23 July 2026

# Urgent Field Safety Notice

## Inogen Rove 4™ Portable Oxygen Concentrator

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|---|---|
| **Product name** | Inogen Rove 4™ Portable Oxygen Concentrator |
| **Catalog Number** | IS-401 |
| **UDI-DI** | 00817131020414 |
| **Single Registration Number (SRN)** | US-MF-000027368 |
| **Affected Serial Numbers** | See **appendix A** for Customer Specific Serial Numbers |
| **Manufacturing Dates** | 4-MAY-2026 to 6-MAY-2026 |
| **Field Safety Notice (FSN) Reference Number** | FSN-2026-002 |
| **Field Safety Corrective Action (FSCA) reference** | FA-2026-002 |

**For attention of: Air Liquide Danmark A/S/VitalAire**

| Contact Details of Local Representative: |
|---|
| Inogen Europe B.V.<br><br>Rijnzathe 7<br>3454 PV Utrecht<br>Pays-Bas<br><br>+31 30 782 0689 |

Dear Valued Customer,

We are writing to inform you of a Field Action involving specific units of the Inogen Rove 4 Portable Oxygen Concentrator replacement columns (sieve bed) shipped to customers May 4, 2026 – May 6, 2026.

**Purpose of Field Action**

This action is being taken due to the identification of non-conforming zeolite material due to moisture. The affected raw material was identified in lot #L250616C.

- We anticipate that non-conforming zeolite within columns can reduce oxygen absorption efficiency, leading to low oxygen concentration output in finished concentrators.

**Health Risk Assessment**

Although no injuries have been reported, Inogen has identified a potential issue that may cause the device to alert/alarm with low O2 or low oxygen concentration.

**Action Plan**

We are proactively replacing all affected Rove 4 replacement columns. Your replacement column(s) have already shipped out. An emailed letter will be sent instructing you to properly dispose of the affected column(s) per local e-waste regulations and how to notify us once affected columns have been properly disposed.

**Our Commitment to You**

At Inogen, we are dedicated to the safety, health, and satisfaction of our customers. We sincerely apologize for any inconvenience this may cause and appreciate your cooperation in ensuring the continued reliability of your oxygen therapy equipment.

If you have any questions or require assistance with your Inogen POC, please contact your sales representative.

Sincerely,

Sincerely,

**Greg Porter**
Sr. Director, Quality Management System and Post Market Surveillance

| Transmission of this Field Safety Notice |
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| This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected columns have been transferred. (As appropriate)<br><br>Please transfer this notice to other organizations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>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. |

## Appendix A – List of Affected Serial Numbers

| Product Type | Serial Numbers Concentrator \| RP-411 Columns | Status of Column(s) (Disposed, Not Found) |
|---|---|---|
| Inogen Rove 4 Replacement Columns | N/A \| COLA-261925917 | |
| Inogen Rove 4 Replacement Columns | N/A \| COLA-261925919 | |
| Inogen Rove 4 Replacement Columns | N/A \| COLA-261925907 | |
| Inogen Rove 4 Replacement Columns | N/A \| COLA-261925901 | |

# Appendix B - Customer Response Form

| 1. Field Safety Notice (FSN) Information | |
|---|---|
| FSN Reference number* | FSN-2026-002 |
| FSN Date* | July-2026 |
| Product / Device name* | Inogen Rove 4 Replacement Column |
| Serial Number (s) | See Appendix A for affected serial numbers |

| 2. Customer Details | |
|---|---|
| Account Number | 307732 |
| Healthcare Organization Name* | Air Liquide Danmark |
| Organization Address* | VitalAire Denmark Taastrup, 2630 - VAT # DK15036117, DK |
| Department/Unit | |
| Shipping address if different to above | Bergsøesvej 36<br>8600 Silkeborg, DK |
| Contact Name* | Rasmus Rise |
| Title or Function | Technician – Head of technical department |
| Telephone Number* | +45 44 92 35 44 |
| Email* | rasmus.rise@airliquide.com |

| 3. Customer Action Undertaken on Behalf of Healthcare Organization | | |
|---|---|---|
| o | I confirm receipt of the Field Safety Notice and that I read and understood its content. | Customer to complete or enter N/A |
| o | I performed all the actions requested by the FSN. | Customer to complete or enter N/A |
| o | The information and required actions have been brought to the attention of all | Customer to complete or enter N/A |

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| | relevant users and executed. | | | |
| o | I have disposed of the affected columns through designated recycling or hazardous waste programs, in accordance with local regulations and applicable laws† – enter number of devices compliantly disposed of and date complete. | Qty: | Serial Numbers: see Appendix A | Date Disposed: XX/XX/2026 |
| | | N/A | Comments: | |
| o | I have a query, please contact me<br>(e.g. need for replacement of the product). | Customer to enter contact details if different from above and brief description of query | | |
| Print Name* | | Customer print name here | | |
| Signature* | | Customer sign here | | |
| Date* | | | | |

| **4. Return Acknowledgement to Sender** | |
|---|---|
| Email | **product_support@inogen.net** |
| Customer Helpline | N/A |
| Postal Address | N/A |
| Web Portal | N/A |
| Fax | N/A |
| Deadline for returning the customer reply form* | Please return the completed form within 30 days of receipt of the field safety notice and this form. |

* mandatory field

**Return the completed form by EMAIL to product_support@inogen.net**