

Medical Device Alert

Action

Ref: MDA/2009/079 Issued: 07 December 2009 at 15:00

Device

Martin Heavy Duty manual wheelchair manufactured by Karma Mobility Ltd.



Problem	Action
<p>The backrest can fail in use causing the occupant to fall from the wheelchair resulting in serious injury.</p>	<ul style="list-style-type: none"> Trace all affected wheelchairs. Contact Karma Mobility for the required parts and fitting instructions. Make arrangements to fit the new backrest to all affected wheelchairs.
Action by	
<p>All those involved in the provision, repair and maintenance of these wheelchairs. In particular wheelchair service managers, rehabilitation engineers, occupational and wheelchair therapists and wheelchair maintenance staff and contractors.</p>	
CAS deadlines	Contact
<p>Action underway: 21 December 2009 Action complete: 08 March 2010</p>	<p>Manufacturer Mr Mark Duffield Karma Mobility Ltd Tel: 0845 630 3436 Fax: 0845 630 3736 E-mail: info@karmamobility.co.uk</p>

Device

Affected wheelchairs were supplied up to June 2006 and have serial numbers up to M06-005616.

Wheelchairs produced after June 2006 (with serial numbers from M06-005617) were manufactured with a reinforced backrest assembly and so are not affected.

Problem

The MHRA has received reports of backrests failing in use. No injuries have been reported so far.

Karma Mobility Ltd changed the design in June 2006 to incorporate a reinforced backrest assembly. However, at that time the manufacturer did not take any retrospective action on wheelchairs already in use.

Karma Mobility subsequently issued a [Field Safety Notice](#) in September 2009 but has been unable to trace all affected wheelchairs, especially where they have been passed on to second or subsequent users.

Karma Mobility will supply, free of charge, a kit which includes all necessary parts and fitting instructions. This kit should be suitable for fitting by local maintenance staff or contractors. If any problems occur Karma Mobility will arrange for its engineers to visit and fit the new backrest.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- OFSTED
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

Onward 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 and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Consultants in rehabilitation medicine/special seating
- Equipment store managers
- Maintenance staff and contractors
- Occupational therapists
- Physiotherapists
- Rehabilitation engineers
- Risk managers
- Wheelchair and seating service managers

Care Quality Commission (CQC) (England only) to:

The MHRA considers this to be important to:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Further education colleges registered as care homes

OFSTED:

The MHRA considers this to be important to:

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

Primary care trusts to:

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

- Community hospitals
- 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
- Equipment store managers
- Maintenance staff and contractors
- Occupational therapists
- Risk managers
- Wheelchair and seating service managers

Contacts

Manufacturer

Mr Mark Duffield
Karma Mobility Ltd
Unit 6 Target Park
Shawbank Road
Redditch
B98 8YN

Tel: 0845 630 3436

Fax: 0845 630 3736

E-mail: info@karmamobility.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2009/079** or **2009/004/023/401/007**.

Brian Mather or Jonathan Smith
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: bav@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

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

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates

Estate Policy Directorate

Stoney Road

Dundonald

Belfast

BT16 1US

Tel: 02890 523 704

Fax: 02890 523 900

E-mail: NIAIC@dhsspsni.gov.uk

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

Scotland

Enquiries and adverse incident reports in Scotland should be addressed 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: nss.irc@nhs.net

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

Wales

Enquiries in Wales should be addressed to:

Dr Jane Ludlow

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff

CF10 3NQ

Tel: 029 2082 3505 / 3922

E-mail: Haz-Aic@wales.gsi.gov.uk

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