

Medical Device/Equipment ALERT

Ref.MDEA(NI)2008/081

Issued: 29th October 2008

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section								
<p>Medical Device/Equipment: Breezy Moonlite manual wheelchair manufactured by Sunrise Medical.</p>	▶ ①								
<p>Problem: Sudden failure of the backrest hinge can lead to injury of the occupant and/or carer.</p>	▶ ②								
<p>Action by: All those involved in the provision, prescription or use of these wheelchairs. In particular: wheelchair service managers, rehabilitation engineers, occupational therapists and maintenance staff /contractors.</p>	▶ ③								
<p>Action:</p> <ul style="list-style-type: none"> Trace all Breezy Moonlite manual wheelchairs in use or in storage. Warn users/carers of the potential for failure of the backrest and that they should cease use until a replacement backrest has been fitted. Contact Sunrise Medical on telephone number 01384 446 666 to obtain a replacement backrest kit and arrange for it to be fitted. 	▶ 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 that have facilities for wheelchair users)</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> <p>For onward distribution see Section 5</p>	Chief Executive of each HSS Board	Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users)	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 contacts and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥								
<p>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>									
<table border="1"> <tr> <td>Acknowledge Receipt of Alert: 31st Oct 2008</td> <td>Action Under Way: 5th Nov 2008</td> <td>Action Complete: 12th Dec 2008</td> </tr> </table>	Acknowledge Receipt of Alert: 31 st Oct 2008	Action Under Way: 5 th Nov 2008	Action Complete: 12 th Dec 2008	▶ ⑦					
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This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

All Moonlite manual wheelchairs manufactured before 08/08/08, with serial numbers preceding ML18T08081033.

These wheelchairs were supplied exclusively to the UK market.

2. PROBLEM:

The MHRA has received a small number of incident reports where the backrest hinge on the Moonlite wheelchair has suddenly failed in use. Such failures can lead to the wheelchair user or the carer falling and injuring themselves. The original hinge material (cast alloy) is not strong enough and Sunrise Medical is providing a replacement kit with steel hinges.

The kit (part no. 52598M) includes fitting instructions. Local repair agents should be able to fit the new kits but if there are any problems, contact Sunrise Medical.

Sunrise Medical issued a Field Safety Notice in September 2008 to dealers and purchasers stating that these wheelchairs should not be used until a replacement kit has been fitted.

3. ACTION BY:

All those involved in the provision, prescription or use of these wheelchairs. In particular: wheelchair service managers, rehabilitation engineers, occupational therapists and maintenance staff /contractors.

4. ACTION:

- Trace all Breezy Moonlite manual wheelchairs in use or in storage.
- Warn users/carers of the potential for failure of the backrest and that they should cease use until a replacement backrest has been fitted.
- Contact Sunrise Medical on telephone number 01384 446 666 to obtain a replacement backrest kit and arrange for it to be fitted.

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:

- Ambulance services directors
- Equipment stores
- Health and safety managers
- Occupational therapists
- Patient transport managers
- Physiotherapists
- Rehabilitation engineers
- Risk managers
- Wheelchair service managers
- Residential special schools
- School transport managers
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Customer Services
Sunrise Medical Ltd.
High Street
Wollaston
Stourbridge
DY8 4PS

Tel: 01384 446 666

Fax: 01384 446 644

E-mail: enquiries@sunmed.co.uk

Enquiries to NIAIC should quote reference number MDEA(NI)2008/081 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

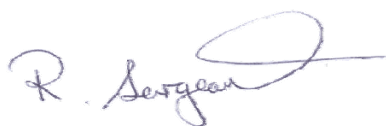
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
31st Oct 2008

Action Under Way:
5th Nov 2008

Action Complete:
12th Dec 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

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