May 29, 2019

UPDATED URGENT FIELD SAFETY NOTICE – FSN-33718-2

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 Field Safety Notice Letter 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:	• 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 x 10^3 cells/µL to 990 x 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.

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ACTION:	• 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:
	  ○ 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:	• 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:
	  • 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
	• **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.

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.

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

If you have any questions regarding this notice, please contact the Customer Support Hotline at 00353 1407 3082 or techsupportie@beckman.com.

We apologize for any inconvenience to your laboratory.

Yours sincerely,

Andy Brown
Quality & Regulatory Affairs Manager, Northern Region Europe
Tel +44 (0) 1494 429184/+44 (0)1494 429219 Fax +44 (0) 1494 429182
Enclosed: Vigilance Response Form

	Document:	Document #:
BECKMAN COULTER	**VIGILANCE RESPONSE FORM**	**UKIE-REG-FRM-0004**

Please complete the appropriate sections below:

Site Name: _____

Instrument Type: _____

Instance/Serial Number(s): _____

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

Or:

☐ The Notification has not been actioned – We do not have this product because **it has been decommissioned and scrapped.**

Or:

☐ The Notification has not been actioned – We do not have this product because **it has been decommissioned and transferred to another laboratory.** Please provide the details of the site where this product was transferred to.

New Site Name: _____

Address: _____

_____

_____

Contact Name: _____

Email Address: _____

Phone Number: _____

- Please continue with page 2 -

Signed: _____ Date: _____

Name: _____ Tel: _____
(Please Print):

Email: _____

Please return this form by fax, post or email to:

Lynn Walker
Beckman Coulter UK Ltd
Oakley Court
Kingsmead Business Park
London Road, High Wycombe
BUCKS, HP11 1JU

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Ref Number: FSN-33718-2

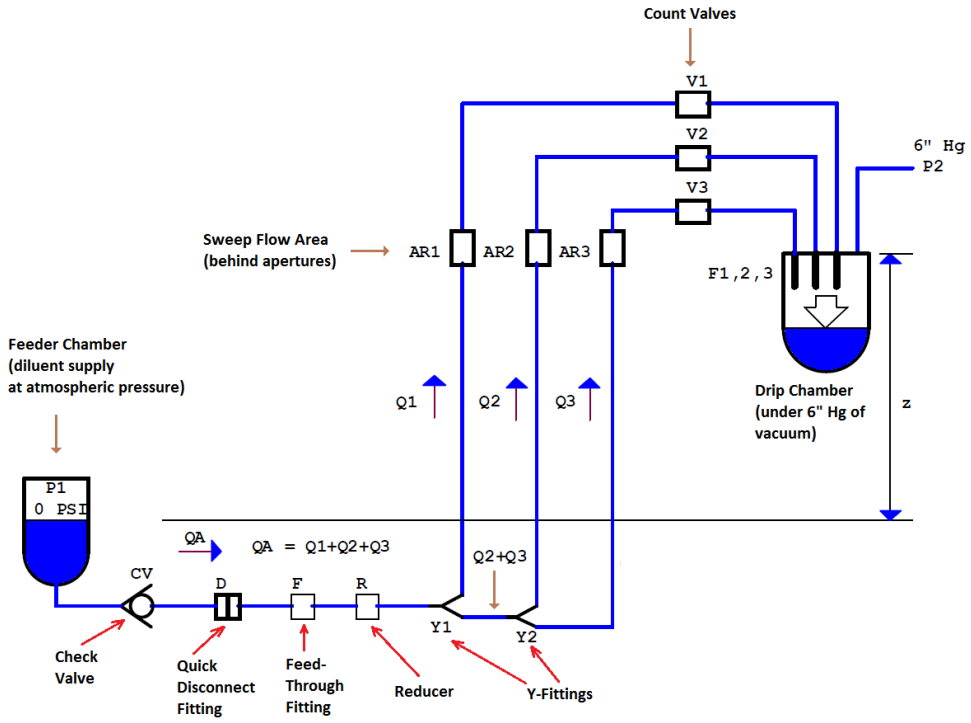

Figure 1 *Sweep flow schematic. Q1/Q2/Q3 are 96 inches of low diameter tubing. Air is injected into the system when one of the lines has air pushed past to the Y1/Y2 fittings from the clearing process originating at F1,2,3.*

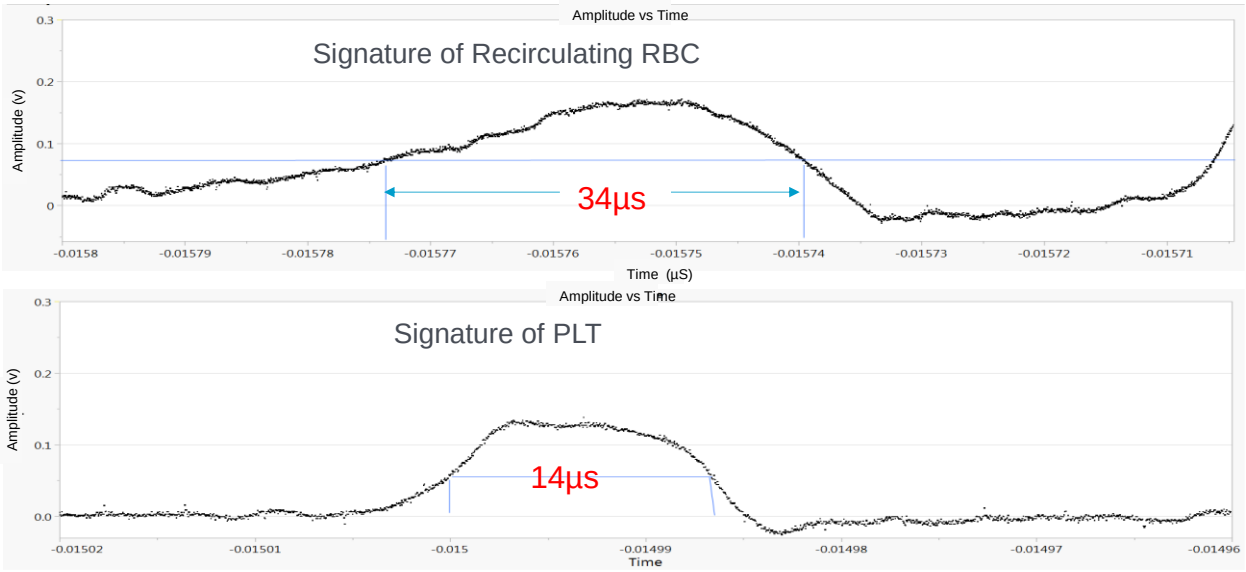

Figure 2 *(Top) Oscilloscope capture of a pulse believed to be a recirculating RBC; (Bottom) Oscilloscope capture of a normal platelet. Note the difference in FWHM.*

Samples	Baseline		T Fitting with yellow choke (0.006 inches ID) connected at the center port	
	PLT	RBC	PLT	RBC
WB1-1	223	4.63	360 (R Flag/PLT Int)	4.49
WB1-2	227	4.61	V-out	4.42
WB2-1	122	5.17	299 (R Flag/PLT Int)	4.95
WB2-2	125	5.23	288 (R Flag/ PLT Int)	4.96
WB3-1	226	4.39	361 (R Flag/ PLT Int)	4.32
WB3-2	217	4.36	369 (R Flag/ PLT Int)	4.21
PRP from WB-1	471	0.02 (R flag)	505	0.02 (R flag)
PRP from WB-2	489	0.01 (R flag)	484	0.02 (R flag)

Table 1 *Table 1 Confirmation of impact on PLT results from obstructed sweep flow can be seen in the whole blood samples WB1/WB2/WB3. Confirmation of origin of recirculating cells can be confirmed by no impact to results on platelet rich protein from WB-1 and W*