

**Stratus® CS 200 Acute Care™ Analyzer & Stratus® CS Acute Care™ Diagnostic System
Rotor Shelf-Life Extension**

Our records indicate that your facility may have received the following product:

Table 1. Stratus CS Acute Care Affected Product

Product	Siemens Material Number (SMN)	Lot Numbers
Rotor	10445088	NH4220320, NH4217420, NH4214920, NH4215620, NH4221120, NH4207920, NH4218320, NH4216220, NH4214120

Reason for Customer Notification

The purpose of this communication is to inform you of the extension of the rotor shelf-life for the product indicated in Table1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. determined that the shelf-life of those rotors can be extended by 3 months and 2 weeks, given further review of product stability data. Your inventory of rotors would have expired on 14 March 2022. Therefore, the lots of rotors listed below in Table 2 can continue to be used until **the new expiry date of 27 June 2022**. All other lots that are not listed in Table1 have expired and should not be used.

Table 2. Rotor Lots Affected and Expiry Date

Rotor Lot #	Previous Expiry Date	New Expiry Date
NH4220320, NH4217420, NH4214920, NH4215620, NH4221120, NH4207920, NH4218320, NH4216220, NH4214120	14 March 2022	27 June 2022

Rotor Shelf-Life Extension

Actions to be Taken by the Customer

Siemens Healthcare Diagnostics is recommending the following actions:

- Continue use of the listed lots until the new expiry date.
- If you had already discarded the lots listed in Table 1 set to expire on 14 March 2022, you may request no-charge replacement product. Complete and return the Product Replacement Form attached to this letter to request your no-charge replacement product.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center at 1800-888-872 or your local Siemens Healthineers technical support representative.

Additional Information

Stratus® CS & CS 200 are a trademark of Siemens Healthcare Diagnostics Inc.

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PRODUCT REPLACEMENT FORM

Rotor Shelf-Life Extension

This form is to be used to request no-charge replacement product for the enclosed Siemens Healthcare Diagnostics Customer Notification POC 22-005.A.OUS dated March 2022 regarding Rotor Shelf-Life Extension.

Return this completed form to Siemens Healthcare Sdn Bhd as per the instructions provided at the bottom of this page.

1. Have you now or ever had any of the noted product(s) on hand? Please check Yes No
inventories before answering.

If the answer to the question above is yes, please continue by answering question #2 below. If the answer to the above is no, no further action is required.

2. Did you already discard the noted product(s) from your inventory? Please check inventories before answering. Yes No

If the answer to the question #2 above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and if replacement product is required.

Product Description Product Catalog #/SMN #/Lot #	Quantity Return/ Replacement Quantity Required
Rotor SMN #10445088 Lot #: _____	

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Customer Sold To #: _____

Customer Ship To #: _____

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

If you have any questions, contact your local Siemens Healthineers technical support representative.

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