

Medical Device Alert

Action

Ref: MDA/2011/018 Issued: 17 February 2011 at 14:30

Device

Action 3 NG manual wheelchairs manufactured by Invacare, fitted with the angle adjustable backrest.



Problem

Due to poor welding during manufacture, the backrest can fail during use, leading to a fall for the user or the carer.

Invacare issued a [Field Safety Notice \(FSN034\)](#) in October 2010 but has been unable to trace all users, especially where the backrest has been supplied as a spare part.

Action by

All those involved in the provision, use and maintenance of these wheelchairs. In particular: wheelchair service managers, rehabilitation engineers, maintenance staff and contractors, and occupational and wheelchair therapists.

Action

- Trace affected wheelchairs manufactured between 01/11/09 and 02/04/10 (serial numbers listed on page 2).
- Trace backrests supplied as spare parts between 01/11/09 and 30/04/2010.
- Obtain replacement backrest assemblies from Invacare and arrange for them to be fitted.

CAS deadlines

Action underway: 17 March 2011

Action complete: 17 May 2011

Contact

Manufacturer
 Technical Services Department
 Invacare
 Tel: 01656 776333
 Fax: 01656 776330
 Email: UK@invacare.com

Device

Invacare has identified a batch of these backrest assemblies that were not manufactured to the correct specification.

Serial numbers of affected wheelchairs

050919126501 050919296869 050919477417 051019829119 051020062620
050919134252 050919317194 050919477765 051019885426 051020087952
050919140038 050919317330 050919604010 051019927096 051020107527
050919171578 050919324628 050919640180 051019940006 051020107540
050919186085 050919333600 050919661420 051019955052 051020140714
050919186568 050919334329 051019707763 051019978928 051020178166
050919195089 050919342563 051019715266 051019979060 051020217356
050919202196 050919383982 051019722185 051019987085 051020225329
050919228025 050919423053 051019754949 051019993748 051020263399
050919235166 050919463698 051019769329 051020033953 051020332567
050919273217 050919470020 051019777679 051020034002
050919296551 050919477147 051019805069 051020047895

During this period Invacare also supplied a number of these affected backrest assemblies as spare parts but they do not carry any specific identifying mark or label to aid traceability.

Distribution

This MDA has been sent to:

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

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:

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

Primary care trusts

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

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- 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
- Wheelchair and seating service 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)
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector

Establishments registered with OFSTED

This alert should be read by:

- Educational establishments with facilities for wheelchair users
- 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

Technical Services
Invacare Limited
Pencoed Technology Park
Pencoed
Bridgend
CF35 5HZ

Tel: 01656 776 333

Fax: 01656 776 330

Email: UK@invacare.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/018** or **2010/002/019/401/009**

Ed Ball or James McVeigh
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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