



## **URGENT MEDICAL DEVICE CORRECTION UPDATE**

**Mobile App Version 2.7 Crashing Resulting in Pump Battery Depletion**

**t:connect® Mobile App v2.8.2 Release**

**FDA Recall Number: Z-1609-2024 (RES# 94312)**

August 20, 2024

On August 9, 2024, Tandem Diabetes Care provided an update to the "Urgent Medical Device Recall" notification, which was classified as Class I by the FDA, to inform you that Tandem would be releasing an update to the **t:connect® mobile app on the Apple iOS platform**. **The purpose of this notification is to inform you that Tandem has released t:connect mobile app version 2.8.2 to the Apple App Store.**

Tandem strongly recommends that you take actions to update your mobile app version 2.8.2 as soon as possible to help mitigate this risk.

If you notice that your t:connect mobile app has already automatically updated to version 2.8.2 or later, Tandem asks that you acknowledge receipt of this notice by following the actions outlined in the 'Mitigations and Actions to be taken by the Customer/User' section of this notice. Instructions for identifying your current app version can be found on the next page.

### **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**

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

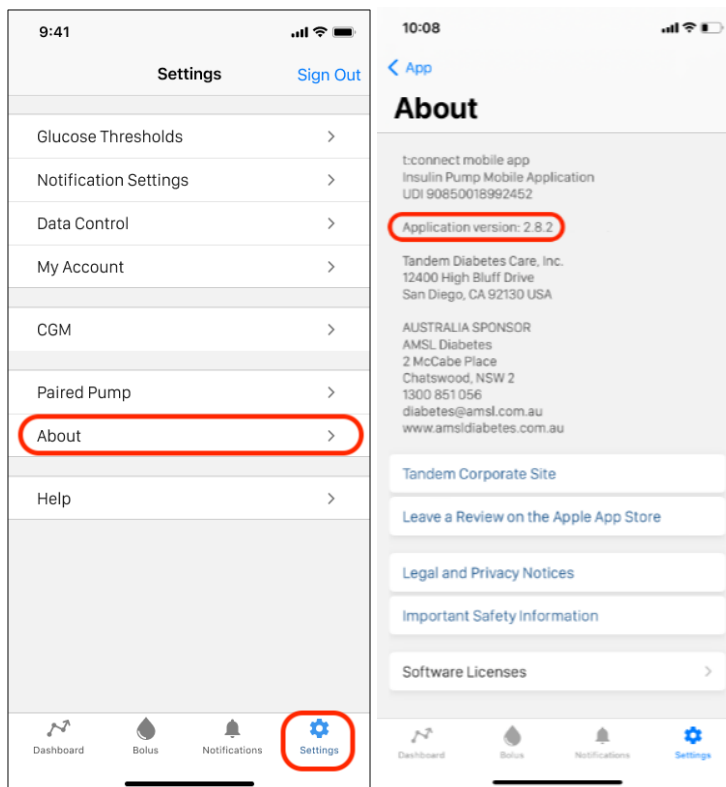
Users may be at higher risk if the accelerated pump battery depletion occurs during the night when one is more vulnerable to missing alerts, including severe hyperglycemia due to a prolonged period of no insulin delivery.

For the t:connect mobile app version 2.7.1, there have been 143 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.

### Mitigations and Actions to be taken by the Customer/User

On August 20, 2024, Tandem released a new version of the mobile app, t:connect® mobile app version 2.8.2, to mitigate the above issue. Starting with t:connect mobile app version 2.8.2, when your pump battery is less than 20%, and you are not actively using your mobile app, your mobile app will no longer upload data wirelessly or provide alerts and alarms to your mobile app. To restore connection with your pump and continue normal use of your mobile app, charge your pump to over 20%.

1. Please **update your mobile app** to version 2.8.2 or later.
2. If you review this update notice and **your mobile app has already been updated to version 2.8.2 or later, there is no update action required.** To identify the software version of the t:connect mobile app, open the app, click the 'Setting' icon on your iPhone's screen, and then click 'About'. More details provided below.



***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. Even if you do not plan on updating your mobile app to version 2.8.2 or later, Tandem asks that you still complete the online form or by using the QR code below:***

<https://campaign.tandemdiabetes.com/Mobile-App-New-Release>



3. 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.
4. **If you receive a low battery alert, Tandem strongly recommends that you begin charging your device as soon as possible.**

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

Adverse reactions or quality problems experienced with using 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 or the Urgent Medical Device Recall Notice Update that I received previously?**

Yes, this notice is different than the two previous Urgent Medical Device Recall notices that were communicated. The purpose of this notice is to inform you that Tandem has now released t:connect mobile app version 2.8.2.

### **2. Is there still an action that I need to take if I updated my t:connect mobile app to the 2.7.1 version?**

Yes, Tandem strongly recommends that you **update your mobile app** to version 2.8.2 or later.

### **3. How do I know what software version my t:slim X2 t:connect Mobile App is?**

To identify the version of t:connect mobile app on your iPhone, open the app, click the 'Setting' icon on your iPhone's screen, and then click 'About'.

### **4. How do I get the latest mobile app version?**

To download the new t:connect mobile app 2.8.2 or later version:

- Access the Apple App Store on your iPhone.
- Search for 't:connect mobile' and select it from the search results.
- If an update is available, tap "Update" next to the app.
- Approve with Face ID, Touch ID, or your password if prompted.

### **5. Who is affected?**

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

### **6. What solution is Tandem offering to 2.7 and 2.7.1 customers?**

Your t:connect mobile app is eligible for an update that includes enhancements to mitigate this issue. To access this update, please visit the Apple App Store and update your t:connect mobile app to version 2.8.2 or later.

To assist in mitigating this issue, starting with version 2.8.2 when your pump battery is less than 20% and you are not actively using your mobile app, your mobile app will no longer upload data wirelessly or provide alerts and alarms. To restore connection with your pump and continue normal use of your mobile app, charge your pump to over 20%.

### **7. What extra precautions should I take?**

Update your t:connect mobile app version as described above. Regularly check your blood sugar as recommended in your training and user guide to ensure you are not having unexpectedly high or low readings. Please monitor your pump battery level closely and always carry back-up supplies.

### **8. 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 older versions of the t:connect mobile app.

**9. Why are you not physically recalling these Tandem Insulin Pumps?**

By updating to version 2.8.2 of your t:connect mobile app, quality improvements are incorporated in the app software that help mitigate the potential issues.

**10. What can be the potential risk?**

Serious injury might occur if the battery fully depletes, which may result in an under-delivery of insulin, and 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.

**11. I haven't had any problems. Do I need to worry about my pump?**

Even if you haven't experienced these issues, ensure your t:connect mobile app has been updated to version 2.8.2 or later as described above.

**12. Is there any training required to update to the latest mobile app version?**

No training is required to use the new mobile app version.

**13. 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 may 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.

**14. 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](mailto: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](http://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.