July 28, 2025

Urgent Field Safety Notice

Inogen Rove 4™ Portable Oxygen Concentrator

Product name	Inogen Rove 4™ Portable Oxygen Concentrator
Catalog Number	IO-401
UDI-DI	00817131020414
Single Registration Number (SRN)	US-MF-000027368
Affected Serial Numbers	See appendix A
Manufacturing Dates	March 17, 2025 through April 9, 2025
Field Safety Notice (FSN) Reference Number	FSN-2025-001
Field Safety Corrective Action (FSCA) reference	QR-00268

For attention of: [Affected Customer]

Contact Details Of Local Representative:
Inogen Europe B.V. Rijnzathe 7 3454 PV Utrecht Netherlands +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 (POC) manufactured from March 17, 2025, to April 9, 2025.

Primary Clinical Purpose Of Device

The Inogen Rove 4™ Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in home, institution, vehicle, and other transport modalities.

This device is to be used as an oxygen supplement and is not intended to be life sustaining or life supporting.

Description Of The Product Problem

971 Rove 4™ POCs were manufactured from 17 Mar 2025 – 09 Apr 2025 with an incompatible EEPROM memory chip. 468 of the 971 affected Rove 4™ POCs have been distributed to the field and are in scope of this field action. Units manufactured with this incompatible chip:

1. May display a Low O2 Alarm when the device is delivering O2 within specification,

or

2. May NOT display a Low O2 Alarm when the device is NOT delivering O2 within specification.

Hazard Giving Rise To The Field Safety Corrective Action (FSCA)

If the sensor occasionally reads within the normal range, it resets the timers on the above alarm conditions. These occasional normal readings can prevent the above alarms from operating properly when the oxygen output is not within specification. As a result, the patient is not receiving oxygen within specification and the device does not alert the patient. Although no serious incidents have been reported, we identified a potential risk. As a result, we are going to replace the affected devices.

Actions To Be Taken By The User:

1. Our records indicate that you have received one or more affected Inogen Rove 4™ portable oxygen concentrators. Please find in Appendix A, the list of affected devices.

2. As a proactive action, we will ship you Inogen Rove 4™ concentrators to replace the affected Inogen Rove 4™ concentrators (IO-401), listed in Appendix A.

3. Once you receive this letter, please identify the location of the affected units and recover them from patients, institutions, inventory.

4. When you receive the new units, please complete the Customer Response form (see Appendix B) and email to product_support@inogen.net.

5. Then please send us back the affected units with the completed Customer Response form to the address:

   Inogen

   600 Shiloh Rd

Plano, TX 75074

United States

Additional Information

Inogen is communicating this information to the appropriate regulatory agencies.

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, please contact your sales representative.

Sincerely,

The Inogen Inc. Team

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 devices 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 Number	Status of Unit (Returning, Not Found)
Inogen Rove 4™ Portable Oxygen Concentrator		

Appendix B - Customer Response Form

1. Field Safety Notice (FSN) Information	
FSN Reference number*	FSN-2025-001
FSN Date*	XX-JUL-2025
Product/ Device name*	Inogen Rove 4™ Portable Oxygen Concentrator
Serial Number (s)	See Appendix A for affected serial numbers

2. Customer Details	
Account Number	
Healthcare Organization Name*	
Organization Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone Number*	
Email*	

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

	relevant users and executed.			
o	I have returned affected devices – enter number of devices returned and date complete.	Qty:	Serial Numbers : see Appendix A	Date Returned:
		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