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# The *Exopulse* *Mollii* Suit.

Drug-free, non-invasive spasticity  
management with innovative near  
full-body neurostimulation.



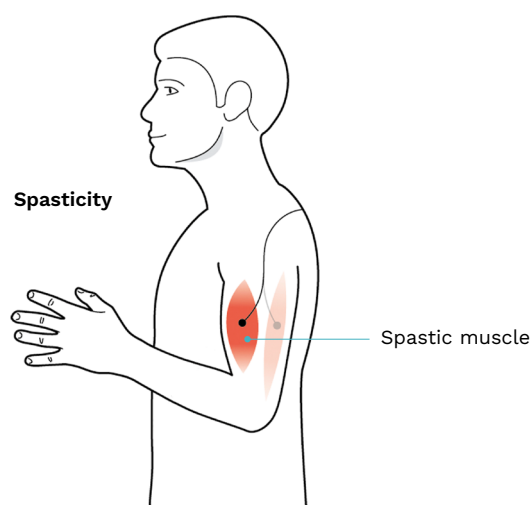


# Rebalancing muscle activity to restore mobility and reduce pain.

The *Exopulse Mollii Suit* is a breakthrough application of neuro-stimulation – a trusted technique that has been extensively evaluated in patients with spasticity. <sup>1-5</sup>

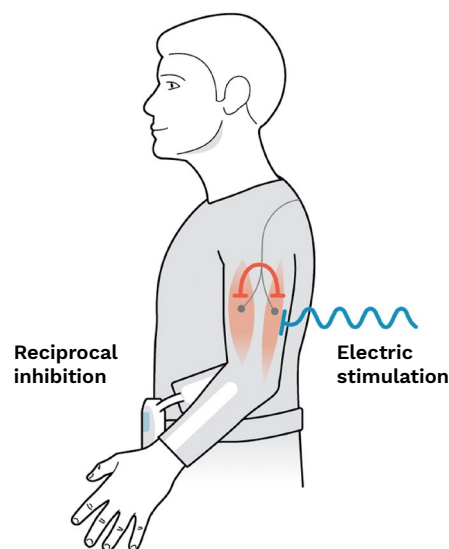
## Spasticity: A debilitating imbalance in muscle activity

- Common in patients with cerebral palsy (CP), multiple sclerosis (MS), stroke, and other neurological conditions and injuries.
- Patients often experience both excessive excitability in affected muscles and a loss of inhibitory signals in their antagonists.
- **Result:** Tense, painful muscles on one side of the muscle group, and weak, deactivated muscles on the other.



## The Suit: Delivering relief through reciprocal inhibition

- Unlike many neurostimulation techniques that focus only on symptomatic muscles, the Suit relieves spasticity and related pain by stimulating the weakened *antagonist* of the spastic muscle.
- This approach helps reactivate signals that naturally inhibit hyperreflexive muscle activity, inducing the spastic muscles to relax.
- **Result:** Rebalancing of the body's natural signaling in affected muscles, which may help patients move more freely, safely, and with less pain.

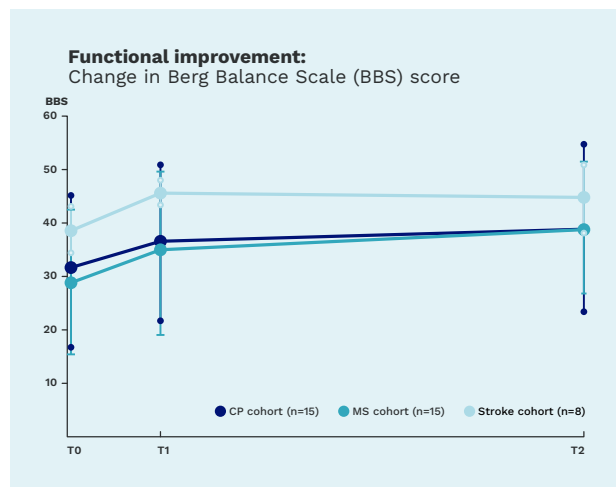


# Swift, sustainable relief for your patients with spasticity.

In preliminary clinical evaluations, patients with CP, MS, and stroke reported significant results after just sixty minutes of stimulation – and sustained them with regular use.<sup>6</sup>

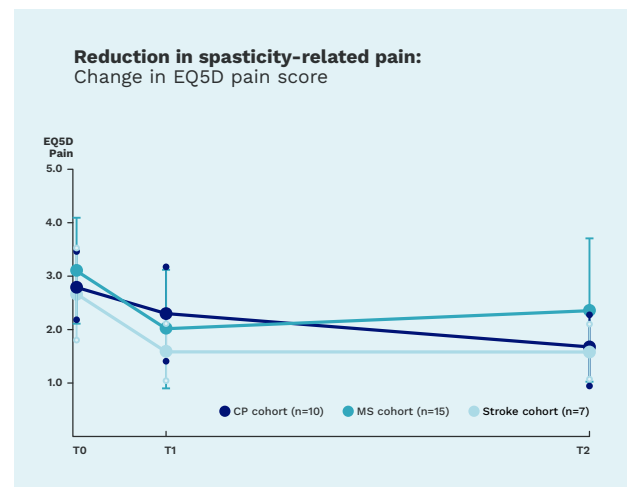
## Better balance and reduced fall risk \*

After an hour of stimulation, patients were already able to move more freely and safely. Four weeks of regular use helped them maintain this rapid improvement.



## Quick, sustained reduction in spasticity-related pain \*\*

Patients with pain reported that their symptoms were rapidly reduced by an hour in the Suit. After four weeks of regular, near full-body stimulation, they continued to feel significantly less pain.



## Exopulse Registry

Open-label study of group-level response in 38 patients with CP (adult + pediatric), MS, or stroke.

- All patients: GMFCS 1-3, BBS score < 45
- CP: n=15 (9 adult, 6 pediatric), mean age 20.9
- MS: n=15, mean age 50.3
- Stroke: n=8, mean age 43.6

# Key features.

## An innovative design tailored to your patient.



### Technology

- **Near full-body stimulation:** The unique wearable configuration is designed to manage spasticity and related pain in both the upper and lower limbs.
- **58 embedded electrodes:** Stimulation through each channel can be customized for the patient, enabling muscle-by-muscle targeting of up to 40 muscle groups.
- **Convenient control unit:** The Suit's activation and programming hub is easily accessible for both clinicians and patients.

### Garments

- **Jacket and pants:** Suit is made up of two wearable pieces that are easy for patients to put on at home.
- **Construction:** Both garments combine comfortable tailoring with durable, reinforced design, optimized for regular use.
- **Material:** The jacket and pants are made of a comfortable, breathable synthetic blend.
- **Machine washable:** Both garments (without the control unit) can be cleaned up to 25 times in a home washer, or regularly in a steam cabinet.

# Using the Suit.

## Convenient, at-home spasticity management.

Here's a step-by-step summary of how clinics like yours can make the Suit part of your patients' care.

- 1 Get training for your team.** Before you start fitting patients, Ottobock experts will guide you through setting up the components, programming the Suit, and coaching your patients on how to maintain it.
- 2 Get your patient started.** First, your patient will visit your clinic so you can show them how to wear and take care of their Suit. During that visit, you'll also customize the stimulation pattern for the patient's unique needs.
- 3 Send them home with their Suit.** Once your patient and/or their caregivers have been trained on the Suit, they can take it home to use as directed. Most spasticity patients should wear it every other day.
- 4 Monitor their progress.** Check in regularly to ensure patients and caregivers are using their Suit properly and getting the results they want to see. If needed, you can make more adjustments to their stimulation.
- 5 Take their standard treatments further.** Regular use of the Suit may help your patient get more out of their ongoing physical therapy or exercise regimen. Unless contraindicated, patients can also continue using prescribed treatments like oral medications or BoTN injections (as directed by their physician).

Stimulation  
for spasticity:

**60**  
**minutes**  
every other day

# More important information.

## Frequently asked questions

### Does the Exopulse Mollii Suit have any reported side effects?

A small number of patients have reported mild, transitory side effects typical of electrical stimulation, including:

- Minor skin irritation
- Redness/erythema
- Minor burns

### Can the Suit be used alongside standard spasticity treatments?

The Exopulse Mollii Suit should preferably be used in combination with physiotherapy, training, or physical activity. It is not contraindicated for use with most standard therapies, such as BoTN injections or oral pharmaceuticals. It should not be used in combination with implanted medical devices, including an intrathecal baclofen pump. Always document the patient's current care regimen before starting stimulation with the Suit and consult the patient's prescribing physician if needed.

### Is the Suit typically covered by insurance and/or reimbursed by national health systems?

Financial coverage for the Suit may vary depending on where your practice is located. For information about coverage in your area, contact your regional Ottobock representative.

### What kind of material is the Suit constructed from?

The Exopulse Mollii Suit jacket and pants are made from comfortable, breathable, washable synthetic materials. The garments contain no animal products or fibers.

### Independent studies

The Exopulse Mollii Suit has been evaluated in several small, independent studies with published outcomes. While these studies provided some directional clinical insights, there were limitations:

- Small, heterogeneous patient cohorts
- Varied endpoints and evaluation methods
- No assessment of immediate clinical impact

These studies and their outcomes should be interpreted carefully in view of these restrictions in their conclusions.

## Care and maintenance



#### Machine-washable

The jacket and pants may be cleaned up to 25 times in a home washer, or regularly in a steam cabinet.



#### Warm water only

Do not clean the jacket and pants in cold or hot water.



#### Do not wash the control unit

This may void the Suit's two-year warranty.

# More important information.

## Contraindications

### Patients should not use the Exopulse Mollii Suit:

- If the user has implanted electronic medical devices or equipment which can be disrupted by magnets (e.g., shunts)
- Together with electronic life-support equipment or high-frequency operation equipment
- Together with EKG-equipment

There is a risk of the Exopulse Mollii Suit disturbing the function of the above-mentioned types of equipment. All incorrect usage is at the user's own risk.

### Stimulation should not be applied:

- Over swollen, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins, etc.).
- Over the neck or mouth. Severe spasms of the laryngeal and pharyngeal muscles may occur, and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Transthoracically, in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Transcerebrally

Patients should not use the Exopulse Mollii Suit without consulting a physician in connection with:

- Epilepsy
- Cardiovascular diseases
- Malignancy (cancer)
- Infectious diseases
- Fever
- Pregnancy
- Skin disease, rashes, or other skin problems
- Another medical device or medical treatment

Usage in connection with the above can expose the user to unnecessary risk and is therefore at the user's own risk.

### Technical specifications

Power	AAA batteries
Pulse Width	25-175 $\mu$ s'
Pulse Shape	Square wave
Frequency	20 HZ
Channels	40
Electrodes	58, made of silicone rubber
Fabric of the Suit	Polyamide/elastane blend

# The Exopulse Mollii Suit.

A breakthrough in wearable neurostimulation for spasticity.

**See where it fits into your practice.**

**Book a demo at [ottobock.com](https://ottobock.com)**

## Indication and usage

The Exopulse Mollii Suit is an assistive medical device for pediatric and adult users with cerebral palsy (CP), multiple sclerosis (MS), stroke, or other neurological disorders, who suffer from spastic and tense muscles, weak muscle activation, and related pain.

The device is recommended to be used every other day, unless otherwise specified by a healthcare provider, preferably together with physiotherapy, training, or activity.

\*Based on change in Berg Balance Scale (BBS) score in 38 patients with impaired balance and an increased fall risk (n=15/15/8 CP/MS/stroke, baseline BBS score < 45). Patients in all cohorts reported significant improvement in BBS score after sixty minutes of stimulation (T1) and after 4 weeks of stimulation every other day (T2).

\*\*Based on change in EQ5D pain levels in a subset of 32 patients who reported spasticity-related pain at baseline (n=10/15/7 CP/MS/stroke, baseline EQ5D pain > 1). Patients in all cohorts reported significant improvement in EQ5D pain score after sixty minutes of stimulation (T1) and after 4 weeks of stimulation every other day (T2).

References: 1. Elbasiouny SM, Moroz D, Bakr MM, Mushahwar VK. Management of Spasticity After Spinal Cord Injury: Current Techniques and Future Directions. *Neurorehabil Neural Repair*. 2010; 24(1):23-33. DOI: 10.1177/1545968309343213. 2. Rabchevsky AG, Kitzman PH. Latest approaches for the treatment of spasticity and autonomic dysreflexia in chronic spinal cord injury. *Neurotherapeutics*. 2011; 8(2):274-282. DOI: 10.1007/s13311-011-0025-5. 3. Stein C, Fritsch CG, et al. Effects of Electrical Stimulation in Spastic Muscles After Stroke: Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Stroke*. 2015; 46(8):2197-2205. DOI: <https://doi.org/10.1161/STROKEAHA.115.009633>. 4. Bosques G, Martin R, et al. Does therapeutic electrical stimulation improve function in children with disabilities? A comprehensive literature review. *J Ped Rehab Med*. 2016; 9(2):83-99. DOI: 10.3233/PRM-160375. 5. Etoom M, Khraiweh Y, et al. Effectiveness of Physiotherapy Interventions on Spasticity in People With Multiple Sclerosis: A Systematic Review and Meta-Analysis. *Am J Phys Med Rehab*. 2018; 97(11):793-807. DOI: 10.1097/PHM.0000000000000970. 6. Exopulse Registry Clinical Research Report; Data on File.

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