Tandem Diabetes Care Issues Voluntary Medical Device Correction for Select t:slim X2 Insulin Pumps

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SAN DIEGO--(BUSINESS WIRE)--Aug. 7, 2025-- Tandem Diabetes Care, Inc. (Nasdaq: TNDM) has announced a voluntary medical device correction for select t:slim X2 insulin pumps to address a potential speaker-related issue that can trigger an error resulting in a discontinuation of insulin delivery.

The error, which appears as a Malfunction 16 alarm to the user, will stop insulin delivery and terminate communication between the insulin pump and the continuous glucose monitoring (CGM) device. If not addressed, this could result in hyperglycemia due to discontinuation of insulin delivery, real-time CGM Estimated Glucose Values, and CGM trends. In severe cases of hyperglycemia, the user may require hospitalization or intervention from a medical professional. There have been 700 confirmed adverse events, defined as a confirmed high blood sugar and/or an event requiring medical intervention, and 59 reported injuries. No deaths have been reported.

Notices were sent directly to impacted customers in the United States (U.S.) between July 22 and 24, 2025 with instructions on what to do in the event of a Malfunction 16. A copy of this customer notification can be found at https://www.tandemdiabetes.com/docs/default-source/legal/company-update/malfunction-16-speaker-issue-tslimx2-qsf0024231.pdf.

More information, including a searchable list of serial numbers for impacted pumps can be found at tandemdiabetes.com/mal16-2025. The U.S. Food and Drug Administration and regulatory agencies outside of the U.S. have been notified of this action.

Tandem will be releasing a software update designed to enhance early detection of speaker failure. This update will also introduce persistent vibration alerts to help reduce potential safety risk. Tandem will notify all pump users when the software update becomes available and request that they complete the update of their insulin pump.

Impacted customers in the U.S. with questions about this recall can contact the Tandem Diabetes Care Technical Support Team 24 hours a day, 7 days a week at techsupport@tandemdiabetes.com or (877) 801-6901. International customers should reach out to their local distributor for more information. Contact information for each country can be found at tandemdiabetes.com.

Forward Looking Statement

This press release contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those anticipated or projected in the forward-looking statements. These forward-looking statements relate to, among other things, the Company’s plan to enhance detection of a speaker failure with this software update, the timing of this software update, and the ability to reach all of our impacted customers about this software update. These statements are subject to numerous risks and uncertainties, including our ability to enhance detection of a speaker failure, the possibility that the rollout of the software update will be delayed and the possibility that not every impacted customer will update their software app to this version as well as other risks and uncertainties identified in the Company’s most recent Annual report on Form 10-K and its other filings with the Securities and Exchange Commissions. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. The Company undertakes no obligation to update or review any forward-looking statement in this press release because of new information, future events or other factors.

Important Safety Information

RX ONLY. The t:slim X2 pump with interoperable technology (the pump) and Control-IQ+ technology (Control-IQ+) are intended for single patient use. The pump and Control-IQ+ are indicated for use with NovoLog or Humalog U-100 insulin. t:slim X2 insulin pump: The pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The pump is indicated for use in persons 2 years of age and greater. Control-IQ+ technology: Control-IQ+ technology is intended for use with compatible integrated continuous glucose monitors (iCGM, sold separately) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. Control-IQ+ technology is intended for the management of Type 1 diabetes mellitus in persons 2 years of age and greater and of Type 2 diabetes mellitus in persons 18 years of age and greater.

WARNING: Control-IQ+ should not be used in anyone under the age of 2 years old with Type 1 diabetes or under the age of 18 years old with Type 2 diabetes. It should also not be used in patients who require less than a total daily insulin dose of 5 units of insulin per day or who weigh less than 20 pounds (9 kilograms), as those are the required minimum values needed for Control-IQ+ to operate safely.

Users of the pump and Control-IQ+ must: use the insulin pump, iCGM, and all other system components in accordance with their respective instructions for use. Failure to follow these instructions for use could result in an over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

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