

# Medical Device Alert

Ref: MDA/2013/039 Issued: 13 June 2013 at 15:00

## Device

Workstation software for computed tomography systems:

Vitreia CT Brain Perfusion 2D application.

Versions 6.0 and above for Vitrea Enterprise Suite, Vitrea, VitreaAdvanced and Vitrea fX are affected.

Manufactured by Vital Images, Inc.

Problem	Action
<p>Risk of patient misdiagnosis, inappropriate treatment or treatment delay due to incompatibility of software with certain protocols or CT units.</p> <p>Analysis of data in Vitrea CT Brain Perfusion 2D may lead to inaccurate perfusion maps if the data is acquired by an unsupported CT scanner.</p> <p>Vital Images has provided advice on the systems that are and are not supported.</p>	<ul style="list-style-type: none"> <li>• Identify affected devices.</li> <li>• Ensure members of staff are aware of the advice and guidance detailed in the manufacturer's <a href="#">Field Safety Notice (FSN)</a>.</li> <li>• Consider the need to review prior examinations.</li> <li>• Place a copy of the FSN into the instructions for use.</li> <li>• Complete and return the manufacturer's 'Effectiveness Check' form.</li> </ul>
Action by	
<p>Radiologists Radiographers Medical physicists</p>	
CAS deadlines	Contact
<p>Action underway: 27 June 2013</p> <p>Action complete: 15 July 2013</p> <p><b>Note: These deadlines are for systems to be in place to take actions.</b></p>	<p><b>Manufacturer</b> Vital Images Customer Support Europe Tel: +31 70 413 5801 Email: <a href="mailto:eusupport@vitalimages.com">eusupport@vitalimages.com</a></p>

## Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- Directors of public health
- Health and Safety Executive
- 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
- NHS England area teams (chief executives)
- NHS England regional teams
- NHS trusts in England (chief executives)
- Public Health England (for information)

### 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
- Medical directors
- Medical physics departments
- Neurologists
- Radiographer superintendents
- Radiologists
- 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
- 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

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Vice President, Quality & Regulatory, and General Counsel  
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Fax: +1 952 540 3717

Email: [inemerov@vitalimages.com](mailto:inemerov@vitalimages.com)

**UK Distributor**

Stuart Ferguson - HII Business Unit Manager  
Vital Images Europe BV  
Bonnington Bond 2 Anderson Place  
Edinburgh  
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United Kingdom

Tel: 0131 472 5723

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**Customer Support**

Vital Images Customer Support Europe

Tel: +31 70 413 5801

Email: [eusupport@vitalimages.com](mailto:eusupport@vitalimages.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/039** or **2013/004/003/291/006**

**Technical aspects**

David Grainger or Francesca Edelmann  
Medicines and Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7199 / 6716

Fax: 020 8754 3965

Email: [david.grainger@mhra.gsi.gov.uk](mailto:david.grainger@mhra.gsi.gov.uk)  
[francesca.edelmann@mhra.gsi.gov.uk](mailto:francesca.edelmann@mhra.gsi.gov.uk)

**For clinical aspects please contact the clinical team**

Carol Lowry or Kayleigh Purdon  
Medicines and Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7248 or 7032

Fax: 020 8754 3965

### 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:

Improving Patient Safety Team

Medical Directorate

Welsh 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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