

Medical Device Alert

Ref: MDA/2011/042 Issued: 11 May 2011 at 14:00

Device

Romachair Anti Microbial
Commode, models 4730/4740,
manufactured by Roma Medical
Aids Ltd.



Problem	Action
<p>The manufacturer issued a Field Safety Notice (FSN) for this device on 21 February 2011, but has not had sufficient confirmation from users that they have received and acted on this information.</p> <p>A copy of the FSN is in the appendix of this alert, and it is also available on the MHRA website.</p> <p>This alert has been issued in support of the manufacturer's actions.</p>	<ul style="list-style-type: none"> • Ensure that relevant members of staff are aware of the problem. • Carry out the actions described in the manufacturer's FSN, including sending any confirmation requests.
Action by	
<p>All those involved in the maintenance and use of these chairs. In particular: equipment store managers, nursing and residential care home managers, nurses, occupational therapists, care staff, maintenance staff and contractors.</p>	
CAS deadlines	Contact
<p>Action underway: 25 May 2011</p> <p>Action complete: 14 July 2011</p>	<p>Manufacturer Paul Richards Roma Medical Aids Ltd Tel: 01656 674 488 Fax: 01656 674 499 Email: info@romamedical.co.uk</p>

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- OFSTED (Directors of Children's Services) for information
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

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

- All wards
- Equipment store managers
- Health and safety managers
- Maintenance staff and contractors
- Nurses
- Nursing executive directors
- Occupational therapists
- Physiotherapists
- Risk managers

Primary care trusts

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

- Community hospital
- Equipment store managers
- Maintenance staff and contractors
- Nurses
- Occupational therapists
- Palliative care team
- Physiotherapists
- Risk managers

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Equipment store managers
- In-house residential care homes
- Maintenance staff and contractors
- Occupational therapists
- Risk managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Nursing agencies

Establishments registered with OFSTED

This alert should be read by:

- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer

Paul Richards
Roma Medical Aids Ltd
York Road
Bridgend Industrial Estate
Bridgend
CF31 3TB

Tel: 01656 674 488

Fax: 01656 674 499

Email: info@romamedical.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/042** or **2010/010/013/401/005**

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

Tel: 01253 596 000

Fax: 01253 596 177

Email: 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

Health Estates Investment Group

Room 17

Annex 6

Castle Buildings

Stormont Estate

Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: 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

Email: 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 Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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Addressees may take copies for distribution within their own organisations

Appendix



FSN 2011.02
Ref: 2010/010/013/401/005

Roma Medical Aids Ltd
York Road
Bridgend Ind. Estate
Bridgend
CF31 3TB
T: 01656 674488
F: 01656 674499

02/03/2011

**Urgent Field Safety Notice
Corrective Action
Romachair Model 4730 / 4740**

Attention: Ward Managers where Romachairs are in use

Roma Medical has been made aware of an incident where an arm became detached from the chair causing the user to fall. It is possible that the arm became detached due to being incorrectly fitted. The arm detaching during use could lead to injury to the user.

To overcome this problem Roma Medical has updated the user manuals to clarify the fitting procedure and developed armrests which will prevent incorrect fitting.

Please contact Roma Medical Aids to arrange replacement armrests and updated user manuals.

Distribution:

This Field Safety Notice should be distributed to all those involved with Infection Control / Ward Managers.

The undersigned confirms that this notice has been transmitted to the appropriate Regulatory Agency (M.H.R.A).

A handwritten signature in black ink, appearing to read "P. Richards".

Paul Richards
Technical Manager
Roma Medical Aids Ltd



Roma Medical Aids Ltd
York Road
Bridgend Ind. Estate
Bridgend
CF31 3TB
T: 01656 674488
F: 01656 674499

FSN 2011.02
Ref: 2010/010/013/401/005

21/02/2011

Confirmation of receipt of Field Safety Notice request.

Action: Armrest update model 4730 / 4740 Romachair

Roma Medical Aids Ltd requires acknowledgement of the receipt of the Field Safety Notice FSN 2011.02.

Please confirm receipt of the notice by faxing back this completed form to 01656 674499 or by email to info@romamedical.co.uk

I,..... acknowledge the receipt of the FSN 2011.02 and confirm that the information has been communicated to the parties involved.

Facility / Address:-

.....
.....
.....
.....

Post Code.....

Contact Name.....

Signature.....

Position.....

Date.....