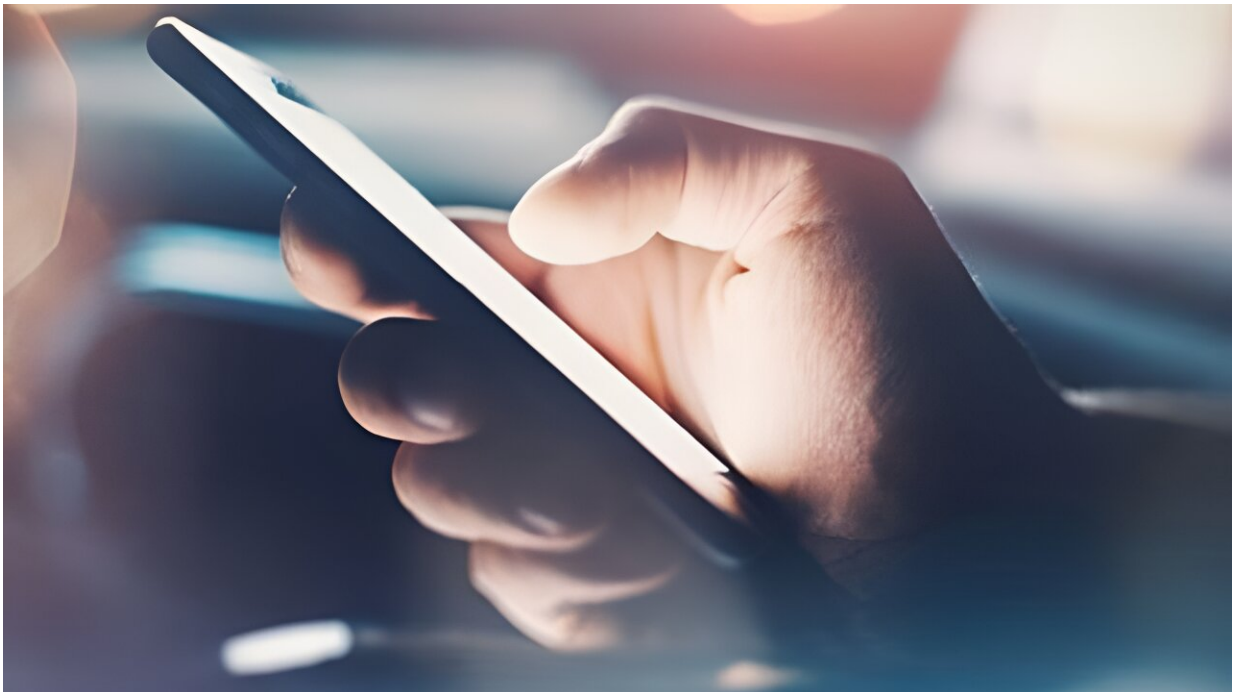


Recall notice after more than 200 insulin pump users injured due to app malfunction

May 9 2024, by Ernie Mundell



The U.S. Food and Drug Administration has issued a Class 1 recall—its most urgent kind—for an IOS app linked to a specific kind of insulin pump used by people with diabetes.

The [recall notice](#), which the FDA says is a "correction" rather than a product removal, involves version 2.7 of the Apple iOS t:connect mobile

app. It's used in conjunction with t:slim X2 [insulin pump](#) with Control-IQ technology.

The problem: The app can repeatedly crash and then restart. Over time, this drains the battery of the insulin pump, which must function in order for patients to stay healthy. Already, nearly 86,000 of the apps have been recalled due to this issue.

"Pump shutdown will cause insulin delivery to suspend, which could lead to an under-delivery of insulin and may result in hyperglycemia or even [diabetic ketoacidosis](#), which can be a life-threatening condition due to high blood sugars and lack of insulin," the FDA explained in a statement released Thursday.

So far, the agency knows of 224 reported injuries from this malfunction as of April 15. No deaths have been reported.

Anyone who uses the t:slim X2 Insulin Pump Mobile App version 2.7 on the Apple iOS platform could be affected.

What to do

According to the FDA notice, Tandem Diabetes Care, Inc. has recalled version 2.7 of the t:connect mobile app, which was first released on the Apple iOS platform on Feb. 12, 2024. It works in conjunction with the t:slim X2 insulin pump, which delivers insulin under the skin at specific but varying rates.

Tandem is urging users to update the software to version 2.7.1 or later. It is available in the Apple App Store.

After that:

- Identify the software version of the t:connect [mobile app](#) by opening the app, clicking the "Setting" icon on an iPhone's screen, and then clicking "About."
- Complete the online form External Link Disclaimer to acknowledge receipt of this notice.
- Keep using the pump as described in the user guide, paying heed to all system alerts and alarms.
- Monitor pump battery level closely to ensure the pump is at or near full charge before going to sleep to help prevent pump shutdown.
- Begin charging device after the first low battery alert.
- Always carry backup supplies for [insulin delivery](#) in the case of insulin pump failure.

More information: Any U.S. customers with questions can reach out to the Tandem Diabetes Care Technical Support Team at 877-801-6901.

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