# URGENT FIELD SAFETY NOTICE

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 30085

To: Director of Biomedical Engineering
Chief of Nursing
Healthcare Administrator / Risk Manager

**RE: T2100 Treadmill Uncontrolled Walking Belt Motion – Customer Owned Spare Parts**

**Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

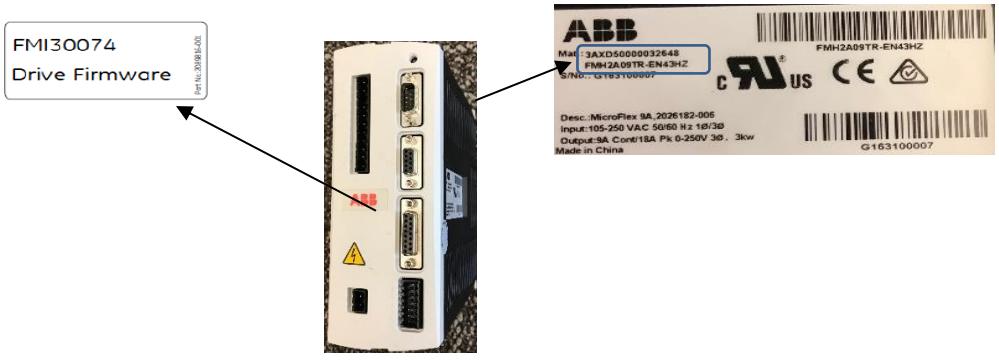
**Safety Issue**

A performance issue with **customer owned** spare parts, T2100 Microflex drive (2026182-002 or 2026182-004), was not addressed with a previous safety correction (GEHC Ref# 30074). If these parts were installed from customer owned stock on the T2100 Treadmill, uncontrolled walking belt motion during a stress exercise test could occur. This motion can be seen as an unexpected slowing, followed by sudden belt acceleration in either the forward or backward direction. When this occurs, engaging the emergency stop button (ESTOP) will not immediately stop the belt. Rather, it will coast to a stop within 35 seconds when slowing from maximum speed. The sudden change in belt speed and/or direction can result in a fall and injury to the patient.

**Safety Instructions**

1) If your spare part drive has a FMI 30074 correction label attached (see below picture) or GE part number (2026182-006) ABB part number (3AXD50000032648, 3AXD50000032647 or FMH2A09TR-EN43HQ), the firmware on the drive was updated and your spare part is not affected. No further action is required except to **complete and return** the attached "Customer Response" form checking box #1 to indicate that you **do not** have affected spare part inventory and e-mail to DCAR.30085@ge.com.

FMI correction label Firmware ABB part number label




Note: The spare part packaging is labeled with the GE part number and the Microflex drive is labeled with the ABB part number.

2) If your spare part drive **does not** have the FMI correction label attached and is GE part number (2026182-002 or 2026182-004) ABB part number (FMH2A09TR-EN43EQ, FMH2A09TR-EN43E, FMH2A09TR-EN43E/12 or FMH2A09TR-EN43GZ), the firmware on the drive was not updated and you have affected spare part inventory. No further action is required regarding your spare part drive except to **complete and return** the attached "Customer Response" form checking box #2 to indicate that you **do** have affected spare part inventory and e-mail to DCAR.30085@ge.com.

3) If you or your service provider installed affected spare part drives on a T2100 treadmill after June 4, 2015, **complete and return** the attached "Customer Response" form checking box #3 to indicate that you **do** or **may** have affected spare parts installed on a T2100 treadmill and e-mail to DCAR.30085@ge.com.

If **any** uncontrolled walking belt motion is observed while the patient is on the treadmill, including unexpected stopping, slowing, acceleration, or change of direction:

Instructions to Clinicians:

- Depress the Emergency Stop (ESTOP) button completely so that it locks


- If the Emergency Stop (ESTP) button does not stop treadmill motion, unplug the power cord from the wall outlet.
- Instruct the patient to:
  - Hold the handrails to help maintain balance
  - Step off the walking belt by placing their feet on the rubberized non-skid surfaces on either side of the walking belt
  - After the walking belt coasts to a complete stop, instruct the patient to step off the treadmill. Depending on belt speed, a full stop may take up to 35 seconds.

    **WARNING:** While the emergency stop switch is depressed or when power is not applied to the treadmill, the walking belt is not locked. The walking belt in this condition is allowed to move which could cause a person to lose balance and fall while standing on the belt. Note, the risk of belt movement is increased with higher treadmill grades or inclines.
- If any uncontrolled motion of the treadmill is observed, discontinue use of the T2100 treadmill and call GE Healthcare Service.

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| **Affected Product Details** | T2100 Microflex Drive spare part GE part number (2026182-002 or 2026182-004) firmware without the FMI 30074 Correction Label. |
| **Product Correction** | GE Healthcare will correct all affected products at no cost to you. Complete and return the attached "Customer Response" form via email to DCAR.30085@ge.com and a GE Healthcare representative will contact you to arrange for a correction if necessary. |
| **Contact Information** | If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative. |

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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,

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer – Medical Safety
GE Healthcare

**MEDICAL DEVICE CORRECTION CONFIRMATION** GE REF: 30085
**CUSTOMER RESPONSE REQUIRED**
*We request that you PLEASE COMPLETE and return this form to GE Healthcare within two (2) weeks.*

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

**It is important that we confirm our customers have received this correction notice.** Please check **one** of the following and complete the requested information and send back via one of the methods below.

☐ #1 - We acknowledge receipt and understanding of the Medical Device Correction Notice and have identified that we **do not** have affected spare part inventory. (See Safety Instruction #1)

☐ #2 - We acknowledge receipt and understanding of the Medical Device Correction Notice and have identified that we **do** have affected spare part inventory. (See Safety Instruction #2)

☐ #3 - We acknowledge receipt and understanding of the Medical Device Correction Notice and have identified that we **do** or **may** have an affected drive installed in a T2100 treadmill. (See Safety Instruction #3)

**Please provide the name of the individual with responsibility for risk and compliance.**

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

**Please return this form using the method below:**
**Scan or take photo of completed form and email to** DCAR.30085@ge.com

**QR (email)**

30085 – XXXX