



URGENT MEDICAL DEVICE CORRECTION t:slim X2 insulin pumps

July 26, 2022

You are receiving this letter because our records indicate that you may be using a t:slim X2 insulin pump with one of the software versions listed below. 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.

Product name	Software versions
t:slim X2	4.3.5.2, 4.3.6
t:slim X2 with G5	5.0.1, 5.0.4, 5.3.1.1
t:slim with Basal-IQ technology	6.0.4, 6.3.1.1, 6.4
t:slim X2 with Control-IQ technology	7.3.1.1, 7.4

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:

https://go.tandemdiabetes.com/Field-Correction-Notice-X.6_US.html



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.

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 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 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 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.

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

Recommended Actions

1. Continue using your Tandem pump as described in the User Guide.
2. Tandem **recommends that you update your pump software** to access quality improvements through a free software update available to t:slim X2 pump users. This software update is called version 6.6.0.1 for Basal-IQ technology and version 7.6.0.1 for Control-IQ technology. You can check your software version directly on your pump. Select options > my pump > pump info and arrow down to t:slim software version. These instructions can also be found in your user guide. To learn more about how to check your software version, visit <https://support.tandemdiabetes.com/hc/en-us/articles/1500011452302-How-do-I-check-what-software-version-is-on-my-pump-video->. If your pump says anything other v7.6.0.1 or v6.6.0.1 you should update your software.
3. The latest software can be downloaded remotely from a computer. Visit <https://portal.tandemdiabetes.com> and login with your t:connect account credentials. Once logged in, click on the "MY DEVICES" tab to view software updates available to you.
4. To update your pump software, please perform this update via the Tandem Device Updater (TDU), with precautions and instructions provided in the user guide for Tandem Device Updater: https://www.tandemdiabetes.com/docs/default-source/product-documents/tandem-device-updater/aw-1004796_c-user-guide-tandem-device-updater-5-4-artwork.pdf. Follow the prompts to update your t:slim X2 insulin pump using the Tandem Device Updater.

Note: When updating your t:slim X2 pump software, always follow all security precautions and instructions provided to you in the user guide for the Tandem Device Updater.

If you have any concerns, please email Tandem Diabetes Care Customer Support Techsupport@tandemdiabetes.com. Our team is available 24/7/365.

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.

Thank you for being a part of the Tandem family.

Sincerely,

Tandem Diabetes Care

Frequently Asked Questions (FAQs)

1. What extra precautions should I take?

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

2. What is a field correction notice?

Correction means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location according to the FDA. In this instance we are alerting you to a potential safety risk from using older versions of t:slim X2 pump software.

3. Why are you not physically recalling these Tandem Insulin Pumps?

By updating the pump software on your t:slim X2 insulin pump, this incorporates quality improvements made to the pump software that mitigate the potential issues.

4. How many Tandem Pumps are affected?

Any t:slim X2 insulin pump running software version 6.4 or 7.4 or earlier.

5. Has there been any serious injury or death related to this potential risk?

Serious injury might occur only if the user does not acknowledge multiple alerts / alarms if one of these issues occurs.

6. I haven't had any problems yet. Do I need to worry about my pump?

Even if you haven't experienced these issues, Tandem recommends updating to the latest software that includes these quality improvements.

7. What solution is Tandem offering to affected customers?

Your t:slim X2 insulin pump is eligible for a software update that includes these software changes and enhancements. To access this remote software update, visit

<https://portal.tandemdiabetes.com> and login with your t:connect account credentials. Once you are logged in, click on the “MY DEVICES” tab to check for available software updates.

To update your pump software, please perform this update via the Tandem Device Updater (TDU), with precautions and instructions provided in the user guide for Tandem Device Updater: https://www.tandemdiabetes.com/docs/default-source/product-documents/tandem-device-updater/aw-1004796_c-user-guide-tandem-device-updater-5-4-artwork.pdf. Follow the prompts to update your t:slim X2 insulin pump using the Tandem Device Updater.

Note: When updating your t:slim X2 pump software, always follow all security precautions and instructions provided to you in the user guide for the Tandem Device Updater.

Note: A prescription and training may be required. If your t:slim X2 pump is out-of-warranty and you are not currently using Control-IQ technology, you will only be able to update to Basal-IQ (6.6.0.1) software.

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

8. How do I know what software version my pump is?

You can check your software version directly on your pump. Select options > my pump > pump info and arrow down to t:slim software version. If your pump says anything other v7.6.0.1 or v6.6.0.1 you should update your software.

To learn more about how to check your software version, visit <https://support.tandemdiabetes.com/hc/en-us/articles/1500011452302-How-do-I-check-what-software-version-is-on-my-pump-video->

9. How will Tandem address this in the future to avoid similar problems?

While your t:slim X2 insulin pump is functioning as intended, we have already implemented additional software changes which are designed to further reduce potential risk to the user. Visit portal.tandemdiabetes.com and login with your t:connect account credentials. Once you are logged in, click on the “MY DEVICES” tab to check for available software updates.

10. Do I need a prescription to access this new software?

If you are currently using Basal-IQ technology, then you can update to the latest version of Basal-IQ technology software (6.6.0.1) without a prescription. If you are currently using Control-IQ technology, then you can update to the latest version of Control-IQ technology software without a prescription (7.6.0.1) If you are not currently using either Basal-IQ or Control-IQ, then a prescription will be required to update to our latest software. If you are currently using Basal-IQ technology, and you wish to update to the latest version of Control-IQ technology, then a prescription is required. Please note that you are not eligible to update from Basal-IQ technology to Control-IQ technology if you are out of warranty.

11. Is there any training required to update to the latest software?

Yes, you will be required to complete a training module prior to updating your pump software.

12. How do I get the new software for my pump?

To request a software update, t:slim X2 pump users should visit <https://portal.tandemdiabetes.com> and once logged in with your t:connect account credentials, click on “MY DEVICES” and look for available updates. If you are currently using Basal-IQ technology and would like to remain on Basal-IQ technology, be sure to request the Basal-IQ technology update.

To update your pump software, please perform this update via the Tandem Device Updater (TDU), with precautions and instructions provided in the user guide for Tandem Device Updater: https://www.tandemdiabetes.com/docs/default-source/product-documents/tandem-device-updater/aw-1004796_c-user-guide-tandem-device-updater-5-4-artwork.pdf. Follow the prompts to update your t:slim X2 insulin pump using the Tandem Device Updater.

Note: When updating your t:slim X2 pump software, always follow all security precautions and instructions provided to you in the user guide for the Tandem Device Updater.

To learn more about how to perform a software update on your pump, visit www.tandemdiabetes.com/X2update.