

Yes, you can:

URGENT – MEDICAL DEVICE FIELD CORRECTION Invacare[®] Perfecto2[™] V Oxygen Concentrator (Model Numbers: IRC5PO2V and IRC5PO2VC)

This letter is to provide you with important information concerning a voluntary recall - field correction involving the Invacare[®] Perfecto2TM 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. Review devices in your possession to locate the affected devices.
- 2. Contact your provider at the number listed below to ensure this field correction repair is conducted on your device at its next scheduled service, or before October 30, 2021.

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

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

Sincerely,

Provider: Affix Your Business Card Here