



MiniMed™ 780G system

Software update guide



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Note: This guide uses app screens from iOS® devices. Screens and pop-ups may vary for other operating systems, or between phone models.

Software update process



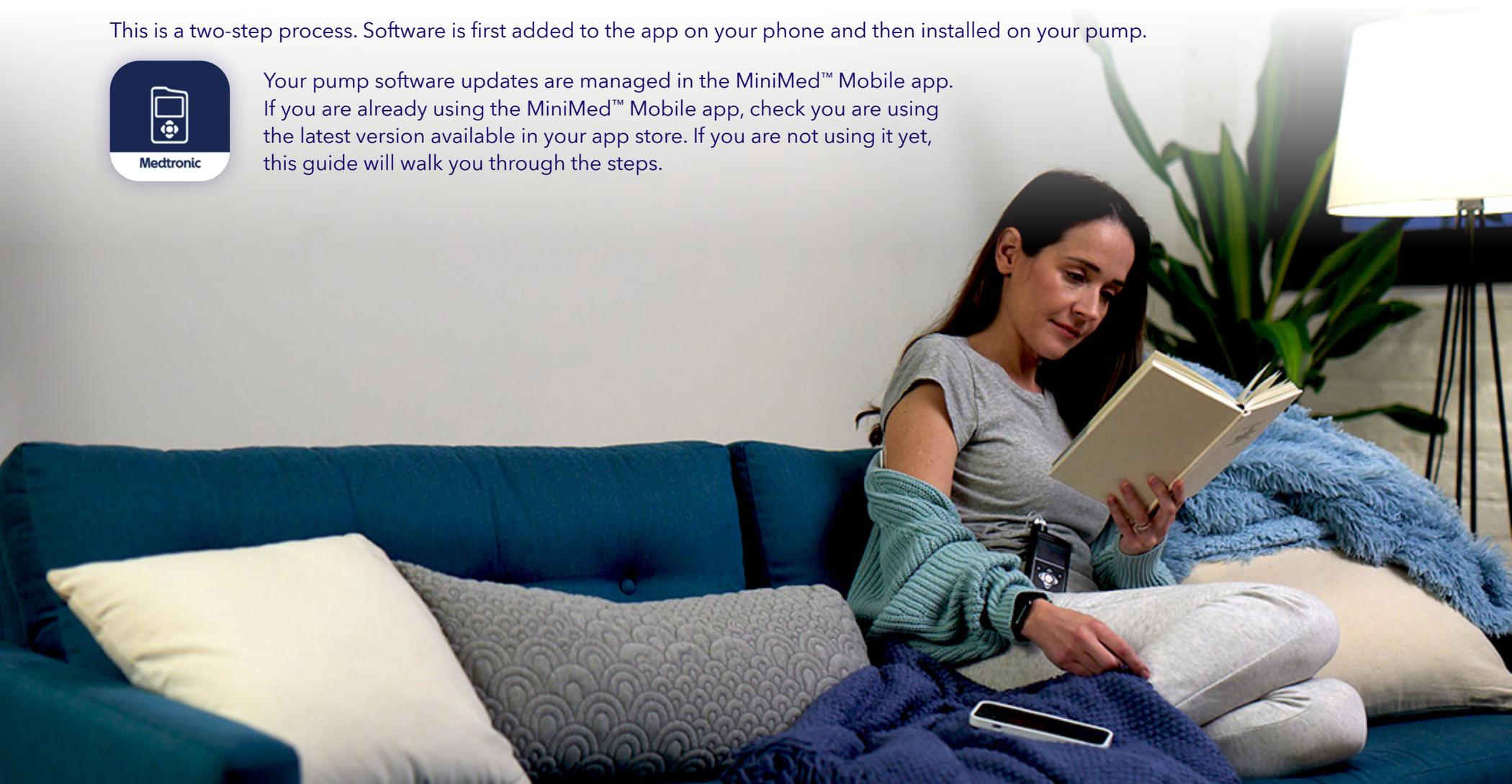
Best practices

- Complete the update early in the day.
- Downloading and installing the software will take 2-3 hours.
- Make sure your phone is fully charged and your pump shows a green battery icon.

This is a two-step process. Software is first added to the app on your phone and then installed on your pump.



Your pump software updates are managed in the MiniMed™ Mobile app. If you are already using the MiniMed™ Mobile app, check you are using the latest version available in your app store. If you are not using it yet, this guide will walk you through the steps.



Step 1: Get ready

1. Record your pump settings.
2. Download the MiniMed™ Mobile app if needed.
3. Login or set up CareLink™ Personal.
4. Sync to CareLink™ (can take several minutes).

Step 2: Download the update

1. Download update to your phone.
 - Takes 45-90 minutes depending on internet speed.
2. App will check your pump for software update.
 - Takes up to 10 minutes.
3. Use pump and phone like you normally do but don't force close the MiniMed™ Mobile app.
4. Disconnect from your pump.

Step 3: Install the update

During this step, there will be no sensor glucose values or notifications sent to your pump or your care partners.

1. Install the new software on your pump.
 - Takes up to 20 minutes.
2. Pair your pump and phone if needed.

Step 4: Complete the checklist

1. Confirm your personal pump settings transferred.
 - 15 minute update check.

Note: Once the update is complete, there is a 5-hour SmartGuard™ technology warm-up.



Important reminder:

Throughout the software update, make sure your pump and your phone are never further apart than 3 meters (10 feet).



Meter Pairing Change

In some countries, the Accu-Chek® Guide Link meter will no longer pair with your pump after this update. You can still enter BG readings manually when needed.

Get ready

- To confirm your settings at the end of the update, you will need to have your current settings written down (pages 5-6 will walk you through this process).

Once these items are completed, move on to Download the update on page 12.

- Do you have the MiniMed™ Mobile app installed?

Yes -- great! Keep going, skip to page 11. **Note:** If it's been a while since you've used it, we recommend deleting and reinstalling the latest version to make sure everything goes smoothly.

No? No problem -- we'll walk you through how to install it on page 7.

- Sync your CareLink™ Personal data via the MiniMed™ Mobile app (page 11).



Find your settings

Tip: To prevent your pump from timing out while you find and record your settings, consider extending the **Backlight** to 3 minutes before starting. Go to **Settings > Device Settings > Display Options** to adjust the timer.



Go to your Main menu and select SmartGuard.

Down arrow and select SmartGuard settings.

- Record your target.
- Record your Auto correction setting.
- Back arrow to Main menu.



From your Main menu, select Insulin.

Down arrow and select Delivery settings.

- Record your bolus settings.
- Record your basal settings.
- Record your max basal and max bolus.
- Back arrow to Main menu.



From your Main menu, select Settings, and Alert Settings.

Down arrow and select High Alert.

- Record your High settings.
- Record your Low settings.



Record your current pump settings here:

SmartGuard™ feature

| | |
|-------------------|-----------------|
| SmartGuard Target | 100 110 120 |
| Auto Correction | ON OFF |

Bolus

| | |
|--------------|----------|
| Bolus Wizard | ON OFF |
|--------------|----------|

| Carb Ratio | | Active Insulin Time | | Insulin Sensitivity Factor | | BG Target | | |
|------------|-----|---------------------|--|----------------------------|-------------|-----------|-----|------|
| Time | g/U | Time | | Time | mg/dL per U | Time | Low | High |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

Record your current pump settings here (continued):

Basal

Basal 1

| 24-Hour Total | |
|---------------|------|
| Time | U/Hr |
| | |
| | |
| | |
| | |

Basal 2

| 24-Hour Total | |
|---------------|------|
| Time | U/Hr |
| | |
| | |
| | |
| | |

| | | |
|-----------|--|------|
| Max Basal | | U/Hr |
| Max Bolus | | U/Hr |

| High Alerts | | | ON OFF | |
|-------------|--------------|---------------|-------------------|------------------|
| Start Time | High setting | Alert on High | Alert Before High | Rise Alert Limit |
| | | ON OFF | ON OFF | ON OFF |
| | | ON OFF | ON OFF | ON OFF |

| Low Alerts | | | | ON OFF | |
|------------|-------------|---------|--------------|------------------|--------------------|
| Start Time | Low setting | Suspend | Alert on Low | Alert Before Low | Resume Basal Alert |
| | | | ON OFF | ON OFF | ON OFF |
| | | | ON OFF | ON OFF | ON OFF |

Set up the MiniMed™ Mobile app



First, download the MiniMed™ Mobile app from the app store onto your Android or iOS phone. Next, open the app and read the introduction screens.

You'll need to log in to CareLink™ Personal software. Don't have an account? Follow the steps below to register.



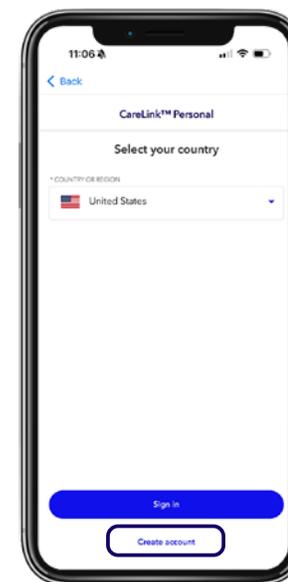
If you have a CareLink™ Personal account but can't remember your username and password, **do not set up a second account for your update**. It is important to link that account to keep all your data together. You can request a reminder online at carelink.minimed.com by selecting **Forgot your password?**

Sign up for CareLink™ Personal

1. Open the app and read the introduction screens.
2. Press **Next** until you get to the **Sign up for CareLink™ Personal** screen.
3. Tap **Create account** to register or **Sign in** if you already have an account.



Takes you to carelink.minimed.com to sign up for a new account.



App not downloading?

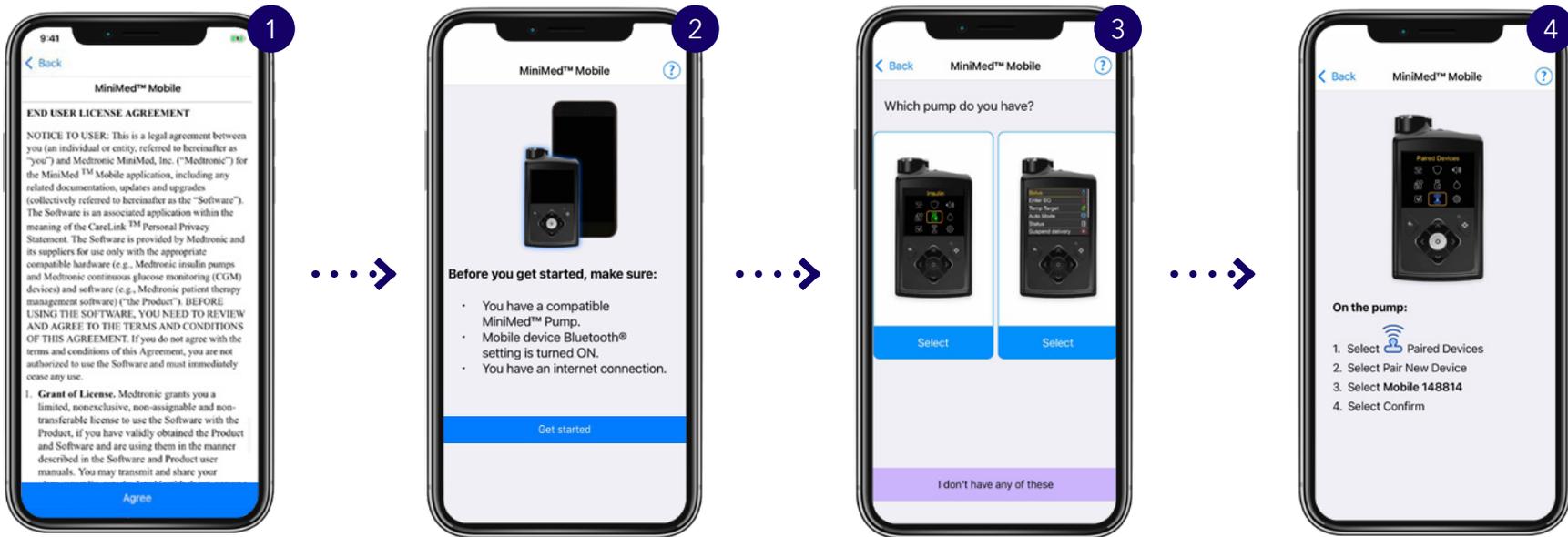
Check your phone compatibility here by scanning the QR code or visiting the link below.
<https://www.medtronicdiabetes.com/customer-support/app-support/device-compatibility>.

A compatible mobile device is needed to complete the upgrade. Don't have one? You can borrow a phone from a friend or family member just for the upgrade process.

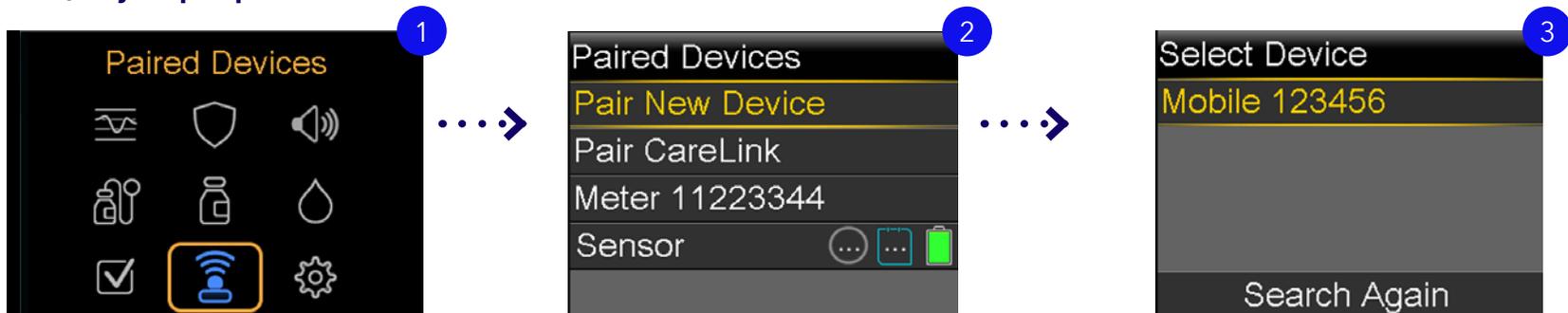
Pair the MiniMed™ Mobile app with your pump

After signing in, you'll need to **agree** to the End User License Agreement and acknowledge the pop-up to continue. The app will then check your pump model and guide you through the pairing process. Follow the on-screen instructions on the app.

First, on your phone:



Then, on your pump:



The pairing process is started on the pump, but you will also need to keep an eye on your phone. To start, go to your pump's **Main menu**.

Select **Pair New Device**.

Select the **Mobile device number** that corresponds with the one listed on your app screen.

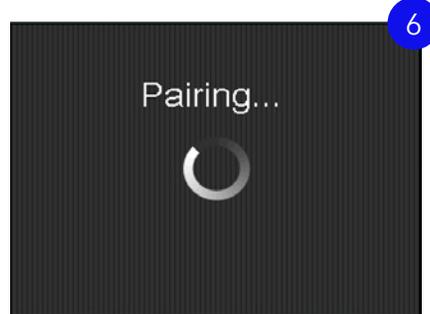


5

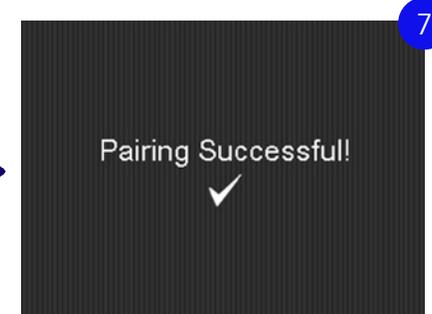


5

Select **Confirm** on your pump.

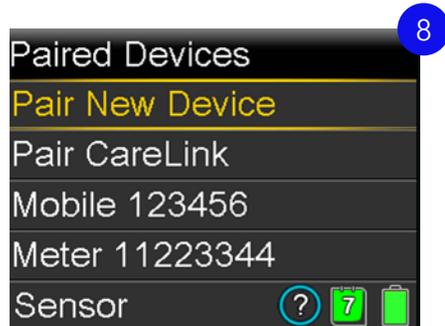


6



7

Your phone will display the pairing screen. Tap **Allow, Agree, or Pair** on all pop-ups.



8

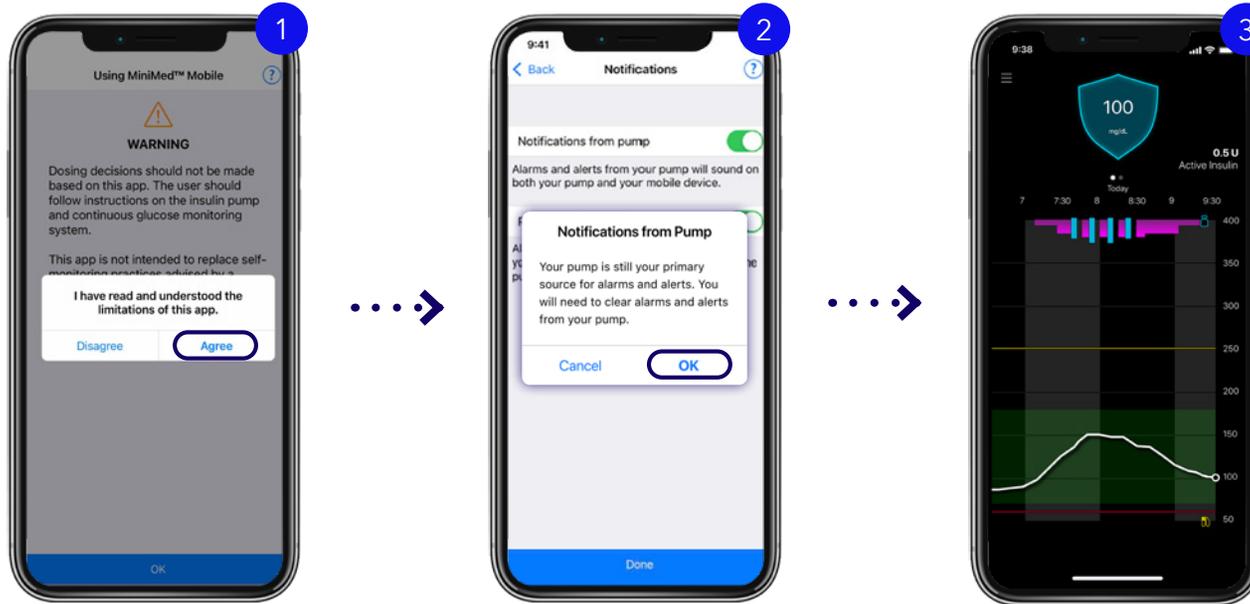


Once pairing is complete, your pump will go back to the **Paired Devices** menu and your mobile device will show a **pump and mobile phone icon with a blue check mark** as shown here.

Your phone and pump are now paired.

Finalize setup of the MiniMed™ Mobile app

Go back to your phone and read the dosing-decision warning, which states not to make dosing decisions based on the MiniMed™ Mobile app. Tap **OK** and **Agree** on the pop-up.



Next, you will be asked to confirm your notification settings. The default is **on**. **If these are turned off, you will only receive notifications on your pump and NOT your mobile phone.**

Once the MiniMed™ Mobile syncs, your data will appear on the Home screen. This may take a few minutes.



The MiniMed™ Mobile app is now set up and you can begin the update.

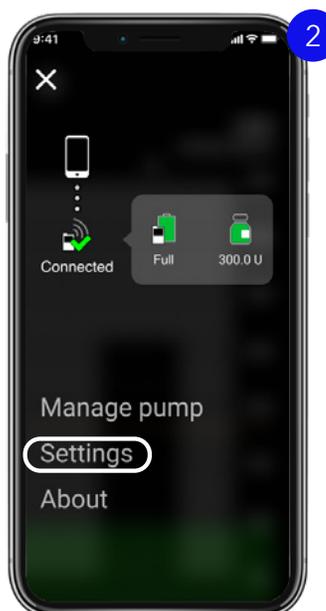
Sync to CareLink™ Personal

As the last step, before starting your update, it is recommended to **sync your existing pump data** to your CareLink™ Personal account. Use the MiniMed™ Mobile app to do this, following the instructions below.

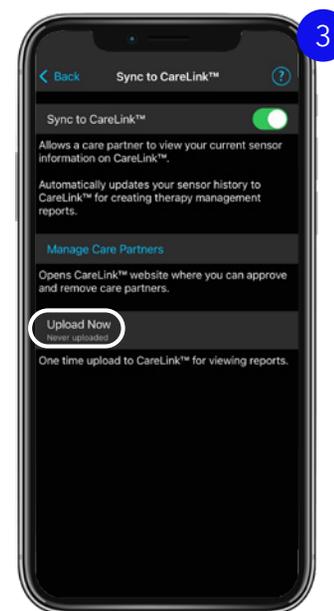
Start here
if you already have
the MiniMed™
Mobile app set up.



From the Home screen, tap on the **Main Menu** icon.



Tap **Settings**, followed by the **Sync to CareLink™** option. **Note:** The **Sync to CareLink™** option may appear in the Main Menu in some software versions.



Tap **Upload Now** to sync your data with your CareLink™ Personal account. This may take a few minutes.

After the data sync is complete, tap **Back** on your app to return to the **Home screen**.

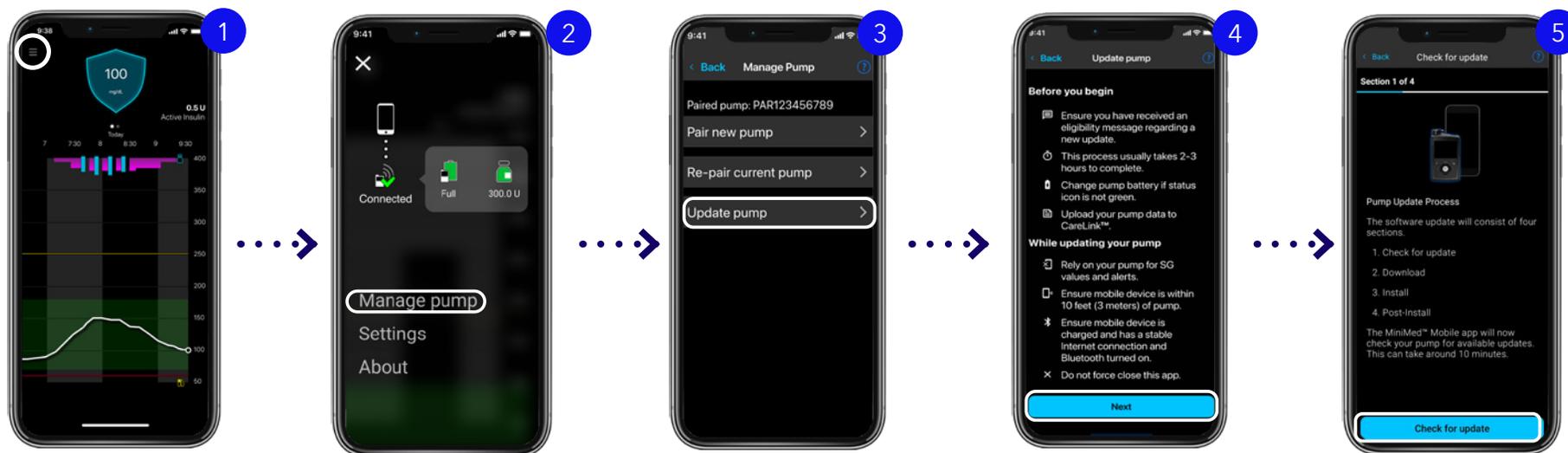
Go to the next page to begin the software update.

Download the update



Check for update

Make sure you have a stable internet connection, preferably Wi-Fi.



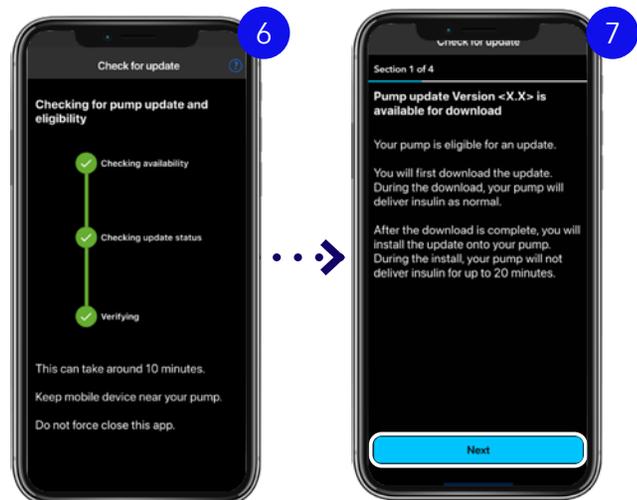
On the MiniMed™ Mobile app, access the **Main Menu** at the top left corner.

Tap **Manage pump**.

Tap **Update pump**. **Note:** The **Update pump** option may appear in the Main Menu in some software versions.

Read the **Before you begin list**. Tap **Next**.

Tap **Check for update**.

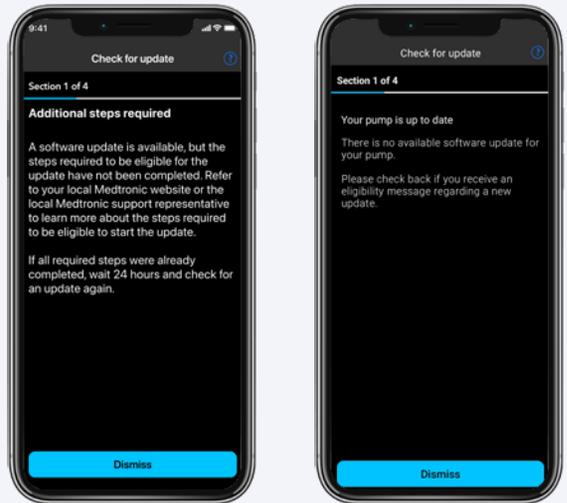


Tap **Next** to begin the download process and proceed to page 14.



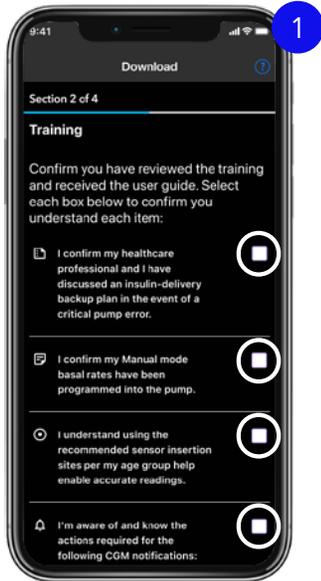
Your software version may differ from this image.

Having trouble updating? If you see the screens below, it means a required step may have been missed, or your device may not be eligible for the update. Call Medtronic Support at 1-800-646-4633 for help.

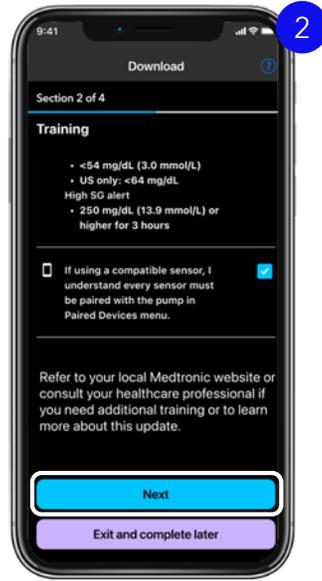



See the troubleshooting section (Appendix E) if you do not see the Update pump option.

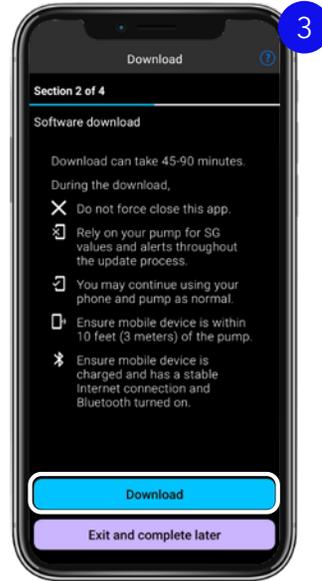
Download the update



Review and confirm statements by tapping the boxes.



Scroll to review and confirm all items and tap **Next**.



Tap **Download**.



Follow the instructions on your app.



The download will take 45-90 minutes. You may see your time remaining go up or down depending on your internet connection and phone use.



Swiping the app window up, on iOS for example, will cancel the download. You may otherwise continue to use your phone and pump as normal, including taking calls, answering messages, and using other apps.[†]

[†]Using other apps/Bluetooth devices may slow the download speed.



When the software download is complete, the app will automatically start checking your pump. This may take up to **10 minutes**. If the check is unsuccessful, try again, and if that doesn't work, consult the troubleshooting section (Appendix D) at the end of this guide.



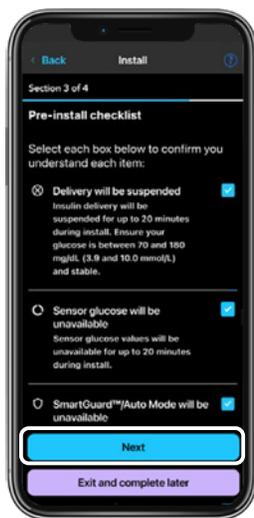
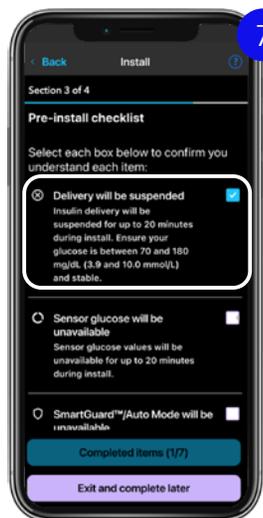
Tap **Next** to move onto the Pre-install checklist.

Install the update



Install the update

The MiniMed™ Mobile app will notify you that the software is ready to install.



Read each item and check the corresponding box to confirm.

Then tap **Next**.



Note: This installation may take up to 20 minutes. If this isn't a convenient time, you can pause and complete it later. However, be sure to **finish it the same day as the download to avoid repeating the process.**

Tap **Exit and complete later** to continue later.



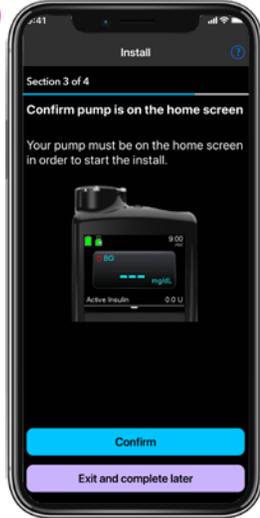
Important: Please pause before continuing. The next steps are critical to completing your setup successfully. To ensure a smooth experience, **make sure your pump and phone are side by side** before moving forward. You'll need to refer to both devices throughout the process. Taking a moment now to prepare will help everything go as smoothly as possible.



Your pump must be on the Home screen before starting the install.

8

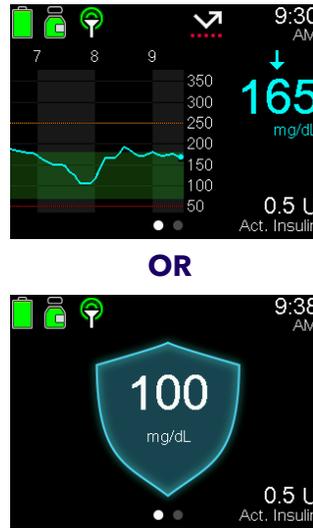
On your phone:



Put down your phone and **pick up your pump**.

Your pump must be on the Home screen (as shown on the right) before starting the install.

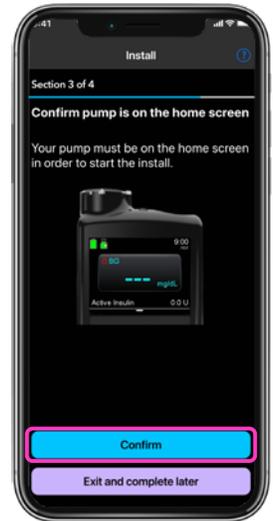
On your pump:



9

If you have confirmed your pump is on the Home screen, tap **Confirm** on your phone.

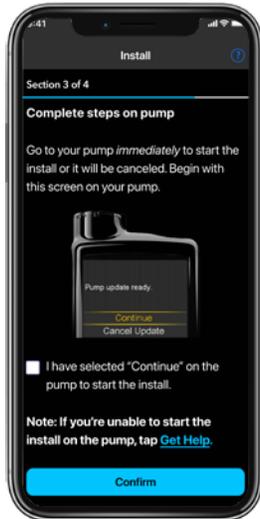
On your phone:



10

This screen appears briefly.

On your phone:



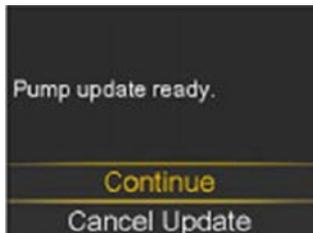
Put down your phone and **pick up your pump**.



11

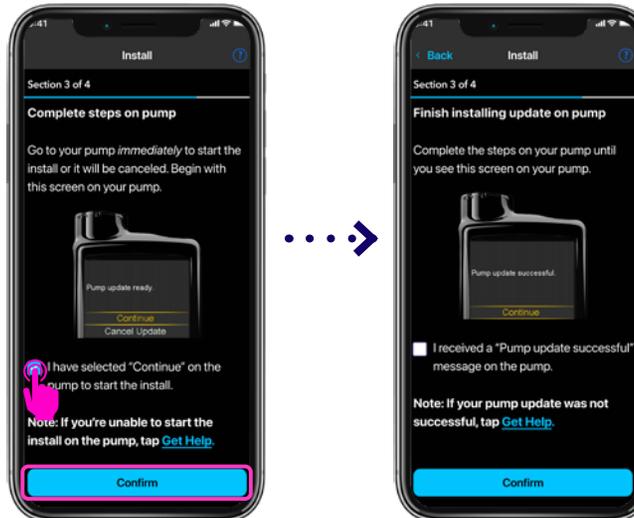
Select **Continue** on your pump to start the install.

On your pump:



Once you have selected **Continue** on your pump, tap the **I have selected "Continue"** on the pump to start the install message on your phone followed by **Confirm**.

On your phone:



Keep going – you're almost there!

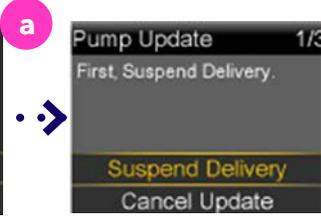
On the next page, follow steps 12a-12f to finish installing the update on your pump.

12 Finish installing the update on your pump with the following steps.

On your pump:



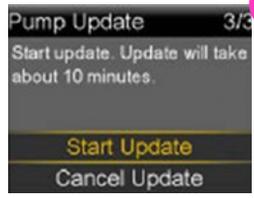
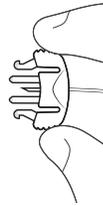
Confirm you see this screen on your pump. Select **Continue**.



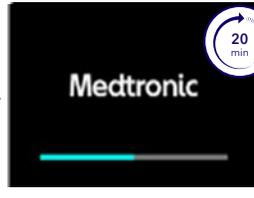
Select **Suspend Delivery**.



Disconnect from your pump. Select **Confirm**.



Select **Start Update**.



The update will install. This may take up to 20 minutes.

If the update isn't successful, reconnect your infusion set. Your pump will continue running the original software with no data loss, and you can try again later. You can keep using the MiniMed™ Mobile app until you're ready to retry the update. If multiple attempts fail, refer to the troubleshooting section (Appendix E) at the end of this guide.



Pump update successful. Select **Continue**.



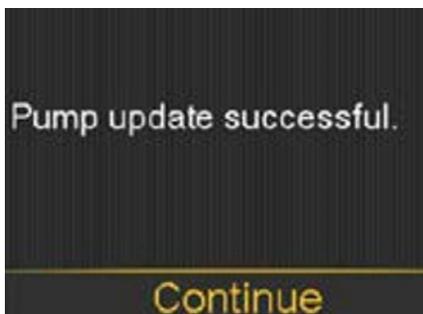
SmartGuard™ feature warm-up:

If you were using the SmartGuard™ feature before the update, you will receive a warning on your pump after the update that the SmartGuard™ feature will take 5 hours to warm up back up before it can be used again. During this warm-up period, you will be in Manual mode. For this reason, it is recommended to turn on the Suspend on low or Suspend before low feature according to your Healthcare Professional's guidance.

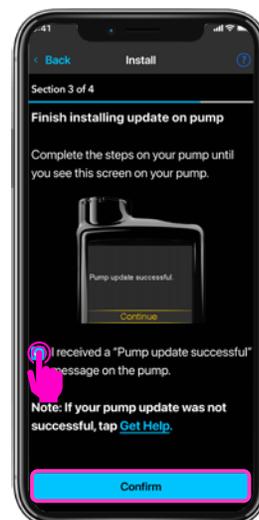
13

Once you see the **Pump update successful** message on your pump, on your phone, tap the **I have received a "Pump update successful."** message on the pump message on your phone, followed by **Confirm**.

On your pump:



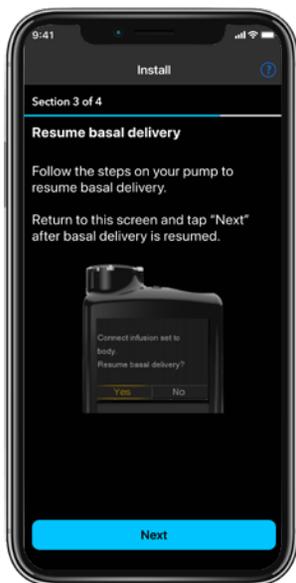
On your phone:



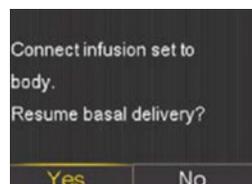
If you did not see the **Pump update successful** message on your pump, on your phone, tap **Get Help** to be taken through some in-app troubleshooting. You can also consult the troubleshooting section (Appendix E) at the end of this guide.

On your phone:

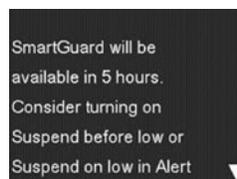
You'll be reminded to resume basal insulin delivery if you haven't already. Confirm your infusion set is reconnected and insulin delivery has resumed.



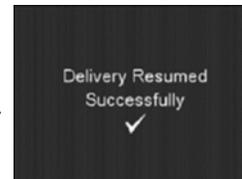
On your pump:



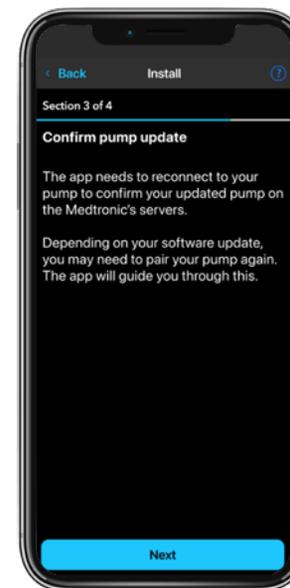
Connect your infusion set, then select **Yes**.



SmartGuard™ warm-up message (if using).



Go back to your phone. Tap **Next**.

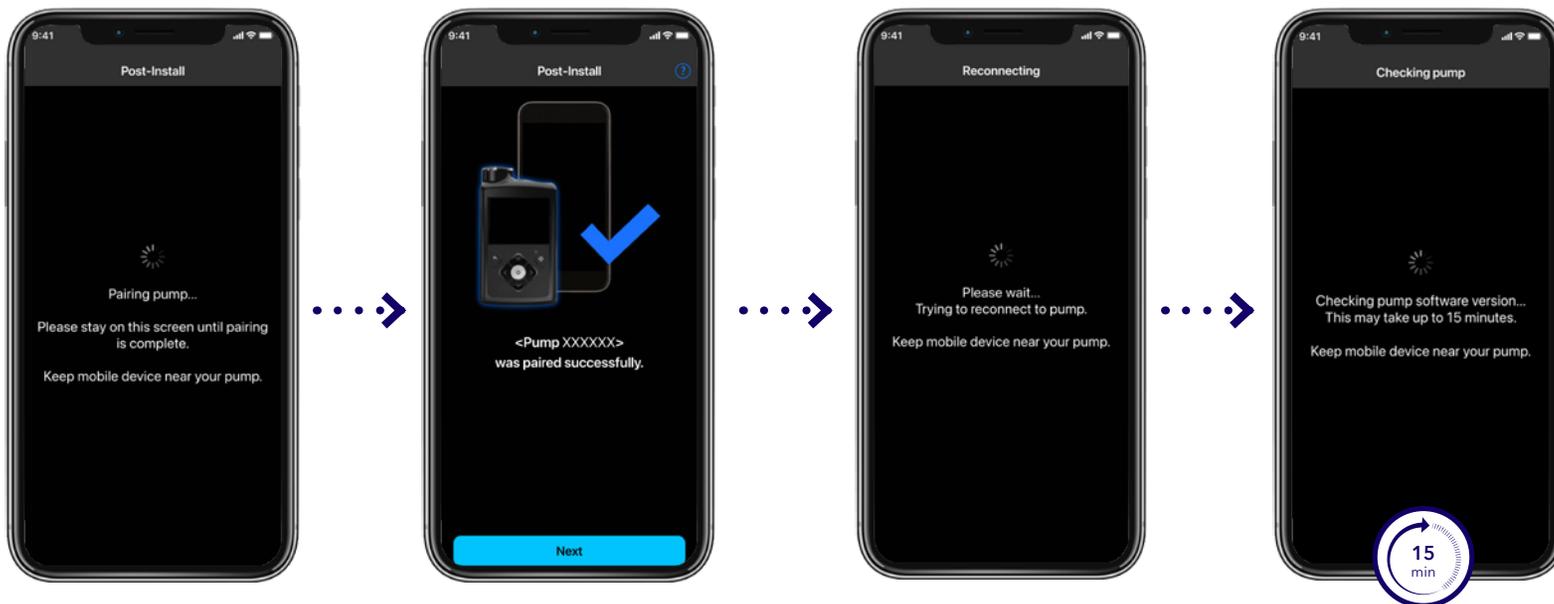
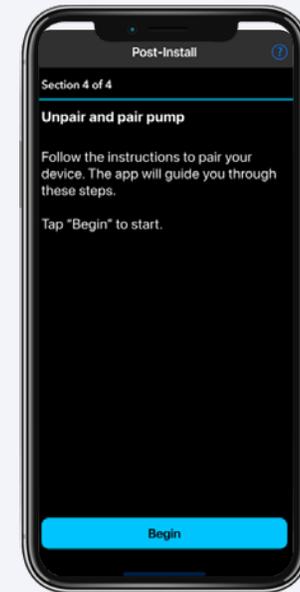


Tap **Next** again.

You may need to unpair and pair your pump and mobile device.

If so, the app will guide you through the steps.

Step by step instructions are also available in the troubleshooting section of this guide (Appendix A).

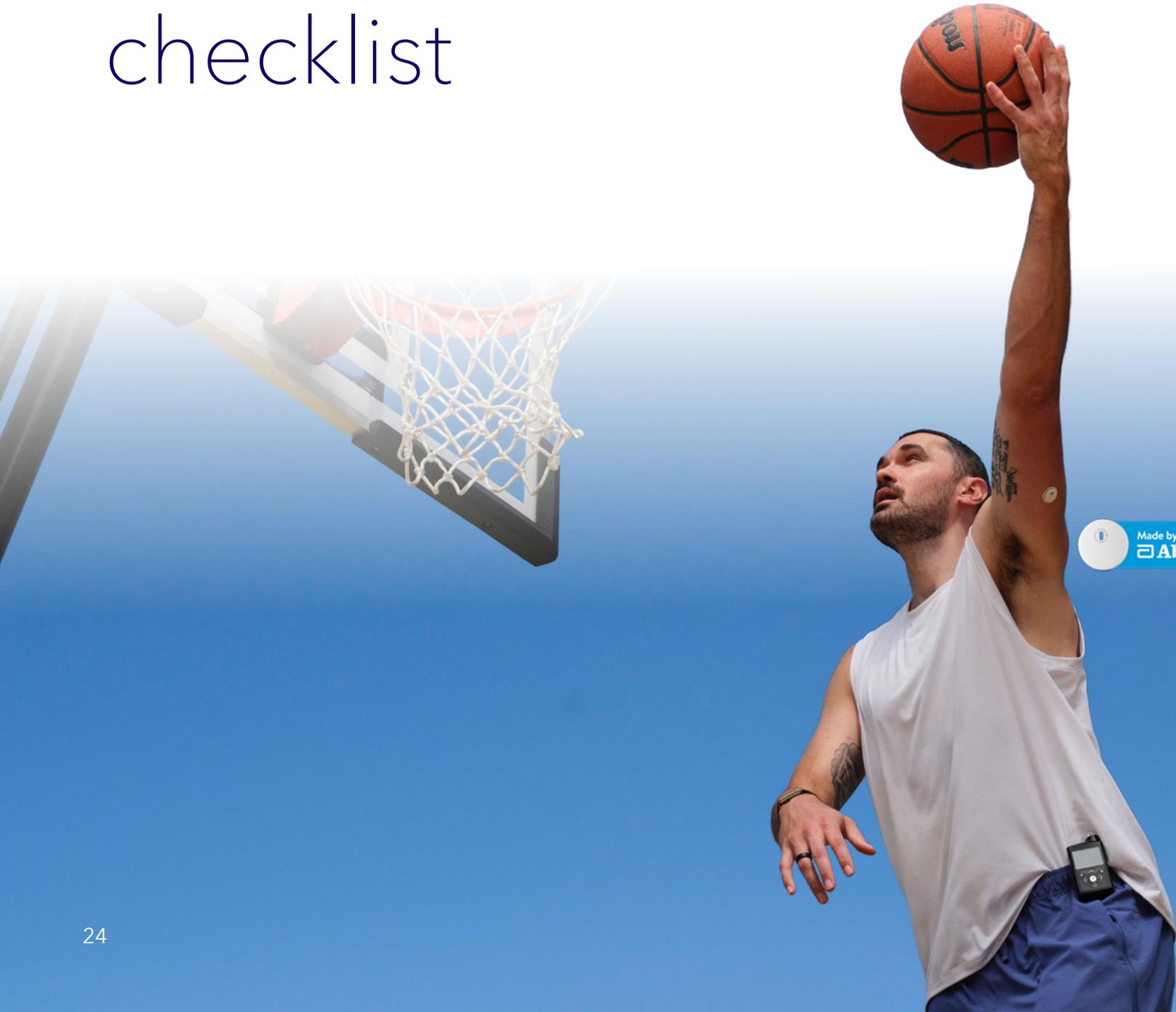


Your phone will reconnect to your pump after pairing, and when successful, it will begin a **15-minute software check** automatically.



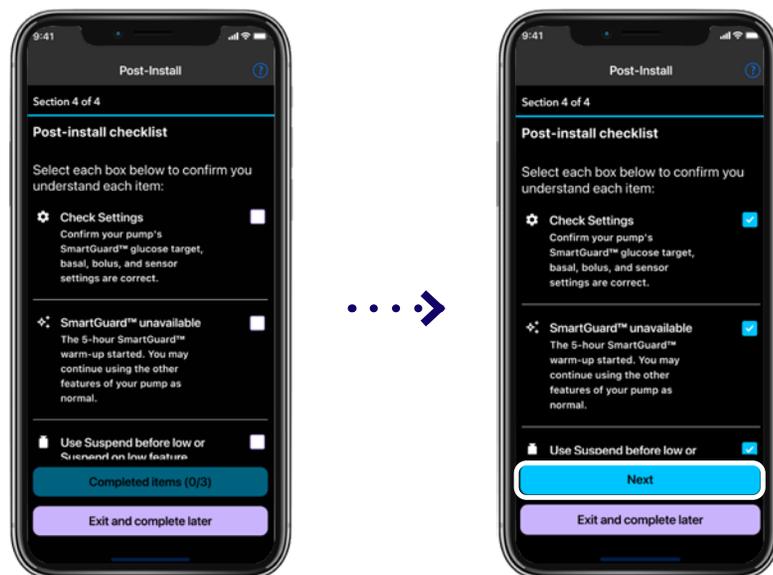
Made by
Abbott

Complete the checklist



Post-install checklist

Please complete the post-install checklist. The **Post-install checklist** will be shown after checking the pump software version. It requires each item to be read, any actions taken, and then the box checked by tapping on it. Turn to the next page for help on where to find these settings.



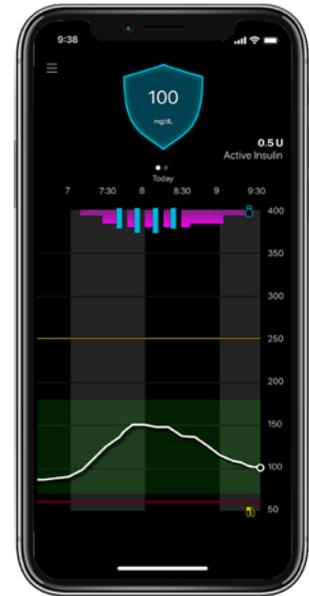
Once all items have been read and checked, tap **Next** to continue.



Once the checklist is complete, you will see **Software update successful**.

Congratulations! Your pump is now updated.

Tap **Return home** to exit the update and return to the MiniMed™ Mobile app Home screen.



Confirm Settings Transferred

Find my settings: Main menu

Check that the settings in your pump match the settings you recorded.



SmartGuard™ settings:

- Confirm your SmartGuard™ target.
- Confirm Auto Correction setting.



Delivery settings:

- Confirm bolus and basal settings.



Paired devices:

- Confirm all devices are still paired.



Alert Settings:

- Confirm high and low alert settings.





Your SmartGuard™ target and Auto Correction setting will **remain at the value set before the update.**

The SmartGuard™ feature will take **5 hours to warm up** before it can be used.

During this warm-up period, you will be in Manual mode. For this reason, it is recommended you turn on the Suspend on low or Suspend before low feature to keep you safe until SmartGuard™ technology can take over.

Follow these steps to turn on one of these features:

1. From the Home screen, press **Select**
2. Select **Settings**
3. Select **Alert Settings**
4. Select **Low Alert**
5. Select **Suspend on low** or **Suspend before low**, edit and **Save according to your HCP's guidance.**

Next steps for your sensor

If you'll be switching to the Instinct sensor, you can start using it as soon as your next sensor order arrives. For help getting started, see Appendix B.

If you'll be switching to the Simplerla Sync™ sensor, you can start using it as soon as your next sensor order arrives. For help getting started, see Appendix C.

If you're currently using a Guardian™ 4 transmitter and sensor, you can continue using it after the update—just follow the usual steps when it's time to change your sensor.

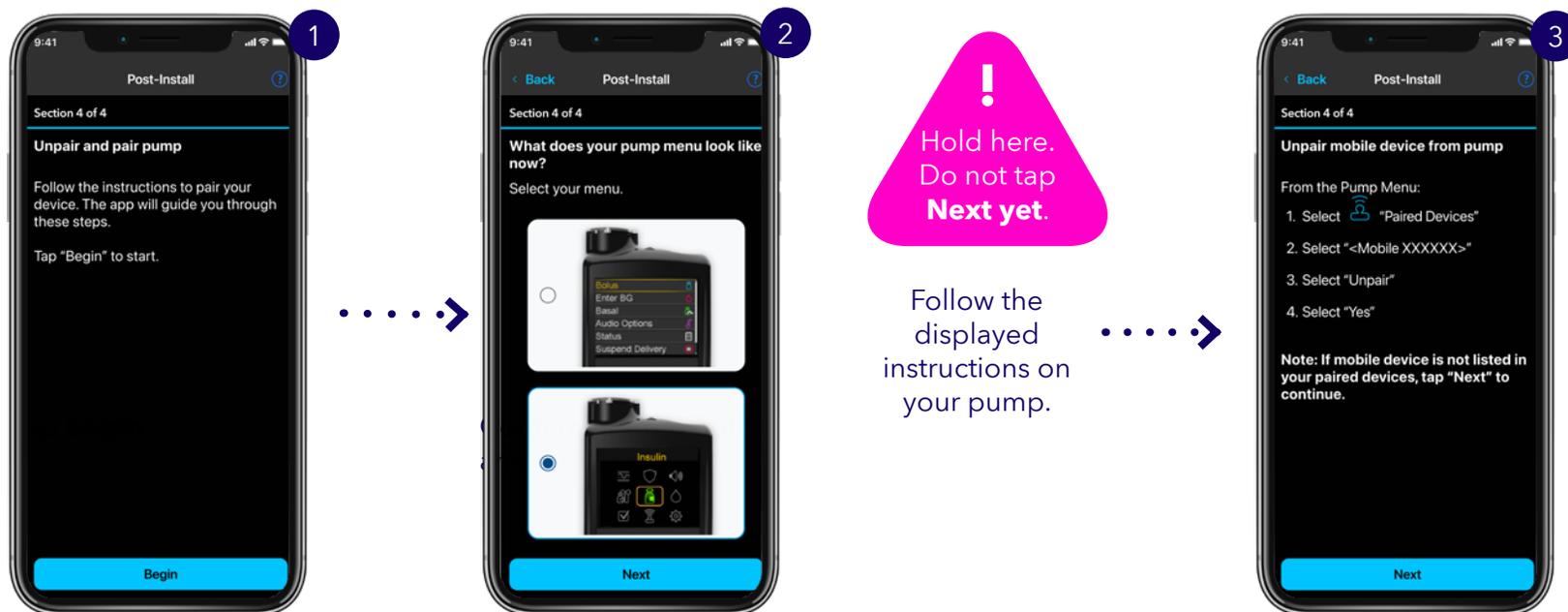
Appendix



Appendix A: Unpair and pair your pump and phone.

Step 1: **Unpair and pair your pump and phone.** You need to unpair your mobile device from your pump. Follow the instructions shown in the app screen.

On your phone:



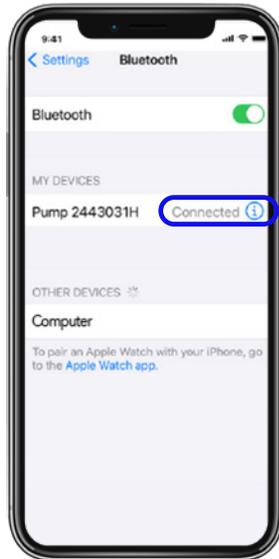
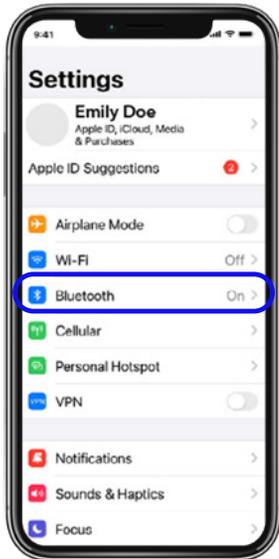
On your pump:



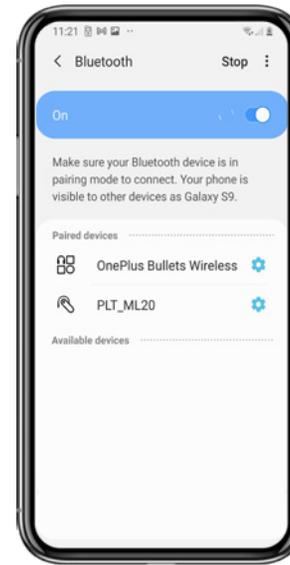
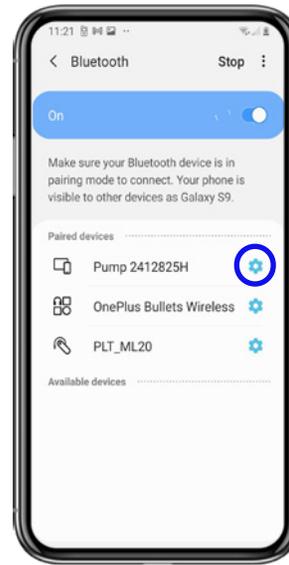
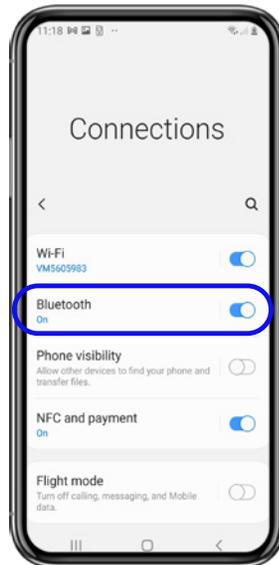
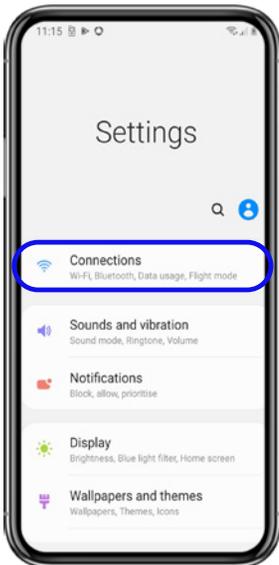
Go to your phone and tap **Next**.

Step 2. Remove your pump from your phone. You have to switch to your phone settings and then **come back to the MiniMed Mobile™ app when you are done** (iOS and Android examples shown).

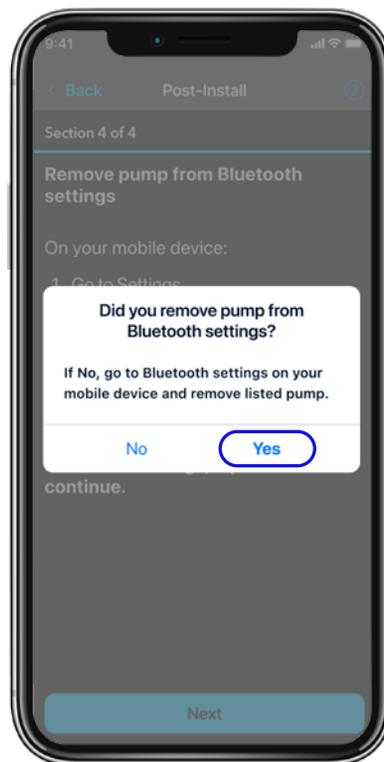
iOS example



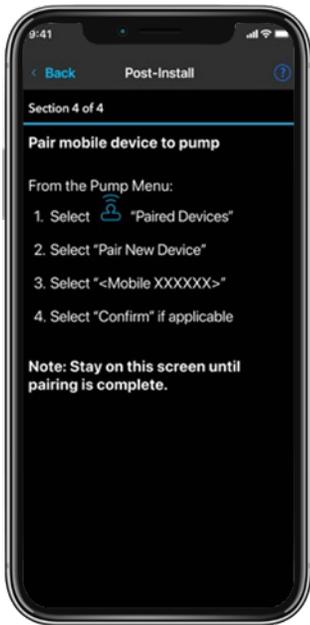
Android example



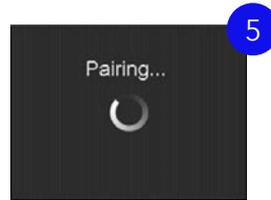
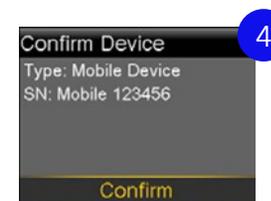
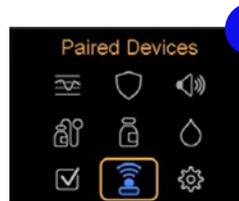
Step 3. Confirm you have removed your pump from your phone, tap **Next**, and select **Yes** on the pop up.



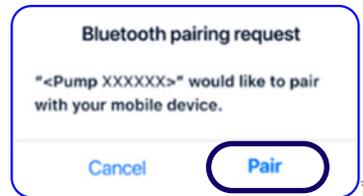
Step 4. **Pair your phone and pump.** Your app will display the instructions.



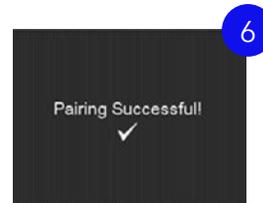
On your pump:



On your phone:



On your pump:



That's it!

Go to your phone to begin the **15 minute software check** automatically (page 22).

*Screen may vary based on phone make, model or operating system.

Appendix B: Connecting an Instinct sensor, exclusively made for MiniMed by Abbott

This section will explain how to connect an Instinct sensor to a MiniMed™ 780G insulin pump.

Important Note: The MiniMed™ Mobile App is required to start the Instinct sensor with your compatible MiniMed™ 780G pump, and you must log in to CareLink™ Personal software.† Don't have an account yet? See page 7 for registration steps.



Scan to view
the sensor
insertion video

Starting the sensor

Step 1:

Tap the **MiniMed Mobile App icon** on your compatible mobile device.

Step 2:

Tap the **Menu button** (three bars at the top left of the Home screen) to open the menu.

Step 3:

Tap **Start sensor**, followed by **Yes, Instinct**.

Applying the sensor

Follow the app or use the instructions below to apply the sensor. For best connection, wear your **pump** and **Instinct sensor** on the same side of your body. Your infusion set can be worn on either side.



1. Select site on the back of upper arm.



2. Wash with plain soap, dry, clean with an alcohol wipe, then let air dry.



3. Unscrew cap from Sensor Applicator.



4. Place the Sensor Applicator over site. Push down firmly to apply sensor.



5. Gently pull Sensor Applicator away from your body.

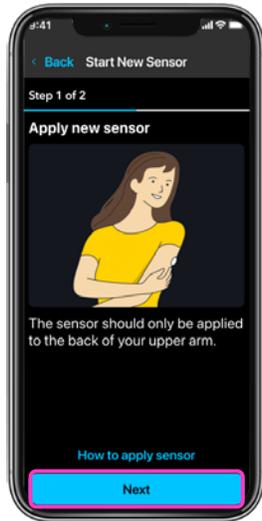


6. Make sure sensor is secure.

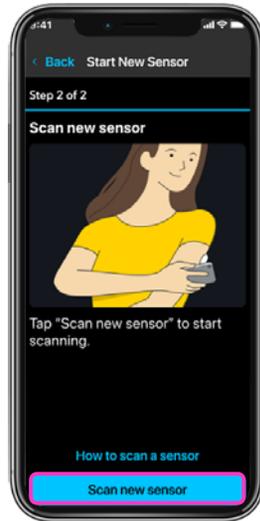
†Before starting a new sensor, pair your compatible device with your pump using the MiniMed Mobile app. Check device compatibility here: medtronicdiabetes.com/app-check. If you don't have a compatible device, call Medtronic at 1-877-585-0208.

Scanning the sensor

Follow the instructions on your app to scan the sensor. See steps below for reference.

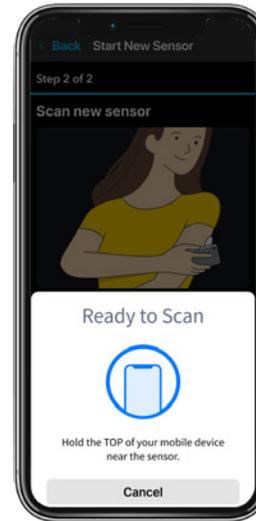


1. On the app, select **Next**.



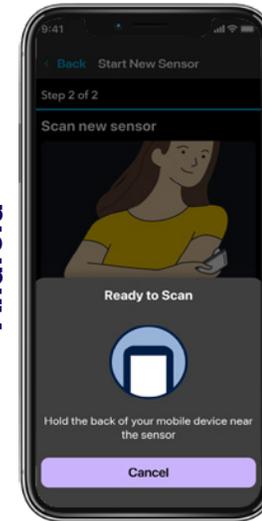
2. Select **Scan new sensor**.

iPhone/iOS



3. Make sure **your pump is on the Home screen**. Hold your mobile device near the sensor until it beeps or vibrates.

Android



Note: Keep the pump near the sensor until pairing is complete. Once your Instinct sensor is paired, the 1-hour warm-up begins.

Note: Starting an Instinct sensor will automatically unpair your previous sensor, whether it's a Guardian™, Simplera Sync™, or another Instinct sensor.

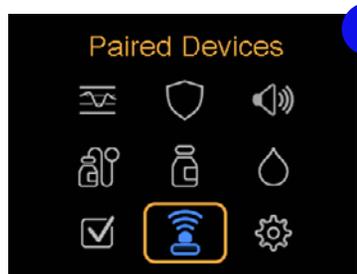


Taking more than 1000 mg of Vitamin C per day may falsely raise your sensor readings, which could cause you to miss a severe low glucose event. Vitamin C can be found in supplements including multivitamins and cold remedies such as Airborne® and Emergen-C®. See your health care professional to understand how long Vitamin C is active in your body.

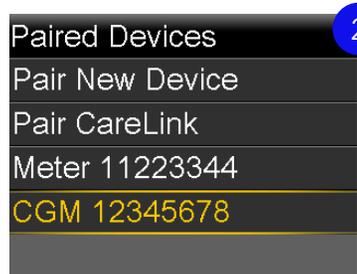
Appendix C: Connecting a Simplera Sync™ sensor

This section will explain how to connect a Simplera™ Sync sensor to a MiniMed™ 780G insulin pump and assumes a Guardian™ series transmitter is already in use. If not, start at step 2. All actions are taken on your pump.

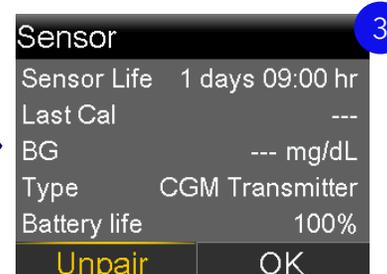
Step 1: Remove your existing Guardian™ series transmitter.



Go to **Paired Devices**.



Select your current sensor.



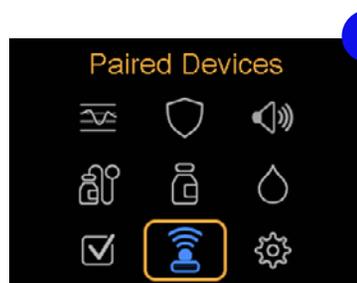
Select **Unpair** and then confirm by selecting **Yes** on the next screen.



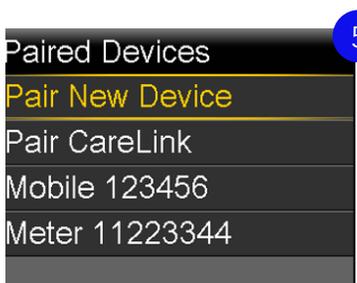
Scan to view the sensor insertion video

Step 2: Pair your Simplera Sync™ sensor.

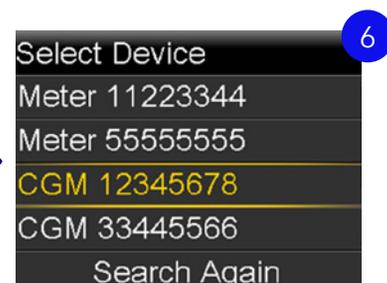
First, insert the sensor following the steps in the System User Guide. You can also scan the QR code above to watch a short video of the process. Then, on your pump:



Go to **Paired Devices**.

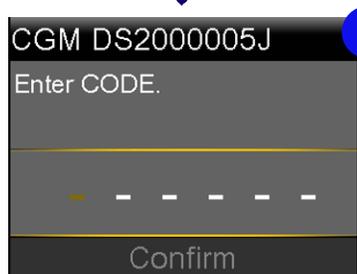


Select **Pair New Device**.

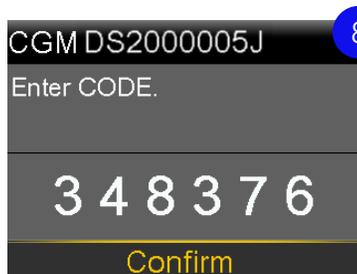


Select the **CGM device number** that matches the serial number located on the top of the inserter.

Note: If the Simplera Sync™ sensor is not paired with the pump within 20 minutes after the cap is removed from the inserter, follow the steps below to pair the sensor manually. Otherwise, proceed to the next page.



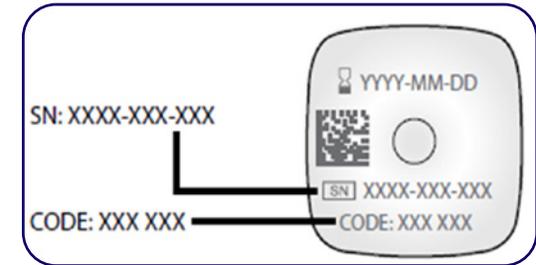
Manually enter the CODE found on the sensor inserter label.



Select **Confirm** to pair the sensor and proceed to the next page.



The **Confirm CODE** screen appears. Confirm the code on the screen matches the CODE on the top of the sensor inserter.



The Simplera Sync™ sensor will now pair with the pump and the 2 hour sensor warm up will begin. When the warm up ends, the pump will display sensor glucose readings.



Note: For future Simplera Sync™ sensor changes, simply pair your new sensor and the old one will disconnect automatically. No unpairing is required.

Appendix D: Changing your infusion set and reservoir



Scan the QR code here to visit the infusion set support page and access educational materials tailored to your specific set.

<https://www.medtronicdiabetes.com/download-library/minimed-780g-system>

Appendix E: Troubleshooting

My MiniMed™ Mobile app and phone will not pair.

Remove your phone from your pump and your pump from your phone. Restart your phone and try again. If the problem persists, call our team of experts at 1-800-646-4633.

I forced close the app during my download. How do I restart?

If you closed the app while the download was occurring, you will need to restart the download from the beginning. To do so, go to the menu on the top left of the home screen, then tap on Update Pump to re-enter the software update process.

The Update Pump menu option is not in my app.

This means your region does not have the ability to update MiniMed™ 700 series devices via the MiniMed™ Mobile app. Call our team of experts at 1-800-646-4633 if you need further information.

The MiniMed™ Mobile app says my pump is up to date.

Review the information in your eligibility message. Make sure all steps have been completed, then try again in 24 hours. If the problem persists, call our team of experts at 1-800-646-4633.

My update failed.

Your pump has returned to its original software version. You can try the upgrade again at a later point. If the problem persists, call our team of experts at 1-800-646-4633.

My update confirmation failed.

Check your internet connection and try again. If the problem persists, call our team of experts at 1-800-646-4633.

Important Safety Information

MINIMED™ 780G SYSTEM WITH SMARTGUARD™ TECHNOLOGY WITH INSTINCT SENSOR

The MiniMed™ 780G system is intended for continuous delivery of basal insulin at selectable rates, and the administration of insulin boluses at selectable amounts for the management of type 1 diabetes mellitus in persons seven years of age and older requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed™ 780G System includes SmartGuard™ technology, which can be programmed to automatically adjust insulin delivery based on the continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the sensor glucose (SG) value falls below or is predicted to fall below predefined threshold values.

The Instinct sensor can be used one time and has a life up to 15 days. The Instinct sensor is not intended to be used directly to make therapy adjustments while the MiniMed™ 780G is operating in manual mode. All therapy adjustments in Manual mode should be based on measurements obtained using a blood glucose meter and not on values provided by the Instinct sensor. The Instinct sensor has been studied and is approved for use in patients ages 7 years and older and in the arm insertion site only. Only apply the sensor to the back of your upper arm. The sensor may not work properly in other areas.

The Medtronic MiniMed™ 780G System consists of the following devices: MiniMed™ 780G Insulin Pump and the Instinct sensor. The system requires a prescription from a healthcare professional.

WARNING: Do not use the SmartGuard™ feature for people who require less than 8 units or more than 250 units of total daily insulin per day. A total daily dose of at least 8 units, but no more than 250 units, is required to operate in the SmartGuard™ feature.

WARNING: Do not use the MiniMed™ 780G system until appropriate training has been received from a healthcare professional. Training is essential to ensure the safe use of the MiniMed™ 780G system.

WARNING: Do not use SG values to make treatment decisions, including delivering a bolus, while the pump is in Manual Mode. When the SmartGuard™ feature is active and you are no longer in Manual Mode, the pump uses an SG value, when available, to calculate a bolus amount. However, if your symptoms do not match the SG value, use a blood glucose (BG) meter to confirm the SG value. Failure to confirm glucose levels when your symptoms do not match the SG value can result in the infusion of too much or too little insulin, which may cause hypoglycemia or hyperglycemia.

Pump therapy is not recommended for people whose vision or hearing does not allow for the recognition of pump signals, alerts, or alarms. The safety of the MiniMed™ 780G system has not been studied in pregnant women, persons with type 2 diabetes, or in persons using other anti-hyperglycemic therapies that do not include insulin. For complete details of the system, including product and important safety information such as indications, contraindications, warnings and precautions associated with system and its components, please consult <https://www.medtronicdiabetes.com/important-safety-information#minimed-780g> and the appropriate user guide at <https://www.medtronicdiabetes.com/download-library>

Important safety information

MINIMED™ 780G SYSTEM WITH SMARTGUARD™ TECHNOLOGY WITH SIMPLERA SYNC™ SENSOR

The MiniMed™ 780G system is intended for the continuous delivery of basal insulin at selectable rates, and the administration of insulin boluses at selectable rates for the management of type 1 diabetes mellitus in persons 7 years of age and older, and of type 2 diabetes mellitus in persons 18 years of age and older requiring insulin. The system is also intended to continuously monitor glucose values in the fluid under the skin. The MiniMed™ 780G system includes SmartGuard™ technology, which can be programmed to automatically adjust insulin delivery based on continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values.

The Simplera Sync™ sensor can be used one time and has a life up to 6 days, followed by a grace period of 24 hours. During the grace period, the sensor will continue to work as it did during the first 6 days, to allow the patient to change their sensor more flexibly. However, some sensors may not survive the full wear period for a variety of reasons. Please be prepared to replace the sensor during the grace period to ensure sensor glucose values continue to be monitored.

The Simplera Sync™ sensor is not intended to be used directly to make therapy adjustments while the MiniMed 780G is operating in manual mode. All therapy adjustments in Manual mode should be based on measurements obtained using a blood glucose meter and not on values provided by the Simplera Sync™ sensor. The Simplera Sync™ sensor has been studied and is approved for use in patients ages 7 years and older and in the arm insertion site only. Do not use the Simplera Sync™ sensor in the abdomen or other body sites, including the buttocks, due to unknown or different performance that could result in hypoglycemia or hyperglycemia.

The Medtronic MiniMed™ 780G System consists of the following devices: MiniMed™ 780G Insulin Pump, Simplera Sync™ sensor, the Accu-Chek™Guide Link blood glucose meter, and the Accu-Chek™Guide Test Strips. The system requires a prescription from a healthcare professional.

WARNING: Do not use the SmartGuard™ feature for people who require less than 8 units or more than 250 units of total daily insulin per day. A total daily dose of at least 8 units, but no more than 250 units, is required to operate in the SmartGuard™ feature.

WARNING: Do not use the MiniMed™ 780G system until appropriate training has been received from a healthcare professional. Training is essential to ensure the safe use of the MiniMed™ 780G system.

WARNING: Do not use SG values to make treatment decisions, including delivering a bolus, while the pump is in Manual Mode. When the SmartGuard™ feature is active and you are no longer in Manual Mode, the pump uses an SG value, when available, to calculate a bolus amount. However, if your symptoms do not match the SG value, use a BG meter to confirm the SG value. Failure to confirm glucose levels when your symptoms do not match the SG value can result in the infusion of too much or too little insulin, which may cause hypoglycemia or hyperglycemia.

Pump therapy is not recommended for people whose vision or hearing does not allow for the recognition of pump signals, alerts, or alarms. The safety of the MiniMed™ 780G system has not been studied in pregnant women or in persons using other anti-hyperglycemic therapies that do not include insulin. For complete details of the system, including product and important safety information such as indications, contraindications, warnings and precautions associated with system and its components, please consult <https://www.medtronicdiabetes.com/important-safety-information#minimed-780g-simplera-sync> and the appropriate user guide at <https://www.medtronicdiabetes.com/download-library>

Important safety information

MINIMED™ 780G SYSTEM WITH SMARTGUARD™ TECHNOLOGY WITH GUARDIAN™ 4 SENSOR

The MiniMed™ 780G system is intended for the continuous delivery of basal insulin at selectable rates, and the administration of insulin boluses at selectable rates for the management of type 1 diabetes mellitus in persons 7 years of age and older, and of type 2 diabetes mellitus in persons 18 years of age and older requiring insulin. The system is also intended to continuously monitor glucose values in the fluid under the skin. The MiniMed™ 780G system includes SmartGuard™ technology, which can be programmed to automatically adjust insulin delivery based on continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values.

The Medtronic MiniMed™ 780G system consists of the following devices: MiniMed™ 780G Insulin Pump, the Guardian™ 4 Transmitter, the Guardian™ 4 Sensor, One-press serter, the Accu-Chek™ Guide Link blood glucose meter, and the Accu-Chek™ Guide Test Strips. The system requires a prescription from a healthcare professional.

The Guardian™ 4 Sensor is intended for use with the MiniMed™ 780G system and the Guardian 4 transmitter to monitor glucose levels for the management of diabetes. The sensor is intended for single use and requires a prescription. The Guardian™ (4) sensor is indicated for **up to** seven days of continuous use.

The Guardian™ 4 sensor is not intended to be used directly to make therapy adjustments while the MiniMed™ 780G is operating in manual mode. All therapy adjustments in manual mode should be based on measurements obtained using a blood glucose meter and not on values provided by the Guardian™ 4 sensor. The Guardian™ 4 sensor has been studied and is approved for use in patients ages 7 years and older and in the arm insertion site only. Do not use the Guardian™ 4 sensor in the abdomen or other body sites including the buttocks, due to unknown or different performance that could result in hypoglycemia or hyperglycemia.

WARNING: Do not use the SmartGuard™ feature for people who require less than 8 units or more than 250 units of total daily insulin per day. A total daily dose of at least 8 units, but no more than 250 units, is required to operate in the SmartGuard™ feature.

WARNING: Do not use the MiniMed™ 780G system until appropriate training has been received from a healthcare professional. Training is essential to ensure the safe use of the MiniMed™ 780G system.

WARNING: Do not use SG values to make treatment decisions, including delivering a bolus, while the pump is in Manual Mode. When the SmartGuard™ feature is active and you are no longer in Manual Mode, the pump uses an SG value, when available, to calculate a bolus amount. However, if your symptoms do not match the SG value, use a BG meter to confirm the SG value. Failure to confirm glucose levels when your symptoms do not match the SG value can result in the infusion of too much or too little insulin, which may cause hypoglycemia or hyperglycemia.

Pump therapy is not recommended for people whose vision or hearing does not allow for the recognition of pump signals, alerts, or alarms. The safety of the MiniMed™ 780G system has not been studied in pregnant women or in persons using other anti-hyperglycemic therapies that do not include insulin. For complete details of the system, including product and important safety information such as indications, contraindications, warnings and precautions associated with system and its components, please consult <https://www.medtronicdiabetes.com/important-safety-information#minimed-780g-simplera-sync> and the appropriate user guide at <https://www.medtronicdiabetes.com/download-library>

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