Field Safety Notice

Dear Beckman Coulter Customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the attached *in-vitro* diagnostics medical device.

We, hereby, enclosed the manufacturer's notification letter of this field corrective action with detailed information on the issue, impact, action need to be taken and resolution on this issue.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

Winnie Hii Lin Lin
Regulatory Specialist

Contact person of this notification	…Toh Xue Yun……
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June 23, 2021

FIELD SAFETY NOTICE

Product	Version	Part Number
Kaluza C Software	1.0*, 1.1.1, 1.1.2	C10574, C10575, C10576, C10577, C10578, C10579, C10580, C10581, C21166

Attention Beckman Coulter Customer,

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

ISSUE:	Beckman Coulter has discovered software anomalies in Kaluza C that may lead to the generation of erroneous results.
ISSUE #1:	Transmission of erroneous results to the Laboratory Information System (LIS) may occur any time a gate has been setup for LIS transmission and one or more gates in the data plot has been deleted (viewed as a Gate in the Select Statistics window and Value (result) for LIS transmission in the LIS Preview window). This issue applies to any computer that uses Kaluza C Software and is connected to a LIS.
ISSUE #2:	The autofluorescence values Kaluza C loads from the listmode (LMD) file do not match the values set in the Advanced Compensation Module of Navios or Navios EX. This issue occurs when all the following 3 conditions are met at the same time: • Kaluza loads an LMD file generated using the Advanced Compensation module. • The acquisition protocol uses a PEAK or TOF parameter in the third position. • The LMD file contains the @AUTOFL20 keyword and the keyword value is not empty. * Kaluza C Version 1.0 is not impacted by this issue.
IMPACT #1	In a worst-case scenario: • Erroneous results could cause a delay in initiating antiretroviral therapy and anti-opportunistic infection preventive treatments, with attendant complications (e.g. opportunistic infections) and disease progression for CD4+ enumeration panel. • For patient with hematologic malignancy, delay or loss of opportunity for planned high dose chemotherapy with rescue stem cell transplant may result in progression of malignancy and related serious complications and/or failure to continue to be a candidate for high dose chemotherapy for cure or remission with stem cell

	"rescue". For stem cell mobilization, placing patient (for autologous transplantation) and healthy matched donor (allogeneic transplantation) at unnecessary risks of repeat cytokine pulse, (which includes risk of splenic rupture), and all risks of high blood volume apheresis collection. • Misclassification or misdiagnosis of hematolymphoid malignancy leading to additional testing and/or re-draw of blood or tissue sample. In a worst-case scenario, there is possible delay in appropriate treatment or initiation of inappropriate treatment with attendant complications. • Transfusion of blood component may be inaccurately labeled as "Leukocytes Reduced" resulting in possible permanent alloimmunization, causing delay or inability of patient to tolerate future urgent or elective blood product transfusion. CMV infection may also occur. In immunocompromised persons, pregnant women, and infants, CMV infection can produce permanent injury.
IMPACT #2	In a worst-case scenario: • Erroneous results could cause a delay in initiating antiretroviral therapy and anti-opportunistic infection preventive treatment, with attendant complications (e.g. opportunistic infections) and disease progression for CD4+ enumeration panel. • Misclassification or misdiagnosis of hematolymphoid malignancy or lymphoproliferative disorder, leading to additional testing and/or re-draw of blood or tissue sample. There is possible delay in appropriate treatment or initiation of inappropriate treatment with attendant complications.
ACTION #1:	If you are using a LIS: • Review the values in the LIS Preview window for each patient and verify that they correspond to the Kaluza C data plot statistics. • If you see erroneous results, remove the incorrect statistic from the LIS Preview window. • Update the LIS export to include the desired gate statistic following the Kaluza C IFU instructions (Exporting Data to the LIS). Save changes. • Verify all LIS Preview window results and transmit to the LIS. • Consult with your Medical Director to determine if a retrospective review of results is warranted. • Report any erroneous results to Beckman Coulter.
ACTION #2:	If you are using Kaluza C with the Advanced Compensation Module of Navios or Navios EX: • Review the statistical results derived from measurements of fluorescence intensity. • If erroneous results are observed, manually adjust autofluorescence values, re-analyze the data using the adjusted autofluorescence values and verify that the correct values are generated. • Consult with your Medical Director to determine if a retrospective review of results is warranted. • Report any erroneous results to Beckman Coulter.

RESOLUTION:	Beckman Coulter will provide an update to Kaluza C Software to resolve the issue.

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.

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 Support Center;

- 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 caused your laboratory.

Sincerely,

Nancy Nadler
Vice President, Quality and Regulatory Affairs

Enclosure: Response Form