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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.

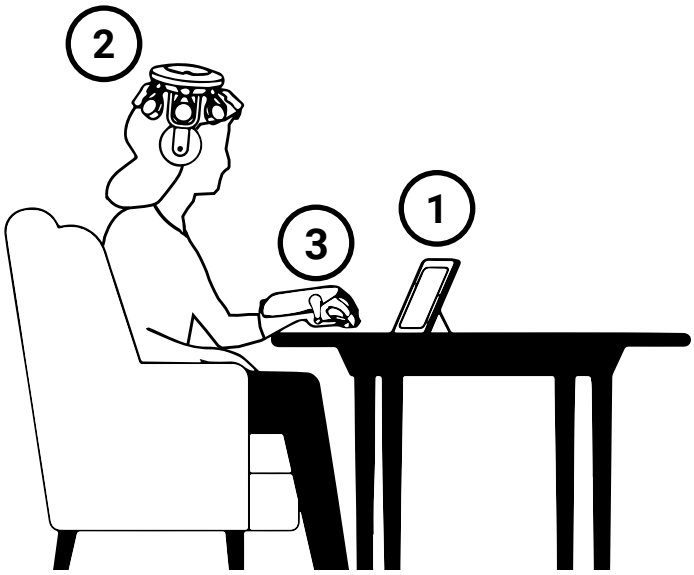
This breakthrough technology allows for delivery of thought-actuated therapy for chronic upper extremity disability in stroke patients, maintaining or increasing range of motion in the upper extremities**.**

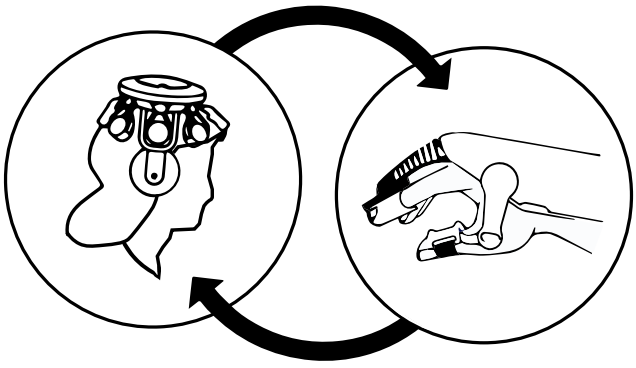
How Does IpsiHand's Technology Work?

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.

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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.

Can I Track Patient Progress?

IpsiHand's digital analytics and remote monitoring features provide real-time visibility into patient progress for both the patient and care teams. This feature allows for immediate feedback and adjustments to therapy regimens based on the specific needs and responses of the patient.

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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IpsiHand Prescription & Assessment Form

Fax to 323-300-2410 *or* **email to Rx@neurolutions.com** | **REQUIRED ATTACHMENTS:** Relevant medical records

PATIENT INFORMATION

Order Date: _____

FIRST NAME: _____ LAST NAME: _____ DATE OF STROKE: _____

DATE OF BIRTH: _____ M: ☐ F: ☐

PHONE: _____ EMAIL: _____

ADDRESS: _____ CITY: _____ STATE: _____ ZIP: _____

CLINIC NAME _____ PHONE _____ FAX _____ CONTACT NAME _____

ADDRESS: _____ CITY: _____ STATE: _____ ZIP: _____

BELOW THIS LINE TO BE COMPLETED BY HEALTHCARE PROVIDER ONLY

MEDICAL NECESSITY ASSESSMENT: *This information must be supported in the patient's medical record and a copy of the record must accompany this prescription.*

Therapies or treatments tried and/or considered (Check all that apply)

- ☐ Occupational and/or Physical Therapy Program
  - ☐ ADL Training
  - ☐ Range of Motion
  - ☐ Strengthening
  - ☐ Biofeedback Training
  - ☐ Task-Specific Training
  - ☐ Constraint-Induced Movement Therapy
  - ☐ Functional Electrical Stimulation
  - ☐ Orthotic Management
  - ☐ Home Exercise Program
  - ☐ Neuromuscular Re-education
- ☐ Pharmacological Management (Spasticity Management)
- ☐ Other _____

Reasons why the therapies or treatments failed, are contraindicated or inappropriate (Check all that apply)

- ☐ Decreased active range of motion of the upper extremity due to impaired coordination and muscle weakness
- ☐ Muscle weakness limits ability to initiate functional movements with the upper extremity
- ☐ Decreased independence for completing ADL's; requires assistance due to decreased upper extremity functional use
- ☐ Lack of coordination (gross motor and fine motor) limit functional use of upper extremity
- ☐ Decreased ability to motor plan and sequence functional upper extremity movements independently
- ☐ Patient's gains and functional improvements have plateaued trialed therapies
- ☐ Other _____

Rx: IpsiHand Upper Extremity Rehabilitation System (HCPCS: E0738) | Check affected upper extremity ☐ Left ☐ Right

Diagnoses: (List ICD-10 codes for primary and secondary diagnoses)

1. _____ 2. _____

Physician HIPAA Authorization (For Neurolutions Patient Insurance Support Program)

By signing this prescription, I attest and certify that:

- The patient indicated herein has requested that Neurolutions provide insurance support services
- The information and documentation provided is accurate and complete to the best of my knowledge
- This information is provided as an information service only
- Neurolutions assumes no responsibility for and does not guarantee the quality, scope or availability of reimbursement support
- These patient support services have no independent value to providers
- I acknowledge that Neurolutions will collect and have on file a signed copy of a current and complete patient HIPAA authorization form, permitting this office to share the patient's protected health information with Neurolutions

PHYSICIAN SIGNATURE _____ DATE _____ EMAIL _____

PHYSICIAN NAME [PRINT] _____ NPI _____ TAX ID _____

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IpsiHand ICD-10-CM[1] Diagnosis Coding Guide

IpsiHand 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. The following possible ICD-10-CM diagnosis codes are used to report upper limb deficits in patients who may be eligible to receive treatment with the IpsiHand system.

Code:	ICD-10 CM Diagnosis Code Description
I69.031	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.032	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.033	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.034	Monoplegia of upper limb following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.051	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right dominant side
I69.052	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left dominant side
I69.053	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting right non-dominant side
I69.054	Hemiplegia and hemiparesis following nontraumatic subarachnoid hemorrhage affecting left non-dominant side
I69.131	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.132	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.133	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.134	Monoplegia of upper limb following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.151	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right dominant side
I69.152	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left dominant side
I69.153	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting right non-dominant side
I69.154	Hemiplegia and hemiparesis following nontraumatic intracerebral hemorrhage affecting left non-dominant side
I69.231	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.232	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.233	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.234	Monoplegia of upper limb following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.251	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right dominant side
I69.252	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left dominant side
I69.253	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting right non-dominant side
I69.254	Hemiplegia and hemiparesis following other nontraumatic intracranial hemorrhage affecting left non-dominant side
I69.331	Monoplegia of upper limb following cerebral infarction affecting right dominant side
I69.332	Monoplegia of upper limb following cerebral infarction affecting left dominant side
I69.333	Monoplegia of upper limb following cerebral infarction affecting right non-dominant side
I69.334	Monoplegia of upper limb following cerebral infarction affecting left non-dominant side
I69.351	Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side
I69.352	Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side
I69.353	Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side
I69.354	Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side
I69.831	Monoplegia of upper limb following other cerebrovascular disease affecting right dominant side
I69.832	Monoplegia of upper limb following other cerebrovascular disease affecting left dominant side
I69.833	Monoplegia of upper limb following other cerebrovascular disease affecting right non-dominant side
I69.834	Monoplegia of upper limb following other cerebrovascular disease affecting left non-dominant side
I69.851	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right dominant side
I69.852	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left dominant side
I69.853	Hemiplegia and hemiparesis following other cerebrovascular disease affecting right non-dominant side
I69.854	Hemiplegia and hemiparesis following other cerebrovascular disease affecting left non-dominant side

[1] https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm

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IPSIHAND™ PATIENT SELECTION GUIDANCE

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 patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the medical necessity. The information should include:

- ☐ Patient's diagnosis and current level of functional limitations
- ☐ Duration of the patient's condition
- ☐ Prognosis (The likely outcome or course of a disease; the 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 (i.e. ADL) or Clinical course (worsening)

IpsiHand FDA Indications for Use

IpsiHand is indicated 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.

Read at https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-device-facilitate-muscle-rehabilitation-stroke-patients

Contraindications

- Severe spasticity or rigid contractures in the wrist and/or digits
- Skull defects due to craniotomy or craniectomy that may interfere with EEG signal acquisition

If you have any questions about The IpsiHand Patient Selection Guidance, please call the Neurolutions Patient Therapy Access Team at (833) 438-4774 or send an email to insurance@neurolutions.com