

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/18

Issued: 13 February 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

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	Section
Medical Device/Equipment: Patient hoists: Invacare C800 series ceiling track.	▶ ①
Problem: There is a risk of injury resulting from falls due to failures of the motor drive in C800 series hoists manufactured between December 2000 and September 2005.	▶ ②
Action by: All those involved in the use and maintenance of ceiling track patient hoists, in particular nurses, care staff and maintenance staff or contractors.	▶ ③
Action: <ul style="list-style-type: none"> Identify Invacare C800 series ceiling track patient hoists with the following chassis numbers: 3117, 3118, 3119, 3132 and 3143 to 5188. If the patient hoist is over 5 years old withdraw from service and arrange for a replacement hoist. If the patient hoist is less than 5 years old contact Invacare to arrange for the motor gearbox units to be replaced. Ensure all C800 series hoist users and maintenance staff are aware of the need for maintenance and replacement as described in the manufacturer's instructions for use. Report any further incidents to NIAIC and Invacare UK Ltd. 	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	Hospices ▶ ⑤
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:

Invacare C800 series ceiling track patient hoists manufactured between December 2000 and September 2005 with chassis numbers 3117, 3118, 3119, 3132, and 3143 to 5188. Both single and double motor models are involved. These hoists may have been purchased from a supplier rather than directly from Invacare and may also have been passed on to subsequent users.

2. PROBLEM:

The MHRA has received reports of adverse incidents resulting from a sudden failure of the motor drive shaft of Invacare C800 series patient hoists manufactured between December 2000 and September 2005. One patient has been injured. There is a risk of similar incidents happening elsewhere as the failure can occur suddenly when the hoist appears to be fully functional.

Some C800 hoists are fitted with two motors, each acting as a failsafe for the other. However, if one of the motor drives fails, the hoist operator and patient may not be aware of the failure as there is no warning device fitted. It is possible to continue to operate the hoist with a reduced lifting speed using one motor drive unit. If the second motor drive then fails there is no failsafe and the patient is dropped. In single motor units the failure is sudden and unexpected.

Invacare recommends that the average life of the C800 series patient hoists is 5 years or 10,000 lift cycles, whichever occurs first. As the hoists do not incorporate cycle counters, units over 5 years old should not be used.

Invacare has compiled a technical bulletin covering these issues, which is attached to this Alert.

3. ACTION BY:

All those involved in the use and maintenance of ceiling track patient hoists, in particular nurses, care staff and maintenance staff or contractors.

4. ACTION:

- Identify Invacare C800 series ceiling track patient hoists with the following chassis numbers: 3117, 3118, 3119, 3132 and 3143 to 5188.
- If the patient hoist is over 5 years old withdraw from service and arrange for a replacement hoist.
- If the patient hoist is less than 5 years old contact Invacare to arrange for the motor gearbox units to be replaced.
- Ensure all C800 series hoist users and maintenance staff are aware of the need for maintenance and replacement as described in the manufacturer's instructions for use.
- Report any further incidents within Northern Ireland to NIAIC and Invacare UK Ltd.

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:

- Clinical governance leads
- Care management team managers
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Domiciliary care providers (personal care services in the home)
- District nurses
- Equipment stores
- Estates and facilities managers
- Health and safety managers
- In-house & external maintenance staff
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Manual handling trainers
- Nurse Directors
- Nursing staff
- Occupational therapists
- Physiotherapists
- Purchasing managers
- Risk managers
- Safety officers

6. CONTACTS:

Enquires to manufacturer should be addressed to:

Darran James or Mike Hughes
Invacare Ltd
South Road
Bridgend Industrial Estate
Bridgend
CF31 3PY
Tel: 01656 664 321
Fax: 01656 667 532

E-mail: mhughes@invacare.com or
djames@invacare.com

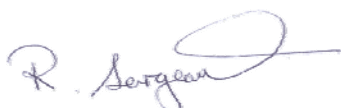
Enquires to NIAIC should quote reference number MDEA(NI)2007/18 and be addressed to:

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:

No 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

Technical Information Bulletin & Field Correction

Action Plan C800 Range of Hoists

The longevity of the C800 ceiling hoist can be best assured with regular inspection and maintenance. As your equipment ages it will be subjected to normal wear and tear from every day usage, parts become worn, and load bearing components may become fatigued. Therefore, it is important that as your hoist ages it is regularly and thoroughly serviced, this is particularly relevant for hoists that are approaching the end of product life (see below). NB. It is also important that your equipment is checked / serviced to the relevant Lifting Operations & Lifting Equipment Regulations (LOLER) at the recommended intervals. More specific details of inspection and maintenance procedures can be found in the product user manual.

A small number of incidents have been reported where the worm of the drive motor has fractured. It is reasonable to assume that the failure risk could have been reduced substantially with thorough preventive maintenance

In the interests of patient safety, any unusual noise or operation seen / heard during operation of your hoist must be reported to your regular repairer / dealer, or, if you prefer, please contact Invacare directly, via the Technical Service Department who will be pleased to assist with any enquiry.

The C800 range has been successfully tested and completed 10,000 lift cycles, which represents the products warranted working life. Invacare recommends that the average usable life of this product is 5 years / 10,000 cycles, providing the product has been correctly maintained according to the manufacturer's recommendations. Consideration should be given to replacing the product, or, as a minimum, replacing the lift motors when the end of life point is reached.

Technical Services Department

Tel. 01656 647327

Fax. 01656 649016

Action Plan

1. C-800 products sold by Invacare-UK in the UK market and covered under warranty (Warranty is 2 years)

Period from January 2005 till Sept. 2005.

1. The affected motor gearboxes will be replaced free of charge by new ones.
2. Customers considering a replacement of the C-800 hoist by a new Invacare Robin hoist will be offered a very attractive price offer.

2. C-800 sold by Invacare UK between 2002 – December 2004

1. All customers are proposed a replacement of the C-800 Hoist by a new Invacare Robin hoist with a very attractive price offer, or
2. The suspected motor gearbox will be replaced free of charge by a new one.

3. C-800 sold by Invacare UK between 1991 – December 2002, more than 5 years in use

The MHRA recommends to refrain using the C-800 hoist, referring to the life expectation of lift devices (hoists), see section 10 DB 2006(05) on the MHRA website. To support the MHRA recommendation, Invacare UK proposes the replacement of the C-800 Hoist by a new Invacare Robin hoist with a very attractive price offer.

Customers who want to consider one of the proposed solutions are invited to contact:

Invacare UK

Technical Services Department

Tel. 01656 647327

Fax. 01656 649016