Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-00614-1
Product Name/Description[iii]	Digital Linear Accelerators of type ARTISTE, ONCOR and PRIMUS with Automatic Sequenced Treatment Delivery Option Catalogue/Lot number: LINAC Systems (Material Numbers 4505200, 5857912, 7360717, 8139789) with SIMTEC ARTG Number: 165502
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	5/06/2014
Responsible Entity[vii]	Siemens Ltd
Reason / Issue[viii]	Siemens became aware of an incident where a patient was pinched between the moving gantry and the tabletop during an auto-sequenced treatment. In this case, an automatic gantry movement during an auto-sequenced treatment led to the collision because: - The auto-sequenced treatment has been created including beams with table angles. AND - No dry run has been performed. AND - The therapist did not monitor the patient during treatment delivery.
Recall Action[ix]	Recall for Product Correction
Recall Action Instructions[x]	Siemens is providing preventative work around instructions in its letter to customers, relating to beam placement, utilisation of dry runs after each change to the treatment plan, treatment interruption during patient repositioning, user care in field entries, patient monitoring and use of an optional inbuilt collision avoidance system such as 'OPTIGARD' if available. Additionally, therapist-identified potential collision between the gantry and the patient during use is preventable by the therapist by three separate button mechanisms. Siemens is also investigating a new method of determining whether there is a significant probability of collision between the LINAC gantry and the patient or the table.
Contact Information[xi]	1800 310 300 - Siemens Technical Support 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