



## **Urgent Field Safety Notice**

### **Invacare® PerfectO2™ and Platinum® Concentrator**

Date: 19<sup>th</sup> November 2014

**Invacare Ref: FSN 82590**

MHRA Ref: 2014/011/019/081/015

#### **Urgent Safety Information:**

Invacare has recently identified a supplier quality issue that potentially affects the Invacare® Platinum® or PerfectO2™ concentrators. This notice is to provide you with the important information concerning the potential for a ruptured capacitor that may occur.

We have five reports from customers where the capacitor in our concentrators has ruptured. In two of those cases, the ruptured capacitor expelled its oily components and caught fire within the concentrator. In one unit, the fire was contained within the shroud and in the second unit, the fire burned through the outer plastic shroud. In both cases the fire was quickly extinguished without assistance from the professional fire brigade. To date Invacare has not received any reported injuries associated with this issue.

#### **What is the problem?**

As a result of its investigation Invacare determined the root cause of these capacitor ruptures is due to the design of the PSI (Pressure Sensitive Interrupter) of the capacitor provided by the subject supplier prior to July 2012.

The capacitor in the oxygen concentrator has an internal pressure relief component (the PSI) which may not operate as intended permitting the capacitor to rupture in certain circumstances. If the PSI does not function to relieve the pressure, then the pressure can cause a rupture in the seam between the housing and the end plate.

These capacitors were utilized in production from March 2010 to August 2012 at one of our manufacturing sites.

#### **What is the potential hazard?**

If the rupture occurs, the oil may be expelled from the capacitor that may result in a fire hazard.

#### **How do you determine affected concentrators?**

Please examine the Invacare® Oxygen Concentrator(s) to confirm it has one of the affected serial numbers listed in Attachment 1.



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Picture: DIANZ Capacitor



**Safety Instruction:**

Locate the serial number at the device and compare with list of affected device serial numbers. The device is labeled at lower back, please refer to user guide.



Picture: Samples of device labeling for identification of Serial number /SN

**What action is required?**

The Capacitor needs to be replaced as soon as possible at the latest when the next maintenance is due and no later than 12 months after receipt of this notice.

Invacare acknowledges that this may be an inconvenience; however it is not an option and must be done immediately to mitigate the potential safety risk.

If you have any questions relating to this bulletin, or should you require any additional information, please contact;

**Technical Services Department**

Tel. 01656 776333

Fax. 01656 776244

Invacare confirm that the relevant Competent Authorities have been informed of this Field Safety Corrective Action.



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