October 9, 2019

## URGENT FIELD SAFETY NOTICE

| Product | Part Number |
|---|---|
| UniCel DxH Slidemaker Stainer (DxH SMS) | 775222 |
| UniCel DxH Slidemaker Stainer II (DxH SMS II)* | C11477 |

*Not available in all regions

Attention Beckman Coulter Customer,

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

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| **ISSUE:** | In rare cases if the Sample Aspiration Module (SAM) is not in a safe position while performing cleaning or troubleshooting procedures, the dispense probe may be inadvertently bent. The DxH SMS/DxH SMS II is designed to generate the error message "Stripper Motor movement cannot be verified" and inactivates the Slidemaker when a probe is bent, however in rare circumstances a slightly bent probe is not detected. This condition may lead to carryover.<br><br>Beckman Coulter has become aware via two customer complaints, and confirmed by internal investigation, that when the dispense probe is slightly bent, residual blood from a sample may be left behind on the edge of the dispense path. When the dispense probe moves to deposit the next sample blood drop, the dispense probe may come in contact with blood from the previous sample. |
| **IMPACT:** | • When the DxH SMS/DxH SMS II dispense probe is slightly bent, there is a potential for cell carryover from the previous sample, and erroneous results could be reported from the slide review.<br>• Erroneous results may be reported from the laboratory which may trigger unnecessary or inappropriate patient treatment. |

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| **ACTION:** | To determine if you are affected by the issue, perform the following steps:<br>1. Ensure the wearing of proper barrier protection according to your local and state laboratory safety regulations.<br>2. If the DxH SMS/DxH SMS II is connected to a Workcell, select the instrument from the System Status screen.<br>3. Select **Menu > Diagnostics > Dx Tools > Release SAM** from the local navigation bar > **Yes** > **Finish** > **Yes** at the prompt to continue.<br>4. Remove the Transport Shield and Lift the Front Cover. The instrument can trigger an audible alarm.<br>5. Select the **Turn Off Alarm** icon.<br>6. Ensure the SAM is moved all the way to the left side to avoid bending the dispense probe.<br>7. Locate the Dispense Probe Wash Cup (see Figure 1 below).<br>8. Locate the Dispense Probe Path (see Figure 2 below). |

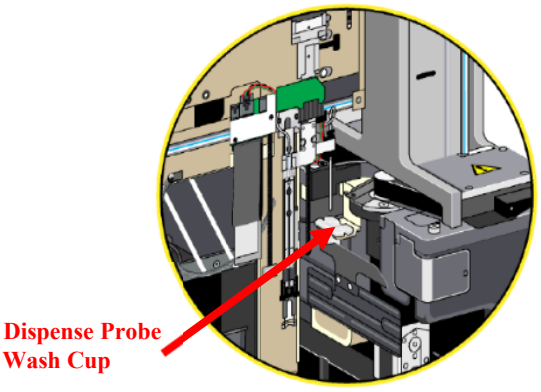


**Figure 1** – Dispense Probe Wash Cup

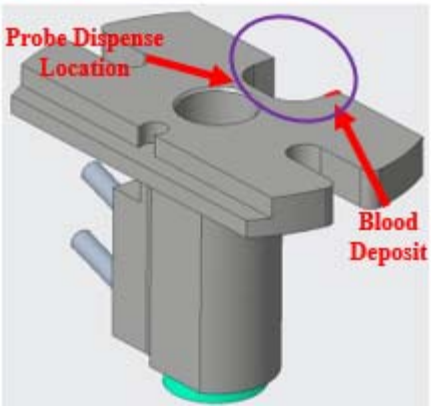


**Figure 2** – Detail Dispense Probe Wash Cup Path

9. Clean the entire edge of the dispense line path with a lint-free swab dampened in distilled water and inspect it for the presence of blood on the swab (see Figure 2 above).

10. If blood is not observed, your Slidemaker does not have a carryover issue.
    - Lower the Front Cover and install the Transport Shield.
    - Review any errors and place the instrument online to continue operation.

11. If blood is observed, locate the spare new dispense probe that was provided with your instrument. If a new dispense probe is not available, please contact Beckman Coulter to order a replacement PN 737812. See figure 3.


**Figure 3** – Dispense Probe

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| | 12. Perform the “Replacing the Dispense Probe” procedure, Chapter 13 in the Instructions for Use (IFU) or System Help, or contact Beckman Coulter for assistance.<br>• After the dispense probe is replaced, remove any remaining blood deposits from the edge of the dispense line path with a lint-free swab dampened in distilled water.<br>• Ensure that the blood buildup is removed from the dispense line path.<br>• Lower the Front Cover and install the Transport Shield.<br>• Review any errors and place the instrument online to continue operation.<br><br>If blood was observed in step 11, consult with your Medical Director to determine if a retrospective review of results is warranted.<br><br>In the future, any time you are performing troubleshooting or cleaning procedures that require opening the front cover, follow the steps above to confirm that the dispense probe is not bent.<br><br>**Reminder to follow instructions in Chapter 13 of the Instructions for Use (IFU) or System Help to avoid the issue:**<br>In accordance with product labeling, when accessing the DxH SMS/DxH SMS II during operator troubleshooting or cleaning procedures, ensure that the Sample Aspiration Module (SAM) is powered OFF and moved completely out of the way before pulling out any module. Follow the steps for each troubleshooting or cleaning procedure in the IFU or System Help to properly place the SAM in a safe position. |
| **RESOLUTION:** | Beckman Coulter has a hardware change in progress to eliminate the possibility of carryover from a slightly bent dispense probe which is projected to be available starting in December 2019. |

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have transferred any of the affected product(s) listed above to other laboratories, please provide them with a copy of this letter.

So that we are assured you have received this important communication, 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 Beckman Coulter Customer Support Center:

- Via our website: http://www.beckmancoulter.com Support > Request Instrument Support.
- Outside of the United States and Canada, contact your local Beckman Coulter Representative.

We apologize for any inconvenience to your laboratory.

Sincerely,

Roger Janczak
Vice President, Quality and Regulatory Affairs

Enclosure: Response Form

## CUSTOMER RESPONSE FORM

| Product | Part Number |
|---|---|
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**Check the appropriate box below:**

☐ I have read and understood the information within the accompanying Beckman Coulter Notification. All relevant personnel have been informed of its contents, any necessary actions taken and records retained as part of our Laboratory Quality System documentation.

Or:

☐ We do not have this product.

Signed: _____ Date: _____

Name: _____ Title: _____

Tel: _____ Email: _____

Please return to: Beckman Coulter Int. S.A.
Ms. Stella Eklou
Regulatory Affairs
22, Rue Juste-Olivier
1260 - Nyon

Fax Number: 0848 850 810