t:flex™
Insulin Pump

10:20 AM
January 9, 2015
100%
B
425 u

BOLUS

OPTIONS

INSULIN ON BOARD (IOB)

Units	1.1 u	Time Remaining	1:09 hrs

User Guide

IPX7

℞ Only

TANDEM®
DIABETES CARE

touch simplicity®

t:flex Insulin Pump User Guide

Software Part Number 007250

At Tandem Diabetes Care, Inc., we listen closely to the diabetes community in order to understand your needs. We recognize and respect the importance of your decision to begin insulin pump therapy as a member of our family. We also recognize that your pump purchase is only the beginning of your relationship with Tandem. Our commitment goes much deeper than simply supplying products to help you in your diabetes management. We pledge to be here to support you with training and education through our network of Clinical Diabetes Specialists. We also pledge to be here to support you with our dedicated Customer Technical Support.

This User Guide is designed to assist you with the features and functions of the t:flex System. It provides important warnings and cautions on proper operation as well as technical information to ensure your safety. It also provides step-by-step instructions on how to properly program, manage and care for your t:flex System.

Changes in equipment, software, or procedures occur periodically; information describing these changes will be included in future editions of this User Guide. Please contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901 to obtain a replacement copy of the User Guide that is the correct version for your pump.

Tandem Diabetes Care, Inc.
11045 Roselle Street
San Diego, CA 92121 USA
(858) 366-6900
www.tandemdiabetes.com

Need help? We are here for you
24 hours a day, 7 days a week
at 1-877-801-6901.

Tandem Diabetes Care, Inc. Patient Bill of Rights

1. Patients have the right to good quality service and high professional standards that are continually maintained and reviewed.

2. A patient has the right to have all records pertaining to his or her medical care treated as confidential, except as otherwise provided by law or third party contractual arrangements.

3. A patient has the right to respectful service provided by competent personnel.

4. A patient, or when appropriate, a patient's representative has the right to be informed of his or her rights at the earliest possible time.

5. A patient has the right to have their personal preferences be heard.

6. A patient has the right to be free from all forms of abuse or harassment.

7. A patient has the right to receive services in a safe setting. A safe setting includes environmental safety, infection control, security, protection of emotional health and safety, including respect, dignity, and comfort, as well as physical safety.

8. A patient has the right to medical services including training without discrimination based upon race, color, religion, gender, sexual preference, national origin or source of payment.

9. A patient shall not be denied the right to designate a legally allowed individual or agency, who is authorized, to act on his or her behalf.

10. Tandem Diabetes Care shall provide a patient, or patient designee, upon written request, access to all information contained in their patient information record.

11. Except for medical emergencies, Tandem Diabetes Care must obtain the necessary informed consent prior to the start of collection or sharing of personal medical information as it relates to the purchase of Tandem products and or services.

12. Tandem Diabetes Care is committed to ensuring the safety of its customers. Tandem has implemented policies covering situations when a Tandem employee believes that a customer is suffering from a medical emergency, including contacting the applicable emergency medical care.

13. A patient has a right to full information and counseling on the availability of known financial resources for his or her health care received by Tandem Diabetes Care for the purpose of beneficiary coverage of Tandem Product and Services.

14. A patient has the right to examine and receive a detailed explanation of his or her financial bill.

15. A patient has the right to be advised when they are being considered for a medical care research program. In this occurrence, Tandem Diabetes Care will send an informed consent agreement to a patient, requesting their participation in a clinical investigation.

16. A patient has the right to decide whether their personal health information could be used for any fundraising efforts.

17. A patient, and when appropriate, a patient's representative has the right to have any concerns, complaints and grievances addressed. Sharing concerns, complaints and grievances will not compromise a patient's care, treatment or services.

18. If a patient has a concern, complaint, or grievance, he or she may contact Tandem Diabetes Care Customer Support by:

    » Calling Customer Support
      1-877-801-6901

    » Writing a letter to Tandem Diabetes Care
      ATTN: Customer Support
      and sending it to
      11045 Roselle Street
      San Diego, CA 92121

Patient Responsibilities

1. Patients and their families when appropriate are responsible for providing correct and complete information when requesting assistance with insurance verification and other services provided by Tandem Diabetes Care.

2. Patients and their families are responsible for reporting unexpected changes with their medical, financial, or insurance condition.

3. Patients and their families are responsible for asking questions when they do not understand the service being provided or the reason for the information being requested.

4. Patients and their families are responsible for following the product training, instructions for use and service that have been developed by Tandem Diabetes Care and agreed to by a patient.

5. Patients and their families are responsible for the outcomes if they do not follow the product instructions for use, service and payment plans.

6. Patients and their families are responsible for being considerate of Tandem Diabetes Care's staff and property, as well as other patients and their property.

7. Patients and their families are responsible to promptly meet any financial obligation agreed to with Tandem Diabetes Care.

8. Patient and their family agree to hold harmless Tandem Diabetes Care from any expenses they may incur as a result of Tandem contacting the applicable emergency medical care on their behalf.

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Section 1

Welcome

Chapter 1

About this User Guide

1.1 Introduction to this Guide

This User Guide is for people who use the t:flex™ Insulin Delivery System (t:flex System). The t:flex System is made up of the t:flex Insulin Pump and the t:flex 4.8 mL (480 units) cartridge.

Only the t:flex 4.8 mL cartridge will connect to and work with the t:flex System. The System is not compatible with any other cartridge.

In this Guide, the t:flex Pump may be referred to as "your pump" or "your t:-flex Pump." The t:flex cartridge may be referred to as "your cartridge." Together, the t:flex Insulin Pump and the t:flex cartridge may be referred to as "your system".

The User Guide is organized in sections that allow you to learn to use your t:flex System. Pump screens used in this guide to demonstrate how to use features are examples only. They should not be considered suggestions for your individual needs.

⚠ WARNING
United States (U.S.) Federal law restricts this device to sale by or on the order of a physician.

1.2 Important Safety Information

This User Guide covers important information on how to operate your t:flex Pump. It provides step-by-step instructions to help you properly program, manage and care for the System. It also provides important warnings and cautions on proper operation and technical information to ensure your safety.

Review all instructions in this User Guide before using the System.

If you are not able to use the System according to the instructions in this User Guide, you may be putting your health and safety at risk.

Pay special attention to Warnings and Precautions in this User Guide. Warnings and Precautions are identified with ⚠.

If you still have questions after reading this User Guide, contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901. We are here for you 24 hours a day, 7 days a week.

1.3 Working with your Healthcare Provider

Any clinical language presented in this User Guide is based on the assumption that you have been educated by your healthcare provider on certain terms and how they apply to you in your diabetes management. Your healthcare provider can help you establish diabetes management guidelines that best fit your lifestyle and needs.

Monitor your blood glucose (BG) with the guidance of your healthcare provider. According to the American Association of Diabetes Educators' white paper *Insulin Pump Therapy: Guidelines for Successful Outcomes*, patients should routinely check their BG levels at least 4 times daily (optimally 6–8 times daily) in order to detect hyperglycemia (high blood glucose) and hypoglycemia (low blood glucose) early. Undetected hyperglycemia or hypoglycemia can result without proper monitoring.

Consult your healthcare provider before using the System to determine which features are most appropriate for you. Only your healthcare provider can determine and help you adjust your basal rate(s), insulin-to-carbohydrate ratio(s), correction factor(s), blood glucose (BG) target, and duration of insulin action.

1.4 Emergency Kit

Make sure that you always have an insulin syringe and vial of insulin with you as a backup for emergency situations. You should also always have an appropriate emergency kit with you. Talk with your healthcare provider regarding what items this kit should include.

Supplies to carry every day:

- Blood glucose testing supplies: meter, strips, control solution, lancets, meter batteries

- Fast-acting carbohydrate to treat low blood glucose

- Extra snack for longer coverage than fast-acting carbohydrate

- Glucagon emergency kit

- Rapid-acting insulin and syringes

- Infusion sets (minimum of 2)

- Insulin pump cartridges (minimum of 2)

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- Infusion site preparation products (antiseptic wipes, skin adhesive)

- Diabetes identification card or jewelry

1.5 Verification of Proper Functionality

A power supply (AC adapter with micro-USB connector) is provided as part of the System. Before using your System, ensure that the following occur when you connect a power supply into the USB port of your t:flex Pump:

- You hear an audible alert

- Your see the green light illuminate from the edge around the Screen On/Quick Bolus Button

- You feel a vibratory alert

- You see a charge symbol (lightning bolt) on the battery level indicator

In addition, before using the System, ensure the following:

- Press the Screen On/Quick Bolus Button to turn the screen on so that you can see the display

- When the display screen is on, the touch screen responds to your finger tap

⚠ PRECAUTION
If any of these conditions fail to occur, do NOT use the t:flex System, as this may be an indication that the pump's alarms, alerts, and other built-in safety features may not be working properly. If the pump is connected to your body, disconnect the infusion set from your body and contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

1.6   Indications for Use and Contraindications

Indications for Use

The t:flex Insulin Delivery System is indicated for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

Contraindications

The t:flex System is not intended for anyone unable or unwilling to:

- Test blood glucose (BG) levels as recommended by your healthcare provider

- Demonstrate adequate carbohydrate-counting skills (preferred, not required)

- Maintain sufficient diabetes self-care skills

- See your healthcare provider(s) regularly

You must also have adequate vision and/or hearing in order to recognize your System alerts.

1.7   Warnings and Precautions

⚠ **Warnings**
Before using your System, consult with your healthcare provider for your individual training needs and ensure that you have been appropriately trained on its use by a certified t:flex Pump trainer.

Incorrect use of your System or failure to follow the appropriate instructions in this User Guide can lead to serious injury or even death. If you have questions or need further clarification on your t:flex System use, ask your healthcare provider or call our around-the-clock Customer Technical Support Department at 1-877-801-6901.

Your t:flex System is designed to deliver insulin reliably, but because it uses only rapid-acting insulin, you will not have long-acting insulin in your body. In order to prevent Diabetic Ketoacidosis (DKA) or a very high BG, you must be prepared to inject insulin if delivery is interrupted for any reason.

Only use Humalog® or NovoLog® U-100 insulin, as any lesser or greater concentration can result in serious

health consequences. Only Humalog® and NovoLog® have been tested by Tandem Diabetes Care, Inc., and found to be compatible for use in the t:flex System. It is not intended for use with any other delivery substance.

Never fill your tubing while your infusion set is connected to your body. Doing so can result in unintended delivery of insulin, which can result in serious injury or death.

Do not disconnect the luer-lock connection between the cartridge tubing and the infusion set tubing. If the connection comes loose, disconnect the infusion set from the site (from your body) before tightening to avoid unintentional insulin delivery.

Do not deliver a bolus until you have reviewed the calculated bolus amount on the pump display. If you dose an insulin amount that is too high or too low, this could lead to a very low or very high BG level. You can always adjust the insulin units up or down before you decide to deliver your bolus.

Use only FDA cleared insulin infusion sets with a standard luer-lock connection and consult its instructions for use. Failure to do so may result in over-infusion or under-infusion and may cause serious injury or death.

Change your infusion set every 48–72 hours. Consult your healthcare provider for more information.

Use only single-use disposable cartridges from Tandem Diabetes Care. The efficacy of your t:flex System cannot be guaranteed if cartridges other than those manufactured by Tandem Diabetes Care, Inc. are used or if cartridges are filled more than once. Use of cartridges not manufactured by Tandem Diabetes Care, Inc. or reuse of cartridges may result in over-infusion or under-infusion and may cause serious injury or death.

Do not remove or add insulin from a filled cartridge. This will result in an inaccurate display of the insulin level on the Home Screen.

Do not modify this equipment. Modification could result in a safety hazard.

⚠ **Radiology and Medical Procedures**
Always notify the provider/technician about your diabetes and your insulin pump.

You must take off your t:flex System and leave it outside the procedure room if you are going to have any of the following procedures. Follow your healthcare provider's instructions to replace missed insulin when you reconnect to the pump. Check your blood glucose before disconnecting from the pump and again when you reconnect and treat high blood glucose levels as recommended by your healthcare provider:

• X-ray

• Computed Tomography (CT) scan

• Magnetic Resonance Imaging (MRI)

• Positron Emission Tomography (PET) scan

• Other exposure to radiation

In addition to the above, you must take off your t:flex System and leave it outside the procedure room if you are going to have any of the following medical procedures:

• Pacemaker/Automatic Implantable Cardioverter Defibrillator (AICD) placement or reprogramming

• Cardiac Catheterization

• Nuclear Stress Test

There are other procedures where you should proceed with caution:

• Laser Surgery – Your System can usually be worn during the procedure. However, some lasers can create interference and cause the System to alarm.

• General Anesthesia – Depending on the equipment being used, you may or may not need to remove your System. Be sure to ask your healthcare provider.

There is no need to disconnect for electrocardiograms (EKGs) or colonoscopies.

If you have questions, contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901

⚠ **Extreme Temperatures**
Avoid exposure of your t:flex to temperatures below 40°F (5°C) or above 99°F (37°C), as insulin can freeze at low temperatures or degrade at high temperatures. Do not steam, sterilize, or autoclave your System at any time.

⚠ **Amusement Park Rides**
Very powerful electromagnets are sometimes used on "free-fall" or thrill rides. Remove your t:flex System and do not take it on these types of rides. Also, you should disconnect the infusion set from your body while on high-speed/high-gravity roller coasters.

⚠ **Aircraft Without Cabin Pressurization**
Disconnect the infusion set from your body before flying in an aircraft without cabin pressurization or in planes used for aerobatics or combat simulation (pressurized or not).

⚠ **Small Parts Potentially Ingestible by Children**
The System includes small parts (such as pieces of the infusion set, rubber USB port cover, and cartridge components) that could pose a choking hazard for small children. Ensure that any small parts are kept away from small children.

⚠ **Strangulation or Asphyxiation**
The System includes parts (such as the USB cable and the infusion set tubing) that could pose a strangulation or asphyxiation hazard. Arrange cables and tubing to minimize the risk of strangulation or asphyxiation. Ensure that these parts are stored in a secure place when not in use.

⚠ **Do Not Use in the Presence of Flammable Anesthetics or Explosive Gases**
The risk of ignition of flammable anesthetics and explosive gases by the pump is remote. While this risk is remote, it is not recommended to operate the t:flex System in the presence of flammable anesthetics or explosive gases. If you have questions, contact

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Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

⚠ **Submersion in Fluid**
The t:flex System is watertight to a depth of 3 feet for up to 30 minutes (IPX7 rating). If your t:flex System has been submerged, check your pump for any signs of fluid entry. If there are signs of fluid entry, disconnect the set from your body, and contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

⚠ **Air Travel**
Your System should not be exposed to X-ray screening used for carry-on and checked luggage. Newer full body scanners used in airport security screening are also a form of X-ray and your System should not be exposed to them. Notify the Transportation Security Administration (TSA) Agent that your System cannot be exposed to X-ray screening and request alternate means of screening other than X-ray.

Your System has been designed to withstand common electromagnetic interference including airport metal detectors.

For further information, contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

⚠ **Additional Precautions**
Your System is a sealed device that should be opened and repaired only by the manufacturer. If your t:flex System seal is broken, the warranty is voided and the System is no longer watertight.

Replace the cartridge every 48 hours if using Humalog®; every 72 hours if using NovoLog®.

Always follow proper aseptic (clean) technique when handling your pump, filling syringe/needle, cartridge, and infusion set.

• Wash your hands with anti-bacterial soap before handling.

• Use only sterile, unopened products, such as needles, cartridges, and infusion sets.

• Thoroughly clean the insertion site on your body.

Always remove all air bubbles when

drawing insulin into the filling syringe. Always hold the pump with the white fill port pointed up when filling the cartridge. Always ensure that there are no air bubbles in the tubing when filling.

Avoid changing your infusion set before bedtime or if you will not be able to test your blood glucose 1-2 hours after the new infusion set is placed.

Before bedtime, always check that your cartridge has enough insulin to last through the night.

Unless otherwise directed by your healthcare provider, do not use the vibrate feature during sleep. Having the volume for alerts and alarms set to high will help ensure that you don't miss an alert or alarm.

Conduct regular checks of your t:flex System and infusion set, particularly:

• Check that your luer-lock connection between the cartridge tubing and the infusion set tubing is tight and secure.

• Check your infusion site for proper

placement and leaks. Improperly placed sites or leaks around the infusion site can result in under-infusion.

• Check your infusion set tubing for any damage, leaks, or kinks while using your t:flex System. Damaged, leaking, or kinked tubing may restrict or stop insulin delivery and result in under-infusion.

• Check your t:flex System's personal settings to ensure they are correct.

• Check your t:flex System's audible tones and vibration to ensure they are easily detectable.

Regularly check your t:flex Pump screen for potential failure conditions that may display.

If you damage or drop your t:flex System, ensure that it is still working properly. If you are unsure about potential damage, disconnect the infusion set from your body and contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

It is very important to set the current time and date accurately to ensure safe insulin delivery. When editing time, always check that the AM/PM setting is accurate. AM is to be used from midnight until 11:59 AM. PM is to be used from noon until 11:59 PM.

When you are connected to the pump and to a charging source, take caution when moving further than the length of the USB cable. Failure to do so may result in the cannula becoming dislodged at the infusion site. For this reason it is recommended not to charge the pump while sleeping.

Your insulin needs may change in response to lifestyle changes such weight gain or loss, and starting or stopping exercise. Consult your healthcare provider for help with adjusting your basal rate(s) and other settings.

When you first use the Quick Bolus feature, you should always look at the screen to confirm correct programming until you are comfortable with this feature.

Interference with your System's electronics by cell phones can occur if worn in close proximity. It is recommended that your pump and cell phone be worn at least 6.4 inches apart.

Always check with your healthcare provider for specific guidelines if you want or need to disconnect from the pump for any reason. Depending on the length of time and reason you are disconnecting, you may need to replace missed basal and/or bolus insulin. Check your blood glucose before disconnecting from the pump and again when you reconnect, and treat high blood glucose (BG) levels as recommended by your healthcare provider.

If you receive a warranty replacement System from Tandem Diabetes Care, ensure that your personal settings are programmed before using the pump.

Always dispose of used cartridges, syringes, needles, and infusion sets following your community's regulations. Wash your hands thoroughly after handling any insulin-holding device.

1.8   Conventions of this Guide

The following are conventions used in this Guide (such as terms, icons, text format-ting, and other conventions) along with their explanations.

Convention	Explanation
Bolded Text	Text that is in bold and in a different font than the rest of the sentence or step indicates an onscreen or physical button name.
Touch Screen	The front glass screen of your pump, which displays all programming, operating, and alarm/alert information.
Tap	Quickly and lightly touch the screen with your finger.
Press	Use your finger to depress a physical button (the Screen On/Quick Bolus Button is the only physical/hardware button on your t:flex Pump).
Hold	Keep pressing a button or touching an icon or menu until its function is complete.
Menu	A list of options on your touch screen that allow you to perform specific tasks.
Icon	An image on your touch screen that indicates an option or item of information, or a symbol on the back of your t:flex Pump or its packaging.

Customer Technical Support: **1-877-801-6901**

Chapter 2

Introduction

2.1 Welcome

Congratulations on the purchase of your new t:flex System. Your decision to use insulin pump therapy is a sign of your commitment to your diabetes care. The t:flex System delivers insulin in two ways: continuous, or basal insulin delivery, and bolus insulin delivery to cover carbohydrates eaten and to lower high blood glucose. The following pages provide step-by-step instructions on how to properly program, manage, and care for your System.

2.2 What your t:flex System Package Includes

Your t:flex System should include the following items:

1. t:flex Insulin Pump

2. Pump Case

3. t:flex User Guide

4. t:connect® Getting Started Guide

5. USB Cable

6. Wall Power USB Adapter

7. Car Power USB Adapter

8. Cartridge Removal Tool

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

📄 **NOTE**
Your t:flex 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:flex 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.
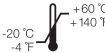
Supply Reordering
To order cartridges, infusion sets, supplies, and accessories, please contact Tandem Diabetes Care, Inc. at 1-877-801-6901 or your usual supplier of diabetes products.

2.3   Explanation of Symbols

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

Symbol	Meaning
⚠	Caution; Consult Manual for Important Safety Documentation
	See Instructions for Use
SN	Serial Number of Device
REF	Part Number
IPX7	Watertight Equipment (protected against the effects of temporary immersion in water)
	Type BF Applied Part (patient isolation, not defibrillator protected)
	Manufacturer
℞ Only	For sale by or on the order of a physician only (U.S.)
	Direct Current (DC) voltage

Symbol	Meaning
	Use By Date
	Do Not Re-Use
STERILE R	Method of Sterilization: Gamma
PYROGEN	Non Pyrogenic
-20 ℃ -4 ℉ +60 ℃ +140 ℉	Temperature Limits
LOT	Lot Number
	Non-ionizing Radiation
	Date of Manufacture

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2.4   Explanation of Icons

The following icons may appear in the status area (to the left or right of the time and date) on your t:flex Pump Home Screen. Tap the icon to access the status screen for more information.

Icon	Meaning
!	A system reminder, alert, error, or alarm is active.
B	Basal insulin is programed and being delivered.
T	A temporary basal rate is active.
0	A basal rate of 0 u/hr is active.
T	A temporary basal rate of 0 u/hr is active.
💧	A bolus is being delivered.
!	All insulin deliveries are stopped.

Customer Technical Support: 1-877-801-6901

2.5   Explanation of System Colors

	Red LED
	» 1 red blink every 30 seconds indicates a malfunction or alarm condition.

	Yellow LED
	» 1 yellow blink every 30 seconds indicates an alert or reminder condition.

	Green LED
	» 1 green blink every 30 seconds indicates the pump is functioning normally. » 3 green blinks every 30 seconds indicate the pump is charging.

	Orange Highlight
BACK 12:00 AM SAVE Basal 0.75 u/hr Correction Factor Press to Set Up Carb Ratio Press to Set Up Target BG Press to Set Up	» When editing settings, changes are highlighted in orange for review before saving.

2.6   Warranty Information

Warranty
t:flex Insulin Pump

The expected life of the t:flex Pump is a maximum of 4 years. Tandem Diabetes Care, Inc. ("Tandem") warrants the t:flex 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:flex Pump, subject to the conditions and exclusions stated herein.

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

• If: damage results from changes or modifications made to the t:flex Insulin 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:flex Pump by any person or entity other than Tandem;

• If: the t:flex Pump seal is broken;

• If: a non-Tandem cartridge is used with the t:flex 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.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the t:flex 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:flex Pump and does not apply to other products or accessories.

THE REMEDIES PROVIDED FOR IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE FOR ANY WARRANT 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 of 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 infusion 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 WARRANT 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.

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t:flex Pump Overview

3.1   t:flex Pump Overview

To turn on your t:flex Pump screen, first press the Screen On/Quick Bolus Button, then 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:flex 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 t:flex Pump has several safety features to prevent unintentional interaction with the touch screen. The screen must be unlocked by tapping 1–2–3 in sequence. On all screens, if three non-active areas of the touch screen are tapped before an active area is tapped, the screen will turn off to prevent accidental button presses.

📄 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. Always position the pump screen away from the skin when worn under clothing.

3.2   System Terminology

Pump 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:flex 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 a high BG. With the t:flex Pump it can be delivered as a Standard, a Correction, an Extended, or a Quick Bolus.

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

Carb
Carbs or 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 1 unit of insulin will cover. Also known as insulin-to-carbohydrate ratio.

Correction Bolus
A correction bolus is given to correct high BG.

Correction Factor
A correction factor is the amount of BG that is lowered by 1 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:flex 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, filling, and replacing a new cartridge and infusion set.

mg/dL
Milligrams per deciliter. The standard unit of measure for blood glucose readings in the United States.

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:flex 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 USB cable connects into the t:flex Pump's micro USB port.

3.3   Screen Lock

1. **Time and Date Display:** Displays the current time and date.

2. **Alert Icon:** Indicates a reminder, alert or alarm is active behind the lock screen.

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

4. **1-2-3:** Unlocks pump screen.

5. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.

6. **Active Bolus Icon:** Indicates a bolus is active.

7. **Status:** Displays current system 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.

10:20 AM
January 9, 2015

100%

425 u

1   2   3

INSULIN ON BOARD (IOB)

Units	1.1 u	Time Remaining	1:09 hrs
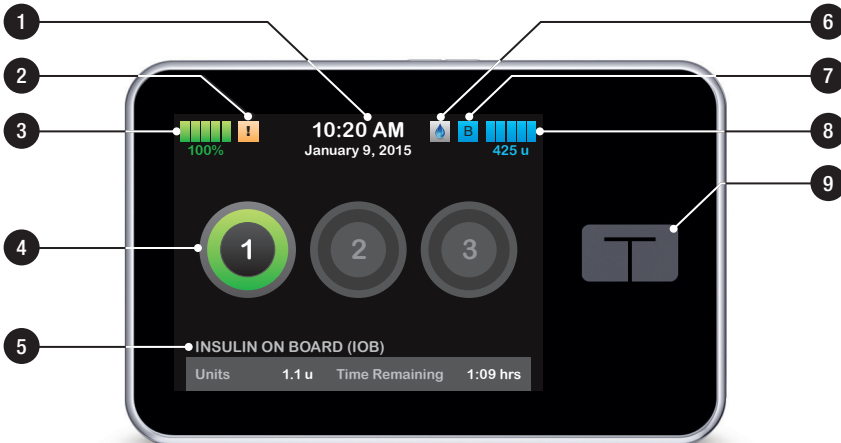
3.4   Home Screen

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:flex 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 system 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 the t:flex Pump screen on/off or programs a Quick Bolus (if activated).

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

10:20 AM
January 9, 2015

100%

425 u

B

BOLUS

OPTIONS

INSULIN ON BOARD (IOB)

Units	1.1 u	Time Remaining	1:09 hrs

10:20 AM
January 9, 2015

B

425
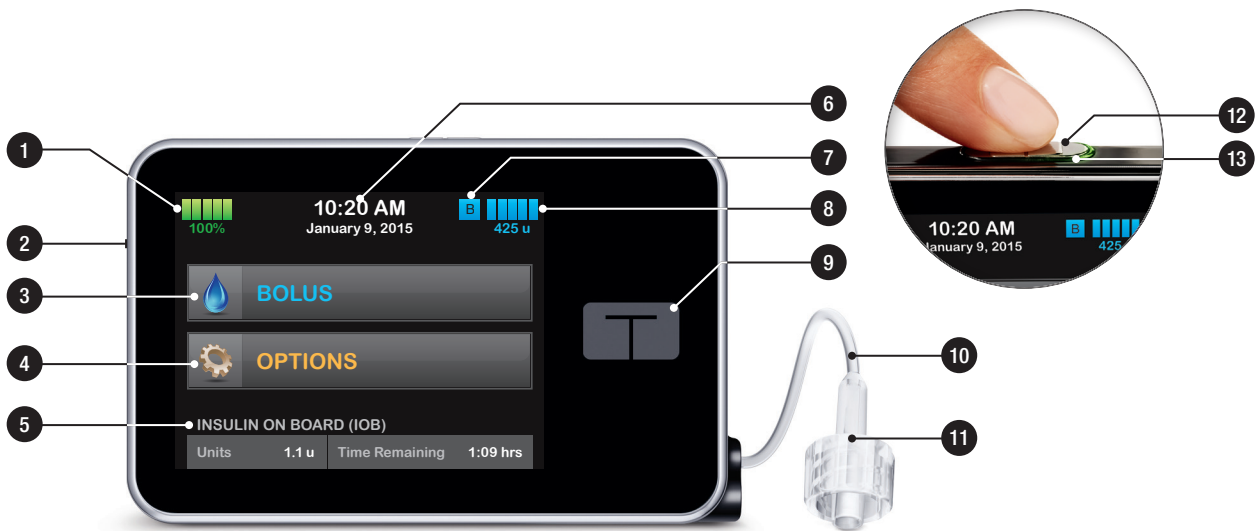
3.5   Status Screen

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

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

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

4. **Carbohydrates:** Indicates whether feature is on or off.

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

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

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

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

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

📄 NOTE
NA represents Not Applicable (does not apply).

📄 NOTE
The status screen can be accessed from the lock screen and the Home Screen. It is for display only, no changes can be made from this screen.

Customer Technical Support: **1-877-801-6901**
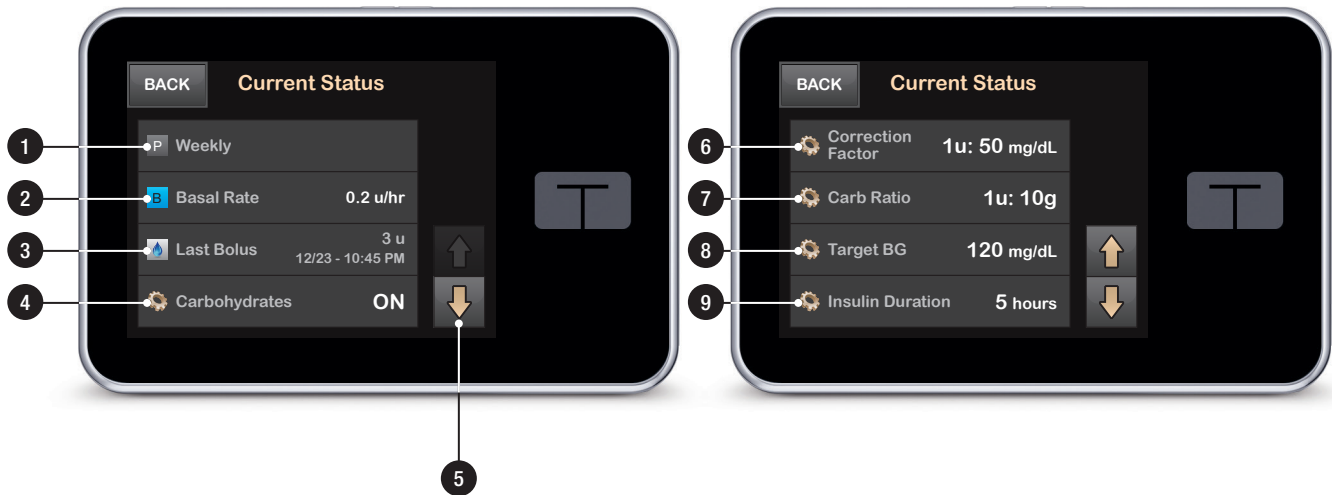
3.6   Bolus Screen

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

2. **Carbs:** Enter grams of carb.

3. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.

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

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

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

7. **Back:** Returns to the Home Screen.

8. **Insulin:** Enter units of insulin.

9. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.

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

11. **Add BG:** Enter blood glucose level.

12. **Next:** Moves to next step.

Using Grams

BACK | 0
units

CARBS | BG

0
grams | Add BG

View Calculation

1 2 3 4 5 6

Using Units

BACK | 0
units

INSULIN | BG

0
units | Add BG

View Calculation

7 8 9 10 11 12
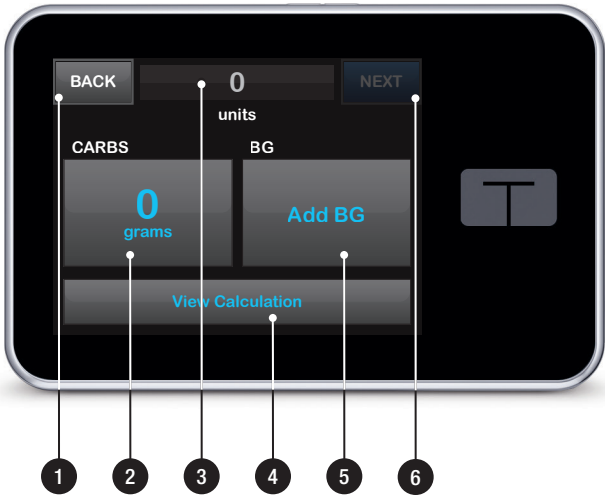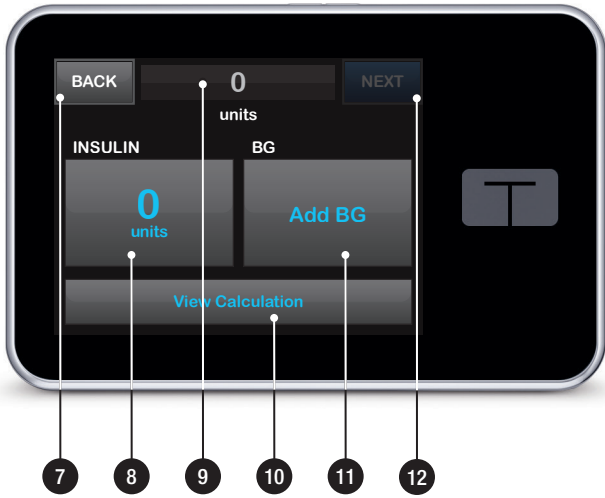
3.7   Options Screen

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

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

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1	BACK
	Options
2	STOP INSULIN
3	My Pump
4	Load
5	Temp Rate
6 7	

	BACK **Options**
8	History
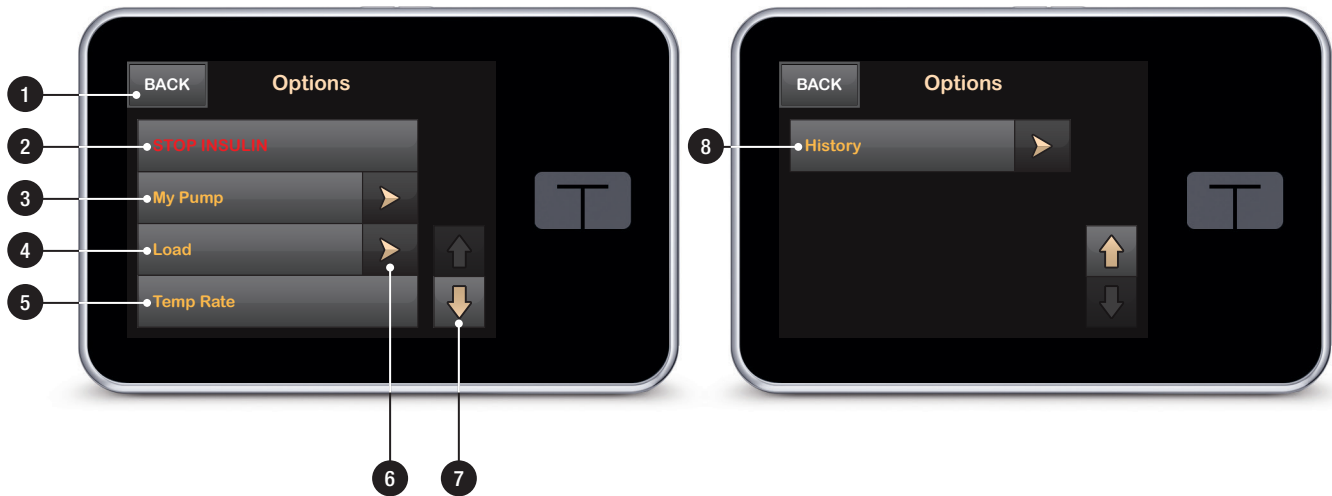
3.8   My Pump Screen

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

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

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

4. **Pump Info:** Displays t:flex Pump serial number, Tandem Diabetes Care Customer Technical Support phone number, website, and other technical information.

BACK   **My Pump**

1 → Personal Profiles ➤

2 → Alert Settings ➤

3 → Pump Settings ➤

4 → Pump Info
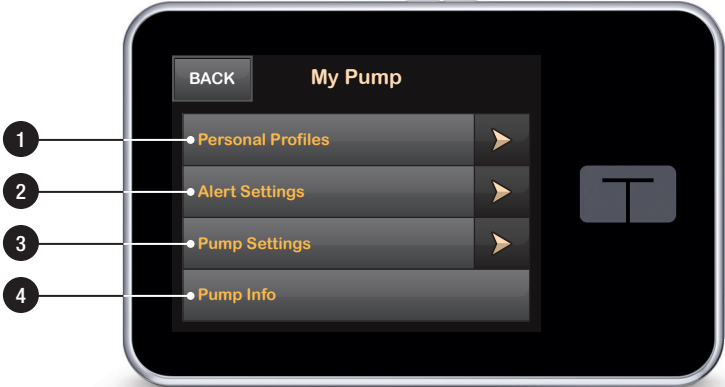
3.9   Number Keypad Screen

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.
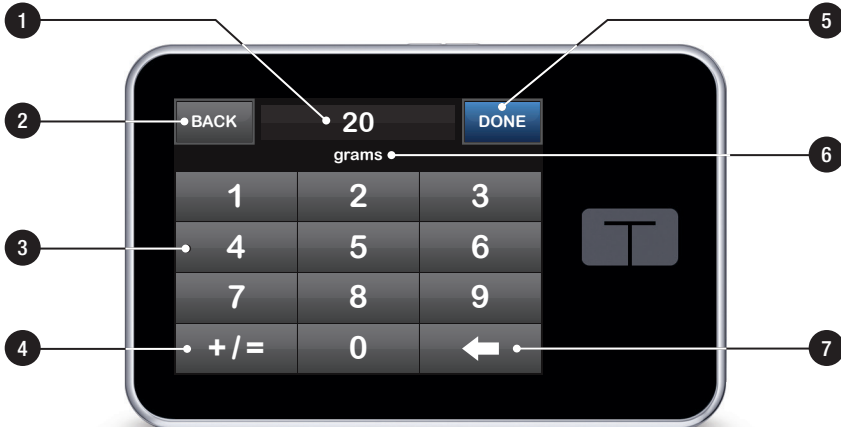
3.10   Letter Keypad Screen

1. **Name of Profile.**

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

3. **Space:** Enters a space.

4. **123:** Changes keypad mode from letters (ABC) to numbers (123).

5. **Save:** Saves entered information.

6. **Letters:** Tap once for first letter displayed, 2 quick taps for middle letter, and 3 quick taps for third letter.

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

   📄 NOTE
   If changing an existing name, begin by tapping the letters on the keypad to enter new text. The maximum number of characters is 16.

Customer Technical Support: **1-877-801-6901**
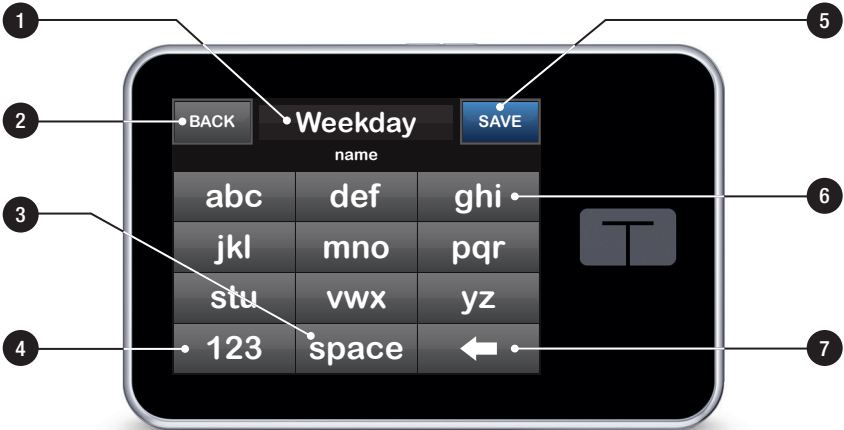
Section 2

Key Pump Features

Chapter 4

Getting Started

Before you can safely and effectively use your t:flex System, it is very important that you carefully follow the instructions in these sections.

4.1   Charging the t:flex Pump

The t:flex Pump is powered by an internal lithium polymer rechargeable battery. A full charge will last up to 4 days with normal use. Accessories for charging from wall and automobile outlets, as well as from a PC USB port are included with the pump. Use only the accessories provided with the System to charge your t:flex Pump. If you lose any of the accessories, or need a replacement, contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

The battery level indicator is displayed in the upper left portion of the Home Screen. The charge amount will increase or decrease by 5% at a time (for example, you will see 100%, 95%, 90%, 85%). When the charge amount is less than 5%, it will begin decreasing

1% at a time (for example, you will see 4%, 3%, 2%, 1%).

When you first receive your t:flex Pump, you will need to connect it to a charging source before it can be used. Charge the pump until the battery level indicator on the upper left portion of the Home Screen reads 100% (initial charge can take up to 2.5 hours).

The t:flex Pump continues to operate normally while charging. You do not need to disconnect from the pump while charging.

⚠ PRECAUTION
When you are connected to the pump and to a charging source, take caution when moving further than the length of the USB cable. Failure to do so may result in the cannula becoming dislodged at the infusion site. For this reason it is recommended not to charge the pump while sleeping.

If you choose to disconnect from the pump while charging, check with your healthcare provider for specific guidelines. Depending on the length of time you are disconnected, you may need to replace missed basal and/or bolus

insulin. Check your blood glucose before disconnecting from the pump and again when you reconnect.

To charge the pump from an AC Power Outlet:

1. Plug the included USB cable into the AC power adapter.

2. Plug the AC power adapter into a grounded AC power outlet.

3. Plug the other end of the cable into the micro USB port on the pump.

To charge the pump using the included Car Power USB Adapter:

1. Plug the USB cable into the included Car Power USB Adapter.

2. Plug the Car Power USB Adapter into a grounded auxiliary power outlet.

3. Plug the other end of the cable into the micro USB port on the pump.

⚠ WARNING
When using the Car Power USB Adapter, the charger must be connected to an isolated, battery powered 12 Volt system, such as an automobile. Connecting the DC vehicle adapter charger to 12 Volt DC that is generated by a power supply connected to alternating current (AC) mains is prohibited.

To charge the pump using a USB port on a Personal Computer (PC):

Ensure that the PC complies with the IEC 60950-1 (or equivalent) safety standard.

1. **Plug the included USB cable into your computer.**

2. **Plug the other end of the cable into the micro USB port on the pump.**

📄 NOTE
Before using a Mac or PC to charge the t:flex Pump, it is recommended that a driver be installed on the computer by downloading the t:connect Uploader Software from our website at www.tandemdiabetes.com. This will also allow communication between the pump, the PC, and the t:connect Application. Depending on your computer, charging time will vary. The pump will display a CONNECTION ERROR ALERT message if it is not charging properly.

When you charge the t:flex Pump, you will notice the following:

•   The screen illuminates

•   An audible alert

•   The LED (edge around the Screen On/Quick Bolus Button) blinks green

•   A vibrating alert

•   A charge symbol (lightning bolt) on the battery level indicator appears

⚠ PRECAUTION
If any of these conditions fail to occur, do NOT use the t:flex Pump, as this may be an indication that the pump's alarms, alerts, and other built-in safety features are not working properly. If the t:flex Pump is connected to your body, disconnect the set from your body and contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

Charging Tips

Tandem Diabetes Care, Inc. recommends periodically checking the battery level indicator, charging the pump for a short period of time every day (10–15 minutes), and also avoiding frequent full discharges.

📄 NOTE
If the battery is fully discharged, the screen will not power on immediately when connected to a charging source. The LED around the Screen On/Quick Bolus Button will blink green every 2 seconds until there is enough charge to power on the touch screen.

📄 NOTE
If the t:flex Pump beeps and vibrates continuously when connected to a charging source, try a different power source or USB cable.

2

Key Pump Features

4.2 Turning on the t:flex Pump Screen

1. To turn on your t:flex Pump screen, press the **Screen On/ Quick Bolus Button**, located on the top of the pump, once.

▷ The Screen Lock screen will be displayed.

📄 NOTE
The pump continues to function normally when the screen is not on.

📄 NOTE
When using the t:flex Pump, tap the Tandem Logo to return to the Home Screen or tap BACK to return to the previous screen.

4.3 Unlocking the t:flex Pump Screen

1. Press **Screen On/Quick Bolus Button**.

2. Tap **1**.

3. Tap **2**.

4. Tap **3**.

▷ The pump screen is now unlocked. The last screen that was viewed will be displayed.

📄 NOTE
You must tap 1–2–3 in sequential order to unlock the pump. If you do not press 1–2–3 in sequential order, the pump will force you to restart the unlock sequence from the beginning.

📄 NOTE
The pump will return to the Screen Lock position after a bolus or temp basal is requested.

📄 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.

4.4   Edit Time

After powering up your t:flex Pump for the first time, set the current time and date. Refer back to this section if you need to edit the time for either traveling in a different time zone or adjusting for Daylight Savings Time.

⚠ PRECAUTION
It is very important to set the current time and date accurately to ensure safe insulin delivery. When editing time, always ensure that the AM/PM setting is accurate. AM is to be used from midnight until 11:59 AM. PM is to be used from noon until 11:59 PM.

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Pump Settings**.

4. Tap **Time and Date**.

5. Tap **Edit Time**.

6. Tap **Time**.

7. Using the onscreen keypad, enter the hour and minutes. Verify and tap **DONE**.

8. Tap **Time of Day** to set AM or PM.

9. Verify the correct time is set and tap **SAVE**.

📄 NOTE
Any edits to Time or Date will not be saved until you tap SAVE.

4.5   Edit Date

1. From the Time and Date screen tap **Edit Date**.

2. Tap **Month**.

3. Find and tap the current month displayed on the right. Use **Up/Down Arrow** to view months not displayed.

4. Tap **Day**. Using the onscreen keypad enter the current day. Verify and tap **DONE**.

5. Tap **Year**.

6. Using the onscreen keypad enter the current year. Verify and tap **DONE**.

7. Verify the correct date is set and tap **SAVE**.

8. Tap **Tandem Logo** to return to the Home Screen.

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Chapter 5

Infusion Site Care and Loading Cartridge

5.1 Infusion Site Selection and Care

⚠ WARNINGS

» Use only FDA cleared insulin infusion sets with a standard luer-lock connection and consult its instructions for use. Failure to do so may result in over-infusion or under-infusion and may cause serious injury or death.

» Change your infusion set every 48–72 hours. Consult your healthcare provider for more information.

» Use only single-use disposable cartridges from Tandem Diabetes Care. The efficacy of your t:flex Pump cannot be guaranteed if cartridges other than those manufactured by Tandem Diabetes Care, Inc. are used or if cartridges are filled more than once. Use of cartridges not manufactured by Tandem Diabetes Care, Inc. or reuse of cartridges may result in over-infusion or under-infusion and may cause serious injury or death.

» Only use Humalog® or NovoLog® U-100 insulin, as any lesser or greater concentration can result in serious health consequences. Only Humalog® and NovoLog® have been tested by Tandem Diabetes Care, Inc., and found to be safe for use in the t:flex Pump.

General Guidelines

Site Selection:

• Your infusion set can be worn anywhere on your body that you would normally inject insulin. Absorption varies from site to site. Discuss options with your healthcare provider.

• The most commonly used sites are the abdomen, upper buttocks, hips, upper arms, and upper legs.

• The abdomen is the most popular site because of access to fatty tissue. If using the abdominal area, AVOID:
  » Areas that would constrict the site such as the belt line, waistline, or where you would normally bend.
  » Areas 2 inches around your belly button.
  » Any scars, moles, stretch marks, or tattoos.
  » Areas within 3 inches of your sensor site, if using Continuous Glucose Monitoring.

Site Rotation:

• The infusion set must be replaced and rotated every 48–72 hours, or more often if needed.

• With experience, you will find areas that not only provide better absorption, but are more comfortable. Keep in mind, using the same areas may cause scarring or lumps which can affect insulin absorption.

• Consult your healthcare provider to establish a rotation schedule that best fits your needs.

Keep it clean:

• When changing your infusion set, use clean techniques to avoid an infection.

• Wash your hands, use antiseptic wipes or infusion site preparation products, and keep the area clean.

• Site preparation products that have both an antiseptic and an adhesive are encouraged.

Areas of Body for Infusion Set Insertion
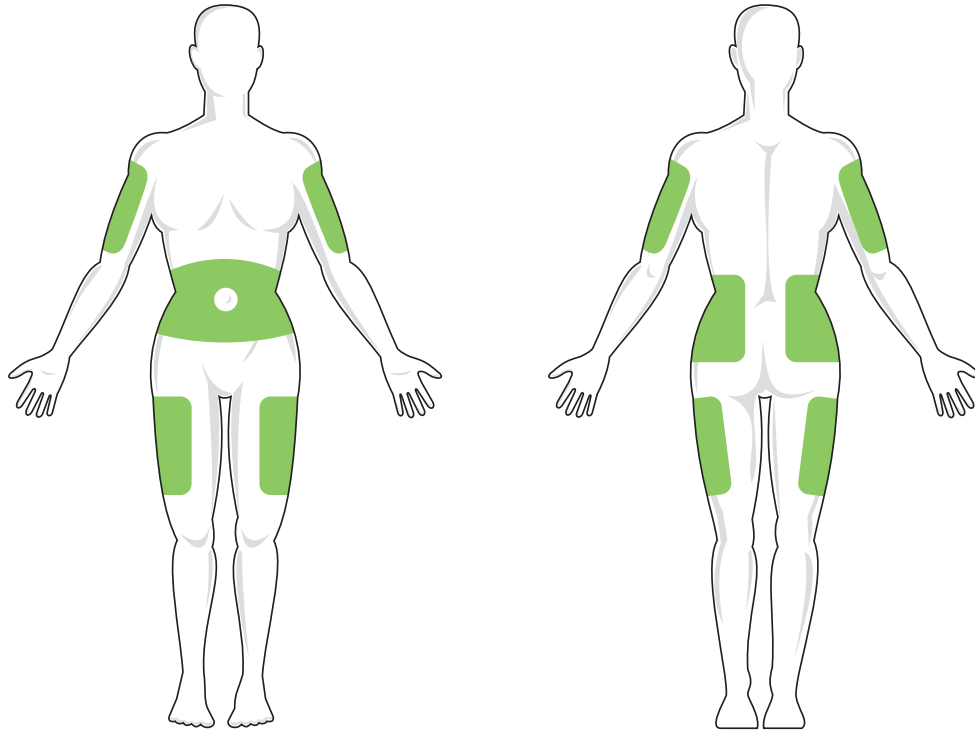
5.2   Cartridge Instructions for Use

For complete cartridge labeling, consult the Cartridge Instructions for Use included in the t:flex Cartridge box.

5.3   Filling and Loading a t:flex Cartridge

This section describes how to fill the cartridge with insulin and load the cartridge into your t:flex Pump. The single-use disposable cartridge can hold up to 480 units (4.8mL) of insulin.

⚠ PRECAUTION
Replace the cartridge every 48 hours if using Humalog®; every 72 hours if using Novolog®.

⚠ PRECAUTION
Inspect the cartridge to ensure that there is no damage. Never use a cartridge that is damaged (cracks, dislodged tip connectors, etc.). If there is damage, call Tandem Diabetes Care Customer Technical Support at 1-877-801-6901 to request a replacement cartridge.

⚠ PRECAUTION
Before you begin, verify that the infusion set is NOT connected to your body.

Before you begin, make sure you have the following items:

• 1 unopened cartridge

• 5.0mL syringe and fill needle

• Vial of Humalog® or NovoLog® insulin

• Alcohol prep swab

• 1 new infusion set

• Infusion set Instructions for Use

📄 NOTE
Do NOT remove the used cartridge from the pump during the load process until prompted on the t:flex Pump screen.

The illustration identifies the luer-lock and insulin fill port used in the cartridge filling process.

Luer-Lock Tail of the Cartridge

Insulin Fill Port
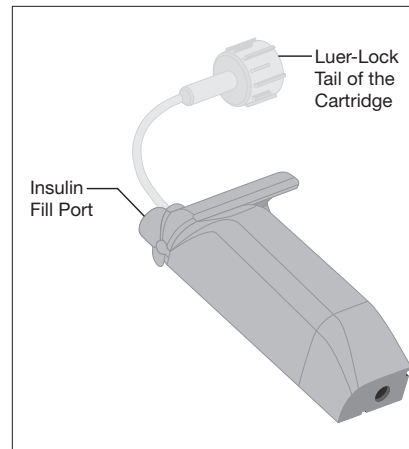
Instructions for Drawing Insulin from Vial into Syringe

⚠ PRECAUTION
Use only the syringe and needle provided by Tandem Diabetes Care, Inc. to fill the cartridge. After filling the cartridge and before connecting and filling the tubing, reduce the possibility of trapped air in the cartridge by holding your t:flex Pump vertically with the cartridge insulin fill port on top.

📄 NOTE
The fill estimate displayed on the pump is the amount of insulin available for delivery. It does not include insulin needed to fill the tubing (up to 30 units) and a small amount of insulin that is not available for delivery. When filling the syringe, add approximately 45 units to the amount of insulin you want available for delivery.

For example, the pump requires a minimum of 100 units available for delivery after fill tubing has been completed. Fill the syringe with approximately 145 units to have enough to fill your tubing and still have 100 units available for delivery.

1. Inspect the needle and syringe package for any signs of damage. Discard any damaged product.

2. Wash your hands thoroughly.

3. Wipe the rubber septum of the insulin vial with an alcohol swab.

4. Remove the needle and syringe from their packaging. Securely twist needle onto syringe. Safely remove protective cap from needle by pulling outward.

5. Draw air into syringe up to the amount of insulin desired *(see image A)*.

6. With insulin vial upright, insert needle into vial. Inject air from syringe into vial. Maintain pressure on syringe plunger *(see image B)*.

2

Key Pump Features
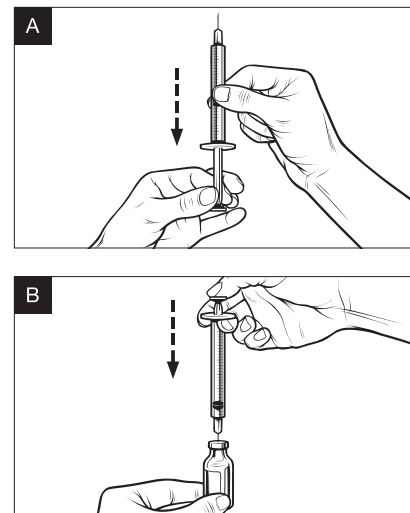
7. With needle still inserted into vial, turn vial and syringe upside down. Release syringe plunger. Insulin will begin to flow from the vial into the syringe.

8. Slowly pull back the plunger to the desired amount of insulin *(see image C)*.

9. While the filling needle is still in the vial and upside down, tap the syringe so that any air bubbles rise to the top *(see image D)*. Then slowly push the plunger upwards, forcing any air bubbles back into the vial.

10. Check the syringe for air bubbles and do one of the following:

    » If there are air bubbles present, repeat step 9.

    » If no air bubbles are present, remove the filling needle from the vial.

    ⚠ PRECAUTION
    Always remove all air bubbles when drawing insulin into the filling syringe.
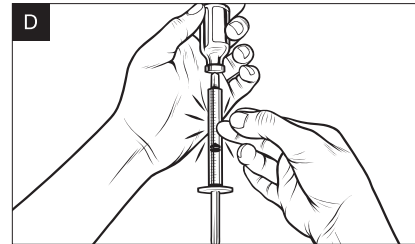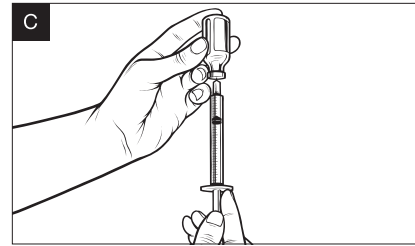
Instructions for Filling the Cartridge

1. Inspect the cartridge package for any signs of damage.
    Discard any damaged product.

2. Open the package and remove the cartridge.

3. Hold the cartridge upright and gently insert the needle into the white
    insulin fill port on the cartridge *(see image E)*. The needle is not intended
    to go all the way in, so do not force it.

4. Keeping the syringe vertically aligned with the cartridge, and the needle
    inside the fill port, pull back on the plunger until it is fully retracted
    (see image F). This will remove any residual air from the cartridge.
    Bubbles will rise toward the plunger.

5. Make sure the needle is still in the fill port and release the plunger.
    Pressure will pull the plunger to its neutral position but it will NOT
    push any air back inside the cartridge *(see image G)*.

2

Key Pump Features
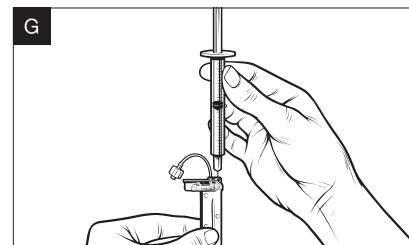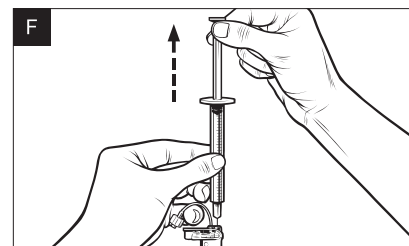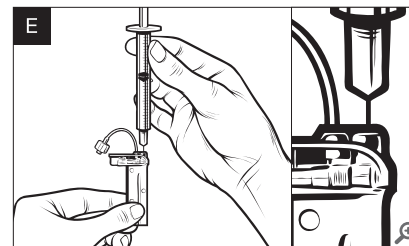
6. Withdraw the needle from the fill port.

7. Turn the syringe upright and pull down on the plunger *(see image H)*. Flick the barrel to make sure that any air bubbles rise to the top.

8. Gently press on the plunger to remove air bubbles until insulin fills the needle hub and you see a drop of insulin at the tip of the needle *(see image I)*.

9. Re-insert the needle in the fill port and slowly fill the cartridge with insulin *(see image J)*. It is normal to feel some back pressure as you slowly press on the plunger.

10. Maintain pressure on the plunger while you remove the needle from the cartridge. Check the cartridge for leaks. If you detect insulin leaking, discard the cartridge and repeat entire process with a new cartridge.

11. Always dispose of used needles, syringes, cartridges, and infusion sets following your community's regulations.

⚠ PRECAUTION
Do not fill the cartridge with more than 480 units. This can cause a cartridge error.

Customer Technical Support: 1-877-801-6901
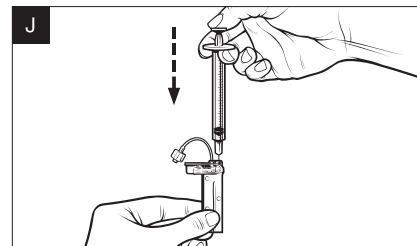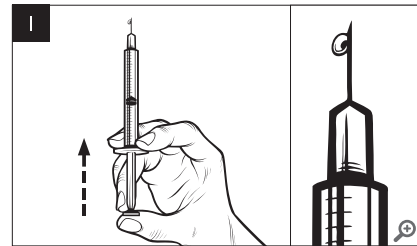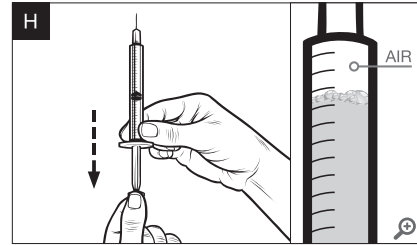
Instructions on How to Install a Cartridge

⚠ PRECAUTION
If this is the very first time you are loading the cartridge, remove the shipping canister (which is not for human use), from the back of the pump.

1. From the Home Screen, tap **OPTIONS**.

2. Tap **Load**.

   📄 NOTE
   During the load sequence, the Tandem Logo is disabled. Tapping it will not return to the Home Screen.

3. Tap **Change Cartridge**.

4. Screen will display that all insulin deliveries will be stopped. Tap **YES** to continue.

   📄 NOTE
   This screen will not be displayed if this is the first time loading a new cartridge and you have not started actively pumping.

5. Disconnect the infusion set from your body and tap **NEXT** to continue.

▷ "Preparing for Cartridge" screen is displayed.

6. Remove the used cartridge and install a filled cartridge. Tap **UNLOCK** icon when completed.

   📄 NOTE
   If needed, place the cartridge removal tool or the edge of a coin in the slot at the bottom of the cartridge and twist to aid in the removal of the cartridge.

   Place bottom of the cartridge at the end of the pump. Make sure cartridge is lined up to both guide tracks.
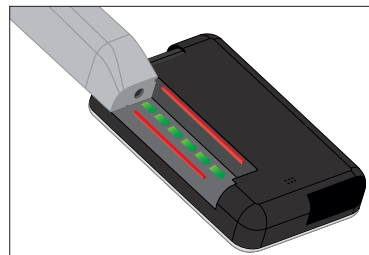
Push on the circular fill port next to the cartridge tubing to slide the cartridge onto the pump.
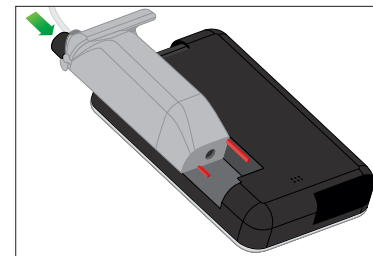
7. Tap **NEXT** to continue.

▷ "Detecting Cartridge" screen is displayed.

📄 NOTE
After completing the cartridge change, the pump will automatically prompt you to fill tubing.

⚠ WARNING
Do not remove or add insulin from a filled cartridge after it is installed on the pump. This will result in an inaccurate display of the insulin level on the Home Screen.

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Key Pump Features

5.4   Filling Tubing

**Filling the Infusion Set Tubing
with Insulin**

This section describes how to fill the infusion set tubing with insulin.

⚠ WARNING
Never fill the infusion set tubing while the tubing is connected to your body. Filling the tubing while it is connected to your body can result in unintended delivery of insulin.

⚠ WARNING
Do not disconnect the luer-lock connection between the cartridge tubing and the infusion set tubing. If the connection comes loose, disconnect the infusion set from the site (from your body) before tightening to avoid unintentional insulin delivery.

⚠ PRECAUTION
Always ensure that there are no air bubbles in the tubing when filling.

🗏 NOTE
If starting from the Home Screen, tap OPTIONS, tap Load, tap Fill Tubing and then follow the instructions. Tap NEW if you installed a new cartridge. Tap FILL if you did not install a new

cartridge and want to continue with filling the tubing.

1. Verify that the infusion set is disconnected from your body.

2. Connect the infusion set tubing to the luer-lock on the cartridge:

    a. Ensure that the new infusion set package is not damaged, and remove the sterile tubing from the package. If the package is damaged or opened, discard of properly and use another tubing set.

    b. Remove the infusion set tubing cap from the luer connector. Be careful to keep the luer connec-tor away from unclean areas.

    c. Attach the infusion set tubing to the luer connector on the cartridge tubing. Twist clockwise until finger tight and then twist another quarter of a turn to en-sure a secure connection.

Tap **NEXT**.

⚠ PRECAUTION
Conduct regular checks of your t:flex Pump and infusion set, particularly:
» Check that your luer-lock connection between the cartridge tubing and the infusion set tubing is tight and secure.
» Check your infusion set tubing for any damage, leaks, or kinks while using your t:flex Pump. Damaged, leaking, or kinked tubing may restrict or stop insulin delivery and result in under-infusion.

3. Hold the pump vertically to ensure any air in the cartridge will be dispelled first. Tap **START**. The pump will beep and vibrate regularly while the tubing is being filled.
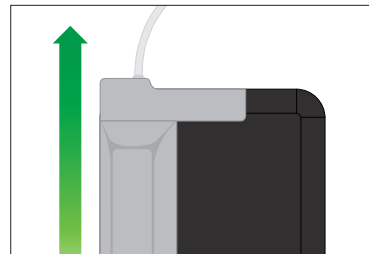
▷ "Starting Fill" screen is displayed.

📄 **NOTE**

The following are approximate amounts of insulin to fill different tubing lengths:

» 15–20 units for 23 inch tubing
» 20–25 units for 32 inch tubing
» 25–30 units for 42 inch tubing

4. Tap **STOP** after 3 drops of insulin are seen at the end of the infusion set tubing.

▷ "Stopping Fill" screen is displayed.

▷ "Detecting Insulin" screen is displayed.

5. Verify that drops are seen and tap **DONE**.

• If you do not see drops, tap **FILL**. The Fill Tubing screen appears, repeat steps 3–5 until you see 3 drops of insulin at the end of the tubing.

• If you did not tap STOP, the "Max fill amount reached!" screen will appear. Do one of the following:

   a. If you are finished filling the tub-ing, tap **DONE**.

   b. If you want to fill the tubing with more than 30 units, tap **FILL** to go back to the Fill Tubing screen.

6. Fill Tubing is complete.

📄 **NOTE**

After tubing fill is complete, when the pump returns to the Home Screen, an estimate of how much insulin is in the cartridge is displayed in the upper right portion of the screen. You will see one of the following on the screen:

» + 90 u   More than 90 units detected in the cartridge
» + 100 u   More than 100 units detected in the cartridge
» + 200 u   More than 200 units detected in the cartridge
» + 300 u   More than 300 units detected in the cartridge
» + 400 u   More than 400 units detected in the cartridge

After 10 units are delivered, an actual number of units remaining in the cartridge will be displayed on the Home Screen

The amount of insulin remaining displayed on the Home Screen will decrease 5 units

at a time (for example, you will see 340, 335, 330, 325). When less than 90 units remain, it will begin decreasing 1 unit at a time (for example, you will see 90, 89, 88, 87) until there is 1 unit remaining.

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Key Pump Features

5.5   Filling Cannula

Filling the Infusion Set Cannula with Insulin

This section describes how to fill the infusion set cannula with insulin.

For the correct cannula fill amount, as well as proper insertion technique, refer to the instructions for use included with the infusion set.

To Fill the Cannula

📄 NOTE
» If starting from the Home Screen, tap OPTIONS, tap Load, tap Fill Cannula and then follow the instructions. Insulin delivery will be stopped and must be resumed upon completion.
» If using a steel needle infusion set, there is no cannula. Skip this section.

1. Tap **Fill Cannula.**

2. Insert a new infusion set and connect filled tubing to site, then tap **NEXT.**

3. Tap **Edit Fill Amount**.

📄 NOTE
The cannula fill amount displayed is based on your last cannula fill amount. Filling stops at this amount (unless you tap STOP before this amount is reached).

4. Select amount needed for cannula fill.

📄 NOTE
If the amount needed is not listed, tap Other amount and use the onscreen keypad to enter a value between 0.1 to 1.0 unit.

⚠ WARNING
Refer to your infusion set instructions for proper insertion and cannula fill amount.

5. Tap **START.**

▷ "Starting Fill" screen is displayed.

▷ After fill is complete, "Stopping Fill" screen is displayed.

📄 NOTE
You can tap STOP at any time during the fill process if you want to stop filling the cannula.

📄 NOTE
The screen will return to the Load menu if the Site Reminder is turned off. Tap DONE to resume insulin if finished. Or tap Site Reminder to set reminder. If Site Reminder is on, the pump will automatically display the Site Reminder Screen (refer to next section).

5.6   Setting Site Reminder

📄 NOTE
If starting from the Home Screen, tap OPTIONS, tap Load, tap Site Reminder then follow the instructions below.

⚠ PRECAUTION
Avoid changing an infusion set before going to bed or if you will not be able to test your BG 1–2 hours after a new set is placed.

1. Tap SAVE if correct. Tap **Edit Reminder** if settings need to be changed.

2. Tap **Remind Me In** and select the number of days (1-3).

    📄 NOTE
    Default reminder is set for 3 days.

3. Tap **Remind Me At**. Use the onscreen keypad to enter time and tap **DONE**.

4. Tap **Time of Day** to change AM or PM. Tap **DONE**.

5. Verify Site Reminder is set correctly and tap **SAVE**.

▷ "Setting Saved" screen is displayed.

6. Load screen is displayed. Tap **DONE**.

▷ A reminder to test BG in 1–2 hours will display.

7. Tap **RESUME**.

    📄 NOTE
    If this is the first time using your t:flex Pump and a Personal Profile has not been defined, a screen will notify you that a profile must be activated to resume insulin. Tap CLOSE.

8. **RESUMING INSULIN** splash screen is displayed.

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Key Pump Features

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Chapter 6

Personal Profile

6.1   Personal Profile Overview

A Personal Profile is a group of settings that define basal and bolus delivery within specific time segments through-out a 24-hour period. Each profile can be personalized with a name. Within a Personal Profile the following can be set:

• Timed Settings: Basal Rate, Correction Factor, Carb Ratio and Target BG.

• Bolus Settings: Insulin Duration, Max Bolus and Carbohydrates setting (on/off).

The t:flex Pump uses the settings in your active profile to calculate the delivery of basal insulin, food boluses and correction boluses based on your Target BG.

Having several Personal Profiles pro-vides more flexibility for your body and lifestyle. For example, you could have "Weekday" and "Weekend" profiles if you have different insulin delivery needs on weekdays and weekends, based on schedule, food intake, activity, and exercise, etc.

📄 NOTE
Up to 6 different Personal Profiles can be created and up to 16 different time segments can be set in each Personal Profile. For example, within your "Weekday" profile you might have time segments set up for 12:00 AM, 5:30 AM and 3:00 PM based on your healthcare provider's recommendation.

📄 NOTE
Once defined, a Personal Profile can be viewed by selecting EDIT from the profile menu.

6.2   Creating a New Profile

Creating Personal Profiles

You can create up to 6 Personal Pro-files, however, only 1 can be active at a time. In the Personal Profiles screen, the active profile is positioned at the top of the list and is marked as ON. When you create a Personal Profile, you can set any or all of the following Timed Settings:

• Basal Rate (your basal rate in units/hr)

• Correction Factor (amount 1 unit of insulin lowers BG)

• Carb Ratio (grams of carbs covered by 1 unit of insulin)

• Target BG (your ideal BG level, measured in mg/dL)

The ranges you can set for Timed Settings are:

• Basal (range: 0 and 0.5 – 15 units/hr)

- Correction Factor (range: 1 unit:1 mg/dL – 1 unit:600 mg/dL)

- Carb Ratio (range: 1 unit:1 gram – 1 unit:300 grams)

- Target BG (range: 70 mg/dL – 250 mg/dL)

  NOTE
  Below a carb ratio of 1:10, increments can be entered in 0.1 g. For example a carb ratio of 1:8.2 can be programmed.

In addition, you can set any or all of the following Bolus Settings:

- Carbs (on indicates entering grams of Carb; off indicates entering units of insulin)

- Insulin Duration (how long a bolus lowers your BG)

- Max Bolus (the maximum amount for a single bolus)

The default settings and ranges for Bolus Settings are as follows:

- Carbs (default: off if no Carb Ratio is defined)

- Insulin Duration (default: 5 hrs; range: 2–8 hrs)

- Max Bolus (default: 10 units; range: 1–60 units)

Insulin Duration and Insulin on Board (IOB)

Your t:flex Pump remembers how much insulin you have taken from previous boluses. It does this by relying on the Insulin Duration. The Insulin Duration reflects the amount of time that insulin is actively lowering your BG.

Insulin Duration in your t:flex Pump is set from the factory at 5 hours but can be changed from 2 to 8 hours. Please consult your healthcare provider to accurately set your Insulin Duration.

While the Insulin Duration setting reflects how long insulin from previous boluses lowers your BG, the IOB feature reflects how much insulin is remaining in your body from previous boluses. IOB is always displayed on the Home Screen and is used in bolus delivery calculations when applicable. When a BG is entered during bolus programming, your t:flex Pump will consider any active IOB and calculate an adjusted bolus if necessary.

NOTE
Although you do not need to define every setting, some pump features require certain settings to be defined and activated. During profile setup, your pump prompts you to set up any required settings before you can continue.

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Personal Profiles**.

4. Tap **NEW** to create a new profile.

5. Using the onscreen keypad, enter a profile name (up to 16 characters) and tap **SAVE**.

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Key Pump Features

📄 **NOTE**

Tap once for first letter displayed, 2 quick taps for middle letter; and 3 quick taps for the third letter.

6. Tap **Press to Setup** to begin setting insulin delivery settings.

BACK	Weekday

Timed Settings

Press to Set Up

Bolus Settings

5 hrs	10 u	OFF
DURATION	MAX BOLUS	CARBS
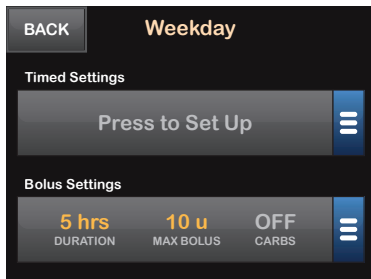
6.3   Programming a New Personal Profile

📄 **NOTE**
Once the Personal Profile has been created, the settings must be programmed. The first time segment will start at 12:00 AM (midnight).
» You must program a basal rate in order to have a Personal Profile that you can activate.
» Be sure to tap SAVE after entering or changing a value.

⚠ **PRECAUTION**
If you only define a basal rate in Timed Settings your pump will only be able to deliver basal insulin and standard and extended boluses. Your pump will not deliver correction boluses or trigger BG alerts.

Timed Settings

BACK	12:00 AM	SAVE

Basal	Press to Set Up
Correction Factor	Press to Set Up
Carb Ratio	Press to Set Up
Target BG	Press to Set Up

1. Once the new profile has been created, Tap **Basal**.

2. Using the onscreen keypad, enter your basal rate and tap **DONE**.

    ⚠ **PRECAUTION**
    Always confirm that the decimal point placement is correct.

3. Tap **Correction Factor**.

4. Using the onscreen keypad, enter your correction factor and tap **DONE**.

    📄 **NOTE**
    Enter the mg/dL that 1 unit of insulin will lower BG.

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5. Tap **Carb Ratio**.

6. Using the onscreen keypad, enter your insulin-to-carbohydrate ratio and tap **DONE**.

    📄 NOTE
    Enter the grams of carb to be covered by 1 unit of insulin.

7. Tap **Target BG**.

8. Using the onscreen keypad, enter your target BG and tap **DONE**.

9. Review entered values and tap **SAVE**.

10. Confirm Settings.

    Tap **YES** if entered data is correct.

    Tap **NO** to make changes.

11. Tap **BACK** to set the Bolus Settings.

    Tap **ADD** to create additional time segments.

BACK	Timed Settings	ADD

    12:00 AM

0.75	1:50	1:10	120
BASAL	CORRECT	CARB	TARGET BG
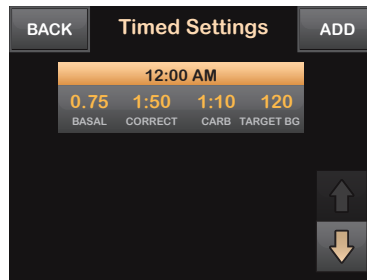
Adding More Time Segments

📄 NOTE
Any settings that you entered in the previous time segment are copied and appear in the new segment. This allows you to simply adjust only the specific settings you want, rather than have to enter them all over again.

1. On the "Add Segment" screen, tap **Start Time**.

2. Using the onscreen keypad, enter the time (hour and minutes) that you want the segment to begin, and tap **DONE**.

3. On the "Add Segment" screen, tap **Time of Day** to select AM or PM.

4. Tap **NEXT**.

5. Repeat steps 1–10 from the "Programming a New Personal Profile" section above for each segment you want to set up (up to 16).

    📄 NOTE
    Once a time segment is set beyond 12:00 PM, the default will change to PM.

    📄 NOTE
    To find time segments in the list that are not displayed on the first screen, tap the scroll arrows.

Bolus Settings

1. Tap the **Bolus Settings Panel**.

```
BACK          Weekday

Timed Settings 12:00a - 12:00a

0.75    1:50    1:10    120
BASAL   CORRECT  CARB  TARGET BG

Bolus Settings

5 hrs     10 u      OFF
DURATION  MAX BOLUS  CARBS
```

2. Tap **Insulin Duration**.
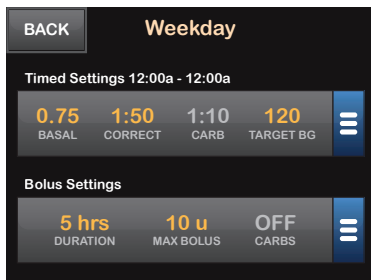
```
BACK      Bolus Settings      SAVE

Insulin Duration        5 hrs

Max Bolus               10 u

Carbohydrates       OFF    ON
```
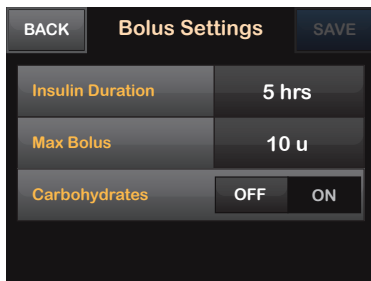
3. Using the onscreen keypad, enter the desired time for the duration of insulin action (2-8 hrs) and tap **DONE**.

4. Tap **Max Bolus**.

5. Using the onscreen keypad, enter the desired amount for maximum bolus (1–60 units) and tap **DONE**.

6. Tap **Carbohydrates** to turn on and use the carb ratio when calculating boluses.

    📄 NOTE
    If not using a carb ratio, do not turn the Carbohydrates setting to ON.

7. Review entered values and tap **SAVE**.

8. Confirm Settings.

    Tap **YES** if entered data is correct.

    Tap **NO** to make changes.

9. Tap **Tandem Logo** to return to the Home Screen.

    📄 NOTE
    Editing, duplicating and renaming an inactive profile will not automatically activate that profile. Refer to Chapter 6.6 for instructions on activating profiles.

Adding More Personal Profiles

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Personal Profiles**.

4. Tap **NEW**.

5. Name the new profile and repeat steps for Timed Settings and Bolus Settings.

    📄 NOTE
    If the first profile is programmed using a carb ratio, any new profile will also have the Carbohydrates option turned ON, but a ratio will still need to be defined.

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6.4 Editing or Reviewing an Existing Profile

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Personal Profiles**.

4. Tap the name of the Personal Profile to edit or review.

5. Tap **Edit**.

6. Tap **Timed Settings Panel**.

7. Tap the desired time segment to edit.

8. Tap **Basal**, **Correction Factor**, **Carb Ratio** or **Target BG** to make changes as needed and use the onscreen keypad to enter changes. Tap **DONE**.

9. View recent changes and tap **SAVE**.

10. Confirm Settings.

    Tap **YES** if entered data is correct.

    Tap **NO** to make changes.

11. Tap **BACK** after editing all of the time segments.

    NOTE
    Edit other time segments within the Timed Settings by tapping on them and using the same steps described above.

    NOTE
    To Add a time segment:
    » Tap **ADD**.
    » Enter desired start time.
    To Delete a time segment:
    » Tap on the **X** to the left of the time segment.
    » Tap **YES** to confirm.

12. Tap the **Bolus Settings Panel** to change DURATION, MAX BOLUS or CARBS as needed. Use the onscreen keypad to enter desired changes. Tap **SAVE**.

13. Confirm Settings.

    Tap **YES** if entered data is correct.

    Tap **NO** and make changes.

14. Tap **Tandem Logo** to return to the Home Screen.

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Key Pump Features

6.5   Duplicating an Existing Profile

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Personal Profiles**.

4. Tap the name of the Personal Profile to duplicate.

5. Tap **Duplicate**.

6. Confirm profile to duplicate by tapping **YES**.

7. Using the onscreen keypad, enter the name (up to 16 characters) for the new profile and tap **SAVE**.

▷   "Profile Duplicated" screen is displayed.

▷   A new Personal Profile will be created with the same settings as the profile copied.

8. Tap the **Timed Settings** or **Bolus Settings Panel** to make changes to the new profile.

6.6   Activating an Existing Profile

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Personal Profiles**.

4. Tap the name of the Personal Profile to be activated.

    📄 NOTE
    » The Activate and Delete options are disabled for the active profile because the profile is already activated. You cannot delete a profile until you have activated another profile.
    » If you have only 1 profile defined, you do not need to activate it (that profile is automatically activated).

5. Tap **Activate**.

▷   A screen to confirm the activation request is displayed.

6. Tap **YES**.

▷ "Profile Activated" screen is displayed.

6.7 Renaming an Existing Profile

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Personal Profiles**.

4. Tap the name of the Personal Profile to be renamed.

5. Tap **Down Arrow**, and then **Rename**.

6. Using the onscreen keypad, rename the profile name (up to 16 characters) and tap **SAVE**.

7. Tap **Tandem Logo** to return to the Home Screen.

6.8 Deleting an Existing Profile

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Personal Profiles**.

4. Tap the name of the Personal Profile to be deleted.

   📄 **NOTE**
   The active Personal Profile cannot be deleted.

5. Tap **Delete**.

6. Tap **YES**.

▷ "Profile Deleted" screen is displayed.

7. Tap **Tandem Logo** to return to the Home Screen.

2

Key Pump Features

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Bolus

7.1   Bolus Overview

A bolus is a quick dose of insulin that is usually delivered to cover food eaten or to correct a high BG.

Your t:flex Pump offers you the ability to deliver different boluses to cover carbohydrate intake (food bolus) and bring your BG back to target (correction bolus). Food and correction boluses can also be programed together.

If Carbohydrates is turned on in your active personal profile, you will enter grams of carbohydrate and the bolus will be calculated using your Carb Ratio.

You can always override the calculated bolus by tapping the area above "units" located at the top of the bolus screen between BACK and NEXT. The override function is always active.

If Carbohydrates is turned off in your active personal profile, you will enter units of insulin to request the bolus.

⚠ WARNING
Do not deliver a bolus until you have reviewed the calculated bolus amount on the pump display. If you dose an insulin amount that is too high or too low, this could lead to a very low or very high BG level. You can always adjust the insulin units up or down before you decide to deliver your bolus.

⚠ PRECAUTION
» Before delivering insulin, always check your pump and infusion set for damage, leaks, or kinks in the tubing, as these problems could restrict or stop insulin delivery and possibly result in under-infusion.
» Before delivering insulin, check your t:flex Pump's personal settings to ensure they are correct.

📄 NOTE
When attempting to deliver a bolus that exceeds the amount of insulin remaining in the cartridge, a message screen appears indicating there is not enough insulin to deliver the requested bolus. You are required to enter a new amount.

7.2   Food Bolus Using Units

📄 NOTE
If bolusing using a carb ratio skip to the next chapter, Food Bolus Using Grams.

1. From the Home Screen, tap BOLUS.

2. Tap 0 units.

3. Using the onscreen keypad enter units of insulin to be delivered, then tap DONE.

    ⚠ PRECAUTION
    Always confirm that the decimal point placement is correct.

4. Tap NEXT to confirm the units of insulin to be delivered.

5. Confirm Request.

    Tap YES if entered data is correct.

    Tap NO to go back to make changes or view calculations.

6. Tap DELIVER.

7. The bolus splash screen is displayed.

7.3   Food Bolus Using Grams

1. From the Home Screen, tap **BOLUS**.

2. Tap **0 grams**.

3. Using the onscreen keypad enter grams of carb and tap **DONE**.

   📄 NOTE
   » To add multiple carb values enter first value, then tap +/=, enter second value, tap +/=. Continue until done.
   » To clear the value entered and start over, tap the back arrow.

4. Check that the grams of carb are entered in the correct location on the screen.

5. Tap **NEXT** to confirm the units of insulin to be delivered.

   📄 NOTE
   Tap View Calculation to display the Delivery Calculation screen.

   📄 NOTE
   Tap the displayed units calculated to override the amount.

6. Confirm Request.

   Tap **YES** if entered data is correct.

   Tap **NO** to go back to make changes or view calculations.

7. Tap **DELIVER**.

8. The bolus splash screen is displayed.

7.4   Correction Bolus

1. From the Home Screen, tap **BOLUS**.

2. Tap **Add BG**.

3. Using the onscreen keypad, enter BG value and tap **DONE**.

   📄 NOTE
   Once DONE is tapped, the BG value is saved in pump History whether or not a bolus is delivered.
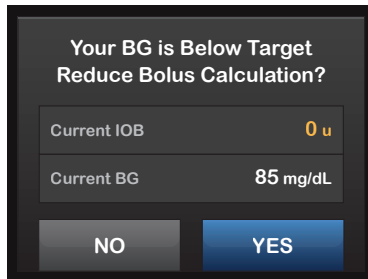
   📄 NOTE
   » Tap the view calculation screen to display the Delivery Calculation Screen.
   » Tap the displayed units calculated to override the amount.

If BG is above the Target BG, a message screen will indicate BG is above Target.

**Your BG is Above Target
Add Correction Bolus?**

| Current IOB | 0 u |
| Current BG | 280 mg/dL |

| NO | YES |
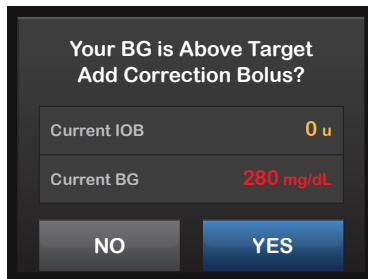
To add a correction bolus tap **YES.**

If BG is below Target BG, a message screen will indicate BG is below Target.

**Your BG is Below Target
Reduce Bolus Calculation?**

| Current IOB | 0 u |
| Current BG | 85 mg/dL |

| NO | YES |

To reduce bolus calculation tap **YES**.

📄 NOTE
When your blood glucose is:
» Above Target BG: the insulin for the food bolus and the correction bolus will be added together. If IOB is present, it will only be used in the calculation of the correction portion of the bolus.
» Between 70 mg/dL and Target BG: You will be given an option to reduce the food bolus to correct for the low blood glucose. In addition, if IOB is present, it will also be used to reduce the bolus calculation.
» Below 70 mg/dL: The food bolus will be reduced to automatically correct for the low blood glucose. In addition, if IOB is present, it will also be used to reduce the bolus calculation.

Always treat hypoglycemia (low blood glucose) with fast-acting carbohydrates according to the instructions of your healthcare provider and then re-test your blood glucose to ensure that the treatment was successful.

4. Tap **NEXT** to confirm the units of insulin to be delivered.

5. Confirm Request.

   Tap **YES** if entered data is correct.

   Tap **NO** to go back to make changes or view calculations.

6. Tap **DELIVER**.

7. The bolus splash screen is displayed.

7.5   Extended Bolus

The Extended Bolus feature allows you to deliver part of the bolus now and part of the bolus slowly over a period of up to 8 hours. This can be helpful for high fat meals such as pizza or if you have gastroparesis (delayed stomach emptying). Talk with our healthcare provider to determine if this feature is appropriate for you as well as for recommendations on the split between now and later and the duration for the later portion.

Only 1 extended bolus can be active at any given time. However, if the DELIVER LATER portion of an extended bolus is active, you can request another standard bolus.

1. From the Home Screen, tap **BOLUS**.

2. Tap **0 grams** (or 0 **units**).

3. Using the onscreen keypad enter grams of carb (or units of insulin). Tap **DONE**.

4. If desired, tap **Add BG** and using the onscreen keypad enter BG value. Tap **DONE**.

5. Tap **NEXT** to confirm the units of insulin to be delivered.

   📄 NOTE
   Tap View Calculation to display the Delivery Calculation screen.

6. Confirm Request.

   Tap **YES** if entered data is correct.

   Tap **NO** to go back to make changes or view calculations.

7. Tap **EXTENDED** to turn on the extended feature, then tap **NEXT**.

8. Tap **50%** under DELIVER NOW to adjust the percentage of the food bolus that is to be delivered immediately.

   📄 NOTE
   The percentage value for DELIVER LATER is automatically calculated by the pump. The default is 50% NOW and 50% LATER. The default for DURATION is 2 hours.

📄 NOTE
A correction bolus will always be given in the DELIVER NOW portion.

9. Use the onscreen keypad to enter the percentage of the bolus to DELIVER NOW and tap **DONE**.

📄 NOTE
For the DELIVER NOW portion, the minimum amount is 0.5 units. If the DELIVER NOW portion is less than 0.5 units, you will be notified and the DELIVER NOW portion will be set to 0.5 units.

10. Tap **2 hrs** under DURATION.

📄 NOTE
The DELIVER LATER portion of the Extended Bolus also has minimum and maximum rates. If you program a DELIVER LATER rate outside of these limits, you will be notified and the duration of the DELIVER LATER portion will be adjusted.

11. Use the onscreen keypad to adjust the length of time the bolus is to be delivered, then tap **DONE**.

12. Tap **NEXT**.

📄 NOTE
Tap View Units to display the breakdown of units to be delivered NOW versus LATER.

13. Confirm Request.

Tap **YES** if entered data is correct.

Tap **NO** to go back to make changes or view calculations.

14. Tap **DELIVER**.

15. The bolus splash screen is displayed.

7.6   Canceling or Stopping a Bolus

Canceling a Bolus If delivery Has Not Started

1. Tap **1-2-3** to access the Home Screen.

2. Tap **X** (stop icon) to cancel the bolus.
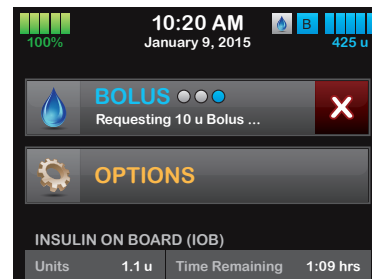
▷ The bolus button will remain inactive while the bolus is being canceled.

▷ Once canceled, the bolus button will become active again on the Home Screen.

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Key Pump Features

Stopping a Bolus if delivery of the bolus <u>Has Started</u>:

1. Tap **1-2-3** to access the Home Screen.

2. Tap **X** (stop icon) to stop delivery.

3. Tap **YES**.

▷ The BOLUS STOPPED screen is displayed and the units delivered are calculated.

4. Units requested and delivered are shown. Tap **CLOSE**.

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Stop/Resume Insulin

8.1   Stopping Insulin Delivery

You can stop all insulin deliveries, including basal, and any active bolus or temp rate at any time.

1. From the Home Screen, tap **OPTIONS**.

2. Tap **STOP INSULIN**.

3. Tap **STOP**.

▷ The "All Deliveries Stopped" screen appears before returning to the Home Screen showing the status "ALL DELIVERIES STOPPED". A red exclamation mark icon also appears to the right of the time and date.

> 📄 **NOTE**
> When you tap STOP on the confirmation screen, any active bolus and any active temp rate are immediately stopped. If you tap BACK on the confirmation screen, bolus delivery continues.
> » No insulin delivery can take place while your pump is stopped.

8.2   Resuming Insulin Delivery

1. If pump screen is not on, press **Screen On/Quick Bolus Button** once to turn on your t:flex Pump screen.

2. Tap **1-2-3** to access the Home Screen.

3. Tap **RESUME**.

4. The RESUMING INSULIN splash screen is displayed.

– OR –

1. From the Home Screen, tap **OPTIONS**.

2. Tap **RESUME INSULIN**.

3. Tap **RESUME**.

4. The RESUMING INSULIN splash screen is displayed.

2

Key Pump Features

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Additional Pump Operations

Chapter 9

Temporary Basal Rate

9.1   Setting a Temp Rate

A Temp Rate is used to increase or decrease (by percentage) the current basal rate for a period of time. This feature can be helpful for situations such as exercise or illness.

When you enter the Temp Rate screen, the default values are 100% (current basal rate) and a Duration of 0:15 min. The Temp Rate can be set from a minimum of 0% of current basal rate to a maximum of 250% of current basal rate in increments of 1%.

Duration can be set from a minimum of 15 minutes to a maximum of 72 hours in increments of 1 minute.

If you program a Temp Rate greater than 0% but less than the minimum allowable basal rate of 0.5 units/hr, you will be notified that the selected rate is too low and that it will be set to the minimum allowable rate for delivery.

If you program a Temp Rate more than the maximum allowable basal rate of 15 units/hr, you will be notified that the selected rate is too high and that it will

be set to the maximum allowable rate for delivery.

1. From the Home Screen, tap **OPTIONS**.

2. Tap **Temp Rate**.

3. Tap **Temp Rate**.

4. Using the onscreen keypad enter desired percentage. Tap **DONE**.

    📄 NOTE
    Current rate is 100%. An increase is greater than 100% and decrease is less than 100%.

5. Tap **Duration**. Using the onscreen keypad enter desired length of time for Temp Rate. Tap **DONE**.

    📄 NOTE
    To see the actual units to be delivered tap View Units.

6. Verify settings and tap **START**.

7. The "TEMP RATE STARTED" splash screen is displayed.

📄 NOTE
If a Temp Rate is active, the status of insulin delivery displays an orange "T". If a Temp Rate of 0% is active, the status of insulin delivery displays a red "T".

8. The Screen Lock screen will be displayed with the icon indicating a Temp Rate is active.

9.2   Stopping a Temp Rate

To stop an active temp rate:

1. From the Home Screen, tap **OPTIONS**.

2. On the Options screen, tap **X** (stop icon) on the right side of Temp Rate.

3. On the confirmation screen, tap **STOP**. The "TEMP RATE STOPPED" screen appears before returning to the Options screen.

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Additional Pump Operations

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Chapter 10

Quick Bolus

10.1   Setting Up Quick Bolus

Setting up the Quick Bolus function enables you to deliver a bolus by simply pressing a button. It is a way to deliver a bolus by following beep/vibration commands without navigating through or viewing the pump screen.

The default for the Quick Bolus function is off. Quick Bolus can be set to either units of insulin or grams of carbohydrate. The increment options are 0.5, 1.0, 2.0, and 5.0 units; or 2, 5, 10 and 15 grams of carb.

The quick bolus delivery setting (grams of carbohydrate or units of insulin) is independent of the active Personal Profile bolus setting.

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Pump Settings**.

4. Tap **Quick Bolus**.

5. Tap **Increment Type**.

6. Tap **units of insulin** or **grams of carbohydrate** to select.

7. Tap **Increment Amount**.

8. Select the preferred increment amount.

    📄 **NOTE**
    The increment amount is added with each press of the Quick Bolus Button when delivering a quick bolus.

9. Review entered values and tap **SAVE**.

10. Confirm Settings.

    Tap **YES** if entered data is correct.

    Tap **NO** to go back to make changes.

11. Tap **Tandem Logo** to return to the Home Screen.

10.2   Delivering Quick Bolus

If the Quick Bolus function is turned On, you can deliver a bolus without having to look at the t:flex Pump's screen. Simply use the Quick Bolus Button to deliver your bolus. Quick boluses are delivered as standard boluses (there is no BG entry or extended bolus).

⚠ PRECAUTION
When you first use the Quick Bolus feature, you should always look at the screen to confirm correct programming until you are comfortable with this feature. Before delivering insulin, check your t:flex Pump's personal settings to ensure they are correct.

1. Press and hold **Quick Bolus Button**. The Quick Bolus screen will appear. Listen for 2 beeps (if Pump Volume is set to beep) or feel for vibrations (if Pump Volume is set to vibrate).

    📄 **NOTE**
    The t:flex Pump will beep and vibrate during a Quick Bolus if a beep volume is set. It will only vibrate if the vibrate option is selected.

2. Press **Quick Bolus Button** for each increment until desired amount is reached. The pump will beep/vibrate for each button press.

3. The pump will beep/vibrate once for each increment pressed to confirm desired amount.

4. After the pump beeps/vibrates, press and hold **Quick Bolus Button** to deliver the bolus.

   📄 **NOTE**
   » If more than 10 seconds have passed with no input, the bolus is canceled and never delivered.
   » If you want to cancel the bolus and return to the Home Screen, tap CANCEL on the QUICK BOLUS screen.
   » If the amount you indicated by your button presses exceeds the Max Bolus amount defined in your active Personal Profile, a different tone will sound, and the Quick Bolus Button does not respond to any more button presses.

   » If you hear a different tone at any point during programming, look at the screen to confirm the bolus amount. If the Quick Bolus screen does not display the correct bolus amount, use the touch screen to enter bolus information.

5. The bolus splash screen is displayed.

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Chapter 11

t:flex Pump Settings

11.1   t:flex Pump Volume

Pump Volume is pre-set to high. A change to the Pump Volume can be made in Pump Settings.

Pump Volume can be personalized for the Button taps, Quick Bolus, Bolus, Reminders, Alerts, and Alarms. Options for Pump Volume include high, medium, low and vibrate.

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Pump Settings**.

4. Tap **Pump Volume**.

5. Tap desired option. Use **Up/Down Arrow** to view additional options.

6. Select preferred volume.

7. Continue to make changes for all Pump Volume options by repeating steps 5 and 6.

    Tap **SAVE** when all changes are complete.

8. Tap **Tandem Logo** to return to the Home Screen.

11.2   Screen Options

The Screen Options for your t:flex Pump include Screen Timeout and Feature Lock.

You can set the Screen Timeout to the length of time you want the screen to stay on. The default for the Screen Timeout is 30 seconds. The options are 15, 30, 60, and 120 seconds.

Feature Lock is pre-set to off. With the Feature Lock turned on, you cannot deliver a bolus, change any pump settings or access any Personal Profiles.

📄 **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.

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Pump Settings**.

4. Tap **Screen Options**.

5. Tap desired option.

For Screen Timeout

1. Tap **Screen Timeout**.

2. Select preferred time and tap **SAVE**.

3. Tap **Tandem Logo** to return to the Home Screen.

For Feature Lock

1. Tap **Feature Lock** to turn On or Off and tap **SAVE**.

▷ A screen to verify that you want to activate the Feature Lock will be displayed.

2. Tap **YES** to confirm.

3. Tap **SAVE**.

4. Tap **Tandem Logo** to return to the Home Screen.

NOTE
If Feature Lock is turned on, Pump Volume will be set to high until the Feature Lock is turned off.

To Turn the Feature Lock Off

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Pump Settings**.

4. Tap **Screen Options**.

5. Tap **Feature Lock**.

6. Tap **YES**.

7. Tap **SAVE**.

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Additional Pump Operations

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t:flex Pump Info and History

12.1　t:flex Pump Info

Your t:flex Pump allows access to information about your pump. In the Pump Info screen you have access to items such as your pump Serial Number, Tandem Diabetes Care Customer Technical Support telephone number, website, and software/hardware versions.

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Pump Info**.

4. Scroll through the Pump Info using the **Up/Down Arrows**.

5. Tap **Tandem Logo** to return to the Home Screen.

12.2　t:flex Pump History

Pump History displays a historical log of pump events. Up to 90 days of data (11,000 events) can be viewed in History. When the maximum number of events is reached, the oldest events are removed from the history log and replaced with the most recent events. The following can be viewed in History:

Delivery Summary, Total Daily Dose, Bolus, Basal, Load, BG, Alerts and Alarms, and Complete.

Delivery Summary breaks down total insulin delivery by basal and bolus types into units and percentages. It can be viewed by the selected time period of: Today, 7 Day, 14 Day and 30 Day Average.

Total Daily Dose breaks down basal and bolus delivery into units and percentages for each individual day. You can scroll through each individual day to see your total insulin delivery.

The Bolus, Basal, Load, BG, Alerts and Alarms, and Complete are categorized by date. The event details in each report are listed by time.

The letter "D" (D: Alert) before an Alert or Alarm indicates the time it was declared. The letter "C" (C: Alert) indicates the time it was cleared.

Bolus History shows the bolus request, the bolus start time, and the bolus completion time.

1. From the Home Screen, tap **OPTIONS**.

2. Tap the **Down Arrow**.

3. Tap **History**.

4. Tap desired option.

5. Tap **Tandem Logo** to return to the Home Screen.

t:flex Pump Reminders

Your t:flex Pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check you BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been confirmed.

Information in this section will help you learn how to respond to Reminders.

Reminders notify you with a single sequence of 3 notes or a single vibration depending on the volume/vibrate setting in Pump Volume. They repeat every 10 minutes until acknowledged. Reminders do not escalate.

13.1   Low BG Reminder

The Low BG Reminder prompts you to re-test your BG after a low BG value is entered. When turning this reminder on, you need to set a low BG value that triggers the reminder, as well as how much time should pass before the reminder occurs.

The default for this reminder is pre-set to off. If on, Remind Me Below 70 mg/dL, and Remind Me After 15 min, but you can set these values from 70–120 mg/dL and 10–20 min.

1.   From the Home Screen, tap **OPTIONS**.

2.   Tap **My Pump**.

3.   Tap **Alert Settings.**

4.   Tap **Pump Reminders**.

5.   Tap **Low BG**.

   📄 NOTE
   If not first-time setup, previous values appear instead of "Press to Turn On."

6. Low BG is set to on; to turn off, tap **LOW BG**.

   a. Tap **Remind Me Below** and using the onscreen keypad, enter a Low BG value (from 70–120 mg/dL) that you want to trigger the reminder, then tap **DONE**.

   b. Tap **Remind Me After** and using the onscreen keypad, enter the time (from 10–20 min), then tap **DONE**.

   c. Tap **SAVE** when all changes are complete.

   d. Tap **Tandem Logo** to return to the Home Screen.

To Respond to the Low BG Reminder

To clear the reminder, tap **CLOSE** and then check BG using your blood glucose meter.

13.2   High BG Reminder

The High BG Reminder prompts you to re-test your BG after a high BG value is entered. When you turn this reminder on, you need to set a high BG value that triggers the reminder, as well as how much time should pass before the reminder occurs.

The default for this reminder is pre-set to off. If on, Remind Me Above 200 mg/dL, and Remind Me After 120 min, but you can set these values from 150–300 mg/dL and 1–3 hrs.

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Alert Settings**.

4. Tap **Pump Reminders**.

5. Tap **High BG**.

   ⊟ NOTE
   If not first-time setup, previous values appear instead of "Press to Turn On".

6. High BG is set to on; to turn off, tap **High BG**.

   a. Tap **Remind Me Above** and using the onscreen keypad, enter a High BG value (from 150–300 mg/dL) that you want to trigger the reminder, then tap **DONE**.

   b. Tap **Remind Me After** and using the onscreen keypad, enter the time (from 1–3 hours), then tap **DONE**.

   c. Tap **SAVE** when all changes are complete.

7. Tap **Tandem Logo** to return to the Home Screen.

To Respond to the High BG Reminder

To clear the reminder tap **CLOSE** and then check BG using your blood glucose meter.

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Additional Pump Operations

13.3   After Bolus BG Reminder

The After Bolus BG Reminder prompts you to test your BG at a selected time after bolus delivery. When turning this reminder on, you need to set how much time should pass before the reminder occurs. The default is 1 hour and 30 minutes. It can be set from 1–3 hours.

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Alert Settings**.

4. Tap **Pump Reminders**.

5. Tap **After Bolus BG**.

> **NOTE**
> If not first-time setup, previous values appear instead of "Press to Turn On".

6. After Bolus BG is set to on; to turn off, tap **After Bolus BG**.

    a. Tap **Remind Me After** and using the onscreen keypad, enter the time (from 1–3 hours) that you want to trigger the reminder, then tap **DONE**.

7. Tap **SAVE** when all changes are complete.

8. Tap Tandem Logo to return to the Home Screen.

To Respond to the After Bolus BG Reminder

To clear the reminder tap CLOSE and then check BG using your blood glucose meter.

13.4   Missed Meal Bolus Reminder

The Missed Meal Bolus Reminder lets you know if a bolus was not delivered during a specified time period. 4 separate reminders are available. When programming this reminder you need to select the Days, the Start Time, and End Time for each reminder.

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.

3. Tap **Alert Settings**.

4. Tap **Pump Reminders**.

5. Tap **Missed Meal Bolus**.

> **NOTE**
> If not first-time setup, previous values appear instead of "Press to Set Up".

6. On the Missed Meal Bolus screen, tap which reminder you want to set (Reminder 1–4) and do the following:

   a. Tap **Reminder 1** (or 2, 3, 4).

   b. Reminder 1 is set to on; to turn **off**, tap **Reminder 1**.

   c. Tap **Selected Days** and tap the day(s) you want the reminder to be on, then tap **BACK**.

   d. Tap **Start Time**, tap **Time** and using the onscreen keypad enter the start time, then tap **DONE**.

   e. Tap **Time of Day** to select AM or PM, then tap **DONE**.

   f. Tap **End Time**, tap **Time** and using the onscreen keypad enter the end time, then tap **DONE**.

   g. Tap **Time of Day** to select **AM** or **PM**, then tap **DONE**.

   h. Tap **SAVE** when all changes are complete.

7. Tap **Tandem Logo** to return to the Home Screen.

To Respond to the Missed Meal Bolus Reminder

To clear the reminder tap **CLOSE** and deliver a bolus if necessary.

13.5   Site Reminder

The Site Reminder prompts you to change your infusion set. The default for this reminder is pre-set to off. If on, the reminder can be set for 1–3 days and at a time of day selected by you.

For detailed information on the Site Reminder feature, refer to Chapter 5.6.

To Respond to the Site Reminder

To clear the reminder tap **CLOSE** and change your infusion set.

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Additional Pump Operations

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Chapter 14

User Settable Alerts and Alarms

14.1   Low Insulin Alert

Your t:flex Pump keeps track of how much insulin remains in the cartridge and alerts you when it is low. The default for this alert is pre-set to 40 units. You can set this alert setting anywhere between 20 and 60 units. When the insulin amount reaches the set value, the Low Insulin Alert beeps/vibrates and appears on the screen.

1.   From the Home Screen, tap **OPTIONS**.

2.   Tap **My Pump**.

3.   Tap **Alert Settings**.

4.   Tap **Pump Alerts**.

5.   Tap **Low Insulin**.

6.   Using the onscreen keypad, enter the number of units (from 20–60 units) that you want the Low Insulin Alert value to be set, and tap **DONE**.

7.   Tap **SAVE** when all changes are complete.

To Respond to the Low Insulin Alert

LOW INSULIN ALERT

Cartridge level:
Less than 20 u remaining.
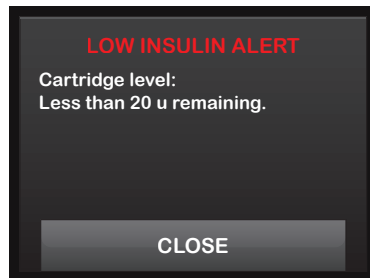
CLOSE

To clear the alert, tap **CLOSE**.

NOTE
Once the LOW INSULIN ALERT occurs, the low insulin indicator (a single red bar on the insulin level) appears in the upper right corner of the Home Screen.

14.2   Auto-Off Alarm

Your t:flex Pump can stop insulin delivery and alert you (or whoever is with you) if there has been no interaction with the pump within a specified period of time. The default for this alarm is pre-set to 12 hours. You can set it anywhere between 5 and 24 hours, or off. This alarm notifies you that there has been no interaction with the pump in the specified number of hours and the pump will shut down after 30 seconds.

When the number of hours since you have tapped on the screen or pressed the Screen On/Quick Bolus Button passes the set value, the Auto-Off Alarm beeps and appears on the screen, and insulin delivery stops.

1.   From the Home Screen, tap **OPTIONS**.

2.   Tap **My Pump**.

3.   Tap **Alert Settings**.

4.   Tap **Pump Alerts**.

5.   Tap **Auto-Off**.

📄 **NOTE**
A confirmation screen will appear. Tap YES to continue. Tap NO to go back.

6. Verify Auto-Off is set to on, then tap **Time**.

7. Using the onscreen keypad, enter the number of hours (from 5–24 hrs) that you want the Auto-Off Alarm to be triggered, and tap **DONE**.

8. Tap **DONE**, then tap **SAVE** when all changes are complete.

9. Tap **Tandem Logo** to return to the Home Screen.

To Respond to Auto-Off Warning

> **WARNING**
> **Auto-Off alarm will shut pump down if no action is taken.**
>
> No buttons pressed in: **12 hrs**
>
> Pump will shut down in: **30 sec**
>
> **DO NOT SHUT DOWN**
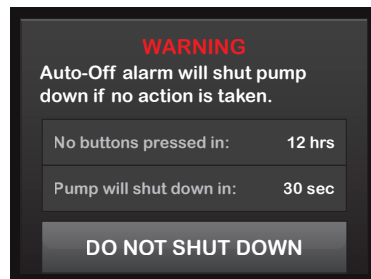
1. Tap **DO NOT SHUT DOWN**.

The warning clears and the pump returns to normal operation.

If you do not clear the warning within the 30-second countdown period, the AUTO-OFF ALARM occurs, accompanied by an audible alarm. This alarm notifies you that your pump has stopped delivering insulin.

Auto-Off Alarm Screen

> **AUTO-OFF ALARM**
> **ALL DELIVERIES STOPPED!**
>
> **No activity for more than 6 hours.**
>
> **CLOSE**
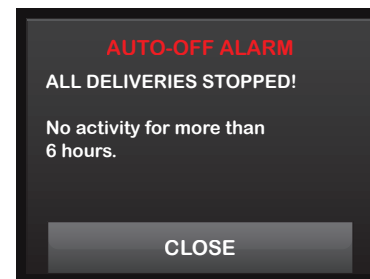
1. Tap **CLOSE**. The Home Screen then appears, indicating a status of "All Deliveries Stopped." You must resume delivery to continue therapy, (refer to Chapter 8.2).

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Additional Pump Operations

Section 4

t:flex Pump Safety
Alerts and Alarms

t:flex Pump Alerts

Your t:flex Pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check you BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been confirmed.

Information in this section will help you learn how to respond to Alerts.

Alerts notify you with 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume. They repeat regularly until acknowledged. Alerts do not escalate.

15.1   Low Insulin Alert

What will I see on the Screen?	What does it mean?
LOW INSULIN ALERT **Change cartridge or pump will stop all deliveries.** **CLOSE**	10 units or less of insulin remain in the cartridge.
	How will the system notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap **CLOSE**. Change your cartridge as soon as possible to avoid the EMPTY CARTRIDGE ALARM and running out of insulin.

4

t:flex Pump Safety Alerts and Alarms

15.2   Low Power Alerts
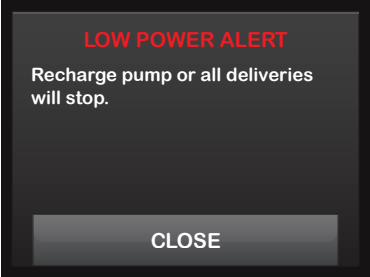
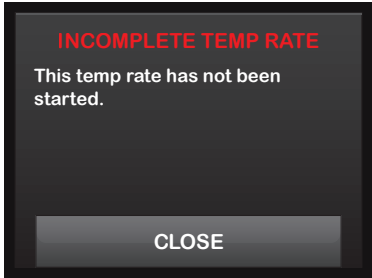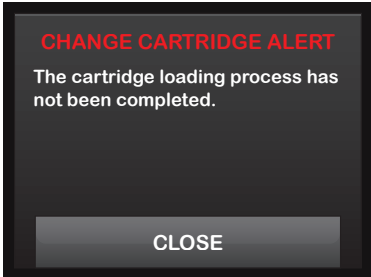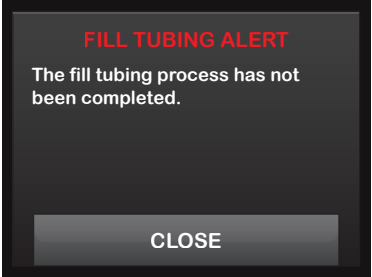| **Low Power Alert 1** **What will I see on the Screen?** **LOW POWER ALERT** Power Level: Less than 25% remaining. **CLOSE**	**What does it mean?** Less than 25% of battery power remains.
	How will the system notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap CLOSE. Charge your pump as soon as possible to avoid the second LOW POWER ALERT.

📄 **NOTE**
Once the LOW POWER ALERT occurs, the low-power indicator (a single red bar on the battery level indicator) appears on the Home Screen

📄 **NOTE**
The battery level display will decrease by 5% at a time. At 5% it will decrease by 1% at a time.

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Low Power Alert 2	**What does it mean?**
What will I see on the Screen?	Less than 5% of battery power remains. Insulin delivery will continue for 30 minutes and then the pump will power off and insulin delivery will stop.
LOW POWER ALERT Recharge pump or all deliveries will stop. **CLOSE**	**How will the system notify me?** 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap **CLOSE**. Charge your pump immediately to avoid the LOW POWER ALARM and system power off.

📄 **NOTE**
Once the second LOW POWER ALERT occurs, the low-power indicator (a red 5% on the battery level indicator) appears on the Home Screen.

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t:flex Pump Safety Alerts and Alarms

15.3   Incomplete Bolus Alert
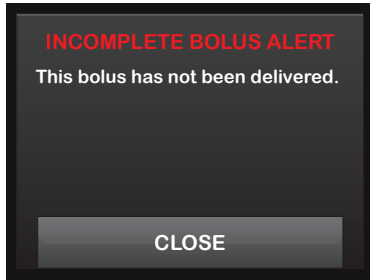
What will I see on the Screen?	
INCOMPLETE BOLUS ALERT This bolus has not been delivered. CLOSE	**What does it mean?** You started a bolus request but did not complete the request within 90 seconds.
	How will the system notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap CLOSE. The Bolus screen will appear. Continue with your bolus request, or tap BACK if you do not want to continue your bolus request.
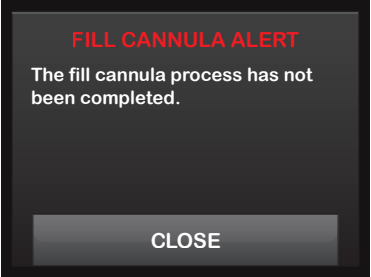
15.4   Incomplete Temp Rate Alert

What will I see on the Screen?	What does it mean?
INCOMPLETE TEMP RATE **This temp rate has not been started.** **CLOSE**	You started to set up a temp rate but did not complete the request within 90 seconds.
	How will the system notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap **CLOSE**. The Temp Rate screen will appear. Continue setting up your temp rate, or tap **BACK** if you do not want to continue setting up your temp rate.
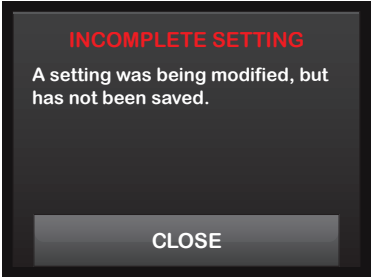
15.5　Incomplete Load Sequence Alerts

Incomplete Cartridge Change Alert	What does it mean?
What will I see on the Screen? **CHANGE CARTRIDGE ALERT** **The cartridge loading process has not been completed.** **CLOSE**	You selected Change Cartridge from the Load menu but did not complete the process within 3 minutes.
	How will the system notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap CLOSE. Complete the cartridge change process.

Incomplete Fill Tubing Alert **What will I see on the Screen?** **FILL TUBING ALERT** **The fill tubing process has not been completed.** **CLOSE**	**What does it mean?** You selected Fill Tubing from the Load menu but did not complete the process within 3 minutes.
	How will the system notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap CLOSE. Complete the fill tubing process.

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t:flex Pump Safety Alerts and Alarms

Incomplete Fill Cannula Alert **What will I see on the Screen?** **FILL CANNULA ALERT** **The fill cannula process has not been completed.** **CLOSE**	**What does it mean?** You selected Fill Cannula from the Load menu but did not complete the process within 3 minutes.
	How will the system notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap CLOSE. Complete the cannula fill process.

Customer Technical Support: **1-877-801-6901**

15.6   Incomplete Setting Alert

What will I see on the Screen?	What does it mean?
INCOMPLETE SETTING A setting was being modified, but has not been saved. CLOSE	You started to set up a new Personal Profile but did not save or complete the programming within 5 minutes.
	How will the system notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap **CLOSE**. Complete programming the Personal Profile.

t:flex Pump Safety Alerts and Alarms

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15.7   Basal Rate Required Alert
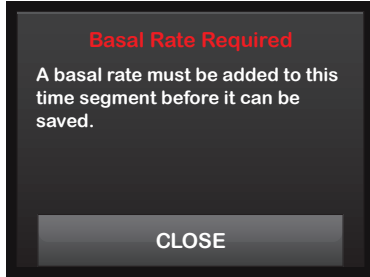
What will I see on the Screen?	What does it mean?
Basal Rate Required A basal rate must be added to this time segment before it can be saved. CLOSE	You did not enter a basal rate in a time segment in Personal Profiles. A basal rate must be entered in each time segment (rate can be 0 u/hr).
	How will the system notify me? Prompt screen only.
	Will the system re-notify me? No. A basal rate must be entered to save the time segment.
	How should I respond? Tap CLOSE. Enter a basal rate in the time segment.
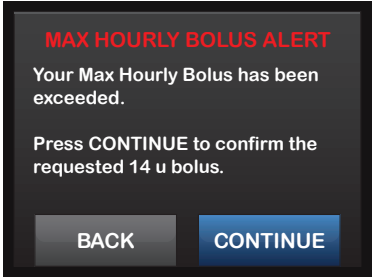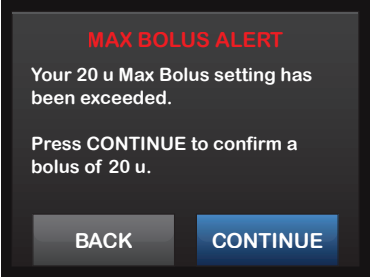
Customer Technical Support: 1-877-801-6901

15.8   Max Hourly Bolus Alert
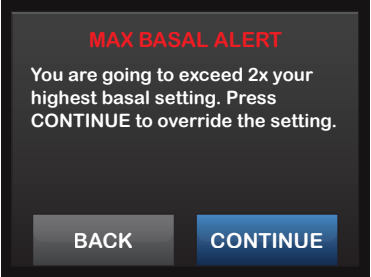
What will I see on the Screen?	What does it mean?
MAX HOURLY BOLUS ALERT Your Max Hourly Bolus has been exceeded. Press CONTINUE to confirm the requested 14 u bolus. BACK CONTINUE	In the previous 60 minutes, you requested total bolus delivery that is more than 1.5 times your Max Bolus setting.
	How will the system notify me? Prompt screen only.
	Will the system re-notify me? No. You must tap BACK or CONTINUE to deliver the bolus.
	How should I respond? Tap BACK to return to the Bolus screen and adjust the bolus delivery amount. Tap CONTINUE to deliver the bolus.

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t:flex Pump Safety Alerts and Alarms
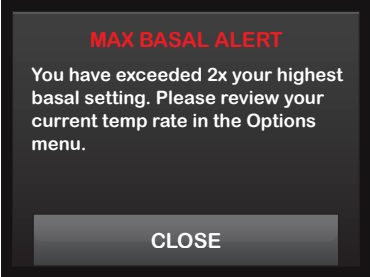
15.9   Max Bolus Alert

Max Bolus Alert **What will I see on the Screen?**	**What does it mean?** You requested a bolus larger than the Max Bolus setting in your active Personal Profile.
MAX BOLUS ALERT Your 20 u Max Bolus setting has been exceeded. Press CONTINUE to confirm a bolus of 20 u. BACK CONTINUE	**How will the system notify me?** Prompt screen only.
	Will the system re-notify me? No. You must tap BACK or CONTINUE to deliver the bolus.
	How should I respond? Tap BACK to return to the Bolus screen and adjust the bolus delivery amount, or tap CONTINUE to deliver the amount of your Max Bolus setting.

Customer Technical Support: 1-877-801-6901

t:flex Pump Safety Alerts and Alarms

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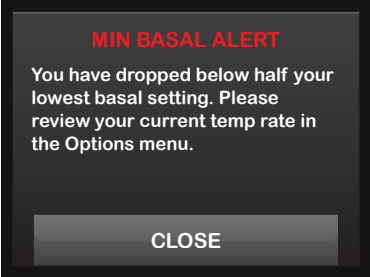
15.10 Max Basal Alerts

Max Basal Alert 1	What does it mean?
What will I see on the Screen?	When entering a basal rate or requesting a temp rate, you requested a basal rate more than 2 times the highest basal rate defined in your Personal Profile.
MAX BASAL ALERT You are going to exceed 2x your highest basal setting. Press CONTINUE to override the setting. BACK CONTINUE	**How will the system notify me?** Prompt screen only.
	Will the system re-notify me? No. You must tap BACK or CONTINUE to move forward.
	How should I respond? Tap BACK to return to the previous screen to adjust the amount, or tap CONTINUE to dismiss the alert and continue with the request.

Max Basal Alert 2

What will I see on the Screen?

> **MAX BASAL ALERT**
>
> **You have exceeded 2x your highest basal setting. Please review your current temp rate in the Options menu.**
>
> **CLOSE**

What does it mean?

An active temp rate exceeded 2 times your highest basal setting defined in your Personal Profile.

How will the system notify me?

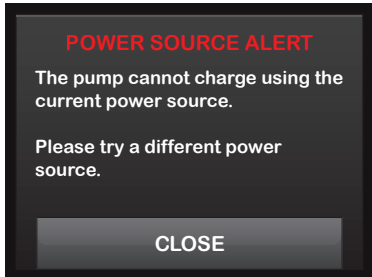2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.

Will the system re-notify me?

Yes, every 5 minutes until acknowledged.
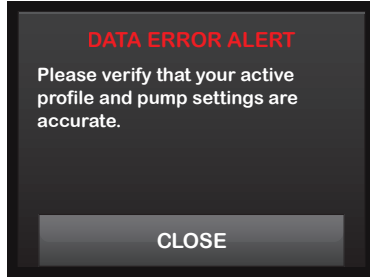
How should I respond?

Tap CLOSE and review your current temp rate in the Options menu.

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t:flex Pump Safety Alerts and Alarms

15.11 Min Basal Alerts

Min Basal Alert 1	What does it mean?
What will I see on the Screen?	When entering a basal rate or requesting a temp rate, you requested a basal rate less than half of the lowest basal rate defined in your Personal Profile.
MIN BASAL ALERT The programmed rate is less than half your lowest basal setting. Press CONTINUE to confirm. BACK CONTINUE	**How will the system notify me?** Prompt screen only. **Will the system re-notify me?** No. You must tap BACK or CONTINUE to move forward. **How should I respond?** Tap BACK to return to the previous screen to adjust the amount, or tap CONTINUE to dismiss the alert and continue with the request.

Min Basal Alert 2

What will I see on the Screen?

MIN BASAL ALERT

You have dropped below half your lowest basal setting. Please review your current temp rate in the Options menu.

CLOSE

What does it mean?

An active temp rate dropped below half of your lowest basal setting defined in your Personal Profile.

How will the system notify me?

2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Settings.

Will the system re-notify me?

Yes, every 5 minutes until acknowledged.

How should I respond?

Tap CLOSE and review your current temp rate in the Options menu.

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t:flex Pump Safety Alerts and Alarms

15.12 Connection Error Alert
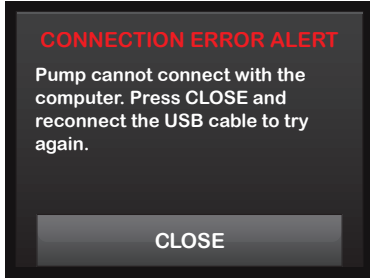
What will I see on the Screen?	What does it mean?
CONNECTION ERROR ALERT **Pump cannot connect with the computer. Press CLOSE and reconnect the USB cable to try again.** CLOSE	You connected your t:flex Pump to a computer with the USB cable to charge it or upload data to t:connect and a connection could not be made.
	How will the system notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Settings.
	Will the system re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap CLOSE. Disconnect and reconnect the USB cable to try again.

Customer Technical Support: 1-877-801-6901

15.13 Power Source Alert

What will I see on the Screen?	What does it mean?
POWER SOURCE ALERT The pump cannot charge using the current power source. Please try a different power source. **CLOSE**	You connected your t:flex Pump to a power source that does not have enough power to charge the pump.
	How will the system notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Settings.
	Will the system re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap **CLOSE**. Connect the pump to a different power source to charge.

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t:flex Pump Safety Alerts and Alarms

15.14 Data Error Alert

What will I see on the Screen?	What does it mean?
DATA ERROR ALERT **Please verify that your active profile and pump settings are accurate.** **CLOSE**	Your t:flex Pump encountered a condition that could potentially result in a loss of data.
	How will the system notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Settings.
	Will the system re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap CLOSE. Check your Personal profiles and pump settings to verify that they are accurate (refer to Chapter 6.4).

Customer Technical Support: **1-877-801-6901**

t:flex Pump Alarms

Your t:flex Pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check you BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been confirmed.

Information in this section will help you learn how to respond to Alarms.

Alarms notify you with 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume. If not acknowledged, alarms escalate to highest volume and vibe.
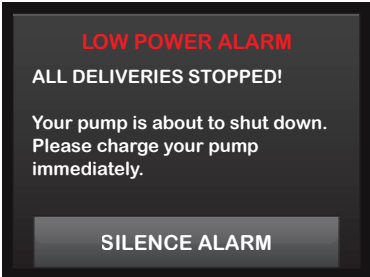
Alarms repeat regularly until the condition that caused the alarm is corrected.

16.1   Resume Pump Alarm

What will I see on the Screen?	What does it mean?
RESUME PUMP ALARM The pump has been stopped for an extended period of time. Select RESUME INSULIN in the Options menu to continue therapy. **CLOSE**	You tapped STOP INSULIN in the Options menu and insulin delivery has been stopped for more than 15 minutes.
	How will the system notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes, if not acknowledged by tapping **CLOSE**, the system will re-notify you every 3 minutes at highest volume and vibrate. If acknowledged by tapping **CLOSE**, the system will re-notify you in 15 minutes.
	How should I respond? To resume insulin, from the Options menu, tap **RESUME INSULIN** and tap **RESUME** to confirm.

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t:flex Pump Safety Alerts and Alarms

16.2   Low Power Alarms

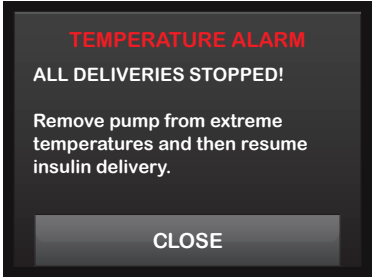| Low Power Alarm 1 What will I see on the Screen? **LOW POWER ALARM** ALL DELIVERIES STOPPED! Your pump is about to shut down. Please charge your pump immediately. CLOSE	**What does it mean?** Your t:flex Pump detected a power level of 1% or less remaining and all deliveries have stopped.
	How will the system notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes, the system will re-notify you every 3 minutes until no power remains and the pump shuts down.
	How should I respond? Tap CLOSE. Charge your pump immediately to resume insulin delivery.

Customer Technical Support: **1-877-801-6901**

Low Power Alarm 2 **What will I see on the Screen?** **LOW POWER ALARM** **ALL DELIVERIES STOPPED!** **Your pump is about to shut down. Please charge your pump immediately.** **SILENCE ALARM**	**What does it mean?** Your t:flex Pump detected a voltage level too low to ensure normal performance and all deliveries have stopped.
	How will the system notify me? A series of rapid beeps at maximum volume for at least 20 seconds before the system shuts down.
	Will the system re-notify me? The pump will power back on once it has been plugged into a charging source and has reached an adequate level of charge.
	How should I respond? Tap **SILENCE ALARM** if the screen is still on. Charge your pump immediately to resume insulin delivery.

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t:flex Pump Safety Alerts and Alarms

16.3   Empty Cartridge Alarm
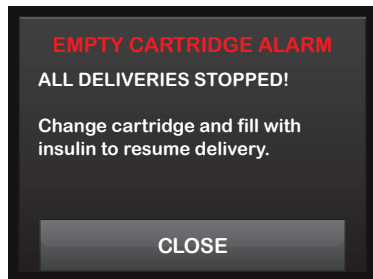
What will I see on the Screen?	
EMPTY CARTRIDGE ALARM ALL DELIVERIES STOPPED! Change cartridge and fill with insulin to resume delivery. CLOSE	**What does it mean?** Your t:flex Pump detected that the cartridge is empty and all deliveries have stopped.
	How will the system notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes. The system will re-notify you every 3 minutes until you change the cartridge.
	How should I respond? Tap CLOSE. Change your cartridge immediately by tapping OPTIONS from the Home Screen, then Load and follow the instructions in Chapter 5.3.

Customer Technical Support: **1-877-801-6901**

16.4   Cartridge Error Alarm

What will I see on the Screen?	What does it mean?
CARTRIDGE ALARM **ALL DELIVERIES STOPPED!** **This cartridge cannot be used. Remove and replace with a new cartridge.** **CLOSE**	Your t:flex Pump detected that the cartridge could not be used and all deliveries have stopped. This can be caused by cartridge defect, not following the proper procedure to load the cartridge, or over filling the cartridge (with more than 480 units of insulin).
	How will the system notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes. The system will re-notify you every 3 minutes until you change the cartridge.
	How should I respond? Tap CLOSE. Change your cartridge immediately by tapping OPTIONS from the Home Screen, then Load and follow the instructions in Chapter 5.3.

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t:flex Pump Safety Alerts and Alarms

16.5   Cartridge Removal Alarm
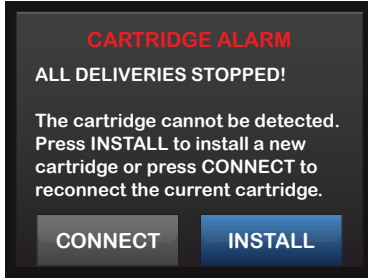
What will I see on the Screen?	What does it mean?
CARTRIDGE ALARM **ALL DELIVERIES STOPPED!** **The cartridge cannot be detected. Press INSTALL to install a new cartridge or press CONNECT to reconnect the current cartridge.** **CONNECT** **INSTALL**	Your t:flex Pump detected that the cartridge has been removed and all deliveries have stopped.
	How will the system notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes. The system will re-notify you every 3 minutes until you reconnect the current cartridge or change the cartridge.
	How should I respond? Tap CONNECT to reattach the current cartridge. Tap INSTALL to load a new cartridge.
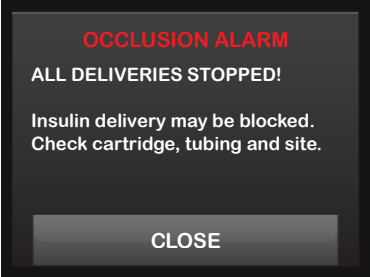
Customer Technical Support: 1-877-801-6901

16.6   Temperature Alarm

What will I see on the Screen?	What does it mean?
TEMPERATURE ALARM **ALL DELIVERIES STOPPED!** **Remove pump from extreme temperatures and then resume insulin delivery.** **CLOSE**	Your t:flex Pump detected a temperature below 35.6 °F (2 °C) or above 113 °F (45 °C) and all deliveries have stopped.
	How will the system notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes. The system will re-notify you every 3 minutes until a temperature in the operating range is detected.
	How should I respond? Tap CLOSE. Remove the pump from the extreme temperature and then resume insulin delivery.

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t:flex Pump Safety Alerts and Alarms
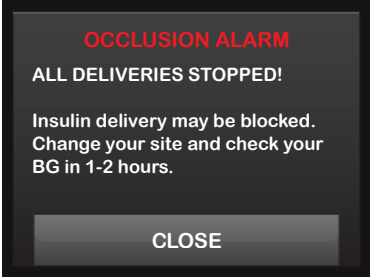
16.7   Occlusion Alarms*

Occlusion Alarm 1 **What will I see on the Screen?** OCCLUSION ALARM ALL DELIVERIES STOPPED! Insulin delivery may be blocked. Check cartridge, tubing and site. CLOSE	**What does it mean?** Your t:flex Pump detected that insulin delivery is blocked and all deliveries have stopped.
	How will the system notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes. The system will re-notify you every 3 minutes until you resume insulin delivery.
	How should I respond? Tap CLOSE. Check the cartridge, tubing, and infusion site for any sign of damage or blockage and correct the condition. To resume insulin, from the Options menu, tap RESUME INSULIN and tap RESUME to confirm.

* See Section 19.2 for more information on how long it can take the system to detect an occlusion.

📄 NOTE
If the occlusion alarm occurs during bolus delivery, after tapping CLOSE, a screen will appear letting you know how much of the requested bolus was delivered before the occlusion alarm.

Occlusion Alarm 2

What will I see on the Screen?

OCCLUSION ALARM

ALL DELIVERIES STOPPED!

Insulin delivery may be blocked. Change your site and check your BG in 1-2 hours.

CLOSE

What does it mean?

Your t:flex Pump detected a second occlusion alarm shortly after the first occlusion alarm and all deliveries have stopped.

How will the system notify me?

3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.

Will the system re-notify me?

Yes. The system will re-notify you every 3 minutes until you resume insulin delivery.

How should I respond?

Tap **CLOSE**. Change the cartridge, tubing, and infusion site to ensure proper delivery of insulin. Resume insulin after changing the cartridge, tubing, and infusion site.

📄 **NOTE**
If the second occlusion alarm occurs during bolus delivery, after tapping CLOSE, a screen will appear letting you know that the amount of bolus delivery could not be determined and was not added to your IOB.

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t:flex Pump Safety Alerts and Alarms

16.8   Screen On/Quick Bolus Button Alarm
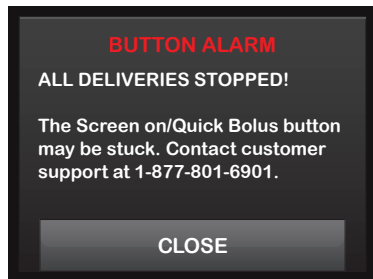
What will I see on the Screen?	
BUTTON ALARM ALL DELIVERIES STOPPED! The Screen on/Quick Bolus button may be stuck. Contact customer support at 1-877-801-6901. CLOSE	**What does it mean?** The Screen On/Quick Bolus Button (on the top of your t:flex Pump) is stuck or not functioning properly and all deliveries have stopped.
	How will the system notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes. The system will re-notify you every 3 minutes until the condition is corrected.
	How should I respond? Tap CLOSE. Contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

16.9   Altitude Alarm

What will I see on the Screen?	What does it mean?
ALTITUDE ALARM **ALL DELIVERIES STOPPED!** **Remove cartridge from pump, reconnect cartridge and then resume insulin.** **CLOSE**	Your t:flex Pump detected a pressure change outside of the operating range and all deliveries have stopped.
	How will the system notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes. The system will re-notify you every 3 minutes until the condition is corrected.
	How should I respond? Tap CLOSE. Remove the cartridge from the pump (this will allow the cartridge to fully vent) and then reconnect the cartridge.

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t:flex Pump Safety Alerts and Alarms

16.10 Reset Alarm
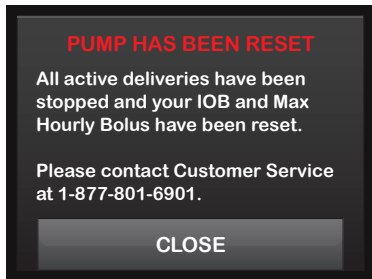
What will I see on the Screen?	What does it mean?
PUMP HAS BEEN RESET All active deliveries have been stopped and your IOB and Max Hourly Bolus have been reset. Please contact Customer Service at 1-877-801-6901. CLOSE	Your t:flex Pump detected that one if its micro-processors experienced a reset and all deliveries have been stopped.
	How will the system notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the system re-notify me? Yes. The system will re-notify you every 3 minutes until you tap CLOSE.
	How should I respond? Tap CLOSE. Contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

Chapter 17

t:flex Pump Malfunction

17.1   Malfunction

If your t:flex Pump detects a system error, the MALFUNCTION screen appears and all deliveries are stopped. Once a malfunction occurs, the pump can no longer be used. Contact Tandem Diabetes Care Customer Technical Support for a replacement pump.

Malfunctions notify you with 3 sequences of 3 notes at highest volume and 3 vibrations. They repeat at regular intervals until acknowledged by tapping SILENCE ALARM.

⚠ PRECAUTION
Monitor your blood glucose (BG) levels frequently with the guidance of your healthcare provider anytime there is an interruption of insulin delivery. If pump therapy cannot be resumed, start backup plan per your healthcare provider.

What will I see on the Screen?

MALFUNCTION
This pump cannot operate. Call customer support immediately.

Call Customer Support:
1-877-801-6901

Malfunction #:
XXXXXXX

SILENCE ALARM
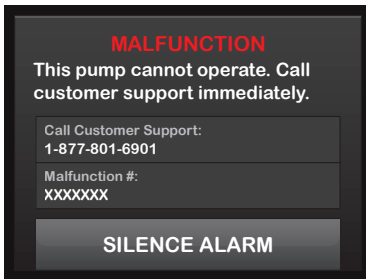
What does it mean?

Your t:flex Pump detected a system error and all deliveries have been stopped.

How will the system notify me?

3 sequences of 3 notes at highest volume and 3 vibrations.

Will the system re-notify me?

Yes, the system will notify you every 3 minutes until you acknowledge the malfunction by tapping SILENCE ALARM.

How should I respond?

Write down the Malfunction Code number that appears on the screen.

Tap SILENCE ALARM. The MALFUNCTION screen will remain on the pump even though the alarm is silenced.

Contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901 and provide the Malfunction Code number that you wrote down.

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t:flex Pump Safety Alerts and Alarms

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Section 5

System Care and Maintenance

Taking Care of Your t:flex System

18.1   Overview

This section provides information on caring for and maintaining your System.

Cleaning Your System

When cleaning your t:flex Pump, use a damp lint-free cloth. Do not use household or industrial cleaners, solvents, bleach, scouring pads, chemicals, or sharp instruments. Never submerge the pump in water or use any other liquid to clean it. Do not place the pump in the dishwasher or use hot water to clean it. If needed, use only a very mild detergent, such as a bit of liquid soap with warm water. When drying your pump, use a soft towel; never place your pump in a microwave oven or baking oven to dry it.

Inspecting Your System for Damage

If you drop your t:flex Pump or it has been hit against something hard, ensure that it is still working properly. Check that the touch screen is working and clear, and that the cartridge and infusion set are properly in place. Check for leaks around the cartridge and at the luer connector to the infusion set. Immediately contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901 if you notice any cracks, chips, or other damage.

Storing Your System

If you need to stop using your t:flex Pump for a long period of time, you can place the pump in storage mode. To place the pump in storage mode, connect the pump to a power source and then press and hold down the Screen On/Quick Bolus Button for 25 seconds. The pump will beep 3 times before going into storage mode. Disconnect the pump from the power source.

Keep the pump protected when not in use. Store at temperatures between -4 °F – 140 °F and at a relative humidity level of less than 90%.

To bring the pump out of storage mode, simply connect the pump to a power source.

Disposing of System Components

Consult your local waste management authorities for instructions for disposal of devices containing electronic waste such as your pump and for instructions for disposal of potentially bio-hazardous materials such as used cartridges, needles, syringes, and infusion sets.

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System Care and Maintenance

System Technical Specifications

Chapter 19

Technical Specifications

19.1   Overview

This appendix provides tables of technical specifications, options, settings, and electromagnetic compliance information for the t:flex System.

19.2   t:flex Pump Specifications

The following table lists the t:flex Pump specifications and their related details.

Specification Type	Specification Details
Classification	External PSU: Class II, Infusion Pump. Internally-powered equipment, Type BF applied part. The risk of ignition of flammable anesthetics and explosive gases by the pump is remote. While this risk is remote, it is not recommended to operate the t:flex Pump in the presence of flammable anesthetics or explosive gases.
Size	3.13″ x 2.0″ x 0.6″ (L x W x H) – (7.95 cm x 5.08 cm x 1.52 cm)
Size with Cartridge	3.13″ x 2.0″ x 0.84″ (L x W x H) – (7.95 cm x 5.08 cm x 2.14 cm)
Weight (with full disposable)	4.05 ounces (115 grams)
Operating Temperature Range	41°F and 98.6°F, 5°C and 37°C at maximum relative humidity of 90% non-condensing
Storage Temperature Range	-4°F and 140°F -20°C to 60°C at maximum relative humidity of 90% non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa (equivalent from 10,000 ft. to Dead Sea elevation)
Reservoir Volume	4.8 mL or 480 units
Cannula Fill Amount	0.1 to 1.0 units of insulin
Insulin Concentration	U-100
Alarm Type	Visual, audible, and vibratory

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Specification Type	Specification Details
Basal Delivery Accuracy at all Flow Rates (tested per IEC 60601-2-24)	±5% *
Bolus Delivery Accuracy at all Volumes (tested per IEC 60601-2-24)	±5% *
Patient Protection from Air Infusion	The pump provides subcutaneous delivery into interstitial tissue and does not deliver intravenous injections. Clear tubing aids in detecting air.
Maximum Infusion Pressure Generated and Occlusion Alarm Threshold	30 PSI
Rate of delivery during Bolus	Bolus > 3 units Approximately 2.8 units/min Bolus ≤ 3 units Approximately 1.6 units/min
Rate of delivery during Prime	Approximately 9.7 units/min
Bolus Duration	Bolus > 3 units duration Approximately 21 seconds/unit Bolus ≤ 3 units duration Approximately 38 seconds/unit
Maximum Bolus Duration	21 minutes for 60 unit maximum bolus
Frequency of Basal Delivery	5 minutes for all Basal Rates
Retention Time of Electronic Memory when Internal System Battery is Fully Discharged (including Alarm Settings and Alarm History)	Greater than 30 days
Infusion Set used for Testing	Unomedical Comfort™ Infusion Set

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* In certain pressure environments, such as a gradual elevation change of 1,000 feet in 15 minutes, delivery accuracy may vary ±15% for short periods of time.

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Specification Type	Specification Details
Statement of Meaning of the Claimed Ingress Protection (IP) Classification	IPX7: watertight to a depth of 3 feet for up to 30 minutes
Internal System Battery Life	4 years minimum under normal use conditions
Typical Operating Time when System is Operating at Intermediate Rate	During normal use, the intermediate rate is 3.33 units/hr; battery charge can be reasonably expected to last up to 4 days from a fully charged state to a totally discharged state
Handling of Over-Infusion or Under-Infusion	The method of delivery isolates the insulin chamber from the patient and the software performs frequent monitoring of system status. Multiple software monitors provide redundant protection against unsafe conditions. Over-infusion is mitigated by continuous self-tests, layering of redundancies and confirmations, and numerous other safeguard alarms. Users are required to review and confirm the details of all bolus deliveries, basal rates, and temp rates to ensure certainty before initiating a delivery. In addition, once bolus deliveries are confirmed, the user is given 5 seconds to cancel the delivery before it is started. An optional Auto-Off alarm triggers when the user has not interacted with the pump's user interface for a pre-defined period of time. Under-infusion is mitigated by occlusion detection and blood glucose monitoring as blood glucose entries are recorded. Users are prompted to treat high blood glucose conditions with a correction bolus.
Bolus Volume at Release of Occlusion	1–2 units at 3.33 units per hour with Unomedical Comfort™ (110cm) infusion set.
Alarm Signal Sound Pressure Range	Minimum sound pressure level of 45 dBA at 1 meter

Time to Occlusion Alarm

Operating Rate	Typical	Maximum
Bolus	46 Seconds	64 Seconds
Basal (3.33 units/hr)	29 Minutes	42 Minutes
Basal (0.5 units/hr)	3 Hours 5 Minutes	3 Hours 36 Minutes

USB Charging/Download Cable Specifications	
Tandem P/N	004113
Length	6 feet
Type	USB A to USB Micro B

Power Supply/Charger, AC, Wall Mount, USB Specifications	
Tandem P/N	03933
Input	100 to 240 Volts AC, 50/60 Hz
Output Voltage	5 Volts DC
Max Output Power	5 Watts
Output Connector	USB type A

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Power Supply/Charger, DC, Vehicle adapter, USB Specifications	
Tandem P/N	003934
Input	12 Volts DC
Output Voltage	5 Volts DC
Max Output Power	5 Watts minimum
Output Connector	USB type A

PC, USB Connector, Specifications	
Output Voltage	5 Volts DC
Output Connector	USB type A
Safety Standard Compliance	60950-1 or 60601-1 or equivalent

The t:flex System is designed to be connected to a host PC for battery charging and data transfer to t:connect. The following minimum characteristics are required of the host PC:

• USB 1.1 port (or later)
• t:connect Uploader Software (available for download at www.tandemdiabetes.com)
• PC compliant with 60950-1 or equivalent safety standard

Connecting the t:flex System to a host PC that is attached to other equipment could result in previously unidentified risks to the patient, operator, or a third party. The user should identify, analyze, evaluate, and control these risks.

Subsequent changes to the host PC could introduce new risks and require additional analysis. These changes can include but are not limited to changing the configuration of the PC, connecting additional items to the PC, disconnecting items from the PC, and updating or upgrading equipment connected to the PC.

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System Technical Specifications

19.3   t:flex Pump Options and Settings

The following table lists the t:flex Pump options and settings, and their related details.

Option/Setting Type	Option/Setting Details
Time	12-hour clock
Maximum Basal Rate	15 units/hr
Insulin Delivery Profiles (Basal and Bolus)	6
Basal Rate Segments	16 per delivery profile
Basal Rate Increment	0.001 at programed rates equal to or greater than 0.5 units/hr
Temp Basal Rate	15 minutes to 72 hours with 1 minute resolution with a range of 0% to 250%
Bolus Setup	Can deliver based on carb input (grams) or insulin input (units). Default is units. (The range for carbs is 1–999 grams; the range for insulin is 0.5–60 units)
Insulin-to-Carb (IC) Ratio	16 time segments per 24-hour period; Ratio: 1 unit of insulin per x grams of carbs; 1:1 to 1:300 (can be set by 0.1 below 10)
BG Correction Target Value	16 time segments. 70 to 250 mg/dL in 1 mg/dL increments
Insulin Sensitivity Factor (ISF)	16 time segments; Ratio: 1 unit of insulin reduces glucose x mg/dL; 1:1 to 1:600 (1 mg/dL increments)
Duration of Insulin Action	1 time segment; 2–8 hours in 1-minute increments (default is 5 hrs)
Bolus Increment	0.01 at volumes greater than 0.5 units

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Option/Setting Type	Option/Setting Details
Quick Bolus Increments	When set to units: 0.5, 1, 2, 5 units (default is 0.5 units); or when set to grams/carbs: 2, 5, 10, 15 grams (default is 2 g)
Maximum Extended Bolus Time	8 hours
Maximum Bolus Size	60 units
Low Reservoir Volume Indicator	Status indicator visible on Home Screen; Low Insulin Alert is user adjustable from 20–60 units (default is 40 units).
Auto-Off Alarm	On or Off (default is On); user-adjustable (5–24 hours; default is 12 hours, which you can change when option is set to On).
History Storage	Up to 90 days of data (11,000 events).
Language	English
Feature Lock	Blocks access to insulin delivery screens and pump setting screens (default is Off).
Screen Lock	Protects from unintentional taps.
Site Reminder	Prompts user to change infusion set. Can be set for 1–3 days at a time selected by user (default is Off).
Missed Meal Bolus Reminder	Prompts user if a bolus has not occurred during the period of time the reminder is set for. 4 reminders available (default is Off).
After Bolus BG Reminder	Prompts user to test BG at a selected time period after a Bolus has been delivered. Can be set between 1-3 hours (default is Off).
High BG Reminder	Prompts user to retest BG after a High BG has been entered. User selects High BG value and time for reminder. (default is Off).
Low BG Reminder	Prompts user to retest BG after a Low BG has been entered. User selects Low BG value and time for reminder. (default is Off).

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19.4 Electromagnetic Compatibility

The information contained in this section is specific to the t:flex System. This information provides reasonable assurance of normal operation, but does not guarantee such under all conditions. If the t:flex System must be used in close proximity with other electrical equipment, the System should be observed in this environment to verify normal operation. Special precautions for electromagnetic compatibility must be taken when using medical electrical equipment. The System shall be placed into service with adherence to the EMC information provided here. Using cables and accessories not specified in this User Guide may adversely impact safety, performance, and electromagnetic compatibility, including increased emissions and/or decreased immunity.

This section contains the following tables of information:

• Electromagnetic Emissions

• Electromagnetic Immunity

• Distances Between the t:flex System and RF Equipment

19.5   Electromagnetic Emissions

The t:flex System is intended for use in the electromagnetic environment specified below. Always make sure that the System is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions, CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions, CISPR 11	Class B	The System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions, IEC 61000-3-2	N/A	
Voltage Fluctuations/Flicker Emissions, IEC 61000-3-3	N/A	

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19.6   Electromagnetic Immunity

The t:flex System is intended for use in the electromagnetic environment specified below. Always make sure that the System is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5% Ur (>95% dip in Ur) for 0,5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (>95% dip in Ur) for 5 sec	<5% Ur (>95% dip in Ur) for 0,5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (>95% dip in Ur) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or a battery. NOTE: Ur is the a.c. mains voltage prior to application of the test level.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	400 A/m (IEC 60601-2-24)t	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 V	Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 0.35\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	30 V/m	80 MHz to 800 MHz, $d = 0.12\sqrt{P}$ 800 MHz to 2.5GHz, $d = 0.23\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the pump is used exceeds the applicable RF compliance level above, the pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

19.7   Distances Between the t:flex Pump and RF Equipment

The t:flex System is intended for use in an electromagnetic environment typically found in the home, at work, retail stores, and places of leisure, where daily activities occur. The chart below can be used as a guideline for determining the recommended minimum distance to maintain between a radio frequency (RF) transmitter and the t:flex System. For specific concerns about a particular RF transmitter interfering with your System's operation, please contact the transmitter manufacturer for its rated power and frequency.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the t:flex System			
The t:flex System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the t:flex System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter in Watts	Separation Distance According to Frequency of Transmitter _inches or feet_ (m)		
	150 kHz to 80 MHz (d _in meters_ = $0.35\sqrt{P}$)	80 MHz to 800 MHz (d _in meters_ = $0.12\sqrt{P}$)	800 MHz to 2.5 GHz (d _in meters_ = $0.23\sqrt{P}$)
0.01	1.6 in (0.04)	0.12 in (0.012)	0.9 in (0.023)
0.1	4.3 in (0.11)	1.5 in (0.038)	2.9 in (0.073)
1	1.1 ft (0.35)	4.7 in (0.120)	9.0 in (0.23)
10	3.6 ft (1.11)	14.9 in (0.379)	2.39 ft (0.727)
100	11.5 ft (3.50)	3.94 ft (1.20)	7.54 ft (2.3)

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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The table below provides a list of typical devices for various levels of transmitter power and frequency, and the recommended separation distances from the transmitter and the System.

Rated Maximum Output Power of Transmitter in Watts	Typical Devices	Recommended Separation Distance Inch (Meters)	
0.001W	Bluetooth Class 3 (standard 1 meter range) Commonly used as bluetooth headset	0.3 in (0.007 m)	
0.01W	Internet to music adaptor Commonly used for FM wireless music streaming	0.5 in (0.013 m)	
0.1W	Bluetooth Class 1 (100 meter range) Wireless router (WiFi)	2.9 in (0.073 m)	
0.5W	Typical cellular/smart phone*	6.4 in (0.163 m)	
1W	Typical microwave oven RF leakage	9 in (0.23 m)	

*Caution: Interference with pump electronics by cell phones can occur if worn in close proximity. It is recommended that your pump and cell phone be worn at least 6.4 inches apart.

19.8 FCC Notice Concerning Interference

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

t:flex 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:flex 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 my cause undesired operation

Compliance with these guidelines provides reasonable protection against harmful interference in a normal residential environment. The t:flex 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:flex 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:flex Pump

• Increase the distance between the t:flex 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.

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System Technical Specifications

Customer Technical Support: 1-877-801-6901

Customer Technical Support: 1-877-801-6901

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