

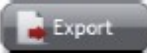

April 13, 2017

URGENT FIELD SAFETY NOTICE

Product	REF	Software Versions
AQUIOS CL Flow Cytometer	B30166	2.0 and 2.0.1

Dear Beckman Coulter Customer,

Beckman Coulter is initiating a field action for the AQUIOS CL Flow Cytometer relating to the Export feature for Tetra Combo testing. This letter contains important information that requires your immediate attention.

ISSUE:	Beckman Coulter has confirmed that the Export feature located in the Results area of the AQUIOS System software is not correctly exporting Tetra Combo CRD files.
IMPACT:	<ul style="list-style-type: none"> • The data and results on the acquisition system are not impacted. • Upon import of the exported file to another AQUIOS workstation, two individual files will be generated in the results tab rather than one combo file. • The possibility for erroneous results will occur under the following sequence of events : <ul style="list-style-type: none"> ○ using the export button to export a Tetra Combo CRD file from the acquisition system and ○ importing the data into a different system with a highly populated database and ○ moving a region in any of the plots will generate erroneous results upon recalculation of the data.
ACTION:	<ul style="list-style-type: none"> • Do not use the Export button  located in the Results area to export Tetra Combo CRD files. • To export the Tetra Combo CRD files from the system, use the export icon,  which exports the run displayed on the screen. • Refer to the AQUIOS Instructions for use, PN B21896 AD, Chapter 6- Data Review for further instructions.
RESOLUTION:	Beckman Coulter has identified the cause to be a software anomaly to be addressed with a subsequent software release.

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.

FA-30317



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 your local Customer Support Center

- From our website, <http://www.beckmancoulter.com/customersupport/support>

We apologize for any inconvenience that this caused your laboratory.

Sincerely,

.....

.....

Encl: Response Form

Beckman Coulter, the stylized logo, and the Beckman Coulter product and service marks mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc., in the United States and other countries.