Australian Government
Department of Health
Therapeutic Goods Administration

Recall Action Notification

C-Series High Energy Linear Accelerator

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Important information on the System for Australian Recall Actions

The TGA publishes information about therapeutic goods supplied in the Australian market that have been subject to a recall action in a publicly searchable database.

Recall action means action taken by the responsible entity (being the person who is responsible for taking the recall action) to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- **Recall actions include: the permanent removal of therapeutic goods from supply in the market, the taking of corrective action in relation to therapeutic goods (such as repair, modification, adjustment or relabelling) and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage patients.**
- **More information about Australian recall actions is available at <**http://tga.gov.au/safety/recalls-about.htm**>**
- **If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional. <**http://www.healthdirect.org.au/**>**

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of recall actions that responsible entities have reported to the TGA or of which the TGA has become aware, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

The information contained in the SARA database is released under s 61(5C) of the Therapeutic Goods Act 1989.

Copyright restrictions apply to the System of Australian Recall actions (SARA) <http://tga.gov.au/about/website-copyright.htm>.

Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-00700-1
Product Name/Description[iii]	C-Series High Energy Linear Accelerator Models: Novalis Tx, Trilogy, Trilogy Tx, Clinac iX, Clinac CX, Clinac 2100 c/D, Clinac 2300C/D, Clinac DX, Clinac 21 EX, Clinac 23 EX ARTG Number: 116839
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	2/07/2014
Responsible Entity[vii]	Varian Medical Systems Australasia Pty Ltd
Reason / Issue[viii]	Varian has seen a trend in reports of unexpected decrease in beam output in C-series High Energy Linacs for 6MV photon treatment mode. Varian has determined the cause of the unexpected variations in beam output to be degradation of the 6MV target. Specifically, the effects of modern, highly modulated treatment modes can create high levels and frequency of stress cycles in the targets particularly if the beam spot size is small. This can lead to the targets' deterioration and failure at an accelerated rate resulting in a rapid change in the beam output and symmetry. Specifically: 1. The photon generation, or bremsstrahlung yield, decreases as fewer electrons are converted to photons in the target, and; 2. Due to a resulting escape of primary electrons the output of photons, as measured by the ion chamber, might appear to be constant, but the actual photon output is decreasing. This failure mode in the target only affects the 6 MV photon treatment modes (6SRS, 6FFF and 6X).
Recall Action[ix]	Recall for Product Correction

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.

Recall Action Instructions[x]	Varian strongly recommends that all sites implement daily output constancy checks of photon beams as recommended by the AAPM. Specifically those provided by: 1. AAPM, Task Group 142 Report: Quality Assurance of Medical Accelerators, Medical Physics publication 36 (9), September 2009, and 2. AAPM Report No. 46, Comprehensive QA for Radiation. It is particularly important that these daily output constancy checks include all 6MV beams [6SRS, 6FFF and 6X]. Sites should particularly check for any sudden decrease in dose output ? 3% per day, or ?6% per week. If any sudden decrease in dose output is observed, cease use of all 6MV beams and contact Varian immediately. A Varian service representative will visit the site and investigate whether the target is degrading, or has failed. A technical fix is planned for implementation in a future Clinac system control software release.
Contact Information[xi]	1800 657 036 - Varian Oncology Help Desk

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.

- Wholesale - includes wholesalers and state purchasing authorities.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- Consumer - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

[v] Recall Action Classification: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- Class I recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk to health.
- Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not Class I.
- Class III recall action occurs when the product deficiency may not pose a significant hazard to health, but action may be initiated for other reasons eg. quality related issues.

[vi] Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

[vii] Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

[viii] Reason / Issue: Reason for the recall action.

[ix] Recall Action: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the

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market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation.

There are three distinct recall actions - recall, recall for product correction and hazard alert.

- Recall - The permanent removal of an affected therapeutic good from supply or use in the market.
- Recall for product correction - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- Hazard alert - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.

[x] Recall Action Instructions: What the customer should do.

[xi] Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.

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