



Yes, you can.®

URGENT – MEDICAL DEVICE RECALL FOR PRODUCT CORRECTION

Invacare® TDX® series and Storm Series® power wheelchairs with 20”-24” width configurations with Formula CG Recline seating system (i.e. Tilt/Recline, Tilt/Recline/Elevate, or Recline only) and a conventional style back.

ARTG: 160385

APRIL 28th, 2015

Dear valued Customer

This letter is to provide you with important information concerning a potential defect involving Invacare® TDX® series and Storm Series (3G)® power wheelchairs. Invacare has recently identified a potential pinch point affecting the wiring involving Invacare® TDX® series and Storm Series (3G)® power wheelchairs with 20”-24” width configurations with Formula CG Recline seating system (i.e. Tilt/Recline, Tilt/Recline/Elevate, or Recline only) and a conventional style back. There is a possibility that if the slack in the wires is not routed and secured correctly, and with flexing of the back pan under the user’s weight, the headrest knob or clamp bracket may pinch, damage or cut the wire creating a hazard. Smoking, sparking, burning or fire may occur if any wire in this area is repetitively pinched at the same location over a period of time. Not all impacted chairs are expected to have slack in the wiring that is not routed and secured correctly.

To date, the manufacturer has received one complaint and there have not been any reported events involving injury associated with this issue. However, Invacare takes patient safety seriously, and the Company wants to ensure this potential wire routing issue is not present with the potentially impacted wheelchairs with power recline seating systems and conventional style back.

What is the problem?

There is a possibility that if the slack in the wires is not routed and secured correctly, and with flexing of the back pan under the user’s weight, the headrest knob or clamp bracket may pinch, damage or cut the wire creating a hazard. Smoking, sparking, burning or fire may occur if any wire in this area is repetitively pinched, at the same location, over a period of time. Not all impacted chairs are expected to have slack in the wiring that is not routed and secured correctly.

How do you determine impacted chairs?

Please examine the Invacare power wheelchair to confirm it has one of the potentially impacted serial numbers listed on the Unit Disposition form and Product Tracking Sheet enclosed. The serial number can be found per the following:

Storm RWD	On the rear of the frame - right side.
TDXSR	Inside of right rear swing arm and on the left side of the battery box.
TDXSP	Inside of right rear swing arm and on the left side of the battery box.

INVACARE AUSTRALIA PTY LTD

ABN 45 074 676 378

1 Lenton Place, North Rocks, NSW 2151

Phone: 1800 460 460 Fax: 1800 814 367 www.invacare.com.au



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What units are impacted?

The potentially impacted chairs with power recline seating systems were manufactured from October 1, 2006- July 31, 2014. Models are as follows:

TDX Series®	Storm Series®
TDXSP	3GTQ-MCG
TDXSP-AUS	STORM TORQUE
TDX SR-AUS	STORM TORQUE-AUS
TDX SR	RANGERX
	3GRX-CG
	ARROW 3G
	3GAR-TS

Why are you being contacted?

According to our records, you received one or more of the potentially impacted power wheelchairs and power recline seating systems. We have enclosed an impacted unit listing of the power wheelchair model and serial number(s) that were shipped to you on the Unit disposition form and Tracking Sheet.

What actions are required?

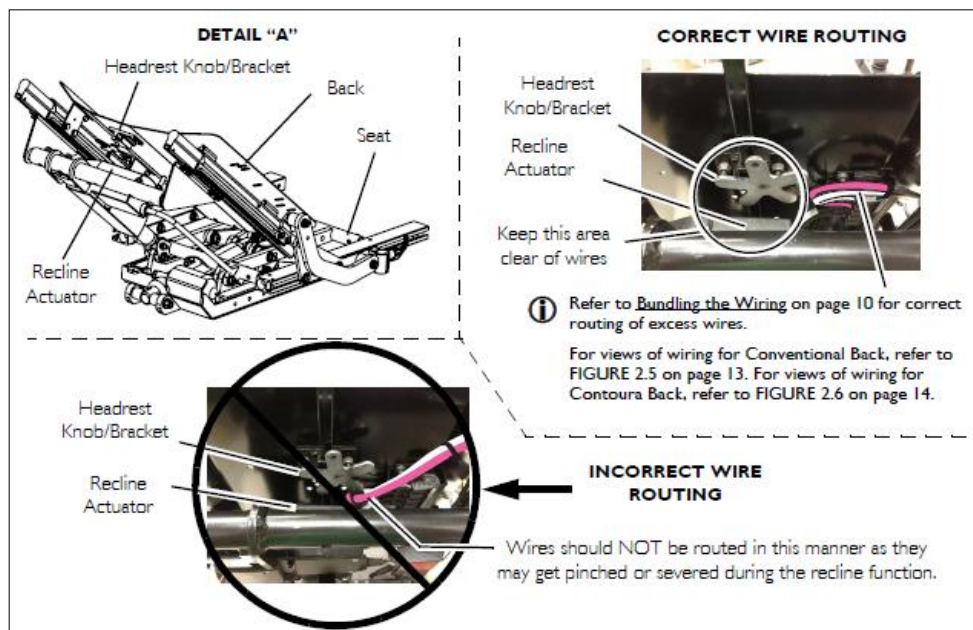
1. Please promptly complete and return the enclosed Provider Response Card to Invacare by FAX 1800 814 367 or email to recalls@invacare.com.au to confirm receipt of recall notification and your agreement to conduct it according to instructions.
2. If you have further distributed this product, please identify the power wheelchair owners and notify them at once of this issue and proposed actions. A recommended consumer letter is enclosed for your reference, and should be mailed immediately upon receipt. Please contact your customer to schedule an appointment to inspect the potentially impacted power wheelchair as soon as possible.
3. A visual inspection of the wiring shall be conducted for each impacted chair. The figures below reference correct wiring (page 8 of Power Wheelchair Wiring Guide):

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4. Verify that the wiring is routed and secured in accordance with the attached Power Wheelchair Wiring Guide. Invacare expects this inspection to take less than 10 minutes. **If the wiring is not as per the above figure, then the wiring should be corrected as directed in the wiring guide.**
5. Document confirmation of inspection and correction (if required) on the included Unit disposition form and Tracking Sheet and send Upon Invacare's receipt of the Unit disposition form and Tracking Sheet,
6. Invacare will apply a credit to your account for each corrected wiring. If the action is taken at your premises \$ 40.00. If a field action is required \$ 90.00. It is expected the inspection and any correction will take 10 minutes. Please ensure the paperwork is completed to receive the credit your account.

If you have any questions concerning these instructions, please call Invacare's recall support line at 1800 460 460 Monday – Friday, 9.00a.m. – 5 p.m. EST, for assistance.

This recall is being conducted with the knowledge of the Therapeutic Goods Administration and is subject to effectiveness checks.

Thank for your immediate attention to this important matter, we apologize for any inconvenience

Yours Sincerely,

Catherine Tinsley
Regulatory Affairs and Quality Manager ANZ
Enclosures:

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