



June 29, 2007

URGENT: PRODUCT CORRECTIVE ACTION
FC 500 with CXP 2.2 Acquisition Software
FC 500 MPL with MXP 2.1 Acquisition Software

Dear Beckman Coulter Customer,

Beckman Coulter has determined based on enhanced processes and internal testing, that erroneous but credible results may be generated if an operator imports cytosettings from another file, after the accumulation of data, and the data being generated is not refreshed or restarted.

The following conditions must be in place for this issue to occur:

1. Data is first accumulated using one set of cytosettings.
2. During acquisition, another set of cytosettings are imported into the existing data set.
3. The Cytometer setup mode is not activated to refresh the data set nor is a restart of the acquisition performed by the user.

Immediate User Preventive Action to avoid this issue:

- a. After importing new listmode cytosettings, restart the acquisition by activating the restart button.
- b. Import listmode cytosettings only after activating the SETUP option in the Cytometer Control screen resulting in a refresh of the data.
- c. Review all data plots and results prior to reporting results.

Please share this information with all laboratory staff and retain this notification as part of your laboratory Quality System documentation. Please complete and return the enclosed response form within 10 days so we may maintain our records.

If you have any questions regarding this Product Corrective Action, please call Beckman Coulter Customer Service at 1-800-526-7694 in the United States and Canada. Outside US and Canada, contact your local Beckman Coulter Representative. We apologize for any inconvenience that this may have caused your laboratory. Thank you for your continued support of Beckman Coulter products.

Sincerely,

Regulatory Affairs Manager - Corporate

Enc: Response Form

PCA-M-E-1025

Beckman Coulter, Inc.
11800 S.W. 147th Avenue
Miami, FL 33198-2500

Mailing Address:
11800 S.W. 147th Avenue
P.O. Box 169015
Miami, FL 33116-9015

Customer Service: (800) 526-7694
Product Information: (800) 526-8932
(800) 327-5531 (305) 980-3800
Internet: www.beckmancoulter.com