



Urgent Field Safety Notice

Invacare Typhoon II Power Wheelchair with Stability Lock

Distributed between December 2007 – October 2010

Serial number Range 060711692035 - 061020927702

Date: 9th December 2010

Invacare ref: FSN033

Urgent Safety Information:

Dear Customer:

In March of 2010, Invacare initiated a recall for its TDX-SP Power Wheelchair with Stability Lock. During our assessment of the technical issue (stability lock feature on some chairs may not be engaging properly or consistently) we have found a similar design for Typhoon II. We have decided to upgrade Typhoon II.

- If the stability lock feature does not engage properly, the wheelchair may exhibit a tendency to do one or more of the following:
 - (1) Veer to one side;
 - (2) Rock forward onto its front riggings;
 - (3) Drive in an unintended circular motion; and/or in worst case but the least probable
 - (4) Fall forward or to one side which could cause the user to fall out of the wheelchair if not wearing a safety belt.

The design of the stability lock, utilizing resistive cylinders, has generally proven quite effective, but in one incident case the stability lock has failed to engage properly.

Please read this letter and the instructions (included instructions are intended to address the correction of these failure) carefully and consider the necessary actions to be taken to help ensure the safety of your customers. If you do not understand or cannot perform what is being asked for, contact Invacare so arrangements can be made.

Invacare is requesting that you complete the required action **within 60 days of receipt of this letter.**

Serial number 061020927703 and above are not affected.

STEP 1: IMMEDIATE COMMUNICATIONS NEEDED

1. Please inform any customers to whom you have distributed this product about this recall.
2. Please immediately examine your inventory (including any presentation models) and quarantine all units in your inventory that are subject to this recall.
3. Please use for communication the provided mounting instruction.
4. Please use number SP1543130 for ordering the upgrade kit.
5. List of affected chairs attached.



STEP 2: DOCUMENTATION FOR COMPLIANCE WITH THIS RECALL

This recall is being monitored by the MHRA (Medicines & Healthcare product Regulatory Agency)

For each unit that you correct, please document your actions on the enclosed tracking sheet and either fax-back or e-mail Invacare UK Technical Services Department. Invacare will credit your account £60 for each wheelchair with Stability Lock that you complete the required corrective action.

Invacare realizes that this inspection, adjustment and installation is an inconvenience, however it is necessary and must be done immediately to prevent the remote chance of **serious injury or death to your customers**. This recall is to be carried out to the end-user level. Invacare is requesting that you complete this action **within 60 days of receipt of this letter**. If you are unable or unwilling to perform this fix or to contact your end-users or those to whom the end user has given the device, please indicate this on the enclosed response form and provide Invacare with a list of the names and addresses of the customers to whom you distributed the device and we will contact them.

Please ensure that the information in this notice is made available to all relevant personnel within your organisation and / or customer base.

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.