Medical Device Alert

Ref: MDA/2014/002 Issued: 07 January 2014 at 13:00

Device

Workstation software for computed tomography systems:

VitreaCore® software versions 6.0 to 6.5 inclusive, including all upgrades (except 6.3.1, 6.4.4 and 6.4.5).

Manufactured by Vital Images.

Problem

Risk of patient misdiagnosis or inappropriate treatment due to incorrect image orientation marking.

This may occur when loading a study into the 3D viewer in VitreaCore, taking a 16-bit secondary capture snapshot of the study and loading this snapshot in a DICOM viewer.

Vital Images has provided advice on how to confirm that snapshots are correctly marked.

Action by

Radiologists
Radiographers

Action

- Identify affected devices.
- Ensure members of staff are aware of the advice and guidance detailed in the manufacturer's Field Safety Notice (FSN).
- Consider the need to review images taken prior to this notification due to the risk of misdiagnosis and/or inappropriate treatment
- Place a copy of the addendum into the instructions for use.
- Complete and return the manufacturer's 'Effectiveness Check' form.

CAS deadlines

Action underway: 21 January 2014

Action complete: 04 February 2014

Note: These deadlines are for actions to be completed.

Contact

Manufacturer

Vital Images Customer Support Europe

Tel: +31 70 413 5801

Email: eusupport@vitalimages.com

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (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:

- MRI units, directors of
- Radiographer superintendents
- Radiographers
- Radiologists
- Radiology departments
- Radiology directors

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
Vincent Swenson
Sr. Director of Quality Systems and Regulatory Affairs
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United Kingdom
Tel: 0131 472 5723
Email: sferguson@vitalimages.com

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

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/002** or **2013/010/025/081/011**

Technical aspects
David Grainger or Paul Sandhu
Medicines and Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ
Tel: 020 3080 7199 / 7266 Fax: 020 8754 3965
Email: david.grainger@mhra.gsi.gov.uk
paul.sandhu@mhra.gsi.gov.uk

Clinical aspects
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Medicines and Healthcare Products Regulatory Agency
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Tel: 020 3080 7128 Fax: 020 8754 3965
Email: mark.grumbridge@mhra.gsi.gov.uk

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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
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 5801 Email: Haz-Aic@wales.gsi.gov.uk