



FIELD CORRECTION NOTICE

t:slim X2 insulin pumps with software versions earlier than 6.4 or 7.4

February 08, 2021

You are receiving this letter because our records indicate that you may be using t:slim X2 insulin pump with software versions earlier than 6.4 or 7.4. Because your safety is our top priority, we are alerting you of a potential safety risk while using your insulin pump. It is important you acknowledge receipt of this notice by completing the online form:

<https://go.tandemdiabetes.com/tandemfieldcorrectionbasalrate.html>

What is the issue?

Insulin pumps from Tandem Diabetes Care include a Personal Profile feature that allows users to personalize the settings that define the delivery of basal and bolus insulin within specific time segments in a 24-hour period. After a user inputs a basal rate into the Personal Profile pump screen, a “Confirm Settings” screen is displayed and must be acknowledged by the user. Even so, a user could inadvertently program and confirm a basal rate with an incorrectly placed decimal point. *For example: The user intends to program a basal rate of 0.7 units/hour, but inadvertently enters and confirms a basal rate of 7.0 units/hour.*

Inputting incorrect values in your Personal Profile can lead to under-delivery or over-delivery of insulin, which could result in hyperglycemia or hypoglycemia.

Tandem Diabetes Care previously provided an Advisory Notice to customers and healthcare providers regarding this issue in March 2020, and we are reinforcing our prior communication with additional information at this time.

What does this mean?

You can continue using your Tandem pump with the extra precautions outlined below. Make sure you are using your Tandem insulin pump as indicated in your user guide.

Recommended precautions when programming basal rate

1. Take extra care when creating or editing a Personal Profile within your Tandem insulin pump.
2. As outlined in the User Guide that you received with your Tandem pump, your pump displays a “Confirm Settings” screen where you confirm that your basal rate change was correctly entered.



3. Double check all values you've entered before you advance past the Confirm Settings screen.
4. Regularly check your blood sugar to ensure you are not having unexpectedly high or low readings.

Other recommended best practices

1. 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.
2. Ensure the t:slim X2 insulin pump is running the latest version of software.

What should you do?

1. Continue using your Tandem pump. Take extra precaution and review confirmation screens when creating or editing a Personal Profile as described above.
2. Tandem **recommends that you update your pump software** to access and use the Basal Limit feature which is available as a free software update to eligible t:slim X2 pump users. This software feature is available on Basal-IQ technology (v 6.4) or Control-IQ technology (v 7.4). 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 available software updates.
3. For specific instructions on how to use the Basal Limit feature please reference your relevant user guide that can be found here:
 - a. [t:slim X2 insulin pump with Basal-IQ technology 6.4](#), refer directly to section 4.10
 - b. [t:slim X2 insulin pump with Control-IQ technology 7.4](#), refer directly to section 4.10
4. If you have any concerns, please email Tandem Diabetes Care Customer Support Techsupport@tandemdiabetes.com. Our team is available 24/7.

It is important you acknowledge receipt of this notice by completing the online form or visiting <https://go.tandemdiabetes.com/tandemfieldcorrectionbasalrate.html>



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 is the issue?

Insulin pumps from Tandem Diabetes Care include a Personal Profile feature that allows users to personalize the settings that define the delivery of basal and bolus insulin within specific time segments in a 24-hour period. After a user inputs a basal rate into the Personal Profile pump screen, a “Confirm Settings” screen is displayed and must be acknowledged by the user. Even so, a user could inadvertently program and confirm a basal rate with an incorrectly placed decimal point. *For example: The user intends to program a basal rate of 0.7 units/hour, but inadvertently enters and confirms a basal rate of 7.0 units/hour.*

Inputting incorrect values in your Personal Profile can lead to under-delivery or over-delivery of insulin, which could result in hyperglycemia or hypoglycemia.

2. What precautions should I take?

Take extra care when creating or editing a Personal Profile within your Tandem insulin pump.

As outlined in the User Guide that you received with your Tandem pump, your pump displays a “Confirm Settings” screen where you confirm that your basal rate change was correctly entered.

Double check all values you’ve entered before you advance past the Confirm Settings screen.

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

3. Are there any other system precautions to avoid this happening?

Yes. As well as the multiple confirmation settings, Tandem insulin pumps also have minimum basal and maximum basal alerts. These are described below:

Min basal alert

When basal rate is adjusted to a value that is less than half of the lowest programmed non-zero basal rate in that profile, a Min Basal Alert is displayed on the pump.

Max basal alert

When basal rate is adjusted to a value that is more than twice as large as the highest programmed non-zero basal rate in the profile, a Max Basal Alert is displayed.

4. 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 inadvertently programming an incorrect basal rate as well as recommended precautions.

5. Why are you not recalling these Tandem Insulin Pumps?

Programming basal rates requires multiple confirmation steps and alerts to avoid inadvertently programmed basal rates. There is no defect identified in relation to the use of this product, we are however providing additional communication to highlight recommended precautions.

6. How many Tandem Pumps are affected?

Programming basal rates requires multiple confirmation steps and alerts to avoid inadvertently programmed basal rates. There is no defect identified in relation to the use of this product. As a result, it can affect any Tandem insulin pump if the user does not take appropriate precautions to program basal rates correctly.

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

Serious injury related to this malfunction is rare and might only occur if the user does not take appropriate precautions to program basal rates correctly or does not recognize that an error was made and take appropriate corrective actions.

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

Your Tandem insulin pump is functioning as intended and as long as you create or edit a Personal Profile correctly, you can continue using your Tandem pump with the extra precautions outlined.

9. What solution is Tandem offering to affected customers?

Your t:slim X2 insulin pump is eligible for a software update that includes an additional feature called Basal Limit which is designed to further reduce the risk of a user accidentally setting a basal rate higher than intended. 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. **Note:**

A prescription and training may be required. If you are not currently using Control-IQ technology, you will only be able to update to Basal-IQ (6.4) software.

If you experience any adverse reactions or quality problems with the use of our products, please call Tandem Diabetes Care Customer Support at 1-877-801-6901. Our team is available 24/7. 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).

10. 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 than Moonlight v7.4 or Carlsbad 6.4 you should update your software.

11. 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 an additional feature called Basal Limit which is designed to further reduce the risk of a user accidentally setting a basal rate higher than intended. This feature is only available through a remote software update to t:slim X2 pumps. 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.

12. What is Basal Limit?

Basal limit is a new safety feature which was released in August 2020 intended to further reduce the risks associated with setting a basal rate higher than intended. Your basal rate settings can be found in your Personal Profile Timed Settings and must be set within each Personal Profile.

13. How should I decide how to set my Basal Limit?

If users want to be able to fully utilize the maximum Temporary Basal Rate value of 250%, consider setting a Basal Limit rate that is 2.5 times the highest programmed basal rate. The default factory setting for Basal Limit is 3 units per hour. If a user is updating their pump from a version that did not previously have the Basal Limit setting, the Basal Limit will be set to a value two times the highest basal rate setting in their pump.

Please review the relevant user guide available here:

- a. [t:slim X2 insulin pump with Basal-IQ technology 6.4](#), refer directly to section 4.10
- b. [t:slim X2 insulin pump with Control-IQ technology 7.4](#), refer directly to section 4.10

NOTE: When Control-IQ technology is enabled, the programmed Basal Limit will not limit or affect the way Control-IQ technology calculates the basal rate it delivers.

14. 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 (6.4) without a prescription. The same is true for current users of Control-IQ technology. If you are not currently using either of these technologies, then a prescription will be required to update to our latest software. If you are currently using Basal-IQ

technology, then a prescription is required if you wish to update to the latest version of Control-IQ technology.

15. 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.

16. 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 update that matches your current algorithm.

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