California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Radiometer Medical ApS ABL90 FLEX and FLEX PLUS

Recall Date	Product Description	Recalling Firm	Recall Reason
04/23/2025	Radiometer ABL90 Series Radiometer ABL90 FLEX Model Number: 393-090 Radiometer ABL90 Series Radiometer ABL90 FLEX PLUS Model Number: 393-092 The Radiometer ABL90 Series is a portable, automated analyzer for use in the laboratory environment, near patients or point-of-care settings.	Radiometer Medical ApS	ABL90 FLEX and ABL90 FLEX PLUS analyzers running with Radiometer Windows 10 versions RWIN10 1.0 and RWIN10 1.1 may unexpectedly freeze (the analyzer ceases to operate) during a sample measurement. The analyzer software includes a feature (watchdog) that detects a freeze and automatically restarts the software to continue operating the analyzer. However, even if a restart occurs, any sample being processed at that time will be lost, potential to lead to delay in test results.

Recall Class	Product Identification	Distribution	Affected Dates
II	Model Number: 393-090 UDI-DI: 05700693930909 Model Number: 393-092 UDI-DI: 05700693930923 Serial Numbers: 090R0643N002 - 092R0507N017	172 analyzers in California	March and prior

For additional information, please visit the FDA Website.