Class 2 Device Recall iQ200 Series

See Related Information[22]

Date Initiated by Firm	August 12, 2026
Date Posted	October 15, 2026
Recall Status[1]	Open[3], Classified
Recall Number	Z-0161-2027
Recall Event ID	99832[23]
510(K)Number	K210127[24] K252580[25] K022774[26]
Product Classification	Automated urinalysis system[27] - **Product Code** KQO[28]
Product	IQ200 SPRINT, REF: 700-3322,700-3322RFB, 700-3325, 700-3326, B48997; IQ200 SELECT, REF: 700-3340, 700-3345, 700-3347, B48998, C10684; IQ200 ELITE, REF: 700-3370, 700-3375, 700-3375RFB, 700-3376, B48999, C10683
Code Information	Product/UDI-DI: IQ200 SPRINT/10837461001256, IQ200 SELECT/10837461001300, IQ200 ELITE/10837461001355. All Serial Numbers
FEI Number	3000203293
Recalling Firm/ Manufacturer	Beckman Coulter, Inc. 11800 Sw 147th Ave Miami FL 33196-2500
For Additional Information Contact	Jennifer Chau 916-857-6006
Manufacturer Reason for Recall	The rinse-line check valve has a shorter service lifespan than originally expected and requires annual replacement to prevent lamina fluid leakage; however, the check valve replacement was excluded from the annual preventive maintenance (PM) requirements without adequate reliability evaluation. When the check valve is not replaced annually, it may allow lamina fluid to migrate internally and leak onto the table or floor, potentially resulting in exposure to physical hazards (slip/fall), chemical hazards (lamina fluid exposure), biohazardous exposure, property damage, and delayed patient results.
FDA Determined Cause [2]	Component design/selection
Action	On 8/12/2026, recall notices were mailed and emailed to customers asking them to take the following actions: 1) 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.
2) Contact the firm's Technical Support Organization immediately if evidence of leakage is observed.
3) Continue routine operation, if no leakage is observed, while maintaining increased awareness for the symptoms described in the impact section of this letter.
4) Post this letter on or near affected Analyzers.
5) Share this information with laboratory staff and retain this notification. If you have forwarded any of the affected products to another laboratory, please provide them a copy of this letter.

Firm is investigating this issue and will continue to address any reported lamina fluid leakage through its Technical Support Organization until this issue has been fully resolved.

If you have any questions regarding this notice, please contact the firm's Customer Support Center: http://www.beckmancoulter.com or 1-800-854-3633 in the United States and Canada.

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Total Product Life Cycle

TPLC Device Report[29]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[30].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database

510(K)s with Product Code = KQO[31]
510(K)s with Product Code = KQO[32]

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