



04 August 2016

**URGENT MEDICAL DEVICE RECALL**  
**UniCel DxH Slidemaker Stainer Coulter Cellular Analysis System**  
**Part Number REF 775222, All Software Revisions**

Dear Beckman Coulter Customer,

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

<b>ISSUE</b>	Beckman Coulter has received and confirmed a report of a fire within the Stainer module of a customer's DxH Slidemaker Stainer. The fire was fully contained within the Stainer module. The event was preceded by a significant increase in the frequency of the automatic top-off of the module's methanol bath. Beckman Coulter is initiating this field action to reduce the potential for flammable liquids coming into contact with electrical components in the Stainer module possibly causing a fire.
<b>IMPACT</b>	<ul style="list-style-type: none"><li>• In the event of a fire, any in-process slides must be discarded.</li><li>• For all DxH Slidemaker Stainers, the Stainer module must be disabled and staining must be performed using an alternative method.</li></ul>
<b>ACTION</b>	<ul style="list-style-type: none"><li>• <b>Immediately discontinue use of the Stainer module.</b></li><li>• Drain all liquids from the Stainer module.</li><li>• Follow the directions in Table 1 below for placing the Stainer module in extended shutdown and disabling the Stainer.<ul style="list-style-type: none"><li>○ Once the Stainer has been disabled, the Slidemaker module may be used to prepare slides for staining.</li><li>○ Slides must be stained using an alternative method.</li></ul></li></ul>
<b>RESOLUTION</b>	<p>Additionally, your service representative will schedule a visit to modify the Stainer module so that it remains disabled and cannot be used until further corrective action is implemented.</p> <p>Beckman Coulter is actively investigating the reported incident to determine the root cause, and define and implement required corrective and preventive actions.</p>

Share this information with your laboratory staff and retain this notice as part of your laboratory Quality System documentation. If you have forwarded the affected product to another laboratory, please provide them with a copy of this letter.

Complete and return the enclosed response form within 10 days so that we are assured you have received this important communication.

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- Outside the United States and Canada, contact your local Beckman Coulter Representative

We apologize for the inconvenience to your laboratory.

**Table 1 - Customer Actions for FA-28677**

**Placing the Stainer in Extended Shutdown and Disabling the Stainer**

Reference: Instructions for Use (B26647AC)

1	Select <b>Menu &gt; Diagnostics &gt; Dx Tools &gt; Slidestainer tab &gt; Fluidics &gt; Drain All Baths.</b>
2	Remove the pickup tubing from Supplies 1 to 4 when the cycle is completed and place it on absorbent material.
3	Select <b>Fill All Baths.</b>
4	Select <b>Drain All Baths.</b>
5	Place all 4 pickup tubes into a container filled with methanol.
6	Select <b>Fill All Baths.</b>
7	Select <b>Drain All Baths.</b>
8	Repeat steps 6 and 7.
9	Remove the pickup tubing from the methanol container and Supply 5 and place them in a clean sealable plastic bag.
10	Select <b>Fill All Baths.</b>
11	Select <b>Drain All Baths.</b>
12	Refer to the Clean Stainer Fill Probes, Drain Probes, and Level Sense Probes procedure in Chapter 12, Cleaning Procedures and perform steps 4 to 16.
13	Select <b>Menu &gt; System Status &gt; Module &gt; Disable Stainer</b>
14	On the Disable Module dialog box, select <b>Stainer</b> and <b>OK</b> to disable it.
15	Select <b>Yes</b> when the system displays: <i>You have requested to temporarily disable a module. Do you want to continue with the request?</i>
16	Discard all staining reagents according to your laboratory standards and local regulations.

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