

June 15, 2017

## FIELD SAFETY NOTIFICATION

PK7300 Automated Microplate System  
Pre-Transfusion Blood Testing System PK7300

Attention Beckman Coulter Customer,  
Copy: Chairman Medical Board/Head of Departments of Affected consignees

Beckman Coulter is initiating a field action for the product listed above. This letter contains important information that needs your immediate attention.

<b>ISSUE:</b>	<p>Beckman Coulter has confirmed that, during sample processing under certain conditions, the PK7300 does not always generate a <i>Reagent Dispensing Pressure Error</i> when the reagent vial becomes empty and no reagent is dispensed.</p> <p>Sample processing will continue after a vial is empty only when the reagent alarm volume, limit volume and associated mode shift alarm <b>have not been</b> set.</p>
<b>IMPACT:</b>	<p>False negative test results with blood grouping reagents may occur. Results will not be generated for tests using cellular or particle reagents. Wells without cellular or particle reagents will be flagged as empty (.E flags).</p>
<b>ACTION:</b>	<ol style="list-style-type: none"><li>1. Verify that the following are all set on all PK7300 analyzers in your laboratory:<ul style="list-style-type: none"><li>• Alarm Volume and Limit Volume in the Common Test Parameter – Name (Reagent tab) menu.</li><li>• Either “To Pause” or “To Measure 2” is selected for “at Short Reagent Volume Alarm” on the Mode Shift tab in the System – System Menu.</li></ul><p>If the parameters described above <b>have not been</b> set on all PK7300s in your laboratory, please follow the instructions in the PK7300 User’s Guide and the information in this letter to set them.</p></li><li>2. When you place the reagent vials in the reagent tray, make sure that each vial is fully seated to the bottom of the tray.</li></ol>
<b>RESOLUTION:</b>	<p>Beckman Coulter will update the PK7300 User’s Guide to include the information described in the actions above to indicate that the settings for the alarm volume, limit volume and associated mode shift are required. Additionally, a statement will be added to insure that the reagent vials are fully seated to the bottom of the reagent tray.</p>

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.

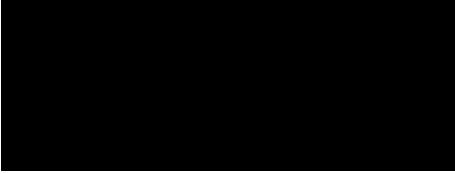
If you have any questions regarding this notice, please contact our Customer Technical Support Center:

- 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

We apologize for the inconvenience that this caused your laboratory.

Sincerely,



David G. Davis  
Director, Quality and Regulatory Affairs

Enclosure:  
Response Form