



Tandem Diabetes Care to Release Updated iOS t:connect Mobile App for t:slim X2 Insulin Pump Users Impacted by March 2024 Nationwide Recall

August 19, 2024

SAN DIEGO--(BUSINESS WIRE)--Aug. 19, 2024-- Tandem Diabetes Care, Inc. (Nasdaq: TNDM) today announced the planned release of version 2.8.2 of its Apple iOS t:connect mobile app in the United States on August 20, 2024 to correct an issue described in a March 2024 recall that can cause rapid depletion of a user's t:slim X2 insulin pump battery. This battery depletion can result in the pump shutting down sooner than expected, which some customers have continued to see following the release of version 2.7.1 of the app in March. Tandem encourages all impacted t:slim X2 iOS users to update their mobile app as soon as the new version is available in the Apple App Store.

Under-delivery of insulin because of a pump shutdown can result in hyperglycemia or diabetic ketoacidosis, which can be a life-threatening condition due to high blood sugar and lack of insulin. There have been 143 confirmed adverse events with this recall. Adverse events are defined as a confirmed high blood sugar and/or an event requiring medical intervention. Two hospitalizations and no deaths have been reported.

Information for Impacted t:slim X2 Pump Users (U.S. iOS app users only)

Only the t:connect Mobile App on iOS devices is impacted by this issue.

About v2.8.2 of the t:connect Mobile App

- Includes additional improvements including one designed to help preserve pump battery life when the pump charge falls below 20 percent
- Does not require a t:slim X2 insulin pump software update
- Available in the Apple App Store on August 20, 2024

Tandem will email impacted customers with instructions on how to update their mobile devices when the new version of the app is available. Any customers without a valid email address will receive the information by U.S. mail.

Impacted customers in the U.S. with questions about this recall or how to update their mobile devices 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.

About Tandem Diabetes Care

Tandem Diabetes Care, a global insulin delivery and diabetes technology company, manufactures and sells advanced automated insulin delivery systems that reduce the burden of diabetes management, while creating new possibilities for patients, their loved ones, and healthcare providers. The Company's pump portfolio features the Tandem Mobi system and the t:slim X2 insulin pump, both of which feature Control-IQ advanced hybrid closed-loop technology. Tandem Diabetes Care is based in San Diego, California. For more information, visit tandemdiabetes.com.

Follow Tandem Diabetes Care on X @tandemdiabetes; use #t:slimX2 #TandemMobi and #TandemDiabetes.

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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 resolve the t:connect iOS mobile app software issue with this software update, including the Company's ability to resolve the software issue with this software update, the timing of this software update, and the ability to reach all of our customers about this software update. These statements are subject to numerous risks and uncertainties, including our ability to resolve the software issue in this release, or at all; the possibility that the rollout of the software update will be delayed; and the possibility that not every customer will update their software app to this version 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. Indications for Use: t:slim X2 insulin pump: The t:slim X2 insulin pump with interoperable technology is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in people 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 intended for single patient use. The pump is indicated for use with NovoLog or Humalog U-100 insulin. The pump is indicated for use in individuals 6 years of age and greater. Users of the pump must: be willing and able to use the insulin pump and all other system components in accordance with their respective instructions for use; test blood glucose levels as recommended by their healthcare provider; demonstrate adequate carb-counting skills; maintain sufficient diabetes self-care skills; see healthcare provider(s) regularly; and have adequate vision and/or hearing to recognize all functions of the pump, including alerts. The t:slim X2 pump must be removed before MRI, CT, or diathermy treatment. t:connect mobile app: The feature set available within the t:connect mobile app is dependent on the pump software version and the compatible smartphone's model and operating system (OS). The *Display and Data Upload* feature set provides a secondary display of pump and continuous glucose monitoring (CGM) information, including display of your pump alerts and alarms, and enables wireless uploading of pump and CGM data to the Tandem cloud through an internet or wireless data connection. Standard carrier data rates may apply. The *Bolus Delivery plus Display and Data Upload* feature set additionally allows users to request, stop, and cancel a bolus on the pump from the t:connect mobile app. At least one smartphone security setting must be enabled to utilize the Bolus Delivery feature of the t:connect mobile app. WARNING: Always rely on your pump to make therapy decisions when using a smartphone that is incompatible with the Bolus Delivery feature. PRECAUTIONS: Always rely on your pump to make therapy decisions if using a smartphone that is incompatible, the smartphone is lost or damaged, or the smartphone loses Bluetooth® connectivity with your pump. Important pump alerts and alarms are only received as app notifications when enabled and the app is either active or running in the background. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

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