

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/062

Issued: 4<sup>th</sup> August 2008



**HEALTH ESTATES**

creating healing environments

For:

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

	Section								
<b>Medical Device/Equipment:</b> Carendo multi-purpose hygiene chair manufactured by Arjo.	▶ ①								
<b>Problem:</b> Risk of entrapment of genitalia.	▶ ②								
<b>Action by:</b> All those involved in the provision and use of the Carendo multi-purpose hygiene chair. In particular: nurses, community care staff, equipment managers and moving and handling co-ordinators.	▶ ③								
<b>Action:</b> <ul style="list-style-type: none"> <li>Trace all Arjo Carendo multi-purpose hygiene chairs that are in use or storage.</li> <li>Contact Arjo/Huntleigh to obtain a copy of the latest edition of the Carendo operating and product care Instructions (see contact on page 2).</li> <li>Ensure that users and care staff are aware of the new instructions for use.</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%;">Hospices</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td></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	Hospices	Chief Executive of each HSS Trust		Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
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<b>Contacts</b> Details of manufacturer and NIAIC contacts for technical and clinical aspects.	▶ ⑥								
<b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b>									
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This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

## 1. DEVICE/EQUIPMENT:

All Carendo multi-purpose hygiene chair manufactured by Arjo. The manufacturer's representative in the UK is Arjo/Huntleigh.

## 2. PROBLEM:

Incidents have been reported in Sweden of male genitalia becoming entrapped between the seat and the base of the chair when the seat/backrest is moved. No incidents have been reported in the UK.

The seating system pivots from the rear of the chair upwards to allow the occupant to be washed through an aperture at the rear of seat. There is the potential, while raising the seat or when the seat is in the raised position, for the occupant's genitalia to slide into the aperture. If the carer or occupant does not notice this, the genitalia can become pinched between the seat and the base of the chair when it is returned to its normal position, causing bruises, cuts or severe wounds.

Arjo reviewed the design and could not establish a suitable modification due to the need to have good access for washing. Arjo has subsequently revised and reissued the instructions for use, including warnings to check that the genitalia do not slide into the aperture during the lowering movement of the seat.

## 3. ACTION BY:

All those involved in the provision and use of the Carendo multi-purpose hygiene chair. In particular: nurses, community care staff, equipment managers and moving and handling co-ordinators.

## 4. ACTION:

- Trace all Arjo Carendo multi-purpose hygiene chairs that are in use or storage.
- Contact Arjo/Huntleigh to obtain a copy of the latest edition of the Carendo operating and product care Instructions (see contact on page 2).
- Ensure that users and care staff are aware of the new instructions for use.

## 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:

- Equipment stores
- Moving and handling co-ordinators
- Nursing executive directors
- Nursing staff
- Occupational therapists
- Physiotherapists
- Risk managers
- Residential and further education colleges
- Schools with facilities for the disabled
- Community equipment stores
- Community hospitals
- District nurses
- Domiciliary care providers
- Nursing agencies
- Independent Health and Social Care Providers – Private Hospitals and Clinics, Residential and Nursing Homes through RQIA

## 6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Customer Support  
Arjo/Huntleigh  
St Catherine Street  
Gloucester GL1 2SL

Tel: 08702 430 430

Fax: 01452 428 344

E-mail: [uksales@arjo.co.uk](mailto:uksales@arjo.co.uk)

Enquiries to NIAIC should quote reference number MDEA(NI)2008/062 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](mailto:NIAIC@dhsspsni.gov.uk)

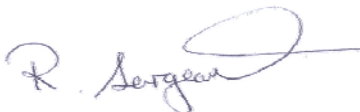
## 7. FEEDBACK:

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

Acknowledge Receipt of Alert:  
6<sup>th</sup> Aug 2008

Action Under Way:  
4<sup>th</sup> Sept 2008

Action Complete:  
4<sup>th</sup> Nov 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](http://www.dhsspsni.gov.uk/niaic)

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