



## URGENT FIELD SAFETY NOTICE

### t:slim X2™ Insulin Pumps - Setting Basal Rates

February ##, 2022

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 6.3.0.1 or lower. Because your safety is our top priority, we are alerting you of a potential safety risk when using your pump within its normal specifications.

#### **How do I know if my pump is affected?**

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.

#### **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.

#### **What does this mean?**

You can continue using your Tandem pump with the extra 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 when programming basal rates**

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 blood sugar.

#### **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). Please contact your distributor to facilitate the software update.

It is important you acknowledge receipt of this notice by completing the online form or visiting

[Country Specific URL link and QR Code]

#### **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-2022-002 when contacting either Tandem or your distributor about this notice.

Sincerely,

...

[Distributor Company Name]

[Distributor Address]

[Distributor Address]

[Distributor Address]

[Distributor Phone Number]

[Distributor Email Address]