



September 12, 2018

## URGENT FIELD SAFETY NOTICE

Kaluza C Flow Cytometry Software  
Versions 1.0

Part numbers: C10574, C10575, C10576, C10577, C10578, C10579, C10580, C10581, C21166

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 #1:</b>	Flow Cytometry Standard (FCS) keywords in the Laboratory Information System (LIS) export window are not updated when datasets are loaded into a previously created analysis template.
<b>IMPACT #1:</b>	The keyword values from the sample used to create the LIS export template are erroneously transmitted as the keyword values for all samples.
<b>ISSUE #2:</b>	Installation of a Microsoft .NET Framework Windows update released between May 2018 and July 2018 causes Kaluza C software to crash with a "Error 99999" when the radial menu is accessed by right clicking an object within the software.
<b>IMPACT #2:</b>	The ability to perform analysis which requires use of the radial menu is impaired due to Kaluza C software crashes.
<b>ACTION:</b>	<p>If you are using an LIS, please review all previous LIS transmissions which included keywords for accuracy by comparing keywords displayed in Kaluza Information plots to those in the LIS system. Report any erroneous transmissions to Beckman Coulter.</p> <p>Please visit the Beckman Coulter website to download version Kaluza C 1.1 and install on all affected systems.</p> <ol style="list-style-type: none"><li>1. Navigate to <a href="http://www.kaluzasoftware.com">http://www.kaluzasoftware.com</a> and click the "Download" icon.</li><li>2. Click "Download Kaluza C 1.1" and fill in the requested information.</li><li>3. Click the link in the registration email to download Kaluza C version 1.1</li><li>4. Install Kaluza C version 1.1 on systems used for analysis.<ul style="list-style-type: none"><li>• The installer will automatically remove the previously installed version.</li><li>• The installer file may be downloaded and used on multiple systems.</li><li>• Kaluza C version 1.1 will utilize the single or network license provided with any previous version of Kaluza C Flow Cytometry software.</li></ul></li></ol>
<b>RESOLUTION:</b>	Installation of Kaluza C version 1.1 will prevent software crashes and result in proper keyword value being transmitted for all samples.

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:

- From our website: <http://www.beckman.com>
- By phone: call 800-369-0333 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 has caused your laboratory.

Sincerely,

A handwritten signature in black ink that reads 'Nancy Nadler'.

Nancy Nadler  
Vice President, Quality Assurance and Regulatory Affairs

Enclosure: Response Form