

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/54

Issued: 14 September 2006

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
Medical Device/Equipment: Haemofiltration machines: Edwards Lifesciences Aquarius.	▶ ①
Problem: Rupturing of the pre-filter pressure dome (on the tubing set) resulting in release of blood at high pressure.	▶ ②
Action by: Renal physicians, Intensivists, Intensive Care Nurses and Theatre Managers.	▶ ③
Action: Ensure you have contacted Edwards Lifesciences to arrange for a device modification to be carried out	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	▶ ⑤
Contacts Details of supplier contacts and NIAIC contacts for clinical aspects.	▶ ⑥
Feedback Requirements to NIAIC None required	▶ ⑦

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

1. DEVICE/EQUIPMENT:

All Aqualine tubing sets used with Aquarius haemofiltration machines.

2. PROBLEM:

The MHRA is aware of a number of incidents where rupturing of the pre-filter pressure dome's membrane on the tubing set of the Aquarius machine has occurred during use. This poses a hazard to staff from the risk of exposure to blood.

The manufacturer has previously undertaken additional training in Trusts in an attempt to address this issue. However a further recent report of dome rupture has been received. The manufacturer will therefore be implementing corrective action by means of a hardware upgrade. This will incorporate the addition of a clamp or 'gate' system on to the pre-filter pressure domes on all UK devices.

3. ACTION BY:

Renal physicians, intensivists, intensive care nurses and theatre managers.

4. ACTION:

Whilst waiting for corrective action to be implemented, please ensure that:

- all pressure transducer domes are securely fitted onto the corresponding sensors as described in the instructions for use/training materials;
- all staff are familiar with local policies for managing exposure to blood and spillages.

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:

- Adult and Paediatric Intensive Care Units
- Anaesthetists
- Biomedical Engineering Staff
- Clinical Directors
- Health & Safety Managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA
- Infection Control Teams
- Intensive Care Consultants
- Medical Directors
- Nursing Executive Directors
- Occupational Health Departments
- Operating Theatres
- Renal Physicians
- Renal Units And Satellites
- Risk Managers
- Safety Officers
- Theatre Managers

6. CONTACTS:

Enquiries to the supplier should be addressed to:

Mr Kieron O'Neil
Edwards Lifesciences Ltd
2 Toomers Wharf
Canal Walk
Newbury
RG14 1DY

Tel: 07770 443 929

Fax: 08706 062 050

E-mail: Kieron_O'Neil@edwards.com

Enquires to NIAIC should quote reference number MDEA(NI)2006/54 and be addressed to:

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

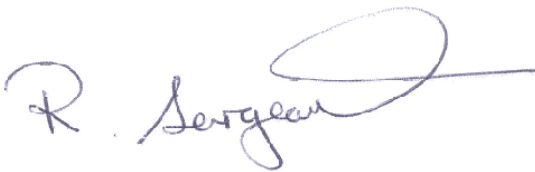
Tel: 028 9052 3868

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