

t:slim™

Insulin Delivery System

User Guide



TANDEM™
DIABETES CARE

Chapter 2

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2.1 Welcome

Congratulations on the purchase of your new t:slim System. Your decision to use insulin pump therapy is a sign of your commitment to your diabetes care! The t:slim Pump is designed using the latest technology. The following pages provide step-by-step illustrative instructions on how to properly program, manage, and care for your pump.

2.2 What your t:slim Insulin Delivery System Package Includes

Your t:slim System should contain the following items:

1. t:slim Insulin Pump
2. t:slim Screen Protector (pre-applied)
3. Protective Case with Rotatable Clip
4. USB Cable (6 ft.)
5. Wall Power USB Adapter
6. Car Power USB Adapter
7. t:slim Reference Guide
8. Emergency Wallet Card
9. USB Memory Card (with User Guide)

If any of these items are missing, contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

NOTE






Your t:slim Pump is shipped from Tandem Diabetes Care, Inc. with a clear screen protector. Do not remove the screen protector. Additional screen protectors can be ordered by contacting Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.





NOTE

Your t:slim Pump is shipped from Tandem Diabetes Care, Inc. with a protective cover in the place where the cartridge is normally inserted. This cover must be removed and replaced with a cartridge prior to initiating insulin therapy.

2.3 Explanation of Symbols



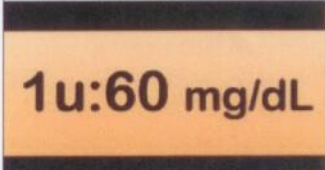
The following are symbols (and their descriptions), which you may find on your t:slim Pump and/or its packaging:

	Caution; Consult Manual for Important Safety Documentation
	Consult Instructions for Use
	Serial Number of device
	Part Number
	Water-tight Equipment (protected against the effects of temporary immersion in water)




	Type BF Applied Part (patient isolation, not defibrillator protected)
	Manufacturer
	For sale by or on the order of a physician only (U.S.)
	Direct Current (DC) voltage

2.4 Explanation of t:slim Colors

Touch Screen Colors

<div>Blue</div> 	<ul style="list-style-type: none"> The use of blue text may relate to Bolus delivery activity.
<div>Orange</div> 	<ul style="list-style-type: none"> The orange text relates to t:slim's setup or delivery settings.
<div>Orange Highlight</div> 	<ul style="list-style-type: none"> The orange highlighted area indicates a recent change made to a setting.

LED Colors

<p>Red LED</p> 	<ul style="list-style-type: none"> 1 red blink every 30 seconds indicates a malfunction or alarm condition.
<p>Yellow LED</p> 	<ul style="list-style-type: none"> 1 yellow blink every 30 seconds indicates an alert or reminder condition.
<p>Green LED</p> 	<ul style="list-style-type: none"> 1 green blink every 90 seconds indicates the pump is functioning normally. 3 green blinks every 90 seconds indicate the pump is charging.

2.5 Warranty Information

Warranty

t:slim™ Insulin Pump

Tandem Diabetes Care, Inc. ("Tandem") warrants the t:slim insulin pump against defects in materials and workmanship for the period of 4 years from the original date of shipment of the pump to the original end use purchaser (the "Warranty Period"). During the Warranty Period, Tandem will replace any defective t:slim Pump, subject to the conditions and exclusions stated herein.

The warranty is valid only if the t:slim Pump is used in accordance with Tandem's instructions and will not apply:

- If damage results from changes or modifications made to the t:slim Pump by the user or third persons after the date of manufacture;
- If damage results from service or repairs performed to any part of the t:slim Pump by any person or entity other than Tandem;
- If the t:slim Pump seal is broken;
- If a non-Tandem cartridge is used with the t:slim Pump;
- If damage results from a force majeure or other event beyond the control of Tandem; or
- If damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the t:slim Pump covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the t:slim Pump and does not apply to other products or accessories.

THE REMEDIES PROVIDED FOR IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE FOR ANY WARRANTY CLAIMS. NEITHER TANDEM NOR ITS SUPPLIERS OR DISTRIBUTORS SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGE OF ANY NATURE OR KIND CAUSED BY OR ARISING OUT OF A DEFECT IN THE PRODUCT. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARE EXCLUDED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Warranty

Infusion Sets and Cartridges

Tandem Diabetes Care, Inc. ("Tandem") warrants its infusion sets and cartridge against defects in materials and workmanship for the period 3 days after the individual cartridge/infusion set sterile packaging has been opened, not to exceed 6 months from date of shipment of the infusion set or cartridge to the end user (the "Warranty Period"). During the Warranty Period, Tandem will replace any defective cartridge or infusion set, subject to the conditions and exclusions stated herein.

The warranty is valid only if the infusion sets and cartridges are used in accordance with Tandem's instructions and will not apply:

- If the infusion set or cartridge has been used for more than a single-time use by a single end-user;
- If damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the associated Instructions for Use;
- If the sterile package is compromised while in the control of the user by any means other than purposeful opening by the user at the time of intended product use;
- If damage results from changes or modifications made to the infusion set or cartridge by the user or third persons after the date of manufacture;
- If damage results from service or repairs performed to any part of the infusions set or cartridge by any person or entity other than Tandem;
- If damage is caused by use of the cartridge or infusion set with any non-Tandem insulin pump;
- If damage results from a force majeure or other event beyond the control of Tandem; or
- If damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty does not apply to insulin pumps and other accessories.

THE REMEDIES PROVIDED FOR IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE FOR ANY WARRANTY CLAIMS. NEITHER TANDEM NOR ITS SUPPLIERS OR DISTRIBUTORS SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGE OF ANY NATURE OR KIND CAUSED BY OR ARISING OUT OF A DEFECT IN THE PRODUCT. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARE EXCLUDED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Chapter 3

t:slim Pump Overview

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3.1 t:slim Pump Overview

Your t:slim Pump uses touch screen technology. To activate and interact with your t:slim Pump, use the pad of your finger to quickly and lightly tap on the screen. Do not use your finger nail or another object to interact with the screen. It will not activate the screen or its functions.

Your t:slim Pump is designed to give you quick and easy access to the functions that you will use in your day to day diabetes management – whether basic or advanced.

NOTE

The Screen Lock feature is automatically activated on your t:slim Pump. This setting cannot be changed.

NOTE

Turn off the pump screen by pressing the Screen On/Quick Bolus button before placing the pump back in its case or any pocket/clothing to prevent unintentional interactions with the touchscreen. Always position the pump screen away from the skin when worn under clothing.

3.2 t:slim System Terminology

Basal

Basal is a slow continuous delivery of insulin, which keeps BG levels stable between meals and during sleep. It is measured in units per hour (units/hr).

BG

BG is the abbreviation for blood glucose, which is the level of glucose in the blood, measured in mg/dL.

BG Target

BG target is a specific blood glucose goal, an exact number, not a range. When a BG is entered in the t:slim Pump, the calculated insulin bolus will be adjusted up or down as needed to attain this target.

Bolus

A bolus is a quick dose of insulin that is usually delivered to cover food eaten or an elevated BG. With t:slim Pump it can be delivered as a Standard, a Correction, an Extended, or a Quick Bolus.

Cannula

The cannula is part of the infusion set that is inserted under the skin through which insulin is delivered.

Carb

Carbohydrates are sugars and starches that the body breaks down into glucose and uses as an energy source, measured in grams.

Carb Ratio

The carb ratio is the number of grams of carbohydrate that one unit of insulin will cover. Also known as insulin-to-carbohydrate ratio.

Correction Bolus

A correction bolus is given to correct elevated BG.

Correction Factor

A correction factor is the amount of BG that is lowered by one unit of insulin. Also known as the Insulin Sensitivity Factor (ISF).

Extended Bolus

An extended bolus is a bolus that is delivered over a period of time. It is commonly used to cover food that takes longer to digest. When administering an extended bolus with your t:slim Pump, enter the DELIVER NOW portion to dose a percentage of insulin immediately and the remaining percentage over a period time.

Grams

Grams are a unit of measurement for carbohydrates.

Insulin Duration

Insulin duration is the amount of time that insulin is active and available in the body after a bolus has been delivered. This also relates to the calculation for Insulin on Board (IOB).

Insulin On Board (IOB)

IOB is the insulin that is still active (has the ability to continue to lower the BG) in the body after a bolus has been delivered.

Load

Load refers to the process of removing, replacing and filling a new cartridge and infusion set.

Personal Profile

A Personal Profile is a personalized group of settings that defines the delivery of basal and bolus insulin within specific time segments throughout a 24 hour period.

Quick Bolus

Quick bolus (using the Quick Bolus Button) is a way to deliver a bolus by following beep/vibration commands without navigating through or viewing the t:slim Pump screen.

Temp Rate

Temp rate is an abbreviation for a temporary basal rate. It is used to increase or decrease the current basal rate for a short period of time to accommodate special situations. 100% is the same basal rate as programmed: 120% means 20% more and 80% means 20% less than the programmed basal rate.

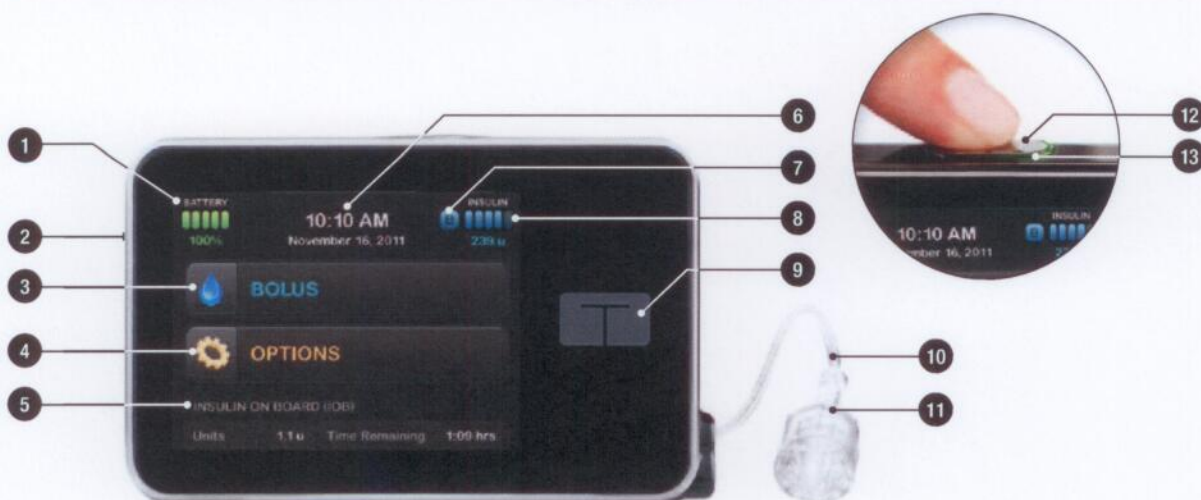
Units

Units are the measurement for insulin.

USB Cable

USB is the abbreviation for Universal Serial Bus. The cable connects into the t:slim Pump's micro USB port.

3.3 Home Screen



1. BATTERY Level: Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.

2. USB Port: Port to charge your t:slim Pump battery. Close the cover when not in use.

3. BOLUS: Program and deliver a bolus.

4. OPTIONS: Stop/Resume insulin delivery, manage Pump Settings, Load cartridge, program a Temp Rate, and view History.

5. INSULIN ON BOARD (IOB): Amount and time remaining of any active insulin on board.

6. Time and Date Display: Displays the current time and date.

7. Status: Displays current pump settings and insulin delivery status.

8. INSULIN Level: Displays the current amount of insulin in the cartridge.

9. Tandem Logo: Returns to the Home Screen.

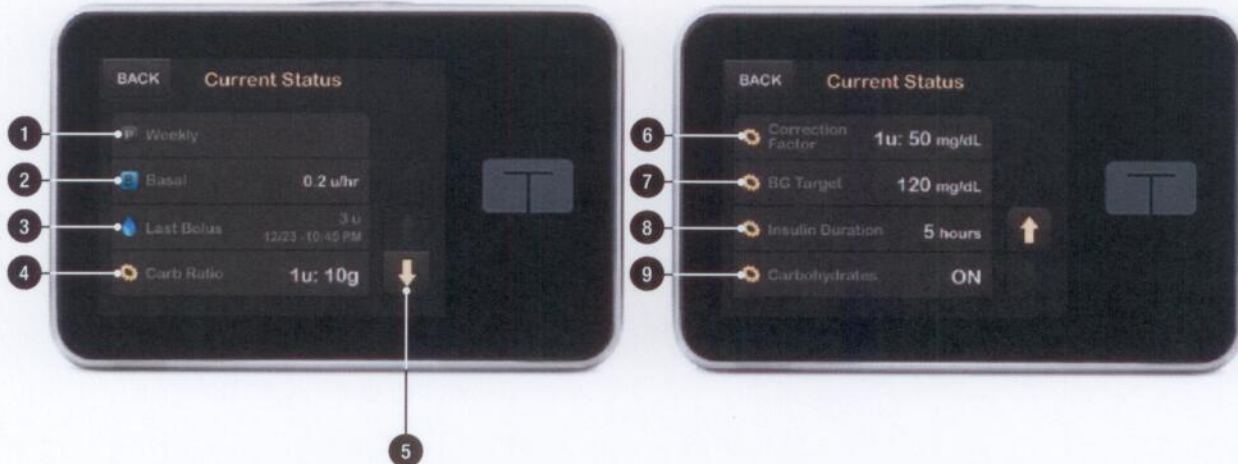
10. Cartridge Tubing: Tubing that is attached to the cartridge.

11. Luer-Lock Connection: Connects the cartridge tubing to the infusion set tubing.

12. Screen On/Quick Bolus Button: Turns on/off the t:slim Pump screen or programs a Quick Bolus (if activated).

13. LED Indicator: Illuminates when connected to a power supply and indicates proper functionality.

3.4 Status Screen



1. **Profile:** Displays current active Personal Profile.

2. **Basal:** Displays current basal rate being delivered. (Temp Rate: If active this displayed in units/hr)

3. **Last Bolus:** Displays the amount, date and time of last bolus.

4. **Carb Ratio:** Displays current carb ratio used to calculate bolus.

5. **Up/Down Arrow:** Indicates there is more information.

6. **Correction Factor:** Displays current correction factor used to calculate bolus.

7. **BG Target:** Displays current BG target used to calculate bolus.

8. **Insulin Duration:** Displays current insulin duration used to calculate insulin on board.

9. **Carbohydrates:** Indicates whether feature is On or Off.

NOTE

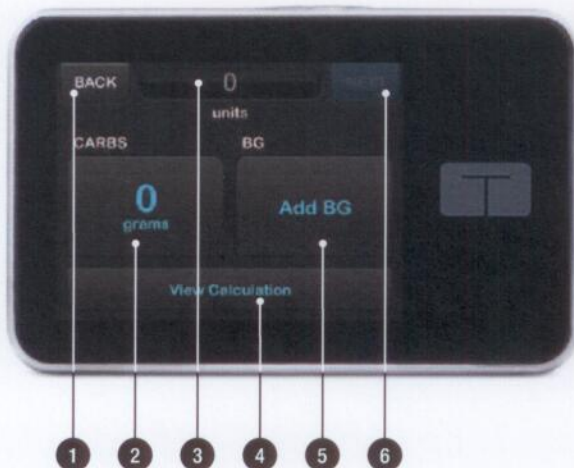
NA represents Not Applicable (does not apply).

NOTE

The status screen is for display only, no changes can be made from this screen.

3.5 Bolus Screen

Using Grams



1. **BACK:** Returns to the Home Screen.

2. **CARBS:** Enter grams of carb to be consumed.

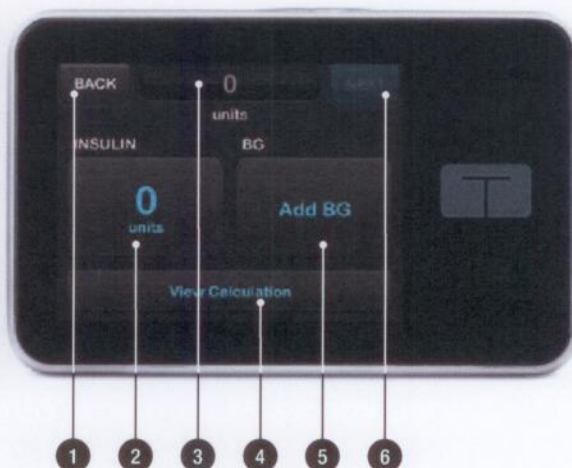
3. **Units:** Displays total units calculated.

4. **View Calculation:** Displays how the insulin dose was calculated using the current settings.

5. **BG:** Enter blood glucose level.

6. **NEXT:** Moves to next step.

Using Units



1. **BACK:** Returns to the Home Screen.

2. **INSULIN:** Enter units of insulin.

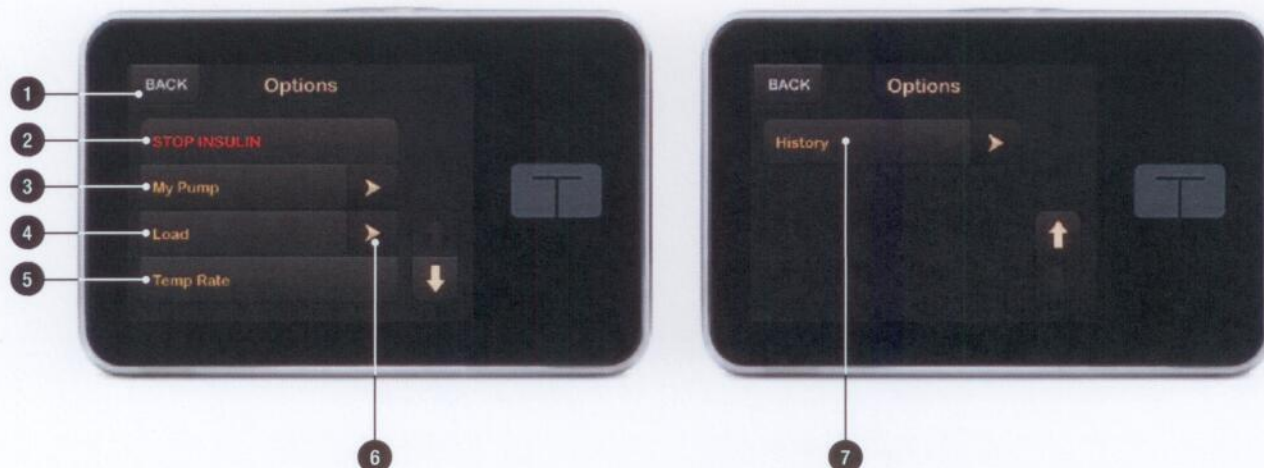
3. **Units:** Displays total units calculated.

4. **View Calculation:** Displays how the insulin dose was calculated using the current settings.

5. **BG:** Enter blood glucose level.

6. **NEXT:** Moves to next step.

3.6 Options Screen



1. **BACK:** Returns to the Home Screen.

2. **STOP INSULIN:** Stops insulin delivery. If insulin delivery is stopped, **RESUME INSULIN** will be displayed.

3. **My Pump:** Personal Profiles, Alert Settings, Pump Settings, and Pump Info.

4. **Load:** Change Cartridge, Fill Tubing, Fill Cannula, and Site Reminder.

5. **Temp Rate:** Programs a temporary basal rate.

6. **Menu Arrows:** Indicates additional menu options are available.

7. **History:** Displays historical log of pump events.

3.7 My Pump Screen



1. **Personal Profiles:** A group of settings that defines basal and bolus delivery.

2. **Alert Settings:** Customize Reminders and Alerts.

3. **Pump Settings:** Customize Quick Bolus, Pump Volume, Screen Options, and Time and Date.

4. **Pump Info:** Displays t:slim Pump serial number, Customer Technical Support phone number and website.

3.8 Number Keypad Screen



1. **Value Entered.**

2. **BACK:** Returns to previous screen.

3. **Keypad Numbers.**

4. **+/=:** Allows numbers to be added on gram screen. If in units, this displays as a decimal point.

5. **DONE:** Completes task and saves information entered.

6. **Units/Grams:** Value of what is entered.

7. **←:** Deletes last number entered.

NOTE

If changing an existing number, begin by tapping the numbers on the keypad to override the current value.

19.9 FCC Notice Concerning Interference

The t:slim Pump complies with FCC/IC RF exposure limits for general population/uncontrolled exposure.

t:slim Pumps equipped with a Bluetooth® RF option transmit at a maximum effective radiated power of 3.4 mW in the 2.4 GHz ISM band, which covers the frequency range from 2.40 GHz to 2.50 GHz.

The t:slim Pump complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation

Compliance with these guidelines provides reasonable protection against harmful interference in a normal residential environment. The t:slim Pump generates, uses, and can radiate radio frequency energy, and may cause harmful interference to radio communications. There is no guarantee that interference will not occur in a particular installation. If the t:slim Pump does cause harmful interference to radio or television reception, the interference may be corrected by one of the following measures:

- Move or relocate the t:slim Pump
- Increase the distance between the t:slim Pump and the other device that is emitting or receiving interference

Changes or modifications not expressly approved by Tandem Diabetes Care, Inc. could void the user's authority to operate the equipment.

Bluetooth is a registered trademark of Bluetooth SIG, Inc.