

IpsiHand Device Eligibility Guidance

PURPOSE: This document provides guidelines for eligibility screening for the IpsiHand™ System and can be utilized prior to or at the time of EEG screening.

KEY FOR RESPONSES:

Yes	Unsure	No
Customer meets criteria	Concerns about eligibility that warrant clinical opinion. In-person or virtual screening may be needed	Customer does not meet criteria

1) CUSTOMER MEETS CRITERIA WITHIN INDICATION FOR USE (IFU)

Indications for Use (IFUs)	Yes	Unsure	No
Chronic stroke (≥6 months post)			
≥ 18 years old			
Arm and/or hand weakness			

2) CUSTOMER MUST MEET THIS CRITERIA

Contraindications	Yes	Unsure	No
No severe spasticity or rigid contractures in the hand/wrist that would prevent the IpsiHand hand piece from being fitted or properly positioned for use			
No skull defects due to craniectomy or craniotomy			

3) CLINICAL CONSIDERATIONS

Clinical Presentation	Yes	Unsure	No
Able to follow one-step visual or written directions that will appear on the tablet screen			

Able to sustain attention for activities that require concentration and focus			
Intact vision/visual perceptual abilities			
Intact cognition			
Full PROM in wrist and hand			
If present, spasticity is not severe in upper limb (clinical note: no greater than MAS 2)			
Other:			

4) ADDITIONAL CONSIDERATIONS

Additional Considerations	Yes	Unsure	No
WiFi and good Internet connection is available			
Strong caregiver support is available for customers identified as needing assistance for system use			
Other:			

5) OUTCOME OF SCREEN

Outcome of Screen	Check if True	Details
Requires more information:	<input type="checkbox"/>	
Requires follow-up:	<input type="checkbox"/>	
Notes related to individualized presentation requiring internal review:	<input type="checkbox"/>	

INDICATIONS FOR USE: The Neuroolutions IpsiHand 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.

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