California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Baxter Healthcare Corporation Recalls Baxter SIGMA Spectrum Infusion Pump

Recall Date	Product Description	Recalling Firm	Recall Reason
7/17/25	Baxter SIGMA Spectrum Infusion Pump V6, Model Number 35700BAX	Baxter Healthcare Corporation	Certain Spectrum infusion pumps may have an incorrect version of software.
7/17/25	Baxter SIGMA Spectrum Infusion Pump V8, Model Number 35700BAX2	Baxter Healthcare Corporation	Certain Spectrum infusion pumps may have an incorrect version of software.

Recall Class	Product Identification	Distribution	Affected Dates
I	UDI-DI: 00085412091570; Serial Numbers: 765100 , 772744 , 789742 , 841197 , 867753 , 920606 , 1024015 770164 788724 , 793079 , 842498 , 918342 , 962810 , 1027523	US States: CA, FL, IL, KS, MI, MS, NY, OH, OK, and VA.	June 2025 and prior
I	UDI-DI: 00085412498683; Serial Numbers: 2006307 , 2052091 , 2093765 , 2095360 , 2104302 , 2119236 , 2141815 , 2025925 , 2067699 , 2094483 , 2095541 , 2105238 , 2119436 , 2143406 , 2034297 , 2074097 , 2094580 , 2096351 , 2105769 , 2135482 , 2143684 ,	US States: CA, FL, IL, KS, MI, MS, NY, OH, OK, and VA.	June 2025 and prior.

	2051591 , 2090658 , 2095202 , 2096856 , 2118940 , 2137976 , 2156201		

For additional information, please visit the Z-2095-2025, Z-2096-2025

Confidential - Low