

# MEDICAL DEVICE ALERT

Issued: 10 December 2007 at 11:00

Ref: MDA/2007/096

<input type="checkbox"/>	Immediate action
<input checked="" type="checkbox"/>	Action
<input type="checkbox"/>	Update
<input type="checkbox"/>	Information request

<b>Device:</b> Kimba Spring paediatric buggies manufactured by Otto Bock.	► Page 2
<b>Problem:</b> Risk of injury to the occupant due to frame failure and the seat suddenly tilting fully forwards or backwards.	► Page 2
<b>Action by:</b> 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.	
<b>Action:</b> <ul style="list-style-type: none"> <li>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).</li> <li>Withdraw from service all those buggies showing signs of damage or cracks and contact Otto Bock for a replacement frame.</li> <li>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.</li> <li>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.</li> </ul>	
<b>Distributed to:</b> NHS trusts in England OFSTED Healthcare Commission (CHAI) Primary care trusts in England Social services in England – Chief Executives* – Directors of Children’s Services – Headquarters – Chief Executives* – Directors* * via CE Bulletin	► Page 2
<b>Contacts:</b> Details of manufacturer contacts and MHRA contacts for technical aspects. Change of address or removal from address list for Healthcare Commission.	► Page 3
<b>Appendix:</b> Photographs of buggy with failure	► Page 4

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

Deadline (action underway): 31 December 2007

Deadline (action complete): 28 February 2008

This notice is also on our website: <http://www.mhra.gov.uk>

## Device:

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.

## 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.

## Distribution:

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

### Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- 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

### Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Children's hospitals in the independent sector

### OFSTED to:

Directors of children's services for onward distribution to:

- Children's services
- Educational establishments with facilities for wheelchair users
- Residential special schools

### Primary care trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- Equipment stores
- Health & safety managers
- Maintenance staff and contractors
- Occupational therapists
- Paediatric service managers
- Physiotherapists
- Rehabilitation engineers
- Risk managers
- Wheelchair service managers

### Social services to:

Liaison officers for onward distribution to all relevant staff including:

- Disability equipment stores
- Equipment supplies managers
- Loan store managers
- Maintenance staff and contractors
- Occupational therapists
- Paediatric service managers
- Residential care homes
- Risk managers
- Wheelchair service managers

## **Contacts:**

Enquiries to the manufacturer should quote reference number TS8423 and 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](mailto:bockuk@ottobock.com)

Enquiries to the MHRA should quote reference number **MDA/2007/096** or **2007/004/010/301/001** and be addressed to:

Maurice Rand or Jonathan Smith  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ

Tel: 01253 596 000

Fax: 01253 596 177

E-mail: [maurice.rand@mhra.gsi.gov.uk](mailto:maurice.rand@mhra.gsi.gov.uk)  
[jonathan.smith@mhra.gsi.gov.uk](mailto:jonathan.smith@mhra.gsi.gov.uk)

## **Change of address or removal from address list for Healthcare Commission:**

Healthcare Commission  
Finsbury Tower  
103-105 Bunhill Row  
London EC1Y 8TG

Tel: 020 7448 0842

E-mail: [contacts@healthcarecommission.org.uk](mailto:contacts@healthcarecommission.org.uk)

### **How to report adverse incidents**

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre  
Medicines and Healthcare products Regulatory Agency  
Market Towers, 1 Nine Elms Lane, London SW8 5NQ  
Telephone 020 7084 3080 or Fax 020 7084 3109  
or e-mail: [aic@mhra.gsi.gov.uk](mailto:aic@mhra.gsi.gov.uk)

(An answerphone service operates outside normal office hours)

**Medical Device Alerts are available in full text on the MHRA website:** <http://www.mhra.gov.uk>

Further information about **SABS** can be found at [www.info.doh.gov.uk/sar2/cmopatie.nsf](http://www.info.doh.gov.uk/sar2/cmopatie.nsf)

MHRA is an executive agency of the Department of Health  
© Crown Copyright 2007

Addressees may take copies for distribution within their own organisations

# Appendix to MDA/2007/096

Figure A

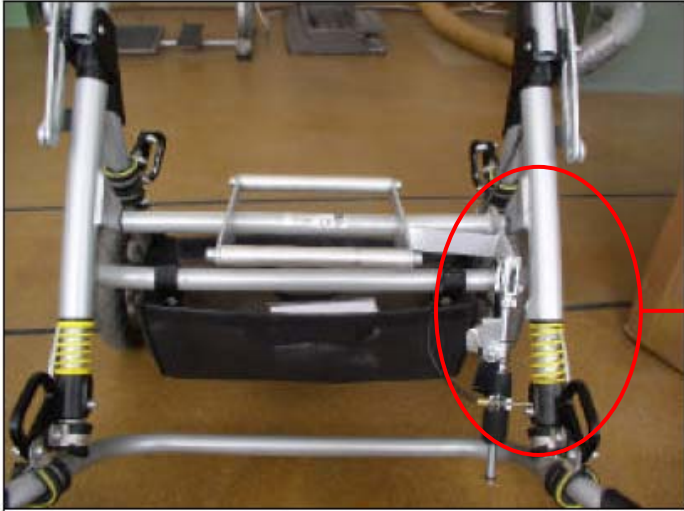


Figure B

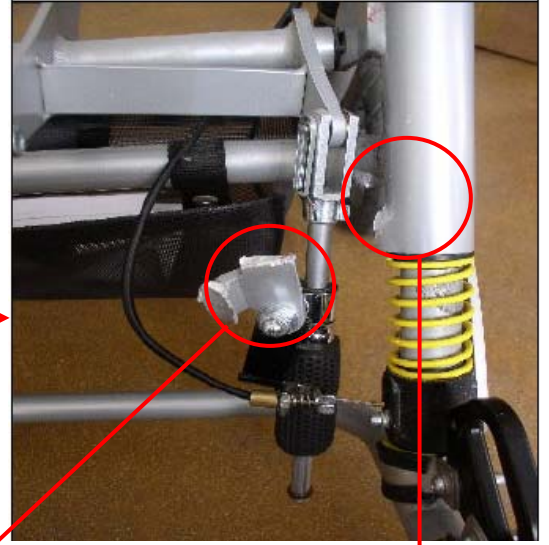


Figure C



Figure D

