



August 28, 2006

URGENT: PRODUCT CORRECTIVE ACTION

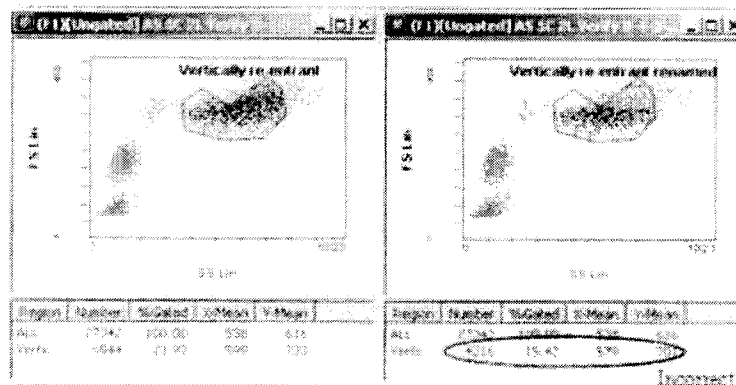
FC 500 with CXP Software, Versions 2.0 & 2.1
FC 500 MPL with MXP Software, Versions 2.0 & 2.1
CXP Analysis Software, Versions 2.0 & 2.1

Dear Beckman Coulter Customer,

Beckman Coulter has confirmed two workflow scenarios associated with renaming regions which may produce incorrect results.

Scenario	Workflow	Affect to Results
1	<ul style="list-style-type: none"> A polygon region is created with a vertically re-entrant angle such as that shown in Example 1. The polygon is then renamed by using the Region Properties dialog accessed by right-clicking the region. 	The renamed region will generate incorrect statistics and the polygon gate will exhibit unexpected shading. See Example 1.
2	<ul style="list-style-type: none"> The operator renames a region that is not defined as a gate (for example a copied region) by double-clicking on the region name. 	The region name within the statistics box for the new plot is not updated. See Example 2.

Example 1: The following plot on the left contains a polygon region with a vertically re-entrant angle. The plot on the right demonstrates the effect to that plot after the region was renamed by right clicking the region and selecting Region Properties.



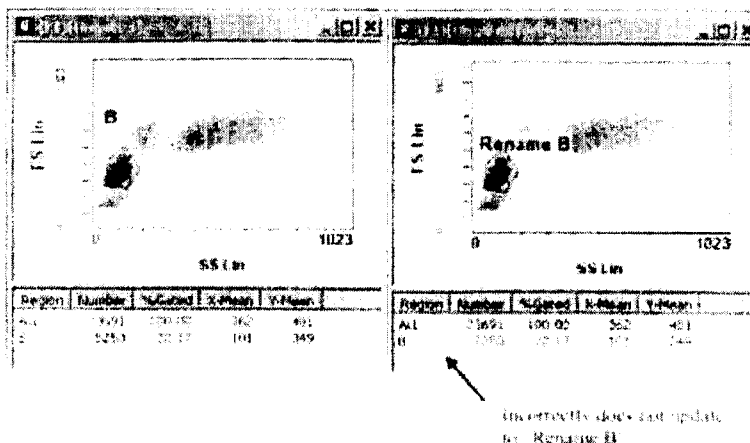
Although the region position and events encompassed by the renamed region remain unchanged, it will generate incorrect statistical results. Statistics from additional plots gated on the renamed region will also be affected in the same manner. The unexpected event coloring can also be seen within the renamed region. It should be noted that these issues only occur with regions containing vertically re-entrant angles.

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Example 2: The following plot on the left contains a copied region. The plot on the right demonstrates the effect to that plot after the region was renamed by double clicking the region name. Note that the region name in the statistics box was not updated to "Rename B".



Immediate user preventive action to remedy both issues:

- After editing region names, refresh the protocol by selecting the View/Modify Regions (from the Analysis Menu or toolbar) and then select OK.
- Review all data plots and results prior to reporting results

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. Complete and return the enclosed Response Form within ten days so we may maintain our records.

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

Sincerely,



Regulatory Affairs Manager - Corporate

Enc - Response Form

