California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Nova Biomedical Corporation StatStrip Glucose Hospital Meter System and StatStrip Glucose Ketone (mmol/L) Hospital Meter System

Recall Date	Product Description	Recalling Firm	Recall Reason
12/20/2024	StatStrip Glucose Hospital Meter System. Model/Catalog Number: 63685. Prescription use blood glucose meter for near-patient testing.	Nova Biomedical Corporation	A software bug within the Gen 2 StatStrip Hospital Meter firmware leads to transmission of erroneous glucose patient test results to a healthcare institution's data management system (DMS) at healthcare sites using WiFi if a user navigates to the Review Results screen while the meter is in the process of transmitting the current glucose test result to the DMS. The risk of this software defect is erroneously high or low glucose results being documented in a patient's medical record, which may lead to incorrect treatment.

	StatStrip Glucose Ketone (mmol/L) Hospital Meter System. Model/Catalog Number: 63910. Prescription use blood glucose ketone meter for near-patient testing		A software bug within the meter firmware leads to transmission of erroneous glucose and/or ketone patient test results to a healthcare institution's data management system (DMS) at healthcare sites using WiFi if a user navigates to the Review Results screen while the meter is in the process of transmitting the current test result to the DMS.

Recall Class	Product Identification	Distribution	Affected Dates
I	Model No.: 63685 UDI-DI: (01)10385480636858 Software Versions: v0.0.13.10 to v0.0.13.44	2,365 units nationwide	November and prior
	Model No.: 63910 UDI-DI: (01)1038548063910 Software Versions: v0.0.13.10 to v0.0.13.44	1,615 units nationwide	

For additional information, please visit: FDA Website (Glucose) and FDA Website (Glucose Ketone)