



URGENT FIELD SAFETY NOTICE

Malfunction 16 - Speaker t:slim X2 Insulin Pump

September 24, 2025

You are receiving this letter because your distributor's records indicate that you may be using a Tandem Diabetes Care™ t:slim X2 insulin pump. Because your safety is our top priority, we are alerting you of a potential risk when using your pump within normal specifications.

Tandem Diabetes Care™ is voluntarily initiating an Urgent Field Safety Notice for t:slim X2 insulin pumps that may exhibit a higher rate of speaker failure.

What is the potential issue?

During normal use, the t:slim X2 insulin pump software monitors current flowing through the speaker during use. Measurements falling within a pre-determined range indicate a functioning speaker while measurements falling outside the range indicate a speaker failure. When current measurements fall outside of the expected range, a malfunction is declared ("Malfunction 16").

Tandem has identified certain speaker versions that have a higher rate of Malfunction 16 events due to a wiring issue within the speaker.

Tandem has determined that your t:slim X2 insulin pump includes a speaker that has exhibited a higher failure rate leading to Malfunction 16.

In addition, Tandem has determined you are part of a subset of pump users who have a higher probability of experiencing a Malfunction 16 or experiencing subsequent adverse events if the Malfunction were to occur.

If a Malfunction 16 is declared on your pump, insulin delivery will stop, and the pump is no longer operational. Please contact your distributor to report the malfunction and to initiate the return and replacement of your pump.

Risk

A Malfunction 16 will stop insulin delivery and terminate communication between the insulin pump and the Continuous Glucose Monitoring device. If not addressed, this could result in hyperglycemia due to the malfunction resulting in the stoppage of insulin delivery and real time Continuous Glucose Monitoring, Estimated Glucose Values, and blood glucose trend

information. In severe cases of hyperglycemia, the user may require hospitalization or intervention from a medical professional.

Mitigations and Actions to be taken by the User

1. If you haven't had a Malfunction 16, continue using your Tandem pump as described in the User Guide, but with added precautions because the Malfunction 16 can occur at any time.
2. If you are using a Dexcom sensor, use the Dexcom mobile app as a secondary means of CGM alerts and alarms.
3. If you receive a Malfunction 16 alert:
 - a. Promptly acknowledge it by pressing "Silence Alarm".
 - b. Contact your distributor to report the malfunction and to initiate the return and replacement of your pump.
 - c. Switch to your backup method of insulin delivery as directed by your physician.
4. Regularly check your blood sugar to ensure you are not having unexpectedly high or low readings.
5. Be prepared with a backup method of insulin delivery as directed by your physician, as set forth in the pump training, and as laid out in the pump user guide.
6. After receiving this notice if you have additional concerns and wish to have your pump replaced, although the malfunction has not yet become apparent, please contact your distributor to initiate a pump replacement.

What to Expect

Tandem Diabetes Care will be releasing a software update aimed at enhancing early detection of speaker failure. This update will also introduce persistent vibration alerts to help reduce potential safety risk.

Your distributor will notify you when the software update becomes available and request that you complete the software update of their insulin pump.

Should you experience any device-related serious incidents, please report them to Tandem, your distributor, a local contact point, or the Federal Institute for Drugs and Medical Devices.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective actions. Tandem Diabetes Care confirms that the German regulatory body has been notified of this notice. At Tandem Diabetes Care, patient safety is our top priority, and we are committed to delivering safe and effective therapies of the highest possible quality and reliability.

We appreciate your time and attention in reading this important notification. Please reference FSCA-2025-001 when contacting either Tandem or your distributor about this notice.

Sincerely,

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