Class 2 Device Recall DxC 500 AU Clinical Chemistry Analyzer with software version 1.4.5 or lower

Class 2 Device Recall DxC 500 AU Clinical Chemistry Analyzer with software version 1.4.5 or lower

See Related Information[22]

Date Initiated by Firm	September 02, 2026
Date Posted	October 02, 2026
Recall Status[1]	Open[3], Classified
Recall Number	Z-0084-2027
Recall Event ID	99800[23]
510(K)Number	K220977[24]
Product Classification	Analyzer, chemistry (photometric, discrete), for clinical use[25] - **Product Code** JJE[26]
Product	DxC 500 AU Clinical Chemistry Analyzers: 1. AU w/out ISE, Part No. C63519 2. AU w/ISE, Part No. C63520
Code Information	Software version 1.4.5 or earlier. 1. UDI-DI 14987666545058 2. UDI-DI 14987666545065
FEI Number	2050012
Recalling Firm/ Manufacturer	Beckman Coulter Inc. 250 S Kraemer Blvd Brea CA 92821-6232
For Additional Information Contact	Ian Pilcher 714-961-5321
Manufacturer Reason for Recall	Beckman Coulter has identified a software issue affecting DxC 500 AU Clinical 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 Pre-Review Reminders Include OII and CDRHRecallGroup@fda.hhs.gov in any discussions on change/elevation of recalls to Class I classification and situations involving additional public communications (FDA and/or firm issued). Post-Review Reminders Final Check: Ensure your documentation accurately reflects the final recommendation prior to signature. Complete CTS: Recall Product tab, Additional Recall Event Info, Regulation, and Act. Upload PDFs of Consult, Review Memo, and Classification Letter for Class I Recall in DocMan. [Click to enter extra reminder]To add reminders, type the reminder in the text field to the left then press the Tab key. Doc ID 03534.05.06 2 of 8 not provide a warning or notification to alert the user that the configured units have reverted to the default units. This issue can result in falsely elevated reported results.
FDA Determined Cause [2]	Software design
Action	On September 2, 2026, the firm began notifying customers via letters titled "URGENT MEDICAL DEVICE RECALL." Customers were instructed to inform their laboratory 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.

- Recall letter should be posted on or near affected analyzers if they have the affected software version.

This issue is resolved in software version 1.5. If your analyzer is currently operating on an earlier software version, your Beckman Coulter service representative will contact you to schedule the upgrade to software version 1.5.

Quantity in Commerce	146 US, 170 OUS
Distribution	Worldwide - US Nationwide distribution.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database	510(K)s with Product Code = JJE[29]

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