


Medical Device Alert

Reissued – revised information on cause of possible interruption.

Ref: MDA/2013/045R **Reissued:** 11 July 2013 at 11:00

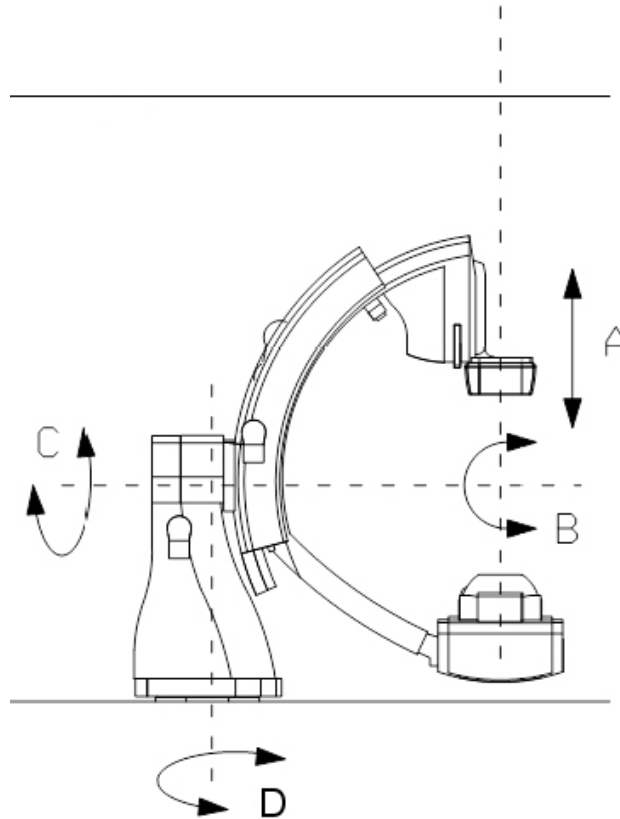
Device	
<p>Biplane cardiovascular X-ray system:</p> <p>Allura Xper FD10/10 Floor Mounted.</p> <p>Manufactured by Philips.</p> <p>All systems are affected.</p>	

Problem	Action
<p>Risk of interruption in treatment/procedure due to an inability to move the table as the motorised geometry control system will reboot if users attempt simultaneous powered and manual movement of the C-arm.</p> <p>The reboot will take approximately 90 seconds during which time the table top is free floating. Motorised movements (height, tilt, and cradle) are not possible. Basic imaging will be available.</p> <p>We have received a report of this issue leading to delay during emergency treatment (introduction of a chest drain during cardiac arrest).</p>	<ul style="list-style-type: none"> Identify affected devices. Inform users of the issue.
Action by	
<p>Superintendent diagnostic radiographers.</p>	
CAS deadlines	Contact
<p>Action underway: 25 July 2013</p> <p>Action complete: 12 August 2013</p> <p>Note: These deadlines are for systems to be in place to take actions.</p>	<p>Manufacturer Philips Customer Care Service Centre Philips Healthcare Tel: 0870 532 9741 Email: ph.cvuk.support@philips.com</p>

Problem

The problem may arise if a user is performing a manual swing movement of the C-arm at the same time as another user requests a "short" motorised movement via the tableside module.

The movement affected is the Beam Swing only (movement D in image below).



During the restart the table top is free floating, allowing it to be moved manually in a transverse as well as a longitudinal direction. Motorised movements (height, tilt, and cradle) are not possible during this restart period.

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:

- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons

- Cardiothoracic surgery directors
- Coronary care departments
- Coronary care nurses
- Day surgery units
- Health and safety managers
- Medical directors
- Medical physics departments
- Radiographer superintendents
- Radiographers
- Radiologists
- Radiology departments
- 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

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

Philips Customer Care Service Centre
Philips Healthcare
Philips Centre
Guildford Business Park
Guildford
GU2 8XH

Tel: 0870 532 9741

Email: ph.cvuk.support@philips.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/045R** or **2013/001/024/401/008**

Technical aspects

David Grainger or Ann Seeruttun
Medicines and Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7199 / 7161

Fax: 020 8754 3965

Email: david.grainger@mhra.gsi.gov.uk
ann.seeruttun@mhra.gsi.gov.uk

For clinical aspects please contact the MHRA clinical team on 020 3080 7248 or 020 3080 7032

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.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

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