

Tandem Diabetes Care Insulin Pumps – Fluctuating Battery Life Display

Advisory Notice

You are receiving this letter because our records indicate that you may be using a Tandem Diabetes Care insulin pump. Because your safety is our top priority, we are alerting you of a potential safety risk

Issue: Fluctuating Battery Life Display

Customers using Tandem insulin pumps may be affected by a Fluctuating Battery Life Display.

During a high battery usage event, the pump’s displayed battery life may appear to fluctuate. For example, during brief time intervals while insulin is being delivered, the displayed battery life may temporarily decrease below actual levels. Once the insulin delivery is completed, the displayed battery life normalizes to display the actual (higher) battery level. If noticed, this fluctuation could create confusion for the user. We refer to this as a ‘Fluctuating Battery Life Display’ event.

As part of the normal operation of the t:slim X2 insulin pump, when the displayed battery life drops to 25% or less, the user will receive one or more of the notifications described below and a single red bar on the battery life display will appear on the home screen.

Low Power Alert / Alarm

It is important that you always respond to any Low Power Alert or Alarm as recommended in the table below.

What will I see on the screen?	Low Power Alert (2T)	Low Power Alert (3T)	Low Power Alarm (12A)
What does it mean?	Less than 25% of battery power remains	Less than 5% of battery power remains. Insulin delivery will continue for 30 minutes and then the pump will power off and insulin delivery will stop	Your t:slim X2 pump detected a power level of 1% or less remaining and all deliveries have stopped
How will the system notify me?	2 sequences of 3 notes or 2 vibrations	2 sequences of 3 notes or 2 vibrations	3 sequences of 3 notes or 3 vibrations

	depending on the volume/vibrate setting selected in Sound Volume	depending on the volume/vibrate setting selected in Sound Volume	depending on the volume/vibrate setting selected in Sound Volume
Will the System re-notify me?	Yes, every 5 minutes until acknowledged	Yes, every 5 minutes until acknowledged	Yes, the System will re-notify you every 3 minutes until no power remains and the pump shuts down
How should I respond?	Tap "OK". Charge your pump as soon as possible to avoid the second Low Power Alert	Tap "OK". Charge your pump immediately to avoid the Low Power Alarm and system power off	Tap "OK". Charge your pump immediately to resume insulin delivery

If you do not charge your pump following a Low Power Alert (2T), when the pump reaches 5% battery life remaining, the pump will display the Low Power Alert (3T), stops reading the battery life and moves to a 30-minute timer prior to shut down.

Therefore, the pump will have a minimum of 30 minutes power remaining after displaying 5% battery life.

If the pump displays 1% battery life remaining, your pump will display the Low Power Alarm (12A), the pump stops displaying CGM data, and all pump operations and all insulin deliveries stop. If you receive a Low Power Alarm (12A) and you do not promptly either (1) charge the pump and resume deliveries or (2) use a backup method of insulin delivery as described in the User Guide (such as manual injections), then you could experience sustained hyperglycemia leading to a serious injury (e.g. DKA).

Precautions and Recommendations:

Please take the following precautions to ensure that your pump is properly charged, and the pump's battery life does not fall below 25% remaining power:

- Periodically check the battery level indicator of your pump
- Regularly charge the pump
- Avoid full battery discharges

In addition, please respond promptly as recommended above if you receive any Low Power Alert or Alarm.

At Tandem Diabetes Care, patient safety is our top priority, and we appreciate your time and attention in reading this important notification. As always, we are here to support you.

Sincerely,
Tandem Diabetes Care