



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 Specialist

Contact person of this notification	...Stephanie Lim.....
Department	...Marketing.....
Telephone	...+60129826560.....
Fax	...603 7772 0551.....
E-mail	...swlim@beckman.com.....



June 25, 2025

URGENT MEDICAL DEVICE RECALL

Instruments:

- 973100 – UniCel DxI 800 Access Immunoassay Analyzer
- A71457 - DxI 800 Access Immunoassay Analyzer W/Dual Gantry
- A71456 - DxI 800 Access Immunoassay Analyzer W/Spot B
- A30260 - UniCel DxI 600 Access Immunoassay Analyzer
- A71461 - DxI 600 Access Immunoassay Analyzer W/Dual Gantry
- A71460 - DxI 600 Access Immunoassay Analyzer W/Spot B

PN	Serial Number
973100	Multiple
A71457	
A71456	
A30260	
A71461	
A71460	

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.

ISSUE:	<p>Beckman Coulter has determined that UniCel DxI 600/800 instruments may experience an increase in pick and place gantry events. Specific events you may encounter in the Event Log include:</p> <ul style="list-style-type: none"> • “Pick and Place hit an unexpected vessel while attempting to place vessel” • “X Home sensor in unexpected position” • “Vessel missing or not detected during pick and place move: Wash Pick and Place” • “Pick and place detected an unexpected vessel: Wash Pick and Place” • “Vessel not detected for pickup: Wash Pick and Place” • “Vessel missing or not detected during pick and place move: Incubator Pick and Place” • “Pick and place detected an unexpected vessel: Incubator Pick and Place” • “Vessel not detected for pickup: Incubator Pick and Place” • “Vessel missing or not detected during pick and place move: Sample Pick and Place” • “Pick and place detected an unexpected vessel: Sample Pick and Place” <p>“Vessel not detected for pickup: Sample Pick and Place”</p>
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Beckman Coulter, Inc.
 1000 Lake Hazeltine Drive
 Chaska, MN 55318, USA

phone: 952.448.4848
www.beckmancoulter.com

FA-25050
 Customer Letter



IMPACT:	<ul style="list-style-type: none"> • The above events will coincide with a system Not Ready mode. When this occurs, the system may cancel tests currently in progress. • If sufficient sample volume is unavailable to repeat a cancelled test, there may be a delay in reporting patient results. • This issue does not cause erroneous test results.
ACTION:	<p>If your laboratory encounters any of the events described in this letter:</p> <ul style="list-style-type: none"> • Perform a system initialization to resume normal operation. <ul style="list-style-type: none"> ○ If repeated initialization attempts fail, contact Customer Technical Support. • Repeat testing for any cancelled tests. • No action is required if your laboratory has not observed the events listed above.
RESOLUTION:	<ul style="list-style-type: none"> • A Beckman Coulter representative will schedule the modification installation when it is available.

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 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 Support:

- From our website: <http://www.beckmancoulter.com>

We apologize for the inconvenience that this caused your laboratory.

Sincerely,
Signed by:

Jennifer Chau



Signer Name: Jennifer Chau
 Signing Reason: I approve this document
 Signing Time: 25-Jun-2025 | 11:47:36 AM PDT

CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau
 Vice President, US Quality Operations

Enclosure: Response Form

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