

Date: 15 July 2024
Reference Number: ID 9807

Field Safety Notice

Name of product: Zen-O lite™ Portable Oxygen Concentrator

Dear customer,

Please review and disseminate the information and instructions set out in this letter to all relevant persons within your organisation or to any organisation to which the affected accessories have been supplied. Please consider end users and others within the supply chain in the circulation of this notice.

Note: There is no immediate risk to end users associated with this FSN.

Details of device:

ROMANA: ENTER SERIAL NUMBER RANGE FOR EACH CUSTOMER

Problem description:

GCE has identified that a limited number of devices have been manufactured and distributed with erroneous calibration values. Review of release records demonstrates that all devices were performing as expected at the end of the manufacturing process. GCE has reviewed and concluded the following:

- As the device ages through intended use, oxygen purity will gradually decrease as expected for all oxygen concentrators;
- As oxygen purity decreases, the erroneous calibration value will result in a displayed oxygen purity which is higher than actually delivered;
- Therefore, as actual purity decreases, the point at which the device alarms to indicate low oxygen purity will be incorrect.

Risk assessment:

GCE has assessed the impact of the erroneous calibration values in conjunction with an independent medical specialist. It has been determined that if the device is used in accordance with the instructions for use, there will be no safety or efficacy issues, as the device will perform at its optimum purity output for as long as would normally be expected. However, as a precaution, GCE is advising that devices are returned at the earliest convenience in order to be corrected.

Recommended actions:

ROMANA: SELECT BASED ON ACTION DECIDED FOR EACH CUSTOMER ON LIST

- Clearly label (REF: FSN ID 9807) and return impacted devices to GCE GmbH at the earliest convenience. The erroneous calibration value will be rectified, and each device thoroughly tested to ensure that it is returned in full working order.

GCE GmbH: Weyherser Weg 8, 36043 Fulda, Germany

- Clearly label (REF: FSN ID 9807) and return impacted devices to GCE s.r.o. at the earliest convenience. The erroneous calibration value will be rectified, and each device thoroughly tested to ensure that it is returned in full working order.

GCE s.r.o.: Žižkova 381, 583 01 Chotěboř, Czech Republic

- Clearly label (REF: FSN ID 9807) and return impacted devices to Cigweld Pty Ltd at the earliest convenience. The erroneous calibration value will be rectified, and each device thoroughly tested to ensure that it is returned in full working order.

CIGWELD ESAB APAC: 71 Gower Street, Preston 3072, Victoria, Australia

- GCE has provided a software update to correct the erroneous calibration value. Full details and instructions have been issued in Technical Bulletin #42 and technical support will be provided by GCE.

Distribution and circulation of this Field Safety Notice

The Field Safety Notice is communicated to all impacted customers and is communicated to competent authorities in the affected markets. Receivers should pass this FSN on to all persons with a need to be advised from within your organisation or to any organisation where the potentially affected products have been supplied. Please consider end users and others within the supply chain in the circulation of this notice. Customer reply form is also attached to this FSN in which we would like to ask you for written confirmation of FSN acceptance and return to GCE.

GCE is committed to providing high quality, safe products. We sincerely apologise for any inconvenience this FSN may cause to you and your operations. If you have any other questions, do not hesitate to contact your local sales representative or any GCE Sales Unit. For local contact information please go to www.gcegroup.com.

For and on behalf of GCE,

Name: Michael
Position: Quality Systems and Regulatory Affairs Specialist
PRRC