

URGENT MEDICAL DEVICE RECALL

Product	PN	SW version
Unicel DxH Slidemaker Stainer Coulter® Cellular Analysis System	PN 775222	3.2

Attention Beckman Coulter Customer,

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

ISSUE:	Beckman Coulter has determined that a fitting installed in a select population of Slidemaker Stainer (SMS) units may not completely seal after being installed.
IMPACT:	<ul style="list-style-type: none"> ▪ Not all fittings installed may be affected. For those affected, one may observe a slow dripping leak of the staining reagents (methanol, alcohol and buffers) into the spill tray below designed for this purpose. ▪ There is no impact to patient results due to this issue. ▪ There is no new or additional safety risk associated with this issue beyond the continued potential of exposure to stain and methanol associated with the handling of these chemicals resulting from a slow dripping leak.
ACTION:	<ul style="list-style-type: none"> ▪ In the event of a leak, immediately contact your Beckman Coulter representative to schedule a service visit. Beckman Coulter Field Service Engineers will replace the fitting on the impacted instruments. ▪ Inspect the reagent supply drawer for spills; if necessary, clean up with absorbent materials such as paper towels, and dispose in accordance with your local regulations and laboratory procedures. ▪ Follow best laboratory practices when using the instrument, which includes the use of appropriate personal protective equipment (PPE) to protect the user from exposure.
RESOLUTION:	This issue will be resolved with the replacement of the correct fitting on all impacted instruments.

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 product listed above to another laboratory, please provide them a copy of this letter.

So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:

- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.



If you have any questions regarding this notice, please contact:

- From our website: <http://www.beckmancoulter.com>
- By 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 the inconvenience that this caused your laboratory.

Sincerely,

A handwritten signature in black ink, appearing to read 'Marwan Fathallah'.

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

FA-31276

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