THE ABILITY HAND[™] USER MANUAL

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1 Introduction

The Ability Hand is an affordable, durable, and accessible bionic hand operated by your own muscles. Powered by long-lasting batteries, the Ability Hand provides users with unique bionic abilities and superior technology. Using sensors embedded in the fingertips, the Ability Hand provides users with sensory or touch feedback. All of these features are offered at a price point that makes advanced activity accessible to more people than ever. We are excited to provide you with an exceptional bionic hand and truly redefine "human".

This document contains information on the usage and care of the Ability Hand. This user manual should be fully reviewed before fitting the Ability Hand.

1.1 Purpose of the Ability Hand

The Ability Hand is an advanced, multi-articulated, prosthetic hand designed to replace missing or lost limbs for congenital or acquired amputees. The Ability Hand allows users to regain missing or lost functionality and complete activities of daily living (ADLs).

Additionally, the Ability Hand has added functionality that enhances user experience by detecting the pressure with which the user is gripping an object. The pressure sensation is transferred to the user via a small vibration motor embedded in their prosthesis.

The Ability Hand is designed to operate seamlessly with most reputable prosthetic devices as an easy plug-and-play prosthetic hand. Please see the External Devices section for a list of compatible components.

1.2 Description of the Device

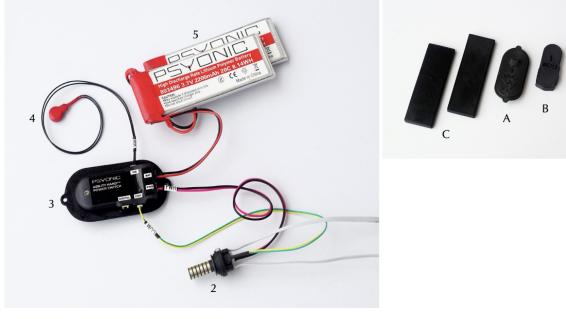
The Ability Hand Prosthesis System is an advanced, multi-articulated, prosthetic hand designed to replace missing or lost limbs for congenital or acquired amputees. The Ability Hand is connected to the user's prosthesis via an industry standard quick disconnect interface. Power supply and control signals are passed through a coaxial plug via connectable interface cables.

There is no physiological, electrical, or mechanical control system supplied with the Ability Hand Prosthesis System. Users will consult with their certified prosthetist to determine which control systems are ideal for their needs and physiological presentation. Power is supplied via the PSYONIC Battery Pack, which is a high capacity, high throughput, 7.4VDC lithium polymer battery.

PSYONIC Battery Pack charging and charge indication is provided via the PSYONIC Power Switch, which contains a plug for USB-C charging, a multi-color status indicator, and a power ON/OFF button. Finally, the PSYONIC Vibration Unit allows for grip pressure to be fed back to the user via a small vibration motor. The intensity of the vibrational feedback is proportional to the grip pressure applied at the fingertips of the Ability Hand.

The Ability Hand Prosthesis System contains the following components:





- 1. Ability Hand
- 2. Coaxial Plug with 6 rings
- 3. PSYONIC Power Switch
- 4. PSYONIC Vibration Unit
- 5. PSYONIC Battery Pack
- 6. USB-C 30W Wall Charger (image not included)
- 7. USB-C Charging Cable (image not included)

Accessories to the Ability Hand include the following:

- A. PSYONIC Power Switch Fabrication Aide (1:1 scale disposable model for use in prosthesis fabrication)
- B. Prosthesis socket cut-out template for the PSYONIC Power Switch
- C. Battery Fabrication Aide
- D. Ability Software User Interface Mobile Application (image not included)

For more information, visit the Fabrication Guide on our website.

1.3 Technical Specifications

Specifications				
Weight	490g - 500g			
Dimensions (Large)	200mm L x 110mm W x 55mm D			
Dimensions (Small)	189mm L x 110mm W x 55mm D			
Max Grip Force (Power Grasp)	66N			
Max Grip Force (Pinch Grasp)	9.3N			
Max Grip Force (Key Grasp)	14N			
Max Grip Speed (Power Grasp)	 *finger + thumb speed (375 degrees/sec) *max thumb rotator speed (550 degrees/sec) 			
Maximum Lifting Force Axially	50 lbs recommended (79 lbs max)			

Device Operation		
Voltage	7.4VDC	
Max Current	14A	
Battery Capacity	2200mAh	
Battery Size	95mm L x 32mm W x 7mm H	
Time to full charge	1 hour	
Charger	18W, 3A	

Environmental Limits				
Water (IEC 60529 IP64)	Protected against water splashes from all directions*			
Dust (IEC 60529 IP64)	Full Protection against dust and other particulates			
Operating (temperature)	-20°C to 45°C			
Storage (temperature)	-20°C to 45°C			

*Caution: Do not place the wrist in water at any time as this may cause damage to the batteries or other components.

1.4 Hand Dimensions

EQD Large Ability Hand



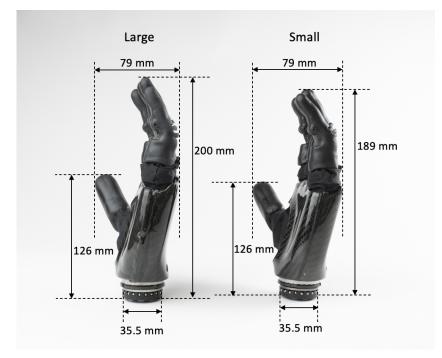
EQD Small Ability Hand



EQD Large versus Small Ability Hand







Short Wrist Ability Hand





Small Short Wrist

Short Wrist versus EQD

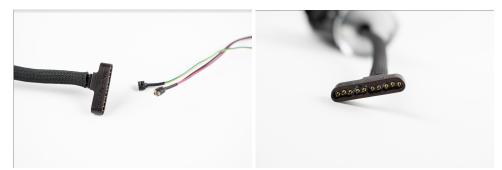


1.5 Short Wrist

The PSYONIC short wrist is designed to minimize the distance between the Ability Hand and the socket. This is specifically for patients who have sustained a more distal level of amputation. As the short wrist provides approximately 90° of pronation/supination, it should be carefully assembled to ensure the hand can rotate throughout its full range of motion.

The Ability Hand can come in one of two different wrists, either an electronic quick disconnect (EQD) or a short wrist. The EQD, shown in the right image above, allows the user to change terminal devices on and off their socket. Conversely, the short wrist, shown in the left image above, does not allow the user to rotate the hand on and off the socket. To change terminal devices, the user must doff their socket entirely and use a separate socket to switch devices. The EQD provides the user the capability to manually rotate the Ability Hand 360° as well as rotate the hand on and off as a quick disconnect. The short wrist only provides 90° of manual supination and pronation.

The short wrist comes with the same socket components as the EQD, shown in the image in section 1.2, EXCEPT for the coaxial plug. Instead, the hand will have a black cable which provides connections for PWR, COM, and both electrodes (see images below).



Warning: When installing and laminating the short wrist, it is crucial to read carefully over this document, <u>short wrist lamination instructions</u>, to prevent incorrect orientation.

2 Operation

Ability Hand is to be purchased and fitted by a certified prosthetist. Contact your certified prosthetist if you have any difficulty operating your Ability Hand or any of its associated components. You may also contact PSYONIC directly at 1-888-PSYONIC (779-6642).

2.1 Powering on

The Ability Hand contains a PSYONIC Power Switch located towards the middle of the socket. The following instructions demonstrate how to properly power on and off the Ability Hand.

- Press the button on the PSYONIC Power Switch once for a couple seconds to turn on the Ability Hand. The light on the PSYONIC Power Switch will flash white three times rapidly and then display the color of the grip your hand was left in after powering it off. If the hand was charged in between the times of powering the hand off and turning it back on, the hand may calibrate, moving each individual finger to its resting position. Make sure each finger is clear of any obstructions to ensure accurate calibration of each finger.
- 2) To turn off the Ability Hand, hold down the power button for a couple of seconds. The light will flash white three times and then will disappear. After the light is gone, the hand is now powered off.

2.2 Charging the Battery

When charging the Ability Hand, use only the charging unit provided to you by PSYONIC. Follow the instructions below to properly charge the Ability Hand.

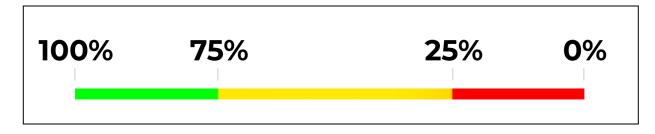
- 1) Before charging the Ability Hand, remove the socket from your residual limb.
- 2) Place the socket with the Ability Hand on a stable surface and plug the charging cord into the USB-C charging port located on the PSYONIC Power Switch.
- 3) Connect the wall adapter to an appropriate wall socket. Charging will begin once the wall adapter is connected. The LED on the PSYONIC Power Switch will illuminate during the charging process. When the hand is charging, the LED will continue to flash a color correlated to the charge level.
 - a. For red, the battery charge is between 0% and 25%.
 - b. For orange, the battery charge is between 25% 50%.
 - c. For yellow, the battery charge is between 50-75%.
 - d. For green, the battery charge is between 75 99%.
 - e. For solid green, the battery is fully charged.

To completely charge the battery after the battery is depleted, approximately one hour of charging time is needed.

The battery life* for the Ability Hand is dependent on the activity level of the individual user. It is recommended that you charge the battery overnight to avoid any possible power issues during normal use. Some odd movements of the hand may be due to lack of battery.

*Note: Only batteries provided by PSYONIC should be used for powering the Ability Hand. The use of any other battery when operating the Ability Hand is not recommended or permitted under the warranty. In addition, the use of other batteries may prevent full performance of the Ability Hand, making it slower and weaker. For external battery use such as an elbow, PSYONIC recommends the use of a PSYONIC Button. More information can be found on the website. To preserve dependable activity of the Ability Hand, the batteries need to be replaced every 12 months.

2.3 Checking Battery Status



To check the battery status when the hand is in use or not charging, quickly tap the button on the power switch either one time, two times, or three times (Note: the number of times to tap on the button depends on the setup in the app. See App Setup Guide for more information. The color displayed in the LED correlates to the charge level.

3 Usage 3.1 Grips

The Ability Hand is designed to provide users with up to 32 grip patterns. Some examples can be found below. We offer 32 grip patterns - currently, 20 are pre-defined and available for use.

Additional customized grips are coming soon.

Power	Кеу	Pincer	Pinch
Ê		Ń	Ú
Relax	Trigger	Cylinder	Hand-Shake
U	ţ-		
Sleeve	Point	Hang Loose	Rock
	ł		fi

Power/Key	Tripod (Closed)	Tripod (Opened)	Rude
Hook	Mouse	Peace	Finger Wave
U		elu	Ú

As you become more familiar with the Ability Hand, you may find yourself seeking in-depth instruction on how to fully integrate the Ability Hand in your daily life. We have also included thorough instruction on the use of our mobile application.

You can visit our website (<u>www.psyonic.io</u>) to view instructional videos and more information on complete control within our mobile application.

3.2 Mobile Application

The PSYONIC App is available on Android and iOS (iPhones, iPads) devices for free. The app allows for users and clinicians to alter:

- EMG responsiveness
- Touch Sensor responsiveness
- Grip Sets

Note: when scanning for an Ability Hand, make sure your bluetooth is turned on in your phone settings; if using an Android, make sure both your bluetooth and location are turned on.

Scan the QR code below or visit your device's app store (via Google Play or Apple App store).



For more information, visit our Mobile Application Set-Up guide on the website.

4 Care

4.1 Cleaning

To lengthen the lifespan of the Ability Hand, careful maintenance is required.

Rinsing the Ability Hand with water as needed will prevent dirt and dust from collecting on the hand. Soap and water may be used to clean the Ability Hand. Preventing dirt and dust build-up will help the Ability Hand operate as intended. The Ability Hand is water-resistant up to the wrist and should be pointed downwards when washing it to prevent damage.

Please note that the Ability Hand is rated to IP64, which allows for the hand to be protected in any direction of water spray (see Safety section 5 under Precautions for more information).

Caution: Cleaning agents such as detergent or bleach may harm the Ability Hand. You should avoid using anything other than soap and water when cleaning the hand.

4.2 Storage and Maintenance

The Ability Hand should be stored in a dry area at room temperature (70°F or 21°C). If the Ability Hand is stored at a temperature outside of the range -4°F to 113°F (-20°C to 45°C), significant damage may occur. We recommend that you do not perform any modifications or maintenance on the Ability Hand. If you believe the Ability Hand is not functioning properly or if the hand has been damaged, please contact your prosthetist to arrange for repair or replacement.

4.3 Troubleshooting

If a finger isn't moving properly, troubleshoot the hand by calibrating it. This can be done one of two ways:

- 1.) With the PSYONIC Power Switch
 - a.) Turn off the hand by pressing Power Switch button
 - b.) Press the button on the Power Switch down for 7 seconds. The light will dim out.
 - c.) Release the button on the Power Switch. The light should flicker white 3 times.
 - d.) Turn the hand back on.
 - e.) All of the fingers should move, signifying that the hand has recalibrated.
- 2.) With a USB-C charging cable

- a.) While the hand is turned on, plug the hand into its USB-C charging cable.
- b.) The hand will turn off and begin charging. Charging is signified by the light on the PSYONIC Power Switch fading in and out in red, yellow, or green.
- c.) Unplug the cable and turn the hand back on. Each finger should recalibrate.

If the hand is not functioning or is not responding to the control system, contact PSYONIC.

5 Safety

5.1 Indications for Use

The Ability Hand is to be used exclusively for people with congenital or acquired limb difference.

5.2 Contraindications

None Known.

5.3 Safety Instructions

The entire contents of this manual must be reviewed before using the Ability Hand. Failure to do so could result in suboptimal performance, injury to the user or the device itself.

Definitions:

- 1. A Warning is intended to alert you to possible risk of severe injury or accidents.
- 2. A Precaution is intended to alert you to possible risk of injury or accidents.
- 3. A Notice is intended to alert you to possible problems associated with the use or misuse causing damage to the product or its equipment.

Using the Ability Hand in a manner that is in violation of the provided Warnings, Precautions, or Notices may result in damage to the Ability Hand, injury to yourself or others, and could void any or all warranty coverage for your Ability Hand.

Warnings

- Do not operate heavy equipment, industrial machines, motor-driven equipment, or machinery while using the Ability Hand, as unexpected actions may cause injury.
- Do not handle power tools while using the Ability Hand, as unexpected actions may cause injury.
- Do not operate a motor vehicle while using the Ability Hand, as unexpected actions may cause an accident, serious injury, or death.
- Do not bring the Ability Hand into the immediate proximity of any active implanted devices (e.g. pacemakers, defibrillators) without written assurance from a qualified healthcare professional that the systems will not interfere. Interference between the

Ability Hand and any implanted devices could cause the implanted device to malfunction.

- Do not at any time handle or operate a firearm while using the Ability Hand, as unexpected actions during firearm operation could result in serious injury or death.
- Do not handle sharp objects or tools (e.g. blades or knives) with the Ability Hand, as unexpected actions during handling of sharp objects could result in serious injury or death.
- Do not use the Ability Hand while the system battery is charging (i.e. connected to a charger that is plugged into AC Mains supply) without written assurance from a qualified healthcare professional that it is safe to do so. Use of the Ability Hand while charging could result in injury.
- Do not puncture, bend, crush, or strain PSYONIC battery packs or their associated components. Mishandling of battery components can result in catastrophic failure or fire and/or chemical outbreak leading to serious injury or death.

Precautions

- Do not submerge the Ability Hand in water past the base of the thumb. The Ability Hand is rated to IP64, which allows for the hand to be protected in any direction of water spray (https://www.dsmt.com/resources/ip-rating-chart/). Exposure outside these limits could result in irreparable damage to the device and lead to device malfunction.
- Do not expose the Ability Hand to extreme temperatures. Keep the device in environments above -20°C and below 45°C at all times. Exposure to either extreme could cause short or long-term damage to the device and lead to device malfunction.
- Do not expose the Ability Hand to excessive moisture, vibration, dust, or shock. Exposure to excessive environmental conditions could cause short or long-term damage to the device and lead to device malfunction.
- Do not expose the Ability Hand to excessive amounts of corrosive substances (e.g. sweat, salt water). Exposure to corrosive substances could cause short or long-term damage to the device and lead to device malfunction.
- Do not clean the Ability Hand with strong chemicals (e.g. acetone, benzene) or similar solutions. Exposure to strong chemicals could cause short or long-term damage to the device and lead to device malfunction.
- Do not use the Ability Hand near sources of high energy radio frequency (RF) systems (e.g. large antennae, satellite dishes). Exposure to high energy RF systems could cause unexpected actions and lead to device malfunction.
- Use care when operating the Ability Hand near an open flame and never allow the device to remain directly over an open flame for any amount of time. Exposure to an open flame could cause the Ability Hand to exceed safe operating temperatures and lead to device malfunction.
- Use care not to allow the Ability Hand to become crushed or smashed, as this kind of misuse can cause irreparable damage to the device and lead to device malfunction.
- Use care not to subject the Ability Hand to any activity or conditions that would injure a physiologic hand
- Use care not to operate the device in areas of excessive electrostatic buildup, as excessive electrostatic discharge into the Ability Hand can lead to device malfunction.
- Do not disassemble or modify the Ability Hand or any associated components in any capacity.

Notices

- Do not attempt to repair the Ability Hand on your own. Please contact your prosthetist or clinician regarding possible repair. Maintenance, upgrades, and repairs shall be performed by PSYONIC only. Mishandling during maintenance, upgrade, or repair can cause damage to the Ability Hand and lead to device malfunction.
- Do not engage in sporting activities while using the Ability Hand without written assurance from a qualified healthcare professional that it is safe to do so. Use of the Ability Hand while engaging in sporting activities can cause irreparable damage to the device and lead to device malfunction.

Unique Conditions

It is important to note that you may or may not be able to use the Ability Hand to operate a motor vehicle. Consult your prosthetist or clinician before operating a motor vehicle. Some laws and regulations may prevent you from legally using the Ability Hand while driving a motor vehicle. Vehicle modifications could be necessary. You may also need an assessment of driving ability while using the Ability Hand.

It is your responsibility to conclude if you can drive a motor vehicle while using the Ability Hand. If you can drive a motor vehicle while using the Ability Hand, be sure to fully charge the Ability Hand before driving a motor vehicle. PSYONIC is not responsible for damage caused to the user or any other individual under any circumstances while the Ability Hand is used to drive a motor vehicle.

In addition to operating a motor vehicle, flying aircraft and operating watercraft are subject to similar conditions. It is your responsibility to determine if you can fly aircraft or operate watercraft. Regulations and laws may apply to said activities while using the Ability Hand.

5.4 Limitations

Individuals with brachial plexopathy or high-level (i.e. forequarter, shoulder disarticulation) amputations may benefit from evaluation by a qualified medical professional before being fit with the Ability Hand.

6 Additional Information

The remainder of this document will provide you with information on external device compatibility, technical support, PSYONIC's Limited Warranty, return policy, and regulatory compliance.

6.1 External Device Compatibility

The Ability Hand is designed to be compatible with most third party prosthetic devices and control systems.

Please contact PSYONIC for an updated list of all supported devices, as work is being done to ensure complete and enhanced portfolio coverage.

Please note that due to its advanced, powerful motors, the Ability Hand operates best with the PSYONIC Power Pack batteries. Third party batteries will cause the Ability Hand to perform sub-optimally.

6.2 Technical Support

For users: If you experience any issues with your Ability Hand, please contact your prosthetist and describe the issue in detail. Your prosthetist may be able to immediately assist with any common issues.

For Clinician/Prosthetist: You can contact us via email at support@psyonic.co or call us at 1-888-PSYONIC (779-6642) for further assistance. Technical support can be reached on extension 4. Our support hours are from 9:00 AM CST to 7:00 PM CST.

6.3 PSYONIC Limited Warranty

PSYONIC provides each Ability Hand user with the most durable commercially available bionic hand. However, problems may still arise during the use of the Ability Hand. If the Ability Hand was delivered under a condition that fits the warranty or lost functionality that falls within the warranty conditions, prompt response and action will be conducted.

Every Ability Hand includes a two-year limited warranty. Each Ability Hand is registered under our limited warranty by your prosthetist as part of the fitting process.

The warranty period begins once the Ability Hand is received and used outside of fitting sessions with a prosthetist.

Conditions covered by the Limited Warranty

Our warranty covers:

- Errors in the assembly of the Ability Hand
- Defects in the material used to build each Ability Hand
- Accidental damage to the Ability Hand that does not exceed any operational limits and disobey any safety guidelines or appropriate usage outlined previously in this manual

Conditions not covered by the Limited Warranty

PSYONIC is not responsible for any defect or loss of function to the Ability Hand caused by:

- Regular wear and tear
- Loss of the Ability Hand
- Theft of the Ability Hand
- Cosmetic or minor damage to the Ability Hand that does not affect the use of the Ability Hand
- Intentional damage to the Ability Hand
- Damage to the Ability Hand caused by neglect
- Use of the hand that does not meet the safety guidelines and appropriate use outlined previously in this manual
- Inclement weather, lightning strike, or any acts of nature that expose the Ability Hand to dangerous conditions
- Any event not within reasonable control or anticipation by PSYONIC
- Damage caused by animals or insects
- Use of batteries and battery chargers not specifically provided by PSYONIC
- Attempts by any individual outside of PSYONIC to repair the Ability Hand or carry out maintenance and service to the Ability Hand
- Connection or installation of the Ability Hand to parts that are not compatible with the Ability Hand
- Alteration or modification to any portion of the Ability Hand

6.4 Return Policy

If you experience any conditions within the boundary of the warranty during the two-year warranty period, please contact your prosthetist for further assistance. Proof of purchase and details describing any alleged defects or damages must be documented. Your prosthetist will need to contact technical support for further assistance if a replacement or repair is necessary. To accommodate the return process, a temporary Ability Hand will be provided via overnight shipment to your prosthetist. The temporary Ability Hand will need to be returned to PSYONIC once a replacement Ability Hand has been provided.

6.5 Regulatory Compliance

FDA Registered

EMC Compliance

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, (2) this device must accept any interference received, including interference that may cause undesired operation.

IEC 60529 – Ingress Protection rated to IP64

IEC 62133 - Safety Test Standard of Li-Ion Cell and Battery