

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/71

Issued: 23 August 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section						
Medical Device/Equipment: Hospital beds: Hill-Rom TotalCare Duo 2.	▶ ①						
Problem: The manufacturer has omitted to provide suitable decontamination instructions with this pressure relieving hospital bed. The MHRA has received two reports of damaged mattress covers that allowed body fluids to soak into the mattress. No instruction was provided on how to check the condition of the mattress and cover. This presents a risk of cross infection.	▶ ②						
Action by: All those using and managing pressure relieving hospital beds, in particular: bed managers, nurses, care staff, maintenance staff and contractors.	▶ ③						
Action: <ul style="list-style-type: none"> Trace all Hill-Rom TotalCare Duo 2 beds in use and in storage. Contact Hill-Rom on 01530 562167 for copies of the cleaning and disinfection instructions. Unzip the mattress covers and check for signs of fluid contamination on the mattress and damage or holes in the mattress covers. Dispose of damaged covers. If replacement or spare mattresses and mattress covers are required, contact Hill-Rom on 01530 411000 Between each patient use check whether any fluids have penetrated the cover and follow Hill-Rom's cleaning, disinfection and laundry advice for the covers and mattresses. 	▶ ④						
Distributed by NIAIC to: <table style="width: 100%; border: none;"> <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> <tr> <td></td> <td>Hospices</td> </tr> </table> <p>For onward distribution see Section 5</p>	Chief Executive of each HSS Board	Chief Executive of each Agency	Chief Executive of each HSS Trust	NIAIC Liaison Officers		Hospices	▶ ⑤
Chief Executive of each HSS Board	Chief Executive of each Agency						
Chief Executive of each HSS Trust	NIAIC Liaison Officers						
	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:- <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">Deadline (Email received)</td> <td>: 24 August 2007</td> </tr> <tr> <td>Deadline (action underway)</td> <td>: 31 August 2007</td> </tr> <tr> <td>Deadline (action complete)</td> <td>: 28 September 2007</td> </tr> </table>	Deadline (Email received)	: 24 August 2007	Deadline (action underway)	: 31 August 2007	Deadline (action complete)	: 28 September 2007	▶ ⑦
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This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Hospital beds: Hill-Rom TotalCare Duo 2.

2. PROBLEM:

The manufacturer has omitted to provide customers with information on how to undertake suitable checks and decontamination procedures. The manufacturer does not include full decontamination details with the instructions for use, due to different requirements in different countries. In the UK they are covered in a separate document, W13001uks rev2.

Two NHS Trusts in England have reported a risk of cross infection with this bed. Residues of body fluids from previous occupants have been found under mattress covers.

Many of these beds are used by intensive care units.

NIAIC and MHRA has not received any adverse incident reports of cross infection occurring due to this problem.

3. ACTION BY:

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

4. ACTION:

- Trace all Hill-Rom TotalCare Duo 2 beds in use and in storage.
- Contact Hill-Rom on 01530 562167 for copies of the cleaning and disinfection instructions.
- Unzip the mattress covers and check for signs of fluid contamination on the mattress and damage or holes in the mattress covers.
- Dispose of damaged covers. If replacement or spare mattresses and mattress covers are required, contact Hill-Rom on 01530 411000
- Between each patient use check whether any fluids have penetrated the cover and follow Hill-Rom's cleaning, disinfection and laundry advice for the covers and mattresses.

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
- Nurse Directors
- Medical, Nursing and Care Staff
- Supplies Staff (RSS)
- All Wards
- Infection Control Teams
- Practice Nurses
- Social Care Staff
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Allied Health Professionals

6. CONTACTS:

Enquires to the 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

Enquires to NIAIC should quote reference number MDEA(NI)2007/71 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

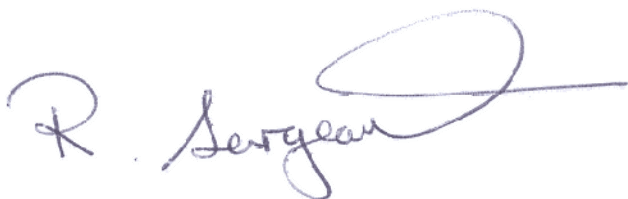
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

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

Deadline (Email received)	: 24 August 2007
Deadline (action underway)	: 31 August 2007
Deadline (action complete)	: 28 September 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