

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/002

Issued: 17th January 2008



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	✓
INFORMATION	

	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 or kneel near the foot end of the bed.	▶ ②
Action by: All those using, providing and maintaining Birthright and Birthcare birthing beds, particularly in maternity units.	▶ ③
Action: <ul style="list-style-type: none"> Note: the recommendations given in this update supersede the advice given in MDEA(NI)2006/060 on 04 October 2006. Identify whether your organisation has Birthright or Birthcare birthing beds. Obtain revised warning labels from the manufacturer (details on page 3). Ensure that the revised warning labels are affixed to each bed in a prominent position, and that users and staff are aware of the risk of tipping. 	▶ ④
Distributed by NIAIC to: <ul style="list-style-type: none"> 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 and NIAIC contacts for technical aspects.	▶ ⑥
Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)	
Acknowledge Receipt of Alert: 18 th Jan 2008	▶ ⑦
Action Under Way: 14 th Feb 2008	
Action Complete: 14 th April 2008	

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).

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

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

On these beds the foot end section of the bed frame and mattress is removable to allow healthcare staff to be close to the patient during the delivery. In this delivery configuration the bed is stable. The foot end section can be fitted to allow the bed to be configured as a normal bed for short term use before or following a delivery. The foot end section is secured to the main base and does not have separate supports. With the foot end section fitted the stability of the whole bed is substantially reduced.

2. PROBLEM:

The MHRA had previously investigated adverse incident reports where the head end of a Birthright bed tipped upwards. A device alert (MDEA(NI)2006/060) was issued in October 2006. This advised organisations with these beds to obtain warning labels and updated instructions for use from the manufacturer, and to ensure that occupants and others do not kneel or sit close to the foot end.

However, a further incident has been reported, where a bed tipped during a delivery. The foot end of the bed had not been removed during the delivery. Also, the original warning label supplied following MDEA(NI)2006/060 was unclear and had been positioned on the base of the bed where it was obscured by the bed clothes and was therefore ineffective.

To reduce further incidents the manufacturer is providing revised warning labels, which are larger and depict the risk. The labels are an interim measure whilst the manufacturer seeks to design a permanent solution. These new labels need to be fixed in more prominent locations, such as the bed's head and foot boards and hand controls, and should not be obscured by the bed clothes or other equipment.

Where organisations use these beds with the foot end attached at all times alternatives should be considered to remove the risk.

3. ACTION BY:

All those using, providing and maintaining Birthright and Birthcare birthing beds, particularly in maternity units.

4. ACTION:

- Note: the recommendations given in this update supersede the advice given in MDEA(NI)2006/060 on 04 October 2006.
- Identify whether your organisation has Birthright or Birthcare birthing beds.
- Obtain revised warning labels from the manufacturer (details on page 3).
- Ensure that the revised warning labels are affixed to each bed in a prominent position, and that users and staff are aware of the risk of tipping.

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:

- Clinical governance leads
- Health and safety managers
- Maintenance staff
- Maternity unit managers
- Medical directors
- Midwifery staff
- Nursing executive directors
- Obstetricians
- Risk managers
- Supplies managers
- Independent Health and Social Care Providers – Private Hospitals & Maternity Clinics, through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Huntleigh Healthcare Limited
310-312 Dallow Road
Luton
Bedfordshire LU1 1TD

Tel: 01582 413104

Fax: 01582 459100

E-mail: sales.admin@huntleigh-healthcare.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/02 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

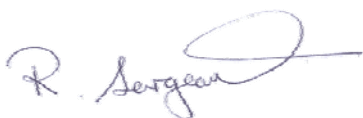
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
18th Jan 2008

Action Under Way:
14th Feb 2008

Action Complete:
14th April 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