



December 14, 2018

FOLLOW-UP URGENT FIELD SAFETY NOTICE – FSN 30417FCL

FC 500 Series Flow Cytometers

Product	Part Number	Software Versions
FC 500™ Series Flow Cytometers (new, reconditioned or refurbished)	All	All

Dear Beckman Coulter Life Sciences Customer,

This notification supplements our previous **Urgent Field Safety Notice dated January 9, 2018 – FSN-30417FC/C24357** concerning an internal electronic component on the circuit “Amplifier” boards in the FC 500 system that may be affected by a manufacturing defect. This letter provides an update on the ‘Resolution’ for the issue.

This update only affects those customers using the LeukoSure application.

RESOLUTION:

- As an interim solution, Beckman Coulter Life Sciences (BEC LS) has released software updates for tetraCXP and stemCXP which includes the additional Time versus Parameter plots.
- All customers using the LeukoSure application will have their Amplifier boards replaced by BEC LS Field Service Engineers. Replacement of potentially defective Amplifier boards with the new Amplifier boards will eliminate the defect leading to signal loss and/or signal drifting. BEC LS will contact you to schedule a site visit to replace your boards.

Please continue following the actions described in FSN-34017 dated January 9, 2018 until your Amplifier Boards are replaced.

Please share this information with your laboratory and retain this notification as part of your laboratory Quality System documentation.

If you have any questions or concerns regarding this follow-up FSN please contact your local Beckman Coulter Life Sciences Representative.

The national competent authority has been informed of this follow-up field safety corrective action.

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.



We apologize for the inconvenience that this caused your laboratory.

Sincerely,
Nancy Nadler

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

Vice President, Quality Assurance and Regulatory Affairs
Enclosure: Response Form