

URGENT – MEDICAL DEVICE FIELD CORRECTION

Invacare Perfecto2 V Oxygen Concentrator (Model Number: IRC5PO2VAW)

Date: January 8, 2021

Invacare reference: FSN-FSCA_PO2V

Important information

This letter is to provide you with important information concerning a 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% worldwide), 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 affected Invacare Perfecto2 V Oxygen Concentrators.

What units are affected?

Invacare Perfecto2 V Oxygen Concentrator, model number IRC5PO2VAW from serial number 17HF030338 to 18IF018523, manufactured between August 2017 and September 2018.

What actions are required?

1. Review your existing stock to locate the affected units.
2. Review the attached instruction sheet (Service Manual - Replacing P.E. Valve - 60127444-B)
3. Check the P.E. Valve part number on the device to see if you have an affected part. If the P.E. Valve has already the correct number (CEME part number 5286EN30S23A53), no exchange is necessary. If so, continue with point 7.
4. Order field correction service kits (Part number 60127443) and conduct field correction activities on affected units during the next regularly scheduled maintenance service.

5. Field correction must be completed on affected units before December 31, 2023. 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.
7. Confirm the executed field activities back to Invacare via “Customer Reply Form”.

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 Notice.

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 your local Invacare customer service:

Tel: 01656 776333

Email: serviceuk@invacare.com