Class 2 Device Recall ABL90 FLEX and ABL90 FLEX PLUS analyzer

Class 2 Device Recall ABL90 FLEX and ABL90 FLEX PLUS analyzer

See Related Information[22]

Date Initiated by Firm	August 18, 2026
Date Posted	October 15, 2026
Recall Status[1]	Open[3], Classified
Recall Number	Z-0190-2027
Recall Event ID	99772[23]
510(K)Number	K041874[24]
Product Classification	Electrode measurement, blood-gases (pco2, po2) and blood ph[25] - **Product Code** CHL[26]
Product	The ABL90 FLEX and ABL90 FLEX PLUS analyzers are intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting. These tests are only performed under a physician's order.
Code Information	UDI-DI: 05700693930923, 05700693930909 Software versions 3.6 and lower. ABL90 FLEX PLUS Instructions for Use versions prior to: 996-223, Version: 202606O. ABL90 FLEX Instructions for Use versions prior to: 996-189, Version: 202606L
FEI Number	3002807968
Recalling Firm/ Manufacturer	Radiometer Medical ApS Akandevej 21 Bronshoj Denmark
For Additional Information Contact	Technical Support 800-736-0600
Manufacturer Reason for Recall	In vitro diagnostic analyzer had a risk of potentially inaccurate results requiring changes to instructions for use and: 1) Sample types, including whole blood samples no longer suitable for testing FHbF and ctBil, 2) Reportable ranges for some parameters, 3) Analyzer configuration, and 4) limitations and warnings.
FDA Determined Cause [2]	No Marketing Application
Action	On 8/18/2026, correction notices were mailed or emailed to customers who were asked to take the actions listed in the correction notice. The firm updated intended use and instructions for use. In addition, the firm is developing an updated software version that will modify the analyzer configuration in accordance with the updated FDA clearances. Customers are asked to do the following: 1) Implement the requested changes to the setup of your analyzer(s) as stated in the correction letter. 2) Review the changes to the labeling for the analyzers as stated in the updated Instructions for Use. 3) Complete and return the Recall Response Form via email to recall@radiometeramerica.com

4) If you are not the end user of the affected product, please ensure that this letter is distributed to the end user.

If you have any questions, contact the firm at 1-800-736-0600 option 1, Monday - Friday 9am to 7pm (EST)

Quantity in Commerce	5395
Distribution	US Nationwide distribution including in the states of CA, OH, LA, MA, FL, NY, CO, IL, TX, GA, NC, PA, SC, MI, OK, WI, AR, MN, OR, UT, WA, SD, IN, TN, AZ, NE, WY, KY, AL, AK, ID, NJ, DE, MT, CT, MS, MO, VT, WV, IA, MD, KS, DC, NV, VA, NM, NH, ND, ME, HI, RI.
Total Product Life Cycle	TPLC Device Report[27]

[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[28].

[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 = CHL[29]

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22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
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28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall

29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=CHL&knumber=&applicant=Radiometer%20Medical%20Aps

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