Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2015-RN-00128-1
Product Name/Description[iii]	T2100 and T2000 Treadmill power cords ARTG number: 118412
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	18/02/2015
Responsible Entity[vii]	GE Healthcare Australia Pty Ltd
Reason / Issue[viii]	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.
Recall Action[ix]	Recall for Product Correction
Recall Action Instructions[x]	GE Healthcare is instructing customers to continue to perform the routine maintenance specified in the T2100 T2000 Service Manuals. This includes the leakage tests performed after each monthly internal cleaning, as specified in the T2100 and T2000 Service Manuals. A GE Healthcare Service Representative will contact customers to arrange a correction.
Contact Information[xi]	1800 659 465 - GE Healthcare National Call Centre

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.