

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/60

Issued: 4 October 2006

For:

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



HEALTH ESTATES

creating healing environments

| | Section |
|---|---------|
| Medical Device/Equipment: Birthing beds: Huntleigh Healthcare Birthright and Hoskins Birthcare. | ▶ ① |
| Problem: These beds can become unstable and tip, if patients, visitors or staff sit on the foot end of an unoccupied bed. | ▶ ② |
| Action by: All those using, providing and maintaining Birthright and Birthcare birthing beds. | ▶ ③ |
| <ul style="list-style-type: none"> • Action: • Identify whether your organisation has Birthright or Birthcare birthing beds. • Obtain updated instructions for use and warning labels from the manufacturer detailed on page 3. • Ensure the updated instructions for use are issued to staff and that the warning labels are affixed to each bed. • Ensure no one sits beyond the foot end warning label. | ▶ 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 manufacturer contacts and MHRA contacts for technical 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:

Birthing beds: Huntleigh Healthcare Birthright, models 170000 (electric) and 35000 (manual).
Hoskins Birthcare, models L10 (electric) and L05 (manual).

2. PROBLEM:

If patients, visitors or staff sit on the foot end of an unoccupied bed, the bed may tip. There is a risk that the unexpected movement of the bed could cause a fall.

MHRA has investigated adverse incidents where the head end of a Birthright bed tipped upwards when one or more people sat at the foot end of an unoccupied bed. This included a patient kneeling near to the foot panel and also a patient and midwife sitting together. The mattress platform was extended to its maximum length, i.e. the normal non-birthing position, when the incidents occurred.

These models can be either electrically operated or manually operated. They have been on the market for 20 years and are used in pre- and post-natal wards and delivery rooms.

Testing has shown that the approximate load required to start to tip these beds is 112kg (17.6 stone) near to the extreme foot end, with the backrest raised. If the backrest is flat the load to start the tip is 122kg (19 stone).

Due to these weight limit effects, the manufacturer has not redesigned the bed but has agreed to provide revised instructions for use and warning labels for each bed to make users and others aware of the risk.

To assist identification on electric versions, the model number is printed on a label on the cross member at the head end of the bed base (see appendix). For older manual versions, the model number label is on the inside face of the mattress platform at the head end and can be seen by raising the backrest.

3. ACTION BY:

All those using, providing and maintaining Birthright and Birthcare birthing beds.

4. ACTION:

- Identify whether your organisation has Birthright or Birthcare birthing beds.
- Obtain updated instructions for use and warning labels from the manufacturer detailed on page 3.
- Ensure the updated instructions for use are issued to staff and that the warning labels are affixed to each bed.
- Ensure no one sits beyond the foot end warning label.

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
- Device Managers
- Clinical Directors
- Nurse Directors
- Independent Health and Social Care Providers – Private Hospitals and maternity Clinics through RQIA
- Special Care Baby Units
- Maternity Wards
- Midwifery departments
- Midwifery staff
- Obstetricians

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Huntleigh Healthcare
Woden Road West
Wednesbury
WS10 7BL

Tel: 0121 556 1511
Fax: 0121 502 2092

E-mail: sales@huntne.co.uk

Hoskins LifeCare
Admail 1001
Birmingham
B1 1HJ

Tel: 0121 707 6600
Fax: 0121 607 5555

E-mail: sales@hoskinsme.co.uk

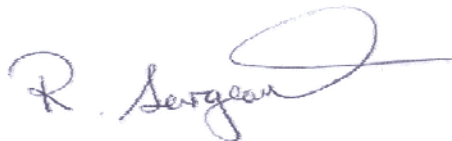
Enquires to NIAIC should quote reference number MDEA(NI)2006/60 and be addressed to:

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



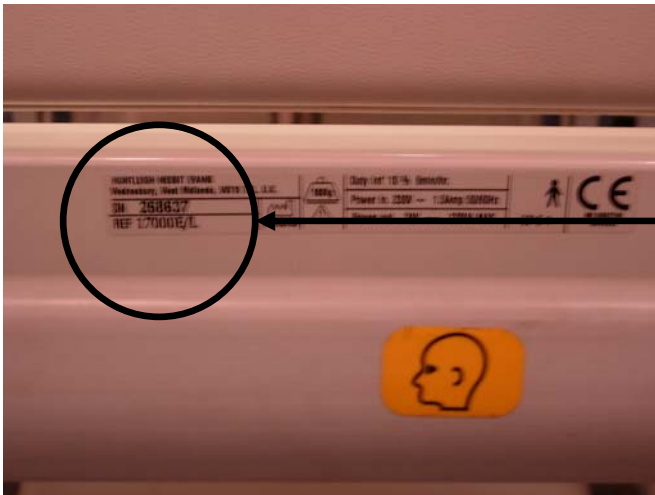
Robert Sergeant
NIAIC Operational Manager

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

Appendix to MEDA(NI)2006/60



Model number can be found here on the white label.



White label can be found here on the head end of the electric bed.



White label can be found here on manual beds.

Birthright label

