

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/81

Issued: 19th September 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section								
<p>Medical Device/Equipment: Invacare Action³ wheelchairs fitted with a manual ratchet recliner mechanism.</p>	▶ ①								
<p>Problem: Risk of injury to the user or carer from the sudden failure of the backrest ratchet</p>	▶ ②								
<p>Action by: All those involved in the provision, prescription, repair, maintenance and use of wheelchairs. In particular wheelchair service managers, loan store managers, rehabilitation engineers, occupational therapists and wheelchair maintenance staff and contractors.</p>	▶ ③								
<p>Action:</p> <ul style="list-style-type: none"> Trace all Action³ wheelchairs fitted with ratchet recliner mechanisms with a serial number lower than 050711235973 and inspect the ratchet plates. Withdraw from service all those wheelchairs showing signs of damage until such time as a new design replacement ratchet can be fitted. 	▶ ④								
<p>Distributed by NIAIC to:</p> <table border="0"> <tr> <td>Chief Executive of each HSS Board</td> <td>Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users)</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Hospices</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	Education and Library Boards (for onward distribution to educational establishments that have facilities for wheelchair users)	Chief Executive of each HSS Trust	Hospices	Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
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NIAIC Liaison Officers									
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥								
<p>Feedback Requirements to NIAIC None required</p>	▶ ⑦								

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

1. DEVICE/EQUIPMENT:

All Action³ manual wheelchairs fitted with a mechanical backrest ratchet recline mechanism with a serial number lower than 050711235973 manufactured between May 2004 and February 2007.

2. PROBLEM:

The MHRA has received reports of the failure of the teeth of the recliner mechanism on Invacare Action³ wheelchairs fitted with the manual ratchet recline option. Some teeth have distorted and others have sheared off allowing the backrest to drop backwards suddenly. Reports of injury, including head injuries, to users falling from their wheelchairs have been received.

The problem arises because the locating pin can float sideways to such an extent that it loses contact with one of the ratchet plates. The load on the backrest is then held by only one of the teeth on the other ratchet plate. In such circumstances, depending on the weight of the user and the usage of the wheelchair, the remaining teeth can fail under the load.

Invacare believes that a manufacturing change first applied on 12 May 2004 may have introduced the problem.

The original instructions for use for the wheelchair give no guidance regarding the need to make any specific routine examination of the reclining mechanism of models fitted with this form of reclining backrest.

In February 2007 Invacare initiated a design change that introduced a steel cage to the outside of the ratchet plate, reducing the free play in the pin and intending to ensure its continuous contact with the ratchet plate on both sides.

3. ACTION BY:

All those involved in the provision, prescription, repair, 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 Action³ wheelchairs fitted with ratchet recliner mechanisms with a serial number lower than 050711235973 and inspect the ratchet plates.
- Withdraw from service all those wheelchairs showing signs of damage until such time as a new design replacement ratchet can be fitted.
- Warn users/carers of those wheelchairs not currently exhibiting damage of the potential failure and advise them to examine regularly until the unit can be replaced.
- Contact Invacare for the required parts and fitting instructions. Make arrangements to fit the new ratchet steel cage to all the identified wheelchairs.

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:

Customer Services
Invacare UK Operations Ltd
South Road
Bridgend Industrial Estate
Bridgend
CF31 3PY

Tel: 01656 647 327
Fax: 01656 649 016

E-mail: uk@invacare.com

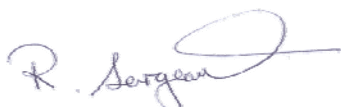
Enquiries to NIAIC should quote reference number MDEA(NI)2007/81 and be addressed to:

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