

TALKING TO YOUR DOCTOR – A Discussion Guide

TALKING TO YOUR DOCTOR

The H200 is a prescription device used to improve hand function and reduce muscle spasms.

You may benefit from using the H200 if you have hand paralysis resulting from:

- Stroke (CVA)
- Traumatic Brain Injury (TBI)
- Incomplete Spinal Cord Injury (SCI)
- Other central nervous system disorders, like Cerebral Palsy or Parkinson's Disease

With over 40 published clinical studies and thousands of users worldwide, the H200 has been shown to help improve hand function, reduce spasticity and promote motor relearning in people with similar conditions. It is important to discuss with your physician how using the H200 System will support your rehabilitation goals.

START A CONVERSATION WITH YOUR PHYSICIAN

It can be as easy as asking, “I want to improve the function of my hand and be more active. Could the H200 System help get me there?”

QUESTIONS TO ASK MY DOCTOR

1. Do you think I could benefit from the H200?
2. Have you had other patients use the H200? How did it work for them?
3. I would like to get evaluated. Would you please write me a prescription for occupational therapy?

IMPORTANT SAFETY INFORMATION

The H200 is not intended for women who are pregnant or may become pregnant, individuals with malignant tumors or lesions on the affected arm or people that have had a recent forearm fracture.

If you use a pacemaker or defibrillator, have a history of seizures, use a baclofen pump or have metallic implants consult your physician before being evaluated for the H200.

Please see a full list of contraindications, precautions and warnings prescribing information for the H200 Wireless Hand Rehabilitation System at www.bioness.com.





Reach For Your **GOALS**

Frequently Asked Questions and Answers about the H200[®] Wireless Hand Rehabilitation System

What is the H200 Wireless Hand Rehabilitation System?

The H200 Wireless Hand Rehabilitation System is an advanced functional electrical stimulation (FES) system that uses mild stimulation of nerves and muscles to help improve hand function in certain individuals. Customizable programs may help you perform tasks and activities of daily living and reeducate muscles over time.^{1,2}

How does the H200 Wireless work?

The H200 Wireless stimulates muscles in the forearm and hand, helping you to open and close your hand. The H200 has two main components that communicate with each other wirelessly and are programmed by your clinician to meet your specific needs and rehabilitation goals.

Who may benefit from using the H200 Wireless?

The H200 Wireless is intended for individuals that have lost hand function due to stroke, traumatic brain injury, spinal cord injury or other certain neurological disorders.

What is FES?

Functional Electrical Stimulation (FES) applies low-level stimulation to specific parts of the body to help restore function. The H200 Wireless delivers stimulation to activate the nerves that control the muscles in the hand and forearm.

How can the H200 Wireless help me?

The H200 Wireless may help you by:

- Improving active hand range of motion and function
- Reeducating muscles to function without the system
- Reducing muscle spasms
- Increasing local blood circulation
- Preventing muscle loss

Is the H200 Wireless easy to use?

The H200 Wireless is unencumbered by cords and simple to use. The system consists of a lightweight and comfortable ergonomically designed orthosis that can be put on and taken off with one hand, and a hand held control unit.

Where can I go for an evaluation to see if the H200 Wireless is right for me?

Contact our Client Relations team at 800.211.9136, option 2 to learn if the system may be right for you and to find the closest healthcare provider for an evaluation. If it is determined that the device will benefit you, Bioness will work with you and your healthcare provider to help you obtain the device.

Does the H200 Wireless require a prescription?

In order to acquire the device for home use, you need a prescription from your physician.

Is the H200 Wireless covered by my insurance?

Your health insurance plan may cover some or all of the cost of an H200 Wireless for home use, and reimbursement is typically based on medical need at the discretion of your insurance carrier.

Are there financing options for the H200 Wireless?

Bioness is committed to helping you explore a variety of payment options – from insurance to financing – so we can find a purchase plan that makes the system affordable. To discuss your payment options, contact our Client Relations team at 800.211.9136, option 2.

“ I feel **WHOLE** again. ”

- LaVerne
H200 User

¹ Alon G, et al. 2002. *J Stroke Cereb Dis.* 11(2):99-106.

² Alon G, et al. 2003. *NeuroRehabil.* 18(3):215-225.

Individual results vary. Consult with a qualified physician to determine if this product is right for you.

Contraindications, Adverse Reactions and Precautions are available on-line at www.bioness.com (also available in the NESS H200 Wireless User's Guide).

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NESS H200[®] Wireless

H200[®] Wireless Hand Rehabilitation System to regain arm and hand function for patients with central nervous system disorders

FDA Clearance: August 10, 2011 | FDA 510k Number: K111767



Product Description

The award winning¹ H200 Wireless System is available by prescription only and requires a patient evaluation prior to use. The H200 Wireless System is an advanced functional electrical stimulation system (FES) that is intended to help patients regain arm and hand function following a neurological injury.

The System consists of two components:

1. Lightweight, ergonomic orthosis that is positioned on the patients' forearm and hand to ensure stimulation is delivered to promote functional task training and activities of daily living (ADL's).
2. Remote Hand Held that allows the patient to control the system, make small stimulation adjustments and choose between two custom therapy programs.

Patient Diagnosis

- Stroke (CVA) – acute, subacute & chronic
- Traumatic Brain Injury (TBI)
- Spinal Cord Injury (SCI)
- Other Central Nervous System Disorders (e.g. Multiple Sclerosis)

Indications for Use

- Improve active hand range of motion (ROM)
- Reeducate muscles to function without the system (neuroplasticity/motor recovery)
- Reduce muscle spasms
- Increase local blood circulation
- Prevent or retard muscle atrophy

Clinical Evidence and Research

Clinical practice guidelines developed and adopted by the US Veterans Affairs/Department of Defense (VA/DoD Guideline), the American Heart Association (AHA), the American Stroke Association (ASA) and the American Association of Physical Medicine and Rehabilitation (AAPM&R) all conclude that there is strong scientific and clinical evidence supporting the use of electrical stimulation to restore function in the upper extremity. Respected, peer-reviewed journals including the Journal of Rehabilitation Medicine and the Journal of Stroke and Cerebrovascular Diseases have published numerous research articles that have studied the effectiveness of the H200 Hand Rehabilitation System.

Findings include:

1. Increasing functional independence outcome measurements (e.g. time to complete tasks) in patients who use the H200 versus those receiving the standard care.^{2,3}
2. Improving hand function in select persons with C5-C6 spinal cord injuries and chronic hemiplegia secondary to stroke.^{4,5}
3. Reducing impairments, such as pain and spasticity, while increasing range of motion (ROM) and improving joint positioning.⁶
4. Demonstrating enduring increases in baseline functional abilities indicating actual motor recovery after repetitive therapeutic use.⁷

1. International Design Magazine, 2004 Best of Category Award Winner

3. Ring H, et al. 2005. *J Rehabil Med.* 37:32-36.

5. Snoek GJ, et al. 2000. *Spinal Chord.* 38(4):244-249.

7. Alon G, et al. 2003. *NeuroRehabil.* 18(3):215-225.

2. Alon G, et al. 2007. *Neurorehabil Neur Repair.* 21(3):207-215.

4. IJzerman MJ, et al. 1996. *J Rehabil Sci.* 9(3).

6. Page SJ, et al. 2008. *Neurorehabil Neural Repair.* 23:595-599.