

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/41

Issued: 19th July 2006

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

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	Section
<p>Medical Device/Equipment: Various devices in cardiac catheterisation and interventional radiology laboratories, especially the x-ray c-arm.</p>	▶ ①
<p>Problem: Devices have been damaged by collision with the x-ray c-arm but have remained in use and subsequently failed, causing injury.</p>	▶ ②
<p>Action by: Directors of radiology, directors of cardiology and staff working in the cardiac catheterisation or interventional radiology laboratories.</p>	▶ ③
<p>Action: Ensure that users are aware of the need to check that there are no objects in the field before initiating movement of the c-arm. Check local procedures and revise them if necessary to identify the steps to be taken whenever a collision takes place between devices.</p>	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None required</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Various devices in cardiac catheterisation and interventional radiology laboratories, especially the x-ray c-arm.

2. PROBLEM:

The MHRA has become aware of collisions between devices and the x-ray c-arm which have resulted in damage to the devices and subsequent failure.

Movement of large x-ray systems such as the c-arm, particularly in a busy environment, can sometimes result in an inadvertent collision with other devices, such as exposure footswitches, monitor boom arms, theatre lamps, power injector systems and their supporting arms. In particular there has been a number of reports where the x-ray c-arm has collided with the ceiling-suspended arm supporting the radiation protection shield. Resulting damage to load-bearing joints may not be immediately apparent. In some circumstances, the damage has led to subsequent failure of the joints supporting the ceiling-suspended device and injury to patient and staff.

In addition, mobile lead shields may become damaged as the patient table is lowered.

3. ACTION BY:

Directors of radiology, directors of cardiology and staff working in the cardiac catheterisation or interventional radiology laboratories.

4. ACTION:

Ensure that local procedures identify the steps to be taken whenever a collision takes place between devices.

An element of care and professional judgement is required in the determination of the severity of the collision and the consequences if that equipment should fail.

Options include:

1. taking the equipment out of service immediately, pending technical assessment
2. completing the procedure but technically assessing the equipment before further use
3. keeping the equipment in service pending technical assessment at earliest available opportunity
4. keeping the equipment in service pending technical assessment at the next scheduled service visit
5. making a record of the incident and the extent of any identified damage.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Cardiologists
- Cardiology Service Managers
- Clinical Directors of Cardiology
- Clinical Directors of Radiology
- Health & Safety Managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA
- Medical Directors
- Medical Physics/EBME
- Radiographers
- Radiologists
- Radiology Service Managers
- Risk Managers

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2006/ 41 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

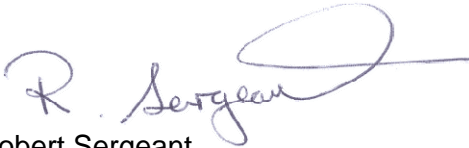
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety