

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/079

Issued: 23rd October 2008



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section		
Medical Device/Equipment: Kid Active folding manual wheelchair with swing away footrests manufactured by Lomax Mobility Ltd.	▶ ①		
Problem: Risk of fall and serious injury due to limited forward stability.	▶ ②		
Action by: All those involved with the use, provision and prescription of these wheelchairs. In particular: carers, wheelchair service managers, occupational therapists and rehabilitation engineers.	▶ ③		
Action: <ul style="list-style-type: none"> Trace all Lomax Kid Active folding manual wheelchairs with swing away footrests. Review each wheelchair user to see if the forward stability of their wheelchair is appropriate, taking into account the manufacturer's updated warnings (see appendix). Consider alternative wheelchairs for users who require higher levels of stability. 	▶ ④		
Distributed by NIAIC to: <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers </td> <td style="width: 50%;"> Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users) Hospices </td> </tr> </table>	Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users) Hospices	▶ ⑤
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Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.	▶ ⑥		
Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)			
Acknowledge Receipt of Alert: 27 October 2008	Action Under Way: 24 November 2008		
Action Complete: 23 January 2009			
	▶ ⑦		

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

1. DEVICE/EQUIPMENT:

All Kid Active folding manual wheelchairs with swing away footrests (Model codes K8S and K9S) manufactured by Lomax Mobility Ltd (now part of Sunrise Medical).

2. PROBLEM:

The MHRA has received a small number of reports where the user has tipped forwards out of the wheelchair and sustained minor injuries. Investigation has shown that the Kid Active folding frame model fitted with swing away footrests has a shorter wheelbase than the standard Kid Active folding frame with outrigger castors. The shorter wheelbase significantly reduces the forward stability. This was not made clear in the manufacturer's pre-sales or usage information. Users who require a wheelchair with good forward stability (e.g. those who sit or lean forwards) may be at risk of serious injury if they are unaware of the limited forwards stability of this model.

Lomax Mobility has updated the warnings in the instructions for use (Issue 4a dated June 2008) for the Kid Active to reflect this (see appendix). They have also issued a Field Safety Notice, which incorporates the updated warnings to purchasers of these wheelchairs. The limited response so far means that the updated warnings have not reached all Kid Active users, especially where the wheelchairs have been passed on to second or subsequent users.

The Kid Active is no longer being manufactured and Lomax Mobility (Sunrise Medical) does not intend to provide a retrofit assembly to improve stability.

3. ACTION BY:

All those involved with the use, provision and prescription of these wheelchairs. In particular: carers, wheelchair service managers, occupational therapists and rehabilitation engineers.

4. ACTION:

- Trace all Lomax Kid Active folding manual wheelchairs with swing away footrests.
- Review each wheelchair user to see if the forward stability of their wheelchair is appropriate, taking into account the manufacturer's updated warnings (see appendix).
- Consider alternative wheelchairs for users who require higher levels of stability.

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 store managers
- Occupational therapists
- Physiotherapists
- Rehabilitation engineers
- Risk managers
- Wheelchair and seating service managers
- 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:

Sunrise Medical
Unit 7b City Quay
Camperdown Street
Dundee DD1 3JA

Tel: 01382 204 374

E-mail: Tom.Forbes@sunmed.co.uk

Enquiries to NIAIC should quote reference number MDEA(NI)2008/079 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

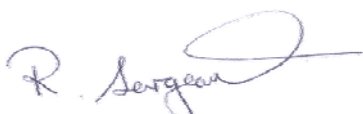
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
27 October 2008

Action Under Way:
24 November 2008

Action Complete:
23 January 2009



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

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

APPENDIX to MDEA(NI)2008/079

Extract of warnings from manual. (Issue 4a dated June 2008)

 The Kid Active Folding Frame with swing away footrests has a shorter wheelbase than the Kid Active Folding Frame with out rigged castors and has a lower and reduced forward stability, which may not be suitable for users who have a tendency to lean forward or who may be in the habit of standing on the footplates.

 Users, carers and attendants attempting to use the wheelchair beyond the manufacturer's recommendations may put themselves at risk of serious injury or even death.