Device Updater

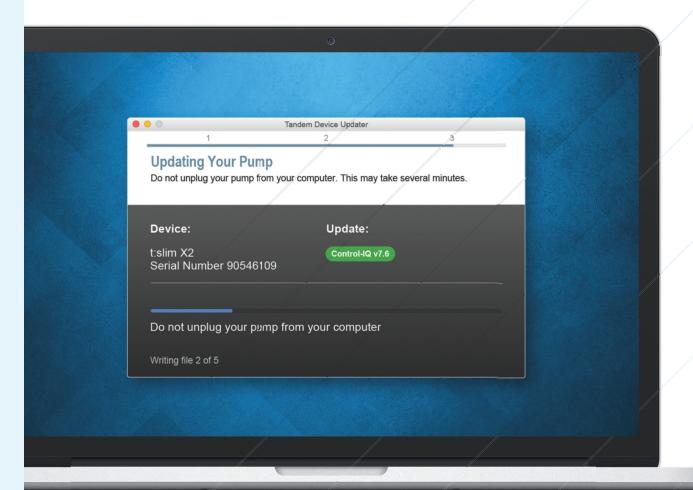




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Important Safety Information

Intended Use

The Tandem Device Updater is intended for use by individuals with diabetes mellitus who use t:slim X2[™] insulin pumps, their caregivers, and their healthcare professionals in home and clinical settings. The Tandem Device Updater remotely updates software for the t:slim X2 insulin pump using a computer with Internet access.

CAUTION: Federal (USA) law restricts t:slim X2 insulin pumps to sale by or on the order of a physician.

Important User Information

Thoroughly review all product instructions for warnings and other important user information before using the Tandem Device Updater. Medical devices, like other computer systems, can be vulnerable to cybersecurity risks, potentially impacting the safety and effectiveness of the device. Incorrect use of the Tandem Device Updater or your failure to follow the instructions, precautions and warnings in this user guide, may result in an inoperable pump or expose your t:slim X2 pump to cybersecurity risks.

The Tandem Device Updater should always connect to a Trusted Computer. A Trusted Computer is a personal computer or a computer controlled by your healthcare provider's office that has the latest security patches for a supported operating system.

For local support in your area, see the contact information on the back cover of this user guide.

■ NOTE

The Tandem Device Updater does not support the t:flex insulin pump, the t:slim G4 insulin pump, or the t:slim™ insulin pump as these pumps do not support software updates. The instructions in this user guide only apply to the t:slim X2 insulin pump, which will be referred to in this guide as the "pump."

SECTION 1 • Important Safety Information

Warnings

WARNING

DO NOT update your pump before reading the User Guide. Incorrect use of the Tandem Device Updater or your failure to follow the instructions, precautions and warnings in this user guide, may result in an inoperable pump or expose your pump to cybersecurity risks. If you have questions or need further clarification on the Tandem Device Updater or pump use, contact Customer Technical Support in the United States and Canada or your local customer support service in other countries. For contact information in your region see the back cover of this user guide.

WARNING

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.

A WARNING

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 BG or Diabetic Ketoacidosis (DKA).

A WARNING

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 updating your pump.

WARNING

DO suspend all pump insulin delivery prior to using the Tandem Device Updater.

WARNING

DO NOT update your pump while your infusion set is connected to your body.

▲ WARNING

D0 confirm your pump's personal settings, date, time, and serial number are correct immediately 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. Closely monitor your insulin delivery and BG following an update. Ensure your symptoms match your therapy data.

A 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.

SECTION 1 • Important Safety Information

Precautions

A PRECAUTION

ONLY use the Tandem Device Updater to update your pump.

A PRECAUTION

ONLY download the Tandem Device Updater following the instructions provided in the Update Instructions section of this user guide.

A PRECAUTION

ENSURE you are always using the latest version of the Tandem Device Updater.

A PRECAUTION

NEVER connect your pump to a public computer. Always use a Trusted Computer.

A PRECAUTION

Use of security features on your Trusted Computer is important. These security features include:

- » The use of a password or PIN to unlock the Trusted Computer.
- » Making sure that your Trusted Computer has current security software.
- » Keeping your software updated when prompted by your Trusted Computer.
- » Some web pages can be unsafe and can affect your Trusted Computer just by visiting them. You should minimize visits to unknown websites and look for 'https' in the browser address or for the padlock symbol next to the URL when visiting websites.
- » You can check system requirements at tandemdiabetes.com/support/software-updates. You can verify the tandemdiabetes.com certificate in the browser by clicking on the padlock symbol next to the URL.

A PRECAUTION

ONLY use the USB cable provided by Tandem Diabetes Care to perform a software update.

A PRECAUTION

Exercise caution whenever you connect your pump to a Trusted Computer and remain in the presence of the pump at all times while updating your pump.

A PRECAUTION

Connecting the pump to a Trusted Computer 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.

A PRECAUTION

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.

A PRECAUTION

DO NOT disconnect from the Internet during an update. Doing so could interrupt the update, and your pump may not function.

A PRECAUTION

DO NOT disconnect your pump from your Trusted Computer during an update unless instructed to do so. Doing so could interrupt the update, and your pump may not function.

SECTION 1 • Important Safety Information

A PRECAUTION

If you had an active CGM sensor session when you started the update process, you will need to resume your current session by tapping **START SENSOR** on the *My CGM* screen of your pump once the update is complete. The CGM sensor session continues to be active, but you will not see your CGM trend graph until your start your CGM sensor session again from your pump.

A 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.

A PRECAUTION

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

Welcome

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 pump as they become available.

Product Overview

The Tandem Device Updater is designed to update the software on your pump. The process is similar to doing software updates for your Trusted Computer or mobile device and shouldn't take more than thirty minutes.

What You Need

Before you begin the update process, there are a few things that you need to do in order to successfully update your pump.

Make sure you are prepared with each of the following items on hand.

- A list of your current pump settings, current IOB, and pump serial number written down. You may
 choose to print your pump settings from the t:connect™ web application if you live in the United
 States.
- 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 BG meter so you can check your BG 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.
- Have supplies to load a new cartridge. We recommend performing the update when you are ready
 for a new cartridge. Otherwise, you will need at least 80 units of insulin remaining in your existing
 cartridge before performing the update.
- Your unique Update ID Number.
 - You should have received an Update ID Number. If you cannot locate your Update ID Number, contact Customer Technical Support in the United States and Canada or your local customer support service in other countries. For contact information in your region see the back cover of this user guide.
- A Trusted 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.
 - 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.
- Charge your Tandem insulin pump battery using the USB cable provided.

SECTION 2 • Welcome

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. The Tandem Device Updater requires access to the USB port on your Trusted Computer. The pump connects to this USB port via a USB cable and requires both sending and receiving data in order to update the pump software.

A PRECAUTION

ONLY use the USB cable provided by Tandem Diabetes Care to perform a software update.

NOTE

The Personal Profiles and History on your pump will be maintained before and after an update. 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 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.

A PRECAUTION

If you had an active CGM sensor session when you started the update process, you will need to resume your current session by tapping START SENSOR on the *My CGM* screen of your pump once the update is complete. The CGM sensor session continues to be active, but you will not see your CGM trend graph until your start your CGM sensor session again from your pump.

A 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 Instructions

To verify that you are eligible for a pump software update follow the instructions below for your region.

For Customers in the United States and Canada

Check eligibility for a pump software update. Visit portal.tandemdiabetes.com and login with your t:connect™ account credentials. Once logged in, click on the My Devices tab to view available software updates.

For Customers in Other Countries

Check eligibility for a pump software update. Contact your local customer support service. In some cases, you will be contacted by your local customer support service directly if you are eligible for an update. For contact information, visit tandemdiabetes.com/contact.

Install the Tandem Device Updater

A PRECAUTION

ENSURE you are always using the latest version of the Tandem Device Updater.

A PRECAUTION

ONLY download the Tandem Device Updater following the instructions provided below.

A PRECAUTION

Use of security features on your Trusted Computer is important. These security features include:

- » The use of a password or PIN to unlock the Trusted Computer.
- » Making sure that your Trusted Computer has current security software.
- » Keeping your software updated when prompted by your Trusted Computer.
- » Some web pages can be unsafe and can affect your Trusted Computer just by visiting them. You should minimize visits to unknown websites and look for 'https' in the browser address or for the padlock symbol next to the URL when visiting websites.
- » You can check system requirements at tandemdiabetes.com/support/software-updates. You can verify the tandemdiabetes.com certificate in the browser by clicking on the padlock symbol next to the URL.

If you have previously downloaded and installed the Tandem Device Updater:

For PC:

- 1. Check the latest version listed on the Tandem Diabetes Care website.
 - To check the latest version for Control-IQ technology, visit tandemdiabetes.com/support/software-updates/control-iq-technology.
 - To check the latest version for Basal-IQ, visit tandemdiabetes.com/support/software-updates/ basal-iq-technology.
- 2. The latest Tandem Device Updater version number will be listed on the right-hand side of the web page in an area titled *Download Updater*.
- 3. Open the Tandem Device Updater icon from your desktop or select the Tandem Device Updater from your Program Files folder.
- 4. In the upper left corner of the Tandem Device Updater, click File.

- 5. Select About Tandem Device Updater.
- 6. Verify that the version number listed matches what is displayed on the web page. If the version number does not match, download the latest version of Tandem Device Updater from the web page.

For Mac:

- 1. Open the Tandem Device Updater from your Mac applications folder.
- 2. In the upper left corner of the Tandem Device Updater, click Tandem Device Updater.
- 3. Select About Tandem Device Updater.
- 4. Verify that the version number listed matches what is displayed within the What's New section on the App Store by visiting apps.apple.com/us/app/tandem-device-updater/id1100870281. If the version number does not match, download the latest version of Tandem Device Updater directly from the App Store.

If you have never downloaded or installed the Tandem Device Updater:

- 1. Download the appropriate update.
 - To download an update for Control-IQ technology, visit tandemdiabetes.com/support/softwareupdates/control-iq-technology.
 - To download an update for Basal-IQ, visit tandemdiabetes.com/support/software-updates/basal-iq-technology.
- 2. Click the Download for Mac or Download for PC button, depending on which type of computer you are using. If you are using a Mac, you can also download the Tandem Device Updater directly from the App Store. Visit apps.apple.com/us/app/tandem-device-updater/id1100870281.
- 3. Open the downloaded Tandem Device Updater.exe file from your Downloads folder.
- 4. Select your language of preference and click OK.
- 5. Read the License Agreement and privacy policies applicable to your region. Click the check box to acknowledge.
- 6. Click INSTALL.
- 7. Click Finish.

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 on your Trusted Computer is complete. Follow the prompts to update your pump. If it does not start automatically, locate the Tandem Device Updater icon on your computer.



PC: The Tandem Device Updater icon will be on your desktop or in your Program Files 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 Trusted Computer using the USB cable provided by Tandem.

A PRECAUTION

NEVER connect your pump to a public computer. Always use a Trusted Computer.

A PRECAUTION

Connecting the pump to a Trusted Computer 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.

A PRECAUTION

Exercise caution whenever you connect your pump to a Trusted Computer and remain in the presence of the pump at all times while updating your pump.

A PRECAUTION

ONLY use the Tandem Device Updater to update your pump.

A PRECAUTION

ONLY use the USB cable provided by Tandem Diabetes Care to perform a software update.

A PRECAUTION

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

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

If your Trusted 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 in the United States and Canada or your local customer support service in other countries. For contact information in your region see the back cover of this user guide.

NOTE

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 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

If you tap **NO** or 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

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

6. You are now ready to use your pump. Unlock your pump, tap **NEXT**, and load a new cartridge to resume your pump therapy. Refer to the *t:slim X2*TM 3 mL cartridge instructions for use. 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.



A WARNING

DO NOT rely on the 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.

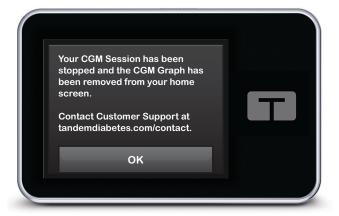
7. Confirm the software has been updated successfully on your pump. On your pump, navigate to the *Pump Info* screen to find the **t:slim Software** version.

A WARNING

D0 confirm your pump's personal settings, date, time, and serial number are correct immediately 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. Closely monitor your insulin delivery and BG following an update. Ensure your symptoms match your therapy data.

8. If you had an active CGM sensor session when you started the update process, you will need to resume your current session by tapping START SENSOR on the *My CGM* screen of your pump

once the update is complete. The CGM sensor session continues to be active, but you will not see your CGM trend graph until your start your CGM sensor session again from your pump.



Troubleshooting

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/support/software-updates for the list of supported pumps. If the warranty on your pump has expired, it may not be eligible for all updates. To confirm your pump is eligible for an update, click the My Devices tab within portal.tandemdiabetes.com (customers in the United States and Canada) or contact your local support service (customers in other countries).

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 Trusted 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 Trusted 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 in the United States and Canada or your local customer support service in other countries. For contact information in your region see the back cover of this user guide.

Frequently Asked Questions

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

What should I do if I am uncertain whether the message about my software update is legitimate?

Be aware of suspicious messaging related to your pump and available software updates. You should exercise caution and ensure that a message is from a trusted source before acting on any information

SECTION 4 • Troubleshooting

contained within it. If in doubt, do not respond and contact Customer Technical Support in the United States and Canada or your local customer support service in other countries. For contact information in your region see the back cover of this user guide.

How do I safely access the Tandem Customer Portal? (for customers in the United States and Canada only)

Only connect to the Tandem portal by typing in portal.tandemdiabetes.com directly into your browser and ensure it has a padlock symbol next to the URL. Some web pages can be unsafe and can affect your computer just by visiting them. You should minimize visits to unknown websites and look for the padlock symbol or 'https' in the browser address when visiting websites.

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 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 in the United States and Canada or your local customer support service in other countries. For contact information in your region see the back cover of this user guide.

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 in the United States and Canada or your local customer support service in other countries. For contact information in your region see the back cover of this user guide.

What do I do if my computer screen displays an error message which prevents me from continuing the update?

Follow the on-screen instructions to resolve the error and continue with your update. If you are unable to continue with your update, contact Customer Technical Support in the United States and Canada or your local customer support service in other countries. For contact information in your region see the back cover of this user guide.

SECTION 4 • Troubleshooting

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 I receive a malfunction when trying to update my pump?

If you received a malfunction on your pump during an update, stop all pump use and contact Customer Technical Support in the United States and Canada or your local customer support service in other countries. For contact information in your region see the back cover of this user guide.

What do I do if my pump settings, date, time, and pump serial number do not match what I wrote down before the software update?

Discontinue use of the pump immediately and check your BG with a blood glucose meter (BGM) and use an alternate insulin delivery plan. Contact Customer Technical Support in the United States and Canada or your local customer support service in other countries immediately. For contact information in your region see the back cover of this user guide.

Why don't I have any available updates?

Some updates may not be available for all pumps. The Tandem Device Updater does not support the t:flex insulin pump, the t:slim G4 insulin pump, or the t:slim™ insulin pump as these pumps do not support software updates. If the warranty on your pump has expired, it may not be eligible for all updates. To confirm your pump is eligible for an update, click the My Devices tab within portal.tandemdiabetes.com (customers in the United States and Canada) or contact your local support service (customers in other countries)

SECTION 4 • Troubleshooting

Can I update more than one pump?

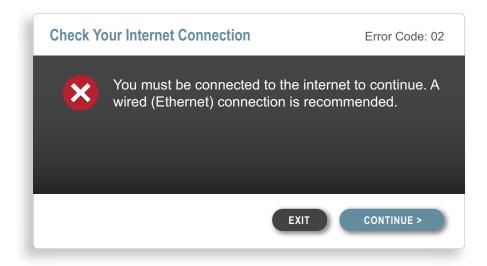
You can update multiple pumps, but each pump has a unique Update ID Number and only one pump can be updated at a time. Complete an update on the first pump and make sure you get the *Update Successful* message. Unplug the first pump, close the Tandem Device Updater, and restart the process with the next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

Can I revert my pump to the previous software version?

You cannot revert your pump software after you've completed an update. If an update is canceled or fails prior to completion, your 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

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 in the United States and Canada or your local customer support service in other countries and reference the Error Code number displayed.

Miscellaneous

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/legal/privacy.

Security

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

Online Resources

Visit the Tandem website to access helpful resources:

- System Requirements A list of current computer and software requirements can be found at tandemdiabetes.com/support/software-updates.
- Getting Started Quick links to download and install the Tandem Device Updater software can be found at tandemdiabetes.com/products/software-apps/tandem-device-updater.
- User Guide The PDF of this user guide can be found at tandemdiabetes.com/products/softwareapps/tandem-device-updater.

Trademarks and Patents

Tandem Diabetes Care, t:connect, t:slim, and t:slim X2 are either registered trademarks or trademarks of Tandem Diabetes Care, Inc., in the United States and/or other countries.

Mac is a trademark of Apple Inc., registered in the U.S. and other countries and regions.

App Store is a service mark of Apple Inc.

All other third-party marks are the property of their respective owners.

For a list of patents, visit tandemdiabetes.com/legal/intellectual-property.



UNITED STATES:

(877) 801-6901 tandemdiabetes.com

CANADA:

(833) 509-3598 tandemdiabetes.ca

OTHER COUNTRIES:

tandemdiabetes.com/contact