

# URGENT MEDICAL DEVICE CORRECTION



Date of Letter Deployment

GE HealthCare Ref. # 30105

To: Hospital Administrators/Risk Managers  
Director of Biomedical Engineering  
Chief of Nursing

RE: **Full Vision Treadmill – Distributed by GE Healthcare (T2100-ST) can accelerate without notice, run backwards, which can lead to patient fall and injury.**

Dear Customer,

This letter is to notify you that Full Vision (a 3<sup>rd</sup> party manufacturer) is conducting a product corrective action related to T2100-ST Treadmill.

A copy of the Full Vision Urgent Medical Device Correction Notice is included in this mailing.

We apologize for any inconvenience this action may have caused and thank you for your continued cooperation and support.

**Affected  
Product  
Details**

T2100-ST Treadmill (GEHC Part# 1092405-001).  
Impacted Treadmill serial number ranges are listed in the Full Vision notice.

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.

**Product  
Correction**

GE HealthCare will correct all affected products at no cost to you. A GE HealthCare representative will contact you to arrange for the correction.

**Actions to  
be taken by  
Customer/  
User**

As part of this corrective action, we ask you to please do the following:

- Review the attached Full Vision notice for instructions, including steps you can take in the interim until GE HealthCare is able to correct the treadmill.
- Ensure all potential users in your facility are made aware of this safety notification and the recommended actions.
- Retain this document for your records.
- Complete and return the attached customer response form via email to **DCAR.Recall@ge.com**.

**Contact  
Information**

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local Service Representative.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Laila Gurney', with a long horizontal flourish extending to the right.

Laila Gurney  
Chief Quality & Regulatory Officer  
GE HealthCare

A handwritten signature in blue ink, appearing to read 'Scott Kelley', with a stylized, looped end.

Scott Kelley  
Chief Medical & Safety Officer  
GE HealthCare

**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT  
RESPONSE REQUIRED**

**Please complete this form and return it to GE HealthCare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.**

\*Customer/Consignee  
Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City/State/ZIP/Country: \_\_\_\_\_

\*Customer Email Address: \_\_\_\_\_

\*Customer Phone Number: \_\_\_\_\_

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

**Please provide the name of the individual with responsibility who completed this form.**

Signature: \_\_\_\_\_

\*Printed Name: \_\_\_\_\_

\*Title: \_\_\_\_\_

\*Date (DD/MM/YYYY): \_\_\_\_\_

\*Indicates Mandatory Fields

**Please return completed form by scanning or taking a photo of the completed form and email to: [DCAR.Recall@ge.com](mailto:DCAR.Recall@ge.com)**





MEDICAL GRADE TREADMILLS

**Full Vision, Inc.**

3017 Full Vision Drive  
Newton, KS 67114

Phone: 316-283-3344  
Fax: 316-283-9522

[www.trackmastertreadmills.com](http://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
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

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

Serial number range:

GEDC-6608 thru GEDC-8382	FVDC-7585 thru FVDC-7601	FVDC-7603 thru FVDC-7631	FVDC-7633 thru FVDC-7819
FVDC-7825 thru FVDC-7890	FVDC-7899 thru FVDC-7858	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-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		

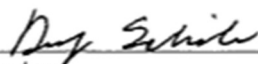
**Product Correction:**

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 complete the included return response acknowledgement and receipt form.

Sincerely,

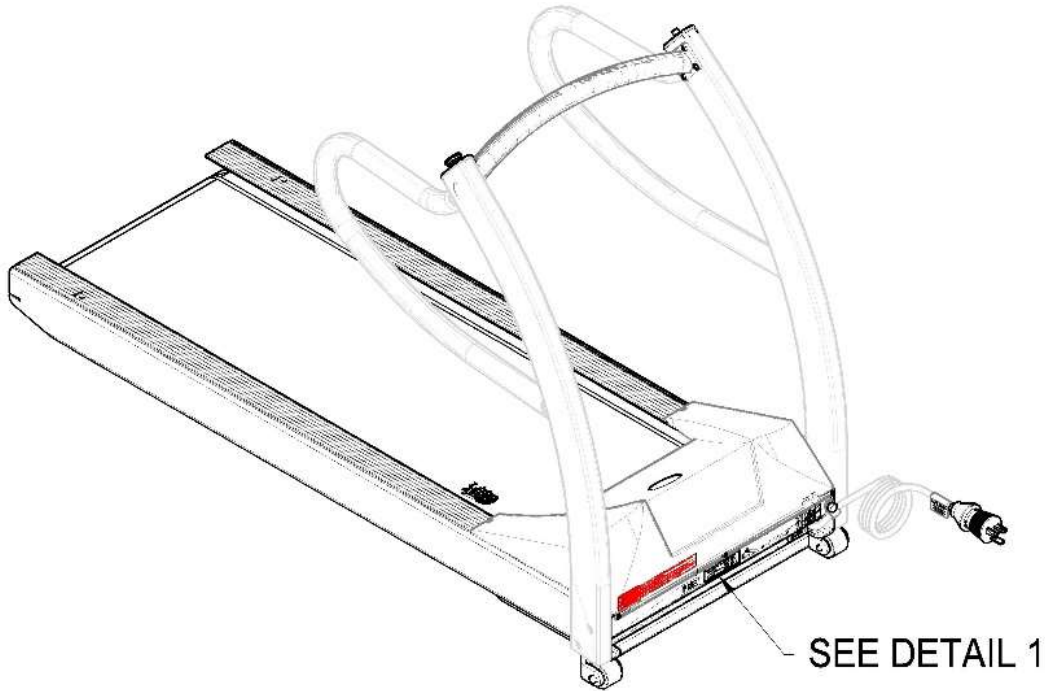
  
 \_\_\_\_\_  
 Signature 5/10/23  
Date of issue  
 Doug Scheible  
 \_\_\_\_\_  
 Name  
 President Newton, KS  
 \_\_\_\_\_  
 Title Place of Issue  
 Full Vision, Inc.



Company Stamp

Appendix A

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

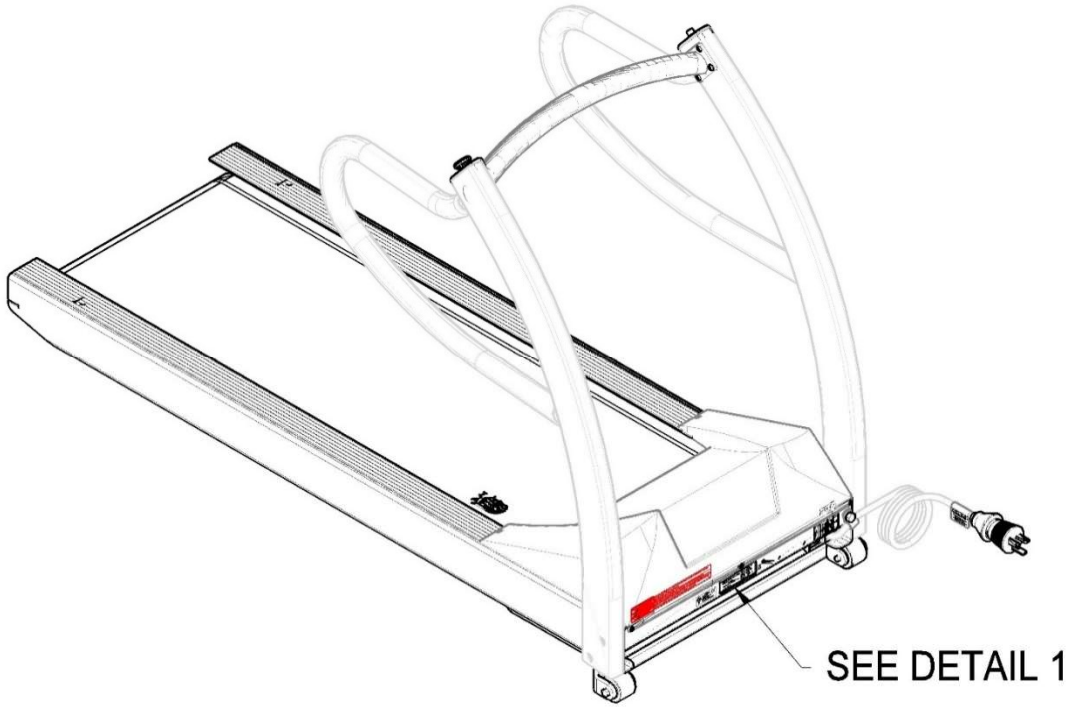


DETAIL 1

<b>MODEL NO. T2100-STX</b> <b>SN GEDC-XXXX</b> <b>REF 2097357-XXX</b>	<b>MFG MODEL NO. TMX428 XXX</b> <b>MFG PART NO. 317-079XX GE</b> <b>VOLTAGE: XXX XXXX ~</b> <b>AMPS: XX HERTZ: XX</b>	<b>ETL CLASSIFIED</b>  <b>CONFORMS TO</b> AAMI STD ES60601-1 IEC STD 60601-1-6 <b>CERTIFIED TO</b> CSA C22.2 # 60601-1 	<b>UDI</b> (01) UDI (11) UDI DATE (21) UDI SN 
<small>Private Label MFG: GE Medical Systems Information Technologies, Inc 9900 Innovation Drive Wauwatosa, WI 53226, USA</small>	<b>FULL VISION INC.</b> <small>3017 FULL VISION DRIVE, NEWTON, KANSAS USA 67114-9750</small>	<b>4TH EDITION PRODUCTION</b> <b>2097357-XXX REV XX</b> 	<small>SERIAL NUMBER</small>  <small>B-CODESN</small>

Enlarged image of serial number decal

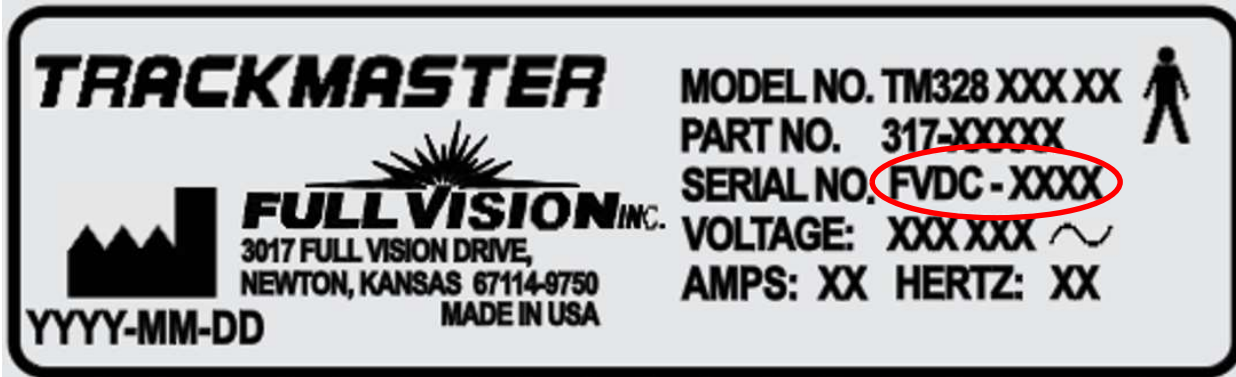
<b>MODEL NO. T2100-STX</b> <b>SN GEDC-XXXX</b> <b>REF 2097357-XXX</b>	<b>MFG MODEL NO. TMX428 XXX</b> <b>MFG PART NO. 317-079XX GE</b> <b>VOLTAGE: XXX XXXX ~</b> <b>AMPS: XX HERTZ: XX</b>
<small>Private Label MFG: GE Medical Systems Information Technologies, Inc 9900 Innovation Drive Wauwatosa, WI 53226, USA</small>	<b>FULL VISION INC.</b> <small>3017 FULL VISION DRIVE, NEWTON, KANSAS USA 67114-9750</small>



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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