

Manufacturer name:	Tandem
About the Recall:	<p>t 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.</p> <p>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”).</p> <p>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.</p>
Products(s) numbers/models that are affected:	<p>To confirm whether your pump is affected, please click the following link to access a pump serial number lookup website:</p> <p style="text-align: center;">www.tandemdiabetes.com/mal16-2025</p>
URL Link(s) to Manufacturer Notice/Web Site:	www.tandemdiabetes.com

**Actions to be
taken by
customer/Patient:**

Should you receive a malfunction code 16 listed above, silence the alarm and contact Tandem for support. Tandem has released a software update aimed at enhancing early detection of speaker failure. This update has introduced persistent vibration alerts to help reduce potential safety risk.

Tandem may be contacted at 1-877-801-6901 or
Techsupport@tandemdiabetes.com