February 21, 2018

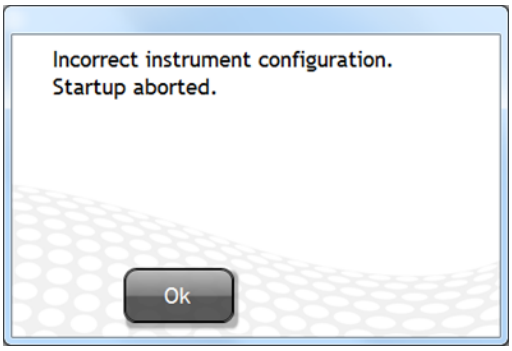
FOLLOW-UP URGENT FIELD SAFETY NOTICE – FSN 31696-B

AQUIOS CL Flow Cytometry System, PN B30166

Dear Beckman Coulter Customer,

Beckman Coulter is pleased to announce the release AQUIOS CL Flow Cytometry System software version 2.1.1. This software update addresses the issue for sample probe misconfiguration during servicing as communicated in the Urgent Field Safety Notice dated August 16, 2017 (FSN-31696).

1. Beckman Coulter has investigated the issue and is providing the resolution in the form of a software update to address this issue. The software update has been released on January 30, 2018.
2. Your Beckman Coulter service representative will contact you to schedule a date for installing the new software.
3. AQUIOS System Software version 2.1.1 verifies that the sample probe configuration is correct during startup. If the sample probe is misconfigured, the error message "Incorrect instrument configuration" will appear and startup will be aborted. If this error occurs, exit and reopen the software, login and then attempt startup again. If the error reappears, contact your local Beckman Coulter service representative. This change to the new software version prevents repeated aspiration of samples from a single tube and verifies that the sample probe is properly configured.



Additionally, the new software version addresses the issues listed below:

Notification Letter Part Number and Date	Issue
FA/FSN-33176, January 2018	Sample mis-identification caused by changing specimen tube in the single tube loader door
FA/FSN-31978, September 2017	Sample ID duplication caused by errors with Default Test mode and LIS connectivity
FA/FSN-31978-B, November 2017	Sample ID duplication caused by errors with ▪ Host Query mode and LIS connectivity ▪ Cassette unloading

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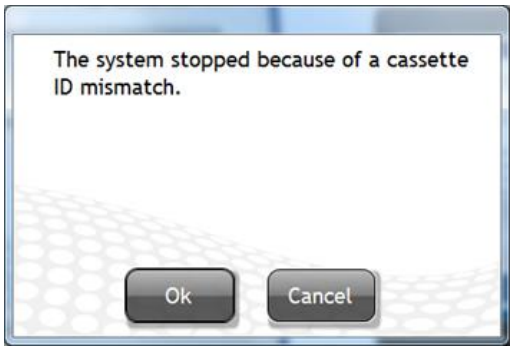
Correction for FA/FSN-33176:

- AQUIOS System Software version 2.1.1 prevents the opening of the single tube loader door until the previously loaded specimen has entered the “Incubating” status, as indicated in the “Details” section on the Running screen. This change prevents the possibility of sample mis-identification caused by changing specimen tubes prematurely in the single tube loader.

Corrections for FA/FSN-31978 and FA/FSN-31978-B:

- AQUIOS System Software version 2.1.1 permits the unrestricted use of the Host Query and Default Test functions on AQUIOS. The software will reject a duplicate test request when there is a test request scheduled or being prepared for a specimen with the same sample ID, tube location, and cassette ID. If an error that could lead to sample mis-identification occurs while scheduling a test, the system will generate the error message “The system stopped because of a cassette ID mismatch.” If this error occurs, exit and reopen the software, login and then perform the Startup again. These changes in the new software version will prevent the occurrence of ID duplication and sample mis-identification when the system is connected to a Laboratory Information System.



The national competent authority has been informed of this follow-up field safety corrective action.

Please take the following actions:

Share this information with your laboratory and retain this notification as part of your laboratory Quality System documentation.

If you have any questions or concerns regarding this follow-up FSN please contact your local Beckman Coulter Representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Nancy Nadler
Vice President, Quality Assurance and Regulatory Affairs

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