



Bulletin Number: FSN014

## **Urgent Field Safety Notice**

### **Transportation of Storm<sup>3</sup> Range (Including Storm<sup>3</sup> TT), Typhoon 1 & 2 Power Wheelchairs. Update to original Medical Device Alerts**

Date: 8<sup>th</sup> November 2008

Ref: FSN007 (Typhoon 1 and Typhoon 11) – MDA/2008/014, 17<sup>th</sup> March 2008  
Ref: MDA/2008/035, 28<sup>TH</sup> May 2008 (Storm<sup>3</sup> and Storm<sup>3</sup> True Track (TT))  
(2008/008/018/301/001)

#### **Urgent Safety Information:**

In the interest of the safety of our product users, we would like to clarify the transportation information provided in the user manual for these Invacare<sup>®</sup> power wheelchairs. Please note that until recently, the four point tie-down systems generally available on the market were only rated to 140 kg. The actual weight of highly configured Invacare<sup>®</sup> power-chairs exceeds 140 kg. 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 Storm<sup>3</sup> and Typhoon Range powerchairs.

New 4 point tie down systems have been successfully tested to ISO 10542-5 and ISO 7176-19. This crash capable system is designed specifically for Storm<sup>3</sup> Range and Typhoon Range powerchairs. Each product range has its own specific part number and maximum weight specification.

Storm<sup>3</sup>, True Track (TT), Unwin part number is TDN-06265-A. (Max. weight 175Kg)  
Typhoon 1 and 11, Unwin part number is TDN-06160-A. (Max. weight 190Kg)

- Please contact Promotability direct to purchase 4 point tie down system specific to your powerchair

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In order to enable safe and correct connection with the new Unwin tie down system, modified tie down brackets are required and are mandatory for safe transportation. Invacare® has replaced the original laser cut brackets assembled on the above models of powerchairs. The new brackets are manufactured with round bar to maximise the performance of the tie down system, and also provides added safety by protecting the tie-down system from risk of damage. As of 21<sup>st</sup> July 2008 all newly purchased powerchairs will have the amended design of bracket assembled to the powerchair when transportation of the chair is required (option selected on prescription form). There is no requirement to take any action relating to this safety notice if your wheelchair was purchased after 21<sup>st</sup> July 2008.

For powerchairs purchased before that date, Storm<sup>3</sup>, Typhoon I and II must be upgraded if you wish to use the powerchair as a seat in a vehicle during transportation. If you have purchased the powerchairs in the past with this option then the upgrade 'brackets' kit will be issued 'Free of Charge'.

Please contact the Invacare® Technical Services Department who will advise you if your chair will be issued with brackets Free of Charge.

Part numbers for the "upgrade kit" are listed below, specific to the design of chair. The correct system is required for the specific chair range.

SP1523487 – Storm<sup>3</sup> (Including True Track (TT))  
SP1523488 – Typhoon 1  
SP1523486 – Typhoon 11

- The kit will contain brackets, screws and a mounting instruction leaflet. The mounting is identical to the old brackets and fasteners.
- Assembly Instructions for all of the above kits are attached.

Consideration will also be given to a call out charge of Euro 45 but this will depend on the customer completing all the necessary steps and notification. Invacare® need to be aware that the upgrade has been completed as per instructions supplied with each kit and the requirement of sending back to Invacare Technical Services a 'Fax Back Acknowledgment' form which will ensure that the field action is closed for each affected chair that has been purchased.

### **Warning Notification:**

The new Unwin 4-point tie down system is not tested with the Storm / Storm<sup>2</sup> powerchairs. The production of Storm / Storm<sup>2</sup> was stopped in mid of 2002. Products or spare parts are no longer available and have exceeded the 5 years spare parts availability policy which was our obligation under the Medical Device Directive 93/42/EEC. Customers who have a Storm / Storm<sup>2</sup> with an unladen weight of more than 140 kg, and require their powerchair to be used as a seat within the vehicle are recommended to change their power wheelchair as the recommended life cycle has been exceeded. Additionally, there is no suitable tie down system available for Storm / Storm<sup>2</sup> chairs weighing over 140kg. However there will be Storm / Storm<sup>2</sup> chairs weighing below 140kg to which you can continue to be transported in the chair using tie downs systems presently available on the

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market for chairs up to 140kg. It is important that your chair is regularly serviced and maintained as directed in your user manual.

A weight indication can be found on the serial label located on your powerchair, usually situated under the seat, on the front frame structure. Alternatively please contact your approved repairer to clarify weight of your chair. If your powerchair is configured with electrical elevating legrests or a seat riser then there is a greater possibility that the weight of the chair is above 140kg. For guidance on the unladen weight of your chair, please refer to the technical data located at the back of the user manual supplied with your powerchair when originally purchased. **NB.** If in doubt, please arrange for your chair to be weighed.

- **Overview**

<b>Powerchair Model</b>	<b>Transportation Solution or Recommendation</b>
Storm / Storm <sup>2</sup>	If over 140Kg then do not use as a seat in transport. Chair can still be used otherwise.
Storm <sup>3</sup>	Unwin Tie down system or Docking station.
Storm <sup>3</sup> TT (Same design chair only specification of motor is the difference)	Unwin Tie down system.
Typhoon 1	Unwin Tie down system or Docking Station
Typhoon 11	Unwin Tie down system or Docking Station

As an alternative solution the Storm<sup>3</sup> range (which includes Storm<sup>3</sup> TT), Typhoon 1 and 11 can be safely transported using a crash tested docking station available from Invacare, part numbers are listed in the table below. Please contact Invacare if you require the details. Invacare strongly urges users of Storm<sup>3</sup> power-chairs to familiarise themselves with the restraint and docking systems they are using and their limitations in use.

<b>Powerchair Model</b>	<b>Part Number (Car fixation kit)</b>	<b>Part Number (Chair Kit)</b>
Storm <sup>3</sup> / Storm <sup>3</sup> TT	1498274	SP1498275
Typhoon 1	1504830	SP1505049
Typhoon 11	1510997	SP1505049

Invacare Product information bulletin PU249 will also be re issued to support this latest information update.

User manuals for Storm<sup>3</sup> and Typhoon 11 are currently being updated and will also be available in the near future to support this change. The IFU (Instruction for Use) will be uploaded to the Invacare UK website as soon as possible. This information will also be added to the 'Product Information Update Bulletin'.

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and / or customer base, and that awareness is maintained for an appropriate period.

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Invacare acknowledges that this may be an inconvenience; however it is not an option and must be done immediately to mitigate the potential safety risk.

If you have any questions relating to this bulletin, or should you require any additional information, please contact;

**Invacare Ireland**

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