Safety notice:
Field Safety Notice (FSN) / Corrective Action (FSCA)

Date: FSN publication: 22.01.2026

Reference: VF2026-0003 | SK2026-0001 | SF2026-0055 | ref260114-00289 | cos101418-02 | cos101000j | cos101000al | cos30001-01va02 | cos30001-01va02-0137

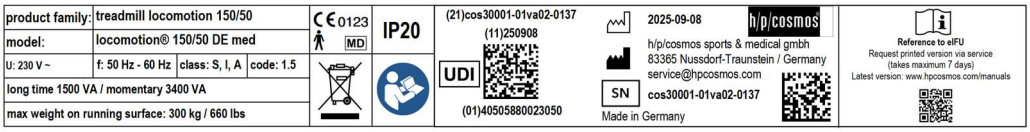
Vigilance report
BfArM:

Manufacturer
h/p/cosmos sports & medical gmbh
Am Sportplatz 8
83365 Nussdorf-Traunstein
Germany
EUDAMED ID Economic Actor: SRN: DE-MF-000006147 safety@hpcosmos.com / www.hpcosmos.com

PRRC contact: Nadine Schott, PRRC Art. 15 MDR nadine.schott@hpcosmos.com / +49 8669 86 42 0

Product category: Treadmill
Product name: Treadmill locomotion 150/50 DE med and locomotion 190/65 DE med
Product item no.: cos30001-01va02 (treadmill) and cos30024va04 (treadmill) | cos101418-02 (emergency stop switch)
Basic UDI-DI: B-40505880023050 and B-4050588002114
UDI-DI: 40505880023050 and 4050588002114
Risk class: IIb
EUDAMED code: Z129006: Treadmills for physiotherapy and/or diagnostic uses
FDA code: IOL, treadmill, powered exercise equipment, 510(K) Exempt, Regulation Number 890.5380

Illustration:



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Countries affected **Austria | Spain | Germany | Great Britain | Ukraine | Morocco**

Affected SN: cos30001-01va02-0142 | cos30001-01va02-0141 | cos30001-01va02-0139 | cos30001-01va02-0138 | cos30001-01va02-0140 | cos30001-01va02-0137 | cos30024va04-0005 | cos30001-01va02-0136 | cos30001-01va02-0135

To: All users, operators, dealers and service partners with locomotion 150/50 DE med and locomotion 190/65 DE med treadmills manufactured after 02/2025

Subject: Possible failure of the stop device to activate via the ripcord with clip and magnetic switch
!! The normal emergency stop button via mushroom button is still functional and not affected by this !!

Description: According to the treadmill standard DIN EN ISO 20957-6, the ripcord is intended as a possible safety-related trigger for the emergency stop function.
A user recently reported to us that, in one of the 9 devices potentially affected when used with patients, this pull cord stop switch did not cause the treadmill belt to STOP.
The treadmill could and had to be stopped using the additional mushroom-shaped emergency stop button.
An internal review of this production batch of a maximum of nine devices revealed that there may be other h/p/cosmos treadmills from this production batch of nine devices where this additional ripcord emergency stop does not trigger reliably in all cases. This means that the required "emergency stop via ripcord" function is not guaranteed at all times. In a situation where immediate stopping is required, it may therefore not be possible to stop the treadmill using the ripcord. The running belt and/or lift motor will only stop when another emergency stop button (e.g. mushroom button, known as the "master emergency stop") that is also available on h/p/cosmos treadmills is activated.
Cause: In this production batch of 9 treadmills built from 2025 onwards with the old MCU5 user terminal, the rated current required for triggering was too high after a component change, so that the required triggering condition was not achieved in isolated cases. As a result, the ripcord may not trigger in certain situations, despite being activated.

Risk/hazards/safety assessment: If the emergency stop trigger via the ripcord does not work, the treadmill cannot be stopped using this trigger type in a situation where immediate stopping would be necessary. This can prolong the reaction time until the treadmill comes to a standstill, unless another emergency stop is activated immediately. This can increase the risk of falls (e.g. loss of balance/stability, drifting backwards). The potential health risks include **abrasions, bruises, sprains** and, depending on the situation and patient, **broken bones or head injuries**. The consequences can be particularly serious for patients with limited mobility. Users also run the risk of having to intervene in an unexpected situation (e.g. supporting or holding the patient), which can lead to **overexertion or injury**. **Third parties** (e.g. accompanying persons) may also be affected by uncontrolled movements or collisions in the vicinity of the device.
It is also important to note that a ripcord is not a fall prevention system. It can stop the treadmill in an emergency, but it does not prevent a fall and therefore cannot replace fall protection. Assuming that the ripcord alone provides "fall protection" can lead to a false sense of security that does not exist in this form.
Therefore, depending on the patient and application, suitable fall prevention measures (e.g. airwalk ap with / safety bar with fall protection) are still required in cases where a fall could pose an unacceptable risk (osteoporosis, high-speed or special applications with persons who cannot jump off the treadmill, such as children, physically impaired persons, etc.).

Immediate measures:

1. Check whether affected: Compare the serial number with the device list. If the device is affected, this FSN applies.

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2. Use only under supervision: The treadmill may only be operated if a trained caregiver is constantly present and can reach the emergency stop immediately at any time.
3. Apply fall prevention: For gait therapy and in cases of increased risk of falling, suitable fall protection (e.g. airwalk ap with fall protection/safety bar) must be used.
4. Quick check before each use: Test the emergency stop button including the ripcord before each use.
5. Take out of service immediately if...
   - the emergency stop does not stop immediately,
   - there is a malfunction in the emergency stop chain, or
   - safe supervision/accessibility of the emergency stop is not guaranteed.
6. Carry out conversion promptly: After receiving the conversion kit, carry out the conversion (2x emergency stop left/right) according to the instructions, perform a function test according to the instructions and confirm by email.

Correction:

We are retrofitting the 9 treadmills in question with an optimised emergency stop control: **In future, these 9 machines will have two easily accessible emergency stop controls (large mushroom buttons) – one on the left and one on the right handrail – in order to comply with the treadmill standard DIN EN ISO 20957-6**.
This allows the emergency stop to be triggered quickly and intuitively from both sides. As part of this improvement, the treadmill will then be operated without a ripcord. The emergency stop function remains fully guaranteed thanks to its accessibility on both sides and continues to meet the normative requirements for the accessibility of the emergency stop control.
All new devices with a UserTerminal Touch (Pro) are **not affected**, as they follow a different technical design.

Corrective measure:

For all 9 affected devices, we are providing our customers with a **free conversion kit** consisting of:

- **2x** cos15933 **emergency stop control element**
- **Adapter cable** cos100770
- **Service/assembly instructions**: "*Installation Guide Emergency Off Locomotion*"
  N:\article\cos30001-01\20260119_cos30001-01va02_Installation_Guide_Emergency_Off_Locomotion_signed.pdf

The conversion can be carried out by the customer themselves and has been deliberately kept simple: The existing emergency stop connection is reconnected using the new emergency stop controls (plug-and-play) – without interfering with the device software and without special tools. After reconnecting, a brief functional test must be carried out in accordance with the enclosed instructions and the implementation must be confirmed (see feedback).

Passing on information:

Please forward these safety instructions to all treadmill users in your facility.

Feedback:

Please confirm that you have implemented the immediate measures by sending an email to: **safety@hpcosmos.com**

Contact:

Christian Melcher, Head of Technical Customer Service
christian.melcher@hpcosmos.com / +49 8669 8642-25

Safety notice:
Field Safety Notice (FSN) / Corrective Action (FSCA)

h/p/cosmos hereby informs all customers, operators and distributors about a field safety corrective action (FSCA) for certain Class IIb medical device treadmill ergometers used for gait therapy applications. This Field Safety Notice (FSN) is issued in accordance with Regulation (EU) 2017/745 (MDR) as information on an FSCA Field Safety Corrective Action; the affected devices are clearly identified by their 9 serial numbers.

As part of our quality monitoring, it was determined that the emergency stop trigger via the ripcord on the 9 affected devices may not be reliable in individual cases. This means that in a situation where immediate stopping is required, the treadmill may not be able to be stopped using the ripcord. If another emergency stop is not activated immediately in such a case, the time it takes for the device to come to a standstill may be extended. This may increase the risk of falls and of entrapment or crushing injuries in the vicinity of moving parts or attached or docked components.

Important: A rip cord is not a fall prevention system. It can stop the treadmill in an emergency, but it does not prevent falls and is not a substitute for suitable fall protection. Assuming that the rip cord alone provides "fall protection" can therefore create a false sense of security that does not exist in this form.

As a precautionary measure, we are improving the emergency stop operation of the affected treadmills by retrofitting two easily accessible emergency stop controls (large mushroom buttons), which are attached to the left and right handrails respectively. This means that the emergency stop can be reached quickly and clearly from both sides in future. After the retrofit, the treadmill will be operated without a ripcord. The emergency stop function will remain guaranteed thanks to its accessibility on both sides of the handrail and will continue to meet the normative requirements for the accessibility of the emergency stop control.

All customers with affected devices will receive a free conversion kit from us consisting of two emergency stop controls (left and right handrails) and an adapter cable for direct connection to the device. The conversion can be carried out by the customer themselves by reconnecting the existing connections in accordance with the enclosed instructions (plug-and-play). No software intervention is necessary. After reconnecting, the functional test described in the instructions must be carried out. We then ask for feedback using the enclosed form so that we can track and document the complete implementation for all affected devices.

Please check whether your device is affected by comparing the serial number with the list of affected devices. The list of affected devices can be found as an attachment on our website. Until the conversion is complete, please ensure that the caregiver can reach an emergency stop button immediately at any time during use. For patients or applications with an increased risk of falling, suitable fall prevention measures (e.g. airwalk ap with fall protection/safety bar) must continue to be used, as a ripcord does not prevent falls. Please also keep the safety area behind the device clear in accordance with the instructions for use and carry out the specified functional checks in accordance with the instructions for use.

If you have any questions about identifying affected devices, retrofitting or functional testing, please do not hesitate to contact us. Please have the serial number ready.

Retrofitting two emergency stop controls on the left and right makes emergency stop operation clearer and more accessible in everyday therapy. You will receive a free plug-and-play set for quick implementation. In this way, we can jointly ensure that your treadmill can be reliably switched off, is user-friendly and can continue to be used in accordance with standards.

h/p/cosmos website:
https://www.hpcosmos.com/de/sicherheit
https://www.hpcosmos.com/de/kontakt-support/media-downloads/manuals

Please forward these safety instructions to all treadmill users at your facility.

We apologise for any inconvenience this may cause and thank you for your cooperation.

h/p/cosmos sports & medical gmbh

Technical Customer Service | Quality Management | PRRC

Safety notice:
Field Safety Notice (FSN) / Corrective Action (FSCA)

Confirmation of field safety corrective action (FSCA)

Please complete this form in full and return it to us by email within **14 calendar days**. Your response is required to ensure that all affected devices have been identified and the measure has been fully implemented.

Customer data:

Device serial number: _____

Company: _____

Department: _____

Street: _____

Postcode, town: _____

Country: _____

FSCA contact person:

First name: _____

Surname: _____

Email address: _____

Telephone number:

Please select an option:

☐ **Option 1 – Affected devices available, conversion already carried out:**

We confirm that we have received and understood the safety information (FSN). We have carried out the retrofit on all affected devices. The previous connections have been reconnected to the **two new emergency stop controls (handrails on the left and right) without pull cords** in accordance with the instructions. The function test has been carried out and was successful.

Date of conversion: _____ (optional incl. photo documentation)

~~☐ **Option 2 – Affected devices available, conversion will be carried out during the next annual maintenance:**~~

(n/a as affected safety function)

~~We confirm that we have received and understood the safety information (FSN). We will carry out the conversion on all affected devices by the date specified below.~~

~~Planned date of conversion by: _____~~

☐ **Option 3 – No affected devices available / no longer in stock:**

We confirm that we have received and understood the safety information (FSN). After checking the serial numbers, we can confirm that there are **no affected devices** in our inventory or that the devices are no longer in use.

Note (optional): _____

Device details (please fill in completely; for additional devices/products, please add as an attachment)

Device / product	Serial number	UDI-DI	Location / Department / Room

Important note on use (until conversion): A ripcord is **not a fall prevention system**. Please ensure that a caregiver can reach at least one emergency stop button at any time during use. Depending on the patient and application, use appropriate fall prevention measures in accordance with the instructions for use.

Date: _____ Name in block letters: _____ Signature: _____