



## PRODUCT ANNOUNCEMENT LETTER

### UniCel® DxH™ 800 Coulter® Cellular Analysis System Software 2.0.2.1 release

Dear Beckman Coulter DxH 800 Customers,

We are pleased to announce the release of the UniCel® DxH™ 800 Coulter® Cellular Analysis System with software version 2.0.2.1. New features, modifications and updated customer documentation are included in this release and major changes are outlined below.

- **New Features:**
  - Partial releasing of patient results manually or automatically via decision rules.
  - Primary barcode scanner added for Host Query capability.
  - Notification for STAT samples that have not been processed or released within an expected time frame.
  - Ability to create and edit decision rules during instrument operation plus pre-defined decision rules using Cell Population Data\*.
  - New Research Use Only parameters for whole blood and body fluid analysis.
- **Usability/Reliability Modifications:**
  - System reliability improvements.
  - Improved software functionality and response time with large databases.
  - Algorithm updates to even further enhance result flagging with overall improvements to operational efficiency.
  - Faster LIS transmission of results.
  - Modified "Release All" configuration that releases all test orders, even those with exceptions, as well the ability to perform automatic rerun or reflex testing.
  - Additional corrections as detailed in Product Announcement Letter, PN B22515AB.
- **Updated Instructions for Use (IFU)**
  - Instruction for Use, PN B16421
  - Host Transmission Manual, PN B19766
  - RUO Addendum, PN B16503
  - Cassette and Tube Specification, PN B19983

IFUs for this product will be available on the Beckman Coulter website. If you are new to Beckman Coulter or not registered on the website you may have to setup a User Account prior to accessing the information. If you have any questions please call Beckman Coulter Customer Service at 1-800-526-7694 in the United States or Canada, or contact your local Beckman Coulter Representative.

Thank you for choosing Beckman Coulter UniCel DxH 800 COULTER Cellular Analysis System as your hematology instrument.

Sincerely,

A handwritten signature in cursive script, appearing to read "Linda Garlaus".

Linda Garlaus  
Product Manager  
Product Management

\*For Research Use Only. Not for use in diagnostic procedures.

## PRODUCT ANNOUNCEMENT LETTER

### UniCel® DxH™ 800 Coulter® Cellular Analysis System PN 629029 Software Revision 2.0.2.1

Dear Beckman Coulter DxH 800 Customer,

Thank you for choosing the UniCel® DxH™ 800 Coulter® Cellular Analysis System. At Beckman Coulter we make every effort to provide the highest quality products and most up to date information. This letter announces the release of Revision 2.0.2.1 software, which includes the corrections for the items listed below. The software update will be performed by your Beckman Coulter service representative.

Notification Letter Part Number & Date	Issue
PCA-13012-A IPCA-13012-A Feb 12, 2010  A91064AA February 2010	<ul style="list-style-type: none"> <li>• Issue 1: The system will substitute or omit the characters # @ [ \ ] ' {   } ~ when the instrument is configured in a language other than English, Chinese, or Japanese.</li> <li>• Issue 2: The characters ? " and * used as part of selected demographics, including patient or Specimen ID, may be omitted from the character string.</li> <li>• Issue 3: Spaces used as leading characters in a Patient or Specimen ID can cause random insertion of extra characters within that identifier.</li> </ul>
PCA-13512 A IPCA-13512 B March 10, 2010  A93515AB March 2010	Use of the Auto Prune Function causes the deletion of Quality Control files.
PCA-15211 IPCA-15211 October 20, 2010  B00179AA October 2010	<ul style="list-style-type: none"> <li>• Issue 1: There is a possibility that a specimen could be diluted if a user requests Diluent Dispense while specimens are being automatically processed in cassette presentation. The dilution may cause erroneous results.</li> <li>• Issue 2: <u>For Panels containing CBC: The RBC and HCT are improperly corrected and not flagged when there is a WBC Pump failure and the WBC <math>\geq 140 \times 10^3 / \mu\text{L}</math>. For Body Fluid Panels: the RBC is improperly corrected and not flagged when there is a WBC Pump Failure.</u></li> <li>• Issue 3: RETIC results may be invalid when the instrument user interface allows reflex processing of a pre-diluted specimen in RETIC test panel.</li> <li>• Issue 4: Body Fluids results may be incorrectly interpreted by the laboratory Information System (LIS).</li> </ul>
PCA-16478 IPCA-16478 February 11, 2011  B04994AB April 2012	<ul style="list-style-type: none"> <li>• Issue 2: The DxH 800 may fail to meet the carryover specification for the WBC Differential (DIFF) when the WBC is greater than <math>70 \times 10^3 \text{ cells}/\mu\text{L}</math> (<math>70 \times 10^9 \text{ cells/L}</math>).</li> <li>• Issue 3: The DxH 800 may fail to meet the carryover specification for NRBC% when the WBC is greater than <math>50 \times 10^3 \text{ cells}/\mu\text{L}</math> (<math>50 \times 10^9 \text{ cells/L}</math>).</li> </ul>

Notification Letter Part Number & Date	Issue
PCA-16752 IPCA-16752 April 12, 2011  B07107AA April 2011	<ul style="list-style-type: none"> <li>• Issue 1: Auto prune will not remove patient results if the patient record includes demographics where the results are less than 30days old.</li> <li>• Issue 2: The last set of results for each panel analyzed without demographics will always be saved.</li> <li>• Issue 3: The DxH 800 may intermittently fail to transmit the correct control files or partially transmit the number of control files requested to the Interlaboratory Quality Assurance Program (IQAP) through the Remote Management System (RMS).</li> <li>• Issue 4: The DxH 800 exports control data intended for Interlaboratory Quality Assurance Program (IQAP) in the reporting units configured by the customer.</li> </ul>
IPN-19800 August 15, 2012  B20516AA August 2012	The DxH 800 with Revision 2.0.0.1 software will not read Codabar labels at the primary barcode reader when the leading and trailing characters do not match (e.g. A12345B).
IPN-19814 August 14, 2012  B20516AA August 2012	Software Revision 2.0.0.1 transmits incorrect histogram identifiers to the host for the WBC, RBC and PLT histograms per the Host Transmission Manual B19766AA: <ul style="list-style-type: none"> <li>• WBC.Histogram.Array transmitted incorrectly as 'WBC Histogram'.</li> <li>• RBC.Histogram.Array transmitted incorrectly as 'RBC Histogram'.</li> <li>• Plt.Histogram.Array transmitted incorrectly as 'PLT Histogram'.</li> </ul>
IPN-19845 August 14, 2012  B20516AA August 2012	Software Revision 2.0.0.1 generates error 75, 'Invalid code', when the host downloads a nil in the Terminator Record field. The field should accept both the nil or N characters as Termination Codes.
IPN-20013 September 25, 2012	DxH 800 Rev. 2.0.0.1 transmits incorrect values in the Patient Race-Ethnic Origin field of the Patient Record for Native American/Alaskan and "Other" ethnic groups to the host. <ul style="list-style-type: none"> <li>• The value for Native American/Alaskan should be NA, but transmits as N.</li> <li>• The value for Other should be OT, but transmits as O (same code for Asian/Pacific Islander).</li> </ul>

Please share this information with your laboratory staff. After installation has been successfully completed, store the software update CD in a safe location with your other system software. Retain this notification as part of your laboratory Quality System documentation.

If you have any questions or concerns regarding this product announcement please call Beckman Coulter Customer Service at 1-800-526-7694 in the United States and Canada. Outside US and Canada, contact your local Beckman Coulter Representative.

Thank you for your business and continued support of Beckman Coulter products.

Sincerely,



Nancy Nadler  
 Director, Regulatory Affairs