

URGENT FIELD SAFETY NOTICE

t:slim X2™ Insulin Pumps with Control-IQ Technology

7.6 Software Version Availability

[Date]

You are receiving this letter because your distributor's records indicate that you may be using a Tandem Diabetes Care™ insulin pump with a software version of 7.4.3 or lower. Because your safety is our top priority, we are alerting you of potential risks when using your pump within its normal specifications and recommending that you update your pump software to mitigate these risks. More details are provided below.

How do I know if my pump is affected?

Tandem's t:slim X2 with Control-IQ technology insulin pumps are affected by this notice. Tandem's t:slim X2 with Basal-IQ technology insulin pumps are not affected.

What are the potential issues?

Tandem has determined that the following issues can increase risk to the user, and we have designed new software for t:slim X2 insulin pumps to mitigate the following four issues. While uncommon, each of these could result in hyperglycemia and/or hypoglycemia:

1. Malfunction 6 Non-Volatile Memory (NVM):
Malfunction 6 is declared when memory corruption is detected, or the memory cannot be written to or read from. When a malfunction occurs, all insulin deliveries are stopped. When this happens, the pump annunciates 3 sequences of 3 notes at the highest volume and 3 vibrations every 3 minutes until the user has acknowledged the malfunction by silencing the alarm.
2. Inaccurate (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. If the decrease in displayed battery life occurs when the battery is very low, then following a sequence of Low Power Alerts and Alarms, the pump may stop all insulin deliveries and power off as soon as 30 minutes after the first Low Power Alert.
3. Touchscreen Staying On:
If the pump's touchscreen senses something continuously touching the screen, the pump's software resets the display screen timeout timer causing the screen to stay on indefinitely resulting in the battery depleting faster than expected. If the battery depletes, then following a sequence of Low Power Alerts and Alarms, the pump will eventually stop all insulin deliveries and power off.

For all three issues outlined above, the result can be an under-delivery of insulin, which can result in hyperglycemia. In severe cases of hyperglycemia, the user can experience diabetic ketoacidosis and can require hospitalization or intervention from a medical professional.

4. Unexpected Open Loop:

Control-IQ technology could turn off unexpectedly due to a software anomaly that results in the pump entering an unexpected open loop. When Control-IQ technology turns off, the pump is no longer adjusting insulin dosing based on CGM readings and the pump reverts to the active personal profile settings.

If this issue occurs, the result can be an under-delivery or over-delivery of insulin, which can result in hypoglycemia or hyperglycemia. In severe cases of hypoglycemia or hyperglycemia, the user can require hospitalization or intervention from a medical professional. In severe cases of hyperglycemia, the user can also experience diabetic ketoacidosis.

What does this mean?

Tandem has made a software update available for the t:slim X2 insulin pump which incorporates quality improvements made to the pump software that mitigates the potential issues outlined in this communication.

You can continue using your Tandem pump following the recommended precautions outlined below. The recommended precautions are consistent with those that are provided in the User Guide and the new pump user training provided. Please ensure that you are using your Tandem insulin pump as indicated in your user guide.

Recommended precautions

Regularly check your blood sugar to ensure you are not having unexpectedly high or low readings.

Other recommended best practices

If you are using a Continuous Glucose Monitor (CGM), we recommend you program High and Low BG Alerts. If you are using a Dexcom G6 CGM, we recommend that you pair your CGM with your t:slim X2 pump to receive alerts directly on your pump.

What should you do?



Continue using your Tandem pump as described in the User Guide.

What to expect?

VitalAire GmbH will be contacting you to arrange to have your pump's software updated to version 7.6 for Control-IQ technology.

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-2022-003 when contacting your distributor about this notice.

Sincerely,


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