



Nov. 17, 2023

**URGENT FIELD SAFETY NOTICE**

## DxA 5000 Automation System

REF	LOT	
B50516	N/A	N/A

Attention Beckman Coulter Customer,

Beckman Coulter is updating a field safety corrective action for the product listed above. This letter contains important information that needs your immediate attention.

<b>ISSUE:</b>	<p>Your DxA has been updated with DxA Software Version 3.1. Beckman Coulter has become aware that the issue described below might still occur.</p> <p>The DxA Software has configuration settings to identify tests that are not to be performed based upon a specific tube type. The DxA does NOT communicate this to the Remisol middleware software quickly enough to prevent the test to be run.</p>
<b>IMPACT:</b>	Tests may be erroneously performed. In cases where a tube contains an additive which could interfere with a test, the test result may be incorrect.
<b>ACTION:</b>	<p>Please continue to follow the "Action" written below until the follow up visit from your Field Service Engineer is completed.</p> <p>Inspect tubes routed to error regions and confirm that the tube type was appropriate per the assay IFU for the test performed.</p>
<b>RESOLUTION:</b>	Please expect a follow-up visit from your Field Service Engineer to perform the additional configuration setting update needed to enable DxA Software Version 3.1 to communicate to the Remisol middleware to prevent test to be run.

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

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

FA-23024-B

Beckman Coulter Biomedical GmbH

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Geschäftsführer/Managing Directors: Ross Michael Bell, Orlaith Anne Lawler



If you have any questions regarding this notice, please contact our Customer Support Center or your local Beckman Coulter Representative:

- From our website: <http://www.beckmancoulter.com>
- Contact your local Beckman Coulter Representative

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

DocuSigned by:  
  
 Signer Name: Cheillan, Franck  
Signing Reason: I approve this document  
Signing Time: 17-Nov-2023 | 7:40:40 AM PST  
6309FFDE61F340FA89FE6856007A4771

Franck Cheillan  
Vice President, Quality & Regulatory Affairs  
Beckman Coulter Biomedical GmbH

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