ÖSSUR®
LIFE WITHOUT LIMITATIONS

TOUCH SOLUTIONS

i-Limb® & i-Digits™ Reimbursement Support

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TOUCH SOLUTIONS
I-LIMB® & I-DIGITS™

INTRODUCTION - PRODUCT FEATURES

The i-Limb hand is a range of 3 hands offering innovative features which enable the user to personalise their prosthesis to their individual daily needs. The i-Limb hand is available in 4 sizes allowing the closest match to users' size. Full range of thumb rotation from tripod to lateral, manual thumb rotation on all models and additional powered thumb rotation on i-Limb Quantum and i-Limb Ultra hands. A wide selection of grips allows the user to select those grips which are most useful to their daily activities. 4 glove types allow the user to express themselves as they wish.

i-Digits are myoelectric prostheses for individuals with partial hand absence, which are custom made for the individual. I-Digits is a functional partial hand solution, with anywhere from one to five digits able to be replaced. Available in two size ranges, I-digits works in conjunction with remaining digits. A wide selection of grips allows the user to select those grips which are most useful to their daily activities; Up to 20 grip patterns can be utilised. The prosthesis appearance can be customised to suit the individual.

Features	Benefits
Conformable grip	Digits wrap around the object giving a stable and secure grip
Automated grips	Ability for user to personalise the prosthesis to their own needs. (18-36 grips depending on i-Limb hand type)
Proportional Control	Allows users to pick up fragile objects. When a user gives a stronger muscle contraction the hand moves faster while a weaker muscle signal will cause the hand to move more slowly.
Stall Out and Compliant Grip	Digits 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 to provide a compliant grip.
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. Useful for tasks that sometimes require extra force, such as opening a package, a container, or even tying one's shoes.
Powered thumb rotation	Thumb can move throughout the range of opposition to lateral positions without the need to use their sound hand. This frees up their sound hand to do other things and not be needed to position the thumb on the prosthesis. (i-limb Quantum and i-Limb Ultra only)
Glove choice	With i-Limb there is a choice of 4 glove types. This enables the user to select which best fits their personality and lifestyle.
Control methods for accessing grips	i-limb Quantum has 4 methods entering specific grips: gesture control, app control, muscle trigger or Grip Chips. Some users will use just one method, others will use multiple. The user can choose which is best for them and their lifestyle.
User and clinician App	The app allows the i-Limb to be configured to the individual user. The clinician app (Biosim) offers more settings which are only required at initial set up or changes that should only be made by the CPO. The user app (My i-Limb) enables the user to make changes to the i-Limb without returning to their CPO, they can use the app for training as it contains a graph where they can monitor and train their muscle signals. Both apps contain a health check feature to check the device status.
Touch Care	2 year standard warranty program. Offers peace of mind to the user due to its accidental damage cover where if damage occurs to the hand through an accident then it is repaired at no cost. The warranty can be extended up to 5 years.

I-LIMB® HANDS USER PROFILE

Suitable for any level of upper limb absence proximal to the wrist.

- Wrist disarticulation
- Trans-radial
- Elbow disarticulation
- Trans-humeral
- Shoulder disarticulation

i-Limb hands are designed for low to moderate level impact. Clients should be motivated and have realistic expectations. Correct user selection and education is key to ensure optimal outcomes. Occupational therapy training is beneficial in educating users on the correct way to complete tasks to get the best out of their i-Limb hand.

Bilateral users can be fitted with i-Limb hands. Like all potential users, their individual requirements and goals should be assessed to ensure appropriate prescription. Both arms may be fitted with an i-Limb or only one side. Occupational therapy will be essential. Consideration should be given to how the user will don/doff the prostheses and manage charging batteries.

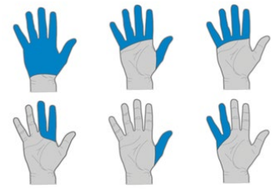
Individuals with bilateral absence are typically heavy on their i-Limbs, therefore a titanium i-Limb hand would be advisable.

I-DIGITS™ USER PROFILE

Level of partial hand loss which is;

- Distal to the wrist
- Proximal of the metacarpal-phalangeal joint
- Absence of 1 or more fingers

i-digits are designed for low to moderate level impact.



FUNCTIONAL BENEFITS

Product Feature	Multi-Articulating Technology
Functional benefit	Improves function: "Improved function for individuals after being fit with multi-articulating full and partial hand prostheses"
Reference	1. Whelan, L., and N. Wagner. **"Analysis of Factors Influencing Outcomes of Full and Partial Hand Multi-Articulating Prostheses."** Journal of Hand Therapy 29, no. 3 (July 2016): 363. https://doi.org/10.1016/j.jht.2014.08.015. (Abstract)

Product Feature	Multi-Articulating Technology
Functional benefit	Reduction in self-perception of disability: "Subjects who utilize electric multi- articulating hand and digits perceived themselves 'less disabled' when compared to hand transplant subjects"
Reference	2. Atkins, D. **"Preliminary Outcomes Comparing Function of Electric Multi-Articulating Hands and Digits, Toe-to-Hand Transfers and Hand Transplantations."** Journal of Proceedings from the American Academy of Orthotists and Prosthetists, 2014. Accessed August 30, 2018. http://media.mycrowdwisdom.com.s3.amazonaws.com/aaop/Resources/JOP/2014/2014-08.pdf. (Abstract)

Product Feature	Multi-Articulating Technology: i-Digits™
Functional benefit	Restores hand function for partial hand amputees: "The prosthesis reduced functional deficits and decreased joint range of motion in individuals with partial hand loss." "Significant improvement was seen in Southampton Hand Assessment Procedure scores in the five-digit limb loss participants using the prosthesis compared with not using the device"
Reference	3. Wanamaker, Andrea B, Lynsay R Whelan, Jeremy Farley, and Ajit MW Chaudhari. **"Biomechanical Analysis of Users of Multi-Articulating Externally Powered Prostheses with and without Their Device."** Prosthetics and Orthotics International, August 30, 2019, 030936461987118. https://doi.org/10.1177/0309364619871185. (Abstract)

Product Feature	Multiple Control Strategy Options
Functional benefit	Individualisation of control methods improves user function: "By allowing the user to choose which strategy to use for each trigger, the user is empowered with improved control and functionality of the device"
Reference	4. Vilarino, Martin, Jayet Moon, Kasey Rogner Pool, Joby Varghese, Tiffany Ryan, Nitish V Thakor, and Rahul Kaliki. **"Outcomes and Perception of a Conventional and Alternative Myoelectric Control Strategy: A Study of Experienced and New Multiarticulating Hand Users."** Journal of Prosthetics and Orthotics 27, no. 2 (2015): 10.

Product Feature	Pre-Defined Grips
Functional benefit	Improved satisfaction by simplifying the use of the multi-articulated hand: "The preset grip patterns simplified the complex control of the multiarticulated i-Limb hand, which also contributed to patient satisfaction"
Reference	5. Niet, Olga van der, Raoul M. Bongers, and Corry K. van der Sluis. **"Functionality of I-LIMB and i-LIMB Pulse Hands: Case Report."** Journal of Rehabilitation Research and Development 50, no. 8 (2013): 1123–28. https://doi.org/10.1682/JRRD.2012.08.0140.

FUNCTIONAL BENEFITS

Product Feature	Individually Powered Digits
Functional benefit	Enabling users to achieve finer, more complex control: "More dexterity can be achieved"
Reference	1. Castellini, Claudio. **"Upper Limb Active Prosthetic Systems—Overview."** In Wearable Robotics, 365–76. Elsevier, 2020. https://doi.org/10.1016/B978-0-12-814659-0.00019-9.

Product Feature	Externally Powered Partial Hand Prosthesis: i-Digits™
Functional benefit	Significant functional improvements in objective hand functional and individualised goals.
Reference	2. Whelan, L., and J. Farley. **"Functional Outcomes With Externally Powered Partial Hand Prostheses."** Prosthetics and Orthotics International, no. 2018;30 (2018): 69–73. https://journals.lww.com/jpojournal/Fulltext/2018/04000/Functional_Outcomes_with_Externally_Powered.3.aspx 3. 8. Miguelez, J., Conyers, D., Prigge, P., Ryan, T., Peterson, J. **"Electric Digits Case Studies: Unique Prosthetic Solutions for Contrasting Limb Presentations"** Journal of Proceedings from the American Academy of Orthotists and Prosthetists, 2014. http://media.mycrowdwisdom.com.s3.amazonaws.com/aaop/Resources/JOP/2014/2014-14.pdf (Abstract)

Product Feature	Gesture Control
Functional benefit	Provides a simplified alternative control strategy for changing grips: "participants showing proficient proportional control were not automatically good at producing well-tuned grip-switching"
Reference	9. Heerschop, Anniek, Corry K. van der Sluis, Egbert Otten, and Raoul M. Bongers. **"Looking beyond Proportional Control: The Relevance of Mode Switching in Learning to Operate Multi-Articulating Myoelectric Upper-Limb Prostheses."** Biomedical Signal Processing and Control 55 (January 2020): 101647. https://doi.org/10.1016/j.bspc.2019.101647.

Product feature	Stall Out and Compliant Grip
Functional benefit	Allows user to individualise a grip quickly for ease of use in daily tasks: **"i-Limb prosthetic hands have six degrees of freedom where some are passively operated; they must be activated by the user using a counteracting surface or the intact limb."**
Reference	10. Castellini, Claudio. **"Upper Limb Active Prosthetic Systems—Overview."** In Wearable Robotics, 365–76. Elsevier, 2020. https://doi.org/10.1016/B978-0-12-814659-0.00019-9.

HEALTH BENEFITS

Product feature	Multi-Articulating Technology
Health benefit	Protection of sound limb by reducing compensatory movements: “The presence of a functioning prosthesis may limit the development of overuse injuries when compared with the use of a static, cosmetic prosthesis or no prosthesis at all.”
Reference	10. Gambrell, Christina Rock. **“Overuse Syndrome and the Unilateral Upper Limb Amputee: Consequences and Prevention.”** JPO Journal of Prosthetics and Orthotics 20, no. 3 (July 2008): 126–32. https://doi.org/10.1097/JPO.0b013e31817ecb16

Product feature	Myo-Electric Control
Health benefit	Reduction in overuse injuries. Carpal tunnel syndrome was found in 0% of myoelectric participants, 33% of body-powered participants, 46% of passive prosthesis wearers, and 100% of non-prosthesis wearers showing a significant association between CTS and type of prosthesis.
Reference	11. Burger, Helena, and Gaj Vidmar. **“A Survey of Overuse Problems in Patients with Acquired or Congenital Upper Limb Deficiency.”** Prosthetics and Orthotics International 40, no. 4 (August 1, 2016): 497–502. https://doi.org/10.1177/0309364615584658.

Product feature	Multi-Articulating Technology
Health benefit	Gains in Quality of Life. Prosthetic use may increase the functional capacity of a person with a missing hand and could shorten the return-to-work process
Reference	12. **“Upper Limb Prostheses - A Review of the Literature With a Focus on Myoelectric Hands.”** 2011, 90. WorkSafe BC Evidence-Based Practice Group; Dr. Craig W. Martin (Working group/meta analysis)

Product feature	Microprocessor Technology
Health benefit	Improvements in upper limb Kinematics: “an externally powered hand prosthesis restores function to individuals with partial-hand limb loss, as demonstrated by improved SHAP scores and changes in upper limb kinematics.”
Reference	3. Wanamaker, Andrea B, Lynsay R Whelan, Jeremy Farley, and Ajit MW Chaudhari. **“Biomechanical Analysis of Users of Multi-Articulating Externally Powered Prostheses with and without Their Device.”** Prosthetics and Orthotics International, August 30, 2019, 030936461987118. https://doi.org/10.1177/0309364619871185. (Abstract)

HEALTH BENEFITS

Product feature	Multi-Articulating Technology: i-Digits™
Health benefit	Reduced compensatory movements: “An externally powered hand prosthesis restores function to individuals with partial-hand limb loss, as demonstrated by improved SHAP scores and changes in upper limb kinematics. The kinematic analysis of three functional tasks resulted in the prosthesis condition having decreased upper limb joint range of motion (ROM) compared to the non-prosthesis condition.”
Reference	3. Wanamaker, Andrea B, Lynsay R Whelan, Jeremy Farley, and Ajit MW Chaudhari. **“Biomechanical Analysis of Users of Multi-Articulating Externally Powered Prostheses with and without Their Device.”** Prosthetics and Orthotics International, August 30, 2019, 030936461987118. https://doi.org/10.1177/0309364619871185. (Abstract)

Product feature	Myo-Electric Technology: i-Digits™
Health benefit	Reduction in phantom pain/sensation: "CAPROQ-R responses also indicate that with electric digits, subjects rely less on others and perceive a reduction in phantom pain/sensation"
Reference	8. Miguelez, J., Conyers, D., Prigge, P., Ryan, T., Peterson, J. **“Electric Digits Case Studies: Unique Prosthetic Solutions for Contrasting Limb Presentations”** Journal of Proceedings from the American Academy of Orthotists and Prosthetists, 2014. http://media.mycrowdwisdom.com.s3.amazonaws.com/aaop/Resources/JOP/2014/2014-14.pdf (Abstract)

Product feature	Myo-Electric Technology: i-Digits™
Health benefit	Psychosocial benefit: ‘Increased independence’ and ‘Improved self-image'
Reference	13. Atkins, D, J. **“A One Year Retrospective Overview of Partial Hand Patients Using ProDigits” From “MEC 11 Raising the Standard,”** Proceedings of the 2011 MyoElectric Controls/Powered Prosthetics Symposium in Fredericton, New Brunswick, Canada, 2011 (Abstract)

Product feature	Multi-Articulating Technology: i-Digits™
Health benefit	Prevention of overuse injuries: ‘Improvements were noted in addressing psychological challenges, preventing overuse of the uninjured hand, and improving patient acceptance of the prosthesis’
Reference	14. Varghese, J. **“Therapeutic Challenges in Partial Hand Prosthetic Rehabilitation”** Journal of Proceedings from the American Academy of Orthotists and Prosthetists, 2014 (Abstract)

Product feature	Myo-Electric Control
Lifestyle benefit	Gains in Quality of Life: "Prosthetic use may increase the functional capacity of a person with a missing hand and could shorten the return-to-work process."
Reference	12. **"Upper Limb Prostheses - A Review of the Literature With a Focus on Myoelectric Hands."** 2011, 90. WorkSafe BC Evidence-Based Practice Group; Dr. Craig W. Martin (Working group/meta analysis)

Product feature	Control Method Technology (Gesture, App and Grip Chips)
Lifestyle benefit	Choice of control strategy for improved control and function: "By allowing the user to choose which strategy to use for each trigger, the user is empowered with improved control and functionality of the device"
Reference	4. Vilarino, Martin, Jayet Moon, Kasey Rogner Pool, Joby Varghese, Tiffany Ryan, Nitish V Thakor, and Rahul Kaliki. **"Outcomes and Perception of a Conventional and Alternative Myoelectric Control Strategy: A Study of Experienced and New Multiarticulating Hand Users."** Journal of Prosthetics and Orthotics 27, no. 2 (2015): 10.

Product feature	i-Digits™
Lifestyle benefit	Independence: "With no prosthesis, partial hand amputees have compromised hand function on the injured side. Electric digits restore significant functional ability to the injured hand. CAPROQ-R responses also indicate that with electric digits, subjects rely less on others and perceive a reduction in phantom pain/sensation."
Reference	8. Miguelez, J., Conyers, D., Prigge, P., Ryan, T., Peterson, J. **"Electric Digits Case Studies: Unique Prosthetic Solutions for Contrasting Limb Presentations"** Journal of Proceedings from the American Academy of Orthotists and Prosthetists, 2014. http://media.mycrowdwisdom.com.s3.amazonaws.com/aaop/Resources/JOP/2014/2014-14.pdf (Abstract)

Product feature	i-Digits™: Customisation
Lifestyle benefit	Highly customisable for specific requirements: "Customised to meet the various presentations and needs of partial hand patients will meet the patient's expectations for rehabilitation and result in improved outcomes. Externally powered prostheses are functional for many daily activities"
Reference	15. Baun, K., N. Kearns, and T. Ryan. **"Partial Hand Amputation – Outcome Measure Data to Support a Patient-Centred Approach to Successful Fitting of New Technologies."** Journal of Hand Therapy 31, no. 1 (January 2018): 160–61. https://doi.org/10.1016/j.jht.2017.11.026 (Abstract)

Product feature	i-Digits™
Lifestyle benefit	Increased independence and Improved self-image: "Those with congenital limb absence found value and benefit with ProDigits particularly as it related to 'Feeling greater potential for successes and 'Overall feeling more capable.' In spite of their perceived independence prior to receiving ProDigits, they indeed see benefits and value in ProDigits as it related to 'Increased independence' and 'Improved self-image.' The eleven individuals who had lost part of one or both hands in traumatic injury or disease, had similar objective responses particularly in the areas of 'Overall well-being' and 'Independence.' Those with bilateral partial hand loss were impacted most by ProDigits as it related to 'Increased activity and participation in life.'
Reference	13. Atkins, D, J. **"A One Year Retrospective Overview of Partial Hand Patients Using ProDigits"** From "MEC 11 Raising the Standard," Proceedings of the 2011 MyoElectric Controls/Powered Prosthetics Symposium in Fredericton, New Brunswick, Canada, 2011 (Abstract)

Product feature	i-Digits™
Lifestyle benefit	Overcoming psychological challenges and patient acceptance of the prosthesis: "Improvements were noted in addressing psychological challenges, preventing overuse of the uninjured hand, and improving patient acceptance of the prosthesis"
Reference	14. Varghese, J. **"Therapeutic Challenges in Partial Hand Prosthetic Rehabilitation"** Journal of Proceedings from the American Academy of Orthotists and Prosthetists, 2014 (Abstract)

OUTCOME MEASURES

Outcome measures are used by health care professionals to help determine the patient's baseline function and progression throughout rehabilitation and beyond. They are an important tool to utilise to provide credible and reliable justification for treatment and reimbursement.

This table outlines examples of validated outcome measures used in practice to objectively determine function, progress and treatment efficacy.

Outcome Measures	Use	Reference
TAPES R	Prosthetic Function and Satisfaction	16. Gallagher et al. **"Trinity amputation and prosthesis experience scales: a psychometric assessment using classical test theory and rasch analysis."** American Journal of Physical Medicine and Rehabilitation. 2010; 89(6): 487-96 http://psychoprosthetics.ie/tapes-r/
DASH	Disabilities of the Arm, Shoulder and Hand questionnaire is a 30-item questionnaire that looks at the ability of a patient to perform certain upper extremity activities. Self-report questionnaire that patients can rate difficulty and interference with daily life on a 5 point Likert scale.	17. Beaton D.E., Davis A.M., Hudak P., McConnell S. **"The DASH (Disabilities of the Arm, Shoulder and Hand) outcome measure: What do we know about it now?"** British Journal of Hand Therapy. 2001; 6(4): 109-118 http://www.dash.iwh.on.ca
SHAP	The Southampton Hand Assessment Procedure (SHAP) is a clinically validated hand function test developed by Colin Light, Paul Chappell and Peter Kyberd in 2002 at the University of Southampton. Originally developed to assess the effectiveness of upper limb prostheses, the SHAP has now been applied to assessments of musculoskeletal and unimpaired participants. The SHAP is made up of 6 abstract objects and 14 Activities of Daily Living (ADL). Each task is timed by the participant, so there is no interference or reliability on the reaction times of the observer or clinician.	5. Niet, Olga van der, Raoul M. Bongers, and Corry K. van der Sluis. **"Functionality of I-LIMB and i-LIMB Pulse Hands: Case Report."** Journal of Rehabilitation Research and Development 50, no. 8 (2013): 1123–28. https://doi.org/10.1682/JRRD.2012.08.0140 http://www.shap.ecs.soton.ac.uk/about-pubs.php
CAPROQ-R	The CAPROQ questionnaire is intended to serve as an opportunity for the patient to provide information and feedback regarding the overall satisfaction they have with their prosthesis and rehabilitation, as well as the function of their prosthesis. Divided into seven sections which include the following: background and demographics, prosthetic history, primary prosthesis satisfaction and comfort, pain, rehabilitation services, ADL/IADL completion, and satisfaction with AAD staff.	15. Baun, K., N. Kearns, and T. Ryan. **"Partial Hand Amputation – Outcome Measure Data to Support a Patient-Centred Approach to Successful Fitting of New Technologies."** Journal of Hand Therapy 31, no. 1 (January 2018): 160–61. https://doi.org/10.1016/j.jht.2017.11.026 (Abstract) 18. Johnson, S, S. **"Comprehensive arm protheses and rehabilitation outcomes Questionnaire (CAPROQ)"** From "MEC 11 Raising the Standard," Proceedings of the 2011 MyoElectric Controls/Powered Prosthetics Symposium Fredericton, New Brunswick, Canada: August 14-19, 2011. https://hdl.handle.net/10161/4749 (Abstract)

ADDITIONAL OUTCOME MEASURES

Tests of Prosthesis Use:

- Activities Measure-Upper Limb Amputee (AM-ULA)
- Assessment of Capacity for Myoelectric Control (ACMC)
- Southampton Hand Assessment Profile (SHAP)
- UNB Test of Prosthetic Function-Modified

Tests of Hand Function:

- Box and Block tests
- Jebsen-Taylor Test of Hand Function

Tests/Surveys of Upper Limb Abilities:

- Orthotics and Prosthetics User Survey (OPUS)
- Upper Extremity Functional Status (UEFS)
- Disabilities of the Arm, Shoulder Hand Outcome Measure (DASH)
- CAPROQ-R (Comprehensive Arm Prosthesis and Rehabilitation Outcome Questionnaire-Revised)

Tests of Satisfaction and QOL:

- Trinity Amputation and Prosthesis Experience Scales (TAPES)
- Nottingham Health Profile (NHP)
- Short Form 36 Health Survey (SF-36)
- DASH: perception of disability

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