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 onthis 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 informus 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

Contact person of this notification	Chong Chuen Ling.....
Department	... Marketing.....
Telephone	...6012 982 6529.....
Fax	...603 7772 0551.....
E-mail	... cchong01@beckman.com .....

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March 5, 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 1.3.0 and 1.3.2
	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.

ISSUE:	Beckman Coulter has determined that the DxC 500i Clinical Analyzer may not run a requested calibration order for a two-part reagent and subsequently prevents any new calibration order from being placed. For two-part reagents, when reagent blank or calibration is ordered during sample processing and then any of the components (R1 and/or R2) depletes to zero tests, the analyzer will not be able to complete the calibration request, and the calibration order will remain pending. The analyzer will not allow additional calibration orders to be requested for any assays.
IMPACT:	• Calibration order for the two-part reagent remains pending. • No new calibration orders can be processed for any clinical chemistry assays which may cause a delay in reporting test results. Existing calibration curves remain valid until expiration of the curve. • This issue does not affect immunoassay processing.
ACTION:	• Do not place calibration orders when the analyzer is processing samples. • Refer to the DxC 500i IFU Reagent Overview section for instructions on Monitoring the Status of Reagents. • Beckman Coulter recommends sharing the content of this letter with your laboratory and/or Medical Director. • If you experience this issue on software version 1.3.0 or 1.3.2, contact Beckman Coulter for service.
RESOLUTION:	• This issue has been resolved in the most recent software release, version 1.3.3. • Your Beckman Coulter service representative will contact you to schedule the software upgrade when it is available.

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:
Jennifer Chau
Signer Name: Jennifer Chau
Signing Reason: I approve this document
Signing Time: 05-Mar-2025 | 3:49:22 PM PST
CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau
Vice President Quality & Regulatory Affairs

Enclosure: Response Form