Neurolutions, Inc.
7033 Hayvenhurst Ave
Van Nuys, CA 91406

Phone: 833-438-4774
Fax: 323-300-2410
insurance@neurolutions.com

Dear Healthcare Professional,

The IpsiHand™ Upper Extremity Rehabilitation System (IpsiHand) is a therapeutic medical device used at-home by chronic stroke survivors to restore lost arm function.

IpsiHand is FDA-cleared, uses a non-invasive Brain Computer Interface (BCI) to promote Hebbian learning, and has been shown to be clinically effective regardless of severity of disability or time since stroke onset.

The documents contained in this packet are intended to simplify prescribing and completing insurance submissions for your patients, and include:

- An Introduction to IpsiHand and How IpsiHand Therapy Works
- Clinical Evidence and Patient Outcomes Overview
- Prescribing Requirements and Considerations for Medical Necessity
- Important Safety Information and FDA Indication for Use
- Prescription and Request for Coverage Form Templates
- Index of Clinical Studies

The Centers for Medicare and Medicaid Services (CMS) categorizes IpsiHand as Durable Medical Equipment and has established Healthcare Common Procedure Coding System **(HCPCS) Level II code E0738** to describe IpsiHand ("Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, including microprocessor, all components and accessories").

If you have any further questions or would like to discuss how IpsiHand can benefit your patients in more detail, please do not hesitate to contact us for further information. We are eager to partner with you to support your patients in their stroke recovery journey.

Best regards,

The Neurolutions Team

NPI Number: 1659070613
FDA De Novo Market Authorization Documents: Neurolutions.com/FDA

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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.

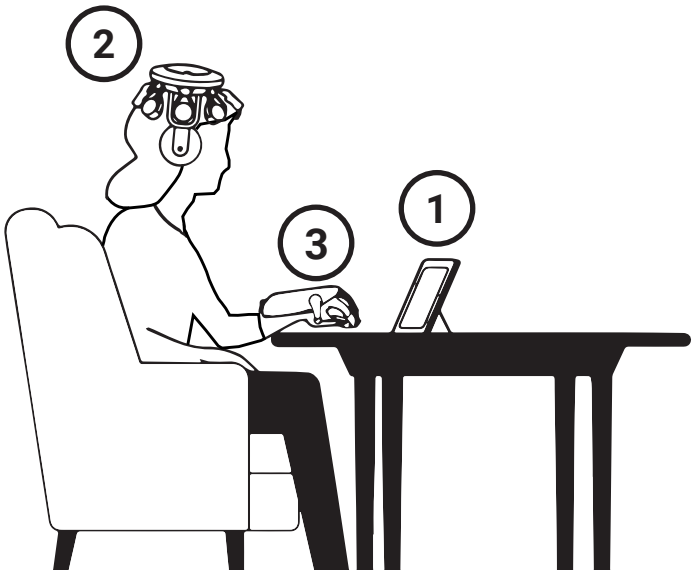
This breakthrough technology allows for delivery of thought-actuated therapy for chronic upper extremity disability in stroke patients, maintaining or increasing range of motion in the upper extremities**.**

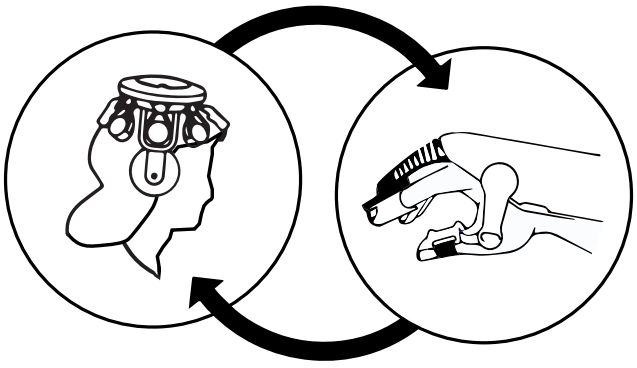
How Does IpsiHand's Technology Work?

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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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)

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Fill in this Insurance Template directly from your computer or print and complete by hand. Send completed and signed prescriptions to insurance@neurolutions.com or fax to (323) 300-2410

1. Patient Information

FIRST NAME: _____ LAST NAME: _____

DOB: ___ /___ / ___ GENDER:_____ EMAIL:_____

ADDRESS: _____ CITY: _____ STATE: _____

PHONE:_____ CELL:_____

EMERGENCY CONTACT NAME: _____ EMERGENCY CONTACT PHONE: _____

2. Medical Information

ICD-10 DIAGNOSIS: _____

AFFECTED UPPER EXTREMITY: _____

PRIOR TREATMENTS ATTEMPTED:_____

3a. Primary Insurance Information

INSURANCE PROVIDER: _____

POLICY ID: _____ GROUP #: _____

ADDRESS: _____

CITY: _____ STATE: _____ ZIP:_____

BENEFITS PHONE:_____

POLICY HOLDER NAME: _____

DOB: ___ /___ / ___ RELATIONSHIP TO PATIENT:_____

Self Spouse Parent Guardian

3b. Secondary Insurance Information

INSURANCE PROVIDER: _____

POLICY ID: _____ GROUP #: _____

ADDRESS: _____

CITY: _____ STATE: _____ ZIP:_____

BENEFITS PHONE:_____

POLICY HOLDER NAME: _____

DOB: ___ /___ / ___ RELATIONSHIP TO PATIENT:_____

Self Spouse Parent Guardian

(Optional)

4. Primary Clinic Point of Contact

FIRST NAME: _____ LAST NAME: _____

PRACTICE NAME: _____ EMAIL:_____

ADDRESS: _____ CITY: _____ STATE: _____

ZIP:_____ PHONE:_____ FAX:_____

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Patient Enrollment and Consent

Please Read and Sign Below:

By signing below, I certify that:

- I would like to enroll in the Neurolutions patient insurance support program and authorize Neurolutions to help me determine whether I can receive insurance coverage for the IpsiHand Device.
- This information is provided as an information service only. Neurolutions assumes no responsibility for and does not guarantee the quality, scope or availability of its assistance with insurance coverage for the IpsiHand device.

Patient Signature:_____ Date: _____

(If personal representative, indicate authority to sign on behalf of patient)

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HIPAA Authorization Form for the Disclosure of Patient Information

For Neurolutions Patient Insurance Support Program

Neurolutions assists patients in obtaining insurance coverage and reimbursement for the IpsiHand device. In order to provide these services, Neurolutions must obtain and share certain information about you from your doctor, other health care providers, and each of your health insurers.

Please complete this authorization, sign and date it, and return it to your doctor as well as Neurolutions Insurance Support at insurance@neurolutions.com or fax to (323) 300-2410.

By signing below, I hereby authorize each of my doctors, and other health care providers and each of my health insurers to disclose to Neurolutions my protected health information, including but not limited to information related to:

- My medical condition and medical treatment
- My social security number
- My address and telephone number
- Information about my health insurance coverage, including my insurance identifiers

Further, I authorize Neurolutions to receive, access, obtain, use, disclose, share and maintain my protected health information, including, but not limited to, the information described above, in order to assist me in obtaining insurance coverage and reimbursement for the IpsiHand device, including contacting me to the extent necessary.

By signing this authorization, I understand the following:

- That information disclosed under this authorization might be disclosed and this redisclosure may no longer be protected by federal privacy laws.
- That I am not required to sign this authorization. My choice about whether to sign will not change the way my healthcare providers or insurers treat me.
- If I refuse to sign this authorization, I understand that this means I will not be able to receive the reimbursement support services described herein.
- This authorization will last until I am no longer receiving reimbursement support services from Neurolutions.
- I give Neurolutions the right to bill for and receive insurance payments for my medical care, and I direct my insurance company and any other entity paying for my medical care ("my insurer") to pay IpsiHand directly for the system. I agree to forward all payments to Neurolutions if my insurer or other responsible party pays me directly. I will be responsible for any applicable co-insurance, copayments, or private pay amounts not covered by my insurance provider.

I understand that I may revoke this authorization at any time by mailing a letter to a doctor or other health care providers by contacting my health insurers. However, I cannot cancel actions that have already been taken by relying on this authorization.

Patient Signature: _____ **Date**: _____
(If personal representative, indicate authority to sign on behalf of patient)

Patient Name (Printed)**:** _____

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HIPAA Authorization Form: Physician Section of Application

For Neurolutions Patient Insurance Support Program

FIRST NAME: _____ LAST NAME: _____

PRACTICE NAME: _____ PHYSICIAN'S NPI: _____

ADDRESS: _____ CITY: _____ STATE: _____

ZIP:_____ PHONE:_____ FAX:_____

PRIMARY CONTACT AT PHYSICIAN'S OFFICE:_____

EMAIL:_____ PHONE:_____

By signing below, 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 the reimbursement support services.
- These patient support services have no independent value to providers.
- I acknowledge that the patient has provided this office with a signed copy of a current and complete HIPAA Authorization form permitting this office to share the patient's protected health information with Neurolutions.

Physician Signature:_____ **Date**: _____

Please complete this authorization, sign and date it, and return it to Neurolutions Insurance Support at insurance@neurolutions.com or fax to (323) 300-2410.

Reminder: Please do not send in patient health information without a valid HIPAA Authorization Form on record.

Fill in the Rx template directly from your computer or print and complete by hand
Send completed and signed prescriptions to rx@neurolutions.com or fax to (323) 300-2410

IpsiHand by Neurolutions

PATIENT INFORMATION

FIRST NAME _____ LAST NAME _____

ADDRESS _____ CITY _____

STATE _____ ZIP _____

ICD-10 CODE _____ BIRTHDATE _____ /_____ /_____
MM DD YYYY

HEALTH CARE PRACTITIONER

FIRST NAME _____ LAST NAME _____

NPI NUMBER _____ EMAIL _____
NATIONAL PROVIDER IDENTIFIER 10-DIGIT NUMBER

ADDRESS _____ CITY _____

STATE _____ ZIP _____ PHONE _____

INSURANCE STATUS ☐ Submitted to Insurance ☐ Will Submit to Insurance ☐ N/A or will not submit

PRESCRIPTION ITEM

IpsiHand Upper Extremity Rehabilitation System

LEFT OR RIGHT SIDE
☐ Left
☐ Right

DATE

_____ /_____ /_____
MM DD YYYY

_____
HCP SIGNATURE

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Neurolutions IpsiHand™ - Request for Prior Authorization

Medical Necessity and Clinical Efficacy: *IpsiHand is the only clinically-proven, non-invasive, at-home therapeutic solution for upper extremity rehabilitation and is the most appropriate option to improve a patient's functional abilities well beyond the capabilities of standard care.*

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

Prerequisite Criteria

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

Clinical Efficacy and Safety

- Superior UEFM Outcomes: The device outperforms standard care, achieving an average improvement of 7.7 UEFM points per twelve weeks. The minimal clinically important difference (MCID) for UEFM is +5.25, indicating significant clinical benefit.
- Durable and Retained Gains: Functional improvements extend to the hand, wrist, and arm, and are retained post-therapy, signifying durable, long-term benefits.
- Zero Adverse Events: Clinical studies report no patient injury or adverse event profile.

Mechanism of Action & Neuroplasticity

- There are portions of the brain involved with same sided limb movements, or ipsilateral motor movements. These are preserved in the setting of a stroke. The IpsiHand detects these signals non-invasively on the ipsilateral side of the brain with the EEG Headset where electrodes are placed on the scalp.
- Next, the ipsilateral signal is then decoded by a brain-computer interface device and relayed to the Handpiece and the tablet. The Tablet guides the user through visual images of a hand on the screen so the individual can engage in action-observation and motor imagery as they visualize opening and closing their affected hand.
- Reset in Phase Amplitude Coupling: The therapy induces significant changes in phase amplitude coupling between theta and gamma rhythms, directly correlating with motor recovery.

Patient Population and Home-Based Therapy

- Addresses Underserved Population: Indicated for chronic stroke patients (≥ six months poststroke) aged 18 or older, it serves an often-neglected demographic with limited therapeutic options.
- Self-Administered Home Therapy: IpsiHand offers the convenience of self-administered, home-based therapy, requiring just one-hour modules five days per week.

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.**

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Letter of Medical Necessity Guide

Below is a guide to assist in drafting a comprehensive letter of medical necessity for your patient. Ensure to include as much detail as possible for the items below:

Patient Information
- Full Name, Date of Birth, Diagnosis
- Include a medical history to include the date of stroke and the amount of time post-stroke
- Describe the patient's upper extremity hemiparesis, hemiplegia and how that impacts their ADLs

Alternative Treatments – List prior courses of rehabilitation and duration
- Physical Therapy
- Occupational Therapy
- List any other treatments completed to assist in improving motor function of their upper extremity

Clinical Rationale
- Documentation that the patient is considered to be in the chronic stage of their recovery
- FDA Indication for Use
- Ensure the patient aligns with the Indication for Use, and document as such.

Assessment of Contraindications – Confirm that your patient does not have an contraindications that would prohibit the from using the IpsiHand system. Contraindications stated below:
- Severe spasticity or rigid contractures in the wrist and/or digits
- Skull defects due to craniotomy or craniectomy

Clinical Evidence
- An Executive Summary and index of clinical studies are included in this packet to assist in documenting clinical evidence in your letter of medical necessity
- For complete details, please review any of the clinical studies listed on the IpsiHand clinical Studies index

Current Clinical Assessment of your Patient
- Document assessment as treating physician in a face-to-face or telehealth visit
- Current Fugl-Meyer Score for the upper extremity, if possible
- Range of Motion Measurements of the affected upper extremity, if possible
- ADL Impairment (requires assistance with e.g. bathing, dressing, grasping objects, hygiene, oral care, etc.)

Expected Outcomes
- Include that given the patient clinical presentation, alignment with the indications you would anticipate motor improvement of the affected upper extremity and increased independence in the management of ADLs

(Please see Sample Letter of Medical Necessity on the following pages)

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Sample Letter Of Medical Necessity

Scan here for editable Word version or visit neurolutions.com/clinical-resources

[Date]
ATTN: [Contact Title/Medical Director] [Contact Name (if available)]
[Payer Name]
[Address]
[City, State, Zip]

Re: Prior Authorization for the The IpsiHand™ Upper Extremity Rehabilitation System (IpsiHand)

Device HCPCS Code: HCPCS E0738: Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, include microprocessor, all components and accessories

Patient Name: [Patient First and Last Name]
Date of Birth: [MM/DD/YYYY]
Subscriber ID Number: [Insurance ID Number]
Subscriber Group Number: [Insurance Group Number]
Case ID Number: [Case ID Number]
Dates of Service: [Dates]

Dear [Contact Name],

I am writing on behalf of my patient, [Patient First and Last Name], to document the medical necessity for treatment with IpsiHand. This letter provides information about the patient's medical history, rationale for the treatment, plan, and summary.

Patient's Medical History
[Patient Name] has been diagnosed with [condition] as of [date]. They have been in my care since [date], having been referred to me by [referring physician name] for [reason].

Rationale for Treatment
[Summary of the rationale for treatment with IpsiHand should include a brief description of the patient's diagnosis, the severity of the patient's condition, prior treatments, durations, and responses, the rationale for discontinuation, as well as other factors or, underlying health issues that have affected prior treatment selection. Also include the impact on the beneficiary's and caregiver's life. Note the limitations without the requested device].

Treatment plan
In April 2020, the FDA classified IpsiHand as a breakthrough device and subsequently granted a De Novo market authorization in 2022, making IpsiHand the first brain-computer-interface (BCI) controlled therapy to be awarded an FDA market authorization. IpsiHand is indicated for use in 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.

IpsiHand is a prescription-only class-II medical device that consists of a dry electrode EEG headset, a hand-worn powered motion assist device, and a tablet computer containing therapy software. The tablet prompts the patient to visualize hand movements; the headset detects their intention to move non-invasively using EEG and instructs the handpiece to complete the intended motion; the handpiece-actuated motion is simultaneously observed and felt by the patient. This thought-actuated therapy is self-administered in the patient's home five days per week as a one-hour therapy module.

For stroke survivors like [patient name] who retain their ability to intend to move, but are unable to do so due to the absence of a functional motor circuit, IpsiHand delivers clinically-proven therapeutic benefits beyond the capabilities of standard care through Hebbian learning, a process of synaptic plasticity, rewiring neurons and neuronal circuits by repeatedly firing them simultaneously while externally circumventing the impaired motor circuit, helping rebuild connections between cortical activation of the intent to move and realized movement. [Include specific benefits resulting increased function and other physical or quality of life benefits that support the use of IpsiHand in this specific case].

Summary
In summary, IpsiHand is the only clinically-proven, non-invasive, at-home therapeutic solution for upper extremity rehabilitation and is the most appropriate option to improve this patient's functional abilities. I believe IpsiHand is appropriate and medically necessary for this patient and request that you provide coverage for this treatment. If you have any further questions about this matter, please get in touch with me at [Physician Phone Number] or via email at [Physician email]. Thank you for your time and consideration.

Sincerely,
[Physician Name and Credentials]

Enclosures
[List enclosures, which may include the letter of medical necessity, prescribing information, clinical notes/medical records, test results, executive summary/relevant peer-reviewed articles, and FDA-approved letter for the device.]

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Index of Clinical Evidence

Bundy, D. T., Souders, L., Baranyai, K., Leonard, L., Schalk, G., Coker, R., Moran, D. W., Huskey, T., & Leuthardt, E. C. (2017). Contralesional Brain-Computer Interface Control of a Powered Exoskeleton for Motor Recovery in Chronic Stroke Survivors. Stroke, 48(7), 1908–1915. https://doi.org/10.1161/STROKEAHA.116.016304

Kim R-K, Kang N, Desai Z, Cauraugh JH. A Meta-Analysis on Dual Protocols for Chronic Stroke Motor Recovery: Robotic Training and tDCS. Applied Sciences. 2023; 13(3):1992. https://doi.org/10.3390/app13031992

Humphries, J. B., Mattos, D. J. S., Rutlin, J., Daniel, A. G. S., Rybczynski, K., Notestine, T., … Leuthardt, E. C. (2022). Motor Network Reorganization Induced in Chronic Stroke Patients with the Use of a Contralesionally-Controlled Brain Computer Interface. Brain-Computer Interfaces, 9(3), 179–192. https://doi.org/10.1080/2326263X.2022.2057757

Rustamov, N., Humphries, J., Carter, A., & Leuthardt, E. C. (2022). Theta-gamma coupling as a cortical biomarker of brain-computer interface-mediated motor recovery in chronic stroke. Brain communications, 4(3), fcac136. https://doi.org/10.1093/braincomms/fcac136

Grefkes, C., & Fink, G. R. (2020). Recovery from stroke: current concepts and future perspectives. Neurological research and practice, 2, 17. https://doi.org/10.1186/s42466-020-00060-6

Dromerick, A. W., Lang, C. E., Birkenmeier, R., Hahn, M. G., Sahrmann, S. A., & Edwards, D. F. (2006). Relationships between upper-limb functional limitation and self-reported disability 3 months after stroke. Journal of rehabilitation research and development, 43(3), 401–408. https://doi.org/10.1682/jrrd.2005.04.0075

Woytowicz, E. J., Rietschel, J. C., Goodman, R. N., Conroy, S. S., Sorkin, J. D., Whitall, J., & McCombe Waller, S. (2017). Determining Levels of Upper Extremity Movement Impairment by Applying a Cluster Analysis to the Fugl-Meyer Assessment of the Upper Extremity in Chronic Stroke. Archives of physical medicine and rehabilitation, 98(3), 456–462. https://doi.org/10.1016/j.apmr.2016.06.023

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