



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# Recall Action Notification

UniCel DxH 800/600/900 Coulter Cellular Analysis System.

An in vitro diagnostic medical device (IVD)

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## Important information on the System for Australian Recall Actions

The TGA publishes information about therapeutic goods supplied in the Australian market that have been subject to a recall action in a publicly searchable database.

Recall action means action taken by the responsible entity (being the person who is responsible for taking the recall action) to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- Recall actions include: the permanent removal of therapeutic goods from supply in the market, the taking of corrective action in relation to therapeutic goods (such as repair, modification, adjustment or relabelling) and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage patients.
- More information about Australian recall actions is available at <<http://tga.gov.au/safety/recalls-about.htm>>
- If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional. <<http://www.healthdirect.org.au/>>

### About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of recall actions that responsible entities have reported to the TGA or of which the TGA has become aware, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

The information contained in the SARA database is released under s 61(5C) of the Therapeutic Goods Act 1989. Copyright restrictions apply to the System of Australian Recall actions (SARA) <<http://tga.gov.au/about/website-copyright.htm>>.

## Recall detail

<b>Type of Product<sup>i</sup></b>	Medical Device
<b>TGA Recall Reference<sup>ii</sup></b>	RC-2019-RN-00808-1
<b>Product Name/Description<sup>iii</sup></b>	<p>UniCel DxH 800/600/900 Coulter Cellular Analysis System. An in vitro diagnostic medical device (IVD)</p> <p>All software versions</p> <p>UniCel DxH 800 Coulter Cellular Analysis System Reference Numbers: 629029, B24465, B24802, B68304, B66445, B63322</p> <p>UniCel DxH 600 Coulter Cellular Analysis System Reference Number: B23858</p> <p>UniCel DxH 900 Coulter Cellular Analysis System Reference Number: C11478</p> <p>ARTG: 177999 (Beckman Coulter Australia Pty Ltd - Instrument/analyser IVDs)</p>
<b>Recall Action Level<sup>iv</sup></b>	Hospital
<b>Recall Action Classification<sup>v</sup></b>	Class I
<b>Recall Action Commencement Date<sup>vi</sup></b>	31/05/2019
<b>Responsible Entity<sup>vii</sup></b>	Beckman Coulter Australia Pty Ltd
<b>Reason / Issue<sup>viii</sup></b>	<p>This action supersedes RC-2018-RN-01103-1.</p> <p>Beckman Coulter (BC) 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. BC has not received complaints of this issue impacting the other reported parameters: HGB, WBC Count, WBC Differential, or RBC results. To date there have been no reports of this issue on the DxH 900.</p> <p>Patients at high risk include those with malignancies (including those with iatrogenic thrombocytopenia), heparin-induced thrombocytopenia, thrombotic microangiopathic anaemia, immune thrombocytopenic purpura &amp; thrombocytopenia associated with pre-eclampsia.</p> <p>To date, no death or serious injury has been reported in association with this issue.</p>
<b>Recall Action<sup>ix</sup></b>	Product Defect Correction

<b>Recall Action Instructions<sup>x</sup></b>	<p>BC is advising:</p> <ul style="list-style-type: none"> <li>- Ongoing investigation indicates that the probable root cause is the sweep flow disruption that may occur following the “Clear RBC Apertures” procedure. Users should discontinue using this procedure.</li> <li>- If users suspect that their instrument has a clogged aperture that won't clear, stop use and contact BC.</li> <li>- Use the following QC measures to aid in identification of discrepant platelet results:             <ol style="list-style-type: none"> <li>1. Follow the laboratory's standard operating procedure to confirm unexpected results</li> <li>2. Repeat testing of samples in a workflow configuration</li> <li>3. Additional instrument and/or LIS features including reference ranges, XM and delta checks</li> </ol> </li> </ul> <p>To detect and flag erroneously elevated platelets due to temporary disturbance of the sweep flow, BC implemented an algorithm improvement. If the DxH 800 / 600 systems have not yet been upgraded with the improved algorithm, please contact BC. All DxH 900 analysers have the improved algorithm incorporated into their original software.</p>
<b>Contact Information<sup>xi</sup></b>	1800 060 881 - Beckman Coulter Customer Support Centre

## Footnotes

<sup>i</sup> Type of Product: Medicine, Medical Device, or Biological

<sup>ii</sup> TGA Recall Reference: Unique number given by the TGA

<sup>iii</sup> Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

<sup>iv</sup> Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- Wholesale - includes wholesalers and state purchasing authorities.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- Consumer - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

<sup>v</sup> Recall Action Classification: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- Class I recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk to health.
- Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not Class I.
- Class III recall action occurs when the product deficiency may not pose a significant hazard to health, but action may be initiated for other reasons eg. quality related issues.

<sup>vi</sup> Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

<sup>vii</sup> Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

viii Reason / Issue: Reason for the recall action.

ix Recall Action: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation.

There are three distinct recall actions - recall, recall for product correction and hazard alert.

- Recall - The permanent removal of an affected therapeutic good from supply or use in the market.
- Recall for product correction - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- Hazard alert - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.

x Recall Action Instructions: What the customer should do.

xi Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.