

Tandem Diabetes Care Insulin Pumps – Basal Rate Setting

Advisory Notice

You are receiving this notice because our records indicate that you may be using a Tandem Diabetes Care® insulin pump. Because your safety is our top priority, we are alerting you of a potential safety risk.

Issue: Incorrectly keying in basal rates

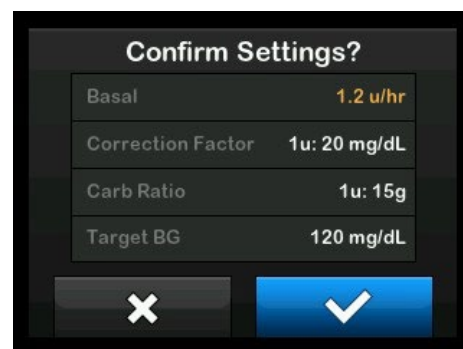
Insulin pumps from Tandem Diabetes Care include a Personal Profile feature that allows you to personalize the settings that define the delivery of basal and bolus insulin within specific time segments throughout a 24-hour period. It is important that you correctly input Personal Profile settings when creating or editing a Personal Profile segment.

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

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:

Confirm settings screen

This issue may affect users on all Tandem insulin pumps.



Recommended precautions

- Take extra care when creating or editing a profile within your Tandem insulin pump.

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

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.

Sincerely,
Tandem Diabetes Care

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Important Safety Information:

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. The t:slim X2 insulin pump with interoperable technology is an alternate controller enabled (ACE) pump that is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in people requiring insulin. The pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The pump is indicated for use in individuals 6 years of age and greater. The pump is intended for single patient, home use and requires a prescription. The pump is indicated for use with NovoLog or Humalog U-100 insulin. The t:slim X2 pump must be removed before MRI, CT, or diathermy treatment. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

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Tandem Diabetes Care | 11075 Roselle Street | San Diego, CA 92121 | USA