

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/109

Issued: 10 December 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section								
<p>Medical Device/Equipment: Kimba Spring paediatric buggies manufactured by Otto Bock.</p>	▶ ①								
<p>Problem: Risk of injury to the occupant due to frame failure and the seat suddenly tilting fully forwards or backwards.</p>	▶ ②								
<p>Action by: All those involved in the provision, prescription, repair, maintenance and use of these buggies. In particular wheelchair service managers, loan store managers, rehabilitation engineers, occupational therapists, paediatric services and wheelchair maintenance staff and contractors.</p>	▶ ③								
<p>Action:</p> <ul style="list-style-type: none"> Trace all Kimba Spring paediatric buggies, in use or held in storage, which were supplied between April 2003 and April 2007 and inspect the seat tilt actuator frame mounting and surrounding area (see photographs in appendix). Further actions on page 2. 	▶ ④								
<p>Distributed by NIAIC to:</p> <table border="0"> <tr> <td>Chief Executive of each HSS Board</td> <td>Education and Library Boards (for onward distribution to educational establishments)</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	Education and Library Boards (for onward distribution to educational establishments)	Chief Executive of each HSS Trust	Hospices	Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
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Chief Executive of each Agency									
NIAIC Liaison Officers									
<p>Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥								
<p>Feedback Requirements to NIAIC None Required.</p>	▶ ⑦								

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

1. DEVICE/EQUIPMENT:

All Kimba Spring paediatric buggies with the following part number(s): HR32901000 (size 1 rigid), HR32911000 (size 1 swivelled) and HR32931000 (size 2 swivelled) supplied between April 2003 and April 2007. Size 1 is intended for children aged approximately 1 to 6 years; size 2 for children aged 4 to 10 years.

2. PROBLEM:

The MHRA has received reports of failures of the seat tilt actuator frame mounting on Kimba Spring paediatric buggies manufactured by Otto Bock (see appendix Figures A – D). The failure may lead to the seating system becoming insecure allowing it to fully tilt forwards or backwards without warning. A head injury has occurred as a result of this happening.

Otto Bock has carried out extensive tests but has been unable to reproduce these failures when the buggy is used in accordance with the IFU. It is possible that the failures were caused by overloading the frame. In May 2007, Otto Bock introduced a modification kit for the Kimba Spring. A bracket is to be fitted that will limit the range of tilt and which reduces the risk to users in the event of a frame failure. With the seat unit removed, fitting of the bracket takes approximately five minutes. Otto Bock has also updated the IFU.

Copies of the latest version of the IFU, catalogue number: 647G116-04.03\3, and the transportation document, catalogue number: 646D158-600-05.07\7, can be obtained from Otto Bock at the address given below.

Users, carers and transport providers should ensure that the buggy is used as stated in the IFU at all times. If it is used in transport, a tie-down system and occupant restraint should be employed in accordance with the IFU from Otto Bock.

3. ACTION BY:

All those involved in the provision, prescription, repair, maintenance and use of these buggies. In particular wheelchair service managers, loan store managers, rehabilitation engineers, occupational therapists, paediatric services and wheelchair maintenance staff and contractors.

4. ACTION:

- Trace all Kimba Spring paediatric buggies, in use or held in storage, which were supplied between April 2003 and April 2007 and inspect the seat tilt actuator frame mounting and surrounding area (see photographs in appendix).
- Withdraw from service all those buggies showing signs of damage or cracks and contact Otto Bock for a replacement frame.
- If no damage or cracks are found on the frame contact Otto Bock for the modification bracket and fitting instructions. Make arrangements to fit the new bracket.
- Ensure that all users have the latest version of the Kimba Spring instructions for use (IFU), including the separate document detailing how it may be used as a seat in transport.

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
- Health and safety managers
- Loan store managers
- Maintenance staff and contractors
- Occupational therapists
- Paediatric service managers
- Physiotherapists
- Rehabilitation engineers
- Risk managers
- Wheelchair service managers
- Independent Health and Social Care Providers – Private Hospitals & Clinics, Nursing and Residential Homes through RQIA
- Educational establishments with facilities for wheelchair users
- Residential special schools

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Russell Pizzey
Otto Bock Healthcare Plc
32 Parsonage Road
Englefield Green
Egham
Surrey TW20 0LD
Tel: 01784 744 900
Fax: 01784 744 949

E-mail: bockuk@ottobock.com

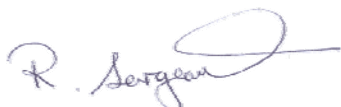
Enquiries to NIAIC should quote reference number MDEA(NI)2007/109 and be addressed to:

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:

None Required.



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

Appendix to MEDA(NI)2007/109

Figure A

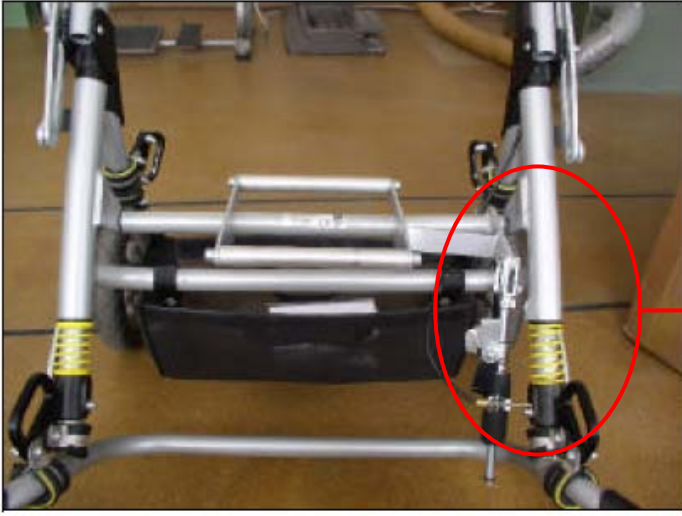


Figure B

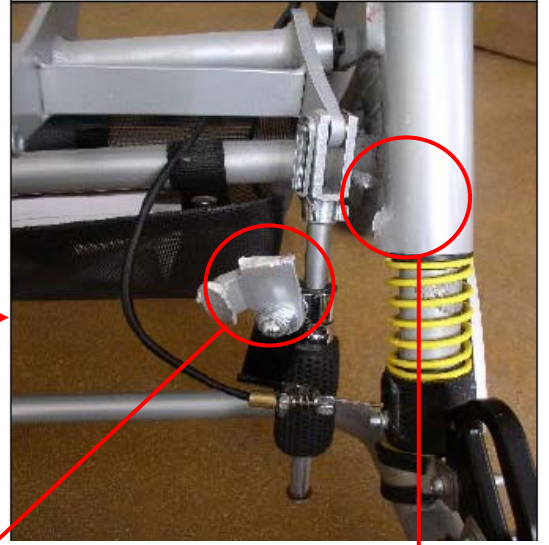


Figure C



Figure D

