Docusign Envelope ID: 94481B3A-49A9-8D19-8082-150C5AFA6AF1

August 27, 2026

URGENT FIELD SAFETY NOTICE

DxC 500 AU Clinical Chemistry Analyzer

Configuration	Analyzer Module	REF	UDI	Software
With ISE	AU w/ISE	C63520	14987666545065	1.4.5 or earlier
Without ISE	AU w/out ISE	C63519	14987666545058	1.4.5 or earlier

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 identified a software issue affecting DxC 500 AU Clinical Chemistry Analyzers when testing plasma samples. Following user configuration of a Clinical Chemistry test to use units different from the system default, a subsequent configuration change and activation of the draft configuration in the System Configuration page may cause the analyzer to revert the test units to the system default setting without notifying the user. The system does not provide a warning or notification to alert the user that the configured units have reverted to the default units. **Note**: In accordance with the Instructions for Use (IFU), QC materials should be analyzed following configuration changes. Performance and review of QC results after any system configuration change will allow users to detect unintended unit reversions and identify the issue prior to reporting patient results.
IMPACT:	• This issue can result in falsely elevated reported results for the following Chemistry tests: Albumin, Bicarbonate, Calcium Arsenazo, Cholesterol, Glucose, HDL-Cholesterol, Inorganic Phosphorous, Lactate, LDL-Cholesterol, Magnesium, Triglyceride, and Urea/Urea Nitrogen. • No other Chemistry tests are impacted by this issue. • Access Immunoassay tests are not impacted. • When this issue occurs, the analyzer correctly processes the patient samples and displays the results using the system default units. However, the unintended unit reversion may result in the following discrepancies:

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	1. Analyzer Flagging Impact ○ The analyzer will display the numerical result generated using the system default units (e.g., mg/dL). ○ Result flags (e.g., High [H]) will be generated based on the user-configured unit. ○ As a result, the displayed numerical result will appear in the system default unit (e.g., mg/dL), while the flag is applied using the user-configured unit limits (e.g., mmol/L). ○ Users may not recognize the discrepancy between the displayed result and the associated flag, potentially leading to misinterpretation of the result. **2. Laboratory Information System (LIS) Impact** ○ The analyzer calculates and transmits numerical results using the system default units (e.g., mg/dL). ○ If the LIS is configured to display the test using the user-configured unit (e.g., mmol/L), the LIS will display the numerical value generated by the analyzer together with the user-configured unit designation. ○ In this scenario, the numerical result would not be converted to the expected unit of measure, resulting in an incorrectly reported value. ○ No flags or alerts are generated in the LIS to indicate the discrepancy. • The patient may be subjected to unnecessary medical treatment and additional noninvasive testing. • Results that were generated on software version 1.5 are not impacted.
ACTION:	• Beckman Coulter recommends sharing the content of this letter with your laboratory and/or medical director to assess laboratory and patient impact. • For analyzers on software versions earlier than 1.5: ○ Users should verify that their instrument displays the intended units in the Test Menu page within the System Configuration page prior to reporting patient results. ○ Beckman Coulter recommends posting this letter on or near the affected analyzers if they have the affected software version.
RESOLUTION:	• This issue is resolved in software version 1.5. • If your analyzer is currently operating on a software version earlier than version 1.5, your Beckman Coulter service representative will contact you to schedule the upgrade to software version 1.5.

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.

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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

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Enclosure: Response Form

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