



August 10, 2018

## URGENT FIELD SAFETY NOTICE – FSN-33718

PRODUCT	REF	Software Versions
UniCel DxH 800 Coulter Cellular Analysis System	629029, B24465, B24802, B68304, B66445, B63322	3.2.0 and below
UniCel DxH 600 Coulter Cellular Analysis System	B23858	1.3.0 and below

Attention Beckman Coulter (BEC) Customer,

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 injury has been reported in association with this issue.

<b>ISSUE:</b>	Beckman Coulter has confirmed complaints of sporadic erroneously elevated platelet results without flags or system messages. Other parameters are not affected by this issue.
<b>IMPACT:</b>	<ul style="list-style-type: none"><li>• The platelet parameter may be erroneously elevated without flags or system messages.</li><li>• Erroneously elevated results could be reported out of the laboratory.</li></ul>
<b>ACTION:</b>	<p>During patient's follow-up, consider unexpected elevated platelet levels as possible erroneous results due to this failure.</p> <p>Ensure implementation of the following actions:</p> <ul style="list-style-type: none"><li>• Use all available features to assess patient results, including reference ranges, action and critical limits, instrument system flags, codes, messages, delta checks, XM, and decision rules.</li><li>• Follow your laboratory's standard operating procedure for confirming unexpected results.</li><li>• Communicate to your medical director the need to avoid patient treatment based solely on any single test result, and to interpret all results in the context of other clinical and laboratory features.</li><li>• Consult with your Medical Director to determine if a retrospective review of results is warranted.</li></ul>
<b>RESOLUTION:</b>	<ul style="list-style-type: none"><li>• DxH 800 version 3.2.1 and DxH 600 version 1.3.1 are not affected by this issue. Beckman Coulter will be prioritising the upgrades for your systems.</li><li>• Alternatively, Beckman Coulter is working on the development of a self-installable software patch option, in lieu of the software upgrade, to expedite resolution and minimise impact on laboratory workflow.</li></ul>



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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 forwarded any of the affected product(s) listed above to another laboratory, please provide them 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](mailto:techsupportie@beckman.com).

We apologise for the inconvenience that this has caused your laboratory.

Yours sincerely,



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Enclosed: Vigilance Response Form