



Tandem Diabetes Care Provides Update on March 2024 Nationwide Recall of t:connect Mobile App for iOS Devices

August 12, 2024

SAN DIEGO--(BUSINESS WIRE)--Aug. 12, 2024-- Tandem Diabetes Care, Inc. (Nasdaq: TNDM) today provided an update on the March 2024 recall of its Apple iOS t:connect mobile app in the United States relating to an issue 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 experience following the release of version 2.7.1 of the app in March. Notices were emailed to impacted customers on August 9, 2024 with updated information and recommendations for helping avoid pump battery depletion. Tandem plans to release a new version of the app to address the remaining issues and will notify all users by email and app push notifications following its release.

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 107 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.

Recommendations for Impacted t:slim X2 Pump Users

Tandem strongly recommends anyone using the Apple iOS t:connect Mobile App with a t:slim X2 insulin pump to do the following:

1. Continue using your Tandem pump and t:connect mobile app as described in the User Guide:
 - a. Charge the pump for a short time every day (10 to 15 minutes) to avoid frequent full battery discharges.
 - b. Monitor pump battery levels closely to ensure the pump is at or near full charge before going to sleep to help prevent pump shutdown.
 - c. Always carry back-up supplies.
2. If a low battery alert is received, Tandem strongly recommends charging the device as soon as possible.

A copy of the customer notification sent on August 9, 2024 can be found at tandemdiabetes.com/docs/battery-depletion.

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.

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.

Follow Tandem Diabetes Care on Facebook at www.facebook.com/TandemDiabetes.

Follow Tandem Diabetes Care on LinkedIn at <https://www.linkedin.com/company/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 a future 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 this software update will be delayed; and the possibility that not every 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. 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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