

UPDATED URGENT FIELD SAFETY NOTICE

PRODUCT	REF	Software Versions
UniCel DxH 800 Coulter Cellular Analysis System	629029, B24465, B24802, B68304, B66445, B63322	All
UniCel DxH 600 Coulter Cellular Analysis System	B23858	All
UniCel DxH 900 Coulter Cellular Analysis System	C11478	All

Attention Beckman Coulter Customer,

This notification replaces our previous urgent Field Safety Notice Letter dated August 10, 2018 concerning sporadic erroneously elevated platelet results. Beckman Coulter is initiating a field action for the products listed above. This letter contains important information that needs your immediate attention. Patient results may be affected. No death or serious injury has ever been reported in association with this issue.

ISSUE:	As reported in our Urgent Field Safety Notice dated August 10, 2018, Beckman Coulter has confirmed complaints of erroneously elevated platelet results with rare occurrences, without flags or system messages. The underlying issue is temporary disturbance of the sweep flow. Preliminary root cause investigation indicates that sweep flow disruption may occur following the Clear RBC Apertures procedure. The issue may affect one or multiple samples tested in sequence. Beckman Coulter has not received complaints of this issue impacting the other reported parameters: HGB, WBC Count, WBC Differential, or RBC results. There have been no reports of this issue on the DxH 900.
IMPACT:	<ul style="list-style-type: none"> • Thrombocytopenia may go unrecognized. • Patients at high risk include those with malignancies (including those with iatrogenic thrombocytopenia), heparin-induced thrombocytopenia, thrombotic microangiopathic anemia, immune thrombocytopenic purpura and thrombocytopenia associated with pre-eclampsia. • The reported magnitude of error ranges from 33×10^3 cells/μL to 990×10^3 cells/μL based on reported complaints. • No additional complaints have been received for this issue on any system with the improved flagging algorithm which is able to generate an R flag message (PLT-Int) in cases with erroneously elevated platelet results.
ACTION:	<ul style="list-style-type: none"> • Ongoing investigation indicates that the probable root cause is the sweep flow disruption that may occur following the “Clear RBC Apertures” procedure. This potential root cause is currently under further investigation. Customers should discontinue using this procedure. • If you suspect that your instrument has a clogged aperture that will not clear, discontinue use of the analyzer and contact your local Beckman Coulter representative for further assistance. • Use the following quality control measures to aid in identification of discrepant platelet results: <ul style="list-style-type: none"> ○ Follow your laboratory’s standard operating procedure to confirm unexpected results. ○ Repeat testing of samples in a workflow configuration may facilitate the identification of discrepancies. ○ Additional instrument and/or LIS features including reference ranges, XM (exponentially-weighted moving average) and delta checks may be informative. • Consult with your Medical Director to determine if a retrospective review of results is warranted. • Report any unflagged erroneously elevated platelet counts experienced in your laboratory to your local Beckman Coulter representative.
RESOLUTION:	<ul style="list-style-type: none"> • To detect and flag erroneously elevated platelets due to temporary disturbance of the sweep flow, Beckman Coulter implemented an algorithm improvement. This algorithm improvement was implemented by way of one of the following: <ul style="list-style-type: none"> • Software upgrades, DxH 800 version 3.2.1 and above and DxH 600 version 1.3.1 and above. • Customer-installable software patch made available in October 2018 • Software version 1.0.0 and above for DxH 900



	<ul style="list-style-type: none">• If your DxH 800 / DxH 600 system has not yet been upgraded with the improved algorithm, please contact your local Beckman Coulter representative. All fielded DxH 900 analyzers have the improved algorithm incorporated into their original software.• Beckman Coulter continues to investigate the unflagged elevated platelets issue and assess the “Clear RBC Apertures procedure” as well as other potential root and/or contributing causes.
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The national competent authority has been informed of this field safety corrective action.

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:

- From our website: <http://www.beckmancoulter.com>
- Outside of US 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

CUSTOMER RESPONSE FORM

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Check the appropriate box below:

- I have read and understood the information within the accompanying Beckman Coulter Notification. All relevant facilities and personnel within the organization 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: _____

Site Name: _____

Site Address: _____

Name: _____ Title: _____

Tel: _____ Email: _____

Please return to:

**0848 850 810
Beckman Coulter Int. S.A.
Ms. Stella Eklou
Regulatory Affairs
22, Rue Juste-Olivier
1260 – Nyon**



*Beckman Coulter International S.A.
22, rue Juste-Olivier, Case Postale 1059
1260 Nyon 1, Switzerland*

Tel. +41 (0)22 365 37 07

Bank: Bank of America, Geneva – VAT No. 204 228

For Beckman Coulter's worldwide office locations and phone numbers, please visit www.beckmancoulter.com/contact