Makers Hive®

Nipun™

User Manual



Doc. No.: MH-IFU-00-1126-01

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Intended Use

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1. Intended Use

Nipun™ is a powered artificial substitute for a missing hand intended to be attached to a natural arm or used as part of an upper-limb external prosthetic system, to replace the appearance and some of the function of the hand. It has surface electrodes in contact with skin that transmit voluntary residual limb/trunk movement to the device motor for function. This is a single patient-use device.

⚠ The Nipun™ hand should be fitted by a certified clinician.

This manual applies to all Nipun™ models:

Model	Name	Side
NP01	Nipun Neo (base)	Right (NP01R), left (NP01L)
NP02	Nipun Flex	Right (NP02R), left (NP02L)
NP03	Nipun Advanced	Right (NP03R), left (NP03L)

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1.1 Key Features



- **Grips.** Power grip on all models. Key grip and open palm grip on Nipun Flex and Nipun Advanced.
- **Manual swivel thumb.** Nipun Flex and Nipun Advanced. Locks in two positions, opposed and non-opposed. Nipun Neo has no manual thumb.
- **270° manual wrist rotation.** Nipun Advanced. Tool-free repositioning with 9 locking positions.
- **Single or dual EMG control.** All models. Switchable. Titanium dry electrodes. A button electrode is available as an option, mainly for transhumeral (above-elbow) amputations.
- **AI-based auto-calibration of EMG.** Nipun Advanced.
- **Dedicated grip lock button.** All models. Holds the grip regardless of the EMG signal.
- **Wireless firmware updates.** Nipun Flex and Nipun Advanced. Over the air using Bluetooth, no cables.
- **KalAssist® mobile application.** Nipun Flex and Nipun Advanced. Support, feedback, firmware updates and EMG signal visualization.
- **USB-C charging.**
- **In the box.** Silicone cosmetic glove included. See 1.2 for the full list.

1.2 What Is in the Box

- Nipun™ hand with cosmetic glove
- Accessory box with 2 EMG sensors, with cables, and 2 EMG sensor dummies
- Battery
- Multi Functional Switch module
- Charger with cable
- Adapter with cable
- User manual
- Welcome card

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Getting Started

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2. Getting Started

2.1 Turning on the Device

The Multi Functional Switch module has an on-off slide switch. Slide the switch towards ON. The device powers up.

The Multi Functional Switch shows solid green. The device is now ready to use.

2.2 Charging the Device

Make sure the battery is in the off position before plugging in the charging cable. Then plug the USB-C charging cable into the charging port on the forearm section. The device then charges.

A charging LED shows the battery status while the charging cable is plugged in.

LED colour	Meaning
Red	Charging in progress
Green	Charging complete

A full charge takes 2 to 3 hours.



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Control Options

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3. Control Options

3.1 App Control

The KalAssist® mobile application connects to the hand over Bluetooth, with no account or login. The user can:

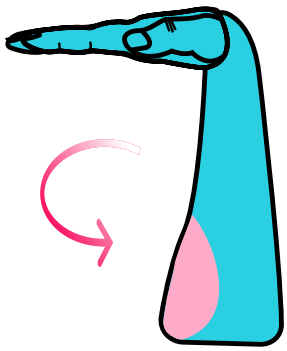
- check the battery level
- see the live EMG signal of each sensor and whether each sensor is working
- set up the device: single or dual sensor, sensor threshold and gain
- update the device firmware from the phone
- open tutorials and call customer support



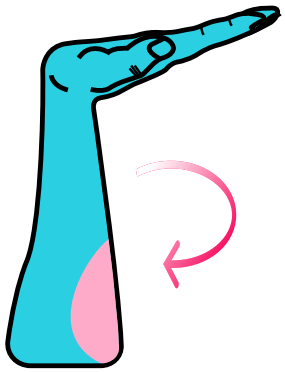
3.2 Muscle Control – Dual Sensors

Two sensors are used. The close sensor goes into the close sensor port and the open sensor into the open sensor port.

- A proportional signal on the close sensor closes the fingers.
- A proportional signal on the open sensor opens the fingers.



Close Signal



Open Signal

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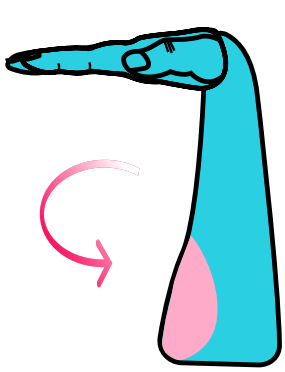
3.3 Muscle Control – Single Sensor

One sensor is used. It goes into the close sensor port.

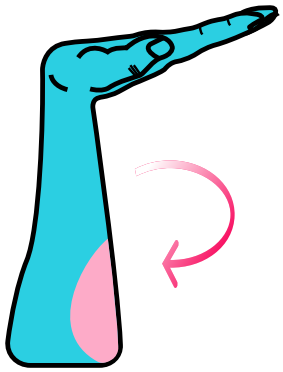
- A proportional signal on the sensor closes the fingers.
- A double pulse on the sensor opens the fingers.

There are no other triggers.



Close Signal

OR



Open Signal

3.4 EMG Triggers and Respective Actions

Action	Single sensor	Dual sensors
Closing fingers	Proportional signal	Proportional signal on the close sensor
Opening fingers	Double pulse	Proportional signal on the open sensor

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How to Use Nipun™

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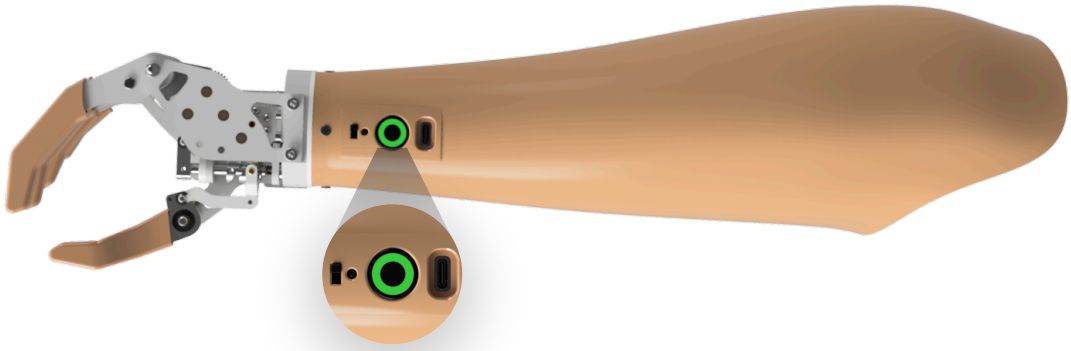
4. How to Use Nipun

4.1 Multi Functional Switch

A Single Switch to Control your Device

The Nipun™ hand has a Multi Functional Switch, which the user presses for the actions below.



Note: The colour of the light shows the action or status (see 4.2).

Desired Functionality

GRIP LOCK	**Short press, up to 1 second. Press again to release**
BATTERY LEVEL INDICATION	**Press for 1 to 3 seconds. The light shows the battery colour for 3 seconds**
BLUETOOTH	**Press for 3 to 6 seconds**

⚠ The charging port and the Multi Functional Switch are applied parts.

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4.2 LED Notifications

The Multi Functional Switch light shows the device status.

GREEN

Normal operation. The device is ready to use

Solid

ORANGE

Grip lock is on

Solid

BLUE

Bluetooth is on and waiting for the app

Blinking

BLUE

The app is trying to connect. Press the switch once to confirm

Faster blinking

BLUE

Connected to the app

Solid

Battery level

Shown when the switch is pressed for 1 to 3 seconds:

GREEN

80% to 100%

Solid

YELLOW

25% to 80%

Solid

RED

10% to 25%. Shown continuously below 25%. Charge the device

Blinking

RED

Below 10%. The device stops responding to EMG signals. Charge the device

Solid

⚠ If the switch is not pressed to confirm within 60 seconds, Bluetooth turns off and the light returns to green. The light also returns to green when the app disconnects.

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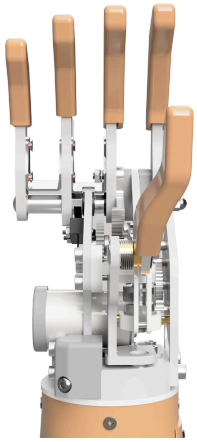
4.3 Thumb and Wrist

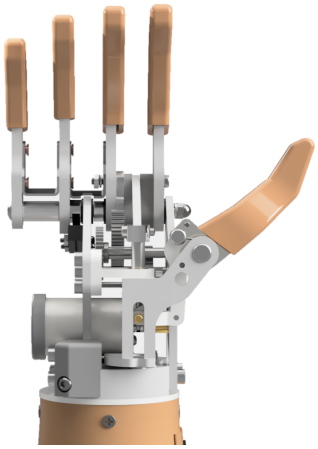
Thumb

Nipun Flex and Nipun Advanced have a manual thumb that locks in two positions, opposed and non-opposed. The user moves the thumb by hand to suit the grip and the object. The thumb has no motor.

⚠ Note: do not change the thumb position in the middle of a grip.



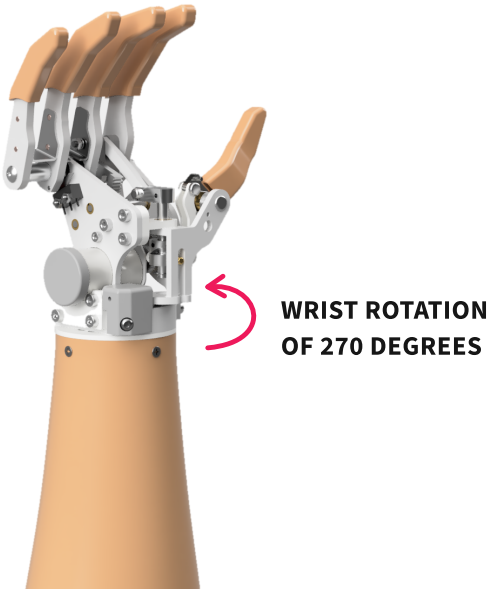
Opposed Position



Non-Opposed Position

Wrist

Nipun Advanced has a manual wrist that locks in 9 different positions. The user can rotate the wrist through 270° to hold objects of various shapes and sizes. Precise locking of the wrist lets the user hold objects firmly.



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4.4 Grips

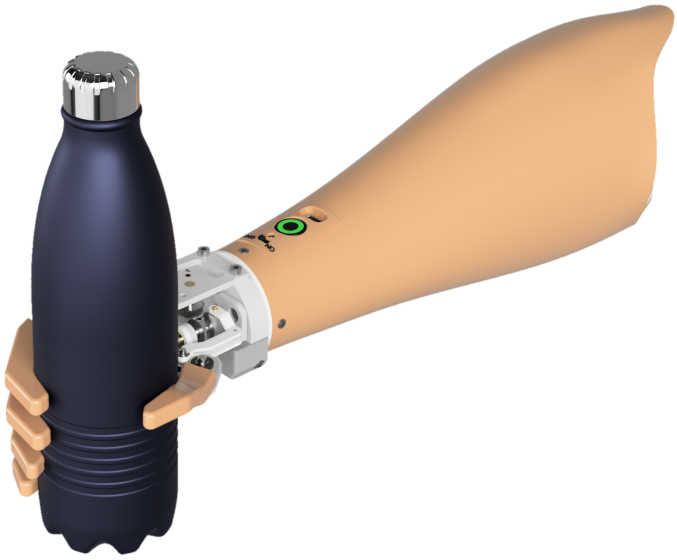
Nipun has three grips. There are no custom grips.

Thumb position	Grip
Opposed	Power grip
Non-opposed	Key grip, open palm grip

Thumb Position: **Opposed**

Power Grip

Whenever the user applies a close signal, all the fingers move towards the palm until the close signal is stopped or the fingers touch an object. The thumb is in the opposed position. Use it to hold objects like a water bottle, ball or cup firmly.



Grip Lock

To hold an object firmly, the user locks the grip with a short press on the Multi Functional Switch. A second short press releases the grip. Grip lock works in all grips. While the grip is locked, the switch light is solid orange.

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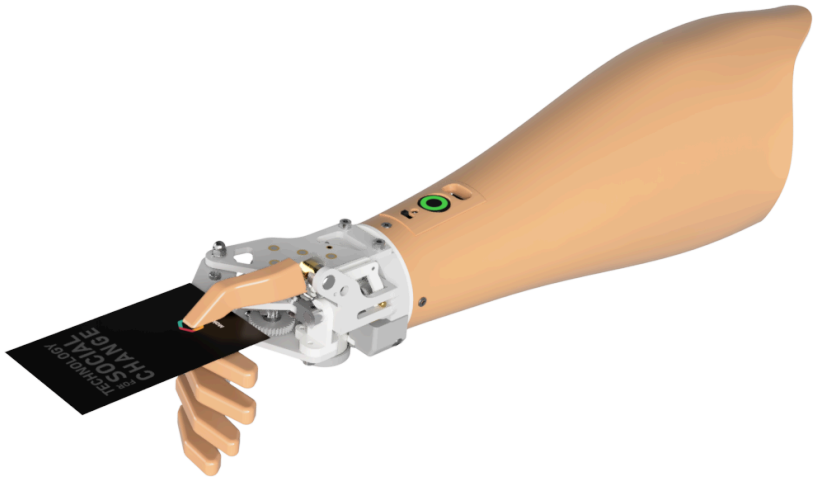
Thumb Position: **Non-Opposed**

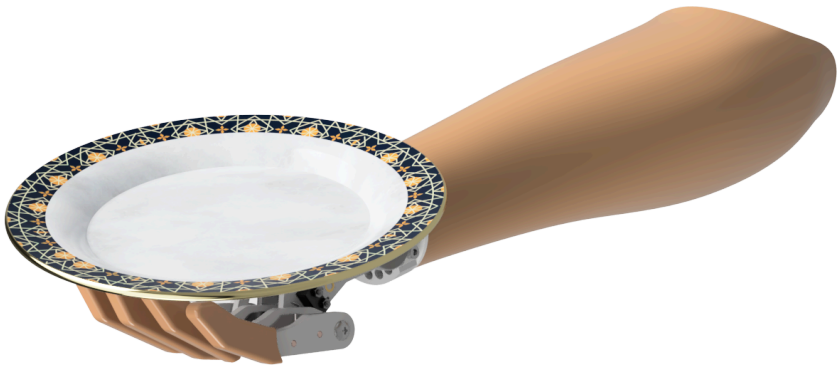
Key Grip

All fingers except the thumb move to a set position. The user applies a close signal to close the thumb and hold objects like a visiting card or credit card. The thumb is in the non-opposed position.



Open Palm Grip

All five fingers stay in the rest position. Use it to hold objects like plates. The thumb is in the non-opposed position. There is no separate switch for this grip. From the key grip position, rotate the wrist so that the palm faces upwards, then place the object on the open palm.



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Storage, Cleaning and Maintenance

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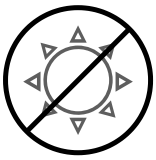
5. Storage, Cleaning and Maintenance

5.1 Storage



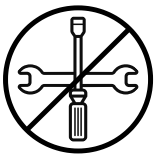
When not using Nipun™, store it carefully at room temperature and out of reach of direct sunlight.

5.2 Cleaning



The Nipun™ hand can be cleaned with a soft damp cloth. Do not submerge the device in water for cleaning. Do not use any chemicals to clean Nipun™. The EMG electrode plates can be cleaned with a damp cloth.

5.3 Maintenance



No special maintenance of Nipun™ is necessary by the user. In case of any issues with the device, the user can reach out to the customer support team.

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Frequently Asked Questions

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6. Frequently Asked Questions

6.1 Switch and LED Notifications

Q: What to do when the Multi Functional Switch is not responding to inputs?
A: Please restart the device. If the problem continues, please contact our customer support.

Q: What to do when the Multi Functional Switch continuously keeps flashing?
A: Please refer to the LED Notifications section of this manual.

6.2 Device Charging

Q: My battery does not seem to last all day. What can I do?
A: Battery life depends on the type of activities you perform and how often you use the device.

Q: How do I know if the device charging is complete?
A: Check the charging LED. Green means the device is fully charged.

6.3 Fingers

Q: The fingers are not closing or opening fully. What should I do?
A: Try restarting the device. If the problem continues, please contact our customer support.

Q: What to do when I can hear the sound of the motors moving but the fingers do not close?
A: The internal components might have been damaged by excessive wear or load. Please contact our customer support.

Q: The fingers are moving abnormally. What to do?
A: Try cleaning the EMG electrode surface with a damp cloth and then restart the device. If the problem continues, please contact our customer support.

6.4 Wrist (Nipun Advanced)

Q: What to do when the wrist rotation is not smooth?
A: Something might have got stuck in the wrist mechanism. Please contact our customer support.

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6.5 Motors

Q: The motors were good earlier but now they are making some sounds. What should be done?

A: It might be because of wear and tear of the motor parts. Try restarting the device. If the problem continues, please get in touch with our customer support team.

6.6 EMG Control

Q: Initially I was able to achieve grips with reasonable signal strength, but now even a slight movement in the muscle moves the fingers. What can I do?

A: Your muscle signals may have become stronger because of frequent use. Please check your EMG signal strength in the KalAssist® application. You can reach out to your clinician to reconfigure your device according to your latest EMG signal strength.

Q: What to do when the fingers are not responding to my EMG signals?

A: Please check if the battery is charged enough. Open the EMG signal graph in the KalAssist® application, move the forearm muscles near the EMG electrode, and check if you can see EMG signals in the graph. If the problem persists, please contact your clinician.

Q: What should be done when the fingers respond randomly to signals?

A: Try cleaning the EMG electrode surface with a damp cloth and then restart the device. If the problem continues, please contact your clinician.

6.7 Bluetooth Connectivity

Q: What to do when the device cannot be connected even after trying multiple times?

A: Ensure the device is within a 5 feet radius. If the problem continues, please restart the device.

Q: The device gets disconnected frequently. What to do?

A: Please restart the application. If the problem continues, please restart the device.

6.8 Mobile Application

Q: What to do when I am unable to save data to the device?

A: Please restart the application. If the problem continues, please restart the device.

Q: What to do when the device health data is not getting updated in the mobile application?

A: Please restart the application. If the problem continues, please restart the device.

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Q: The application crashes frequently. What should be done?
A: Restart the application. If the problem continues, please contact our customer support.

Q: What should I do when the application is not showing the battery percentage?
A: Please restart the application. If the problem continues, please restart the device.

6.9 Forearm

Q: The forearm is too tight. What should I do?
A: Please contact your clinician.

Q: What to do when the forearm socket drops off as I lift heavy weights?
A: Please contact your clinician.

Q: The forearm socket was tight initially and now it has become loose. What to do?
A: Please contact your clinician.

6.10 Physical Damage

Q: What if the device gets damaged?
A: Please refer to the Warranty and Returns section of this manual.

6.11 Others

Q: What if the device gets wet in the rain?
A: Switch off the device. Dry off any visible water. Leave the hand to dry completely and then try to switch it on. If the device does not turn on, please contact our customer support.

Q: I have an issue with the device but I don't use the mobile application. What can I do?
A: Please contact your clinician.

Q: What details are required when contacting customer support?
A: Please give the product serial number and date of purchase to the support executive.

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General Safety, Warning and Precautions

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7. General Safety, Warning and Precautions



Please refer to this section for general safety information and guidance on how to take care of the Nipun™ hand. The end user is the intended operator of the device and is responsible for its use.

- Nipun™ is not water resistant. Please protect it from any form of water, as it might damage internal components.
- Do not subject Nipun™ to excessive moisture, heat, flame, vibration, shock and dust.
- You should not wear Nipun™ on the forearm while it is charging.
- You should not subject Nipun™ to excessive loads or impacts.
- Do not pull or push objects with fingertips.
- Do not use Nipun™ to operate heavy machinery or drive automobiles.
- Do not disassemble, modify or repair the Nipun™ hand or its components in any way.
- Do not use Nipun™ to operate electronic devices while they are connected to a mains outlet, as this can affect the EMG signals.
- It is not recommended to use your device while undergoing treatment that involves other medical electrical equipment.
- Disposal of the device has to be done in accordance with local regulations, or it can be returned to Makers Hive for disposal.
- Maintenance and repairs should be performed only by qualified Makers Hive technicians.
- Avoid dirt or fluids coming in contact with the electrode.

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- Do not program or control Nipun™ with unapproved, alternative software or hardware systems. Doing so will void the warranty.
- Nipun™ was developed for everyday use and must not be used for unusual activities. These include, for example, extreme sports (free climbing, paragliding, etc.) or activities causing excessive strain or shock to the prosthetic device (push-ups, mountain biking, etc.).
- Driving any vehicle with Nipun™ is not recommended.

Battery

- Only Makers Hive batteries should be used with Nipun™.
- Battery replacement should be done only by the clinician or by qualified Makers Hive technicians.
- Batteries must not be replaced by the end user.
- Batteries are to be replaced annually by service personnel, for optimal performance.
- Do not apply excessive pressure, heat, or pierce the battery.
- Do not bend or exert excessive pressure on the battery.
- Do not disassemble or short circuit the battery.
- Only use the charger provided with the device to charge the battery.
- Disposal of the battery should be done in accordance with local regulations.
- If you are not going to use Nipun™ for a long period of time, contact your clinician to get the battery removed and store it in a cool, dry place.

⚠ **If you observe any leakage or swelling from the battery:**

1. Immediately turn off the device.
2. Disconnect the charger.
3. Move to a safe area and observe for 15 minutes.
4. Contact your clinician and get the battery replaced.

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Warranty, Disposal and Return Policy

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8. Warranty, Disposal and Return Policy

This section is a summary. For the full details, refer to the Nipun Warranty, Disposal and Return Policy, available on www.makershive.io and from your clinician.

Warranty



The Nipun™ device carries a warranty of 2 years from the date of the invoice. The battery and charger carry a warranty of 12 months from the date of the invoice.

The warranty covers manufacturing defects only. Parts that wear out in normal use are not covered.

The warranty is void if:

- the safety instructions, warnings and precautions in this manual are not followed
- the device is opened, modified, repaired or serviced by anyone other than Makers Hive
- the device is exposed to water, moisture, heat, flame, shock or dust, or is used for unusual activities
- a battery, charger or adapter other than the ones supplied by Makers Hive is used
- the damage is from theft, fire, flood, acts of nature, accident, misuse or abuse

To make a claim, stop using the device and contact customer support within 7 days of noticing the defect. Give the product serial number and the invoice.

Return Policy

Once a device is sold, it cannot be returned for a refund. A device is repaired or replaced only if Makers Hive confirms a manufacturing defect during the warranty period. Returns are made through your clinician.

Disposal

Do not put the device or the battery in household waste. Return the device and used batteries to Makers Hive through your clinician for safe disposal.

For full details, refer to the Nipun Warranty, Disposal and Return Policy, available on www.makershive.io and from your clinician.

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Regulatory Information

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9. Regulatory Information

Makers Hive declares that it meets appropriate standards for the design, manufacture and supply of prosthetic products and user software. Continued compliance with the standards is monitored by a programme of internal and external audits.

Standard	Description
ISO 22523:2006	External limb prostheses and external orthoses. Requirements and test methods
ISO 10993-23:2021	Biological evaluation of medical devices. Part 23: Tests for irritation
ISO 10993-5:2009	Biological evaluation of medical devices. Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices. Part 10: Tests for skin sensitization
IEC 60601-1:2005/ AMD1:2012	Medical electrical equipment. Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 (CISPR 11 radiated emission, IEC 61000-4-2 electrostatic discharge, IEC 61000-4-8 power frequency magnetic field)	Electromagnetic disturbances. Requirements and tests
IEC 61000-4-3:2020	Electromagnetic compatibility (EMC). Part 4-3: Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test
ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied
IEC 60068-2-1:2007	Environmental testing. Part 2-1: Tests. Test A: Cold
IEC 60068-2-2:2007	Environmental testing. Part 2-2: Tests. Test B: Dry heat

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Technical Information

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10. Technical Information

Voltage	7.4 V (nominal)
Max. current	1 A
Battery	Rechargeable lithium ion, 7.4 V (nominal), 1100 mAh
Max. load lift in hook grip	8 kg
Time from full open to full close	1 second
Operating temperature	-10 °C to +55 °C
Product service life	5 years

Weight and Dimensions

	Nipun Neo	Nipun Flex	Nipun Advanced
Weight	380 g	440 g	470 g
Length	165 mm	165 mm	160 mm
Width	72 mm	72 mm	72 mm
Wrist diameter	48 mm	48 mm	48 mm

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Symbols Used

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11. Symbols Used


Indicates the manufacturer


Indicates the device shall only be used with a rechargeable battery


Indicates Class II equipment, which provides double isolation to protect against electric shock


Indicates a Type BF applied part, complying with IEC 60601-1


Indicates the need for the user to consult the instructions for use


Indicates a medical device that needs to be protected from moisture



Indicates the product serial number that uniquely identifies the device



Indicates the device model number



Indicates the batch or lot code


Indicates the date of manufacturing


Indicates that the device should not be used after the date accompanying the symbol


Indicates the temperature limits within which the device has to be used


Indicates important information


Indicates that the product should not be discarded as unsorted waste but disposed of in accordance with local regulations



Indicates that the product is a medical device

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Abbreviations & Glossary

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12. Abbreviations and Glossary

Abbreviations

A: Ampere

BLE: Bluetooth Low Energy

EMG: Electromyography

ISO: International Organization for Standardization

IEC: International Electrotechnical Commission

MFSW: Multi Functional Switch

mm: Millimetres

V: Volt

Glossary

Amputation: Amputation is the separation of a bone in healthy tissue or the removal of a limb at a joint (exarticulation). Amputation surgery may be necessary if an injured or diseased limb is not expected to heal and if life is endangered as a result. Possible causes include circulation issues, infections, accidents, cancer, or a congenital malformation of the limb.

Amputation level: The location at which the body part is amputated.

EMG: Electromyography is an electro-diagnostic medicine technique for evaluating and recording the electrical activity produced by skeletal muscles.

Grip patterns: The different finger positions that are possible using a myoelectric hand to grasp or hold different objects.

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Contact Us

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13. Contact Us



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2nd Floor, Plot No 11, Survey No 64, Yashshree Tech Park,
Huda Techno Enclave, Sector 3, Near Raidurgam Metro Station,
GHMC Serilingampally, Hyderabad, Rangareddy,
Telangana, 500081, India

Customer Support

You can reach our support team at
customersupport@makershive.io
or on the toll-free number 1800 309 7790.

For more details, please visit www.makershive.io.

Document Version History

Please refer to our website for the latest version of the user manual.

- This document is Version 1.0.

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