



MEDICAL GRADE TREADMILLS

Full Vision, Inc.

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Newton, KS 67114

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www.trackmastertreadmills.com

Date: May 10, 2023

## URGENT MEDICAL DEVICE CORRECTION

Dear Valued Customer:

The purpose of this letter is to notify you of an intermittent, unexpected occurrence with certain Full Vision medical treadmills (see Table 1 affected products section of this letter). We have completed the root cause investigation and are advising you of a corrective action at this time.

### Issue and Risk to Health:

We recently became aware that certain Full Vision medical treadmills (see Table 1 affected products section of this letter) may accelerate forwards or backwards without notice. This scenario occurs during the initialization of the treadmill and within the first seconds of sending the start belt command. If the treadmill behaves unexpectedly in this fashion, while the patient is standing on the belt, the patient may fall and suffer an injury.

Also, during operation of the treadmill it can come to a controlled yet unexpected stop.

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### Immediate Actions to be taken by Customer/User:

These steps are the recommendation of the Manufacturer to prevent injury and allow use of the device.

- Step 1: Instruct patient to straddle the belt and hold on to the handrails during initialization of the treadmill before starting the test
  - Step 2: Send start/run command to the treadmill with patient still straddling the belt, wait 30 seconds to ensure there is no uncommanded motion
  - Step 3: Instruct patient to carefully step on the belt while holding on to the handrails, begin walking and continue with the test
  - Step 4: Patients unable to perform steps 1-3 must not use the treadmill
  - Step 5: **Print Appendix B and attach to the treadmill until corrections are made and ensure it is visible to the clinician and user**
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### 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.

**Table 1 Affected Products:**

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

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

Serial number range:

FVDC-7585 thru FVDC-7601	FVDC-7603 thru FVDC-7631	FVDC-7633 thru FVDC-7819	FVDC-7825 thru FVDC-7890
FVDC-7899 thru FVDC-7958	FVDC-7964 thru FVDC-8056	FVDC-8064 thru FVDC-8068	FVDC-8104 thru FVDC-8185
FVDC-8190 thru FVDC-8387	FVDC-8389 thru FVDC-8392	FVDC-8396 thru FVDC-8399	FVDC-8407 thru FVDC-8412
FVDC-8414 thru FVDC-8420	FVDC-8426 thru FVDC-8445	FVDC-8456 thru FVDC-8547	FVDC-8552
FVDC-8554 thru FVDC-8556	FVDC-8558 thru FVDC-8618	FVDC-8629 thru FVDC-8650	FVDC-8654 thru FVDC-8701
FVDC-8727 thru FVDC-8731	FVDC-8757 thru FVDC-8767	FVDC-8784 thru FVDC-8803	FVDC-8805 thru FVDC-8810
FVDC-8812 thru FVDC-8816	FVDC-8819 thru FVDC-8828	FVDC-8849	FVDC-8860 thru FVDC-8869
FVDC-8885 thru FVDC-8886	FVDC-8888		

**Product Correction:**

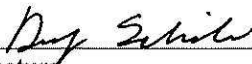
Safety and Quality are a top priority for Full Vision; therefore, we have put the treadmills on a production hold as of April 10, 2023. Upon completion of the root cause investigation and verification of the corrective action, we will contact you to arrange for a correction, free of charge to you.

**Receipt Response:**

To ensure we have reached all our customers and users, we ask that you 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,

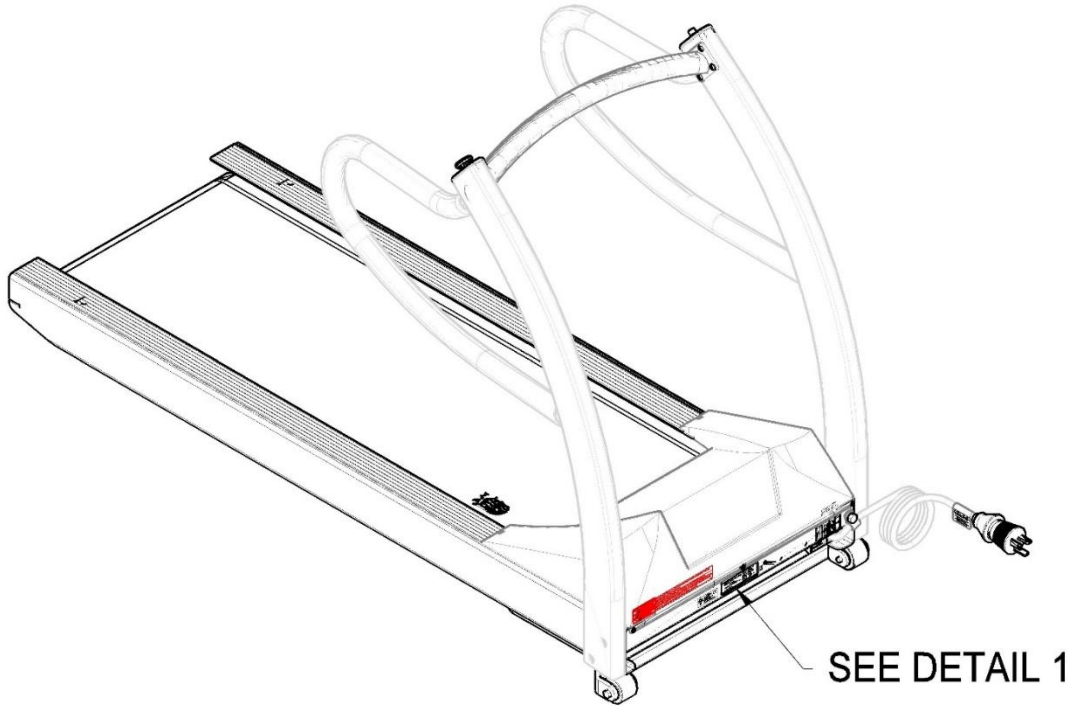
  
 \_\_\_\_\_  
 Signature 5/10/23  
 Date of issue  
 \_\_\_\_\_  
 Doug Scheible  
 Name  
 \_\_\_\_\_  
 President Newton, KS  
 Title Place of Issue  
 \_\_\_\_\_  
 Full Vision, Inc.



Company Stamp

Appendix A

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



DETAIL 1



Enlarged image of serial number decal



## Appendix B

Print this page and attach to the treadmill until corrections are made.

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