



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

Contact person of this notification	Chong Chuen Ling.....
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March 30, 2023

URGENT FIELD SAFETY NOTICE

AU / DxC AU Bicarbonate Reagent OSR6x90

REF	LOT	⌚
OSR6190	All lots	All
OSR6290	All lots	All

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:	<p>Beckman Coulter has confirmed a premature decrease in calibration ODs for the following lots of Bicarbonate OSR6x90:</p> <table border="1"><thead><tr><th colspan="3">Table A</th></tr><tr><th>REF</th><th>LOT</th><th>⌚</th></tr></thead><tbody><tr><td rowspan="3">OSR6190</td><td>2631</td><td>01 Aug 23</td></tr><tr><td>2632</td><td>01 Aug 23</td></tr><tr><td>2633</td><td>01 Sep 23</td></tr><tr><td rowspan="2">OSR6290</td><td>2628</td><td>01 Aug 23</td></tr><tr><td>2629</td><td>01 Sep 23</td></tr></tbody></table> <p>It is possible that all Bicarbonate lots may also be impacted by this issue, therefore all lots are subject to this field action.</p>	Table A			REF	LOT	⌚	OSR6190	2631	01 Aug 23	2632	01 Aug 23	2633	01 Sep 23	OSR6290	2628	01 Aug 23	2629	01 Sep 23
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IMPACT:	<p>The abnormal decrease in calibrator ODs may result in calibration failures and/or QC failures. The risk of generating falsely elevated, clinically impactful patient test results is remote.</p> <p>Data analysed internally has determined that, if the failure mode is generated, a positive shift of between 2 and 8 mEq/L for patient samples in the range of 20 – 39 mEq/L, would be observed.</p> <p>It is possible that all Bicarbonate lots may also be impacted by this issue, therefore action is required and outlined in the following section.</p>																		
ACTION:	<ul style="list-style-type: none">• Safely dispose of Bicarbonate OSR6x90 lots listed in Table A in the Issue section of this letter. Beckman Coulter have confirmed that																		

these specific lots *are* impacted by premature calibration OD decrease.

- Contact your local Beckman Coulter representative for replacement and re-imburement.
- Retrospective review of patient data is not required due to the remote possibility of generating falsely elevated, clinically impactful results which could cause a change in treatment. However, Beckman Coulter recommends sharing the content of this letter with your laboratory and/or medical director regarding the need to review previous patient test results.
- To avoid generation of elevated data on other lots of Bicarbonate OSR6x90, the Calibration OD range **Low** has been adjusted. Please take action to update the Calibration OD range on your analyzer with the updated values outlined in the table below.

	Current OD Range Low	Updated OD Range Low
Point-1	0.0500	0.0750
Point-2	0.1000	0.1550

- To change the Calibration OD Range Low on your AU / DxC AU analysers, follow the below outlined instructions:

DxC 700 AU:

- Select **Menu List > Calibration > Calibration Setup> General**
- Select the **Test Name** and scroll to the Bicarbonate test
- Select **Edit**.
- For OD Range Low, enter updated values for **Point-1** and **Point-2**
- Confirm that information is correct, then select **Save**.

AU480/AU680/AU5800: Select **Menu List > Parameters > Calibration Parameters > Calibration Specific > General**

- Select the **Test Name** and scroll to the Bicarbonate test
 - Select **Edit**.
 - For OD Range Low, enter updated values for **Point-1** and **Point-2**
 - Confirm that information is correct, then select **Confirm**.
- After making the change to the Calibration OD range Low values, Calibrate the bicarbonate test and confirm QC is acceptable before proceeding.



	<ul style="list-style-type: none">In the event of a calibration failure or sudden shift in control values, attempt to re-calibrate the assay. If re-calibration or QC fails, discard the reagent bottle and replace with a bottle from a different lot.
RESOLUTION:	<p>The Bicarbonate Setting Sheet BSOSR6X90 has also been revised to align with this updated Calibration OD Range. BSOSR6X90.04 will be available on the Beckman Coulter website under <i>Technical Documents</i>.</p> <p>Beckman Coulter is currently investigating the root cause of this issue. Beckman Coulter will continue to monitor the situation moving forward and keep you informed of any further developments.</p>

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:

- From our website : <http://www.beckmancoulter.com>
- You may request replacement product by contacting your local Beckman Coulter Representative for replacement.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Cartha Donovan
Senior Director, Quality & Regulatory Affairs

Enclosure: Response Form

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