



URGENT MEDICAL DEVICE CORRECTION
Malfunction 16 - Speaker
t:slim X2 Insulin Pump

July 22, 2025

The purpose of this letter is to advise you that Tandem Diabetes Care is voluntarily initiating an Urgent Medical Device Correction for t:slim X2 insulin pumps that may exhibit a higher rate of speaker failure. You are receiving this letter because our records indicate you may be operating an affected t:slim X2 insulin pump.

If you receive this Urgent Medical Device Correction notice, 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:

campaign.tandemdiabetes.com/FCA-Malfunction-16

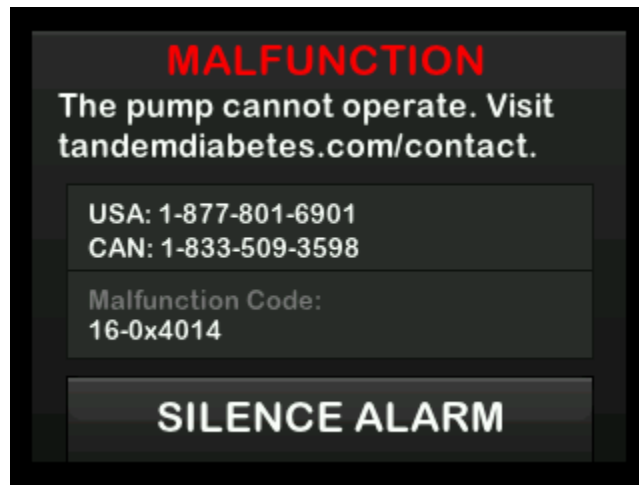


To confirm whether your pump is affected, please click the following link to access a pump serial number lookup website:

www.tandemdiabetes.com/mal16-2025

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.

If a Malfunction 16 is declared on your pump, insulin delivery will stop, and the pump is no longer operational. If this happens, please contact Tandem Diabetes Care Customer Technical Support (CTS) via phone at 1-877-801-6901 or email at Techsupport@tandemdiabetes.com.

Risk

A Malfunction 16 will stop insulin delivery and terminate communication between the insulin pump and the CGM device, as well as the Tandem t:slim mobile app. If not addressed, this could result in hyperglycemia due to the malfunction resulting in the stoppage of insulin delivery and real time CGM Estimated Glucose Values (EGVs) and CGM trends. In severe cases of hyperglycemia, the user may require hospitalization or intervention from a medical professional.

There have been 700 adverse events reported and 59 reported injuries. There have been no reports of death.

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. Use the Tandem t:slim mobile app with push notifications turned on so if the malfunction does occur, you will be notified by the app.

If you need assistance with enabling smartphone notifications to receive alerts from your mobile app, please click the link below to access an article on Tandem's support page:

<https://www.tandemdiabetes.com/support-center/software-and-apps/tandem-tslim-mobile-app/article/enable-smartphone-notifications-to-receive-alerts>

3. If you are using a Dexcom sensor, use the Dexcom mobile app as a secondary means of CGM alerts and alarms.

Note: If you are unable to download and use the Tandem t:slim mobile app and/or your Dexcom mobile app, please contact Tandem at 1-877-801-6901 or Techsupport@tandemdiabetes.com for support.

4. If you receive a Malfunction 16 alert:
 - a. Promptly acknowledge it by pressing "Silence Alarm".
 - b. Contact Tandem at 1-877-801-6901 or Techsupport@tandemdiabetes.com to arrange for a replacement pump.
 - c. Switch to your backup method of insulin delivery as directed by your physician.
5. Regularly check your blood sugar to ensure you are not having unexpectedly high or low readings.
6. 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.
7. As requested above, please complete the online form acknowledging receipt of this notice.

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.

Tandem will notify affected pump users when the software update becomes available and request pump users to complete the software update of their insulin pump.

If you have concerns, please call 1-877-801-6901 or email 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 to this important notification.

Thank you for being a part of the Tandem family.

Sincerely,

Tandem Diabetes Care

Frequently Asked Questions (FAQs)

1. Who is affected?

If you are receiving this Urgent Medical Device Correction notice, then your t:slim X2 insulin pump is affected.

2. What solution is Tandem offering?

Tandem Diabetes Care will be releasing a software update that is designed to provide an early detection of speaker failure and introduce persistent vibration alerts to mitigate the potential safety risk.

Tandem will notify users of affected pumps when the software update becomes available and to request the user to complete the software update of their insulin pump.

3. What extra precautions should I take?

- 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.
- Use the Tandem t:slim mobile app with push notifications turned on so if the malfunction does occur, the user will be notified by the app.

If you need assistance with enabling smartphone notifications to receive alerts from your mobile app, please click the link below to access an article on Tandem's support page:

<https://www.tandemdiabetes.com/support-center/software-and-apps/tandem-tslim-mobile-app/article/enable-smartphone-notifications-to-receive-alerts>

- If you are using a Dexcom sensor, use the Dexcom mobile app as a secondary means of CGM alerts and alarms.

Note: If you are unable to download and use the Tandem t:slim mobile app and/or your CGM mobile app, please email Techsupport@tandemdiabetes.com for support.

- If you receive a Malfunction 16 alert:
 - Promptly acknowledge it by pressing "Silence Alarm".
 - Also call 1-877-801-6901 or email at Techsupport@tandemdiabetes.com
 - Switch to your backup method of insulin delivery as directed by your physician.
- Regularly check your blood sugar to ensure you are not having unexpectedly high or low readings.
- 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.
- As requested above, please complete the online form acknowledging receipt of this notice.

4. What is an Urgent Medical Device Correction?

According to the FDA, a correction means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

5. What can be the potential risk?

This issue will stop insulin delivery and terminate communication between the insulin pump and the CGM device, as well as the Tandem t:slim mobile app. If not addressed, this could result in hyperglycemia due to the malfunction resulting in the stoppage of insulin delivery and real time CGM Estimated Glucose Values (EGVs) and CGM trends. In severe cases of hyperglycemia, the user may require hospitalization or intervention from a medical professional.

6. I haven't had any problems. What do I need to do?

Even if you haven't experienced a Malfunction 16 issue, please acknowledge receipt of this notice by completing the online form using the URL link or QR Code provided above.

In addition, please follow the extra precautions outlined above.

7. What do I do if I experience an adverse event or problem?

If you experience any adverse reactions or quality problems with the use of our products, please call Tandem Diabetes Care Customer Technical Support at 1-877-801-6901 or email Techsupport@tandemdiabetes.com. 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.