



January 21, 2026

URGENT MEDICAL DEVICE RECALL

BECKMAN COULTER DxC 700 AU
 BECKMAN COULTER CHEMISTRY ANALYZER AU5800

Analyzer	Part Number	Serial Number
BECKMAN COULTER DxC 700 AU	Refer to Appendix A for the affected instrument.	
BECKMAN COULTER CHEMISTRY ANALYZER AU5800		

Attention Beckman Coulter Customer,

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

ISSUE:	<p>Beckman Coulter has determined that the DxC 700 AU and AU5800 Clinical Chemistry Analyzers listed above may unexpectedly generate the errors described below when transitioning from Standby to Measure 1, or from Measure 2 to Measure 1, using PC pre-installed with Microsoft® SQL Server® 2022 Express, and analysis may not be started:</p> <ul style="list-style-type: none"> • 9000 PROGRAM ERROR (... CAL History DB Open Error.(SqlErr) ...) • 9000 PROGRAM ERROR (... RB History DB Open Error.(SqlErr) ...) <p>This error is caused by the inability to open the Regent Blank (RB) and Calibration databases. If this issue occurs, the system will stop analyzing, and Beckman Coulter Field Service Engineer (FSE) visit is required to restore the system.</p> <p>Our investigation has confirmed that this issue occurs when the Calibration Monitor remains open for more than 15 minutes. Refer to Picture1 and Picture 2.</p> <p>Picture1 for DxC 700 AU</p>
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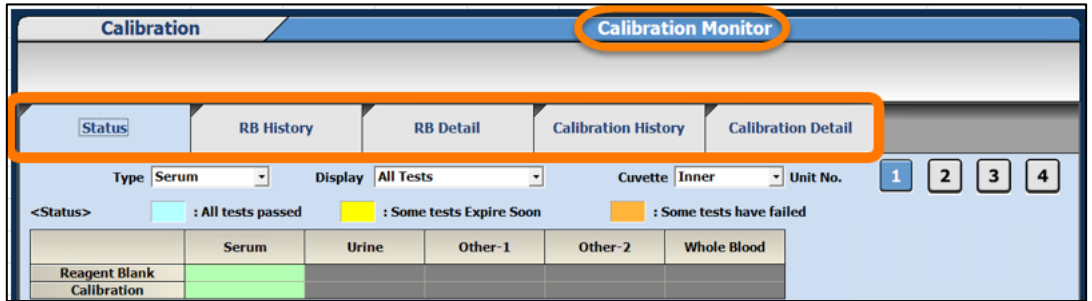
Beckman Coulter, Inc.
 250 S. Kreamer Boulevard
 Brea, CA 92821, USA

Telephone: (800) 854-3633
 Internet:
 www.beckmancoulter.com

FA-001491



Picture2 for AU5800



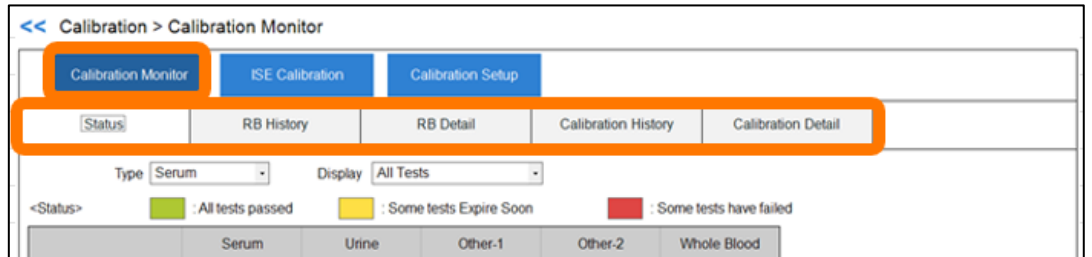
IMPACT:

- If no alternative measurement method is available, in a worst-case scenario, delay in reporting patient results may lead to a delay in diagnosis and/or patient treatment.
- This issue does not cause incorrect test results.

ACTION:

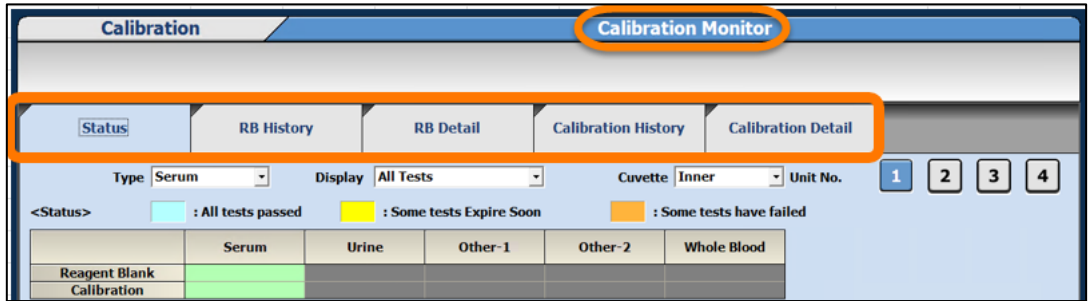
- Beckman Coulter has identified the root cause and will resolve the issue by applying a Software solution to the impacted systems. BEC service team will contact you to schedule the Software solution application, and a Field Service Engineer (FSE) will perform the on-site work.
- Until the Software solution is installed, please follow these precautions:
 - Do not leave the Calibration Monitor open for more than 15 minutes (including the five tabs under the Calibration tab: Status, RB History, RB Detail, Calibration History, Calibration Detail) even in modes other than Measure mode, such as Stand-by mode. Refer to **Picture3** (same as Picture1) for DxC 700 AU and **Picture4** (same as Picture2) for AU5800.
 - Perform System Shutdown (END Process) daily. (This backs up the RB and Calibration databases.) For AU5800, ensure the backup checkbox is selected during System Shutdown. DxC 700 AU does not have a checkbox as backup is done automatically when System Shutdown process. Refer to **Picture5** for AU5800 System Shutdown.

Picture3 for DxC 700 AU

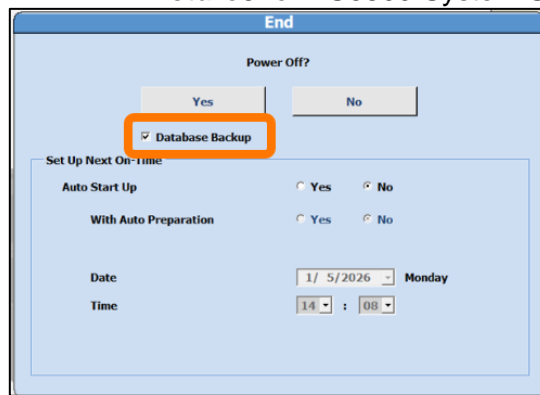




Picture4 for AU5800



Picture5 for AU5800 System Shutdown (END Process)



- Beckman Coulter recommends posting this letter on or near the affected analyzers.

RESOLUTION: Beckman Coulter will dispatch Field Service Engineers to apply the software Solution on the affected systems to resolve the issue.

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.

So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:

- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.

If you have any questions regarding this notice, please contact our Customer Support Center.

- From our website: <http://www.beckmancoulter.com>

We apologize for the inconvenience that this caused your laboratory.



Sincerely,

Signed by:

A small, handwritten signature in blue ink, appearing to read 'Franck Cheillan'.



Signer Name: Cheillan, Franck
Signing Reason: I approve this document
Signing Time: 21-Jan-2026 | 11:31:09 AM PST

6309FFDE61F340FA89FF6856007A4771

Franck Cheillan
Vice President, International Quality Operations

Enclosure: Response Form

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Appendix A

Analyzer	Instrument Installed with PC preinstalled with Microsoft® SQL Server® 2022 Express	
BECKMAN COULTER DxC 700 AU	REF	Serial Number
	B86443	From SN 2025060052 to SN 2025120498
	B86444	
	B86445	
	B86446	
	C88431	From SN 2025095056 to SN 2025125073
	C88432	
	Instrument Replaced with PC preinstalled with Microsoft® SQL Server® 2022 Express	
	REF	Serial Number
	B86444	2017050064, 2017100174, 2017120220, 2018030312, 2018040352, 2018100561, 2018110599, 2019010712, 2019010713, 2019111170, 2020021348, 2021021852, 2021092300, 2021102318, 2021112381, 2021122441, 2021122458, 2022022579, 2022042631, 2022052705, 2022062775, 2023063701, 2024064408, 2024064419, 2024064440
B86446	2024024167, 2024104602	
BECKMAN COULTER CHEMISTRY ANALYZER AU5800	Instrument Installed with PC preinstalled with Microsoft® SQL Server® 2022 Express	
	REF	Serial Number
	B96697	From SN 2025061441 to SN 2025121633
	B96698	
	C88433	From SN 2025097456 to SN 2025127580
	C88434	
	Instrument Replaced with PC preinstalled with Microsoft® SQL Server® 2022 Express	



	REF	Serial Number
	A94914	1070021-1
	B23279	2014011316, 2014071647, 2014121858, 2014121906
	B23280	2015102414, 2016022593
	B23281	5094354
	B96697	2017043260, 2019064648, 2019074683
	B96698	2017063377, 2019114891, 2021075971, 2021075977, 2021080036, 2024101288