

July 10, 2026

URGENT FIELD SAFETY NOTICE

DxC 500i Clinical Analyzer

Configuration	Analyzer Module	REF	UDI	Software
With ISE	DxC 500 AU Module w/ISE, DxC 500i	C63522	14987666545089	1.5 or lower
Without ISE	DxC 500 AU Module, DxC 500i	C63521	14987666545072	1.5 or lower

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 a modification made by operators to the below 25 predefined calculated rules, which are included as part of the parameter package, will revert to the default expression following parameter package or software upgrades.		
	Rule ID	Default Expression	Region*
	calc_LDL	$([CHOL]-[HDLC])-[TRIG]/5$	US
	VLDL	$[TRIG]/5$	US
	CHOL_HDL	$[CHOL]/[HDL]$	US
	calc_TIBC1	$[IRON]+[UIBC]$	US
	% Iron Sat1	$([IRON]/([IRON]+[UIBC]))*100$	US
	% Iron Sat2	$([IRON]/([TRF]*1.40))*100$	US
	BUN_CRE	$[BUN]/[CRE]$	US
	Globulin	$[TP]-[ALB]$	US
	ALB_Globulin	$[ALB]/([TP]-[ALB])$	US
	AGAP1	$([NA]+[K])-[Cl]+[CO2]$	US
	AGAP2	$([NA]+[K])-[Cl]+[CO2-]$	US
	Indirect BIL1	$[TBIL]-[DBIL]$	US
	Indirect BIL2	$[TBIL]-[DBIL+]$	US
	UALB_CRE	$[UALB]/[CRE]$	US
	calc_LDL-	$([CHOL]-[HDL+])-[TRIG-]/5$	OUS

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	calc_LDLx	$(([\text{CHOLx}] - [\text{HDLc}]) - [\text{TRIG}]) / 5$	OUS
	% Iron Sat1-	$(([\text{IRON-}] / ([\text{IRON-}] + [\text{UIBC-}])) * 100$	OUS
	% Iron Sat1LV	$(([\text{LV_IRON-}] / ([\text{LV_IRON-}] + [\text{UIBC-}])) * 100$	OUS
	% Iron Sat2-	$(([\text{IRON-}] / ([\text{TRF}] * 1.40)) * 100$	OUS
	% Iron Sat2LV	$(([\text{LV_IRON-}] / ([\text{LV_TRF}] * 1.40)) * 100$	OUS
	UALB_CR-E	$[\text{UALB}] / [\text{CR-E}]$	OUS
	UALB_CRE-A	$[\text{UALB}] / [\text{CRE-A}]$	OUS
	UALB_CRE-B	$[\text{UALB}] / [\text{CRE-B}]$	OUS
	G6PDH	$[\text{G6PD}] / [\text{G6PDHb}]$	OUS
	calc_TIBC2	$[\text{TRF}] * 1.4$	Global
* Not all calculated rules are available in all regions, general regions are included			
IMPACT:	- This issue reverts to default calculation settings, which may lead to an unexpected calculated result based on the operator's modifications. - The potential risks are dependent on the assays being used, and the extent to which the Beckman Coulter predefined calculated rules were edited. - In the worst case, a physician may incorrectly assess that a patient has an elevated anion gap, potentially resulting in inappropriate medical treatment and delay in diagnosis and treatment for the underlying medical condition. - Any Chemistry rule not listed on the table above is not impacted. - This issue does not impact rules that are configured and run through host systems.		
ACTION:	- Do not change any of the 25 predefined calculated rules. In the case that the default expression does not meet your laboratory requirements, BEC has developed the attached Job Aid, which outlines the workflow required if laboratories require calculated test rules outside of those predefined calculated rules. - Beckman Coulter suggests consulting with the Laboratory Manager and/or Medical Director to determine whether any of the predefined rules in the table above were modified from the default expression during or following analyzer installation. - If no default expression was modified, there is no action to be taken. - If a predefined calculated rule was modified as compared with the default expressions in the above table, follow the steps below to configure this rule as a custom calculated rule in System configuration and to disable the predefined calculated rule that was modified.		

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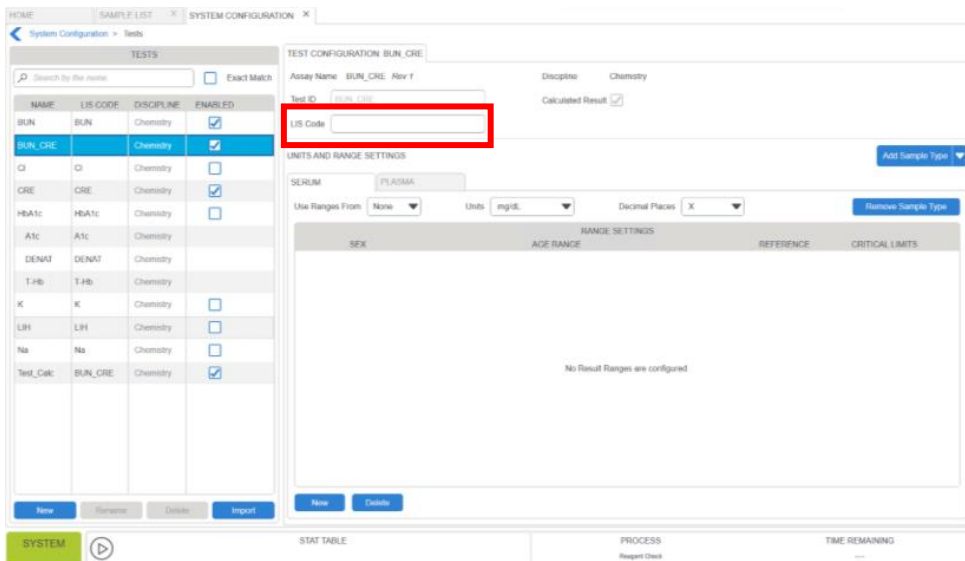
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1. Navigate to Test Menu (**MENU > System Configuration > Test Menu**) and deselect the predefined calculated test that has been modified.
2. Delete the LIS code, as shown in the screenshot below from the predefined calculated test. This step is required to ensure the same LIS code can be used for the new custom calculated rule.



The screenshot shows the 'System Configuration - Tests' interface. On the left, a table lists tests with columns: NAME, LIS CODE, DISCIPLINE, and ENABLED. The 'BUN_CRE' test is highlighted in blue. On the right, the 'TEST CONFIGURATION: BUN_CRE' panel is shown. The 'LIS CODE' field is highlighted with a red rectangle and is currently empty. Below the table, there are buttons for 'New', 'Remove', 'Delete', and 'Import'. At the bottom, there are buttons for 'New' and 'Delete'.

3. Proceed to follow the attached Job Aid to Configure a Calculated Result Rule. The same LIS code can be used for the new custom calculated rule as previously used for the predefined calculated test, provided step 2 is completed.

- Beckman Coulter suggests sharing this letter with your Medical Director to determine if performing a retrospective review of results is necessary.
- Beckman Coulter recommends posting this letter on or near the affected analyzers.

RESOLUTION:

- Beckman Coulter will implement checks to be carried out by our Service Engineers during future upgrading procedures.
- Beckman Coulter is investigating this issue and will implement the correction with a future software release.

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>

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
Job Aid: Configuring Calculated Result Rules

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Job Aid

DxC 500 AU and DxC 500i: Configuring Calculated Result Rules

The DxC 500 AU and DxC 500i chemistry parameter package includes 25 predefined calculated result rules. These calculated result rules are automatically added based on the chemistry tests and region configured on your system.

Rule Name	Default Expression	Region
calc_LDL	$([CHOL]-[HDL])-[TRIG]/5$	US
VLDL	$[TRIG]/5$	US
CHOL_HDL	$[CHOL]/[HDL]$	US
calc_TIBC1	$[IRON]+[UIBC]$	US
% Iron Sat1	$([IRON]/([IRON]+[UIBC]))*100$	US
% Iron Sat2	$([IRON]/([TRF]*1.40))*100$	US
BUN_CRE	$[BUN]/[CRE]$	US
Globulin	$[TP]-[ALB]$	US
ALB_Globulin	$[ALB]/([TP]-[ALB])$	US
AGAP1	$([NA]+[K])-([Cl]+[CO2])$	US
AGAP2	$([NA]+[K])-([Cl]+[CO2-])$	US
Indirect BIL1	$[TBIL]-[DBIL]$	US
Indirect BIL2	$[TBIL]-[DBIL+]$	US
UALB_CRE	$[UALB]/[CRE]$	US
calc_LDL-	$([CHOL-]-[HDL-])-[TRIG-]/5$	OUS
calc_LDLx	$([CHOLx]-[HDLx])-[TRIG-]/5$	OUS
% Iron Sat1-	$([IRON-]/([IRON-]+[UIBC-]))*100$	OUS
% Iron Sat1LV	$([LV_IRON-]/([LV_IRON-]+[UIBC-]))*100$	OUS
% Iron Sat2-	$([IRON-]/([TRF]*1.40))*100$	OUS
% Iron Sat2LV	$([LV_IRON-]/([LV_TRF]*1.40))*100$	OUS
UALB_CR-E	$[UALB]/[CR-E]$	OUS
UALB_CRE-A	$[UALB]/[CRE-A]$	OUS
UALB_CRE-B	$[UALB]/[CRE-B]$	OUS
G6PDH	$[G6PD]/[G6PDHb]$	OUS
calc_TIBC2	$[TRF]*1.4$	Global

Do not modify the default expression for predefined calculated result rules. If the default expression does not meet your laboratory requirements, it is required to configure a new calculated result rule and disable the predefined calculated result rule. Ensure custom calculated result tests and rules have unique names from the default names.

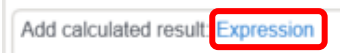
Refer to the instructions in this job aid on how to configure a calculated result rule.

Configuring Calculated Result Rules



You must be logged in as a user with Super User or System Configuration authorization to access and make System Configuration changes.

Step	Action
1. Open Tests Page	a. Select Menu > System Configuration . b. Select Test Menu from the System Configuration Menu.
2. Create the Calculated Result Test	a. Select New in the lower left corner of the Tests list. b. Enter a unique name for the test in the Name field. c. Select the discipline from the Discipline list. d. Select OK .
3. Configure the LIS Code, Units, and Ranges	a. In LIS Code , enter the code that the LIS or middleware will use for receiving results. b. Select Done . c. Select the Calculated Result checkbox. d. Select an option from the Add Sample Type menu. e. Select the units to use for reporting results from the Units list. f. Select the number of decimal places to report in Decimal Places . g. <i>(Optional)</i> Configure the ranges.
4. Return to System Configuration Page	a. Select < System Configuration in the breadcrumb links to return to the System Configuration page.  The System Configuration page displays errors at the bottom, because no rules have been defined. These errors are resolved when a calculated result rule is added in the next steps.
5. Add a New Calculated Result Rule	a. Select Rules from the System Configuration Menu. b. Select New . c. Enter a unique name for the rule in Name . d. Select OK .

Step	Action
6. Configure General Settings	a. (Optional) In the General settings, select the Description field, and in the Text Input dialog, enter a description of the rule, and select Done. b. Select Next. c. On the Conditions settings, select Next.  Do not select any conditions. Conditions are not supported for calculated results.
7. Configure Action for Calculated Result Rule	a. In the Actions settings, select the Add calculated result: [Expression] box.  Do not select any other actions. Calculated results cannot be combined with other rule actions. b. Select the Expression link at the bottom part of the page.  c. In Name of the calculated result, select the calculated result test that you created in step 2. d. In Sample Type, select the sample type.
8. Define the Calculated Result Expression	a. In the Create expression here field: • Select from the test buttons to add a test result to the calculation. • Type mathematical operators to create an arithmetic expression. Supported operators are listed in Supported operations are: area of the dialog. b. Select OK to close the Set Value dialog. c. Select Next.  Do not select any exclusions. Exclusions are not supported for calculated results. d. Select < System Configuration in the breadcrumb links to return to the System Configuration page.

Step	Action
9. Activate the Draft Configuration	a. Examine the list in the Draft Configuration section to confirm that the draft configuration has all of the intended changes. b. Select Activate Draft . c. <i>(Optional)</i> Enter a comment about the changes in the Activation Comments field. d. Select OK .



CUSTOMER RESPONSE FORM
DxC 500i Clinical Analyzer

Configuration	Analyzer Module	REF	UDI	Software
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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)

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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: _____

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