# Medical Device Alert

Ref: MDA/2012/081 Issued: 29 November 2012 at 12:00

## Device

Workstation software for computed tomography systems: Vitrea fX, Vitrea and Vitrea Enterprise Suite.

Manufactured by Vital Images.

Various software versions are affected.

## Problem

Risk of misdiagnosis and treatment of vessels due to incorrect calcium scores.

There is the potential for errors in calcium score values in restored snapshots of studies generated through use of these devices.

If these calcium scores are relied upon, less–healthy vessels may be incorrectly considered as healthy, which may lead to incorrect or sub optimal treatment paths being followed.

## Action

- Identify affected systems.
- Contact the manufacturer to arrange installation of the software update
- Follow the workarounds described in the manufacturer's Field Safety Notice regarding selection of manual method and interpolate functions
- Assess the need to review previous patients' treatment plans.

## Action by

Radiologists, cardiologists, cardiac and vascular surgeons.

## CAS deadlines

Action underway: 13 December 2012

Action complete: 02 January 2013

**Note: These deadlines are for workarounds to be in place and a plan for installation of software update and reviewing patients to be in place.**

## Contact

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

## Device

Affected software versions are:

- Vitrea fX – versions 3.1, 6.0, 6.1, 6.2
- Vitrea – versions 5.2, 6.0, 6.1, 6.2
- Vitrea Enterprise Suite – versions 1.3, 6.0, 6.1, 6.2

## Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- 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:

- Cardiologists
- Cardiology, directors of
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads
- Coronary care departments
- Director of nursing
- Medical directors
- Medical physics departments
- Radiation & medical oncology departments
- Radiographer superintendents
- Radiographers
- Radiologists
- Radiology directors
- Risk managers
- Vascular surgeons

### 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
- Private medical practitioners

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**
Parthiv Shah
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Minnetonka
MN 55343-4414 USA
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Fax: +1 952 487 9510
Email: pshah@vitalimages.com

Vital Images Customer Support
USA
Tel: +1 800 208 3005
Email: support@vitalimages.com

**UK Distributor**
Paul Hughes
Sales Manager
Vital Images UK
50 Broadway
London SW1H 0RG
Tel: 07960 685 267
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## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/081** or **2012/009/006/081/009**

**Technical aspects**
David Grainger or Gica Leclerc
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7199 or 6610
Fax: 020 8754 3965
Email: david.grainger@mhra.gsi.gov.uk
gica.leclerc@mhra.gsi.gov.uk

**Clinical aspects**
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Medicines & Healthcare products Regulatory Agency
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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