Urgent Field Safety Notice (FSN)

ABLE Exoskeleton - Minimization of the risk of fractures in patients with limited ankle dorsiflexion

Code: **FSN-EN-20260507**
Issue date: **12-05-2026**
Affected product: **ABLE Exoskeleton**
Type: **New FSN**

Notice addressed to

This Urgent Field Safety Notice is addressed to all healthcare professionals and distributors who have purchased or use the ABLE exoskeleton.

Contact point for further information

E-mail	**support@ablehumanmotion.com**
Telephone	**(+34) 613 08 83 23**
Address	**ABLE Human Motion, S.L.** c/ Marie Curie 8-14, 08042 Barcelona, España

Will you receive further advice or information?

No At this time, no follow-up information or new notice is anticipated.

Competent Authority review of this notice

The Competent Authority of your country has been informed about this communication.

Affected Device(s)

Device Details

Commercial Name	ABLE Exoskeleton
Unique Device Identifier (UDI-DI)	8437025514A1EF

Device Model or Part Number	A1
Intended Purpose	The ABLE Exoskeleton is intended to perform rehabilitation therapy in a clinical or controlled non-clinical setting, under the supervision of a therapist, or equivalent clinical professional, certified by ABLE Human Motion. The device is intended to perform ambulatory functions by mechanically mobilising the lower extremities of the patient. The device is intended to be used with a compatible walking aid (crutches or walker) or an additional therapist to aid balance. Users can interact with the device using a mobile application (ABLE Care) and a Remote Controller attached to the walking aid. The therapist must complete a training program before the use of the device. The device is not intended for sports or stair climbing.
Software Version	All software versions
Affected Serial Number Range	All serial numbers
Associated Devices	No more associated devices

Manufacturer Information

Manufacturer Name	
Address	
EU Single Registration Number (SRN)	**ES-MF-000037009**

Reasons for the Field Safety Corrective Action

Description of the problem and identified hazard

Bone fractures are a known and inherent risk associated with the use of exoskeletons and may be related to multiple contributing factors.

A potential increased risk of fractures associated with the use of the ABLE exoskeleton has been identified in certain patient profiles, related to ankle alignment and functional mobility during gait. In particular, it has been observed that some patients may meet the inclusion criterion of a 90° ankle range of motion (ROM) in the neutral position, while presenting limitations in functional dorsiflexion. The exoskeleton design incorporates a passive foot system that induces an approximate range of dorsiflexion during gait, which may generate additional mechanical loads on the ankle joint in such cases.

During training on the use of the exoskeleton, the use of orthoses (e.g., AFO, DAFO, or equivalent devices) has been recommended in patients with muscle tone abnormalities such as spasticity or hypertonia, joint limitations, or difficulty maintaining proper foot alignment during gait.

In the exoskeleton Instructions for Use, section “5.2.3. Measurements” (version v15), therapists are advised that: “*If the ankle cannot move beyond the neutral position, an orthosis may be used to maintain the ankle in a fixed neutral position when using the exoskeleton.*”

This specific recommendation is not included in the safety section of the Instructions for Use. Although it is mentioned elsewhere, its omission from that section may contribute to a lack of consistency in the application of clinical criteria. This situation could increase the risk in patients who, despite meeting the current inclusion criteria, present functional limitations that have not been assessed.

Based on the above, if additional support measures, such as orthoses, are not used, there may be an increased risk of adverse events associated with use of the device in certain patients. This effect could increase the risk of:

- Bone fractures, including fractures of the tibia, fibula, ankle region, and subtalar region
- Joint or ligament injuries
- Worsening of pain or spasticity

Further information to help characterise the problem

The typical patient **meets the criterion of 90° ankle ROM** at rest but may present with l**imited dorsiflexion**. Since the exoskeleton induces dorsiflexion through a passive foot system, this condition could generate additional load on the joint and bony structures of the ankle.

Probability of the problem arising and predicted risk to patient/users

In relation to the total number of devices in use and sessions performed, the probability of fracture remains low, at fewer than 3 per 1,000 patients, and is within the ranges reported in the literature for similar devices, approximately 11 per 1,000 patients. This use may be only a contributing factor, in conjunction with other concurrent circumstances, such as the increased fracture risk in the device's target populations.

Background on the Issue & Other Information

This risk was identified through incident reports from the clinical setting.

Action to Mitigate the Risk

This Field Safety Notice is intended to reinforce safety in patient selection and in the conditions of device use by clarifying clinical criteria and recommendations for use.

Actions to be taken by you

- Assess the ankle before use: **confirm ROM ≥ 90°** and **assess functional dorsiflexion**.
- Use of orthoses: **in patients with limited dorsiflexion, spasticity**, or foot **alignment abnormalities**, use an **appropriate orthosis**, such as an AFO, DAFO, or equivalent, during use of the exoskeleton.
- In patients with long-standing spinal cord injury (>5–10 years), even those who regularly perform standing activities, the **possible presence of osteoporosis should be considered, particularly with distal predominance**. This condition may increase the risk of fragility fractures under axial loading during gait. A **specific assessment of bone status** is recommended, such as bone densitometry or clinical risk assessment, and the indication for therapy and its progression should be adjusted accordingly, with particular caution during the initial weight-bearing phases.
- Reminder of the existing contraindication: do not use the device in patients who do not achieve 90° or who present with non-reducible equinus foot.
- Reminder of the existing monitoring measures: discontinue use in the event of pain, increased spasticity, or other clinical signs, and perform a medical assessment.
- Immediate application: these measures should be considered additional safety information regarding the conditions of use.
- No withdrawal, quarantine, or technical modification of the device is required.

If the recommendations included in this FSN are followed, namely functional assessment of dorsiflexion and use of appropriate orthoses where applicable, the residual risk is considered reduced and acceptable, although not completely eliminated.

When should you complete the actions?

The actions described in this Field Safety Notice must be implemented immediately in all current and future patients before continuing or initiating use of the exoskeleton, particularly with regard to assessment of ankle range of motion and the use of orthoses where appropriate.

Do you need to reply to ABLE Human Motion?

Yes You should return the Acknowledgement of Receipt sent to you with this document before **29-05-2026**. Detailed instructions on how to send it are included in the Acknowledgement of Receipt.

Do you need to communicate this FSN to the patient or users?

No You do not need to communicate this FSN to the patient or user.

Actions taken by ABLE Human Motion

As a corrective action, specific information on this risk will be included in the Instructions for Use and training materials in future editions.

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware of it within your organisation or to any organisation where the ABLE Exoskeleton has been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

Please report all device-related incidents to ABLE Human Motion, your distributor or local representative, and the National Competent Authority if appropriate, as this provides important feedback.