California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Tandem Diabetes Care, Inc. Recalls Insulin Pump with Interoperable Technology

Recall Date	Product Description	Recalling Firm	Recall Reason
04/11/2025	t:slim X2 Insulin Pump with Interoperable Technology	Tandem Diabetes Care, Inc.	A software defect in Version 7.9 of the pump software for Tandem t:slim X2 and Tandem Mobi pumps, when used with Control IQ+ technology, will cause the pump to incorrectly interpolate glucose trends when the Estimated Glucose Value (EGV) is above 255 mg/dL at the start or end of a gap in data collection due to a lapse in connection from a paired continuous glucose monitor (CGM) sensor, which can lead to under-delivery or over-delivery of insulin based on inaccurate result leading to severe cases of hypoglycemia or hyperglycemia.
04/11/2025	Tandem Mobi Insulin Pump with Interoperable Technology	Tandem Diabetes Care, Inc.	A software defect in Version 7.9 of the pump software for

			Tandem t:slim X2 and Tandem Mobi pumps, when used with Control IQ+ technology, will cause the pump to incorrectly interpolate glucose trends when the Estimated Glucose Value (EGV) is above 255 mg/dL at the start or end of a gap in data collection due to a lapse in connection from a paired continuous glucose monitor (CGM) sensor, which can lead to under-delivery or over-delivery of insulin based on inaccurate result leading to severe cases of hypoglycemia or hyperglycemia.

Recall Class	Product Identification	Distribution	Affected Dates
I	Software versions 7.9/UDI: 00389152407012	63 units in US: AZ, CA, CO, CT, FL, HI, IA, ID, IL, IN, MD, ME, MI, MO, MS, NC, ND, NE, NJ, NM, NV, NY, OH, PA, TX, UT, VA, WA, WI OUS: N/A	February 2025 and Prior
I	Software versions 7.9/UDI: 00389152480114	85 units in US: AZ, CA, CO, CT, FL, HI, IA, ID, IL, IN, MD, ME, MI, MO, MS, NC, ND, NE, NJ, NM, NV, NY, OH, PA, TX, UT, VA, WA, WI OUS: N/A	February 2025 and Prior

For additional information, please visit this FDA Website Slim X2 Insulin Pump with Interoperable Technology and this FDA Website Tandem Mobi Insulin Pump with Interoperable Technology.