

Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/34

Issued: 30 October 2003

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	✓
INFORMATION REQUEST	



HEALTH ESTATES

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section												
<p>Medical Device/Equipment: Sunrise Breezy SL manual wheelchair with 16" (40 cm) seat canvas depth and 24" (60 cm) rear wheels.</p>	▶ ①												
<p>Problem: The previously issued NIAIC Safety Notice (SN(NI)2003/03) incorporated a temporary solution to remove the potential for footrest hangers to release parking brakes. This MDEA updates SN(NI)2003/03 and provides a permanent solution to the problem.</p>	▶ ②												
<p>Action by: Those who have Breezy SL manual wheelchairs manufactured between October 2000 and November 2002 and found to have a brake setting problem (described in the earlier Safety Notice SN(NI)2003/03).</p>	▶ ③												
<p>Action: Contact Sunrise Medical Ltd for replacement brakes and fitting instructions.</p>	▶ ④												
<p>Distributed by NIAIC to:</p> <table border="0"> <tr> <td>Chief Executive of each HSS Board</td> <td>General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Education and Library Boards (for</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>onward distribution to educational</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td>establishments that have facilities</td> </tr> <tr> <td></td> <td>for wheelchair users)</td> </tr> <tr> <td></td> <td>Hospices</td> </tr> </table>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	Education and Library Boards (for	Chief Executive of each Agency	onward distribution to educational	NIAIC Liaison Officers	establishments that have facilities		for wheelchair users)		Hospices	▶ ⑤
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<p>Contacts Details of supplier contacts, NIAIC contacts for technical aspects.</p>	▶ ⑥												
<p>Feedback Requirements to NIAIC Only if problems occur.</p>	▶ ⑦												

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

1. DEVICE/EQUIPMENT:

Sunrise Breezy SL manual wheelchair with 16" (40 cm) seat canvas depth and 24" (60 cm) rear wheels.

2. PROBLEM:

The Medicines and Healthcare products Regulatory Agency (MHRA) initially received reports of footrest hangers on the Breezy SL manual wheelchairs releasing the parking brakes when the footrests were swung aside. The problem was caused by incorrect positioning of the brake assemblies. A Safety Notice (SN(NI)2003/02) was issued in Northern Ireland to make users aware of the problem and to provide a temporary solution to allow the wheelchairs to continue to be used safely.

Since this time MHRA have monitored the progress of the manufacturer in their development of a permanent solution to the problem. The manufacturer has now developed a new brake assembly which is more compact and is not affected by movement of the footrests. In addition it can be easily positioned on the frame of the wheelchair.

The manufacturer has agreed to supply the new brake assembly along with fitting instructions for use on all 16" seat canvas depth models with a 24" wheel size. Sunrise Medical Ltd will supply the new type of brake free of charge and will refund any reasonable cost of fitting. Any costs should be agreed with the manufacturer before work commences.

Other sizes of the Breezy SL are not affected because the footrest hanger is set sufficiently far away from the rear wheel and the brake assembly, so that no contact should occur.

600 wheelchairs are known to have been supplied in England, Scotland and Wales; these were all manufactured between October 2000 and November 2002. It is not known if these have been supplied in Northern Ireland and we are therefore issuing this MDEA as a precaution.

3. ACTION BY:

Those who have Breezy SL manual wheelchairs manufactured between October 2000 and November 2002 and found to have a brake setting problem (described in the earlier Device Alert MDA/2003/002).

4. ACTION:

Contact Sunrise Medical Ltd for replacement brakes and fitting instructions.

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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Estates Managers
- Wheelchair Service Managers
- Occupational Therapists
- Physiotherapists
- Rehabilitation Engineers
- Medical Directors
- Nurse Directors
- Supplies Staff (RSS)
- Loan Store Managers
- Practice Managers
- Practice Nurses
- District Nurses
- Health Visitors
- Directors of Public Health
- Social Care Staff
- Community Care Staff
- Day Care Centres
- Independent Health and Social Care Providers – Independent Clinics, Residential and Nursing Homes

6. CONTACTS:

Enquiries to the supplier should be addressed to:

Sunrise Hotline
Sunrise Medical Ltd
High Street
Wollaston
West Midlands
DY8 4PS

Tel: 01384 446 667
Fax: 01384 446 674

Enquires to NIAIC should quote reference number MDEA(NI)2003/34 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:

No feedback required from this Alert unless any problems occur which should be referred to NIAIC.



Brian Godfrey
NIAIC 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 Safety Notice SN (NI) 2003/01. 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