



December 24, 2018

FOLLOW-UP URGENT FIELD SAFETY NOTICE – FSN 30417-FC

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 17, 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.

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.
- As a permanent solution, BEC LS has released a software update that incorporates a software detection feature to address this issue. An auto-detection software feature has been added that will detect a signal loss and/or signal drift on any amplifier board. The auto-detection software feature is being added to the CXP (version 2.3) and MXP (version 2.3) FC 500 system software which provides the acquisition functionality. Therefore, any application or protocol that operates on the FC 500 CXP or MXP software will automatically have the auto-detection software feature capability.
- Please note that the auto-detection software has the limitations where certain patients may present problems due to altered or very low counts of certain cellular populations. The auto detection algorithm will not detect less than 200 consecutive events, and requires at least 400 events to determine any signal variation. If your application/assay falls within the limitations of the software detection tool, please contact your BEC LS representative; BEC LS will either replace boards on your unit or work with your lab to identify suitable alternate options.

Your Beckman Coulter Life Sciences service representative will contact you to schedule a date for installing the new software. With the installation of the new software version, please follow the instructions provided in the updated labeling (in the FC 500 CXP and FC 500 MXP Software Addendum, PN C18505).

Please continue following the actions described in FSN-30417 dated January 17, 2018 until the new software has been installed.



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Please share this information with your laboratory staff and retain this notice as part of your laboratory Quality System documentation. If you have forwarded the affected product to another laboratory, please provide them with a copy of this letter.

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

Please complete and return the enclosed response form within 10 days so that we are assured you have received this important communication.

If you have any questions regarding this notice, please contact the Customer Support Hotline at 00353 1407 3082 or techsupportie@beckman.com.

We apologize for the inconvenience that this caused your laboratory.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'AB' with a long horizontal stroke extending to the right.

Andy Brown
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Enclosed: Vigilance Response Form