

**StreamLAB® Automation Solutions
Aptio® Automation
FlexLab**

Hettich Centrifuge Bucket Model 4464-R

Our records indicate that your laboratory may have one of the affected products listed below.

Table 1. Affected Products

Hettich Rotanta 46 RSC Robotic and Rotanta 460 Robotic Centrifuge Modules listed below use Hettich Centrifuge Bucket Model 4464-R	Siemens Material Numbers (SMNs) of Hettich Centrifuge Bucket Model 4464-R and Centrifuge Modules that use Hettich Bucket Model 4464-R are listed below
StreamLAB Centrifuge Module	10372372 or 10444807 or 10706836
Aptio Centrifuge Module	10703032 or 10713761
FlexLab High Throughput Centrifuge Module	11171747
FlexLab and Aptio Centrifuge Module	10628157 or 11266581
Hettich Centrifuge Bucket Kit	10723514

Reason for Correction

Siemens Healthcare Diagnostics is issuing an Urgent Field Safety Notice for the buckets (Model 4464-R) (SMN 10723514: Hettich Centrifuge Bucket Kit) of the Hettich Rotanta 46 RSC Robotic and Rotanta 460 Robotic Centrifuges that are listed in Table 1.

Hettich, the centrifuge manufacturer is currently investigating the reason for premature bucket failures.

Risk to Health

When the Hettich Centrifuge bucket fails during centrifugation, the potential exists for a delay in patient testing and the potential for movement/rotation of the Centrifuge. The risk for user injury and/or for potential clinical impact due to a delay in testing is negligible.

Actions to be taken by the Customer

To avoid potential centrifuge failure and laboratory interruption, Siemens Healthcare Diagnostics is advising you to follow the instructions provided in the attached letter from Hettich.

Siemens Healthcare Diagnostics continues to strongly recommend that customers thoroughly follow the centrifuge maintenance instructions in the product operator manuals.

We assure you we are working closely with Hettich to achieve a long term solution.

Please review this letter with your Medical Director.

Please retain this letter with your laboratory records and if the system has been relocated please forward this letter to the appropriate current user facility.

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

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FIELD CORRECTION EFFECTIVENESS CHECK

Hettich Centrifuge Buckets (Model 4464-R)

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice LAI 16-02.A.OUS dated May 2016 regarding Hettich Centrifuge buckets. Please read the question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Automation System Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

Please fax this completed form to the Customer Care Center at **(###) ###-####**. If you have any questions, contact your local Siemens technical support representative.