



December 14, 2010

URGENT: FIELD SAFETY NOTICE

Product	Part Number	Software Revision
Coulter® HmX and HmX AL Hematology Analyzers	6605522, 6605523, 6605524, 6605525, 6605526, 6605527, A85566, and A85564	All
Coulter® MAXM and MAXM AL Hematology Analyzers	6604569, 6604687, 6705995, 6705996, 6705997, 6705998, 6705999, 6706000	All

Dear Beckman Coulter Customer,

Beckman Coulter has confirmed an issue with the above mentioned Hematology Products. This issue requires your immediate attention.

- ISSUE:** The MAXM, MAXM AL, HmX and HmX AL Analyzers omit the tilde (~) character when the tilde is used as part of the Sample ID within a barcode label scanned by the primary mode barcode reader. As an example, '123~456' would result as '123456' with the tilde character omitted. Download of a tilde character is allowed from manual entry and from a host computer.
- IMPACT:** There is a potential for Specimen or Patient misidentification to occur. This could in turn lead to misleading patient diagnosis, management and treatment for broad spectrum of clinical conditions, having minor to serious consequences depending on the conditions.
- ACTION/
RESOLUTION:** Do not use the tilde (~) character in Specimen or Patient identifiers.

Complete and return the enclosed response form within 10 days so we may maintain our records.

Quality continues to be the single most important function of Beckman Coulter. We sincerely apologize for any inconvenience that this may have caused your laboratory. Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation.

If you have any technical questions regarding this Field Safety Notice, contact your local Beckman Coulter representative. Thank you for your continued loyalty.

Sincerely,



Group Manager, Corporate Quality and Regulatory Affairs

FSN-16014

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