MEDICAL GRADE TREADMILLS

Full Vision, Inc.

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URGENT Field Safety Notice

Trackmaster Treadmills
FSCA 20221018
FSCA

Date: 2022-11-28

Attention: Users and operators of Trackmaster Treadmills built between May 27, 2022 thru July 22, 2022.

The purpose of this letter is to advise you that Full Vision is conducting a field safety corrective action. Please ensure all individuals in your organization are made aware of this notification and the actions below.

Intended Use:
The medical treadmills are intended as stressing devices, by providing motion to patient, to be interfaced with a variety of cardiac and pulmonary stress testing systems. The treadmill is intended to be operated by the physician, therapist, or operator acting under authorization of the physician with training per IFU under the supervision of a physician and / or therapist, with sufficient knowledge of the indications and contraindications.
The medical treadmills are intended to be used in a medical facility or wellness center.
Certain models have a control panel to operate the treadmill.
Caution: Treadmill does not provide any kind of medical treatment diagnostic or assessment.

Affected Product:

Model #	Description	UDI-DI
317-07926	TREADMILL TMX428 110V	00860176000606
317-07927	TREADMILL TMX428 220V	00860176000613
317-07928	TREADMILL TMX428CP 110V	00860176000620
317-07929	TREADMILL TMX428CP 220V	00860176000637
317-07926GE	TREADMILL GE T2100-ST1 110V	00860176000668
317-07927GE	TREADMILL GE T2100-ST2 220V	00860176000675
317-07927GE CHINA	TREADMILL GE T2100-ST2 220V CHINA	00860176000675

Description of the problem:
Trackmaster treadmills manufactured between May 27, 2022 and July 22, 2022 are equipped with a PCB Board Assembly and Magnetic Safety Tether with clip, that when activated in the event of a fall, stops the running belt at a controlled speed in order to minimize the effects of the fall and holds the belt at 0mph for 3 minutes or until the power is cycled. In the event that the Magnetic Safety Tether fails to activate, all treadmills also have an Emergency Stop Button that may be activated that cuts power to the motor and drive allowing the belt to freewheel to a stop.

In a worst case scenario during a fall, where the Magnetic Safety Tether fails, the patient could come in contact with the running belt in such a way which could result in minor injuries or abrasions. It is important to note that per the instructions for use, there should be a safety clearance minimum of 6ft behind the device and 3ft on either side and the operator assisting the patient should be stationed within reach of the Emergency Stop Button. This clearance space is critical so that the fallen person does not become pinched between the running belt and the wall or other obstacle. In addition, the test should be

monitored by a Health Care Professional where it would be unlikely that the potential Magnetic Safety Tether failure would result in a more severe type of fall.

This has been identified a rare occurrence, under a specific scenario, where the circuit is found in a latch-up condition on the PCB that controls the safety function of the Magnetic Safety Tether, that when the magnet is pulled loose as during a fall, the treadmill may fail to stop. A treadmill with a potential nonconforming PCB Assembly that is initially powered up and started, will operate as intended when the Magnetic Safety Tether and PCB Assembly are activated. The specific scenario was found during subsequent testing that a treadmill with a potential nonconforming PCB Assembly, when the power is cycled (turned off and back on) with the power switch for less than 5 seconds, the PCB will latch-up and not operate as intended. When the power is cycled either with the Emergency Stop Button or the power switch for longer than 30 seconds, the treadmill stops as intended when the Magnetic Safety Tether and PCB Assembly are activated.

The potential for a faulty safety tether had been identified previously as a potential risk in Risk Assessment which is why a primary Emergency Stop Button is installed and in close proximity to the operator to be activated in case of an emergency stopping scenario and the Safety Tether to be used as secondary method. In addition, the operator or Health Care Professional is there to assist the patient in the event of an emergency stopping scenario as another means of risk mitigation.

Risk to Health:
In the event that a patient is falling, they may come in contact with the belt suffering a temporary injury, where the risk of injury is there whether the Safety Tether is fully functional or not but is designed to limit the duration of injury or extent of injury. The Emergency Stop Button is the primary means of stopping the device and the Magnetic Safety Tether as a secondary stopping method. In addition, the operator assisting the patient should be stationed within reach of the Emergency Stop Button and is there to assist the patient in the event of an emergency stopping scenario as other means of risk mitigation. No injuries have been reported as a result of this potential event.

Actions to be taken by the Customer/User:
A simple test can be performed to determine if the unit has the incorrect component installed on the PCB Assembly. The user should turn the device on. Then cycle the power with the power switch by turning it off, waiting 5 seconds, then turn it back on. Start the belt at 2 mph and pull the Magnetic Tether. If the assembly has the incorrect component the device should fail to stop. If the assembly has the correct component the device should stop. The assemblies that fail to stop should be replaced with the c-clip style safety tethers, provided by Full Vision. To continue using the treadmill with the Magnetic Tether assemblies until they can be replaced, you can prevent this condition from occurring by cycling the power for 30 seconds before turning the device back on.

Product Correction:
Full Vision has scrapped all the non-conforming components (Magnetic Safety Tether and PCB Board Assembly) from the inventory. All nonconforming components will be replaced.
For any questions regarding the replacement, please contact Rocky in Treadmill Service at 316-283-3344 ext 109 or tmservice@full-vision.com.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Contact reference person:
Doug Pauls
Full Vision Inc
3017 Full Vision Drive
Newton, KS 67114 USA
316-283-3344
dp@full-vision.com

The undersign confirms that this notice has been provided to the appropriate Regulatory Agency.

Signature	Date of issue
Doug Pauls	Newton, KS
Name	Place of Issue