

Atellica® UAS 800 Urine Sediment Analyzer
Atellica® 1500 Automated Urinalysis System

Device Door Gas Spring Failure

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

Table 1. Affected Product

Product	Siemens Material Number (SMN)	Software Version
Atellica® UAS 800 Urine Sediment Analyzer Atellica® 1500 Automated Urinalysis System	11065004	All versions

Reason for this Urgent Field Safety Notice

Siemens Healthcare Diagnostics has confirmed that the door gas spring which holds the analyzer door open is failing before its specified lifetime. Due to this failure, a door in the open position may intermittently descend slowly until it reaches an approximately horizontal position, then has the potential to close more rapidly. The closing door has the potential to hit operator who is either unaware of the slowly descending door or who chooses to ignore the closing door while performing routine maintenance or replacing consumables on the system at the time of the failure.

Risk to Health

It is possible that the unexpected closing of the door may result in an impact to the arms or hands of an operator, causing pain. Due to the small mass of the door, the amount of force generated by the falling door is unlikely to be sufficient to cause an injury which would require medical attention.

Actions to be Taken by the Customer

- Until the door gas spring has been replaced, it is recommended that anytime the operator has the door open to perform maintenance or replace consumables, a second operator monitors the door to ensure the door does not close due to the gas spring failure.
- Complete and return the Field Correction Effectiveness Check form attached to this letter within 30 days.

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- Review this letter with your Medical Director.
- Keep this letter with your User's Guide for reference, as needed, and forward this letter to those who may have received this product.

The analyzer door gas spring of the affected systems will be replaced.

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.

Additional Information

Atellica UAS 800 and Atellica 1500 are trademarks of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

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This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 22-002.A.OUS dated February 2022 regarding Device Door Gas Spring Failure with Atellica UAS 800 Urine Sediment Analyzer and Atellica 1500 Automated Urinalysis System. Please read the question below and indicate the appropriate answer.

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

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

Name of person completing questionnaire: _____

Title: Vicky Fitzgerald _____

Institution: Cruinn Diagnostics _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____ Vicky Fitzgerald _____

Phone: _____ Country: _____

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

Date:
2022.02.
23
14:42:17
Z

Please send a scanned copy of the completed form via email to CruinnFSNGroup@cruinn.ie. Or to fax this completed form to the Siemens Customer Care Center at 016297401

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