


October 6, 2014

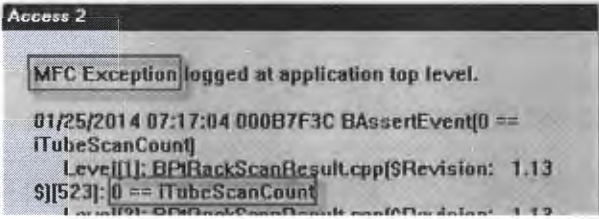
**URGENT FIELD SAFETY NOTICE**
**Small Form Factor Console PC  
For use with the Access 2 Immunoassay Systems Family\***

\* This device recall only affects the Access 2 Immunoassay System and the UniCel DxC 600i SYNCHRON Access Clinical System.

Description	REF
Small Form Factor Console PC	B23083 (small PC with silver faceplate) 

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.

<b>ISSUE:</b>	<p>Beckman Coulter has determined that the Access 2 Console PC (B23083) may experience an "MFC Exception" error during normal operation. If this error occurs, the system will exit the Access 2 User Interface (UI) screen and display a window that notifies the user of a "0==iTubeScanCount" event. If the UI is re-launched, the system will prevent access to the Sample Manager screen to request samples for processing and the same "MFC Exception" error will occur.</p>  <p>According to our records a service representative installed an Access 2 Console PC (B23083) with your new immunoassay system, or as a replacement part for your existing system.</p>
<b>IMPACT:</b>	<ul style="list-style-type: none"> <li>The Access 2 Console PC UI error can cause a delay in reporting results, but will not cause erroneous results.</li> </ul>
<b>ACTION:</b>	<ul style="list-style-type: none"> <li>Continue operating your system normally.</li> <li>Please contact our Customer Support Center if this error occurs.</li> </ul>
<b>RESOLUTION:</b>	<ul style="list-style-type: none"> <li>Only a Beckman Coulter trained representative can resolve this issue.</li> <li>Your Service Representative will contact you and schedule a service visit to modify your Console PC.</li> </ul>



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 products 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 our Customer Support Center

- From our website: <http://www.beckmancoulter.com>.
- Or contact your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

A handwritten signature in cursive script that reads "Noreen Galvin".

Noreen Galvin, Ph.D.  
Vice President Quality & Regulatory Affairs

Enclosure: Response Form

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