



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 30074

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

RE: **T2100 Treadmill Uncontrolled Walking Belt Motion**

GE Healthcare has recently become aware of a potential safety issue due to uncontrolled motion of the walking belt on your T2100 Treadmill. **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 the T2100 treadmills can cause uncontrolled walking belt motion during a stress exercise test. 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

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



- 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.

**Affected
Product
Details**

This issue can occur on all GE Healthcare T2100 Treadmills.

**Product
Correction**

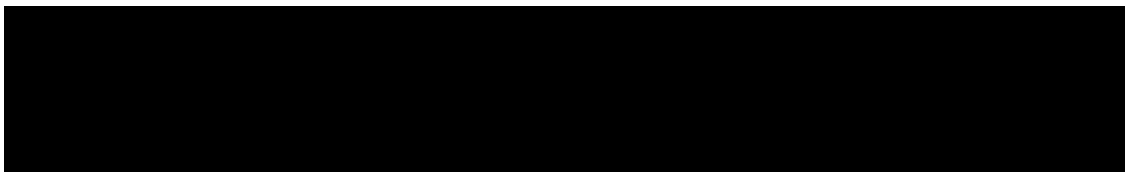
GE Healthcare will correct all affected systems at no cost to you. A GE Healthcare Service Representative will contact you to arrange for this correction.

**Contact
Information**

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 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,



James W. Dennison
Vice President Devices
GE Healthcare

Werner Van den Eynde, M.D.
Acting Chief Medical Officer
GE Healthcare