



November 08, 2013

URGENT PRODUCT CORRECTION

LH 750 Hematology System, Part Numbers 6605632 and A85570
LH 780 Hematology System, Part Numbers 723585 and A90728

Dear Beckman Coulter Customer,

Beckman Coulter is initiating a recall for the product listed above. This letter contains important information that needs your immediate attention.

Issue:	Complaints related to optical degradation have increased on the LH 750 and LH 780 Hematology Systems. Customers have reported an increase in LS offset error messages during Startup, Background, control and/or patient analysis.
Impact:	<ul style="list-style-type: none"> • The optical degradation may potentially cause a delay in reporting results for nucleated red blood cells (nRBC), white blood cell differential and/or reticulocytes. • The rate of occurrence of this issue on your system may vary. • CBC panel results are available for reporting and are not affected by this issue.
Actions:	Perform the following steps to reduce the occurrence of this issue: <ul style="list-style-type: none"> • Perform Clear Flow Cell and Extended Cleaning as indicated in the flowchart in Attachment 1. • Continue to perform routine Daily Shutdown. A longer daily Shutdown cycle may help decrease the occurrence of the issue. When possible, leave your system in Shutdown as long as your laboratory workflow will permit. • If you continue to experience this issue, contact Beckman Coulter for additional support.
Resolution:	Beckman Coulter is investigating this issue in order to provide a resolution.

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, please provide them 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 regarding this notice, please contact our Customer Support Center

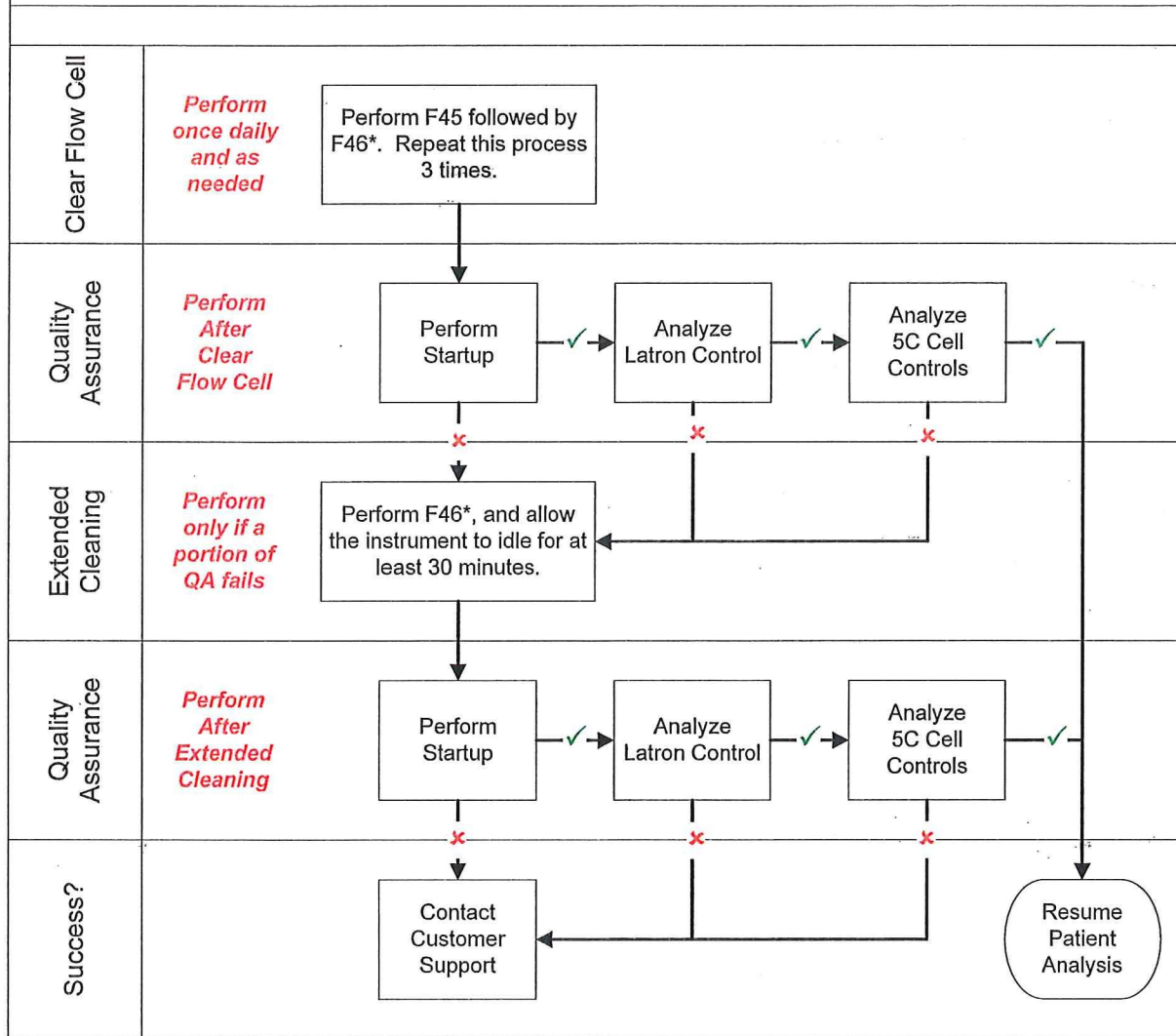
- Via our website, <http://www.beckmancoulter.com/customersupport/support>
- Via phone, call 800-526-7694 in the United States and Canada.
- Outside the United States and Canada, contact your local Beckman Coulter Representative.

We apologize for any inconvenience this has caused your laboratory.

Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs
Encl: Response Form and Attachment 1

PCA-22198

Attachment 1: Clear Flow Cell and Extended Cleaning for LH 750/LH 780 Systems



✓ Pass or acceptable results

✗ Fail or unacceptable results

* Instructions for accessing the functions through the Diluter numeric keypad are shown in

- online HELP (search numeric keypad)
- LH 750 Operator's Guide PN 4277249DE, Chapter 1 Controls and Indicators, 1.2 – Diluter
- LH 780 Instructions for Use PN 773022BE, Chapter 1 Controls and Indicators, 1.2 – Diluter