

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/48

Issued: 25 August 2004

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION REQUEST	



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section								
<b>Medical Device/Equipment:</b> Electrically operated beds.	▶ ①								
<b>Problem:</b> Risk of entrapment and crushing involving the accidental operation of the foot controls.	▶ ②								
<b>Action by:</b> Those responsible for the acquisition, issue and use of electrically operated beds.	▶ ③								
<b>Action:</b> <ul style="list-style-type: none"> <li>Determine if your establishment has any electrically operated beds.</li> <li>Assess the likelihood of accidental operation of foot controls and the consequent risk of entrapment.</li> <li>If necessary take steps to reduce the risk.</li> </ul>	▶ ④								
<b>Distributed by NIAIC to:</b> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Hospices</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	Hospices	Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
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<b>Contacts</b> NIAIC contacts for technical and clinical aspects.	▶ ⑥								
<b>Feedback Requirements to NIAIC</b> Any safety concerns regarding entrapment hazards should be discussed with the manufacturer or supplier and reported to NIAIC.	▶ ⑦								

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

## 1. DEVICE/EQUIPMENT:

All electrically operated, height adjustable and profiling beds, used in the community and in hospitals.

## 2. PROBLEM:

An adverse incident has been reported which resulted in the death of a patient. It appears that the patient either fell or climbed out of her electric profiling bed and ended up lying with her head on the foot control, thereby activating the platform lowering function which crushed the patient, preventing nursing staff from releasing her. This incident is currently under investigation by the Medicines and Healthcare products Regulatory Agency (MHRA).

This is the only known incident in the UK; however, the MHRA has also received reports from France of a number of incidents where people have become trapped under electric height adjustable hospital beds. Three of the incidents in France have been fatal. It appears that these incidents were the result of the foot controls on the bed being accidentally operated. Most of the incidents have occurred at night, in geriatric or long-term patient departments and generally involved patients who were weak, disorientated or agitated.

## 3. ACTION BY:

Those responsible for the acquisition, issue and use of electrically operated beds.

## 4. ACTION:

- Listed below are some factors which you may wish to consider where electrically operated beds are used. This is not a definitive list and will depend upon local circumstances:
  - Access to the bed (for example by patients, carers, visitors, and persons cleaning or transporting the bed.)
  - The type of bed.
  - The environment.
  - The patient (for example: are they disorientated or confused?).
  - The carer's training.
  - The level of supervision.
  - The use of accessories (for example bed rails).
  - The controls on the bed. For example:
    - Are foot controls necessary?
    - Could the foot controls be operated accidentally?
    - Are all the controls clear and easy to understand?
    - Would it be appropriate to lock out some or all the controls?
- The use of lock out controls and covers or guards on foot pedals should reduce the risk of these controls being accidentally operated, but it may be appropriate to remove the foot pedals if an unacceptable risk of entrapment is identified. Contact the manufacturer/supplier of the bed for advice on the safe use of your particular bed's foot controls. Some manufacturers have designed various solutions which can be fitted retrospectively to the bed.

## 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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Estates Managers
- All Wards and Departments
- Back Care and Manual Handling Advisors
- Loan Store Managers
- Medical Directors
- Nursing Directors
- Medical, Nursing and Community Care Staff
- District Nurses
- Occupational Therapists
- Directors of Public Health
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSS Board R&I Units

## 6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2004/ 48 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

For Nursing Aspects:

Mrs Elizabeth Qua

Principal Nurse

Health Estates

Stoney Road

Dundonald

Belfast BT16 1US

Tel: 028 9052 3828

Email: elizabeth.qua@dhsspsni.gov.uk

## 7. FEEDBACK:

Any safety concerns regarding entrapment hazards should be discussed with the manufacturer or supplier and reported to NIAIC.



Brian Godfrey  
NIAIC 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)2004/01. 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](http://www.dhsspsni.gov.uk/niaic)

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