California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Dexcom, Inc. Continuous Glucose Monitoring

Recall Date	Product Description	Recalling Firm	Recall Reason
9/4/25	Brand Name: Dexcom ONE+ Continuous Glucose Monitoring System Product Name: Dexcom ONE+ Android CGM App Model/Catalog Number: SW14245 Software Version: versions 1.4.0 and earlier Product Description: Dexcom ONE+ Androind CGM App Component: Dexcom ONE+ Continuous Glucose Monitoring System	Dexcom, Inc.	The affected devices are the Dexcom G7 Continuous Glucose Monitoring System (CGM System) using iOS, watchOS and Android App software (versions 2.8.0 or earlier) and Dexcom ONE+ CGM System using iOS and Android App software (versions 1.4.0 or earlier), henceforth referred to as the \x1cApp\x1d. The affected App does not provide an expected "Sensor Failed" alert when the transmitter sends a "transmitterFailed" error message to the App when the CGM experiences a hardware or firmware failure. Instead, the App ends the CGM sensor session, stops reporting glucose values and displays the \x1cStart Sensor\x1d screen or \x1cNo active sensor\x1d message

			without alerting the user, which can lead to missed detection of a hyperglycemic or hypoglycemic event and a delay in treatment.
9/4/25	Brand Name: Dexcom G7 Continuous Glucose Monitoring System Product Name: Dexcom G7 CGM Android App Model/Catalog Number: SW12299 Software Version: version 2.8.0 and earlier Product Description: Dexcom G7 CGM Android App SW12299 Component: Dexcom G7 Continuous Glucose Monitoring System	Dexcom, Inc.	The affected devices are the Dexcom G7 Continuous Glucose Monitoring System (CGM System) using iOS, watchOS and Android App software (versions 2.8.0 or earlier) and Dexcom ONE+ CGM System using iOS and Android App software (versions 1.4.0 or earlier), henceforth referred to as the \x1cApp\x1d. The affected App does not provide an expected "Sensor Failed" alert when the transmitter sends a "transmitterFailed" error message to the App when the CGM experiences a hardware or firmware failure. Instead, the App ends the CGM sensor session, stops reporting glucose values and displays the \x1cStart Sensor\x1d screen or \x1cNo active sensor\x1d message without alerting the user, which can lead to missed detection of a hyperglycemic or hypoglycemic event and a delay in

			treatment.

Recall Class	Product Identification	Distribution	Affected Dates
I	Lot Code: UDI: SW14245 - 00386270004314	41629 Worldwide	July 2025 and prior.
I	Lot Code: UDI: SW12299 - 00386270001870	532821 Worldwide	July 2025 and prior.

For additional information, please visit the FDA Website for Dexcom ONE+ and Dexcom G7.