



Yes, you can.[®]

URGENT – MEDICAL DEVICE FIELD CORRECTION

Invacare® Perfecto2™ V Oxygen Concentrator (Model Number: IRC5PO2V and IRC5PO2VC)

Date: 10/26/2020

This letter is to provide you with important information concerning a voluntary recall - field correction involving the Invacare® Perfecto2™ V Oxygen Concentrator.

Issue Description:

Invacare Corporation is initiating a field correction to replace the P.E. (Pressure Equalization) valve assembly in the Invacare Perfecto2 V Oxygen Concentrator to reduce the potential for a failure that can, in infrequent instances (< 0.0196%), result in a short duration and self-extinguishing thermal reaction.

Why are you being contacted?

According to our records, you received one or more potentially impacted Invacare Perfecto2 V Oxygen Concentrators.

What units are affected?

Invacare Perfecto2 V Oxygen Concentrator, Model numbers IRC5PO2V from Serial # 14HF039890 to 18JF007415 and IRC5PO2VC from Serial # 14IF004028 to 18JF028633, manufactured between August 2014 and October 2018.

What actions are required?

1. Visit www.Invacare.com/RC928 within five (5) business days of receiving this notice. Enter the requested identification information to access the list of affected device serial numbers sold to you and instructions to conduct this field correction. You will be prompted to provide responses to information requested regarding this field correction and affected units.
 2. Review your existing stock to locate the affected devices.
 3. Review the Repair Instructions provided on the www.Invacare.com/RC928 website.
 4. Order field correction service kits and conduct field correction repair activities on affected devices during their next regularly scheduled maintenance service. Details on how to order the service kits are provided on the website www.Invacare.com/RC928.
 5. Field correction repairs must be completed on affected units before October 30, 2021. If you currently use a service provider for maintenance and repair, they can execute this field action service.
 6. You are responsible for ensuring that this field correction is conducted with your customers. Customers who own affected units should be contacted and informed about this field correction. We recommend that you provide them with the “Consumer Letter” provided on the www.Invacare.com/RC928 website.

This field correction is being conducted with the knowledge of the FDA and Health Canada and is subject to FDA effectiveness checks.

If you have any questions concerning these instructions, please call Invacare's field correction support line at (877) 413-6008 (U.S. Customers) or Customer Service at (800) 668-5324 (Canada Customers), Monday – Friday, 8 a.m. – 5 p.m. EST, for assistance.

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