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December 10, 2015

Field safety notice to ripcords for treadmills built in 2014/2015

Addressee:

Users and operators of h/p/cosmos treadmills built in 2014/2015

Identification of concerned medical devices and equipment:

All h/p/cosmos treadmills built in 2014 and 2015 equipped with a ripcord, clip and magnetic switch:

Product family: treadmill h/p/cosmos 150/50 LC	Including the relevant OEM treadmills from CareFusion, COSMED, Proxomed, SCHILLER, zebris, FREI, LMT and HUR (h/p/cosmos is the producer of these devices – see nameplate)
Product family: treadmill h/p/cosmos 150/50	
Product family: treadmill h/p/cosmos 170-190/65	
Product family: treadmill h/p/cosmos 170-190/65 3p	
Product family: treadmill h/p/cosmos 200-300/75-125	

Description of the problem including the determined cause:

Almost all h/p/cosmos treadmills built in 2014 and 2015 (except for some models with safety arch) are equipped with a red ripcord and a clip (article number cos101699) that stops the running belt automatically through a magnetic switch in case a fall occurs in order to minimize the effects of the fall.

A malfunction of the ripcord has no additional fall risk, because even a properly applied and functional ripcord cannot prevent a fall!

An effective minimization of the risk of a fall can only be achieved by the use of a fall prevention, like a safety arch or a body weight support system.

For the above-mentioned model series built in 2014 and 2015 it is possible, that in exceptional cases, the red cord between the magnet and the clip may not maintain the required tensile strength. This premature aging is probably caused by intense sunlight (UV radiation).

In this context we point out that any kind of damage or wear and tear will cause safety-related functional limitations or even the loss of function. This is not only but especially valid for textiles and plastics and may be caused by strong sunlight, strong UV radiation, aggressive disinfectants, incorrect cleaning, squeezing or damage caused by sharp or pointed objects.

In case the material is worn seriously, the cord might rip off and the magnet switch would not stop the running belt when a fall occurs. In the worst case the patient might come to rest on the running belt in such a way that the moving belt could suffer minor injuries (abrasions).

On this position it is important to note, that behind every treadmill there should be a safety distance of at least 2 meters length and the treadmill's width, so that the fallen person has sufficient space to come to a rest and does not crash against an obstacle or will be pinched between the running belt and the wall. See also standard EN 957-6 and safety instructions on the treadmill.

Within each annually required maintenance and safety check, an authorized service technician checks all safety-related functions of your device. All consumables (also textile parts like the ripcords) are checked as well. If needed they are replaced.

According to our instructions for use, also the user has to perform a daily preventive maintenance. This preventive maintenance includes safety checks and monitoring work of safety equipment and basic functions.

See also German medical device operator regulations „Medizinprodukte-Betreiberverordnung – MPBetreibV“

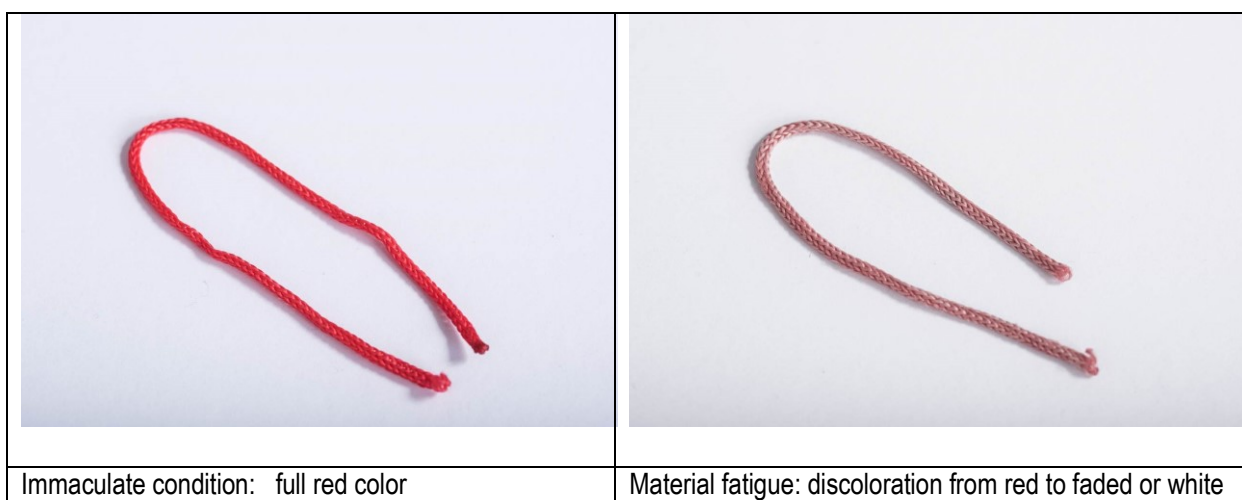
Source: <http://www.gesetze-im-internet.de/bundesrecht/mpbetreibv/gesamt.pdf>

What measures does the user have to take?

1. Please make a visually and functional control of the ripcord including clip and magnetic switch.
2. The cord must have a full red color and must not show any cracks or damages.
3. Apply a tensile load of about 1 kg (10 N) at the clip. The cord must pull the magnet off the magnetic switch. The treadmill has to stop.
4. If the color fades this indicates premature aging due to external influences. The same applies for any cracks or other obvious damages of tissue.

In case of any detected or assumed damage or malfunction, please inform us immediately via email to safety@h-p-cosmos.com or call us on +49 86 69 86 42 0.

We will send you the appropriate spare parts promptly and without charge.



Publication of the information described in this statement:

Please make sure that all users of the aforementioned products and other relevant person within your organization will be aware of this **field safety notice**. If you have passed the products to third parties, please forward a copy of this information or inform the below mentioned contact person.

Since December 1, 2015 all affected treadmill models are equipped with a changed ripcord (article number cos101699-03), which has an increased protection against UV light and chemical influences (e.g. through aggressive cleaning agents or disinfectants).

Nevertheless, the obligation for regular monitoring of functions and safety devices by the operator is maintained.

Always follow the prescribed intervals for preventive maintenance and safety checks.

From January 1, 2016 the red cord shall be replaced annually during the preventive maintenance and safety check service as recommended by the manufacturer.

Please keep this information at least until the action has been completed.

The responsible German government authorities „Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)“ have a copy of this filed safety notice.

Contact person:**Michael Hesper, Safety Officer for medical devices**

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Nussdorf-Traunstein, December 10, 2015



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President & CEO / R & D Manager



Michael Hesper
Safety Officer for medical devices
German Medical Devices Act §30