

**Notice Information: - Advisory
11 November 2011**

Part 1. Product Information

- a) Title: Storm3 Range (including Storm3 TT), Typhoon I & Typhoon II Power Wheelchairs
- b) Product Name/Type: Storm3 Range (including Storm3 TT), Typhoon I & Typhoon II Power Wheelchairs
- c) Reference: SN2011(25)
- d) Manufacturer/Supplier: Invacare Ireland Limited

Part 2. Target Audience

- a) Target Audience:
- General public
 - Hospital CEOs
 - Risk Managers
 - Procurement Managers
 - Loan Store Managers
 - HSE Offices
 - Community Care Centres
 - Occupational Therapists
 - Community Care Managers
 - Community Therapists
 - Health Visitors
 - Carers
 - Educational Establishments

Part 3. Problem/Issue

a) Problem/Issue:

Invacare issued a field safety notice informing their customers of an update to transportation information provided in the user manual for the Storm3 and Typhoon Range power wheelchairs. Users of Storm3 and Typhoon Range power wheelchairs should read the attached Invacare field safety notice to determine if this information may have an impact on their transportation requirements.

Part 4. Background Information

a) Background Information:

Until 2008, the four point tie-down systems generally available on the market were only rated to 140 kg. The actual weight of highly configured Invacare® power wheelchairs exceeds 140 kg. Therefore, there is a risk of failure of the existing tie-down system if the vehicle is involved in an accident while using a four-point tie down system with the Storm3 and Typhoon Range power wheelchairs.

A new 4 point tie down system is now available from Invacare, which has been tested to ISO 10542-5 and ISO 7176-19. This crash capable system is designed specifically for Storm3 Range and Typhoon Range power wheelchairs. As outlined in the attached field safety notice, this issue only affects power wheelchairs purchased before 21st July 2008 and these affected Storm3, Typhoon I and II must be upgraded if users wish to use the power wheelchair as a seat in a vehicle during transportation. All relevant information relating to this upgrade can be found in the attached field safety notice, FSN014, issued by Invacare on the 8th November 2008.

Invacare have been unsuccessful in their attempts to date to locate all devices in Ireland affected by this field safety corrective action. There are approximately 50 Storm3 and Typhoon Range power wheelchairs on the Irish market, where this upgrade is outstanding.

Part 5. Action to be taken

a) Action to be taken:

The IMB advises that users:

1. Ensure the appropriate personnel are made aware of this notice.

2. Identify the location of all affected power wheelchairs.

3. If you / your institution have affected power wheelchairs, follow the manufacturer's recommendations as outlined in the attached field safety notice and ensure that the corrective action is completed on all affected medical devices.

Part 6. Enquiries

- a) All enquiries should be made to:

Enquiries to the manufacturer should be addressed to:

Neil Harvey

Invacare Ireland Limited

5 Seatown Business Campus

Seatown Road

Swords

Co. Dublin

Telephone: 01-8107084

Fax: 01-8107085

Email: nharvey@invacare.com

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

[Please click here to download of PDF copy of this Safety No](#)

Please click here to download of PDF copy of this Safety Notice

Please click here to download a copy of the Field Safety Notice