



Yes, you can.

URGENT – MEDICAL DEVICE CORRECTION
Invacare® Assist Rail (Model Number 6632)

Date: May 12, 2017

Dear Provider:

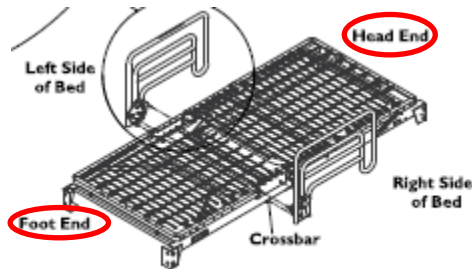
This letter is to provide you with important information concerning a recall involving the Invacare® “6632 Assist Rail”. This recall should be carried out to the installer level.

What is the problem?

Invacare has identified a typographical error in a revision D of the user manual P/N 1130185 supplied with the rail between November 13, 2014 and February 28, 2017. This error has the potential to result in rail installation difficulty or error for rails purchased within that time frame.

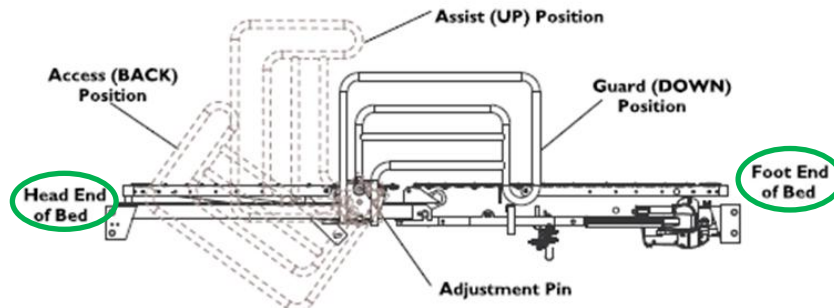
Specifically, the image on page 4 of the user manual incorrectly reversed the “Head End” and “Foot End” as seen below.

INCORRECT IMAGE



The step by step text installation instructions and subsequent image on page 5 of the user manual are correct.

CORRECT IMAGE:



What units are affected?

Finished Device: Invacare® Assist Bed Rails model 6632 produced between November 13, 2014 and February 28, 2017.

Has anyone been injured?

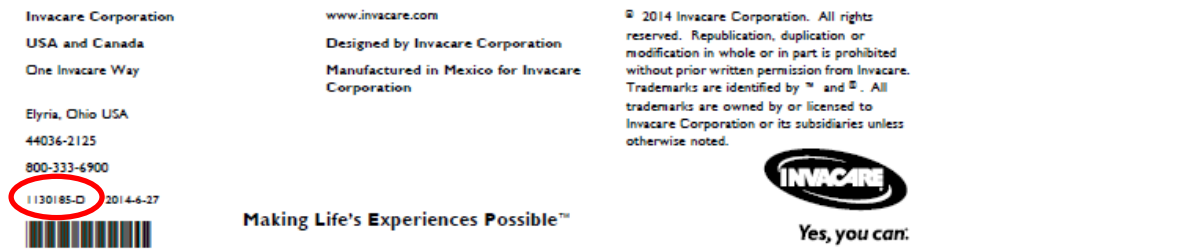
No. There have been no reports of injuries due to installation errors.

Why are you being contacted?

Per our records, you purchased and or received one or more 6632 Assist Rails with a user manual containing the installation instruction error.

What actions are required?

1. Dispose of all copies of user manuals P/N 1130185 that you may have at or below revision D. The revision level of the user manual can be determined by looking at the part number on the back cover. As highlighted by the red circle below, the letter following the 1130185 is the revision level.



2. Acknowledge your receipt and understanding of this recall notification on the enclosed Provider Response Card within five (5) business days. Fax the completed Provider Response Card to Invacare Regulatory Affairs at 440-326-3544 or email to recall@invacare.com. Your response;
 - a. Confirms that all copies of user manual P/N 1130185 at or below revision D in your possession have been destroyed.
 - b. Acknowledges that 6632 Assist Rails you purchased between November 13, 2014 and February 28, 2017 were installed correctly as shown in the “CORRECT IMAGE” above. A copy of the current user manual P/N 1130185 Rev F is enclosed as a reference.
 - c. If you were unsure as to whether the 6632 Assist Rails were installed correctly, that you have contacted your customer (the patient or patient’s family) to inquire and if necessary have visited the facility / home to confirm or correct any installation.

This recall, which will be classified by the U.S. Food and Drug Administration (FDA) as a recall, is being conducted with the knowledge of the FDA and is subject to FDA effectiveness checks. You or Invacare may be contacted by the FDA inquiring as to your specific compliance with this recall.

If you have any questions concerning these instructions, please call Invacare’s recall support line at (877) 413-6008, Monday – Friday, 8 a.m. – 5 p.m. EST, for assistance.

Visit www.invacare.com/recall for more information about this recall. Additional copies of the current user manual P/N 1130185 can be obtained from Invacare’s website @ www.invacare.com or through Invacare’s recall support line @ (877) 413-6008.

Thank you for your immediate attention to this important matter. We appreciate your cooperation.

Enclosures:

1. Provider Response Card
2. Impacted Unit List
3. User Manual P/N 1130185 Rev F