



URGENT FIELD SAFETY NOTICE
t:slim X2™ Insulin Pumps – Software Update Available
Healthcare Providers

February ##, 2024

Dear Healthcare Provider,

This letter is a reminder to instruct your patients to update their Diabetes Care™ insulin pumps with a software version of 6.4.1 or 7.4.3 or lower. Tandem requires that users update their pump software to the latest version to access quality improvements through a free software update available to t:slim X2 pump users. More details are provided below.

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 three issues for both the Basal-IQ and Control-IQ technology. While uncommon, each of these could result in an unexpected disruption to insulin delivery:

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 provides 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 could be an under-delivery of insulin, which may result in hyperglycemia. In severe cases of hyperglycemia, the user may experience diabetic ketoacidosis and may require hospitalization or intervention from a medical professional.

In addition, the designed new software for t:slim X2 insulin pumps mitigates a fourth issue that is related to the Control-IQ technology. While uncommon, this issue could result in an under-delivery or over-delivery of insulin:

4. Unexpected Open Loop:

Control-IQ technology could turn off unexpectedly due to a software anomaly that results in the pump entering open loop (pining mode). 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 occurs, this could result in hypoglycemia or hyperglycemia. In severe cases of hypoglycemia or hyperglycemia, the user may require hospitalization or intervention from a medical professional.

If this issue occurs, the first step to attempt to resolve the issue is to perform a complete pump reboot to recover. If the pump reboot does not resolve the issue, please discontinue the use of the Control-IQ algorithm or contact your distributor to have the pump replaced.

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.

Users can continue using their 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. It is important to remind patients to use the Tandem insulin pump as indicated in the user guide.

How does a user know if their pump is affected?

Pump Models and Software Versions Affected:

1006419 - t:slim X2 with Basal-IQ Technology software version 6.4.1

1005611 - t:slim X2 with Control-IQ Technology software version 7.4.3

Users can check their software version directly on their pump. Select options > my pump > pump info and arrow down to t:slim software version.

Recommended precautions

Remind users to regularly check their blood sugar to ensure they are not having unexpectedly high or low readings.

Other recommended best practices

1. If users are using a Continuous Glucose Monitor (CGM), we recommend they program High and Low BG Alerts. If users are using a Dexcom G6 CGM, we recommend they pair their CGM with their t:slim X2 pump to receive alerts directly on their pump.
2. Ensure the t:slim X2 insulin pump is running the latest version of software.

What should users do?

1. Users should continue using their Tandem pump as described in the User Guide.
2. Tandem ***requires that users update their pump software*** to access quality improvements through a free software update available to t:slim X2 pump users. Users should contact their distributor to facilitate the software update.
3. Please complete the Customer Response Form that is enclosed with this Field Safety Notice, and please return the completed form to VitalAire Schweiz AG by email or postal mail.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective actions. The undersign confirms that this notice has been notified to the appropriate National Competent Authorities.

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.

Please note that a similar letter has been sent to users in which our records indicate may be using a Tandem pump with a software version of 6.4.1 or 7.4.3 or lower. The same advice outlined in this letter was also provided in the communication to the users.

Sincerely,

Mick Trier
Director, Global Post Market Surveillance
Tandem Diabetes Care
11075 Roselle Street
San Diego, California, USA 92121
mtrier@tandemdiabetes.com

SWITZERLAND
VitalAire Schweiz AG
Waldeggstrasse 38
3097 Liebefeld, Schweiz
0800 480 000
info@vitalaire.ch
<https://www.vitalaire.ch/diabetes>