Medical Device Alert

Ref: MDA/2013/023 Issued: 12 April 2013 at 14:00

Device

Workstation software for computed tomography systems:

Vitrea Enterprise Suite, Vitrea, VitreaAdvanced, VitreaCore (VitalConnect) and Vitrea fX, all versions prior to version 6.3.3.

Manufactured by Vital Images, Inc.

Problem

Risk of measurement error when images are rotated at the time of reconstruction.

There is the potential for volume errors of -50% and length errors of -29%, depending on the degree to which the images are rotated.

Action by

Radiologists
Radiographers
Oncologists
Medical physicists

Action

- Identify affected devices.
- Ensure members of staff are aware of the advice detailed in the manufacturer's Field Safety Notice (FSN) and its update.
- Ensure that all measurements associated with the error described in the FSN are verified against results from other technologies.
- Notify Vital Images that you have received the FSN to arrange for installation of a software patch.
- Assess the need to review previous patients' treatment plans.

CAS deadlines

Action underway: 26 April 2013

Action complete: 13 May 2013

Note: These deadlines are for systems to be in place to take actions.

Contact

Manufacturer
Vital Images Customer Support Europe
Tel: +31 70 413 5801
Email: eusupport@vitalimages.com

Problem

This problem occurs when images are rotated at the time of reconstruction by the scanner in non-90 degree increments of the transverse/axial plane (rotation around the z-axis), while not being simultaneously rotated around the x-axis and y-axis.

For these scans, the images will shrink. The severity of the shrinking is dependent on the degree (or extent) of image rotation.

The maximum error is seen with a 45 degree rotation which results in a length measurement being under-reported by 29% and a volume measurement being under-reported by 50%.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- Public Health England (PHE)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities 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:

- Medical directors
- Medical oncology, directors of
- Medical physics departments
- Nursing Directors
- Purchasing managers
- Radiation & medical oncology departments
- Radiation oncologists
- Radiation oncology, directors of
- Radiographer superintendents
- Radiographers
- Radiologists
- Radiology departments
- Radiology directors
- 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

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 and requesting this facility.

Contacts

Manufacturer
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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/023** or **2013/002/008/081/006**

Technical aspects
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Clinical aspects
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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

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.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ

Tel: 029 2082 3922 Email: Haz-Aic@wales.gsi.gov.uk