California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Dexcom, Inc. Recalls Dexcom One+ Continuous Glucose Monitoring System

Recall Date	Product Description	Recalling Firm	Recall Reason
6/16/25	Dexcom One+ Continuous Glucose Monitoring System, SKU(Part Number): STK-D7-013 (MT28285-1), STK-D7-014 (MT28285-1), STK-D7-103 (MT28285-2)	Dexcom, Inc.	Defective foam or an assembly error may cause the receiver speaker to lose contact with the printed circuit board, leading to missed audible alerts for low or high blood glucose values. A missed audible alert for low or high blood glucose values could lead to untreated hypo or hyperglycemia which can cause seizures, vomiting, loss of consciousness, or death.
6/16/25	Dexcom One Continuous Glucose Monitoring System, SKUs(Part Number): STK-DO-006 (MT27409-1), STK-DO-013 (MT27409-1), STK-DO-103 (MT27409-2), STK-DO-109 (MT27409-2)	Dexcom, Inc.	Defective foam or an assembly error may cause the receiver speaker to lose contact with the printed circuit board, leading to missed audible alerts for low or high blood glucose values. A missed audible alert for low or high blood glucose values could lead to untreated hypo or hyperglycemia which

			can cause seizures, vomiting, loss of consciousness, or death.

Recall Class	Product Identification	Distribution	Affected Dates
I	UDI: STK-D7-013 - 00386270003812; STK-D7-014 - 00386270003843; STK-D7-103 - 00386270003836	26,291 units Globally	May 2025 and prior.
I	UDI: STK-DO-006 - 00386270003188 STK-DO-013 -00386270002327 STK-DO-103-00386270002969 STK-DO-109 -00386270002792	38,127 units units Globally	May 2025 and prior.

For additional information, please visit the FDA Website Dexcom One+ Continuous Glucose Monitoring System and Dexcom One Continuous Glucose Monitoring System .