

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/008

Issued: 22 February 2008



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	✓

	Section				
<p>Medical Device/Equipment: Hospital beds. Hill-Rom Avantguard 1200 and 1400 with manually operated lock-out function.</p>	▶ ①				
<p>Problem: Lack of use of the manual lock-out function has lead to fatalities from crush injuries.</p>	▶ ②				
<p>Action by: All those using, managing and maintaining hospital beds, in particular: nurses, bed managers, maintenance staff and contractors. Note:- All affected customers within Northern Ireland have been contacted by the local representative and a program of modification has been agreed and in place to be completed within the Action deadline.</p>	▶ ③				
<p>Action:</p> <ul style="list-style-type: none"> Ensure that the Hill-rom agent has identified all Hill-Rom Avantguard 1200 and 1400 hospital beds with the manually operated lock-out function. Serial numbers HRP000070411 to HRP000131071 inclusive. Ensure the height controls for those beds are manually locked out following every bed height adjustment before the patient is left unattended. Contact Hill-Rom on 01530 562 167 to arrange for the foot pedal height controls on both sides of the bed to be permanently removed. 	▶ ④				
<p>Distributed by NIAIC to:</p> <table style="width: 100%;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">Chief Executive of each Agency</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>NIAIC Liaison Officers</td> </tr> </table>	Chief Executive of each HSS Board	Chief Executive of each Agency	Chief Executive of each HSS Trust	NIAIC Liaison Officers	▶ ⑤
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<p>Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥				
<p>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>					
<table border="1" style="width: 100%;"> <tr> <td style="width: 33%;"> <p>Acknowledge Receipt of Alert: 26th Feb 2008</p> </td> <td style="width: 33%;"> <p>Action Under Way: 20th Mar 2008</p> </td> <td style="width: 33%;"> <p>Action Complete: 20th May 2008</p> </td> </tr> </table>	<p>Acknowledge Receipt of Alert: 26th Feb 2008</p>	<p>Action Under Way: 20th Mar 2008</p>	<p>Action Complete: 20th May 2008</p>	▶ ⑦	
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This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

1. DEVICE/EQUIPMENT:

The beds with manual lock-out function were supplied between June 2002 and December 2003 and can be identified by their serial numbers which run from HRP000070411 to HRP000131071, located on a plate on the head end of the bed frame. All models within this serial number range are affected with the exception of model reference PRS50010 as this model is fitted with an automatic time-out function and is therefore not affected.

Later versions of these Avantguard models supplied from December 2003 are unaffected, as they have a system that automatically locks out the foot pedal operation after 60 seconds of non-operation of the bed. This revised system cannot be retrofitted to the earlier models. There have been no reported entrapment incidents on beds with an automatic lock-out system.

Beds identified within Northern Ireland and already on a program of modification are found at the, Ulster Hospital, Royal Maternity, Antrim Renal and Erne Hospital.

2. PROBLEM:

An elderly patient fell from a bed to the floor. As the patient lay on the floor her leg pressed onto the foot pedals, raising the bed and then lowering it back down, crushing her other leg. She suffered a cardiac arrest and died. This is the second fatality from similar circumstances. The Hill-Rom Avantguard 1200 bed involved in this incident was of an early design which has a manually activated lock-out function for the foot and hand operated height controls. However, in both cases the lock-out function was not enabled before the patient was left unattended, contrary to the manufacturer's instructions for use and previous NIAIC advice in Medical Device\Equipment Alert MDA/2005/045 and MDEA(NI)2004/48.

All foot pedal assemblies on both sides of the Avantguard 1200 and Avantguard 1400 beds with the manually activated lock-out function should be permanently removed to avoid further serious or fatal incidents occurring. Once the foot pedals have been removed, the hand operated control system will continue to provide height control of the bed along with its bed base profiling functions.

Hill-Rom are now planning and managing a programme for each customer location to remove the foot pedal height controls on all affected Avantguard 1200 and Avantguard 1400 beds. Pedal removal can be carried out by an organisation's own maintenance staff, if preferred. Hill-Rom will provide full technical instructions to facilitate this; see the contact details on page 3.

Until the foot operated controls can be removed the manual lock-out function, which acts on both the hand operated height controls and the foot pedal height controls, should always be activated following every bed height adjustment before the patient is left unattended. The hand and the foot controls are interlinked and cannot be locked out independently.

Note: The manufacturer has recently reversed the foot pedals on some beds so that they are operated from underneath. This modification has not removed the risk of inadvertent operation and fatal entrapment if the height control is not locked out in accordance with the instructions for use. These modified foot pedals should also be removed.

This Alert supersedes MDEA(NI)2005/45.

3. ACTION BY:

All those using, managing and maintaining hospital beds, in particular: nurses, bed managers, maintenance staff and contractors.

Note:- All affected customers within Northern Ireland have been contacted by the local representative and a program of modification has been agreed and in place to be completed within the Action deadline.

4. ACTION:

- Ensure that the Hill-rom agent has identified all Hill-Rom Avantguard 1200 and 1400 hospital beds with the manually operated lock-out function. Serial numbers **HRP000070411** to **HRP000131071** inclusive.
- Ensure the height controls for those beds are manually locked out following every bed height adjustment before the patient is left unattended.
- Contact Hill-Rom on 01530 562 167 to arrange for the foot pedal height controls on both sides of the bed to be permanently removed.

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:

- All wards
- Bed managers
- Clinical governance leads
- EBME departments
- Equipment stores
- Estates & Facilities departments
- Health and safety managers
- Maintenance staff and contractors
- Nurses
- Nursing executive directors
- Risk managers
- Supplies managers
- Independent Health and Social Care Providers – Private Hospitals & Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Diane Pitchford
Hill-Rom
Clinitron House
Ashby Park
Ashby de la Zouch
Leicestershire LE65 1JG

Tel: 01530 562 167
Fax: 01530 562 029
E-mail: uk.customer.care@hill-rom.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/008 and be addressed to:

Northern Ireland Adverse Incident Centre
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:
26th Feb 2008

Action Under Way:
20th Mar 2008

Action Complete:
20th May 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