



Full Vision, Inc.

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MEDICAL GRADE TREADMILLS

Date: October 4, 2022

URGENT MEDICAL DEVICE CORRECTION

The purpose of this letter is to advise you that Full Vision is voluntarily implementing a medical device 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

Serial number range: FVDC-7585 thru FVDC-7631, FVDC-7633 thru FVDC-7717, FVDC-7719 thru FVDC-7737

See Appendix A for location of decal. Serial numbers are located on the front of the device.

Reason for the Correction:

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.

1. Make sure the device is plugged in and turn the device on using the power switch.
2. Cycle the power by turning the power switch off, waiting 5 seconds, then turn the device back on with the power switch.
3. Start the belt at 2 mph using the interfaced stress system or start it using the test plug procedure.
 - a. If using the test plug procedure, the test plug needs to be plugged in and the button pressed while performing step 2.
4. After the belt has started moving, pull the Magnetic Tether.
 - a. If the device fails to stop, this unit has the incorrect component on the assembly and should be replaced immediately.
 - b. If the device stops, this unit has the correct component on the assembly and can be used until the magnetic tether is replaced.
5. The devices that fail to stop should be pulled from use until replaced with the c-clip style safety tether, provided by Full Vision, but to continue using the 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.

Receipt Response:

Scan the below QR code to complete an online form to document that you have received this letter and have no questions. This form also provides a section for comments or additional questions and a section for feedback for any issues or need for additional information.



Sincerely,

<u>Doug Scheible</u> Signature	<u>10/4/22</u> Date of issue
<u>Doug Scheible</u> Name	
<u>President</u> Title	<u>Newton, KS</u> Place of Issue

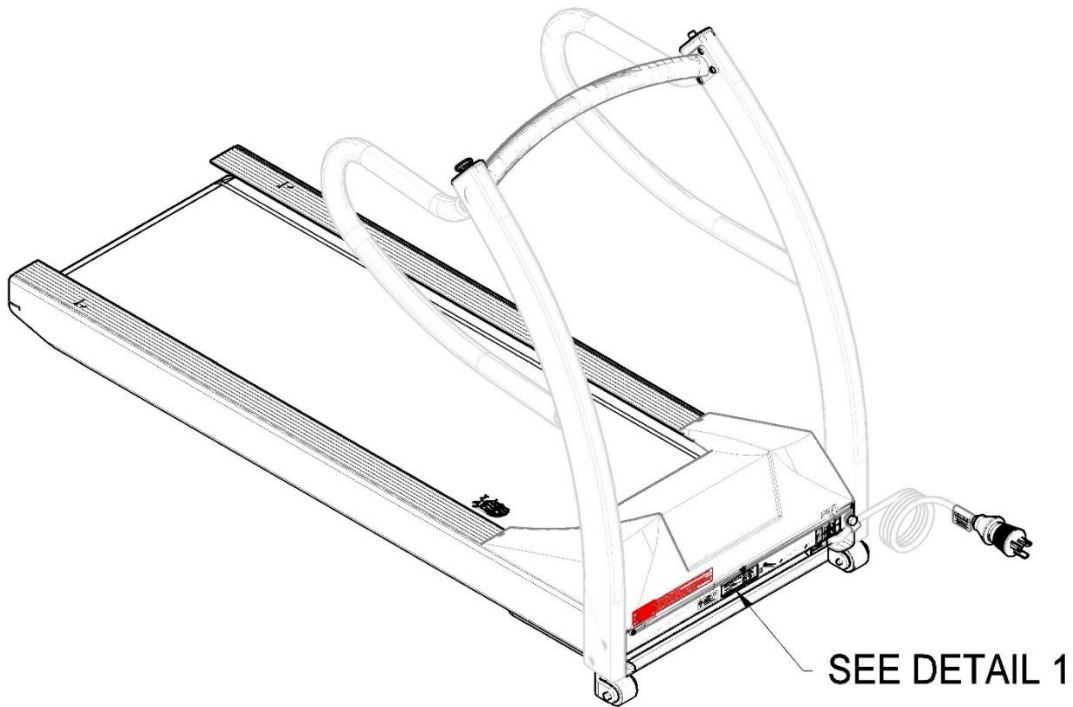


Company Stamp

Full Vision, Inc.

Appendix A

See images below for reference to identify the serial # of your device(s).



DETAIL 1



Enlarged image of serial number decal

