

Urgent Field Safety Corrective Action

Invacare Dolomite Gloss Rollator – seat broken

Date: 12-December-2023

Ref. Invacare: 2023_FSCA_Invacare Dolomite Gloss

Ref. MPA: 6.6.2-2022-55968

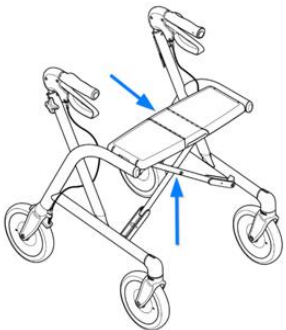

Ref. HPRA: CRN00DY5R

Important information

This letter is to provide you with important information concerning a Field Safety Corrective Action involving the Invacare Dolomite Gloss rollator.

Issue description

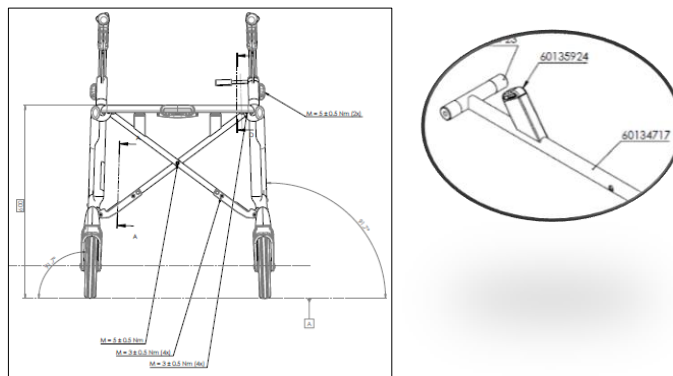
Invacare has identified that a limited quantity of Invacare Dolomite Gloss rollators is not behaving as intended when intensively used, or when subject to strong external impacts.

Failure Points	Example of failure – plastic eyelets of the folding mechanism of the seat broken	
		

The Gloss rollator has been tested and conforms to fatigue and static loading tests according to ISO 11199-2 Standard.

However, it was found that the durability of the Seat is impacted with a possible adverse effect on its resistance, that can break up prematurely during use.

Therefore, Invacare has decided to replace the complete Crossbar on the affected Invacare Dolomite Gloss rollators in the field, by a new improved and more resistant Crossbar, to ensure they can be used safely.



All Invacare Dolomite Gloss rollators on the market are affected by this Field Safety Corrective Action (manufacturing date between February 2020 and October 2022 - Serial Number Range from 20BHL0002 to 22J02000316).

Invacare has quarantined the current stock of Invacare Dolomite Gloss rollators.

Why are you being contacted?

According to our records, you received one or more potentially affected Invacare Dolomite Gloss rollators, manufactured between February 2020 and October 2022 (**Serial Number Range from 20BHL0002 to 22J02000316**).

What actions are required?

1. Customers must Stop using the devices and place them in quarantine.
2. Please contact Invacare in alignment with the affected serial number range.

Invacare will supply the means for the replacement of components or device(s), in the affected serial number range. Invacare will arrange the return of device(s) for replacement or will supply a replacement kit with Mounting Instructions - Part number:

FA60136224 – Gloss 450

FA60136225 – Gloss 520

FA60136226 – Gloss 600

FA60136227 – Gloss 680

to Customers that request it. The replacement can only be performed by a Qualified Technician.

3. A "Customer Reply Form" will be sent to Customers, for confirmation of the executed activities in order to be recorded and monitored by Invacare. Please fill and return with the performed actions.

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

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

Thank you for your immediate attention to this important matter.

We appreciate your cooperation.

If you have any questions relating to this Field Safety Notice, or should you require any additional information, please contact us at:

Invacare UK Ltd.

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