

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/80

Issued: 19th September 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section		
Medical Device/Equipment: Invacare Action 2000 wheelchairs (blue frame).	▶ ①		
Problem: Sudden detachment of the seat canvas allowing the user to fall.	▶ ②		
Action by: All those involved in the management, repair and maintenance, and use of wheelchairs. In particular wheelchair service managers, loan store managers, rehabilitation engineers, occupational therapists and wheelchair maintenance staff and contractors.	▶ ③		
Action: <ul style="list-style-type: none"> Trace all Action 2000 wheelchairs with blue frames, in use or in storage, supplied from Invacare between 01 November 2006 and 30 June 2007 with serial numbers as shown on page 2 and ensure that all seat canvas fixing rods are replaced. Contact Invacare for new seat canvas fixing rods and fitting instructions for those within the serial number range. 	▶ ④		
Distributed by NIAIC to: <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers </td> <td style="width: 50%;"> Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users) Hospices </td> </tr> </table>	Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users) Hospices	▶ ⑤
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Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.	▶ ⑥		
Feedback Requirements to NIAIC None required.	▶ ⑦		

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Five batches of Action 2000 wheelchairs are potentially involved. They were all manufactured in 2006 and supplied to purchasers between 01 November 2006 and 30 June 2007. Invacare states that the models affected all have blue coloured frames.

The serial number ranges of the affected wheelchairs are as follows:

7006514025 to 7006514270
7006517882 to 7006518127
7006518128 to 7006518378
7006519406 to 7006519651
7006520118 to 7006520363

2. PROBLEM:

The MHRA has received reports of seat canvasses on Action 2000 wheelchairs suddenly detaching from the seat rail. In some cases the users have fallen and sustained injuries. The seat canvas is slung between two seat frame rails. The canvas is retained within a groove in each rail by a hollow plastic tube inserted into the looped edge of the canvas. Investigation has revealed that some of the hollow tubes have been produced with an irregular wall thickness. The thinning of the wall is such that the tube can suddenly collapse allowing the seat canvass to pull out of the groove. Collapse may not necessarily occur the first time the wheelchair is used. It may arise during subsequent use or following a heavy landing when transferring. The failure is sudden and without warning.

3. ACTION BY:

All those involved in the management, repair and maintenance, and use of wheelchairs. In particular wheelchair service managers, loan store managers, rehabilitation engineers, occupational therapists and wheelchair maintenance staff and contractors.

4. ACTION:

- Trace all Action 2000 wheelchairs with blue frames, in use or in storage, supplied from Invacare between 01 November 2006 and 30 June 2007 with serial numbers as shown on page 2 and ensure that all seat canvas fixing rods are replaced.
- Contact Invacare for new seat canvas fixing rods and fitting instructions for those within the serial number range.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Equipment stores
- Health and safety managers
- Independent Health and Social Care Providers – Private Hospitals, Clinics, Residential and Nursing Homes through RQIA
- Loan store managers
- Maintenance staff and contractors
- Occupational health departments
- Occupational therapists
- Physiotherapists
- Rehabilitation engineers
- Risk managers
- Wheelchair service managers
- Community Care Staff
- Social Care Staff

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Technical Services Department
Invacare UK Operations Limited
South Road
Bridgend Industrial Estate
Bridgend
CF31 3PY

Tel: 01656 647 327

Fax: 01656 649 016

E-mail: uk@invacare.com

Enquiries to NIAIC should quote reference number MDEA(NI)2007/80 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

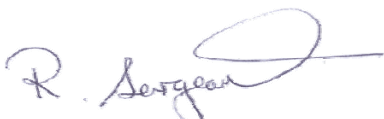
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required.



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety