



## 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

<b>Contact person of this notification</b>	... Alice Wong.....
<b>Department</b>	... Marketing.....
<b>Telephone</b>	... 6012-296 0320.....
<b>Fax</b>	... 603 7772 0551.....
<b>E-mail</b>	... awong02@beckman.com .....

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January 19, 2023

## URGENT MEDICAL DEVICE RECALL

Access 2 Immunoassay Analyzer  
Access 2 Section, DxC 600i

REF	Serial Number
81600N 386220 A65531 A25640	See Appendix A for a full list of affected serial numbers.

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.

<p><b>ISSUE:</b></p>	<ul style="list-style-type: none"> <li>Beckman Coulter has determined that the Access 2 wash arm lead screw nut band is susceptible to breakage. See Image 1 for examples of broken and intact nut bands.</li> <li>Appendix A includes a complete list of Access 2 Immunoassay System serial numbers that contain susceptible nut bands.</li> </ul> <div data-bbox="441 1102 1356 1419"> </div> <p><b>Image 1:</b> Examples of a broken nut band are on the left and middle and an intact nut band is on the right.</p>
<p><b>IMPACT:</b></p>	<ul style="list-style-type: none"> <li>An Access 2 Immunoassay System wash arm may not move as intended if the nut band is broken. <ul style="list-style-type: none"> <li>This may lead to <b>Wash Arm Motion Errors</b> in the Event Log. <ul style="list-style-type: none"> <li>A broken nut band may increase the risk of erroneous quality control or patient results if the compromised wash arm movement does not generate a Wash Arm Motion Error. A broken nut band may lead to multiple assay QC failures and/or several erroneous results.</li> </ul> </li> </ul> </li> </ul>



	<ul style="list-style-type: none"> <li>– Erroneous results associated with a broken nut band generally demonstrate increased relative light units (RLUs). Higher RLUs are associated with higher results in sandwich assays and lower results in competitive assays.</li> </ul>
<b>ACTION:</b>	<ul style="list-style-type: none"> <li>• Upon receiving this letter, inspect the wash arm lead screw nut band for damage following the instructions in Appendix B. Repeat this inspection during weekly maintenance until the affected nut band has been replaced.</li> <li>• If the nut band appears to be intact and undamaged: <ul style="list-style-type: none"> <li>○ You may continue normal operation of the instrument.</li> <li>○ If you observe <b>Wash Arm Motion Errors</b>, <ul style="list-style-type: none"> <li>▪ Inspect the nut band following the instructions in Appendix B.</li> <li>▪ If the nut band appears intact and undamaged, follow the troubleshooting steps for Wash Arm Motion Errors provided in the system Help or the <i>Access 2 System Reference Manual</i>.</li> <li>▪ Contact your local Beckman Coulter representative for further assistance.</li> </ul> </li> </ul> </li> <li>• If the nut band appears to be damaged in any way: <ul style="list-style-type: none"> <li>– Perform quality control to confirm validity of results since the last acceptable quality control was performed.</li> <li>– Discontinue using the Access 2 system.</li> <li>– Contact your local Beckman Coulter representative for further assistance and to schedule immediate replacement of the nut band.</li> </ul> </li> </ul>
<b>RESOLUTION:</b>	<ul style="list-style-type: none"> <li>• Beckman Coulter will replace the affected nut bands for all Access 2 Immunoassay Systems listed in Appendix A. The replacement nut bands are not affected.</li> <li>• Your service representative will contact you to schedule your wash arm lead screw nut band replacement.</li> </ul>

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 Technical Support Center or contact your local Beckman Coulter representative.

- From our website: <http://www.beckmancoulter.com>
- By phone: call 1-800-854-3633 in the United States and Canada.
  - Outside the United States and Canada, contact your local Beckman Coulter representative.

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,

DocuSigned by:

*Rachel Davison*

Signer Name: Rachel Davison  
Signing Reason: I approve this document  
Signing Time: 19-Jan-2023 | 7:11:24 AM PST

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Rachel Davison  
Vice President of Quality & Regulatory Affairs

Enclosures:

- Response Form
- Appendix A - List of Affected Serial Numbers
- Appendix B - Instructions for Inspecting the Wash Arm Lead Screw Nut Band for Damage

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