



25<sup>th</sup> of April, 2014

**FOLLOW-UP URGENT FIELD SAFETY NOTICE**

**UniCel DxI Immunoassay Systems\***

\* Includes the UniCel DxI 800 and UniCel DxI 600 systems, and the UniCel DxC 880i, 860i, 680i, and 660i integrated systems

<b>REF</b>	<b>Version</b>
Part Number: B14162	Software Versions: 4.6 and 4.6.1

Dear Beckman Coulter UniCel DxI Immunoassay System Customer:

This notice contains important information regarding an upcoming UniCel DxI system software release that needs your immediate attention.

**The Access, Access 2, UniCel DxC 600i, and SYNCHRON LXi 725 Immunoassay Systems are not affected by this notice.**

Beckman Coulter will release UniCel DxI system software version 5.1 update. This software version update addresses the issue described in Field Safety Corrective Action (FSCA) 22035.

<b>ISSUE:</b>	<ul style="list-style-type: none"><li>With UniCel DxI software versions 4.6 and 4.6.1, Beckman Coulter introduced a recommended shut down and restart once every 7 days AND/OR when you perform 5000 test interval maintenance to minimize the occurrence of “timing issue” events.</li></ul>
<b>RESOLUTION:</b>	<ul style="list-style-type: none"><li>The software version 5.1 update eliminates the need to shut down and restart. Therefore, customers will no longer be required to shut down and restart.</li><li>Your Service Representative will contact you to arrange software version 5.1 installation.</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 product(s) listed above to another laboratory, please provide them a copy of this letter.

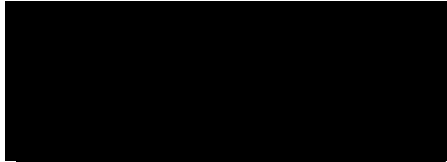
Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.



If you have any questions regarding this notice, please contact your local Beckman Coulter representative or from our website: <http://www.beckmancoulter.com>.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,



Vice President Quality & Regulatory Affairs

*Enclosure: Response Form*

*Beckman Coulter, the stylized logo, Access, UniCel, and DxI are trademarks of Beckman Coulter, Inc., and are registered with the USPTO.*