

January 27, 2026

URGENT FIELD SAFETY NOTICE

BECKMAN COULTER DxC 700 AU
BECKMAN COULTER CHEMISTRY ANALYZER AU5800

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

Single Registration Number (SRN): US-MF-000010288

Attention Beckman Coulter Customer,

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

ISSUE:

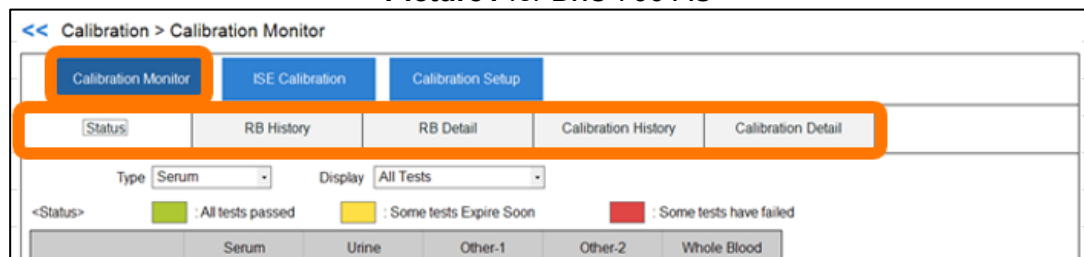
Beckman Coulter has determined that the DxC 700 AU and AU5800 Clinical Chemistry Analyzers listed above may unexpectedly generate the errors described below when transitioning from Standby to Measure 1, or from Measure 2 to Measure 1, using PC pre-installed with Microsoft® SQL Server® 2022 Express, and analysis may not be started:

- 9000 PROGRAM ERROR (... CAL History DB Open Error.(SqlErr) ...)
- 9000 PROGRAM ERROR (... RB History DB Open Error.(SqlErr) ...)

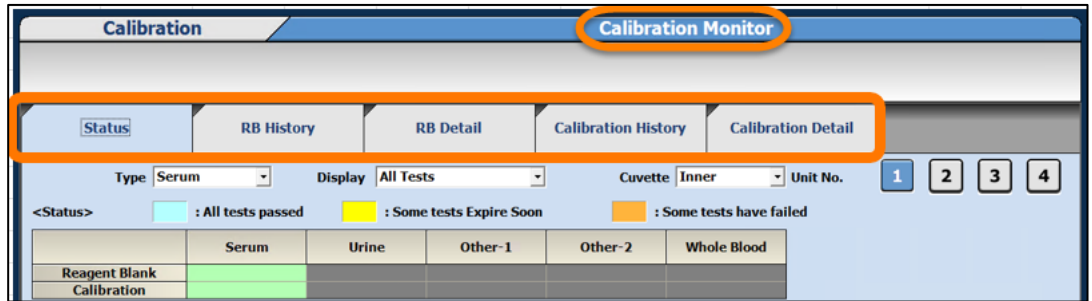
This error is caused by the inability to open the Reagent Blank (RB) and Calibration databases. If this issue occurs, the system will stop analyzing, and Beckman Coulter Field Service Engineer (FSE) visit is required to restore the system.

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**.

Picture1 for DxC 700 AU



Picture2 for AU5800



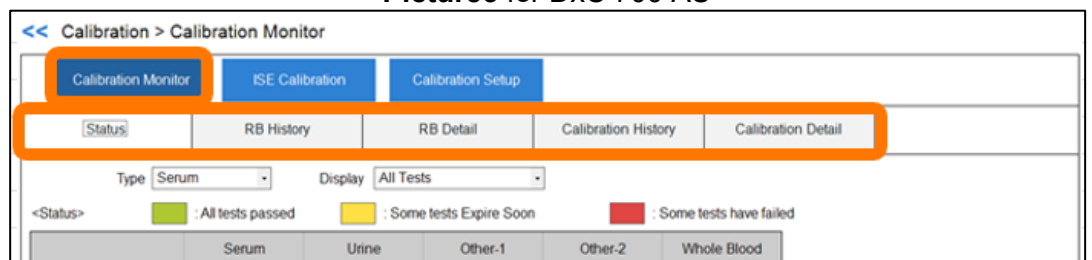
IMPACT:

- 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.

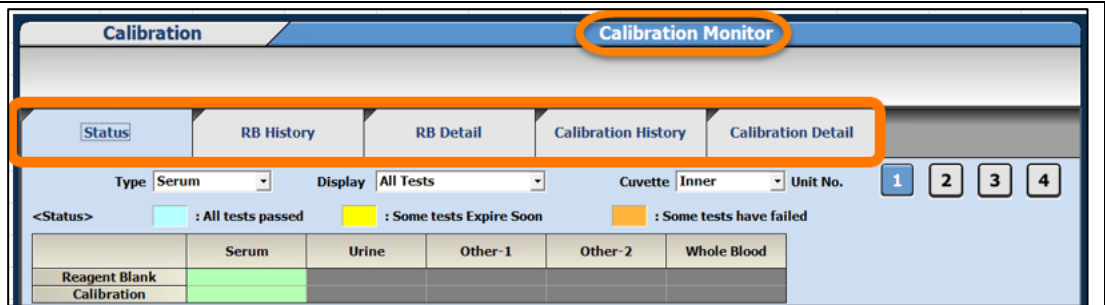
ACTION:

- 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.

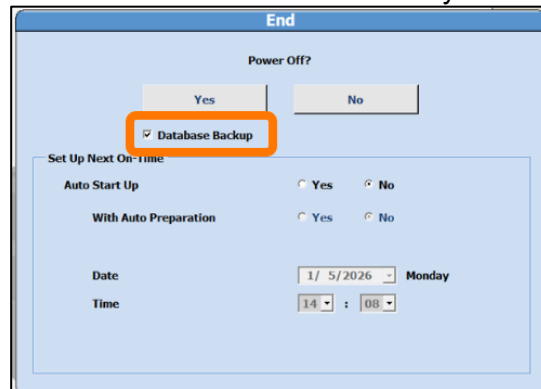
Picture3 for DxC 700 AU



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.

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.

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,



Enclosure: Response Form

Beckman Coulter, the stylized logo and the Beckman Coulter product and service names mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries.

Appendix A

Analyzer	Instrument Installed with PC preinstalled with Microsoft® SQL Server® 2022 Express		
BECKMAN COULTER DxC 700 AU	REF	UDI	Serial Number
	B86443	14987666542491	From SN 2025060052 to SN 2025120498
	B86444	14987666542545	
	B86445	14987666542507	
	B86446	14987666542514	
	Instrument Replaced with PC preinstalled with Microsoft® SQL Server® 2022 Express		
	Serial Number		
	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	2024024167	2024104602
BECKMAN COULTER CHEMISTRY ANALYZER AU5800	Instrument Installed with PC preinstalled with Microsoft® SQL Server® 2022 Express		
	REF	UDI	Serial Number
	B96697	14987666543016	From SN 2025061441 to SN 2025121633
	B96698	14987666543023	
	Instrument Replaced with PC preinstalled with Microsoft® SQL Server® 2022 Express		
	Serial Number		
	1070021-1	2014011316	2014071647



	2014121858	2014121906	2015102414
	2016022593	5094354	2017043260
	2019064648	2019074683	2017063377
	2017063377	2019114891	2021075971
	2021075977	2021080036	2024101288



CUSTOMER RESPONSE FORM
BECKMAN COULTER DxC 700 AU
BECKMAN COULTER CHEMISTRY ANALYZER AU5800

Analyzer	REF	Serial Number
BECKMAN COULTER DxC 700 AU		See Appendix A in letter.
BECKMAN COULTER CHEMISTRY ANALYZER AU5800		

Check the appropriate box below:

- ☐ I have read and understood the information within the accompanying Beckman Coulter Notification. All relevant personnel have been informed of its contents, any necessary actions taken, and records retained as part of our Laboratory Quality System documentation.

Or:

- ☐ We do not have this product. I have read and understood the information within the accompanying Beckman Coulter Notification and have retained this record as part of our Laboratory Quality System documentation.

Name and Address of Laboratory / Hospital / Organization / Institution:

or

«CUST_NAME»
«ADDRESS»
«CITYSTATEZIP»

Signed: _____ Date: _____

Name: _____ Title: _____

Tel: _____ Email: _____

Beckman Coulter Customer Number: _____

Please return to: Beckman Coulter, Inc.
xxxx (address)
Attn: Regulatory Affairs
Fax number: xxx – xxx-xxxx
Other site-specific response return information



Beckman Coulter is updating the customer address list for field action notifications. If the contact information on your notification is inaccurate, please update:

Customer Number: _____

Contact Name: _____

Title: _____

Tel: _____

Email: _____

Mailing Address: _____