⚠️ **Field Safety Notice FSN** ⚠️

## Warning! Automatic program / profile modes on treadmills without instruction can cause "unwanted acceleration"

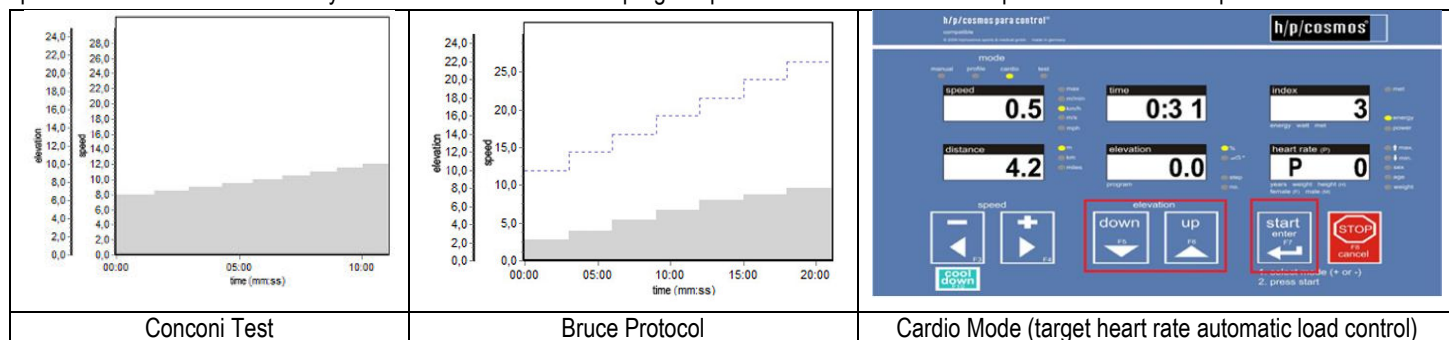| | | symbol images: |
|---|---|---|
| reference | ref230907-04245 \| VF2023-3391 \| SF2023-1418 \| cos30026va01-0174, cos30026va01-0175 case 4389/07  sn03098100716 VF2022-0478 07.03.2022 \| VF2023-1587 27.03.2023 SF2023-0593 SK2023-0001 VF2023-0813 20.02.2023 SF2023-0301 \|  VF2022-2287 23.11.2022  \| VF2023-3391 07.09.2023 |  |
| vigilance report | BfArM: 4389/07 Nov. 2007 / March 2009 with injuries due to fall and lack of instruction. No defects on h/p/cosmos devices. | |
| product | treadmill, line powered, FDA product code: IOL,  GMDN code: 33015 | |
| effected devices and serial no. | potentially all treadmills (all brands and models of all manufacturers, not only h/p/cosmos) with automatic program and profile modes, tests or cardio mode control or remote control via interface | |
| manufacturer | h/p/cosmos sports & medical gmbh Am Sportplatz 8, 83365 Nussdorf-Traunstein / Germany EUDAMED ID Economic Actor: SRN: DE-MF-000006147 |  |
| effected clients | potentially all treadmill users who utilize automatic program and profile modes, tests or cardio mode control of treadmills | |
| potential risk | Falling on a treadmill due to unexpected / unwanted start/stop and acceleration or load change of the treadmill when the subject and operator are not prepared and fail to press the emergency button in time. Falling on a treadmill may result in serious injury! | |
| risk mitigation and control | 1) perform sufficient instruction to users and operators in operation of treadmill, point out and obey all warnings. For this utilize the installation, commissioning and instruction protocol form cos15228-05_en_de: https://www.hpcosmos.com/sites/default/files/uploads/documents/20220204_cos15228-05_en_de_form_hpcosmos_commissioning_instruction_protocol.pdf 2) teach and practice the emergency dismount on treadmills as described on the operation manual 3) supervise the operation of the treadmill as described in the operation manual IFU instructions for use and never leave children or patients alone on treadmills. 4) temporarily lock and deactivate the automatic program and profile modes or cardio mode control if not needed and activate them only on demand. MCU5: With option 41 ... 44 the modes (manual, profile, cardio, test) can be locked. 5) secure treadmill against unauthorized operation. MCU5: See "option 40" in chapter 5.11 "Optional settings User Options" 6) utilize safety arch [cos10170xx] with harness, chest belt as fall prevention device for any application where falling might cause an unacceptable risk | |

Dear customers, distributors, field service engineers and manufacturers,

A potential risk for patients and/or subjects on a controlled treadmill may arise, if the instruction has not been performed in a sufficient way and if patients or subjects are left alone without understanding proper operation of the treadmills.
Especially if modern motor powered and computerized treadmills have also automatic program and profile modes or cardio mode control or remote control via interface.

Users need to be instructed and need to understand, that in an automatic mode the treadmill will start and stop automatically and will change speed and elevation automatically based on the defined test or program profile. Below see some examples of such tests and profiles.



| Conconi Test | Bruce Protocol | Cardio Mode (target heart rate automatic load control) |
|---|---|---|

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h/p/cosmos has been informed about some accidents (some of them with injuries) which occurred when operators, patients or subjects have not been instructed properly or when they have been left alone on treadmills without supervision.

Also almost all modern cars and road vehicles have advanced driver-assistance systems such as Automatic Speed Control or Adaptive Cruise Control (ACC) where for example the car will maintain, increase or decrease the speed automatically in order to the maintain a safe distance from vehicles ahead.

See also https://en.wikipedia.org/wiki/Adaptive_cruise_control

In such cases drivers also need to be instructed and need to understand, that the car will not slow down anymore if the foot was removed from the accelerator pedal (accel pedal). The car only slows down when the Automatic Speed Control or Adaptive Cruise Control (ACC) was deactivated or when the brake pedal was pressed by the driver.

Same situation applies for modern treadmills.

The treadmill belt will start and/or stop, increase speed and/or elevation based on the activated profile, program or test mode or commands received via interface in remote control mode.

In case there was no sufficient instruction and/or warning, treadmill users may start and activate such profiles, programs or test modes without realizing the functionality and the consequences.

The emergency stop buttons and normal stop buttons will still work on treadmills and can stop the belt immediately.

However, we have heard about cases and accidents, that patients and subjects have been left alone on treadmills and they have been caught by surprise due to the automatic functions and acceleration of the treadmill which then caused panic to the patient/subject.

Due to the panic in some cases they did not press the emergency button and fell on the treadmill which caused serious injuries.

**Therefore please allow to repeat the obligatory and necessary steps and risk mitigation and risk control:**

1) perform sufficient instruction to users and operators in operation of treadmill, point out and obey all warnings.
   For this utilize the installation, commissioning and instruction protocol form cos15228-05_en_de:
   https://www.hpcosmos.com/sites/default/files/uploads/documents/20220204_cos15228-05_en_de_form_hpcosmos_commissioning_instruction_protocol.pdf
2) teach and practice the emergency dismount on treadmills as described on the operation manual
3) supervise the operation of the treadmill as described in the operation manual IFU instructions for use and never leave children or patients alone on treadmills
4) temporarily lock and deactivate the automatic program and profile modes or cardio mode control if not needed and activate them only on demand. MCU5: With option 41 ... 44 the modes (manual, profile, cardio, test) can be locked.
5) secure treadmill against unauthorized operation. MCU5: See "option 40" in chapter 5.11 "Optional settings User Options"
6) utilize safety arch [cos10170xx] with harness, chest belt as fall prevention device for any application where falling might cause an unacceptable risk

For any questions and/or support and/or PMS observations on that please send an eMail to safety@hpcosmos.com

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