

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/021

Issued: 27th March 2008



HEALTH ESTATES

creating healing environments

For:

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

| | Section |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| Medical Device/Equipment: Nursing beds. Models 3010 and 5020 manufactured by Volker. | ▶ ① |
| Problem: Risk of asphyxiation or injury from entrapment of head, neck or chest in the bed rail's gaps. | ▶ ② |
| Action by: All those using, managing and maintaining nursing beds. In particular: nurses, care staff, bed managers, maintenance staff and contractors. | ▶ ③ |
| Action: <ul style="list-style-type: none"> Trace all Volker 3010 and 5020 nursing beds made before 2003, which are in use or in storage. Contact Bakare Beds Ltd on 01752 512 227 to obtain the modification kits required and arrange for them to be fitted. | ▶ 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 Hospices | ▶ ⑤ |
| Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects. | ▶ ⑥ |
| Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS) | |
| Acknowledge Receipt of Alert: 31 st March 2008 | ▶ ⑦ |
| Action Under Way: 24 th April 2008 | |
| Action Complete: 26 th June 2008 | |

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

1. DEVICE/EQUIPMENT:

The Volker models 3010 and 5020 have integral, two-section, collapsible bed rails on each side of the bed.

They have either been supplied new by Bakare Beds Ltd from 1999 to the end of 2002 or obtained new or second hand from sources outside the UK. Beds manufactured since the start of 2003 are unaffected.

The model number, year of manufacture and serial number are present on a label on the bed frame, below the head board in this format: 3010-2002-**-** - **.

2. PROBLEM:

When the bed rails are in use, large gaps are present at the head end of the bed between the headboard and the first vertical rail and also in the centre between the two bed rail sections (see appendix). Although there have been no reports to the MHRA of entrapment incidents with these models, occupants of these beds are at risk of asphyxiation or injury from head, neck or chest entrapment.

The German manufacturer modified the design from 2003 to make both of these gaps smaller. However, these modifications have only now been offered to the UK market as a retrofit.

3. ACTION BY:

All those using, managing and maintaining nursing beds. In particular: nurses, care staff, bed managers, maintenance staff and contractors.

4. ACTION:

- Trace all Volker 3010 and 5020 nursing beds made before 2003, that are in use or in storage.
- Contact Bakare Beds Ltd on 01752 512 227 to obtain the modification kits required and arrange for them to be fitted.

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:

- Bed Managers
- Equipment stores
- Health and safety managers
- Maintenance staff or contractors
- Nursing executive directors
- Purchasing managers
- Risk managers
- Supplies managers
- Community nurses
- Equipment managers
- Equipment stores
- Maintenance staff or contractors
- Occupational therapists
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Bakare Beds Ltd
Unit 1, ERC, Bell Close
Plympton
Plymouth PL7 4JH

Tel: 01752 512 227

Fax: 01752 511 117

E-mail: service@bakare.co.uk

Enquiries to NIAIC should quote reference number MDEA(NI)2008/021 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

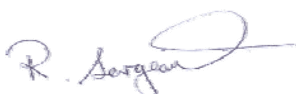
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
31st March 2008

Action Under Way:
24th April 2008

Action Complete:
26th 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

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

Diagram showing gaps in bed rails.

