Neurolutions

What is IpsiHand?

IpsiHand is a class II medical device, available by prescription only, that consists of a dry electrode EEG headset, a hand-worn powered motion assist device, and a tablet computer containing therapy software.

IpsiHand is the first and only **brain-computer-interface (BCI) controlled therapy** to be awarded FDA authorization.

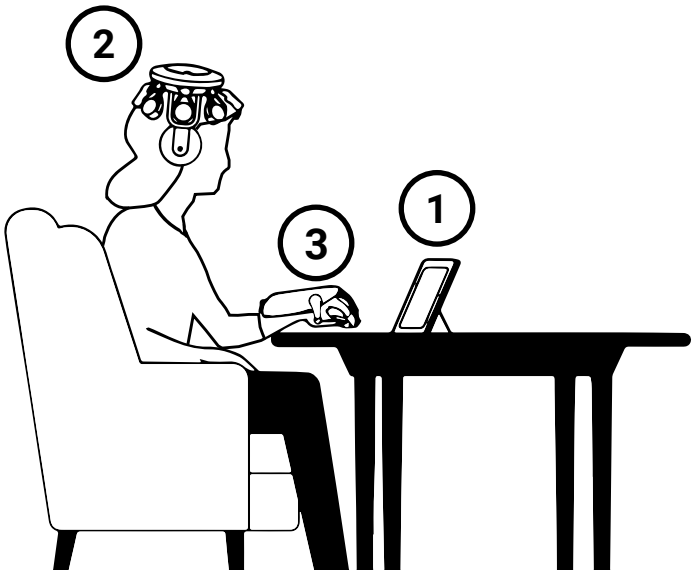
This breakthrough technology allows for delivery of thought-actuated therapy for chronic upper extremity disability in stroke patients, maintaining or increasing range of motion in the upper extremities**.**

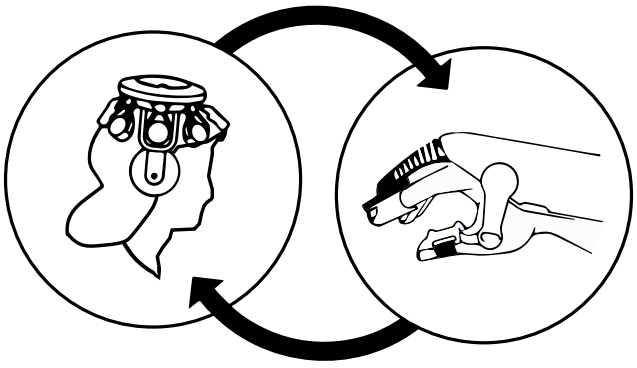
How Does IpsiHand's Technology Work?

IpsiHand works by promoting Hebbian learning — a process of synaptic plasticity, rewiring neurons and neuronal circuits by repeatedly firing them simultaneously. Stroke survivors who have lost function retain their ability to visualize and 'intend' to move; however, they are unable to realize movement due to the absence of a functional motor circuit. **IpsiHand helps rebuild connections between cortical activation of the "intent to move" and movement by externally circumventing the impaired motor circuit.**

(1) The tablet prompts the patient to visualize hand movements; **(2) the headset** detects their intention to move non-invasively using EEG and instructs the handpiece to complete the intended motion; **(3) the handpiece**-actuated motion is simultaneously observed and felt by the patient.

IpsiHand is used at home, typically for 1 hour per day, 5 days per week. These sessions allow a patient's imagined motor movements to be repeatedly realized via the external prosthetic motor circuit, reconnecting intent with action. In function, the system provides therapy by coupling a temporary prosthetic motor circuit with a peripheral, proprioceptive sensory neurostimulation unlike any product that has come before it.





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

What fires together, wires together.

Phone: 833-438-4774 | Fax: 323-300-2410 | 7033 Hayvenhurst Ave, Van Nuys, CA 91406 | insurance@neurolutions.com

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What Happens After a Patient is Prescribed IpsiHand?

Upon receipt of a valid prescription and insurance approval for coverage, the Neurolutions clinical staff works with the patient to schedule an EEG Signal Test and evaluate the patient's motor intent signals. This crucial step ensures the patient is a suitable candidate capable of benefiting from the therapeutic advantages of IpsiHand.

How is IpsiHand Administered?

IpsiHand is self-administered in the patient's home five days per week as a one-hour therapy module.

What Clinical Evidence Backs IpsiHand?

100% of the patients in enrolled in IpsiHand clinical studies demonstrated improvement on the primary outcome measure. A total of 66.7% exceeded the minimal clinical important difference (MCID). The MCID is defined as either Action Research Arm Test (ARAT) improvement of 5.7 points or average Fugl-Meyer Upper Extremity (FMUE) improvement of 5.25 points.

Results of testing across 3 clinical studies and 40 total patients demonstrated that following 12-weeks of use of the Neurolutions System, chronic stroke survivors all showed increases in the mean change from their baseline scores on the primary outcome measure.

Ten of the 40 patients were assessed utilizing ARAT as the primary outcome measure and the mean scores exceeded the MCID of 5.7 points. Thirty of the total 40 patients were assessed utilizing the FMUE assessment as the primary outcome measure. For 66.7% of these 30 patients, mean scores exceeded the MCID of 5.25 points. On average, the improvement on the FMUE was +7.77 points.

IpsiHand provides superior FMUE outcomes and outperforms standard care, achieving an average improvement of 7.7 FMUE points per 12 weeks. The minimal clinically important difference (MCID) for FMUE is +5.25, indicating significant clinical benefit. Clinical studies report no patient injury or adverse events.

Do Results Last After Use?

IpsiHand results are durable and retained. Six months after using IpsiHand, improvements in upper extremity function remained consistent. This sets IpsiHand apart from other rehabilitation technologies, which typically show no carryover in function.

(See our complete Index of Clinical Studies for more information)

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Prescribing Requirements

Standard prescription and insurance forms are included on the following pages for your convenience and completion when prescribing the IpsiHand System for your patient:

Please send completed and signed **Prescription Forms** and submit completed **Insurance Forms** as well as a **copy of the front and back of insurance cards** to insurance@neurolutions.com or fax to (323) 300-2410.

Patient Selection Criteria

Indication for Use

- For chronic stroke patients (≥ six 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.

Contraindications

- Severe spasticity or rigid contractures in the wrist and/or digits
- Skull defects due to craniotomy or craniectomy

Prior Treatments & Physician Recommendation

- An EEG Signal Test and evaluation is performed on each patient prior to dispensing.

Neurolutions Customer Care Team

After receiving the completed documents, our team is committed to providing you and your patient the support needed throughout the entire care journey.

Beginning with reimbursement, our team will be available to you and your patients. Upon insurance approval, Neurolutions will conduct an EEG signal test. During delivery, we will provide in-depth training and will continue to support your patient as they progress through therapy.

If you or your staff have any questions about your patient's IpsiHand prescription, please do not hesitate to contact our **Customer Care team at 1-833-438-4774** or **insurance@neurolutions.com.**

We look forward to working together to provide the best possible care for your patient.

(Please find RX and insurance forms on the following pages)