



URGENT FIELD SAFETY NOTICE

GE Healthcare

9900 Innovation Drive
Wauwatosa, WI 53226
USA

14th April 2015

GEHC Ref# 30073-2

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

RE: **Improper assembly of GE Healthcare T2100 and T2000 Treadmill power cords**

GE Healthcare has recently become aware of a potential safety issue due to improper assembly associated with the power cords of your T2100 and T2000 Treadmills. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

A GE Healthcare internal quality inspection has found that the power cord connecting directly to the T2100 and T2000 Treadmills may not have been assembled according to specifications. If the power cord was improperly assembled and a separate secondary electrical fault condition exists (e.g., a frayed extension or power cord touching the treadmill chassis), this could possibly result in an electrical shock to the patient or operator. There have been no reported incidences of the Treadmill power cord leading to an electrical shock of a patient or operator at this time.

Safety Instructions

Visual inspection alone cannot be used to detect improper assembly of the power cord. The potential for the electrical shock hazard described above can be determined through the monthly leakage current tests performed by qualified and trained personnel after internal cleaning, as specified in the T2100 and T2000 Service Manuals. If the results of monthly leakage current tests have been and continue to be acceptable, this indicates the chassis is not energized and that no secondary fault, as described above, is present at the time of the test. If the leakage current tests do not pass, do not use the equipment and call GE Healthcare Tech Support for assistance.

You should continue to request routine maintenance as specified in the T2100 and T2000 Service manuals.

If routine product maintenance as specified in the T2100 and T2000 Service manuals is not currently being performed on your device, you should request these maintenance activities immediately and ensure that they are continued as specified in the manuals.

Note: The Service Manual (written in English language) is not directed to the end user but to qualified and trained professionals. This Safety Notice is addressed to the owner/end user of the device in order to make sure, that the above mentioned Service activities will be performed until the final solution is implemented.

Affected Product Details

This issue can occur on GE Healthcare T2100 and T2000 Treadmills with power cord part numbers:

- **408930-001 (all revisions)** manufactured from June 1st, 2006 to December 10th, 2014. Power cords outside these dates or marked with a RWK label adjacent to the part number label have been inspected and are assembled correctly. For example, a power cord dated 2014 OCT 13 with the RWK label is correct and no further action is required.



Figure 1 Incorrect power cord, falls within date range



Figure 2 Correct power cord in date range with RWK label

- **408930-002 (all revisions)** manufactured from June 1st, 2006 to January 19th, 2015. Power cords outside these dates are assembled correctly and no further action is required.



Figure 1 Improperly assembled power cord, falls in date range

- **2028038-008 (all revisions)** – manufactured from December 1st, 2006 to January 28th, 2015. Power cords outside these dates are assembled correctly and no further action is required.



Figure 2 Improperly assembled power cord, falls in date range

- NOTE: Alternate four digit date codes may appear on some power cords rather than an actual date as shown above. The first two digits represent the year manufactured. The second two digits the week manufactured. For example, 0648 would be read as 2006, week 48 or the week of November 26, 2006.

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 or your local Service Representative at:

UKI Technical Support Representative.
01707 263570 or askuktechnicalsupport@ge.com

UKI Regulatory Affairs
Paul Mardle
01707 263570 or paul.mardle@ge.com

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,

A handwritten signature in black ink, appearing to read 'JDennison', with a large loop at the end.

James W. Dennison
Vice President Devices
GE Healthcare

A handwritten signature in blue ink, appearing to read 'Werner Van den Eynde', with a long horizontal stroke at the end.

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