

MEDICAL DEVICE ALERT

Issued: **29 October 2008** at 12:00

Ref: **MDA/2008/078**

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

Device: Breezy Moonlite manual wheelchair manufactured by Sunrise Medical.	▶ Page 2														
Problem: Sudden failure of the backrest hinge can lead to injury of the occupant and/or carer.	▶ Page 2														
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.															
Action: <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. 															
Distributed to: <table> <tr> <td>NHS trusts in England</td> <td>– Chief Executives*</td> </tr> <tr> <td>OFSTED</td> <td>– Directors of Children’s Services</td> </tr> <tr> <td>Commission for Social Care Inspection (CSCI)</td> <td>– Headquarters</td> </tr> <tr> <td>Healthcare Commission (CHAI)</td> <td>– Headquarters</td> </tr> <tr> <td>Primary care trusts in England</td> <td>– Chief Executives*</td> </tr> <tr> <td>Social services in England</td> <td>– Directors*</td> </tr> <tr> <td>NHS Boards in Scotland</td> <td>– Chief Executives</td> </tr> </table> <p style="text-align: right;">* via CE Bulletin</p>	NHS trusts in England	– Chief Executives*	OFSTED	– Directors of Children’s Services	Commission for Social Care Inspection (CSCI)	– Headquarters	Healthcare Commission (CHAI)	– Headquarters	Primary care trusts in England	– Chief Executives*	Social services in England	– Directors*	NHS Boards in Scotland	– Chief Executives	▶ Page 2
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Contacts: Details of manufacturer contacts and contacts for technical aspects. Change of address or removal from address list for CSCI and Healthcare Commission.	▶ Page 3														

Action deadlines for the Central Alerting System (CAS)

Deadline (action underway): 05 November 2008 | **Deadline (action complete): 10 December 2008**

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

Device:

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

These wheelchairs were supplied exclusively to the UK market.

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.

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:

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

- Equipment store managers
- Maintenance staff and contractors
- Nursing directors
- Occupational therapists
- Physiotherapists
- Rehabilitation engineers
- Risk managers
- Wheelchair and seating service managers

Primary care trusts to:

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

- Equipment store managers
- Maintenance staff and contractors
- Occupational therapists
- Physiotherapists
- Rehabilitation engineers
- Risk managers
- Wheelchair and seating service managers

Social services to:

Liaison officers for onward distribution to all relevant staff including:

- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Equipment stores managers
- Maintenance staff and contractors
- Occupational therapists
- Wheelchair and seating service managers

Commission for Social Care Inspection (CSCI) to:

Headquarters for onward distribution to:

- Care homes providing nursing care
- Care homes providing personal care
- FECs registered as care homes

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Hospices
- Hospitals in the independent sector

OFSTED to:

- Educational establishments with facilities for wheelchair users
- Residential special schools

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 the MHRA should quote reference number **MDA/2008/078** or **2008/005/028/401/006** and be addressed to:

Technical aspects:

Jonathan Smith or Brian Mather
Medicines & Healthcare products Regulatory Agency
Centre for Assistive Technology
241 Bristol Avenue
Bispham
Blackpool
FY2 0BR

Tel: 01253 596 000

Fax: 01253 596 177

E-mail: jonathan.smith@mhra.gsi.gov.uk

brian.mather@mhra.gsi.gov.uk

Enquiries for Scotland should be directed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

E-mail: iric@shs.csa.scot.nhs.uk

Change of address or removal from address list for CSCI and Healthcare Commission:

CSCI Customer Service Unit
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 0845 015 0120

E-mail: enquiries@csci.gsi.gov.uk

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

Tel: 020 7448 0842

E-mail: 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

(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 **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

MHRA is an executive agency of the Department of Health

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