

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/014

Issued: 10<sup>th</sup> March 2008



**HEALTH ESTATES**

creating healing environments

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	

	Section			
<b>Medical Device/Equipment:</b> <b>Medical air plant: risks associated with critical component failure.</b>	▶ ①			
<b>Problem:</b> Two incidents have been reported involving failure of 4-bar medical air plant due to a fault in the central control unit (CCU) printed circuit board (PCB) and motor control unit (MCU) PCB with fuses. This resulted in the loss of all three medical air compressors for over 24 hours, requiring the hospital to use the emergency reserve manifold (ERM) and secure sufficient replacement medical air cylinders to meet demand.	▶ ②			
<b>Action by:</b> This notice should be brought to the attention of all appropriate Estates & Facilities managers and staff.	▶ ③			
<b>Action:</b> The Medical Air Plant should be assessed for the need of the following spares to be available locally: <ul style="list-style-type: none"> <li>• Central Control Unit PCBs,</li> <li>• Motor Control Unit PCBs and fuses,</li> <li>• Central Control Units Printed Circuit Board software.</li> </ul> See Page two for further actions.	▶ ④			
<b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	▶ ⑤			
<b>Contacts</b> Details of manufacturer and NIAIC contacts for technical and clinical aspects.	▶ ⑥			
<p style="text-align: center;"><b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b></p>	▶ ⑦			
<table border="1" style="width: 100%;"> <tr> <td style="width: 33%;"> <b>Acknowledge Receipt of Alert:</b>            14<sup>th</sup> March 2008         </td> <td style="width: 33%;"> <b>Action Under Way:</b>            30<sup>th</sup> April 2008         </td> <td style="width: 33%;"> <b>Action Complete:</b>            30<sup>th</sup> June 2008         </td> </tr> </table>	<b>Acknowledge Receipt of Alert:</b> 14 <sup>th</sup> March 2008	<b>Action Under Way:</b> 30 <sup>th</sup> April 2008	<b>Action Complete:</b> 30 <sup>th</sup> June 2008	
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This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

## **1. DEVICE/EQUIPMENT:**

Medical air plant: risks associated with critical component failure.

## **2. PROBLEM:**

Two incidents have been reported (not within Northern Ireland) involving failure of 4-bar medical air plant due to a fault in the central control unit (CCU) printed circuit board (PCB) and motor control unit (MCU) PCB with fuses. This resulted in the loss of all three medical air compressors for over 24 hours, requiring the hospital to use the emergency reserve manifold (ERM) and secure sufficient replacement medical air cylinders to meet demand.

## **3. ACTION BY:**

This notice should be brought to the attention of all appropriate Estates & Facilities managers and staff.

## **4. ACTION:**

The Medical Air Plant should be assessed for the need of the following spares to be available locally:

- Central Control Unit PCBs,
- Motor Control Unit PCBs and fuses,
- Central Control Units Printed Circuit Board software.

Checks should be carried out to confirm that spare units and software will function as intended in the event of a failure or loss of the CCU and that these are available and can be installed within a reasonable time.

Tests should be carried out to determine the capacity of the ERM under normal demand and that further supplies of medical air can be provided if required.

Where suppliers or contractors, providing maintenance services under contract, are to hold spares, hospitals should be satisfied that the correct components will be available within an acceptable time.

## **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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Estates & Facilities Managers
- Estates Staff
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA

## 6. CONTACTS:

Enquiries to NIAIC should quote reference number MDEA(NI)2008/014 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](mailto:NIAIC@dhsspsni.gov.uk)

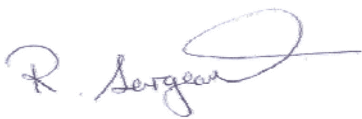
## 7. FEEDBACK:

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

Acknowledge Receipt of Alert:  
14<sup>th</sup> March 2008

Action Under Way:  
30<sup>th</sup> April 2008

Action Complete:  
30<sup>th</sup> June 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](http://www.dhsspsni.gov.uk/niaic)

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