# URGENT MEDICAL DEVICE CORRECTION UPDATE

## Mobile App Version 2.7 Crashing Resulting in Pump Battery Depletion
## Additional Actions Requested
## FDA Recall Number: Z-1609-2024 (RES# 94312)

August 9, 2024

On March 26, 2024, Tandem Diabetes Care issued an "Urgent Medical Device Recall" notification, which was classified as Class I by the FDA. It has come to our attention that users may still be experiencing occurrences of pump battery depletion after updating their t:connect mobile app to version 2.7.1.

Tandem is providing this updated recall notification because our records indicate that you may be operating the **t:connect® mobile app on the Apple iOS platform** with the t:slim X2 insulin pump and you should take actions to update your mobile app version as soon as the next version of the t:connect mobile app is available to help mitigate this risk. Tandem will notify you via email and an in-app push notification when the next version of the t:connect mobile app has been released. There is no app update action that is required at this time.

**Mitigations to be taken by the Customer/User**

Tandem strongly recommends that you 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. Please monitor your pump battery level 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 you receive a low battery alert, Tandem strongly recommends you begin charging your device as soon as possible.**

**What is the potential issue?**

Pump Battery Depletion:

The mobile app may intermittently retrieve significantly more data than is necessary from the pump and do so repeatedly due to an app crash or being terminated and automatically relaunched by the iOS operating system. As this cycle intermittently repeats, it leads to excessive Bluetooth communication that may result in pump battery drain and may lead to the pump shutting down sooner than typically expected.

**Risk**

As a result of a fully depleted battery, the pump may shut down earlier than typically expected. Pump shutdown will cause insulin delivery to suspend, which could lead to an under-delivery of insulin and may result in hyperglycemia, including severe hyperglycemia.

The pump will provide notification prior to shut down by declaring a low power alert and alarm. In severe cases of hyperglycemia due to a prolonged period of no insulin delivery, the user may experience diabetic ketoacidosis and may require hospitalization or intervention from a medical professional.

Users may be at higher risk if the accelerated pump battery depletion occurs during the night when one is more vulnerable to missing alerts, including severe hyperglycemia due to a prolonged period of no insulin delivery.

For the t:connect mobile app version 2.7.1, there have been 107 confirmed adverse events and 2 confirmed injuries requiring hospitalization associated with accelerated pump battery depletion resulting in pump shutdown. There have been no reports of death.

**Actions to be taken by the Customer/User**

***It is important to acknowledge receipt of this notice by completing the online form available at the following link or by using the QR code below:***

https://campaign.tandemdiabetes.com/Mobile-App-Acknowledgement

If you have concerns, please email Tandem Diabetes Care Customer Technical Support Techsupport@tandemdiabetes.com. Our team is available 24/7/365.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

We appreciate your time and attention in reading this important notification.

Thank you for being a part of the Tandem family.

Sincerely,

Tandem Diabetes Care

Frequently Asked Questions (FAQs)

1. **Is this notice different than the Urgent Medical Device Recall notice that I received previously?**
   Yes, this notice is different than the Urgent Medical Device Recall that was communicated on March 26, 2024. There will be additional updates to the t:connect mobile app as users may still be experiencing occurrences of pump battery depletion after updating their t:connect mobile app to the 2.7.1 version.

2. **Who is affected?**
   If you are using t:connect mobile app versions 2.7 or 2.7.1 on iOS, you may be affected.

3. **What extra precautions should I take?**
   Please monitor your pump battery level closely and always carry back-up supplies. Regularly check your blood sugar as recommended in your training and user guide to ensure you are not having unexpectedly high or low readings.

4. **What is a field correction notice?**
   Correction means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location according to the FDA. In this instance we are alerting you to a potential safety risk from using the 2.7 or 2.7.1 versions of the t:connect mobile app.

5. **What can be the potential risk?**
   Serious injury might occur if the battery fully depletes resulting in an under-delivery of insulin, which may result in hyperglycemia. In severe cases of hyperglycemia, the user may experience diabetic ketoacidosis and may require hospitalization or intervention from a medical professional.

6. **What is an adverse event? What is a medical intervention?**
   An adverse event is any undesirable experience associated with the use of a medical product in a patient. In this case, for example, pump shutdown will stop insulin delivery which could lead to an under-delivery of insulin and may result in an adverse event of hyperglycemia.

   In severe cases of adverse events, patients may require a medical intervention from a medical professional and in some cases, hospitalization to address the condition.

7. **What do I do if I experience an adverse event or quality problem?**
   If you experience any adverse reactions or quality problems with the use of our products, please email Techsupport@tandemdiabetes.com or call Tandem Diabetes Care Customer Technical Support at 1-877-801-6901. Our team is available 24/7/365. Alternatively, you can also utilize the FDA's MedWatch Adverse Event Reporting program either online (www.fda.gov/medwatch/report.htm), by regular mail or by fax (1-800-332-0178). As always, if you are having a medical emergency, call 911.