



December 1, 2015

## URGENT MEDICAL DEVICE RECALL

PRODUCT	REF	SOFTWARE VERSION
Unicel® DxH™ 800 Coulter® Cellular Analysis System	629029, B24465, B24802	3.0.2.0
Unicel® DxH™ SMS Coulter® Cellular Analysis System	775222	3.0.2.0
Unicel® DxH™ 600 Coulter® Cellular Analysis System	B23858	1.1.1.0

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field action for the products listed above regarding the possibility of sample misidentification. This notice pertains to systems configured as a stand-alone DxH SlideMaker Stainer, DxH 800 or DxH 600, or as a workcell with multiple DxH 800s without a DxH Slidemaker Stainer. This letter contains important information that needs your immediate attention.

<b>ISSUE:</b>	<p>During internal testing, Beckman Coulter determined that the software for the DxH systems noted above allows the creation of multiple orders with the same Specimen identification (ID) but different Patient identification when manually editing pending orders at the System Manager. The issue does not occur for edits of released results or for test orders requested through host transmission.</p> <ul style="list-style-type: none"><li>• A duplicate Specimen ID can be manually edited into an existing pending test order at the DxH System Manager's Worklist – Pending or Worklist – Review tab.</li><li>• The software does not reject the edit or generate a message stating that duplicate Specimen IDs are not allowed.</li><li>• The software prompts the user to verify the change in Specimen ID with the following message: <i>Change Specimen ID for the current specimen?</i> <i>Select OK to change the Specimen ID, the change will take effect immediately.</i> <b>&lt;OK&gt; &lt;Cancel&gt;</b></li><li>• Upon selecting <b>OK</b>, a duplicate Specimen ID will be assigned to the edited test order. The system will now have two active test orders for the same Specimen ID, one with a possible Specimen ID to Patient ID mismatch.</li><li>• After processing, incorrect results may be observed at the System Manager, on printed reports, in transmission, and in exported files.</li></ul>
<b>IMPACT:</b>	The issue creates the potential for sample misidentification and possibility of releasing erroneous results.
<b>ACTION:</b>	Do not edit the Specimen ID for a pending test order at the System Manager's Worklist – Pending or Worklist – Review tabs.
<b>RESOLUTION:</b>	The issue will be corrected in the next software release in early 2016.

FA-26617

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Please share this information with your laboratory staff and retain this notice 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.

Complete and return the enclosed Response Form within 10 days so that we are assured you have received this important communication.

If you have any questions regarding this notice, please contact our Customer Support Center

- Via our website, <http://www.beckmancoulter.com/customersupport/support>
- Via phone, call 800-526-7694 in the United States and Canada
- Outside the United States and Canada, contact your local Beckman Coulter Representative.

We apologize for the inconvenience to your laboratory.

Sincerely,



Marwan Fathallah  
Vice President, Quality Assurance and Regulatory Affairs

Enclosure: Response Form