



March 25, 2020

URGENT MEDICAL DEVICE RECALL
Computer for iQ200 and iChemVELOCITY

Product	Part Number
iChemVELOCITY Urine Chemistry System	All Part Numbers
iQ200 Series Urine Microscopy Analyzer	All Part Numbers

This Field Action only affects an internal cable in the Personal Computer version 6 (PC6).

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field action for the products listed above. This letter contains important information that needs your immediate attention.

ISSUE:	Beckman Coulter has become aware of a manufacturing defect affecting an externally supplied Serial Advanced Technology Attachment (SATA) adapter cable. This cable is used internally in the Personal Computer version 6 (PC6) connected to the iQ200 and/or the iChemVELOCITY. The cable provides power to the Optical CD Drive in the Computer. Instruments with these computers were installed between July 2012 and December 2014.
IMPACT:	<p>The defect in the SATA power adapter cable within the instrument's computer has the potential risk for an electrical short that may lead to the following outcomes:</p> <ul style="list-style-type: none"> • Charring and/or melting of the SATA adapter cable within the computer's metal enclosure. <ul style="list-style-type: none"> • Smoke emanating from PC6. • Flames contained within PC6. • Inability to use the device's CD-ROM. <p>Testing process may be interrupted. Delay in patient results are not expected to occur.</p>
ACTION:	<p>Should flames and or smoke be detected within the computer follow the actions below:</p> <ul style="list-style-type: none"> • Follow your laboratory's safety guidelines. • Contact Beckman Coulter: <ul style="list-style-type: none"> • By phone: call 800-526-7694 in the United States and Canada. • Outside the United States and Canada, contact Beckman Coulter hotline or your local Beckman Coulter representative. • Follow your Standard Operating Procedures (SOP) for Instrument backup testing methodology.



Iris

RESOLUTION:	Your Beckman Coulter service provider will proactively schedule a service visit to inspect the PC6 computer and replace the affected cable, if necessary.
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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.

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 email.
- Manually, complete and return the enclosed Response Form.

If you have any questions regarding this notice, please contact Beckman Coulter Customer Support Center:

- From our website: <http://www.beckmancoulter.com>
- By phone: call 800-526-7694 in the United States and Canada.
- Outside the United States and Canada, contact Beckman Coulter hotline or your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Roger Janczak
Vice President, Quality and Regulatory Affairs
Enclosure: Response Form

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