Rev 1: September 2018

FSN Ref: FSN-FSCA_PO2V_2020-11-27 **FSCA Ref:** FSCA_PO2V_2020-11-27

Date: 27.11.2020

Urgent Field Safety Notice
Invacare Perfecto2 V Oxygen Concentrator (Model Number: IRC5PO2VAW)

For Attention of*: our customers and users of the affected devices

Contact details of local representative (name, e-mail, telephone, address etc.)*
Invacare GmbH, Am Achener Hof 8, D- 88316 Isny

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1. Information on Affected Devices*	
1.	**1. Device Type(s)***
	Oxygen Concentrator
1.	**2. Commercial name(s)**
	Invacare Perfecto$_2$ V Oxygen Concentrator
1.	3. Unique Device Identifier(s) (UDI-DI)
	n/a
1.	**4. Primary clinical purpose of device(s)***
	The Invacare Perfecto$_2$ V Oxygen Concentrator is intended for patients with respiratory disorders requiring supplemental oxygen at flow rates of 1 to 5 liters per minute. The device is not intended to sustain or support life.
1.	**5. Device Model/Catalogue/part number(s)***
	IRC5PO2VAW
1.	**6. Affected serial or lot number range**
	Affected serial range: IRC5PO2VAW: 17HF030338 - 18IF018523 Impacted units were manufactured between August 2017 to September 2018. Please be advised that if you have purchased products from within the affected serial number ranges you will be notified separately by Invacare.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	**1. Description of the product problem***
	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. The potential failure can occur when there are multiple failures including a breakdown of the sound abatement washer and metal on metal wear inside the P.E. valve.
2.	**2. Hazard giving rise to the FSCA***
	The risk assessment concluded that the described issue can lead to a potential risk of injury for the user or service technician since there is a potential for a failure that can, in infrequent instances, result in a short duration and self-extinguishing thermal reaction.

2.	**3. Probability of problem arising**
	Low, infrequent instances (< 0.0196%)
2.	**4. Predicted risk to patient/users**
	The risk assessment concluded that the described issue can lead to a potential risk of injury for the user or service technician since there is a potential for a failure that can, in infrequent instances, result in a short duration and self-extinguishing thermal reaction. Two non-serious injuries to bystanders have been reported as a result of the failure.
2.	**5. Further information to help characterise the problem**
	n/a
2.	**6. Background on Issue**
	The potential failure can occur when there are multiple failures including a breakdown of the sound abatement washer and metal on metal wear inside the P.E. valve of the Invacare Perfecto2 V Oxygen Concentrator.
2.	**7. Other information relevant to FSCA**
	Please be advised that if you have purchased products from within the affected serial number range you will be notified separately by Invacare.

	3. Type of Action to mitigate the risk*		
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions for Use (IFU) - Replacement Instructions (Service Manual - Replacing P.E. Valve - 60127444-A) ☒ Other ☐ None Replace the P.E. valve assembly on the affected product according to the replacement instructions provided. Notify Invacare after the replacement was executed via customer reply form.		
3.	**2. By when should the action be completed?**	Field correction must be completed on affected units before December 31, 2023.	
3.	**3. Is customer Reply Required? *** (If yes, form attached specifying deadline for return)		Yes

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3.	**4. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU change ☒ Other ☐ None A notification will be sent to impacted consignees via mail. The notification process will include provider instructions and a replacement instruction explaining how to replace the P.E. valve assembly. (Service Manual - Replacing P.E. Valve - 60127444-A)	
3	5. By when should the action be completed?	Field correction must be completed on affected units before December 31, 2023.
3.	6. Is the FSN required to be communicated to the patient /lay user?	Yes
3	7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Yes Appended to this FSN	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Invacare Corporation
	b. Address	2101 E Lake Mary Blvd., Sanford, FL 32773
	c. Website address	www.invacare.com
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	4. List of attachments/appendices:	APPENDIX I: Service Manual - Replacing P.E. Valve - 60127444-A (on separate page) APPENDIX II: FSN Provider Letter (on separate page) APPENDIX III: FSN Consumer Letter (on separate page)
4.	5. Name/Signature	Madeleine Gloy - Regulatory Affairs and Compliance Manager EMEA

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	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

APPENDIX I: Service Manual - Replacing P.E. Valve - 60127444-A (on separate page)

APPENDIX II: FSN Provider Letter (on separate page)

APPENDIX III: FSN Consumer Letter (on separate page)