



23 July 2026

Urgent Field Safety Notice

Inogen Rove 4™ Portable Oxygen Concentrator

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. Rijnzathe 7 3454 PV Utrecht Pays-Bas +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,

Transmission of this Field Safety Notice

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)

Please transfer this notice to other organizations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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 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		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
☐	I performed all the actions requested by the FSN.	Customer to complete or enter N/A
☐	The information and required actions have been brought to the attention of all	Customer to complete or enter N/A

	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 (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