Neurolutions
Kandu

IpsiHand® System

Rebuild movement one thought at a time.

IpsiHand is a Class II, prescription-only medical device. It is the first and only FDA-cleared noninvasive brain-computer interface device for stroke rehabilitation.[4]

IpsiHand is indicated for adult stroke survivors who are six or more months post-stroke with persistent upper extremity motor impairment. IpsiHand therapy supports improvement in function of the affected arm and hand.[8]

The system includes a dry-electrode EEG headset, a hand-worn powered motion-assist device, and a tablet with therapy software. Together, these components detect brain activity associated with motor intent and use that signal to support repetitive movement of the affected hand.[8]

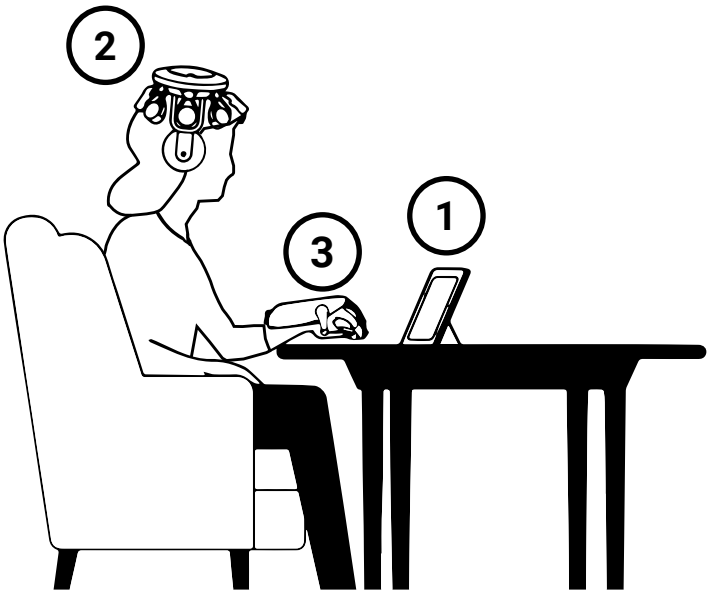
IpsiHand System Overview

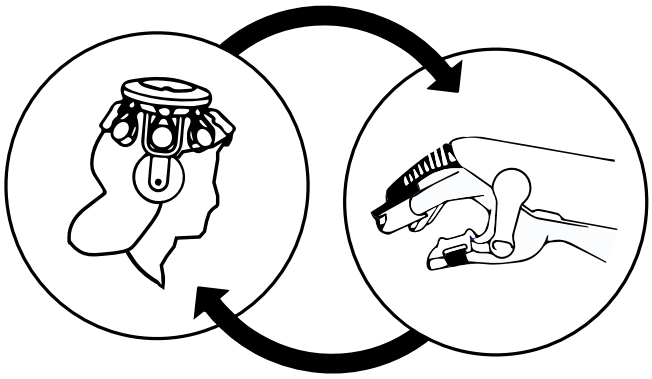
IpsiHand leverages Hebbian learning, strengthening neural pathways through repeated, paired activation. Many stroke survivors may be able to visualize movement or intend to move, but cannot generate movement because the motor circuit is disrupted. [1,2,3]

IpsiHand detects that intention and links it to actual hand motion through the device, helping reestablish the connection between cortical activation and functional movement over time.

1. The tablet displays the movement task.
2. The EEG headset detects the patient's intention to move.
3. The Handpiece completes the motion so the patient can see and feel it. [1,2,3]

IpsiHand is recommended for daily use. With repeated closed-loop practice, patients often show improvement in motor function even when the device is not in use. [1,2,8]





Repeated therapy may improve motor function by strengthening connections and encouraging new pathways to healthy parts of the brain.[1,3]

What fires together, wires together.

Consistent use over time may improve motor function by strengthening connections and encouraging new neural pathways from the uninjured parts of the brain associated with hand movement. [1,3]

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What to Expect Once IpsiHand Is Prescribed

Once a prescription and insurance approval are in place, your patient is evaluated for clinical appropriateness for the device. An EEG Signal Test is done to assess the patient's motor-intent EEG signals. This step determines whether the patient is an appropriate candidate who can participate in IpsiHand therapy.

How is IpsiHand Administered?

IpsiHand is a self-directed therapy patients use at home each day.

IpsiHand Clinical Evidence

Prospective IpsiHand studies enrolled adult stroke survivors at least six months post-stroke, including individuals many years beyond stroke onset. Participants represented all levels of upper extremity motor impairment, a population in which standard rehabilitation typically provides little additional recovery.[1,6,7]

Across studies, all participants improved on the primary motor outcome after 12 weeks. In the Rustamov analysis (n=26), the mean Fugl-Meyer Upper Extremity gain was 8.1 points, surpassing the 5.25 MCID. Gains were independent of baseline severity, and secondary outcome measures indicated functional improvement in daily activities.[1]

Motor improvement correlated with total hours of device use, underscoring the importance of consistent and repeated closed-loop repetitive practice. These findings support the mechanism of pairing cortical intent with assisted movement to facilitate neuroplasticity in chronic stroke.[10,11]

Real-world use demonstrates the same pattern of improvement. In a retrospective analysis of 56 commercial users, 64 percent achieved clinically meaningful improvement by week 12, including those with severe baseline impairment. Some continued to show MCID-level gains beyond week 12. This alignment between trial and real-world results supports IpsiHand as a practical option for chronic upper extremity motor recovery.[9]

Durable Outcome

The results are durable. Among patients assessed six months after completing therapy, without further IpsiHand use, average Fugl-Meyer scores changed by ± 1-2 points, indicating sustained motor gains.[6,7]

Citation:

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Patient Selection Criteria Checklist

- ❑ Chronic Stroke (≥ 6 months post-stroke)
- ❑ Age 18 or older
- ❑ Undergoing rehabilitation to facilitate muscle re-education and for maintaining or increasing range of motion in the upper extremity

Optimal Candidate Checklist

- ❑ Able to hold head upright for without head support for 60 minutes
- ❑ Able to follow one step visual or written commands; severe cognitive impairment may not be appropriate for the device
- ❑ Visual skills within ability to follow graphics on a tablet

Documentation Needed for Medical Necessity

For any DME item to be covered, the medical record must document the patient's condition with sufficient detail to support medical necessity. Required information includes:

- ❑ Patient's diagnosis and current level of function.
- ❑ Duration of patient's condition
- ❑ Prognosis with likely outcome of course of diagnosis, and chance of recovery or recurrence.
- ❑ Statement of benefit for increasing motor function as it directly relates to patients ADL's, IADL's, prior level of function, and subsequent independence or quality of life
- ❑ Timeline of reported trialed therapeutic interventions with result (Constraint-Induced Movement Therapy, Pharmacotherapy and Botox Injections, Assistive Devices and Orthotics, etc.)
- ❑ PT and OT notes which address ADLs and/or clinical course of therapy (worsening).

INDICATION FOR USE
The Neurolutions® Upper Extremity Rehabilitation System is indicated for use in chronic stroke patients (≥ 6 months post stroke) age 18 or older undergoing stroke rehabilitation, to facilitate muscle re-education and for maintaining or increasing range of motion in the upper extremity.
- Intended Use Environment: The Neurolutions System is designed for use in clinic or home settings as part of prescribed therapy.

CONTRAINDICATIONS
The Neurolutions System is contraindicated for use in patients having any of the following conditions:
- Severe spasticity or rigid contractures in the wrist and/or digits that would prevent the Neurolutions Handpiece from being properly fit or positioned for use.
- Skull defects due to craniotomy or craniectomy.

IMPORTANT SAFETY INFORMATION
- System components contain lithium-ion batteries that MUST NOT be exposed to flame, excessive heat, or incinerated; personal injury may occur.
- Only use the Charging Adapters provided with the Neurolutions System to recharge system components and avoid risk of shock.
- Use of the Neurolutions System adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the Neurolutions System and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Neurolutions System. Otherwise, degradation of the performance of the Neurolutions System could result.
- The Neurolutions Handpiece enclosure may reach a maximum temperature up to 43°C during use. To reduce the risk of discomfort, you should remove the Handpiece from your hand if the device feels warm on your skin.
- Tight straps on the Handpiece may restrict your circulation. Therefore, always check that the straps are not too tight throughout your range of motion to ensure proper circulation during use.
- The Neurolutions System should only be used on intact skin, and the System should be cleaned and disinfected regularly to minimize possible contamination and risk of infection.

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