

Customer Notification

POC 24-014.A.OUS

RAPIDLab® 348EX Analyzer

Gas Cartridge Pack

Title	Gas Cartridges Not installing Due to Defective Threading
Date Issued	MAY-2024
Issue Description	Siemens Healthcare has confirmed through the investigation of customer complaints that some Cal and Slope gas cartridges are unable to be installed on the RAPIDLab 348EX instruments due to defective threads on the gas cartridges. When a gas cartridge cannot be installed, the instrument will not be able to calibrate nor measure pO2 and pCO2. Not all gas cartridges within the lots listed below are affected by this issue.

Products

Product	Siemens Material Number	Unique Device Identification	Lot Numbers
Gas Cartridge Pack*	10309768	00630414055657	3045XX through 4024XX
Gas Cartridge Pack (South Korea)	11065081	00630414601809	Slope Gas Cartridge lot# 312408 and 331713
			Cal Gas Cartridge lot# 321409 and 331714

* Each Pack Includes 1 Cal Gas Cartridge and 1 Slope Gas Cartridge.

Customer Actions	<ul style="list-style-type: none"> • Please review this letter with your Medical Director to determine the appropriate course of action. • If you experience this issue with your RAPIDLab 348EX System, please use another gas cartridge. You may request no-charge replacement product from your local Siemens Healthineers or distributor office. • Complete and return the Product Replacement Form attached to this letter within 10 working days. • If you are a distributor, please ensure your customers receive this letter. • Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
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Resolution	<ul style="list-style-type: none"> • New gas cartridge pack lots will be unaffected.
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RAPIDLab is a registered trademark of Siemens Healthcare Diagnostics Inc.

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PRODUCT REPLACEMENT FORM

This response form is to request no charge replacement product for the enclosed Siemens Healthineers Customer Notification POC 24-014.A.OUS dated MAY-2024. Please read the question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1, immediately contact your local Siemens Healthineers Customer Care Center at 1800-815-508 or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

1. Do you have any of the noted product with the gas cartridge installing issue? Please check inventories before answering. Yes No

If the answer to the question #1 above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory Returned Quantity Required		
Gas Cartridge Pack, SMN# 10309768 Lot# 3045XX through 4024XX			
Gas Cartridge Pack, SMN# 11065081 Slope Gas Cartridge lot# 312408 and 331713 Cal Gas Cartridge lot# 321409 and 331714			
Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		State:	
Phone:		Country:	

Please send a scanned copy of the completed form via email to fsreportingunit.my@siemens-healthineers.com

We apologize for the inconvenience this situation may cause.

If you have any questions, please contact your Siemens Healthineers Customer Care Center at 1800-815-508 or your local Siemens Healthineers technical support representative.