ottobock.

exopulse suit.
Near-full body neuromodulation.

Information for clinicians

EXOPULSE®

About the suit.
An innovative wearable approach to neuromodulation.

With the latest ***exopulse suit***, near-full body stimulation is an even more powerful and user-friendly option for patients with spasticity and symptoms of fibromyalgia. It's a innovative way to deliver proven neuromodulation almost anywhere your patients need it.

This unique assistive device works alongside standard therapies for both conditions, giving you an effective new way to advance your patients' care and empower their everyday lives.

Indications & mechanisms

Spasticity & related pain
These debilitating symptoms are common with neurological conditions like cerebral palsy (CP), multiple sclerosis (MS) and stroke. The suit uses reciprocal inhibition to release spastic muscles, rebalance muscle activity, and help patients move more freely and with less pain.

Fibromyalgia
Patients with this complex condition often experience chronic pain, fatigue, and reduced quality of life. The suit provides relief by activating nervous system mechanisms that block debilitating symptoms before they reach the central nervous system.

Latest updates.
A more user-friendly suit.

1 Optimized electrodes
The redesigned suit now features an array of 50 enlarged, combined electrodes that can be exactly positioned over the belly of target muscles, for even more precise stimulation.

2 New material
The jacket and pants are now made from a stretchier single-layer fabric that makes the garments even more comfortable to put on, take off, and wear.

3 New clinician & user apps
Both apps connect directly to the control units via Bluetooth, providing a streamlined setup process for clinicians and enabling users to make personalized adjustments to their stimulation.

4 Updated control units
The garments now have separate, rechargeable control units that eliminate the hassle and waste of disposable batteries. Both units can be accessed and adjusted with either app.

5 Magnet-free design
The updated control units no longer have magnetic connections that can interfere with implanted devices, so even more patients are now eligible to use the suit.

Customizable approach
The electrodes' stimulation pattern can be adapted to individual patient needs.

Complementary care
The suit works alongside standard-of-care treatments for spasticity and fibromyalgia.

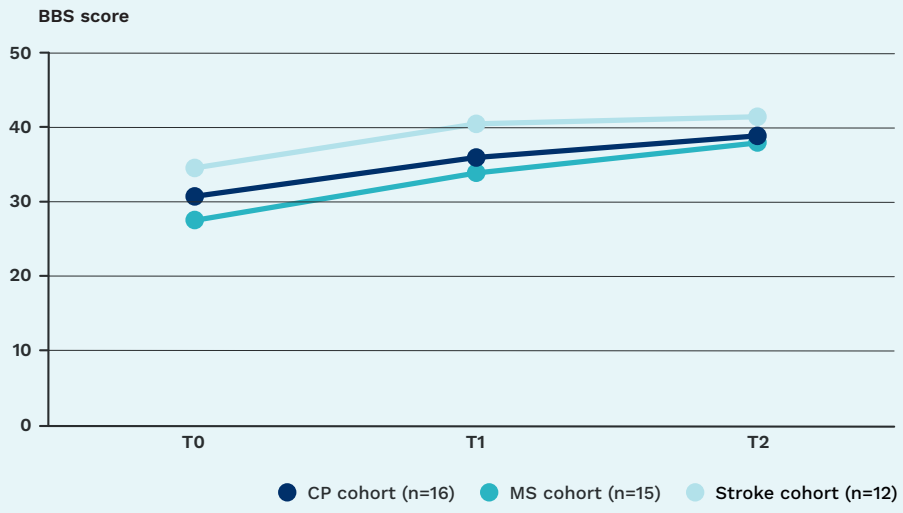
Non-invasive
Patients can start using the suit with no uncomfortable or intensive procedures.

Clinical evidence: Spasticity.
Results of a study in patients with CP, MS & stroke.

Suit users can move more freely.*,[1]

- Clinical results show that patients with CP, MS, and stroke had better balance and reduced their risk of falls after just 60 minutes in the suit.
- Regular, every-other-day stimulation helped them maintain their improvement.

Functional improvement:
Change in Berg Balance Scale (BBS) score

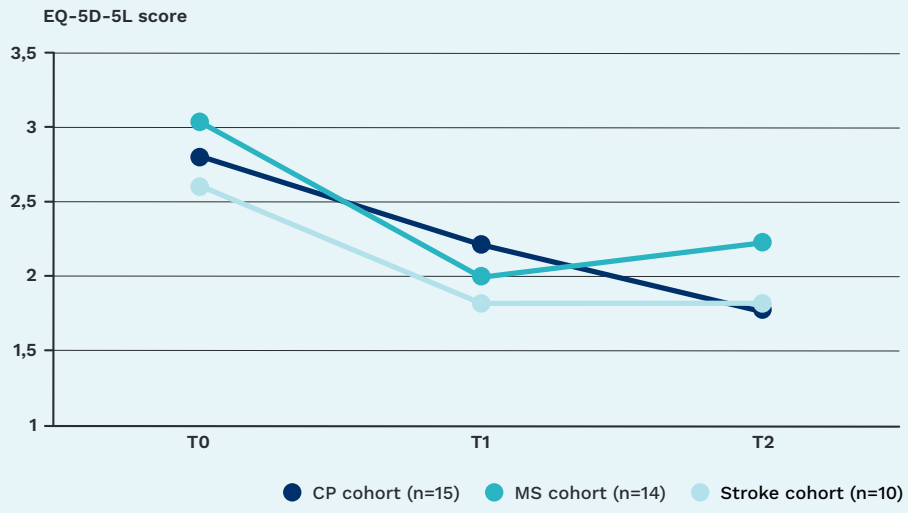


* Based on change in Berg Balance Scale (BBS) score in an open-label study of group-level response to suit stimulation in patients with CP (adult and pediatric), MS, and stroke. Results of this study were evaluated in 43 patients with impaired balance and an increased fall risk (n=16/15/12 CP/MS/stroke, baseline BBS score < 45). Patients in all cohorts reported significant improvement in BBS score after 60 minutes of stimulation (T1) and after 4 weeks of stimulation every other day (T2).

Users also achieve swift, sustained relief from spasticity-related pain.**,1

- In the same study, an hour in the suit helped significantly reduce pain symptoms in patients who reported them.
- Four weeks later, patients who regularly used the suit experienced continuing reduction in pain.

Reduction in spasticity-related pain:
Change in EQ-5D-5L pain score



** Based on change in EQ5D pain levels in an open-label study of grouplevel response to suit stimulation in patients with CP (adult and pediatric), MS, and stroke. Change in pain levels was evaluated in a subset of 39 patients who reported spasticity-related pain at baseline (n=15/14/10 CP/MS/stroke, baseline EQ5D pain > 1). Patients in all cohorts reported significant improvement in EQ5D pain score after 60 minutes of stimulation (T1) and after 4 weeks of stimulation every other day (T2).

Clinical evidence: Fibromyalgia.
Results of two recent studies.

Open-label study (n=50)

Rapid pain relief in 60 minutes[2]

- In a study of patients' response to a single hour of stimulation, some users reported feeling significantly less fibromyalgia-related pain after just one session in the suit.

Randomized, sham-controlled study (n=33)

Significant relief in just two weeks[3]

With ***exopulse suit*** after 2 weeks of daily usage compared to baseline, active condition (phase 1; no sig. changes for sham condition reported):

- **Pain:** 14% reduction in VAS pain scale, 17% FIQ pain subscale, 16% in BPI pain interference subscale
- **Fibromyalgia impact:** 18% reduction in total FIQ score, 19% in FIQ physical impairment and 17% in FIQ fatigue subscales
- **Quality of life:** 47% improvement in SF-36 bodily pain and vitality subscales
- **Depression:** 25% decrease in FIQ anxiety score and 13% in HADS anxiety score
- 64% improvement in Global Clinical Impression

Increased relief with regular use[3]

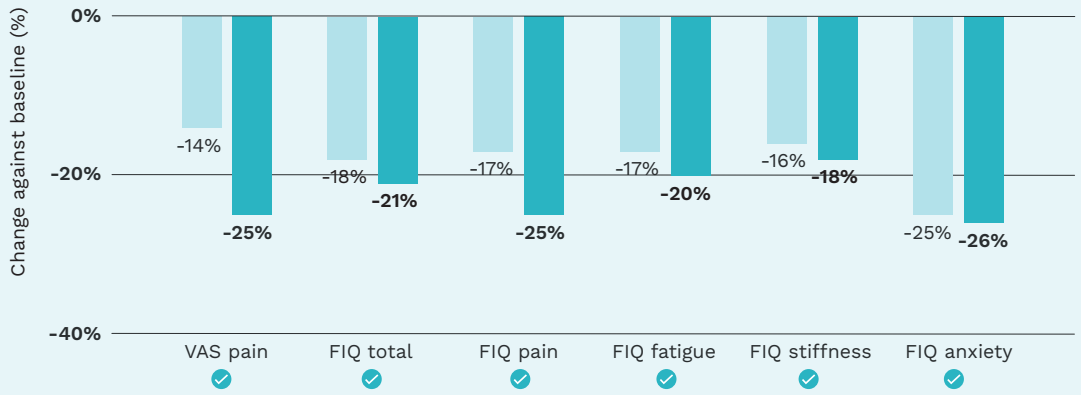
With ***exopulse suit*** after 4 weeks of daily usage compared to baseline, open label phase (phase 2):

- **Pain:** 25% reduction in VAS & FIQ pain scales, 16% in BPI pain severity and 17% in BPI pain interference subscales
- **Fibromyalgia impact:** reduction in 21% total FIQ score, 20% FIQ fatigue subscale
- **Quality of life (SF-36):** 20% increase in social functioning, 35% in health change, 54% in vitality, 92% in role emotional and 161% in role physical subscales
- **Depression:** 26% reduction in FIQ anxiety, 14% reduction in HADS anxiety and 12% in HADS depression subscales
- 79% of users demonstrated improvement in global clinical impression

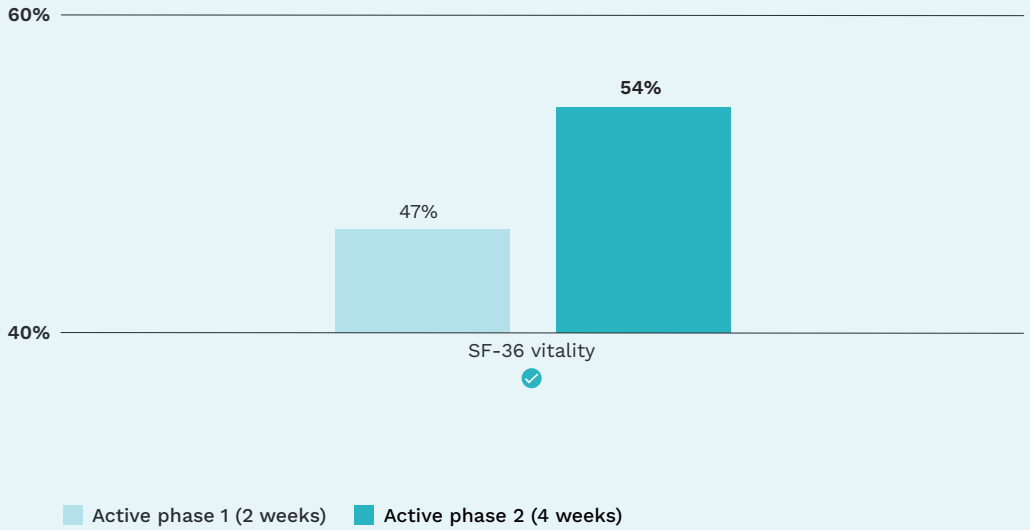
Physical and psychological relief

After 4 weeks of daily stimulation, users also reported significant improvement in fibromyalgiarelated symptoms of anxiety and depression[3]

Treatment's benefits over time, significant decrease in:



Treatment's benefits over time, significant increase in:



Efficacy of treatment (% change before and after active treatment) for outcomes showing significant ($p<0.05$) improvement already at 2 weeks usage; green checkmark denotes results above minimal clinically important difference (MCID; MCID thresholds extracted from literature)

Frequently asked questions.

Is the suit associated with any side effects?
Skin irritation and burns beneath the electrodes have been reported with the use of transcutaneous stimulators.

Can the suit be used alongside standard treatments for spasticity and fibromyalgia?
In most cases, patients who add the suit to their treatment regimen may also continue drug, physical, psychiatric, or other therapies to manage their condition.

Always document the patient's current care regimen before starting stimulation with the suit and consult the patient's primary physician if needed.

Is the suit typically covered by insurance and/or reimbursed by national health systems?
For patients with spasticity, financial coverage for the suit may vary depending on where your practice is located.

For patients with fibromyalgia, the suit is currently available on a cash-pay basis only. It is not covered by commercial insurance or regional/national health systems.

Contact your regional Ottobock representative for more information about typical costs and coverage for the suit.

What kind of material is the suit constructed from?
The jacket and pants are constructed from a stretchy single-layer fabric (polyamide/elastane blend) that contains no animal products or fibers.

Has the suit been evaluated in any independent clinical studies?
Several small, independent studies have evaluated the suit for spasticity management. Their published outcomes should be interpreted carefully in view of several important limitations:

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

The suit has also been evaluated in two clinical research studies in patients with a definitive diagnosis of fibromyalgia:

- A randomized, double-blind, sham-controlled study of 33 patients with fibromyalgia, evaluating the suit's impact on a spectrum of fibromyalgia symptoms.[3]
- An open-label trial of 50 patients with fibromyalgia, evaluating the impact of a single 60-minute session on participants' pain levels.[2]

Machine-washable garments
The jacket and pants may be cleaned up to 60 times in a home washer at 40°C/104°F.

Do NOT wash control units.
This may void the suit's two-year warranty.

Contraindications.

Do NOT use the suit:

- Together with electronic life-support equipment, e.g. cardiac demand pacemakers, or high-frequency operation equipment
- Together with ECG-equipment

There is a risk of the suit disturbing the function of the above

Do NOT use the suit without consulting a doctor if any of the following apply:

- Cardiac diseases or other types of related conditions
- Cancer
- Infectious diseases
- Fever
- Epilepsy
- Skin disease, rashes or other skin problems
- Usage together with another medical device

Usage in connection with the preceding scenarios or conditions can expose the user to unnecessary risk and is therefore at the user‘s own risk.

exopulse suit.

Discover how it can help alleviate symptoms of spasticity and fibromyalgia and create new possibilities for your patients' care. Book a clinical demo for your practice at **www.ottobock.com.**

Indication and usage

The ***exopulse suit*** is intended to provide

- relaxation of tense and spastic muscles and muscle activation, improved local blood circulation and pain relief in patients with cerebral palsy (CP), multiple sclerosis (MS), stroke, and other neurological disorders which may cause such type of symptoms, together with
- pain relief in patients with fibromyalgia, and other neurological disorders which may cause such type of symptoms.

Technical specifications

Power	Rechargeable
Pulse Width	Variable between 20 µs and 400 µs
Pulse Shape	Square wave
Frequency	20 Hz
Channels	40
Electrodes	50, made of silicon rubber
Garment fabric	Polyamide/elastane blend

References:

1. Hahn A, Moeller S, et al. Effects of a full-body electrostimulation garment application in a cohort of subjects with cerebral palsy, multiple sclerosis, and stroke on upper motor neuron syndrome symptoms. Biomedical Engineering / Biomedizinische Technik. 2024; 69(1):49-59.
2. Riachi N, Chalah MA, Ahdab R, Arshad F, Ayache SS. Effects of the TENS device, Exopulse Mollii Suit, on pain related to fibromyalgia: An open-label study. Neurophysiol Clin. 2023 Aug;53(4):102863.
3. Mattar JG, Chalah MA, Ouerchefani N, Sorel M, Le Guilloux J, Lefaucheur JP, Abi Lahoud GN, Ayache SS. The effect of the EXOPULSE Mollii Suit on pain and fibromyalgia-related symptoms-A randomized sham-controlled crossover trial. Eur J Pain. 2024 Sep 18. doi: 10.1002/ejp.4729. Epub ahead of print. PMID: 39291602.

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