



July 29, 2009

URGENT: FIELD SAFETY NOTICE

UniCel® DxH™ 800 Coulter® Cellular Analysis System

Dear Beckman Coulter Customer:

ISSUE:

Beckman Coulter has confirmed an issue with the UniCel DxH 800 during in-house testing. It was determined that there is a potential for a false increase in platelet results, due to micro-bubbles.

IMPACT:

This situation could present a risk of falsely increased platelet results in patient samples as diluent containers are depleted.

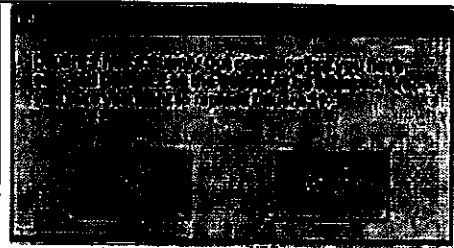

ACTION/RESOLUTION:

Your Beckman Coulter Service representative has made temporary changes to the Supplies setup. These changes will:

- Ensure that the system runs with one diluent container which will force the Supplies icon to be in **Yellow** at all times.
- Temporarily modify the Diluent container replacement procedure as follows:

- 1) Scan a new diluent container and select Diluent #2.

The following messages will appear, press OK after each message.

	Press OK
	Press OK

- 2) Press the <Enter> key in the keyboard
- 3) Press OK in the Setup Supplies dialog window.

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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

In addition to the Supplies setup change, one of the following workflow options must be implemented to ensure no results are affected. Please continue to follow one of the options listed below until a permanent fix is available.

Option A: Monitor Diluent cycles

1. Monitor Diluent cycles under "Cycles Remaining" in the Supplies screen.
2. Ensure that you have enough diluent available prior to running specimens.
Note: In order to get the actual count of cycles remaining you must press "Refresh" in the Supplies screen.
3. Change the diluent container anytime before the cycles remaining reaches (0) following the temporary diluent replacement instructions outlined in this letter.

Option B: Unable to monitor Diluent cycles

1. Set Release Rules to: Hold All Results.
2. Check "Cycles Remaining" in the Supplies screen. If the diluent container is not depleted, you may release results. Refer to instructions under Chapter 6: "Data Review" of your system HELP.
3. Once the diluent container is depleted the Supplies icon turns Red, change the diluent following the temporary diluent replacement instructions outlined in this letter.
4. After replacing the diluent perform a "Prime CBC Module" (Menu > Diagnostics> Dx Tools> CBC tab > Fluidic > Prime CBC Module).
5. Review the Platelet count on the last specimen analyzed prior to the Supplies icon turning red.
6. Please follow the instructions on how to release results under Chapter 6: "Data Review" of your system HELP.

Based on your laboratory procedures, if you wish to review previous released results you may have generated while utilizing a dual container configuration:

- Go the Supplies event log and search for the date/time of the "Diluent Source Switched" message.
- Match the Date/Time of the diluent source switch to the date/time on the patient runs listed in the Release Tab of the Worklist.
- Review the results of the five specimens analyzed after the "Diluent Source Switched" message was generated.

A long term solution to eliminate this risk is being developed and will be provided as soon as available.

Please share this information with your laboratory staff. If you have any questions regarding this Product Corrective Action, please call 800-526-7694 in the United States 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