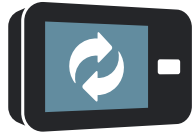
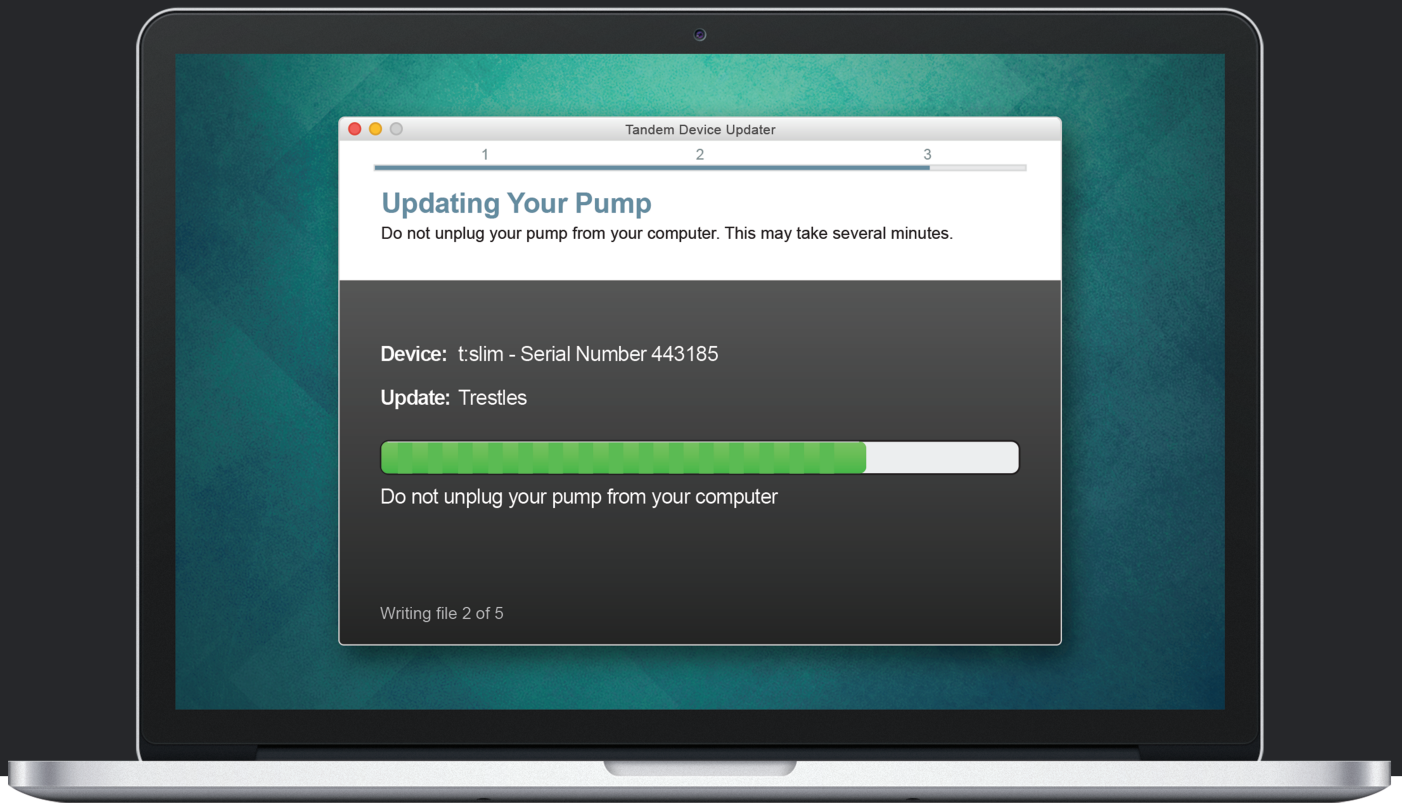


Tandem Device Updater



User Guide



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DIABETES CARE

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Intended Use

The Tandem Device Updater is intended for use by individuals with diabetes mellitus who use Tandem Diabetes Care® insulin pumps, their caregivers, and their healthcare professionals in home and clinical settings. The Tandem Device Updater provides Tandem insulin pump users the ability to update their device software remotely using a computer with internet access.

CAUTION: Federal (USA) law restricts Tandem Diabetes Care insulin pumps to sale by or on the order of a physician.

WARNINGS

- **DO NOT** update your Tandem insulin pump before reading the User Guide. Incorrect use of the Tandem Device Updater or failure to follow the appropriate instructions can lead to an inoperable pump. If you have questions or need further clarification on the Tandem Device Updater or pump use, contact Customer Technical Support.
- **DO NOT** update your pump while your infusion set is connected to your body. Always ensure that the infusion set is disconnected from your body before updating your pump software.
- **DO** suspend all pump insulin delivery prior to using the Tandem Device Updater.
- **DO** check your blood glucose (BG) prior to suspending delivery and be sure to treat high or low BG levels as directed by your healthcare professional prior to update.
- **DO** be prepared to inject insulin with an alternative method in case you encounter any issues while updating your pump. Failure to have an alternative method of insulin delivery can lead to very high blood glucose or Diabetic Ketoacidosis (DKA).
- **DO** complete the training appropriate to your device and feature set before starting to use the updated software. Failure to complete necessary training could result in serious injury or death.
- **DO NOT** rely on the Insulin On Board (IOB) displayed on your pump after an update until your prior IOB has been depleted. Your IOB will be reset to zero during the update process. Since the calculated bolus amount relies on IOB, it could prompt you to deliver more insulin than needed and result in hypoglycemia. Consult with your healthcare professional for how long you need to wait after an update before you can rely on the IOB calculation.
- **DO** confirm your pump's personal settings, date, and time are correct after the update. Incorrect settings can result in over delivery or under delivery of insulin. Consult with your healthcare professional as needed to establish appropriate settings.

PRECAUTIONS

- **DO NOT** shut down your computer or allow it to go into “hibernate”, “sleep” or “standby” mode during an update. If you are using a laptop, do not close the laptop. Doing so could interrupt the update, and your pump may not function.

- **DO NOT** disconnect from the internet during an update. Doing so could interrupt the update, and your pump may not function.
- **DO NOT** disconnect your pump from your computer during an update unless instructed to do so. Doing so could interrupt the update, and your pump may not function.
- **DO NOT** rely on the Max Hourly Bolus Alert for 60 minutes following an update. Your Max Hourly Bolus will be reset to zero during the update process.

Important User Information

Thoroughly review all product instructions for warnings and other important user information before using the Tandem Device Updater. Incorrect use may result in an inoperable pump. For contact information in your region see the back cover of this user guide.

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The following pages will provide you with a step-by-step guide on how to use the Tandem Device Updater from Tandem Diabetes Care.

The Tandem Device Updater gives you access to new features and updates for your eligible Tandem insulin pump as they become available.

Product Overview

The Tandem Device Updater is designed to update the software on your Tandem insulin pump. The process is similar to doing software updates for your computer or mobile device and shouldn't take more than thirty minutes. In order to make sure your pump is up to date, it is best to install software updates as they are released.

What You Need

Before you begin the update process, make sure that:

- **You have your unique Update ID Number ready.**
You should have received an Update ID Number. If you cannot locate your Update ID Number, contact Customer Technical Support.
- **You have a computer with an uninterrupted internet connection available.**
During the update, you must remain connected to the internet. If possible, a wired (Ethernet) connection is recommended.
- **You charge your Tandem insulin pump battery using the USB cable provided.**
In order to start the update, your pump battery must have at least a 20% charge. You will need the Tandem USB cable that came with your pump in order to complete the update.

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To determine if there is an available update for your Tandem pump, visit tandemdiabetes.com/products/tandem-device-updater.

If an update is available, click the associated link and complete the following steps.

1. Install the latest version of the Tandem Device Updater on your computer
2. Prepare for an Update
3. Update your Pump Software

Install the Tandem Device Updater

From the product information page, click the **Mac** or **PC** button, depending on which type of computer you are using. Follow the step-by-step instructions to download and install the latest version of the Tandem Device Updater.

NOTE: Driver Installation

You may need to install the Tandem Diabetes Care device software, which allows the Tandem Device Updater to communicate with your pump. If prompted, click **Install**.

Prepare for an Update

After you have installed the Tandem Device Updater, there are a few things that you need to do in order to successfully update your pump.

Before you begin an update, make sure you are prepared with each of the following items on hand:

- A backup insulin delivery option, such as a syringe and fast-acting insulin, in case there are any issues updating your pump. These items should be part of your Emergency Kit and with you at all times.
- Your blood glucose meter so you can check your blood glucose prior to starting the update.
- A convenient time to stop all insulin delivery, detach your infusion set, and remove your cartridge. We recommend performing the update when you are ready to change your cartridge.
- A computer with an internet connection. If you are using a laptop, make sure it remains plugged in to a wall outlet during the half hour it will take to complete the update.
- Your unique Update ID Number. If you cannot locate your Update ID Number, contact Customer Technical Support.

You will be required to confirm each of these items before moving forward with updating your pump. Before proceeding, review your current Insulin on Board (IOB) as it will be reset to zero following an update.

NOTE: Personal Profiles and History

The Personal Profiles and History on your pump will be maintained before and after an update. The Insulin on Board (IOB) and Max Hourly Bolus will be reset to zero during the update process. If you have enabled the Site Reminder on your pump, do not rely on the Site Reminder for your first site change following an update.

WARNING


DO NOT rely on the Insulin On Board (IOB) displayed on your pump after an update until your prior IOB has been depleted. Your IOB will be reset to zero during the update process. Since the calculated bolus amount relies on IOB, it could prompt you to deliver more insulin than needed and result in hypoglycemia. Consult with your healthcare professional for how long you need to wait after an update before you can rely on the IOB calculation.

⚠ PRECAUTION

DO NOT rely on the Max Hourly Bolus Alert for 60 minutes following an update. Your Max Hourly Bolus will be reset to zero during the update process.

Update Your Pump Software

After you have installed the Tandem Device Updater and confirmed that you have everything you need available, follow the steps below to update your pump.


1. The Tandem Device Updater should automatically start once installation is complete. If it does not start automatically, locate the icon  on your computer.
Windows®: The Tandem Device Updater icon will be on your desktop or in your programs folder.
Mac®: The Tandem Device Updater icon will be in your Mac applications folder.
2. Confirm that you are ready to update your pump. You will need your Update ID Number, an internet connection, a charged pump battery with at least 20% power, and your backup insulin delivery supplies. Connect your pump to your computer using the USB cable provided by Tandem.
3. The Tandem Device Updater will detect your device and determine which updates are currently available. If an update is available, you will see the details listed. Follow the instructions on the screen to complete the update.

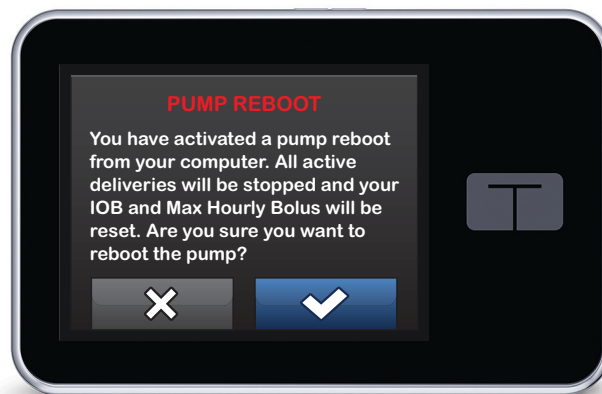
📖 NOTE: Device Detection

If your computer does not detect your pump, unplug it from the USB port on your computer and try a different USB port. If it is still not detected, contact Customer Technical Support.

📖 NOTE: Update Completion

You must complete the update once you click **Continue** on the *Important Safety Information* screen. If you do not complete the entire process, your pump may not function.

4. Depending on the software version currently available on your Tandem insulin pump, you may be prompted to reboot your pump. Follow the instructions on your computer screen to complete the pump reboot. You will need to tap **YES** or  on your pump screen.



NOTE: Pump Reboot Declined

If you tap **NO** or **X** on the *Pump Reboot* screen, you will need to close the Tandem Device Updater. Reopen the Tandem Device Updater if you would like to restart the update process.

5. Once an update is complete, your pump will display the Update Successful message.



NOTE: Update Successful

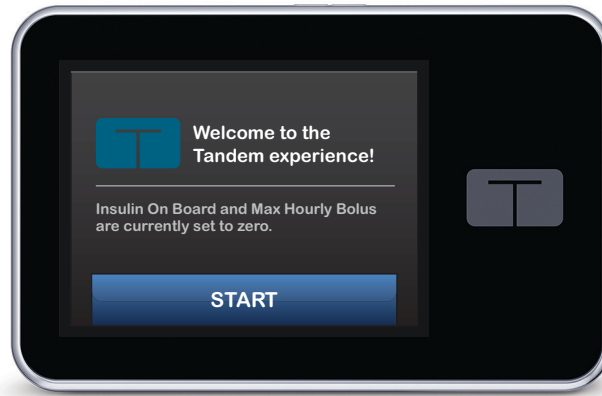
Once you see this screen, you can disconnect your pump from your computer.

WARNING

DO confirm your pump's personal settings, date, and time are correct after the update. Incorrect settings can result in over delivery or under delivery of insulin. Consult with your healthcare professional as needed to establish appropriate settings.

6. You are now ready to use your pump. Unlock your pump, tap **START**, and load a new cartridge to resume your Tandem insulin pump therapy. Your Personal Profiles and History have been maintained.

The Site Reminder will not activate until after your first site change following an update. Follow the instructions from your healthcare professional on site change frequency. All future site changes will be prompted per your Site Reminder settings.



⚠ WARNING

DO NOT rely on the Insulin On Board (IOB) displayed on your pump after an update until your prior IOB has been depleted. Your IOB will be reset to zero during the update process. Since the calculated bolus amount relies on IOB, it could prompt you to deliver more insulin than needed and result in hypoglycemia. Consult with your healthcare professional for how long you need to wait after an update before you can rely on the IOB calculation.

⚠ PRECAUTION

DO NOT rely on the Max Hourly Bolus Alert for 60 minutes following an update. Your Max Hourly Bolus will be reset to zero during the update process.

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Update Issues

If you are having trouble getting your pump to connect or start the update using the Tandem Device Updater, try the following:

- **Check that your pump is supported by the Tandem Device Updater.**

If your pump is not supported, you will not be able to perform an update. Visit tandemdiabetes.com/products/tandem-device-updater for the list of supported pumps.

- **Close any other software that communicates with your pump.**

Only one program can communicate with your pump at a time. If you have another program open, such as data management software, the Tandem Device Updater may not be able to communicate with your pump. Close the other program and then try opening the Tandem Device Updater again.

- **Unplug the USB cable from your computer and plug it back in.**

This will reset the connection. Be sure that you unplug the cable from the computer and not just from the device. Plug it back in and try the update again.

- **Close the Tandem Device Updater and then open it again.**

Try resetting the Tandem Device Updater by closing it and then opening it again.

If you still cannot connect your device:

- Disconnect the USB cable from your computer
- Reboot your computer
- Plug the USB cable back into your computer
- Start the Tandem Device Updater software

If none of the steps above resolve the issue, please contact Customer Technical Support.

Frequently Asked Questions

The following questions are common when installing or completing an update.

Can I stop an update once I've begun?

No, you cannot stop an update once you've started. After you complete the safety steps and start an update, you must complete the update process in its entirety.

What happens if I enter an invalid Update ID Number?

The update will be denied. You must enter the correct 7-digit Update ID Number in order to update your Tandem insulin pump. In order to maintain security during the update process, each Update ID Number is associated with a specific pump serial number and can only be used once. Review your Update ID Number and confirm you've entered it in correctly. If you cannot locate the correct Update ID Number, contact Customer Technical Support.

Why am I having problems connecting to the Tandem servers?

In order to ensure the Tandem Device Updater meets your needs, we must periodically bring the servers down for service, updates, or repairs. During these maintenance windows, the Tandem Device Updater may be unavailable and you may not be able to update your pump.

What do I do if my pump displays a Connection Error Alert?

You may see a Connection Error Alert when the Tandem Device Updater is unable to communicate with your pump. Depending on your computer, the time it takes to establish communication will vary. If the issue persists, contact Customer Technical Support.

What do I do if I lose my internet connection?

You must be connected to the internet in order to update your pump. The Tandem Device Updater will display a message if the connection is lost during an update. Reconnect to the internet, click **Continue**, and follow the on-screen instructions.

How much time do I have to complete the update?

There is an update timer that will ask you to restart the update if more than 60 minutes have passed since you started the process. Click **Restart** and follow the on-screen instructions.


What do I do if my pump is unplugged during the update process?

Depending on when during the update process your pump was unplugged, you may be able to continue. Follow the on-screen instructions.

What do I do if my computer goes into “hibernate,” “sleep,” or “stand-by” during an update?

The update process may be interrupted. Bring your computer out of this mode and follow the on-screen instructions.

What happens if I tap NO or on the Pump Reboot screen?

If you decide you no longer want to update your pump and tap **NO** or  on the Pump Reboot screen, your pump will not allow the update. You will need to exit the Tandem Device Updater. Your pump software will not be updated, but you can update at another time by restarting the Tandem Device Updater.

What do I do if an update fails to install on my pump?

If you started an update and it failed, stop all pump use and contact Customer Technical Support.

Why don't I have any available updates?

Some updates may not be available for all Tandem insulin pumps. You can check back at any time to see if updates are available by visiting tandemdiabetes.com/products/tandem-device-updater.

Can I update more than one pump?

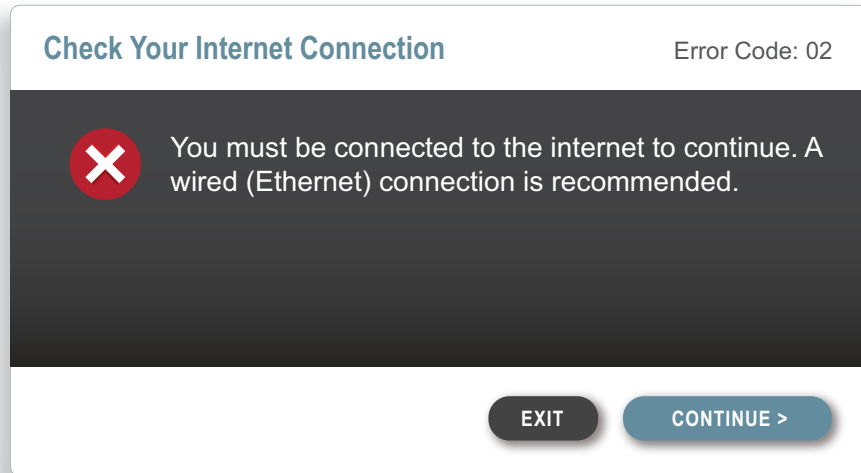
You can update multiple pumps, but each pump has a unique Update ID Number and only one pump can be updated at a time. Complete an update on the first pump and make sure you get the *Update Successful* message. Unplug the first pump, close the Tandem Device Updater, and restart the process with the next pump. You will not need to reinstall the Tandem Device Updater or use a different computer for each pump update.

Can I revert my pump to the previous software version?

You cannot revert your Tandem insulin pump software after you've completed an update. If an update is canceled or fails prior to completion, your Tandem insulin pump will revert to the previous software version.

Error Messages

If the Tandem Device Updater encounters a condition that will not allow you to continue with an update, you will see an error message on your computer. Follow the on-screen instructions to resolve the error condition and continue with your update.



NOTE: Error Message Codes

Each error message has an associated Error Code number displayed in the upper right corner of the error window. If you cannot continue, contact Customer Technical Support and reference the Error Code number displayed.

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Privacy Policy

Tandem Diabetes Care, Inc. ("Tandem") is firmly committed to your privacy and we have implemented policies and practices that protect personal data. You can find our Notice of Privacy Practices by visiting tandemdiabetes.com/privacy.

Security

The Tandem Device Updater uses enterprise-class Transport Layer Security (TLS) with 256-bit encryption for communication between your computer and the secure Tandem servers. All updates require an Update ID Number that is specific to your Tandem insulin pump, and which can only be used one time.

Online Resources

Visit tandemdiabetes.com/tandem-device-updater to access helpful resources:

- **System Requirements** – Web-based version of current computer and software requirements
- **Getting Started** – Quick links to download and install the Tandem Device Updater software
- **User Guide** – PDF of this user guide



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