

HN (NI) 2002/10

DATE: 19 November 2002

**For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency**



**HEALTH ESTATES
ESTATE POLICY**

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

TITLE:

**INVACARE LTD – STORM³ POWERED
WHEELCHAIR – RISK OF DRIVE WHEEL
BECOMING DETACHED**

MANUFACTURER/SUPPLIER

Invacare Ltd

PROBLEM

There have been instances of drive wheels becoming detached due to an assembly error during manufacture. If detachment occurs when the wheelchair is in use, the user could sustain injury as the wheelchair tips.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Device Managers
- Estates Managers
- Nurse Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Wheelchair Service Managers
- Supplies Staff
- General Medical Practitioners (for information)
- Social Care Staff
- Community Care Staff
- Occupational Therapists (involved in wheelchair provision)
- Physiotherapists (involved in wheelchair provision)
- Rehabilitation Engineers
- Wheelchair Repair Services
- Day Care Services for elderly or Disabled People
- Day Centres
- Education and Library Boards
- Residential and Nursing Homes
- Hospices
- Private Clinics

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

IMMEDIATE ACTION

Trace all Storm³ powered wheelchairs delivered between 28 February 2002 and 25 July 2002 with serial numbers in the range IGIAB220672001 to IGIAB262762001 and 0602010784 to 0602981022. Arrange for the wheel fixing screws to be replaced as soon as possible in accordance with the manufacturer's instructions – see Invacare Safety Bulletin T1009 at appendix A .

**HAZARD
NOTICE**



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BACKGROUND

Reports have been received by both the Medical Devices Agency (MDA) and Invacare Ltd, of the rear wheels becoming loose on the Storm³ powered wheelchair. In one particular incident the user was injured when the wheel became fully detached.

Invacare Ltd has issued a Safety Bulletin to all affected customers, advising that immediate action needs to be taken to eliminate the possibility of further incidents.

During production a faulty tool did not tighten the wheel fixing screws to the correct torque. As a result there is a possibility that the fixing screws can work loose and the wheel detach. All Storm³ wheelchairs delivered between 28 February 2002 and 25 July 2002 are affected and will require the wheel fixing screws to be replaced.

The action necessary to eliminate the problems is described in the manufacturer's Safety Bulletin (see appendix A) and consists of replacing the four fixing screws on each drive wheel with new screws supplied by the manufacturer. There will also be a reimbursement of fitting costs of £35.00 for each wheelchair rectified.

Note: Only the Storm³ wheelchairs are affected. Other variants of the Storm use different fixing methods.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Kevin Humphries
Director of Technical Services
Invacare Ltd
South Road
Bridgend Industrial Estate
Bridgend
Mid Glamorgan
CF31 3PY
Tel: 01656 753270
Fax: 01656 649016

Enquires to the NIAIC should quote the reference number HN(NI) 2002/10 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US
Marked for the attention of Mr Brian Godfrey

Tel: 02890 523714
Fax: 02890 523900
Email: brian.godfrey@dhsspsni.gov.uk

Brian Godfrey
NIAIC 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 Safety Notice SN (NI) 2002/01. 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
Aisíneacht Feidhmeannach don Roinn Sláinte, Serbhísí Sóisialta agus Sábháilteacht Phoiblí*



Bulletin no: TI009
Date: 5th September 2002

SAFETY BULLETIN - POSSIBILITY OF LOOSE SCREWS ON STORM³ REAR DRIVE WHEELS

We have been notified by our manufacturing unit in Germany that due to an assembling error it could be possible that the 4 off M8 x 30 screws securing the rear wheel can start to loosen.

An air pressure driven screwdriver with a defined torque of 30 Nm was used but during some checks found the torque was less than 30 Nm.

This could effect a number of Storm³ wheelchairs manufactured before 21st May 2002, which will need to be checked immediately.

From our records you have been supplied with some of these wheelchairs and may have provided them to your customers.

To eliminate any possibility of the rear wheels coming loose, please carry out the necessary rectification action by removing the 4 fixing screws from both rear wheels and replacing them with the fixing kit supplied. The kit comprises of; 8 X M8 X 30 screws. (These have locking compound already applied to the screw threads). Fitting instructions are enclosed.

The screws have to be tightened to a torque of 30 Nm.

Invacare Limited will reimburse you the sum of £35.00 for each chair you rectify.

To advise of chair(s) that have been rectified, please complete the information in the attached list and return it to:

Mr Kevin Humphries
Director Technical Services
Invacare Ltd, South Road, Bridgend Industrial Estate,
Bridgend, CF31 3PY.

Invacare Ltd
South Road Bridgend Industrial Estate Bridgend CF31 3PY
Tel: 01656 647327 Fax: 01656 649016