

May 16, 2024

PROVIDER ALERT: FDA & TANDEM DIABETES CARE WARNING ON INSULIN PUMP PROBLEM

MedStar Family Choice District of Columbia (MedStar Family Choice-DC) wants to make you aware of a defect with the **t:slim X2 Insulin Pump Mobile App [version 2.7 on the Apple iOS platform]**. This defect was discovered in the device software and a recall notice was issued. On May 8, 2024, the Food and Drug Administration (FDA) identified this defect as a Class I recall, the most serious type of recall.

This recall is due to an issue with the software that may cause the mobile app to crash and the pump battery to drain. This may lead to the pump shutting down sooner than typically expected. Pump shutdown will cause insulin delivery to stop, which could lead to an under-delivery of insulin. This can be a life-threatening condition due to high blood sugars and lack of insulin.

On March 26, 2024, Tandem Diabetes Care, Inc. sent all customers who are using this insulin pump an Urgent Medical Device Correction letter. The letter requested customers to:

- Update the mobile app to version 2.7.1 or later, available in the Apple App Store
 - To identify the software version of the t:connect mobile app, customers must:
 1. open the app,
 2. click the 'Setting' icon on an iPhone's screen, and
 3. click 'About'.
- Complete the online form to acknowledge that they received this notice. This form can be found at <https://campaign.tandemdiabetes.com/FCN-Mobile-App-Battery>.
- Continue to use the pump as described in the User Guide and pay attention to all system alerts and alarms.
- Monitor the 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 the device after the first low battery alert.
- Always carry backup supplies for insulin delivery in the case of insulin pump failure.

Please contact the Tandem Diabetes Care Technical Support Team at **877-801-6901** for questions about this recall. You may also call the Food and Drug Administration toll-



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free at **888-INFO-FDA (888-463-6332)** or visit www.FDA.gov for more information about this recall.

For general questions concerning this Provider Alert, please contact the MFC-DC Provider Customer Service Department, Monday through Friday, 8 a.m. to 5:30 p.m.

Phone: **800-261-3371**

Email: mfcdc-providerrelations@medstar.net

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