

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/42

Issued: 22 May 2007

For:

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|-------------------------|---|
| IMMEDIATE ACTION | ✓ |
| ACTION | |
| UPDATE | |
| INFORMATION | |



HEALTH ESTATES

creating healing environments

| | Section |
|---|-----------------|
| Medical Device/Equipment: Bariatric profiling beds – Nightingale Pro Axis and Pro Axis Plus. | ▶ ① |
| Problem: Ignition of flammable gases from an overcharged battery within the main control box can result in the metal cover being blown off, putting those in the vicinity at risk of injury. | ▶ ② |
| Action by: All those responsible for the maintenance of beds. This includes maintenance staff or contractors. | ▶ ③ |
| Action: <ul style="list-style-type: none"> Trace all Nightingale Pro Axis and Pro Axis Plus beds manufactured before 01 April 2007. Any of these beds known or suspected of having had their charging systems repaired or replaced should not be used until electrical checks have been carried out. Contact the manufacturer on 01978 661 699 to arrange for these checks and subsequent modification of the beds. | ▶ 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 For onward distribution see Section 5 | ▶ ⑤ Hospices |
| Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects. | ▶ ⑥ |
| Feedback Requirements to NIAIC In accordance with PEL(06)17 acknowledgment of assurance should be given:- | ▶ ⑦ |

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

1. DEVICE/EQUIPMENT:

Bariatric profiling beds – Nightingale Pro Axis and Pro Axis Plus.

2. PROBLEM:

The MHRA has received a report of the battery charging circuit being damaged by the failure of the DC power supply in this range of electrically operated bariatric profiling beds.

The power supply had recently been replaced without checking for other related damaged circuitry in the control box. Investigation found that damage had occurred to the charging circuitry, which rendered the charging voltage cut off non-operational.

Overcharging of the battery led to the ignition of battery vented hydrogen within the semi sealed control box. The control box was distorted and the metal control box cover was blown off, presenting a risk of injury.

3. ACTION BY:

All those responsible for the maintenance of beds. This includes maintenance staff or contractors.

4. ACTION:

Where DC power supplies are known or thought to have previously been replaced or repaired, beds should not be used until checked by the manufacturer and modifications made.

All beds manufactured since 01 April 2007 have a modified charging circuit to ensure overcharging cannot occur. The manufacturer is retrofitting this new circuit to all existing beds as a field modification.

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 intensive care units
- All wards
- Estates & EBME departments
- Equipment stores
- Fire officers
- Health and safety managers
- Maintenance staff or contractors
- Nursing staff
- Risk managers
- Supplies managers
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Care management team managers
- Community care staff
- Community Equipment stores managers
- Community Loan store managers
- Community Occupational therapists

6. CONTACTS:

Enquires to the manufacturer should be addressed to:

Mr Kevin Eames
Nightingale Care Beds Ltd
Unit 20 Abenbury Way
Wrexham Industrial Estate
Wrexham
LL13 9UZ

Tel: 01978 661699

E-mail: kevineames@nightingalebeds.co.uk

Enquires to NIAIC should quote reference number MDEA(NI)2007/42 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

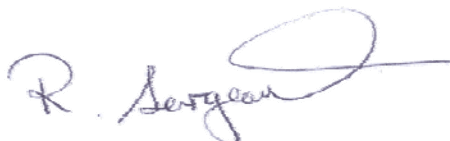
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

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| Deadline (Email received) | : 24 May 2007 |
| Deadline (action underway) | : 01 June 2007 |
| Deadline (action complete) | : 15 June 2007 |



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