



FIELD CORRECTION NOTICE

t:slim, t:slim G4 & t:flex insulin pumps

February 08, 2022

You are receiving this letter because our records indicate that you may be using a t:slim, t:slim G4 or t:flex insulin pump. 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>

List of Tandem Insulin Pumps Affected:

Pump Model	Part Numbers
t:slim	007262, 005472, 004629, 007435, 007444, 007264, 004889, 004891, 004755, 006694, 003218
t:flex	007666, 007473, 005365, 007516
t:slim G4	008114, 006194, 007829, 008542

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.

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. 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 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.

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

While your Tandem insulin pump is functioning as intended, we have already implemented an additional feature called Basal Limit on our t:slim X2 insulin pumps which is designed to further reduce the risk of a user accidentally setting a basal rate higher than intended.

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

Currently your Tandem insulin pump is not capable of remote software updates. In order to get access to this software you will need to purchase a new t:slim X2 insulin pump. You will also require a new prescription and additional training on new pump features. Please contact Tandem Diabetes Care Customer Support at 1-877-801-6901.

12. I have a t:slim X2 insulin pump, why I am receiving this letter?

Our records indicate that you have purchased one of the affected pumps listed above. If you no longer use this pump or have upgraded to a t:slim X2, we still require acknowledgment of this notice. If you never owned one of the pumps listed, please call Tandem Diabetes Care Customer Support at 1-877-801-6901 so we can update our records.

13. What is Basal Limit?

Basal limit is a new 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.

14. 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.

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.