



July 28, 2014

UPDATE FOR URGENT FIELD SAFETY NOTICE – FSN 22198-3

LH 750 Hematology System, PNs 6605632 and A85570
LH 780 Hematology System, PNs 723585 and A90728
LH Cleaner 5L, Lot Number 332236F

Dear Beckman Coulter LH Series Customer,

Beckman Coulter is pleased to provide this update to communications that you previously received concerning optical degradation on the LH 750 and LH 780 Hematology Systems (previous communications listed below). The additional clear flow cell and extended cleaning actions outlined in the previous letters, FSN-22198 and B43108AA, are **no longer required**.

Letter Identifier	Date
FSN 22198	November 2013
B43108AA	November 2013 (instruments installed after 08-Nov-2013)
FSN 22198-2	February 2014

Update:

- The results of our investigation have shown that the LH Cleaner and Coulter Clenz that were identified in the prior letter, FSN-22198-2, were the main contributors to the optical degradation issue.
- All lots identified in the prior letter have been removed from Beckman Coulter inventory.
- Beckman Coulter has received a decrease number of optical degradation complaints since the identified lots were removed from Beckman Coulter inventory.

Actions:

- Discard the existing LH Cleaner lot from your inventory as listed in Table 1.
- Your laboratory can discontinue performing the additional clear flow cell and extended cleaning actions outlined in the previous letter.
- Please follow the existing directions in the Instructions for Use (IFU):
 - If a flow cell clog error occurs, perform troubleshooting as directed in the IFU.
 - Perform routine Shutdown as recommended in the IFU.
 - Only perform cleaning procedures as described in the current IFU.

The national competent authority has been informed of this field safety corrective action update.

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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 products listed above to another laboratory, provide them with a copy of this letter.

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 or concerns regarding this product announcement please contact the Customer Support Hotline at 00353 1407 3082 or techsupportie@beckman.com.

We apologize for the inconvenience that this has caused your laboratory.

Thank you for your continued loyalty.



Yours sincerely,



Quality / Regulatory Affairs Manager - Northern Region Europe
Tel 01494 429184/01494 429128
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Enclosed: Fax Response Form

Table 1
Affected Lot Numbers

DESCRIPTION	REF		
LH Cleaner 5L	721542	332236F	15-Aug-2014