

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/005

Issued: 13th Feb 2008



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section			
<p>Medical Device/Equipment: Hard-shell venous reservoirs and oxygenators used for cardiopulmonary bypass during heart surgery: various manufacturers.</p>	▶ ①			
<p>Problem:</p> <ul style="list-style-type: none"> A bolus of air was forced up the venous line to the heart when a quick-prime line was misconnected to the vent port of a hard-shell venous reservoir. A problem with a vaporiser prevented the oxygen supply reaching the oxygenator. 	▶ ②			
<p>Action by: Clinical Perfusion Scientists and Cardiac Anaesthetists.</p>	▶ ③			
<p>Action:</p> <ul style="list-style-type: none"> Incorporate checking of the hard-shell venous reservoir vent port and correct functioning of the oxygen supply in the pre-bypass check procedure. Ensure that a pressure relief valve is always used with hard-shell venous reservoirs. Ensure that the standards of monitoring recommended by the Society of Clinical Perfusion Scientists of Great Britain and Ireland (SOPGBI) are always undertaken for heart lung bypass procedures. (Available on the MHRA website www.mhra.gov.uk) Ensure an alternative oxygen supply is always available for cardiopulmonary bypass (e.g. an oxygen cylinder with appropriate regulator, flow meter and tubing, which must be checked as functioning correctly and containing an adequate supply). <p>NOTE: These actions have been endorsed by the SOPGBI.</p>	▶ ④			
<p>Distributed by NIAIC to:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;">Chief Executive of each HSS Board Chief Executive of each HSS Trust</td> <td style="width: 50%; border: none;">Chief Executive of each Agency NIAIC Liaison Officers</td> </tr> </table>	Chief Executive of each HSS Board Chief Executive of each HSS Trust	Chief Executive of each Agency NIAIC Liaison Officers	▶ ⑤	
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<p>Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥			
<p>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>				
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; color: magenta;"> Acknowledge Receipt of Alert: 15th Feb 2008 </td> <td style="width: 33%; color: magenta;"> Action Under Way: 27th Feb 2008 </td> <td style="width: 33%; color: magenta;"> Action Complete: 12th Mar 2008 </td> </tr> </table>	Acknowledge Receipt of Alert: 15 th Feb 2008	Action Under Way: 27 th Feb 2008	Action Complete: 12 th Mar 2008	▶ ⑦
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This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

1. DEVICE/EQUIPMENT:

Hard-shell venous reservoirs and oxygenators are heart-lung bypass devices that are used in heart surgery.

2. PROBLEM:

1. A quick-prime line was misconnected to the vent port of a hard-shell venous reservoir. The reservoir was primed and fluid circulated prior to going on bypass. As the vent port was blocked, the reservoir was pressurised when the cardiotomy suction was turned on. When the venous clamp was removed to initiate bypass, a bolus of air was forced up the venous line to the heart.
2. An anaesthetic vaporiser was placed into the oxygen line supplying the oxygenator. A problem with the vaporiser, and back-bar mounting, prevented the oxygen supply reaching the oxygenator. This fault was not detected in pre-use checks; therefore bypass was severely delayed while an alternative oxygen supply was found.

3. ACTION BY:

Clinical Perfusion Scientists and Cardiac Anaesthetists.

4. ACTION:

- Incorporate checking of the hard-shell venous reservoir vent port and correct functioning of the oxygen supply in the pre-bypass check procedure.
- Ensure that a pressure relief valve is always used with hard-shell venous reservoirs.
- Ensure that the standards of monitoring recommended by the Society of Clinical Perfusion Scientists of Great Britain and Ireland (SOPGBI) are always undertaken for heart lung bypass procedures. (Available on the MHRA website www.mhra.gov.uk)
- Ensure an alternative oxygen supply is always available for cardiopulmonary bypass (e.g. an oxygen cylinder with appropriate regulator, flow meter and tubing, which must be checked as functioning correctly and containing an adequate supply).

NOTE: These actions have been endorsed by the SOPGBI.

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:

- Anaesthesia, directors of
- Cardiac anaesthetists
- Cardiac surgeons
- Cardiac theatre managers
- Clinical perfusion scientists
- Health and safety managers
- Medical Directors
- Risk managers
- Independent Health and Social Care Providers – Private Hospitals through RQIA

6. CONTACTS:

Enquiries to NIAIC should quote reference number MDEA(NI)2008/005 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:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
15th Feb 2008

Action Under Way:
27th Feb 2008

Action Complete:
12th Mar 2008



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)2007/01. 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