

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 National Competent Authority.

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

Field Safety Notice FSN4680

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN4680
FSN Date	03.07.2026
Product name	Kröber O2 / Kröber O2 Version 4.0
Product Codes	REF KRO2.00 / REF KR4.00
Serial Numbers	Annex B

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return Acknowledgement to Sender	
Email	fsca@kroeber.de
Distributor/Importer Helpline	+49 2607 94040 +49 171 1474053
Postal Address	Kröber GmbH Salzheck 4 56332 Dieblich Germany
Deadline for returning the Distributor reply form incl. part 4	17.07.2026
Deadline for returning the Distributor reply form incl. part 5	30.08.2026

4. Distributors/Importers (Tick all that apply) Immediate action		
4.1 ☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	
4.2 ☐	I have checked my stock and quarantined inventory	Add S/N of quarantined devices in inventory
4.3 ☐	I have identified all customers that received or may have received this device and I have informed the identified customers of this FSN and supplied the user information (Annex C).	
4.4 ☐	I have taken the affected devices out of operation and supplied an alternative O2 supply.	Add S/N and Date of taking out of operation.

5. Distributors/Importers (Tick all that apply and fill in the requested information)		
Final action		
5.1 ☐	I have reworked affected devices.	Add SN and Date Reworked
5.2 ☐	I have returned affected devices to the manufacturer.	Add Serial Number/ and Date Returned

Print Name	Distributor/Importer print name here
Signature	Distributor/Importer sign Here
Date	

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Thank you very much for your cooperation.

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Appendix C
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Corrective Actions Step-by-Step Work Instructions

ID	Instruction	Picture
1.	Disconnect the device from mains.	
2.	Open the cover by loosening the 5 housing screws with a screwdriver. Remove the cover and set it aside in a safe place.	
3.	Locate the vacuum check valve just before the oxygen outlet inside the housing.	
4.	Rotate the T-connector so that the check valve faces outward.	
5.	Use your fingers to pull the check valve, including the short silicone hose, off the T-connector.	
6.	Dispose of this check valve in accordance with local regulations.	
7.	Take a new check valve assembly and attach it to the open port of the T-connector.	
8.	Rotate the check valve back to its original position.	
9.	Secure the cover again with the 5 screws.	
10.	Connect the device to mains.	
11.	Turn on the device, set the flow rate to 3.0 lpm, and use an external flow meter to verify that the reading is between 2.7 and 3.3 lpm.	
12.	Turn off the device.	

If necessary, please reach out to our support team in Dieblich at fsca@kroeber.de or by phone at +49 2607 / 94040 or +49 171 1474053.

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Appendix D
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Necessary User Actions

Until the required rework has been completed, perform the following procedure each time before using your oxygen concentrator:

1. Switch on the oxygen concentrator and note the currently set oxygen flow rate.
2. Adjust the oxygen flow rate to **5 L/min**.
3. Briefly block the oxygen flow, for example by kinking the nasal cannula tubing or blocking the outlet.
4. Adjust the oxygen flow rate to the original setting.
5. The oxygen concentrator can now be operated without restrictions.