure 2) to provide a compliant grip. This is a significant advancement over the single-grip style hands which only offer a 3-Jaw Chuck (Tripod) style grip for all tasks.



Figure 2. Compliant grip allows hand to take shape of the object

Proportional Control

Both the i-limb ultra revolution and the i-limb ultra function with proportional control, meaning the stronger the muscle contraction, the faster the hand will move. Likewise, a weaker muscle signal will cause the hand to move more slowly. A helpful analogy to describe this is an accelerator pedal on a car, where the vehicle's speed is controlled by the amount of pressure placed on the pedal. With the i-limb hands, once a user grasps an object, the hand will continue to hold the object until a clear open signal is given.

vari-grip

The compliant grip of the hand allows a firm grasp on most objects, but there are tasks that sometimes require extra force, such as opening a candy bar, a container, or even tying one's shoes. For these types of tasks, vari-grip allows for an increase in grip force when a sustained close signal is given. This extra ratcheting down of force increases the grip or pinch strength.

auto-grasp

When engaging in tasks such as putting away the dishes, some individuals may be concerned about dropping a glass if they were to accidentally fire an open signal while moving. Autograsp assists in these cases by detecting inadvertent open signals and re-closing the hand when a short un-intentional open signal is detected, thereby improving the user's control over objects.

Non-backdrivable digits

All digits of the i-limb ultra revolution and i-limb ultra are non-backdrivable, which means that each digit is capable of sustaining a load. This saves battery power since no power is applied when the hand is static with no EMG signal. It also means the digits should not be forced open manually.

The commonalities and differences between the i-limb ultra revolution and the i-limb ultra are summarized below:

Product Features	i-limb ultra	i-limb ultra revolution
Five articulating digits	√	1
Individual stall out ability	1	1
Compliant grip	1	1
Enhanced grip feature (vari-grip)	✓	1
Automated grip patterns & gestures	14	24
12 additional customized my-grips™	×	1
Thumb	Rotated manually	Powered rotating with manual override
Compatible with mobile app	1	1
Use of Quick Grips in control app	×	✓

ACTION	i-limb ultra revolution and i-limb ultra
Push up from wheelchair, full hand	83kg/183lbs
Push against one digit	22kg/48.5lbs
Carry heavy bag, full hand	90kg/198lbs
Carry heavy bag, one digit	32kg/71lbs
Carry heavy bag on thumb	36 kg/79lbs
Lateral Pinch	3.5 kg/7.7lbs*
Tip Pinch	2.1kg/4.6lbs*
Power Grip	13.9kg/30.6lbs*

^{*}With activation of vari-grip pulsing technology by continuation of the "close" muscle signal

2.2 Features Overview

The functionality of the i-limb hand enables it to mimic many of the basic grasp patterns of the natural human hand: spherical, cylindrical, hook, pinch, tripod, and lateral (Figure 3). These grasp patterns or grips (called "Features") can be achieved in various ways. The user can program Triggers, quick grips™, grip chips™, or, alternatively, the user can leverage the i-limb conformable grip technology while operating in Standard Hand mode. With the latter approach, the user can manually position the thumb to the desired position (oppositional or lateral), then simply close the hand to achieve the desired grasp.

Figure 3. Patterns of the natural hand











1-Triggers

Triggers are signals that tell the hand to change function. Each Trigger instructs the i-limb ultra revolution or i-limb ultra to activate an automated Feature (e.g. tripod or lateral grip).

There are 4 potential Triggers a user can select:

- `hold open' (sustaining the open signal for a set period of time)
- `double impulse' (two quick open signals after the hand is fully open)
- `triple impulse' (three quick open signals after the hand is fully open)
- `co-contraction' (contracting both the open and close muscles simultaneously)

The number of Triggers programmed depends on each individual's ability to control and activate the signals. More detailed information about Triggers and appropriate training techniques is available in the prosthetic training section.

2- quick grips™

In both the mobile apps and desktop software, you will find "quick grips." This is another way you can enter and exit features and offers instant access to 24 different grip patterns. By clicking the "quick grip" button for the selected grip, your hand will enter that mode. To exit, click the "quick grip" again.

3- grip chips™

"grip chips" enable users to easily activate "quick grips", "my grips", or "favorites" for i-limb ultra revolution.

Using the my i-limb app, patients can easily program grip chips with any grip pattern or gesture they choose and place in a desired location. Simply holding an i-limb ultra revolution device within close range to a grip chip will activate the programmed feature.





Precision Pinch Grip Options

Precision pinch grip options are best for picking up small items between and the thumb and index finger. There are 4 options available depending on how you want the other digits to perform while doing the pinch. The most popular is Thumb Precision Pinch Closed.

Feature	Picture Example	Description	Use	Task Examples
Standard Precision Pinch Open		Middle, ring and little fingers remain open while the index finger and thumb open and close together to provide grip.	Allows for a wider space opening to pinch larger objects. Positions the other three fingers out of the way to avoid interference with tasks.	Returning cards or money to wallet Picking up napkins Folding laundry
Thumb Precision Pinch Open		Middle, ring and little fingers remain open. Thumb automatically moves to a partially closed position. Only index finger will move to provide grip against the fixed thumb.	Accuracy is improved when picking up an object by allowing you to place the thumb against the object to be pinched. Only the index finger moves to grasp the object. Ideal for repetitive tasks.	Pick up pencil or slim, long objects Thread needle Sort/Pick up medications
Standard Precision Pinch Closed	AB:	Middle, ring and little fingers remain closed. Both index finger and thumb open and close together to provide grip.	Allows for a wider web space opening to pinch larger objects. Allows better visual access to objects when the working surface is not at eye level. Positions the other three fingers so as not to block the user's view of the task.	Retrieve small object from shelf over head Pick up small object from floor
Thumb Precision Pinch Closed		Middle, ring and little fingers remain closed. Thumb automatically moves to a partially closed position. Only index finger will move to provide grip against the fixed thumb.	Can improve accuracy for picking up an object by allowing you to place the thumb against the object to be pinched and only the index finger moves to grasp the object. Ideal for repetitive tasks.	1. Pick up and open sugar packet from a coffee stand 2. Pick up coins 3. Alternative way to tie shoes (also see "lateral grip")

Tripod Grip Options

Tripod Grip, also known as 3-Jaw Chuck, is achieved when the thumb opposes both the index and long fingers. Typically, Tripod Grip is preferred over Precision Pinch when handling slightly larger objects for more stability. There are 4 options for the Tripod Grip that are categorized the same as the Precision Pinch options on the previous page.

Feature	Picture Example	Description	Use	Task Examples
Standard 3 Jaw Chuck (Tripod) Open	(B)	Ring and little fingers remain open. Thumb, index and middle fingers actively open and close to provide grip.	Allows for larger objects to be grasped using the tripod pinch. Can also improve positioning. May also decrease compensation at shoulder for tasks where closed digits get in the way of the pinch.	1. Preparing food with ring and little finger clear, such as slicing cucumber or carrot 2. Holding cell phone (would manually rotate thumb laterally based on size of phone or setup custom grip)
Thumb 3 Jaw Chuck (Tripod) Open		Ring and little fingers remain open. Thumb automatically moves to a partially closed position. Only index and middle fingers will move to provide grip against the fixed thumb.	For smaller motion, but increased accuracy. Tripod grip allows for greater stability with larger or round objects in comparision to Precision Pinch. May also decrease elbow compensation when seated.	Grab spices from cupboard Open bag of chips
Standard 3 Jaw Chuck (Tripod) Closed		Ring and little fingers remain closed. Thumb, index and middle fingers actively open and close together to provide grip.	Allows for a wider space opening tio pinch larger objects. Tripod grip allows greater stability for larger or round objects in comparision to precision pinch.	Open bag of chips Pull up socks
Thumb 3 Jaw Chuck (Tripod) Closed		Ring and little fingers automatically close and switch off. Thumb auto- matically moves to a par- tially closed position. Only index and middle fingers will move to provide grip against the fixed thumb.	Can improve stability and control grasping larger objects. With thumb in a static position, your ability to align an object can improve particularly on small objects. Can also decrease elbow compensation when seated.	Repetitive factory type work moving pieces Grasp pen for writing Laundry Pack bag

Note: Due to the stall out ability of each individual digit, both Precision Pinch and Tripod Grip can be achieved in the Standard Hand Mode (i.e. no Features have been activated).

Additional Features

Feature	Picture Example	Description	Use	Task Examples
Thumb Park Continuous		Thumb rotates to palmar adduction and the other four fingers remain fully open. Only the thumb moves open and closed.	For longer dressing period that will require more than the 1.5 seconds of thumb park quick or grasping light weight flat objects. Can also use stalling out digits to complete, putting pressure against index to little and closing thumb in to hand.	1. Put on jacket 2. Grasp flat objects, such as a book or a tablet computer or clipboard 3. Opening letters or sorting paperwork.
Thumb Park Quick		Thumb rotates to palmar adduction and the other four digits remain fully open. Only the thumb moves open and closed for 1.5 seconds of run time. In contrast to Thumb Park Continuous, this feature returns to the Standard Hand Mode after the open signal is sent.	Dressing or putting on a coat. You can achieve this position by using the stall out capability of digits against a table if you do not want to program.	1. Put on jacket or shirt
Lateral Grip		Thumb automatically rotates into lateral position and partially closes. All four fingers fully close and switch off. Only thumb will move.	Holding onto plate, papers, CD or other flat objects. Improved stability with use of the side of the index finger. See additional images on page 10.	 Hold plate while serving food Hold clipboard Get card from ATM Open ziplock bag Tie Shoe Laces Hold a utensil
Index Point		Thumb automatically rotates into lateral position and fully closes. Thumb switches off. Middle, ring and little fingers fully close and switch off. Index finger remains open and active	Used for pushing buttons, typing on computer, or simply pointing. Can be achieved with stall out.	Keyboarding (pressing shift key, CTRL, ALT, DEL, general typing) Push Button for elevator
Custom Gesture		All digits automatically move to a user defined position with each digit option as open or closed. There are 2 programmable custom gestures available in this feature.	Allows user to customize the hand. Many positions can be obtained using stall out if the user does not have enough available triggers to use this feature.	Boy scout salute Sign Language gestures such as "I love you"
Custom Grip		Digits move to user defined position with options for degree of open or closed and option to keep selected digits "active."	Can be used to fully customize for use of specific tool for work or hobby. Multiple can be set up as "favorites" on iPod.	1. Customize grip to specific work or hobby type tool 2. Supporting and operating a camera

Extra Features Available with the i-limb ultra revolution

The i-limb ultra revolution offers ten additional Features than the i-limb ultra, for a total of 24 pre-set Features.

Feature	Picture Example	Description	Use	Task Examples
Rotate Thumb on Exit		Thumb and all four fingers fully open. Only thumb will rotate for 2.5 seconds of run time.	No flexion or extension of the digits will occur, one signal will rotate thumb laterally and the other will rotate into the palm.	1. Used to position the thumb when you do not want to use the manual override. Can ONLY be used if the option to rotate the thumb when exiting the feature is turned off.
Open Palm		Thumb automatically rotates laterally and closes partially. All fingers remain open. All digits switch off.	For tasks where balancing an object on the open hand is useful.	Stabilize a tray of food Balance a Bowl
Cylindrical		Thumb rotates automatically to a semi lateral position. All digits are active in this feature.	Many handled type objects require this cylindrical grip. You can also use the manual override of the thumb to position manually rather than having to use this feature.	Shovel or Rake Hair Brush or Hair Dryer
Mouse		Hand forms shape appropriate for using a computer mouse.	Note that multiple steps are involved in this grip: Step 1: Place the closed little finger against the side of the mouse. Step 2: Provide a close signal until the thumb rests against the other side of the mouse (the thumb must detect pressure, so you may also provide pressure with your other hand if the thumb will not stop) Step 3: The index digit will now close with the signal to click the left mouse button, relaxing signal will re-open.	1. To left click, use signal to close index digit 2. To right click, use motion of the arm to put pressure on the mouse from the ring digit
Handshake		Thumb automatically rotates into semi lateral position and partially closes and switches off. All fingers remain fully open. When a close signal is given the fingers close, when this signal is relaxed the fingers open.	Note that with this feature the thumb moves to a slightly closed position and only the digits will move with the closed signal. As soon as you relax the signals the hand will automatically re-open.	1. Shaking hands

Feature	Picture Example	Description	Use	Task Examples
Grasp		Hand adopts partially closed position. When a close signal is given the hand closes at full speed. (no proportional control). When the close signal is relaxed the hand will fully open and then reposition into its partially closed starting position again.	For grasping objects where crushing the object is not a concern. Note that as soon as you stop giving a signal the hand will open automatically and reset to the slightly flexed position.	1. Sorting objects 2. Grasping large soft objects such as socks when packing a suitcase
One Finger Trigger		Thumb automatically rotates into opposition and partially closes. All fingers partially close. When a close signal is given the thumb, middle, ring and little fingers close. Once they have stalled around an object the next close signal will operate the index finger in squeeze mode (when a close signal given index will close, when signal relaxed index will open).	Note this feature requires multiple steps: Step 1: Enter the feature using either the trigger or "Quick grip". Step 2: Provide a close signal until the thumb, middle, ring, and small digits have fully closed around the object being held. Step 3: Providing a close signal will close the index digit onto the trigger and relaxing the signal will re-open the digit.	1. Pulling trigger on a small spray bottle
Two Finger Trigger		Thumb automatically rotates into opposition and partially closes. All fingers partially close. When a close signal is given the thumb, ring and little fingers close. Once they have stalled around an object the next close signal will operate the index and middle fingers in squeeze mode (when a close signal is given the index and middle will close; when the signal is relaxed the index and middle digits will open).	Note this feature requires multiple steps: Step 1: Enter the feature using either the trigger or "Quick grip" Step 2: Provide a close signal until the thumb, ring, and small digits have fully closed around the object being held Step 3: Providing a close signal will close the index digit onto the trigger and relaxing the signal will re-open the index and middle digits	1. Pulling trigger on spray bottle
Thumb Trigger		Thumb automatically rotates to a semi lateral position and partially closes. All fingers partially close. When a close signal is given, fingers will close around the object, once fingers are stalled the thumb will operate in squeeze mode (when a close signal given thumb will close, when signal relaxed thumb will open).	Note this feature requires multiple steps: Step 1: Enter the feature using either the trigger or "Quick grip". Step 2: Provide a close signal until the index, middle, ring, and small digits have fully closed around the object being held. Step 3: Providing a close signal will close the thumb onto the trigger and relaxing the signal will re-open the thumb.	1. Pressing down on a small aerosol can button
Donning or Doffing a cover		Hand forms the proper shape for donning and doffing a cover.	When changing out covers for the hand to avoid too much pressure against the thumb.	Putting on covers Taking off covers

More Information on the Lateral Grip

Also known as 'key grip', the Lateral grip occurs when the thumb closes down on the side of the index finger. The Lateral grip allows the user to grasp flat shaped items such as a plate, or key. It enables the individual to comfortably hold a plate or to manipulate credit cards when making a payment transaction. Some other examples of tasks in which lateral grip can be useful are dressing and writing. This grip pattern can significantly reduce the need for compensatory techniques with many tasks. Users also find that the flat surface area and increased pinch force in this grip pattern assists with opening packages and getting a firmer grip on objects.

Rather than programming this grip, many unilaterally involved individuals will simply rotate the thumb laterally and place the object directly into the hand. However, the Lateral grip feature allows the four digits from index to small to fully close and switch off, a valuable capability for performing many tasks (i.e. picking a plate off a table or opening a drawer). In many of the tasks where Lateral grip is useful, the object sometimes blocks the user's view of the digits. By making the digits inactive, one can minimize this challenge.

Additional Images for Lateral Grip Uses:











2.3 Operating in Standard Hand Mode

Although there are many benefits that come from using the available grip modes in the i-limb hand, it is important to note that by using the Standard hand mode with compliant (or conformable) grasp capability, the hand can achieve many common grasp patterns without any additional programming. These include:

Power Grip

Power grip occurs when the thumb and four fingers close to create a gross grasp. The i-limb is able to adapt and conform to the unique composition, shape and size of an object. For example, proportional control technology allows for the slow movement of the digits to lightly grasp around an object such as another person's hand. Vari-grip allows the user to adjust the grip strength depending on the item and task at hand. This is helpful when performing more difficult tasks such as tying one's shoe or opening a jar. This power grasp can also be utilized in activities such as holding tools.



Spherical Grasp

The Spherical grasp is designed to be a compliant grip that will stabilize the object without exerting a damaging amount of force. Examples of this include holding a ball or stabilizing fruits/vegetables when peeling them.



Hook Grasp

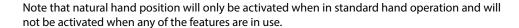
Hook grasp is utilized for carrying heavier loads such as a briefcase or light suitcase. All four digits are used to create a strong hook position. Clinicians should train the user to position the weight of the object as close to the knuckle block and palm as possible and to fully close around the object to prevent unnecessary torque on the digits.

When lifting objects, using a palms up to the ceiling method ensures the object stays balanced over the strongest point on the hand. This will help prolong the life of the prosthesis. Refer to "Usage Do's and Don'ts" in section 5.3 of the Appendix for more precautionary measures.



Natural Hand Position

The hand will return to a natural hand position after the hand has been fully opened and there are no additional input signals for a predetermined amount of time (between 2 to 30 seconds). The hand must be fully opened for Natural Hand to be activated. This ensures the hand does not accidentally go into the natural hand position when the user is holding an object. This feature can be programmed "on" or "off" and the position of the natural hand can be adjusted to the user's preference.





Rotate Thumb On Exit

Rotate thumb on exit programs the thumb to automatically rotate to the palmar position every time the user exits a different grip pattern.



vari-grip and auto-grasp

vari-grip and auto-grasp come as standard on i-limb ultra revolution and i-limb ultra. Both can be turned off or on depending on user preference and functional tasks. For example, a user may decide to turn vari-grip on when tying their shoes or opening a jar of pickles.

2.4 Wrist Options

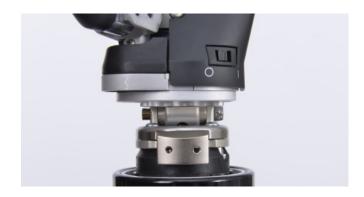
The i-limb ultra revolution and the i-limb ultra are compatible with several wrist options. Wrist options add weight and length to the overall prosthesis and the prosthetist often determines if they are necessary /appropriate for the user. The standard i-limb hands come with the Quick Wrist Disconnect (QWD), a wrist that the user can manually rotate to achieve supination and pronation. Another option is the Wrist Disarticulation (WD), which is fixed and provides no rotation. The WD is fabricated directly into the socket frame, then attached to the i-limb. The prosthetist may choose to add an electric wrist rotator to help with supination/pronation particularly if the patient is involved bilaterally. It is important that the therapist understands how the wrist componentry functions to provide the best support possible to the user.

Other wrist options include Flex Wrist and Multi-flex Wrist:

Flex Wrist

The flex wrist option offers a locking wrist that can be positioned in three wrist positions: 30° dorsiflexion, 0° neutral and 30° palmar flexion. The lock button is easy to control and may be particularly helpful for individuals involved bilaterally for tasks at midline.

For more information, see the document library on the Touch Bionics website: www.touchbionics.com/downloads/document-library.



Multi-flex Wrist

A multi-flex wrist allows for passive flexion, extension, radial and ulnar deviation and can compensate for loads placed on the hand.

The lock can be used to lock the wrist up to 30° dorsiflexion, 0° neutral and 30° palmar flexion. However, many users keep the wrist unlocked for a more natural feel.

If the lock is used, it is important to note the wrist is spring-loaded and the user must release the spring tension when un-locking by pushing the hand in the direction it was locked. The wrist cannot be locked in ulnar or radial deviation.

For more information, see the document library on the Touch Bionics website: www.touchbionics.com/downloads/document-library.



3.0 Training Protocol

3.1 Pre-Prosthetic Training Phase

Below is an overview of the phases and key elements for pre-prosthetic training.

3.1.1 Acute Pre-Prosthetic Training Phase

Evaluation

In the early acute phase of pre-prosthetic training, the client's therapist should complete a standard functional and orthopedic-based evaluation. Your evaluation should address functional difficulties in activities of daily living (ADL), instrumental activities of daily living (IADL), work, and leisure tasks. The therapist should also assess wound healing, edema, sensation, pain, body symmetry, and the range of motion and strength of all remaining joints. If the involved side was the dominant one, the therapist should also assess sound-side prehension and dexterity. Subjectively, it is also important to understand the client's previous level of function, individual goals, home environment and whether or not the client has access to psychosocial support. Depending on what this assessment uncovers, the therapist may need to recommend home modifications or adaptive equipment to improve the client's independence. Also, the loss of a limb has been equated psychologically with the loss of a sibling; therefore a strong support system is essential and additional psychosocial intervention may be necessary (Forducey, Ruwe, & Kaur, 2006).

ADL Training

When the client's limb loss or deficiency has affected his or her feeding, oral hygiene, and toilet hygiene, these are typically the first priority (Smurr, et al., 2008). Additional ADLs can be prioritized based on the client's goals and functional level. When possible, continue to incorporate the affected side during training. This prevents individuals from becoming too reliant on their sound side and helps them think about tasks in a bilateral manner.

3.1.2 Subacute Pre-Prosthetic Training Phase

In the subacute pre-prosthetic training phase, the therapist should continue many of the interventions begun in the acute phase such as body symmetry, ROM, strength, desensitization and edema management. During this phase, many of these interventions can be transitioned to home therapy programs to make room for additional in person pre-prosthetic training with the therapist.

Progression of ADL Training: In this phase, ADL training and the use of adaptive equipment should progress to allow for more independence with ADL and IADL tasks. These tasks should be determined according to client preference.

Myosite Testing and Training

In order to effectively operate a myoelectric controlled prosthesis, the clinician must first identify the appropriate myosites on the individual's residual limb. Conducting myosite testing early on in the process has been shown to greatly benefit training and improve outcomes overall. For this reason, military facilities typically conduct myosite testing and training within three weeks of the amputation (Smurr et al., 2008).

Myotesting helps to determine the sites that will provide the most strength and control for operating the prosthesis effectively. The biofeedback from myotesting helps to further strengthen and build endurance in these identified sites, providing optimal results for the user.

The virtu-limb, Touch Bionics' wireless simulation and training tool for myolectric upper limb prostheses, assists clinicians with the myosite testing and training process. The virtu-limb can be used with i-limb products or several other myoelectric devices, and is compatible with remote electrodes, compact electrodes and FSR touchpads. By placing electrodes on top of a patient's myosites, the virtu-limb can measure the myoelectric signals to determine the best muscle sites for the prosthesis. The virtu-limb also assists with training patients on how to control their muscle signals and how to use the myoelectric device's features. The practitioner has the option to use either an on-screen representation of an i-limb ultra revolution, or connect the myoelectric terminal device to the virtu-limb to create a simulated environment for training purposes (see figure 4). The virtu-limb provides the added benefit of helping to establish realistic user expectations around the prosthesis' capabilities.





Figure 4

Top Image: i-limb ultra connected to the virtu-limb docking station. Close signal closes the i-limb hand.

Bottom Image: Computer screen simulation. Open signal is reflected on the screen.

Instructions for Myosite Testing

A detailed overview of myosite testing is provided below. A team approach in this phase can improve user success (Smurr, et al., 2008). Typically the prosthetist selects ideal sites for the therapist to train with during sessions. As training continues, the therapist may identify issues isolating muscle contractions, relaxing the muscles in certain positions, or challenges with overall control. By communicating this information back to the prosthetist prior to the final fitting, adjustments can be made to improve ease of use for the individual being fit.

Step 1: Prepare the Client

- 1. Once the prosthetist has identified the myosite you would like to test/train, lightly clean the skin surface with an isopropyl alcohol swab. This will remove any oils that could interfere with testing.
- 2. Palpate antagonistic muscle groups for two-site control, or a single usable muscle group for single-site control. (See common muscle sites below.)
- 3. Once you have identified the middle of the muscle belly, make a small mark on the area with an indelible pencil or a permanent marker.
- 4. Moisten the skin with a wet paper towel to improve electrode conductivity.

Common myosites used to control the i-limb hand include:

Transhumeral Level

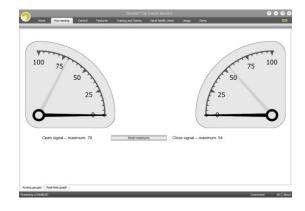
Bicep and tricep muscles

Transradial Level:

- Wrist flexors
- Wrist Extensors

Step 2: Begin Myotesting

- Begin by rotating the dial on the back of the electrode to set the electrode gain between 4 and 5. Place the electrode over one of the marked locations established in step
 Make sure the electrode runs longitudinally with the muscle belly.
- 2. If using the virtu-limb, establish a wireless connection between the virtu-limb and the biosim software by connecting the provided Bluetooth dongle (or "Handshake") to the USB port on your computer and following the three easy steps on the biosim home page. Alternatively you may connect to the biosim app on various mobile devices.
- 3. Once you have successfully connected, select the "myotesting" link in the biosim program home page. This takes you to the analog gauges screen. Instruct your client to contract his or her muscles, aiming to produce open and close signals between 25 and 75 each. If the individual is struggling, you can coach them to contract the same muscle(s) on the sound side (if applicable) in order to help them identify what the movement should feel like. The therapist can further assist by applying manual resistance to the contralateral side while mirroring the desired motion.
- 4. Once the individual is able to establish a strong enough signal, ensure you have established the optimal site by moving the electrode proximal to the initial site while instructing the patient to continue to contract and relax the muscle as you move the electrode to new locations. Once the signal strength begins to decrease, mark a line along the proximal edge of the electrode.
- 5. Next, move the electrode distally from the initial site and, when the signal begins to decrease, mark the client's skin along the distal border of the electrode.



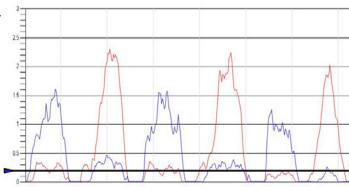
- 6. Repeat these steps in the radial and ulnar directions from your initial mark so you end up with a border around the proposed electrode site. The ideal electrode site should now be in the center of this outlined area.
- 7. If multiple electrode sites are to be used, repeat 1 through 6 for these locations.

Step 3: Verify Isolated Control

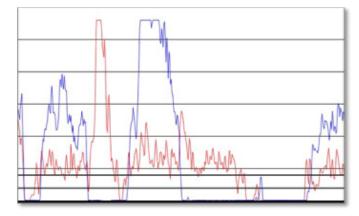
Now that you have established the proper electrode placement, you will need to ensure the client can independently isolate each muscle contraction to establish good separation between the open and close signals.

- 1. Open the real-time graph tab at the bottom of the myo-testing page. This provides excellent biofeedback for isolated control training. To begin, instruct your client to contract the "open" muscle group, relax, and then contract the "close" muscle group. The red lines that show up on the graph upon contraction refer to the open signals and the blue lines refer to the close signals. While your client repeats these muscle contractions, verify that the opposing muscle group remains relaxed or, at least does not overtake the active muscle group.
- 2. Ensure that the electrodes are in the ideal locations and are not picking up interference from other muscle groups or from general motion at remaining joints.
- 3. The prosthetist can make gain adjustments to the electrodes to provide appropriate separation of signals, but at least 40% signal strength should be obtainable from each electrode site. Ideal gain settings are between 3 and 5 on the dial on the back of the electrode. Higher gains settings may indicate too weak of a muscle. A higher than desired gain setting will often decrease as the client's muscle and control are strengthened and refined from the training process.
- 4. Coach your client to relax all muscle signals while moving in various planes of motion to ensure muscle signals stay at a minimal level (less than 0.5). Also ensure that the client is able to activate the muscle groups across various planes of motion by creating a range of signal strengths in various positions.

Optimal Graph: Red (open signal) and blue (close signal) stay isolated with one always stronger than the other



To the right is a graph demonstrating poor control. When the red (open signal) and blue (close signal) mix, the hand will jump back and forth, causing frustration to the user.



Once myosites have been selected, the therapist can begin training with either games or by using the on-screen virtual representation of the i-limb ultra revolution. These training games are found by selecting the "training" link on the home page of biosim.

The bottom right corner of the virtual hand screen allows the therapist to watch the strength of each muscle contraction while the client works to open and close the virtual hand. The client can also practice triggers to engage the various features of the hand such as the tripod pinch and precision pinch modes. The virtual hand can be rotated around on the screen to the client's preference by clicking and dragging with the mouse.

Adire forces Tomas

Games can work on signal strength, signal separation, or any of the triggers required to activate the hand's features.



3.2 Prosthetic Training Phase

Basic Training with the Prosthesis

Orientation to the hand opening and closing is important to review and reinforce. If adequate myoelectric testing and training has been accomplished, this should be an easy exercise. It may also be quite meaningful for the patient to view his or her new hand responding to this thought of open/close. Practice positioning of the thumb is also important to discuss and practice prior to engagement in tasks.

Achieving Independence in Donning and Doffing the Prosthesis

When training the patient to don and doff the prosthesis on their own, it is important to establish independence as early as possible. The therapist should carefully review donning and doffing with the prosthetist before training the client. Donning a transradial socket is typically achieved by push-in, pull sock or silicone liner-assisted methods (Figure 5). The therapist and client should be familiar with the method of choice and practice it during each visit.

Figure 5
Silicone Liner Method



Push- in Method



Pull-in Sock Method



Understanding Device Componentry

If there are additional components to the terminal device, the therapist should review each one to ensure the individual understands how to use it. For example, with the flex wrist, you can show your client how to flex or extend the wrist by pressing the button on the volar aspect of the wrist using either the contralateral hand or the edge of a table. The wrist will move into flexion or extension with gravity or by manually positioning with the contralateral hand. The therapist should also discuss the benefits of each position. For example, wrist flexion helps with tasks completed at midline while wrist extension can help to decrease compensation at the shoulder for certain tasks.







Orientation to Prosthetic Wearing Schedule

It is extremely important to review a prosthesis wearing schedule early in the training process, ideally within the first few visits. This is often prescribed by the prosthetist. By the end of the first week, the individual may be wearing his/her prosthesis all day, barring any complications. It is also important to keep in mind that muscle endurance will build up over time, so frequent rest breaks will help avoid the frustration and loss of control often associated with muscle fatigue. Educate the patient to be aware of the signs of fatigue so they can start to become responsible for their own wearing schedule.

Care of the Prosthesis

Since at this point, your client will be taking his/her prosthesis home each day, it is a good time to address "Warnings and Precautions" and "Charging the Battery", which can be found in the i-limb ultra revolution User Manual within the website's document library: www.touchbionics.com/downloads/document-library. "Warnings and Precautions" is also available in the Appendix.

Care of the prosthesis should be followed according to the prosthetist's directions. Oftentimes this is accomplished with a dish soap and damp towel. Other times, the prosthetist might prefer rubbing alcohol to help prevent bacteria buildup on the inside of the socket.

Evaluation of Progress with Prosthesis

The therapist is often re-evaluating progress in ADL/IADL function as well as ROM, strength, and other initially evaluated body functions and structures. It is also helpful at this phase to evaluate baseline data on prosthesis control. The Patient Care Pathway is a unique platform designed by Touch Bionics to measure the progress of patients, through validated outcome measures. Pre fitting scores are established from the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH) and the Trinity Amputation and Prosthesis Experience Scales – Revised (TAPES-R). Refer to the Patient Care Pathway literature on www.touchbionics.com for more information and guidance for use.

The biosim software can also assist in tracking usage data and watching muscle signals during functional training. More information on biosim can be found in section 4 of this manual.

Education on Pre-positioning the Prosthesis for Function

Appropriately positioning the prosthesis to achieve different functional tasks is key to avoiding compensatory movements at remaining joints. Thus, the individual should be taught to appropriately supinate or pronate the hand based on the task.

Orientation to Grasp and Release Activities

1) Objects of various sizes including cones and blocks can be used to orient the user to basic grasp and release patterns. A Form Board is another useful training tool during the preparatory pre-ADL task training.

By placing a variety size and shaped objects in corresponding size and shaped spaces on the form board, the client is able to practice and perfect pre-positioning and control of the hand. While going through this exercise, pay special attention to any awkward or compensatory body motions as the client approaches or releases an object. These movements include hiking up the shoulders, winging out the elbow, awkward neck positions, excessive internal/external shoulder rotation, and trunk compensation. If you notice any awkward or compensatory movements, remind your patient not to adjust his/her body when approaching a task. By utilizing a variety of objects, the individual will learn how to pre-position the thumb to achieve different grips, eventually mastering lateral, pinch, tripod and spherical grasps. This will also help the patient to understand why certain grips are appropriate for different objects, and allow them to choose the most functional grip for the task. Teaching the individual how to transition between the various grip patterns prior to the ADL training makes these movements more natural once the time for ADL training has arrived.

The following items can be incorporated into the basic grasp/release activity:

- Blocks
- Balls
- Dice
- Triangular piece of foam
- Styrofoam and/or paper cup
- Stones or marbles
- Soda can, bottle or cones
- Coins
- Pencil or pen
- Paper clip/safety pin
- Nail/Nut/Bolt
- Fork/spoon
- Small candies
- Checkers
- Keys
- Credit card or playing cards

2) Grasp and Release in Various Planes

After mastering grasp and release at midline, you can begin mixing things up, placing the objects at various heights and angles. Increasing the variability of training tasks has been shown to allow improved functional outcomes and greater improve application of skills to novel functional tasks (Weeks et al, 2003). Learning to relax the muscles can sometimes prove more challenging for the client than grasping and releasing. It is natural for the client to feel he/she must sustain the close signal in order to maintain a firm hold on an object. However, the i-limb ultra revolution is built so that once the hand has grasped an object, the wearer can relax the muscle without having to worry about dropping it. This ensures the wearer does not exhaust his or her muscles in the process. The weight of the prosthesis and movement of the residual limb can also make it more difficult to maintain a relaxed signal. Practicing grasping and releasing objects at various heights will help to ensure the wearer can activate and relax muscle signals across all planes of motion and with different loads placed onto the prosthesis.

The therapist may begin incorporating purposeful functional activities at this time; however, perfection and skill of how to approach, position, and release an object are of utmost importance, and should be the focus during this phase of training. After mastering basic grasp and release patterns, you can begin shifting your focus to more unilateral and bilateral grasping tasks. By appropriately grading activities, the therapist can provide a "just right" challenge for the client. The therapist should continue to provide verbal cueing to avoid compensatory motions and to pre-position appropriately for the task.





3) Stacking Plastic Cups:

Another excellent activity for reinforcing grasp and release is to have your client stack large plastic or Styrofoam drinking cups into a pyramid formation. This task helps to train proportional control as it forces the user to give small, concise muscle signals to avoid crushing the cups. Mastering this task will result in the individual's ability to hold a cup of coffee or any other beverage without crushing the cup.

4) Training with Games:

Jenga (Hasbro, Inc.), Connect 4 (Hasbro, Inc.), Dominoes, and Mancala--Games can be a fun and challenging way to practice incorporating multiple grasp patterns throughout a task. The therapist should be confident that the client is ready for this challenge to avoid unnecessary frustration.

Unilateral ADL Task Training

To minimize frustration and enhance learning, task-based activities should begin only when the client is completely familiar with the control site operation and can control grasp and release.

Unilateral task training includes ADL and IADL grasping tasks. For individuals with unilateral involvement, the prosthesis will act as a functional assist to the sound hand for these types of tasks. For example, when pouring a drink the individual will most likely use the prosthesis to stabilize the cup while pouring with the sound side. It may be helpful to practice both ways so the individual can practice control and also determine the manner in which they find the most benefit of the prosthesis. For those individuals with bilateral involvement, control should be mastered on each side independently before progressing to having one hand stabilize while the other side engages with the task.

Again, attention should be given to the client's posture and positioning to ensure that the task is performed in a natural manner. Each of these tasks reinforces the different grasping possibilities of the i-limb ultra revolution and i-limb ultra. There are numerous other tasks as well, and those listed are simply examples.

Unilateral Tasks performed while sitting may include:

- Bringing a glass, bottle, or can to mouth (Note: Factors such as socket design and residual limb length might limit elbow movement, making this task more difficult for some to achieve).
- Writing with a pen or pencil (or stabilizing the paper)
- Picking up Skittles, M&Ms, or grapes to eat or put in a bowl
- Grasping a fork, spoon, or knife
- Using a salt or pepper shaker
- · Using a mouse or keyboard
- Putting on a sock
- Picking up a coin
- · Holding a cell phone
- Eating potato chips or crackers
- Playing cards using a card holder
- Turning pages of a book or newspaper

Unilateral Tasks performed while standing may include:

- · Carrying a glass, bottle or can
- Walking while carrying a bag or briefcase
- Using a key in a lock or turning a doorknob
- Retrieving items from shelf or refrigerator

















Bilateral ADL Task Training

For the unilateral amputee, the bilateral ADL task training reinforces the real value of the i-limb ultra revolution hand as a "functional assist" in bilateral activities. The selection of activities will be based, in part, on the client's preference, depending on his or her interests. A variety of activities should be used to expose the client to a wide range of grasping patterns. Creative thinking and planning, on the part of both the therapist and patient, can make this a fun and engaging part of the therapy process.

Bilateral Tasks performed while sitting may include paper and pencil tasks:

- 1. Use a ruler to draw a 4 x 4 square; cut out the square using scissors
- 2. Wrap a gift box (or paperback book) use scissors, scotch tape, and tie a bow
- 3. Fold a letter in an envelope, seal the envelope, open the envelope, and remove the letter
- 4. Remove an ink cap from a pen or marker
- 5. Use a paper clip to secure papers together









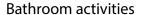






Home activities

- Cut a length of thread with scissors; thread needle
- Use a cell phone and make a call
- Open a variety of bottles and containers
- Handle money (bills in wallet, coins in purse)
- Use knife and fork to cut food
- Butter a slice of bread
- Playing cards
- Sew button
- Strike match
- Serve food onto a plate buffet style
- Tie up garbage bag



- Shaving
- Brushing teeth (putting toothpaste on toothbrush)
- Fastening and unfastening clothing
- Toileting
- Putting on deodorant
- Styling hair
- **Cutting Nails**

Dressing activities

- Put on shirt
- Fasten buttons
- Put on trousers and belt
- Fasten pants, pull up zipper
- Put on shoes
- Tie shoe laces
- Put on glasses
- Pull on socks
- Put on jacket and zip or button







Kitchen activities

- Cut fruit or vegetable on a cutting board
- Meal preparation
- Open milk/juice container
- Pour liquid from pitcher into different sized glasses/bowls
- Open a bag of chips or zip-lock bag
- Open jar
- Eat banana











Household maintenance activities

- Iron clothes
- Sweep floor with broom
- Use dust pan and brush
- Remove file from drawer, open file, remove paper, and replace file in drawer
- Replace book on shelf
- · Fold Laundry
- Make bed

Advanced ADL Task Training

The Advanced ADL task training phase is the final stage of training and focuses on helping the client to achieve their personal, leisure, recreational, and/or vocational goals. Community re-integration training is also common in this phase. The personalized nature of this phase makes it important to focus these sessions on the specific interests of the client, whenever possible.

Activities might include:

- Preparing a full meal
- Using light tools and completing a small and simple woodworking project
- Simple repairs or home "fix-it" projects
- Grocery shopping
- Visiting a mall/shopping/negotiating a food court
- Visiting a local home store to test out various tools

TRAINING TIP: When performing these tasks the user may find the need to activate 'vari-grip' to improve performance. When utilizing 'vari-grip', if the user has any difficulty, the therapist should use the biosim graph of myosite signals to provide feedback. The closing signal must be maintained above 1 on the myo-testing graph for a preset amount of time (default = 500ms) before the vari-grip will activate.











Discharge from Therapy

The therapist can begin to lessen the frequency and intensity of training once the client has mastered proper use of the prosthesis and has begun to integrate the prosthesis into their daily life. At this point, you can consider taking a month hiatus from training, asking your client to continue to use the prosthesis daily and schedule a 30 day follow up appointment to ensure no new challenges have arisen. If at the follow up, the user is able to continue adapting tasks and using the prosthesis appropriately then it may be time to discharge them from therapy.

When discharging a client from therapy, make sure to remind your client that he or she should continue to follow up with their prosthetist with any concerns. Also, consider any additional services your client might benefit from such as Vocational Rehabilitation or Driver's Rehabilitation. Use this final visit to answer any outstanding questions for your client such as charging the battery, troubleshooting problems, and safety/efficiency guidelines for use. For more information about these subjects, please refer to the i-limb ultra revolution User Manual under the document library of our website: www.touchbionics.com/downloads/document-library.

4.0 biosim Overview for Therapists

4.1 biosim Overview

biosim is the software for programming the set up and personalization of the i-limb ultra revolution and i-limb ultra as well as the control software for the virtu-limb. The i-limb ultra revolution and the i-limb ultra are fitted with a Bluetooth® receiver enabling them to work with biosim. biosim-pro is the clinician's version of biosim and biosim-i is the version designed for patient users. biosim makes it possible to make changes to the functionality of the hand. biosim-i, the simplified patient user version of the software, provides access to training and games features along with some basic 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 health check.

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.

4.2 Connecting to biosim

The biosim software program must be downloaded from the Touch Bionics website at: http://www.touchbionics.com/downloads/biosim. After downloading the software, load biosim by clicking on the biosim icon (fig. 6) which should be clearly visible on the biosim home screen. The biosim Handshake device (fig. 7) must also be inserted into a USB port to allow the Bluetooth signal to be received by the i-limb prosthetic device. The Handshake Bluetooth receiver will pick up signals within a 10 meter range.

The opening welcome screen will load. The language can now be changed from the default English to either German, Spanish French or Italian. This is done by clicking on the language indicator at the bottom right hand side of the screen and scrolling to the required language. The first numerical icon "insert handshake" request will flash. On insertion of the handshake (biosim device) the icon will be constantly lit, the "handshake installed and ready" box will then self-tick. The second icon will now be constantly lit and the third icon "Connecting to device" will flash. The tab marked "connect" must now clicked for the connection to be made, this will take approximately 15 seconds.

If there is more than one i-limb device within range of the Bluetooth receiver then a box will appear listing all devices by serial number. The correct i-limb device can then be selected from the list. The hand serial number is located at the wrist portion of the hand at the base of the thumb.

Figure. 6

Figure. 7

Figure. 7

Figure. 7

Figure. 7

4.3 Navigating biosim

The areas of biosim that are important for therapists to know about are listed below. A more comprehensive overview of biosim can be found in the i-limb ultra revolution Clinician's Manual at www.touchbionics.com/documents/document-library.

The "You're now connected" screen will now be showing with eight options as illustrated, this is the homepage and can be accessed at any time from subsequent pages.

Myotesting icon provides a quick and easy myosite test along with a more detailed analysis screen. This is excellent for providing biofeedback during therapy sessions.

Control strategy details the choice and information around the range of control options as well the logging of user information. This is mostly used by the prosthetist to set up the hand.

Features allows the set-up of the i-limb ultra revolution by linking triggers with grip patterns and gestures. The therapist might find it beneficial to explore different feature options in therapy and communicate needs and/or changes with the prosthetist.

Training provides access to the training suite and a selection of games to improve overall hand control. These may be used in the pre-prosthetic training phase or if the individual is struggling with control.

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

Usage icon provides access to a tally of individual movements with additional analysis. This may be helpful to review to see how much the individual is using the hand outside of therapy.

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

Don or Doff icon positions the i-limb ultra revolution for putting on or taking off a cover.







Control strategy



Features



Training



Hand health check



Usage



Exi



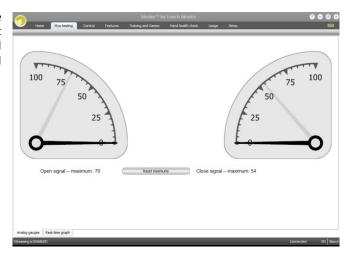
Don or Doff

4.3.1 Myo-testing



Myo-testing

The details of myo-testing can be found in the Pre-Prosthetic training section. In the Prosthetic training phase, the real -time graph is beneficial for providing biofeedback during functional training.



The Real-time graph screen plots a graph of impulses in realtime, with open impulses in red and closed impulses in blue.

Gain and Threshold levels are set by the prosthetist.

Training mode option enables training with specific triggers.

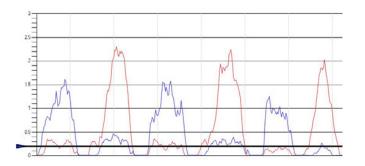
Start/stop graph

Start/stop graph

Rewind History View Saved Zoom Out

Graph

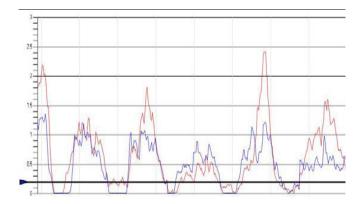
The graph below shows good separation of inputs with the opposing channel remaining below the threshold level. Ideal signals are between 1.5 and 2.5 in order to obtain full speed of the hand.



The graph to the right shows poor signal separation with both signals being activated together.

Training Tip for better signal separation:

- 1. Start by having your client rest his or her prosthesis on the table for support.
- 2. Mirror motions with contralateral side (if applicable).
- 3. Provide resistance to the contralateral side motion for additional feedback.
- 4. Try different ways to activate the muscles such as having your client extend wrist and fingers rather than just the wrist or relaxing the fingers and just moving the wrist.



4.3.2 Features



Features

Click on the features icon to enter the features suite. The 'Features' tab allows for the selection of what features (grip patterns of the hand) the user has programmed and what trigger (the signal used to change modes) the client will use to activate that feature. Typically for a new user, only one feature will be programmed

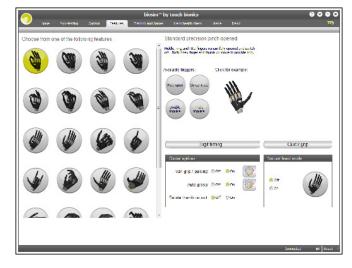
until that is mastered upon which point, additional features will be added.

When training the user, it is helpful to set up the feature and trigger(s) and then return to the myo-testing tab to observe signals using the "training modes". The therapist should ensure the user can enter and exit the feature and that they do not accidentally enter the feature during normal motion. If training doesn't improve function, the therapist should consult with the prosthetist so that he or she can make trigger adjustments.



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 in Touch Bionics lime green. 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. The illustration indicates the Standard Precision Pinch Open feature linked to the precision pinch open feature.



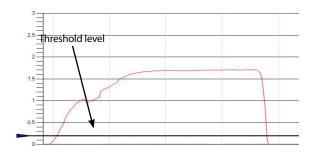
4.3.3 Triggers

A trigger is the signal sensed by the electrode. Four potential triggers are available, Hold open, Co-contraction, Double impulse and Triple impulse.

1 Hold open (a prolonged open signal), this is preset to 2,000ms (2 seconds) and can be customized from 2,000 to 5,000ms.

The graph shows a good hold open trigger, the signal strength is well above 1.0V and the signal duration is around 3 seconds.

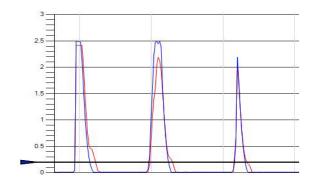
The user should be able to maintain a strong prolonged signal to successfully use this trigger.



Co-contraction is the creation of quick simultaneous open and closed signals. Co-contraction may be customized if a patient has difficulty with activation within the default time.

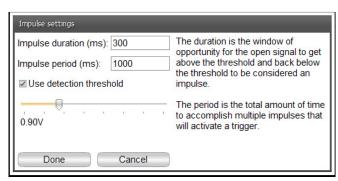
The therapist should work to have the individual fire both muscles strong (above 1 on the graph) and quickly. Training strategies include having the user think about making a tight fist, flicking water off his or her fingers, or making a "hang ten" gesture.

If the individual was struggling with signal isolation, this trigger should be avoided until they master control.



3 Double impulse (two quick uninterrupted open signals) the impulse duration is the period of time that the impulse is above the threshold. It is preset at 300ms and can be customized from 30 to 3,000ms. The impulse period, or period within which the impulse must occur to be recognized, is preset at 1,000ms and can be customized from 500 to 3,000ms.

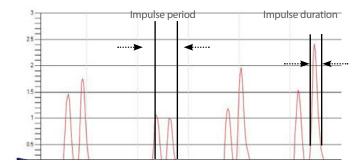
Additionally you may adjust the threshold used to detect an impulse. This is beneficial to weed out inadvertent open signals that may be detected as impulses. If your patient is reporting accidentally jumping into the feature associated with an impulse trigger, consider raising this threshold after consulting with the prosthetist.



The graph to the right shows an optimal double impulse. Both impulses are of sufficient strength to break the threshold, the first impulse drops below the threshold to allow recognition of the second impluse. Both impulses are activated within the preset impulse period.

The hand must first be fully opened before impulsing. the therapist should train the client to hold open for half a second before impulsing.

The therapist can begin by training quick open signals. Users will often fire the close signal when trying to relax quickly. The therapist should encourage "open", "relax", "open", "relax."

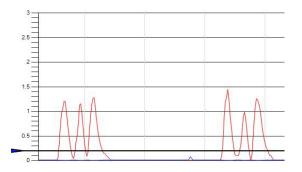


Triple impulse (three quick uninterrupted open signals) settings are the same as with the Double impulse trigger

The graph shows an optimal triple impulse. In a similar manner to the double impulse, the three impulses are of sufficient strength to break the threshold. The first and second impulses drop below the threshold to allow recognition of subsequent impulses. All three impulses are activated within the preset impulse period (impulse period is not indicated on the graph).

The i-limb hand must be fully opened prior to performing the impulses. Using the "training mode" on the myo-testing graph provides feedback on when the hand is fully open and ready for impulses.

Once the trigger is linked to a feature the settings tab appears, providing the option to make changes to timings. In addition the feature is now labeled with the relevant trigger. 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.

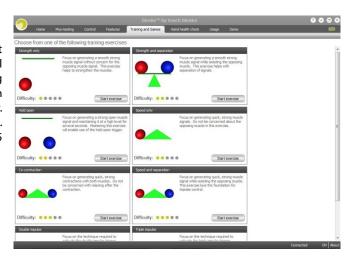


4.3.4 Training



Training

The training suite contains a variety of short training exercises aimed at developing control of the i-limb ultra revolution. The opening screen highlights the series of exercises which can be selected individually and in any order. Both open and close signals can be practiced. An indication of difficulty is provided by the 5 point scale on each module.



4.3.5 Usage

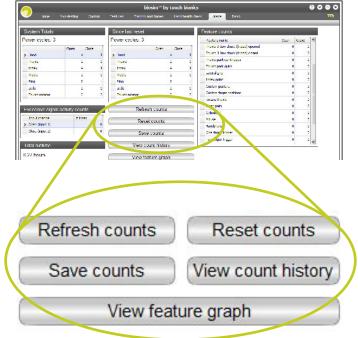


Usage

The Usage suite provides usage information on the number of power cycles (the number of times the hand has been switched on), the total number of runtime in hours, as well as the number of open and close motions for each digit overall.

Feature count gives the number of times the open and closed command has been used with in a specific grip pattern.

The therapist may wish to review this during sessions to see how much the hand is being used as well as common grip patterns used.



4.4 Mobile Apps

Mobile apps are available for both clinicians and i-limb users. The app for clinicians is called biosim, and the app for users is called my i-limb. The therapist may download biosim onto any compatible Apple device, such as:

- iPod 5 or newer
- iPhone 4s or newer
- iPad 4th generation or newer
- iPad mini

The i-limb wearer can access the my i-limb mobile app with the iPod 5, which is provided as part of the package with both the i-limb ultra revolution and the i-limb ultra. The therapist should encourage the user to bring this tool to therapy.

For more detailed instructions on how to use and operate both the patient and clinician versions of the app, visit the my i-limb app, biosim app & biosim software section of the Document Library on Touch Bionics' website:

www.touchbionics.com/downloads/document-library.





5.0 Appendix

5.1 Warnings and Precautions

i-limb ultra revolution

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 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 ultra revolution.

If utilizing a multi-flex wrist, the hand should be locked if carrying an object.

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.

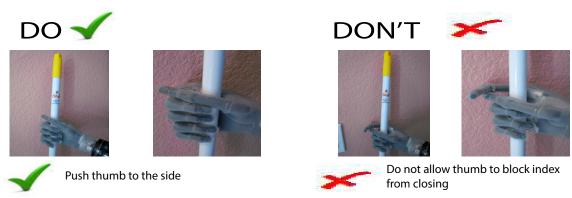
Only use the appropriate Touch Bionics charger to charge Touch Bionics batteries.

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

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

5.2 Usage Do's and Don'ts



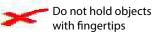
Hold handles or similarly shaped objects securely in palm near the base of the fingers. Move the thumb to the side so that it doesn't block the index from closing



Ensure all digits are fully closed around objects. Do not lift objects with the tips or sides of the digits



Hold objects close to palm with all fingers fully closed



Do not hold objects with side of fingers



Apply the same rules to opening appliances and pulling handles (refridgerators, ovens, car doors, etc.)





Grasp objects close to palm with all fingers fully closed



Do not pull objects with figertips



Use palm up position when lifting/holding heavy objects



Do not lift heavy objects with palm-down position

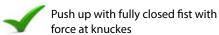


Do not lift with fingertips

5.2 Usage Do's and Don'ts Continued...



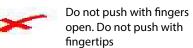












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