



February 12 2010

URGENT: FIELD SAFETY NOTICE
Coulter® LH 500 Analyzer

Dear Beckman Coulter Customer,

Beckman Coulter has confirmed two issues related to the use of specific characters on the Coulter LH 500 Analyzer.

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- ISSUE 1:** The system will substitute or omit the characters # @ [\] ' { | } when the system is configured in a language other than English or Chinese. Example: Using the character @, a substitution in the string '123@456' would result in '123#456' and an omission would result in '123456'
- ISSUE 2:** The system will omit the character ~ regardless of language.
- IMPACT:** There is a potential for Specimen or Patient misidentification to occur.
- ACTION/RESOLUTION:** Do not use the characters # @ [\] ' { | } ~ in Specimen or Patient identifiers.
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Complete and return the enclosed response form within 10 days so we may maintain our records. Please share this information with your laboratory staff, and retain this notification as part of your Quality System documentation.

If you have any questions regarding this Product Corrective Action, please call 800-526-7694 in the United States or Canada, or contact your local Beckman Coulter Representative.

We sincerely apologize for any inconvenience that this may have caused your laboratory. Thank you for your continued support of Beckman Coulter products.

Sincerely,

Group Manager, Corporate Quality and Regulatory Affairs

PCA-13012-C

Beckman Coulter, Inc.
11800 S.W. 147th Avenue
Miami, FL 33196-2500

Mailing Address:
11800 S.W. 147th Avenue
P.O. Box 169015
Miami, FL 33116-9015

Customer Service: (800) 526-7694
Product Information: (800) 526-6932
(800) 327-6531 (305) 380-3800
Internet: www.beckmancoulter.com



February 12, 2010

URGENT: FIELD SAFETY NOTICE

**Coulter® LH 750 Analyzer
Coulter® LH 780 Analyzer
Coulter® GEN®S Analyzer**

Dear Beckman Coulter Customer,

Beckman Coulter has confirmed an issue related to the use of specific characters on the instruments noted above.

ISSUE: The system will substitute or omit the characters # @ [\] ' { | } ~ when the system is configured in a language other than English or Chinese. Example: Using the character @, a substitution in the string '123@456' would result in '123#456' and an omission would result in '123456'

IMPACT: There is a potential for Specimen or Patient misidentification to occur.

ACTION/RESOLUTION: Do not use the characters # @ [\] ' { | } ~ in Specimen or Patient identifiers.

Complete and return the enclosed response form within 10 days so we may maintain our records. Please share this information with your laboratory staff, and retain this notification as part of your Quality System documentation.

If you have any questions regarding this Product Corrective Action, please call 800-526-7694 in the United States or Canada, or contact your local Beckman Coulter Representative.

We sincerely apologize for any inconvenience that this may have caused your laboratory. Thank you for your continued support of Beckman Coulter products.

Sincerely,

Group Manager, Corporate Quality and Regulatory Affairs

PCA-13012 -B

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February 12, 2010

URGENT: FIELD SAFETY NOTICE
UniCel[®] DxH[™] 800 Coulter[®] Cellular Analysis System

Dear Beckman Coulter Customer,

Beckman Coulter has confirmed several issues related to specific character use on the DxH 800 System.

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- ISSUE 1:** The system will substitute or omit the characters # @ [\] ' { | } ~ when the instrument is configured in a language other than English, Chinese or Japanese. Example: Using the character @, a substitution in the string '123@456' would result in '123#456' and an omission would result in '123456'.
- ISSUE 2:** The characters ? " and * (question mark, quotation mark, and asterisk) used as part of demographics, including Patient or Specimen ID, may be omitted from the character string. This occurs independent of language or input method used.
- ISSUE 3:** Spaces used as leading characters in a Patient or Specimen ID can cause random insertion of extra characters within that identifier.
- IMPACT:** There is a potential for Specimen or Patient misidentification to occur.
- ACTION/RESOLUTION:**
1. Do not use the characters # @ [\] ' { | } - ? " or * in demographics, including Specimen or Patient identifiers.
 2. Do not use spaces in the leading or trailing position of a Specimen or Patient ID.
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Complete and return the enclosed response form within 10 days so we may maintain our records. Please share this information with your laboratory staff, and retain this notification as part of your Quality System documentation.

If you have any questions regarding this Product Corrective Action, please call 800-526-7694 in the United States or Canada, or contact your local Beckman Coulter Representative.

We sincerely apologize for any inconvenience that this may have caused your laboratory. Thank you for your continued support of Beckman Coulter products.

Sincerely,

Group Manager, Corporate Quality and Regulatory Affairs

PCA-13012-A

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