FSN4680
FSCA4680

July 2026

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Urgent Field Safety Notice

Oxygen Concentrator Kröber O2 / Kröber O2 Version 4.0

Dear Sir or Madam,

Quality and patient safety are top priorities at Kröber Medizintechnik.

For this reason, we would like to inform you of the following **Urgent Field Safety Notice (FSN)** regarding a potential safety issue.

Manufacturer
Kröber Medizintechnik GmbH
Salzheck 4
56332 Dieblich - Germany

Intended Recipients
Distributors, operators, and users of the Kröber O2 and Kröber O2 Version 4.0 oxygen concentrators.

Affected Products
Kröber O2 and Kröber O2 Version 4.0 oxygen concentrators with production dates in **March, April, May, and June 2026** (see Appendix B).

Description of the Problem and Root Cause
Based on customer feedback, conditions were identified in which oxygen concentrators delivered a lower oxygen flow than the flow rate set by the user.
The issue is caused by a specific batch of an internal check valve, which may develop an internal leak under certain circumstances.

Corrective Action
The potential issue is limited to devices equipped with a check valve from an identified batch. Replacing this component will eliminate the potential for this issue to recur.

Impact / Potential Hazards
Depending on the extent of the internal leak, the preset oxygen flow rate may not be delivered, preventing the intended therapeutic effect from being achieved. This may result in insufficient oxygen supply, including hypoxia.
Depending on the patient's clinical condition, a serious deterioration of the patient's health cannot be ruled out if the leak remains undetected and no corrective action is taken.
When the device is used in accordance with its intended purpose (non-life-sustaining and non-life-supporting oxygen therapy), a life-threatening deterioration of the patient's condition is not expected.

Risk Assessment
For the treated patient, there is a potential risk of insufficient oxygen supply due to reduced oxygen flow.

Actions to Be Taken by Distributors and Service Providers

- Identify all customers and users who have received affected oxygen concentrators.
- Inform users as soon as possible about the measures necessary to ensure the safe operation of devices that have not yet been reworked (see Appendix D).
- Ensure that your customers also inform all end users about the actions necessary to ensure the safe operation of devices that have not yet been reworked (see Appendix D).
- Take the affected devices out of operation as soon as possible, provide the user with a replacement device as soon, but no later than **July 17, 2026**, and quarantine the affected device.
- Confirm receipt of this Field Safety Notice by returning **Appendix A**, including the completed **Section 4**, no later than **July 17, 2026**.
- Complete the product rework (see Appendix C) by **August 30, 2026**. Alternatively, return the affected devices to the manufacturer for rework.
- Confirm completion of this corrective action by completing **Section 5 of Appendix A** and returning it by **August 30, 2026**.

Distribution of This Safety Information
Please ensure that all relevant personnel within your organization, including all users of the affected products, receive this Urgent Field Safety Notice.

If you have supplied the affected products to third parties, please forward this Urgent Field Safety Notice, including all appendices, to them or inform the contact person listed below.
Please retain this information until all corrective actions have been completed.

A copy of this Urgent Field Safety Notice has been provided to the Danish Medicines Agency.

We sincerely regret any inconvenience this safety action may cause.
However, these corrective measures are necessary to ensure the continued safety of patients.

If you have any questions, please contact our support team in Dieblich by email at **fsca@kroeber.de** or by telephone at **+49 2607 94040** or **+49 171 1474053**.

Kind regards,

Dirk Westhues
Person Responsible for Regulatory Compliance

Appendix A: Reply Form
Appendix B: List of the affected products that were delivered to you.
Appendix C: Rework Instructions
Appendix D: Necessary User Actions