

FDA Approved EMF Devices

Neuromuscular Electrical Stimulation (NMES)

Neuromuscular Electrical Stimulation (NMES)

“Neuromuscular electrical stimulation (NMES) is a treatment method used to create muscle contractions through electrical impulses. NMES mimics the body's nervous system during voluntary muscle activation, but instead of the signal originating in the brain, it comes from an electrical stimulator. This is achieved by placing electrodes on the skin over the target muscle.

The use of electricity for medical treatment dates back to ancient Egypt and Greece, where electric eels were used for pain relief. Modern NMES evolves from Galvani's 18th century discovery that electric current can induce muscle contraction (1). Today, electrical stimulation is applied in various medical contexts, such as transcutaneous electrical nerve stimulation (TENS) for pain management (2) and NMES in rehabilitation settings. NMES is commonly used to strengthen weakened muscles, reduce muscle atrophy during immobilization (e.g., after surgery or injury), and complement exercise to optimize training effects.”

Source:

[https://pmc.ncbi.nlm.nih.gov/articles/PMC11660796/#:~:text=Introduction,effects%20\(3%2C%204\)](https://pmc.ncbi.nlm.nih.gov/articles/PMC11660796/#:~:text=Introduction,effects%20(3%2C%204))

1. H-Wave Pro (H-Wave H4 model) is a portable, non-invasive electrical stimulation device that delivers a unique biphasic exponentially decaying waveform for drug-free pain relief and muscle conditioning by stimulating nerves and muscle fibers at low and high frequencies.

"The H-Wave® (model H-4) is a portable battery operated electrical stimulation device with two channels, two sets of lead wires, three packages of self-adhesive electrodes, and a battery charger."

"The H-Wave H4 is indicated for the treatment of chronic pain, acute pain, post-surgical pain, and temporary pain."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103738.pdf

<https://www.h-wave.com/>

Manufacturer: Electronic Waveform Lab, Inc.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103738.pdf

<https://www.h-wave.com/about/>

Website: <https://www.h-wave.com/>

Primary Indications: Indicated for the treatment of chronic pain, acute pain, post-surgical pain, and temporary pain; also for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, and maintaining or increasing range of motion.

"The H-Wave H4 is indicated for the treatment of chronic pain, acute pain, post-surgical pain, and temporary pain."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103738.pdf

<https://www.h-wave.com/>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K103738>

Is it FDA Approved?: Yes, FDA-cleared (510(k) clearance as Class II device).

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103738.pdf

<https://www.h-wave.com/>

FDA Approval Details: Cleared via the 510(k) premarket notification pathway as a Class II device (substantially equivalent to predicate devices). Clearance date: June 1, 2011 (for H-Wave model H-4). 510(k) number: K103738; Dec 2011 (Pain Relief Update) 510(k) number: K112485; (multiple prior clearances for earlier models, e.g., K915230 for P-

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4). Clearance based on substantial equivalence to predicate powered muscle stimulators for the listed indications; no new questions of safety or effectiveness raised.

"The H-Wave model H4 is substantially equivalent to its predicate device."

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K103738>

https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103738.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K112485>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K915230>

How It Works: The device delivers a proprietary biphasic exponentially decaying waveform through skin electrodes to stimulate small-diameter nerve fibers and muscle contractions, providing deep analgesia (high-frequency mode) and non-fatiguing muscle activation for circulation and recovery (low-frequency mode); patient-administered at home.

"The H-Wave signal is a bipolar, exponential decaying waveform that supposedly overcomes the disadvantages of other electrotherapy machines."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103738.pdf

<https://www.h-wave.com/>

Frequency Used: Dual modes: Low frequency (1-2 Hz or up to 70 Hz range) for muscle stimulation and high frequency (around 60 Hz) for pain control.

"Electrodes are placed on the areas to be treated with conductive electrode gel and the frequency set to either muscle pump (2Hz) or pain relief (60Hz)."

"Frequency 1-70 Hz."

Sources:

<https://emilycatford.co.uk/h-wave/>

https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103738.pdf

<https://www.h-wave.com/>

Is it Non-Thermal?: Yes. The low-level electrical stimulation does not cause tissue heating, focusing on neuromuscular effects.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103738.pdf

<https://www.h-wave.com/>

Is it Non-Ionizing?: Yes. The electrical impulses are non-ionizing.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103738.pdf

<https://www.h-wave.com/>

Side Effects: Generally well-tolerated with no known significant adverse effects; non-invasive and drug-free. Possible mild skin irritation at electrode sites or temporary discomfort. Rare reports of increased pain or burning sensation in isolated cases. No contraindications beyond standard electrical stimulator warnings (e.g., pacemakers).

"No known significant adverse effects have resulted from the use of this device."

"I was using the h-wave device as per instructions on a video conference with an h-wave representative. The device caused severe pain in my joints that were in the treatment area as well as a severe burning sensation in my spine outside of the treatment area, and a migraine. These effects have lasted, thus far, for 3 hours, and have no indication of reducing, despite taking pain relieving medications such as codeine."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103738.pdf

<https://www.h-wave.com/>

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=17810348&pc=IPF

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2. WalkAide II / WalkAide 2.0 / XFT-2001E “is an advanced functional electrical stimulation (FES) system designed to assist individuals experiencing foot drop – a condition where lifting the front part of the foot is difficult due to neurological impairments. By delivering mild electrical impulses to stimulate the peroneal nerve, Walkaide® II facilitates dorsiflexion during walking, promoting a more natural gait pattern.” It features a “Self-contained, slim design” that “fits discreetly under clothing without the need for external wires.”

“XFT-2001E Formerly known as WalkAide II.” (translated from Norwegian)

Sources:

<https://royalrehablifeworks.com.au/equipment-technology/walkaide-ii/>

<https://www.cypromed.no/xft2001e>

Manufacturer: Shenzhen XFT Medical Limited (under the model name XFT-2001E). To clarify the industry history, while the original first-generation WalkAide was famously developed and manufactured by Innovative Neurotronics, Inc. (a subsidiary of Hanger Orthopedic Group), the next-generation WalkAide II is manufactured by Shenzhen XFT Medical Limited and distributed globally by various orthotics partners and successors.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf16/K162718.pdf

<https://walkaide.ru/about/neyro-ortopedicheskiy-tsentr-walkaide/postavshchik-neyro-ortezov-walkaide/>

https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193276.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K162718>

https://www.accessdata.fda.gov/cdrh_docs/pdf16/K162718.pdf

<https://www.cypromed.no/xft2001e>

Website: <https://www.xft-china.com/products/xft-2001e-g4.html>

Primary Indications: “Walkaide II is an advanced functional electrical stimulation (FES) system designed to assist individuals experiencing foot drop – a condition where lifting the front part of the foot is difficult due to neurological impairments. By delivering mild electrical impulses to stimulate the peroneal nerve, Walkaide® II facilitates dorsiflexion during walking, promoting a more natural gait pattern.”

Who it can help

- People recovering from stroke
- People with spinal cord injury
- People with acquired brain injury
- People with multiple sclerosis
- People with cerebral palsy
- Individuals experiencing foot drop due to upper motor neuron lesions”

“It is worn by people that are experiencing a condition called foot drop which is caused by lower limb muscle and nerve injuries, muscle disorders, and brain and spinal disorders.”

“Indications:

- Stroke
- Multiple Sclerosis
- Cerebral Palsy
- Traumatic Brain Injury
- Incomplete Spinal Cord Injury
- Familial/Hereditary Spastic Paresis”

Sources:

<https://royalrehablifeworks.com.au/equipment-technology/walkaide-ii/>

[https://oapl.com.au/walkaide-](https://oapl.com.au/walkaide-ii/#:~:text=Why%20would%20I%20need%20to,the%20ground%20throughout%20their%20gait.)

[ii/#:~:text=Why%20would%20I%20need%20to,the%20ground%20throughout%20their%20gait.](https://oapl.com.au/walkaide-ii/#:~:text=Why%20would%20I%20need%20to,the%20ground%20throughout%20their%20gait.)

<https://www.opchealth.com.au/walkaide-ii>

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Is it FDA Approved?: Yes.

“We conclude that the proposed XFT- 2001D (K162718, predecessor of the XFT- 2001E) Foot Drop System is substantially equivalent to the WalkAide System (K123972) characteristics.”

“The Nerve and Muscle Stimulator (K193276; Model: XFT-2001E, XFT-2001EA) is substantially equivalent to the predicate device (K162718).”

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K162718>

https://www.accessdata.fda.gov/cdrh_docs/pdf16/K162718.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K123972>

https://www.accessdata.fda.gov/cdrh_docs/pdf12/K123972.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K193276>

https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193276.pdf

FDA Approval Details:

Key 510(k) Clearances and Dates

- Foundational Hardware Clearance (K162718): Cleared on November 30, 2017, this authorized the XFT-2001D Foot Drop System. The FDA agreed that this hardware was substantially equivalent in safety and efficacy to the original Innovative Neurotronics WalkAide (K123972).
- The "2.0" Modernization Clearance (K193276): Cleared on September 23, 2020, this 510(k) covered the modernized XFT-2001E models. This specific clearance authorized the significant hardware leaps that define the WalkAide II today: integrating a rechargeable lithium battery, a self-contained splash-resistant housing, stainless-steel electrodes, and Bluetooth integration for smartphone app controls.

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K162718>

https://www.accessdata.fda.gov/cdrh_docs/pdf16/K162718.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K123972>

https://www.accessdata.fda.gov/cdrh_docs/pdf12/K123972.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K193276>

https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193276.pdf

How It Works: “While wearing the WalkAide II on the lower leg, an internal sensor identifies the leg motion and speed as the person takes just a few steps. Smart Technology uses that information to create a customised walking program. With each subsequent step, the WalkAide® II sends gentle, electrical impulses to nerves in the leg that tell the muscles to lift the toes. Stimulation timing adjusts to accommodate changes in walking speed, ensuring appropriate stimulation with every step. Walking and training program adjustments can be made by the user to promote optimal results.”

“With each subsequent step, the WalkAide® II sends gentle, electrical impulses to nerves in the leg that tell the muscles to lift the toes. How does it know when to stimulate? Well, whilst wearing the WalkAide® II on the lower leg, an internal sensor identifies the leg motion and speed as the person takes just a few steps and then uses that information to create a customised walking program. Stimulation timing adjusts to accommodate changes in walking speed in real-time, ensuring appropriate stimulation with every step and enabling the user’s toes to clear the ground throughout their gait. Walking and training program adjustments can be made by the user to promote optimal results.”

“The WalkAide 2 delivers mild electrical impulses to the nerves in the leg with each step, prompting the muscles to lift the foot. The device uses an internal sensor to detect the leg’s motion and speed, adjusting the stimulation to fit the user's walking pattern. This ensures that the stimulation timing adapts in real-time to accommodate variations in walking speed, so the toes clear the ground properly during each step. Users can also modify walking programs to optimise their walking experience.”

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Sources:

<https://www.opchealth.com.au/walkaide-ii>

<https://oapl.com.au/walkaide-ii/>

<https://www.orthotics.co.uk/types-of-orthotics/functional-electrical-stimulation/walkaide-2-fes-system/>

Frequency Used: "Frequency 16.7-50 Hz ($\pm 10\%$), Wave Form - Asymmetric biphasic balanced wave"

Sources:

https://www.opchealth.com.au/files/attachments/34_ENGLISH-MNL-0023-WalkAide-II-User-Manual-Update-ENG-Word-0-Final.pdf

Is it Non-Thermal?: Yes. The technology uses "mild electrical impulses" to trigger motor nerve action potentials and muscle contractions. It operates strictly via neuromuscular electrical stimulation and entirely avoids the generation or transfer of thermal heat energy to the patient's skin or leg tissue.

Sources:

<https://royalrehablifeworks.com.au/equipment-technology/walkaide-ii/>

Is it Non-Ionizing?: Yes. As a wearable, battery-operated functional electrical stimulation device, it relies purely on low-voltage, non-ionizing electrical currents delivered through integrated surface electrodes, carrying none of the cellular-level risks associated with ionizing radiation exposure.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf16/K162718.pdf

Side Effects:

Skin Irritation and Redness

- The device may cause temporary redness due to increased blood flow, but persistent or severe redness could indicate irritation. "It is normal that skin slightly turns red, which shows faster blood flow." However, "If the skin in the area covered by the electrode and the host band is severely red, stinging or allergic, stop using it immediately." To prevent this, the skin should be ventilated regularly: "In order to allow the skin area covered by the unit to be breathable and to prevent skin irritation and redness, the unit should be suspended and removed at regular intervals to allow the skin to be fully breathable in the process of using the product."

Pain, Rash, or Allergic Reactions

- Users may experience pain or rash from stimulation: "If you keep feeling pains or rash, please stop using this product." Additionally, "If any skin irritation or allergy occurs, please stop using the stimulator immediately and follow doctor's instructions." Preventive measures include avoiding application on skin with makeup, oil, or hair: "Do not position on the skin with makeup or oil. Remove arm's hair for better electrical conductivity. Electric razor or a pair of scissors is recommended." "Do not position on allergic area."

General Physical Abnormalities

- Broader concerns include any unusual bodily responses: "Please stop using this product if the body shows any physical abnormality."

Potential from Device Malfunction (Related Model)

- For the similar XFT-2001D model, software issues could indirectly cause minor issues: "the software failure or design flaw prior to mitigation may lead to an error in the intensity or timing of stimulation that could result in minor injury such as skin irritation to the patient." No other adverse reactions are specified.

Sources:

<https://fcc.report/FCC-ID/2AS2I2001E/4268706.pdf>

https://www.accessdata.fda.gov/cdrh_docs/pdf16/K162718.pdf

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3. NESS H200 / Bioness NESS H200 Wireless Hand Rehabilitation System is a portable, non-invasive functional electrical stimulation (FES) device that delivers low-level electrical pulses to the forearm and hand muscles via a splint with surface electrodes to improve hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury.

"The H200 Wireless System is an electrical stimulation device indicated for the following uses: Functional Electrical Stimulation (FES); Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury."

"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... 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."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf12/K123636.pdf

<http://bionessmedical.com/wp-content/uploads/2021/12/MP612-00964-001-Rev.-B-efile.pdf>

https://www.l300go.com/wp-content/uploads/2021/11/01902_h200_discssn_gd_web_r05v01.pdf

Manufacturer: Bioness Inc. (Valencia, CA, USA; now part of Bioness Medical, Inc.).

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf12/K123636.pdf

<https://bionessmobility.com/h200/>

Website: <https://bionessmobility.com/>, <https://bionessmobility.com/h200/>

Primary Indications: Indicated for improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury.

"The NESS H200 Wireless Hand Rehabilitation System is an electrical stimulation device indicated for the following uses:

Functional Electrical Stimulation (FES):

- Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury

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- Maintenance and/or increase of range of motion
- Prevention and/or retardation of disuse atrophy
- Increase of local blood circulation
- Reduction of muscle spasm
- Muscle re-education"

"The H200 Wireless System may help you improve function in your hand and wrist and get back to your daily activities, if your condition is due to:

- Stroke
- Traumatic brain injury
- Spinal cord injury
- Certain neurological disorders"

"In addition to helping you improve hand function, the H200 Wireless System may:

- Improve active hand range of motion and function
- Reeducate muscles to function without the system
- Reduce muscle spasms
- Increase local blood circulation
- Prevent muscle loss (atrophy)"

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Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf12/K123636.pdf

<https://bionessmobility.com/h200/>

https://bionessmobility.com/wp-content/uploads/2025/04/005033A_H2W-DTC-trfld_v5-RDR.pdf

Is it FDA Approved?: Yes, FDA-cleared (510(k) clearance as Class II device).

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf12/K123636.pdf

<https://bionessmobility.com/h200/>

FDA Approval Details: Because it went through the 510(k) pathway, it was "cleared" rather than "approved." This means Bioness demonstrated to the FDA that the NESS H200 is "substantially equivalent" to predicate medical devices already legally marketed in the United States, allowing it to bypass the stricter Premarket Approval (PMA) required for Class III life-sustaining devices.

The device has evolved over the years, resulting in multiple 510(k) clearances as new features (such as wireless capabilities and alternative triggers) were added:

- **K022776 (Cleared September 11, 2002):** The device was originally cleared under the name "Handmaster NMS I," which was later rebranded to the NESS H200. This established its baseline clearance for improving range of motion, reducing muscle spasms, and providing muscle re-education.
"The NESS System is substantially equivalent to the market-cleared Handmaster NMS1. The only difference between the NESS System and the Handmaster NMS1 is the provision of additional plastic splints to allow the system to treat other sites on the limbs: the upper arm, the thigh, and the lower leg."
- **K111767 (Cleared September 15, 2011):** This clearance was granted for the modernized NESS H200 Wireless Hand Rehabilitation System, removing the bulky cables of the original design.
- **K123636 (Cleared May 1, 2013):** This clearance added a product line extension for the NESS H200 Wireless System—an optional "Intelli-Connect Earpiece Triggering Device" that detects teeth clicks to wirelessly trigger the stimulation unit.

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K022776>

https://www.accessdata.fda.gov/cdrh_docs/pdf2/K022776.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K111767>

https://www.accessdata.fda.gov/cdrh_docs/pdf11/K111767.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K123636>

https://www.accessdata.fda.gov/cdrh_docs/pdf12/K123636.pdf

How It Works: The orthosis with embedded electrodes delivers patterned electrical stimulation to finger and thumb flexors/extensors, producing functional grasp/release or exercise modes while stabilizing the wrist; controlled wirelessly by a handheld unit.

"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.

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."

*"According to research by
Alon et al.*

"Sometimes, a muscle and its nerve supply remain healthy but communication from the brain cannot occur due to a central nervous system problem. In these cases, the H200 Wireless can use FES to activate the nerves that control the

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muscles in the hand and forearm. Programs customized for a user's specific needs and rehabilitation goals may help the user perform daily activities and also reeducate the muscles over time¹⁻³."

"How does the H200 Wireless work?

The device has two components for patients:

- The comfortable **orthosis** fits the forearm and wrist. Inside the orthosis, electrodes deliver mild stimulation that helps the hand move. The orthosis is lightweight, ergonomically designed, easy to put on with one hand, and custom positioned to ensure the user receives the precise the stimulation needed.
- The **handheld control unit** communicates wirelessly with the system, letting the user adjust the level of stimulation. This small, handheld unit is easy to operate, has a rechargeable battery, and may be carried discreetly in a pocket or purse.

A clinician fits the orthosis and sets up the control unit with a customized therapy program to stimulate the appropriate nerves and muscles. After the initial fitting and setup, the user can put on the orthosis and use the system as needed to perform activities."

Sources:

https://www.l300go.com/wp-content/uploads/2021/11/01902_h200_discssn_gd_web_r05v01.pdf

<https://bionessmedical.com/h200/patients/how-does-it-work/>

<http://bionessmedical.com/wp-content/uploads/2021/12/MP612-00964-001-Rev.-B-efile.pdf>

<https://bionessmedical.com/h200/references/>

Frequency Used: Pulse Repetition Rate 20–45 Hz, 5-Hz resolution

Sources:

<https://bioness.com/wp-content/uploads/2021/12/Technical-Specifications.pdf>

<https://bionessmedical.com/wp-content/uploads/2021/12/MP612-00964-001-Rev.-B-efile.pdf>

Is it Non-Thermal?: Yes. The technology applies a "low-level stimulation to specific parts of the body to help restore function" via electrical impulses rather than thermal heat transfer, completely avoiding the generation of heat within the patient's forearm or hand tissue.

Sources:

https://www.l300go.com/wp-content/uploads/2021/11/01902_h200_discssn_gd_web_r05v01.pdf

Is it Non-Ionizing?: Yes. The device utilizes strictly non-ionizing electrical impulses to trigger muscle contractions. In fact, the manufacturer's clinical manual explicitly labels the equipment with the universal regulatory symbol for "Non-Ionizing Radiation" to confirm it poses no cellular-level radiation risks

Sources:

<https://bionessmedical.com/wp-content/uploads/2021/12/MP612-00964-001-Rev.-B-efile.pdf>

Side Effects: "After removing the H200 Wireless Orthosis, it is normal for the areas under the cloth electrodes to be red and indented. The redness should disappear in approximately one hour. Persistent redness, lesions, or blisters are signs of irritation." The manufacturer issues a strict safety warning: "Do not use the NESS H200 Wireless System if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Use of the NESS H200 Wireless System in conjunction with any of the above may cause electric shock, burns, electrical interference, or death."

"Adverse Reactions

In the unlikely event that any of the following occurs, stop using your H200 Wireless System immediately and talk to your doctor or clinician.

- Signs of significant irritation or pressure sores where the H200 Wireless Orthosis contacts the skin.
- A significant increase in muscle spasticity.
- A feeling of heart-related stress during stimulation. Chapter 2 - Safety Information 5
- Swelling of the hand, wrist, or forearm.
- Any other unanticipated reaction.

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Skin irritations and burns beneath the stimulating electrodes have been reported with the use of powered muscle stimulators.”

Sources:

<https://l300go.com/wp-content/uploads/2021/12/Device-Description-and-Safety-Information.pdf>

<https://bionessmedical.com/wp-content/uploads/2021/12/MP612-00964-001-Rev.-B-efile.pdf>