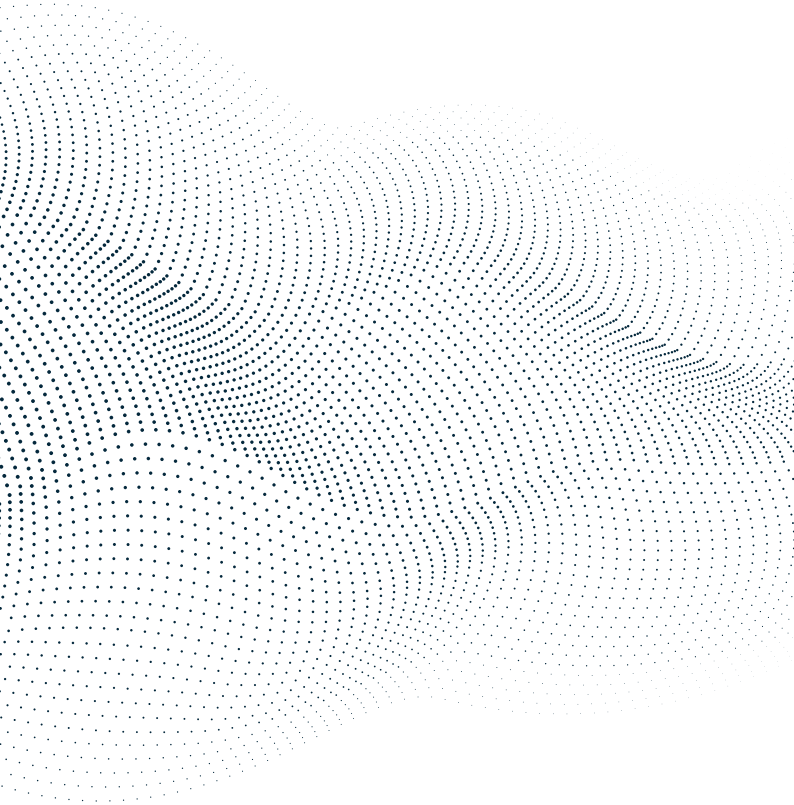
MyHand Adapt user manual

Revision: 02 —— Date: January 2022



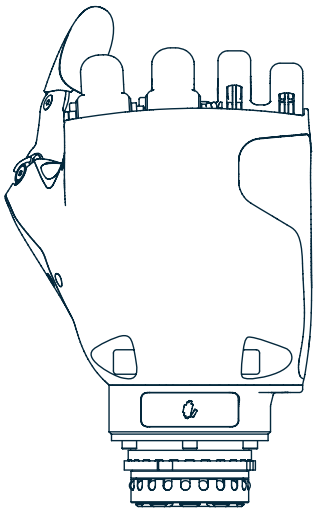
user id:		H45
product nr:		
date of manufacture:		

INTRODUCTION

Thank you for choosing Hy5 as your prosthesis supplier. This manual along with the training and support of your clinical team will help you take full advantage of your MyHand Adapt. It contains important information for the correct use of MyHand Adapt. For instruction videos, please visit our website www.hy5.no.

Read this document thoroughly before using your MyHand Adapt.

MyHand Adapt is intended for anyone with a hand amputation or dysmelia, to regain independence in their daily social and work life, helping to perform everyday activities that able-bodied individuals take for granted. Available in four different sizes, MyHand Adapt can be used by any teenage or adult user, independent of gender, height, weight, and age.



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1. GETTING STARTED (FOR CLINICIANS)

1. Check

Check if following preconditions are met:
- The prosthetic socket is equipped with a female electric quick disconnect, a 7.2V 2200mAh+ battery (see Product Integration Guide for battery model specifications) and one or two myo sensors.
- If the prosthesis will be used with a glove, a silicon MySkin Adapt needs to be purchased seperately.

Check if everything is included in the packaging:
- MyHand Adapt
- MyHand Adapt User Manual
- Product Integration Guide
- MyWrist User Manual
- MyWrist Protection Cap & Force Adjustment Tool
- MyWrist hex key tool
- MyWrist Unlocking Tool
- MyWrist spare ball bearings - 5 pcs.

Allow your MyHand Adapt to warm/cool to recommended operating temperature window (0 to 35°C)

The MyHand Adapt is powered by a rechargeable battery located in the socket. Typically the battery should be fully charged for the start of each day in order to maintain operation throughout the day. Battery life is user dependent and thus can vary.

2. Prepare

Verify all 3rd party components with Product Integration Guide.

Download Hy5 App (for iPhone & iPad)

Book Hy5 technical support so we are on standby during the fitting.

3. Connect

Clean the coaxial plug with a dry cloth (the plug should be cleaned at least once per week).

Align hand with the socket and push in firmly towards the wrist. Rotate 90 degrees in either direction - the MyHand Adapt will turn on automatically and be ready to use!

4. Disconnect

Holding the MyHand Adapt securely, rotate by 360 degrees – when increased resistance is felt, continue to rotate and your MyHand Adapt can be gently released from the socket. Your Myhand Adapt should be disconnected from the socket when not in use to maximise battery life.

5. Login & connect

Log in to the Hy5 App and follow instructions to connect to your MyHand Adapt (your MyHand Adapt must be physically present to connect)

6. Configure settings

Use the toggle switches to define preferred settings.

7. Tune EMG sensitivity

Tune your EMG sensors and the in-App sensitivity settings to match the user's needs.

EMG setting #4 and MyHand Adapt sensitivity 81% are recommended default starting points.

2. OPERATION

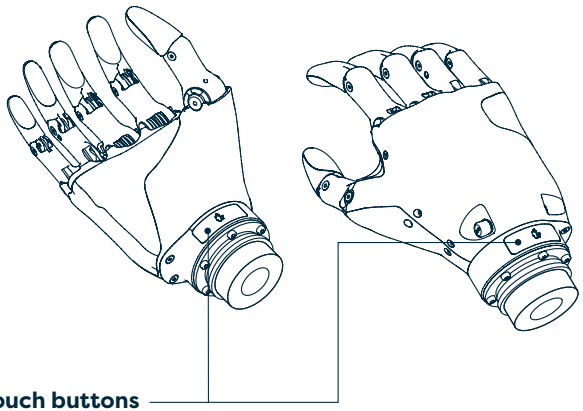
2.1 Connect & disconnect

Clean the coaxial plug with a dry cloth (the plug should be cleaned at least once per week).

Align the device with the socket and push in firmly towards the wrist. Rotate 90 degrees in either direction - your MyHand Adapt will turn on automatically and is ready to use!

To disconnect your MyHand Adapt from the socket, securely rotate by 360 degrees – when increased resistance is felt, continue to rotate and your MyHand Adapt can be gently released from the socket. Your Myhand Adapt should be disconnected from the socket when not in use to maximise battery life.

⚠ CAUTION! —— Your socket must include a Hy5 recommended or supplied battery to function optimally. If you experience unintentional behaviour or MyHand Adapt does not work as expected, take off your MyHand Adapt and contact your clinician.



2.2 Touch buttons

The MyHand Adapt is provided with two touch buttons on the wrist. The On/Off button is located at the back of the wrist, the Function button on the inside of the wrist.

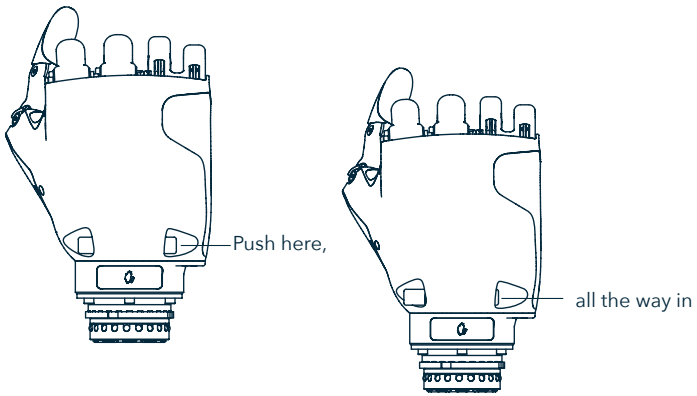
By default the MyHand Adapt is on when connected to a power source. To switch off the device, press the On/Off button once. A sound feedback indicates the device being switched off. Press the button again to turn the device back on. The fingers will make a short movement to indicate that the hand is turned on.

By default, the function button is programmed to control the speed of the device. The MyHand Adapt has 3 different speed modes, 1. Power Saver mode, 2. Default mode, 3. Fast mode. The device is automatically turned on in Default mode. Pressing the function button two times shortly, changes the speed to Fast Mode, pressing two times again brings the device in Battery Saver mode.

When using the Hy5 App it is possible to configure the Function button.

2.3 Emergency Release Switch

An emergency release switch is situated just above the On/Off button on the backside of the hand. If for any reason you should need to quickly release the fingers from a grip, hold the emergency release with your thumb and index finger, and push the release switch to the side. The fingers will open instantly. Left hand users shall push the switch to the right, and right hand users shall push the switch to the left.

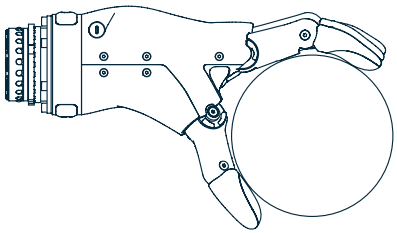


⚠ CAUTION! —— Push the release switch back to its initial place to activate the MyHand Adapt for use again. It is very important that the switch is pushed all the way back.

3. GRIPS

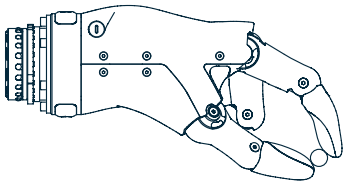
MyHand Adapt has several adaptive grips. The fingers will fold around any given form or object. To make a key grip, hook or cylinder grip, you have to actively help the hand to achieve the desired grip position.

3.1 Power grip



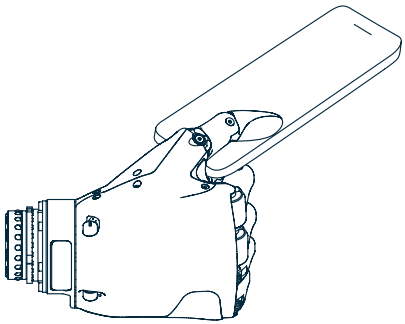
All five fingers close together to grip around larger objects such as a bottle, a ball or a piece of fruit.

3.2 Precision grip



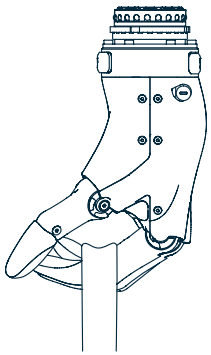
Close the hand, and the fingers will form a precision grip.

3.3 Key grip



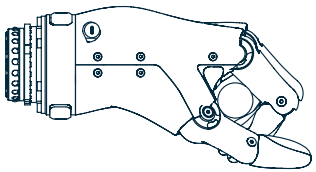
Hold back the thumb while closing all the other fingers, then release the thumb.

3.4 Hook grip



Hold back the thumb and close the fingers until the finger tips are bent. Use a hook grip to carry a suitcase or shoppingbag.

3.5 Cylinder grip



Hold back the thumb while closing all the other fingers, then release the thumb. Use the cylinder grip to securely hold around a bar, handle or steering wheel.

⚠ CAUTION! —— MyHand Adapt has a powerful grip and can damage items and/or the body if you squeeze too hard.

4. LIMITATIONS OF USE

The MyHand Adapt is designed to perform a wide range of daily life activities and is intended for use in a home healthcare environment. As a general rule, you should not use the MyHand Adapt for activities that would cause damage to your natural hand. Additionally, some high-impact and high-load activities must be avoided, as well as activities where the device is fully submerged in water. Please follow these guidelines carefully to get the best experience with your MyHand and to avoid damage.

4.1 Appropriate use

The following are typical examples of appropriate use activities:

Activities where force is applied to the hand:
- carrying a bag/suitcase
- gardening
- low-impact workshop activities
- low and medium intensity exercise activities
- low and medium intensity resistance training (dumbells <3kg)

Activities where the hand gets wet, but not fully submerged in water:
- lightly washing hands
- washing a car
- walking in the rain

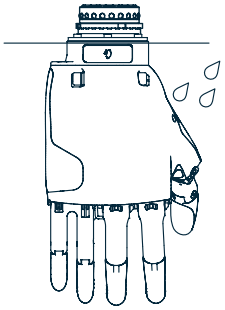
4.2 Inappropriate use

The following are typical examples of inappropriate use activities:

Activities where excessive force and/or vibration is applied to the hand:
- high intensity resistance training (e.g. dumbells >3kg, own body mass)
- heavy duty workshop activities like using a hammer, motorized saw or hammer drills
- contact sports
- operating a firearm

Activities where the hand gets fully submerged in water:
- swimming
- bathing

⚠ CAUTION! —— The prosthesis is splash proof up to the wrist.



4.3 Battery

The MyHand Adapt is powered by a rechargeable battery located in the socket. Typically the battery should be fully charged for the start of each day in order to maintain operation throughout the day. Battery life is user dependent and thus can vary.
MyHand Adapt is only garanteed to work with a battery model that is specified in the Product Integration Guide.

4.4 Safety precautions

Hy5 accepts no responsibility for any damage or injury caused by inappropriate use.

- Do not subject the MyHand Adapt to excessive loads
- Do not fully submerge in water
- Do not use to operate heavy / industrial machinery
- Do not use machinery with moving parts that may cause personal injury or damage.
- Do not use to lift hot objects.
- Do not use while sunbathing.
- 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 MyHand Adapt for extreme activities that may cause injury.
- Do not expose for 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 Hy5 technicians and technical partners.
- Charge the battery when the speed of the prosthesis starts to slow down considerably.
- Do not use while batteries are charging.
- Do not use portable RF equipment (including cables and antennas) closer than 30 cm to the MyHand Adapt. Performance of the MyHand Adapt might be degraded or lost.
- Do not use MyHand Adapt adjacent to or stacked with other equipment, because it could result in improper operation.
- Do not use accessories other than those specified in the Product Integration Guide as this could result in increased electromagnetic emissions or decreased electromagnetic immunity of MyHand Adapt and result in improper operation.

5. CLEANING & MAINTENANCE

Please inspect your prosthesis regularly. Do not adjust, dismantle or attempt to maintain or modify your prosthesis. If the MyHand Adapt does not function as expected, please contact your prosthetic provider. When cleaning MyHand Adapt, use a damp cloth.

For instructions on how to clean the glove, read the dedicated MySkin user manual. If water enters the internal components of the hand, component failure can occur. Inspect the prosthesis regularly for glove damage. Try to avoid contact with sharp or pointed objects. When in need of a replacement glove please contact your prosthetic provider.

A regular service interval of 12 months should be maintained for the MyHand Adapt. This requires the MyHand Adapt to be sent to Hy5 or a Hy5 approved workshop. A service reminder shall be sent one month in advance of the due date.

The 12-monthly service interval is mandatory in order to maintain the product warranty. A grace period of -1/+2 months is allowed for service returns.

6. HY5 APP

The Hy5 App is created together with upper extremity CPO´s and patients to make it easy to customize MyHand Adapt to the patients desired settings and to train the myoelectrical muscle signals. The App can be used by both patient and CPO.

The App communicates with MyHand Adapt using Bluetooth. You need to pair MyHand Adapt to a mobile or tablet, when you have downloaded the App. The Bluetooth in MyHand Adapt will be activated by holding both touch buttons proximately 5-6 seconds.

In the Dashboard module of the App, you can see the battery status, and the service status of MyHand Adapt.

In the Diagnostics module, you can check the status of MyHand Adapt by running a diagnostic and send the report to the Hy5 team. When you do this, Hy5 will analyze the results and get back to you. You can also run a log report. This function is mainly so we can log the EMG signals and suggest an optimal setting for the patient.

The Training module contains a function where you can see how the myo-signal response is right now, as well as several games which can be used for muscle training to get a better performance with MyHand Adapt.

In the Settings module, you can adjust the settings of MyHand Adapt and the myo-sensors to your preferences.

On our website you can find a step-by-step tutorial on how to use the Hy5 App.

7. FAQ

Q	A
Will I be able to move each digit individually?	While there are a number of possible grip patterns, you will not have individual control of each digit.
Q	**A**
How long will it take to learn to use the MyHand Adapt?	MyHand Adapt should work instantly, but a short learning period is to be expected.
Q	**A**
Can I use MyHand Adapt for sports?	Yes. MyHand Adapt can be used for most sports. Consult with your prosthesis provider if you have questions regarding usage limitations.
Q	**A**
My battery does not last all day, what can I do?	Ensure your socket is fitted with a Hy5 recommended battery and it is fully charged before use.
Q	**A**
I had good control when I first got the hand, but now it seems like I drop items more easily. Why is that?	The signals you are giving may have become stronger over time since you have been using the hand more. Now even a small muscle contraction may make the hand move. Your prosthetist may help you to adjust the sensitivity of the myo-sensors in your sleeve.
Q	**A**
How should I clean it? And how often?	You should clean your MyHand Adapt on a regular basis. When cleaning MyHand Adapt, use a damp cloth.

Q	A
What is the best way to tie my shoes?	Many MyHand Adapt users prefer to use the pinch grip.
Q	**A**
How can I put a coat on if my device is already on?	Using the pinch grip will bring the thumb and fingers together, and makes the hand as slim as possible.

8. TECHNICAL SPECIFICATIONS

Principal dimensions (S/M/L/XL)

Maximum opening (thumb to index finger)	96/106/116/122 mm
Thumb swing through angle	67/65/61/58 °

Performance specification (S/M/L/XL)

Maximum power grip	120 N
Maximum pinch grip	60 N
Minimum time to open/close: power grip	1.0 Sec.
Minimum time to open/close: pinch grip	0.75 Sec.
Maximum static load: hook grip	40 kg
Maximum load individual finger - hook grip	20 kg
Fingertip extension load	8 kg
Weight	560/570/600/610 g
Sizes	S/M/L/XL

Battery

Maximum current	5A
Voltage	7.2V
Battery capacity	rechargeable lithium polymer, 2200mah

Environmental conditions

Storage and transport in original packaging	-5°C to 40°C / 23F to 104F
Storage and transport without packaging	-5°C to 40°C / 23F to 104F
Operation (slower speed if below min. temp)	0°C to 35°C / 41F to 95F

9. SERVICE

9.1 MyHand Adapt health checklist

The following checks can be made to identify if the hand needs to be returned to Hy5 for maintenance:

1. **Check for any visible signs of damage.**
   How: Check all around the hand for any signs of broken or deformed components
2. **Check if the hand turns on/off reliably.**
3. **Check if hand closing time < 0,75s.**
   How: Use video camera to film several closing sequences, from fully open to point of first contact (pinch).
4. **Check if hand has a strong grip.**
   How: Use battery pack to perform pinch grip around your open hand. If the pinch force becomes uncomfortable, this is a clear indication that the hand grip force is adequate. Stop gripping before the hand exhibits excessive force.
5. **Check for any signs of oil leaks.**
   How: Examine closely for oil in the following locations:
   – Around edge of mounting frames
   – Around emergency release switch
   – Around edge of quick disconnect
   – Around cylinder rods
6. **Check if fingers move freely.**
   How: Rotate each finger joint individually. Each joint should spring back under spring force, and there should be no rubbing or grinding in the joint
7. **Check if emergency valve functions as intended – both open and close.**
   How: Close hand using battery pack. Open emergency release switch – fingers should open. Return emergency switch back to normal position to resume operation.
8. **Check quick disconnect connects/disconnects in a reliable manner.**
   How: Use battery pack to check reliable connect/disconnect. Hand should not switch off when rotating.

If the hand fails on any of these points, it should be returned to Hy5 for maintenance.

9.2 Replacement of fingerpads

The finger pads can be replaced by a clinician or technician. First remove the glove (if any). Use a sharp bladed knife to carefully peel the pad from the fingertip. Scrape away any glue residue with the knife blade and clean the fingertip with an alcohol based cleaner. Carefully apply new Loctite 401 / 406 (or equivalent cyanoacrylate glue) on the contact surface of the fingertip and press the finger pad in place. Remove any excessive glue.

⚠ CAUTION! —— Use suitable Personal Protective Equipment, especially safety glasses.

9.3 Troubleshooting

MyHand Adapt does not operate.	• Ensure that MyHand Adapt is switched ON. • Ensure the battery is charged and connected properly. • Ensure that MyHand Adapt is fully engaged at the wrist. • Check if the electrodes have good contact with the skin. • Check if the electrode cable is correctly fitted to the electrode.
MyHand Adapt stops halfway through an action.	• Electrode settings may need adjustments. • Check if the electrode cable is not damaged. • Check if the battery cable is not damaged. • Check if the coaxial plug and bushing are clean.
User reports that MyHand Adapt is difficult to operate.	• Electrode settings may need adjustment. • Ensure that the electrodes maintain good contact with the skin. • Check electrode placement and wiring. • Ensure that the battery has good charge.
MyHand Adapt opens when a close signal is given.	• Swap input signals or switch the electrode connections on the coaxial plug
MyHand Adapt stops working due to electromagnetic interference.	• Increase the distance between MyHand Adapt and the source of the disturbance.

If problems continue please contact your local supplier or Hy5. www.Hy5.no

9.4 Disposal

When disposing of MyHand Adapt, please send it back to Hy5 AS for safe disassembly and disposal.

10. QUALITY ASSURANCE & WARRANTY

10.1 Quality Assurance

Hy5 is registered with the Directory of health in Norway.
Hy5 is marked with a CE mark indicating that it complies with the requirements of the Medical Devices Directive 93/42/EC.

10.2 Warranty statement

MyHand Adapt comes with a 2-year-standard warranty. The warranty covers any defects in materials or workmanship under normal use during the warranty period. The 2-year warranty period begins when the product is taken into use, which should be no later than 6 months from the date of product shipment from Hy5's production facility, Norway.

Taken into use is defined as date of shipment to practitioner/ end user. When a claim is made under warranty, this claim must be supported by appropriate documentation, including proof of sale and shipment date.

The warranty will be void on all system components if any components have been subject to abuse, repair or maintenance by an uncertified person; deliberate damage; loads beyond those for which the product was designed; or by modification or neglect.

The warranty does not cover products that have not been subject to the recommended maintenance schedule. The regular maintenance schedule is required in order to maintain components subject to wear and tear, in addition to bleeding air from the hydraulic system.

Any repair must be performed by Hy5 or a Hy5 certified workshop. Upon return, the hand will be assessed, repaired, and where deemed beyond repair replaced if the warranty is applicable.

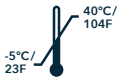
10.3 Incident reporting

Complaints or accidents involving Hy5 products should be reported via the 'contact' page on the Hy5 website www.hy5.no

FDA
FDA Registration Number: 3014936213

CE mark
Declaration of conformity according to the applicable European directives

Legal manufacturer
Hy5Pro AS, Raufoss Industripark, Bygning 100, 2830 Raufoss, NORWAY



Storage & Shipping Temperature:
-5°C/23F to +40°C/104F