



## Field Safety Notice

Dear Beckman Coulter Customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the attached *in-vitro* diagnostics medical device.

We, hereby, enclosed the manufacturer's notification letter of this field corrective action with detailed information on the issue, impact, action need to be taken and resolution on this issue.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

Nur Aishah  
Regulatory Affairs Specialist

<b>Contact person of this notification</b>	...Stephanie Lim Shu Wen.....
<b>Department</b>	... Marketing.....
<b>Telephone</b>	... 601 2982 6560.....
<b>Fax</b>	... 603 7772 0551.....
<b>E-mail</b>	... <a href="mailto:SWLIMc@beckman.com">SWLIMc@beckman.com</a> .....

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July 30, 2025

**URGENT MEDICAL DEVICE RECALL**

DxC 500i Clinical Analyzer

Product	Configuration	Analyzer Module	REF	UDI	Software
DxC 500i Clinical Analyzer	With ISE	DxC 500 AU Module w/ISE, DxC 500i	C63522	14987666545089	SW 1.3.3 and 1.3.4
	Without ISE	DxC 500 AU Module, DxC 500i	C63521	14987666545072	

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.

<b>ISSUE:</b>	<ul style="list-style-type: none"> <li>Beckman Coulter has determined that on the DxC 500i Clinical Analyzer, when ordering a Clinical Chemistry (CC) combination test simultaneously with an Immunoassay (IA) test, if the IA test is processed between the Clinical Chemistry constituent tests, the sample status of the Clinical Chemistry test will remain "In Progress" with no error events.</li> </ul>
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>The CC combination tests that may be impacted are the following:                             <ul style="list-style-type: none"> <li>- Direct Bilirubin (OSR6X11)</li> <li>- Total Bilirubin (OSR6X12)</li> <li>- Hemoglobin A1c (B93009)</li> <li>- Sentinel Glucose-6-Phosphate Dehydrogenase (E05BCS180954)</li> </ul> </li> <li>This may cause a delay in processing the CC combination test result.</li> <li>The IA test result is not impacted and will be processed with no delay.</li> </ul>
<b>ACTION:</b>	<ul style="list-style-type: none"> <li>This issue only impacts software versions 1.3.3 and 1.3.4. To check your software version, select Menu &gt; About page.</li> <li>For DxC 500i Clinical Analyzers running software version 1.3.3 or 1.3.4, if this issue occurs, you will need to place a new order for the CC combination test,                             <ul style="list-style-type: none"> <li>Select Home &gt; Sample List task indicator, then select Active in the upper left corner of the Sample List to display samples "In Progress".</li> <li>Program the CC combination tests for these "In Progress" samples using a new rack and Sample ID, apply the new barcode, then load the rack onto the analyzer for processing.</li> <li>Set aside the rack with "In Progress" samples and contact your Beckman Coulter representative to clear them.</li> </ul> </li> <li>Beckman Coulter recommends sharing the content of this letter with your laboratory and/or Medical Director.</li> </ul>



<b>RESOLUTION:</b>	<ul style="list-style-type: none"><li>• Beckman Coulter has resolved this issue in Software version 1.3.5.</li><li>• Your Beckman Coulter service representative will contact you to schedule the software upgrade.</li></ul>
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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>

If you have any questions regarding this product, please contact your local Beckman Coulter Representative, or use the following link for a listing of local contact information.

<https://www.beckmancoulter.com/en/support/contact-us>

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:  
  
 Signer Name: Jennifer Chau  
Signing Reason: I approve this document  
Signing Time: 30-Jul-2025 | 11:54:10 AM PDT  
CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau  
VP US Quality Operations

Enclosure: Response Form

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