

# Medical Device Alert

## Action

Ref: MDA/2011/040 Issued: 21 April 2011 at 10:30

### Device

Eclipse treatment planning system.

Manufactured by Varian Medical Systems Inc.

### Problem

Potential for incorrect radiotherapy dose.

When editing or changing the multi leaf collimator (MLC) using Eclipse, the dose plan may not recalculate automatically, as expected.

This problem occurs intermittently.

Therefore, users should be extra vigilant, as they may not receive a warning that a dose recalculation is necessary.

Varian is investigating this problem.

### Action

- Be alert to the possibility that the plan may not automatically recalculate the dose, following an edit or change in the MLC. Manual recalculation may be required.
- Report any occurrences of this problem to Varian and the MHRA.

### Action by

Staff involved in treatment planning in radiotherapy or medical physics departments.

### CAS deadlines

Action underway: 11 May 2011

Action complete: 27 May 2011

### Contact

#### Manufacturer

Per Persson or Michael Pignataro  
Varian Medical Systems UK Ltd

Tel: 01293 601 200

Fax: 01293 533 509

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## Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- Health Protection Agency (HPA) (Directors)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- EBME departments
- Health and safety managers
- Medical directors
- Medical physics departments
- Radiation and medical oncology departments
- Radiologists
- Radiotherapy departments
- Radiotherapy superintendent radiographers
- Risk managers

### Independent distribution

#### Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

### Manufacturer

Per Persson or Michael Pignataro

Varian Medical Systems UK Ltd, Gatwick Road, Crawley, West Sussex, RH10 9RG

Tel: 01293 601 200 Fax: 01293 533 509

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/040** or **2010/012/003/081/018**

### Technical aspects

Miss Nicola Ridd or Mrs Mel King

Medicines & Healthcare products Regulatory Agency

151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7039/7286 Email: [nicola.ridd@mhra.gsi.gov.uk](mailto:nicola.ridd@mhra.gsi.gov.uk) [mel.king@mhra.gsi.gov.uk](mailto:mel.king@mhra.gsi.gov.uk)

### **Clinical aspects**

Dr Susanne Ludgate  
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### **How to report adverse incidents**

Please report via our website <http://www.mhra.gov.uk>  
Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## **Northern Ireland**

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.  
Enquiries and adverse incident reports in Northern Ireland should be addressed to:  
Northern Ireland Adverse Incident Centre, Health Estates Investment Group, Room 17, Annex 6, Castle Buildings, Stormont Estate, Dundonald BT4 3SQ  
Tel: 02890 523 704 Fax: 02890 523 900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk) <http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

### **How to report adverse incidents in Northern Ireland**

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>  
Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## **Scotland**

Enquiries and adverse incident reports in Scotland should be addressed to:  
Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland, Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB  
Tel: 0131 275 7575 Fax: 0131 314 0722 Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)  
<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## **Wales**

Enquiries in Wales should be addressed to:  
Dr Sara Hayes, Senior Medical Officer, Medical Device Alerts, Welsh Assembly Government, Cathays Park Cardiff CF10 3NQ  
Tel: 029 2082 3922 Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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