

Medical Device Alert

Ref: MDA/2011/048 Issued: 17 May 2011 at 11:00

Device

Heavy Duty Rollator – titanium coloured.

Model Number – L97986.

Manufactured by Nottingham Rehab Supplies (NRS).

Manufactured from 2007 to February 2010.



Problem

Due to a manufacturing fault, the device is not strong enough for the intended maximum user weight.

There is potential for a sudden failure of the device that could cause the user to fall.

The manufacturer has reduced the maximum user weight for this model and issued a [Field Safety Notice \(click here\)](#).

Action by

All those involved in the prescription, provision, maintenance or use of these rollators. In particular: occupational therapists, physiotherapists, equipment store managers, maintenance staff and contractors.

Action

- Trace all affected rollators and immediately withdraw from use if the user weighs more than 136kg (21st)
- Contact NRS to arrange for a suitable replacement.
- If continued use is appropriate, ensure that the revised labels are fitted to affected rollators and revised instructions for use, obtainable from the manufacturer, are supplied to the user.

CAS deadlines

Action underway: 02 June 2011

Action complete: 14 July 2011

Contact

Manufacturer/supplier

Mr John Turner
Nottingham Rehab Supplies
Tel: 01530 418363

Email: jturner@nrs-uk.co.uk

Problem

For a period of three years this model of rollator was manufactured using tubing of a thinner wall material than originally specified.

This model has been supplied with a label and instructions that indicate a maximum user weight of 227kg (36st). As a result of the incorrect tube thickness the maximum user weight is reduced to 136kg (21st).

Wider models of this rollator are coloured blue and are not affected.

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 (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- 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

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

- Equipment store managers
- Health and safety managers
- Maintenance staff and contractors
- Occupational therapists
- Physiotherapists
- Purchasing managers
- Risk managers
- Supplies managers

Primary care trusts

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

- Community hospitals
- Equipment library and store Manager
- Maintenance staff and contractors
- Occupational therapists
- Physiotherapists

Social services

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 store managers
- In-house residential care homes
- Occupational health departments
- Occupational therapists

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

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

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Nottingham Rehab Supplies (NRS)
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Ashby de la Zouch
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LE65 1JG

Tel: 01530 418363
Fax: 0845 121 8112
Email: jturner@nrs-uk.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/048** or **2010/010/020/401/007**

Technical aspects

Christopher Hill 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

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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