



Urgent Field Safety Notice

Invacare XLT wheel chair

Date: 28th July 2010

Invacare ref: FSN031

Ref : 2009/003/010/301/001

Urgent Safety Information:

In the interests of the safety of our customers we would like to advise owners of XLT wheelchairs that some of the configurations are not suitable to be used as seat in transportation.

By this notification we would also like to point out that there is always risk involved in being transported whilst seated in the wheelchair.

The risk for injury during an incident increases when the wheelchair is fitted with a low backrest. INVACARE strongly advise against the use of XLT as a seat in a vehicle if the backrest is lower than **40 cm**.

Advice on action to take:

If you are owner of an XLT wheelchair with backrest lower then **40 cm** we would like you to cover the “hook” label with a warning label. The warning label is provided by Invacare customer service.



The instructions for use and the prescription form have been amended accordingly. Current revision of the user manual, part no 1512799-4 can be downloaded from the Invacare website – www.invacare.co.uk . Alternatively, please contact Technical Service Department, where you may request a copy of the latest revision of the user guide for your wheelchair.

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and / or customer base where the potentially affected devices have been transferred. Please also ensure that awareness is maintained for an appropriate period.

Affected National Competent Authorities will be advised by FSCA and FSN.

If you have any questions relating to this bulletin, or should you require any additional information, please contact Customer Service Department at Invacare,

Technical Services Department

Tel. 01656 776333

Fax. 01656 776330

Invacare confirms that the relevant Competent Authorities have been informed of this Field Safety Corrective Action.



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Transporting wheelchairs with users in vehicles

The Invacare Rea™ wheelchairs are designed to offer the user the best comfort and safety possible during all kinds of situations in everyday life. This means that compromises have to be made in order to make the product useful. During transport in cars, it is always safest to ride in the car's normal seat with the seatbelt on. You *should* ride in the car's normal seat and use the seatbelt if possible. If, for some reason, it is impossible to be transported in any other way the wheelchair can be used as a seat in a vehicle if the following rules and regulations are followed.

We would like to point out that there is always a risk involved in being transported seated in your wheelchair. The risk for injury during an incident increases when you have a wheelchair with a low backrest. The lower the back, the higher the risk for injury. Therefore, Invacare strongly advise against the use of XLT as a seat in a vehicle if the backrest is lower than 40 cm.

Even if the Invacare Rea™ products and the following rules are meant to increase safety during transport in vehicles, injuries to passengers can still occur if an accident should happen. Invacare does not leave any guaranties for the outcome of any accidents during transport of wheelchairs and users in vehicles.



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Customer response to Field Safety Corrective Action – FSN 031

Action Completed – please tick below	
Distribution of amended IFU	
Replacement kit / parts fitted	

This is to confirm that the necessary corrective action, as documented in the Field Safety Notice, FSN 031, dated 18th July 2010, is now complete.

Please send fax-back form to the Quality department at Invacare UK, fax number 01656 776244

Please note this is a new fax number which became active from 01/01/10 following Invacare’s change of premises. The previous number, 01656 753244 became inactive from 28/02/10.

The serial number(s) of the inspected / repaired product(s) are as follows:

Action Completed

Signed.....

Company.....

Contact No.....

Date.....

N.B. Please include all the serial numbers listed above on your invoice, this will enable Invacare to process your invoice quickly and ensure payment, where appropriate.

You have a responsibility under the Medical Device Directive to notify the manufacturer when corrective actions have been completed.