



August 5, 2026

**URGENT MEDICAL DEVICE RECALL****iQ200 Series Analyzers and DxU 840m/850m Iris Analyzers**

| PRODUCT       | REF                                                       | Serial Numbers     |
|---------------|-----------------------------------------------------------|--------------------|
| DxU 840m Iris | C76947                                                    | All Serial Numbers |
| DxU 850m Iris | C49513                                                    |                    |
| IQ200 SPRINT  | 700-3322, 700-3322RFB, 700-3325, 700-3326, B48997         |                    |
| IQ200 SELECT  | 700-3340, 700-3345, 700-3347, B48998, C10684              |                    |
| IQ200 ELITE   | 700-3370, 700-3375, 700-3375RFB, 700-3376, B48999, C10683 |                    |

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field action for the product listed above. This letter contains important information that needs your immediate attention. There is no impact on patient results.

|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
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| <b>ISSUE:</b>  | Beckman Coulter has received customer complaints about lamina fluid leaks in iQ200 Series Analyzers and DxU 840m/850m Iris Analyzers. Investigation determined that the leaks are caused by a check valve in the rinse line becoming structurally compromised. This may allow lamina fluid to migrate to internal instrument surfaces and eventually leak onto the table surface and/or floor.                                                                                                                                                                                                                                           |
| <b>IMPACT:</b> | <ul style="list-style-type: none"> <li>Examples of customer observations that may be indicative that the issue is occurring include, but are not limited to: <ul style="list-style-type: none"> <li>Visible lamina leakage from the rinse line</li> <li>Fluid collecting on or around the instrument</li> </ul> </li> <li>iQ Lamina is a colorless, odorless liquid that is not classified as hazardous according to EC 1272/2008 (CLP/GHS), US-OSHA HCS 2012 and UN GHS. Refer to iQ Lamina (PN# 300-7628) Safety Data Sheet for complete safety, handling and disposal information.</li> <li>Potential health consequences:</li> </ul> |

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|                    | <ul style="list-style-type: none"> <li>Slip and fall hazard to laboratory staff from lamina fluid leaking onto the floor, with potential outcomes ranging from bruises or sprains to fractures, head injury, or musculoskeletal trauma.</li> <li>Discharge of lamina fluid waste in the form of spills, sprays, mist or aerosolization may lead to chemical exposure of operators, service personnel and other users. In a worst case, exposure to &lt;0.15% phenoxyethanol may cause minor eye irritation symptoms, and if they occur, would typically be temporary burning, stinging, tearing, or redness.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>ACTION:</b>     | <ul style="list-style-type: none"> <li>Perform the daily Cleaning Instrument Surfaces maintenance described in Chapter 12, Maintenance Procedure of the DxU 840/850m Instructions for Use (PN# C49320AB), (PN# D38676AA), or iQ200 Instructions for Use (PN# 300-4320CE), (PN# 300-4321EE). During the cleaning, inspect the instrument for signs of lamina leakage, including fluid accumulation on or around the instrument, or evidence of fluid on the laboratory bench or floor. If you determine that there is a leak, discontinue use of the analyzer and clean any spilled fluid in accordance with your laboratory's safety procedure. <ul style="list-style-type: none"> <li>Contact Beckman Coulter Technical Support Organization immediately if evidence of leakage is observed.</li> </ul> </li> <li>Continue routine operation, if no leakage is observed, while maintaining increased awareness for the symptoms described in the impact section of this letter.</li> <li>Beckman Coulter recommends posting this letter on or near iQ200 Series and/ or DxU 840m/850m Iris Analyzers.</li> </ul> |
| <b>RESOLUTION:</b> | <ul style="list-style-type: none"> <li>Beckman Coulter is actively investigating this issue.</li> <li>Beckman Coulter will continue to address any reported lamina fluid leakage through its Technical Support Organization until this issue has been fully resolved.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

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 products listed above to another laboratory, please provide them a copy of this letter.

So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:

- Electronically, if you received this communication via electronic system.
- Manually, complete and return the enclosed Response Form.

If you have any questions regarding this notice, please contact our Customer Support Center.

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- From our website: <http://www.beckmancoulter.com>
- By phone: call 1-800-854-3633 in the United States and Canada.
  - Outside the United States and Canada, contact your local Beckman Coulter representative.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:  
  
Signer Name: Jennifer Chau  
Signing Reason: I approve this document  
Signing Time: 05-Aug-2026 | 3:09:58 PM PDT  
CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau  
Vice President, U.S. Quality Operations  
Beckman Coulter

Enclosure: Response Form

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