MiniMed[™] 780G system Changing the MiniMed Mio[™] Advance Infusion Set and Reservoir



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WARNING: The following warning applies to changing the reservoir and infusion set, changing the reservoir only, and changing the infusion set only.

Always confirm that the infusion set tubing is disconnected from the body before doing the following steps:

- placing the reservoir into the pump
- rewinding the pump
- loading the reservoir
- filling the infusion set tubing

Failing to disconnect the infusion set tubing from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.







The MiniMed Mio Advance infusion set and the reservoir can be used for up to three days. In most cases, the infusion set and reservoir should be changed at the same time.



Follow these steps to change the infusion set and reservoir.



Wash hands with soap and water. On the pump, press \odot to go to the menu screen.

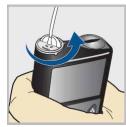


Select (a), and then select New Reservoir & Set.



Remove the infusion set by loosening the adhesive and pulling the set away from the body. Select **Next**.





Remove the used reservoir from the pump.



Select Rewind.

Do not connect the infusion set to the body.

WARNING: Always confirm that the infusion set is disconnected from the body before rewinding the pump. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.



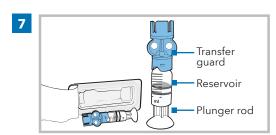


Follow the next steps to fill the new reservoir with insulin and to connect the new infusion set tubing.

Do not select **Next**.

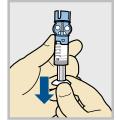


Fill the reservoir



Remove the reservoir from the package. Make sure the insulin vial is at room temperature to reduce the risk of air bubbles.

8

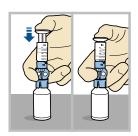


Pull the plunger down based on the planned 2-3 day insulin fill amount. 9



Wipe the top of the vial with isopropyl alcohol. Place the vial on a sturdy, flat surface. Firmly press the transfer guard onto the vial.

10

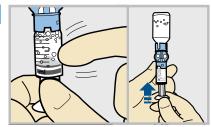


Push and hold the plunger down.

11

Keeping a thumb on the plunger, flip the vial over so the vial is on top. Release the thumb and pull the plunger down to fill the reservoir with insulin.

12



Tap the reservoir to move air bubbles to the top of the reservoir. Push the plunger up to move air into the vial.

13



Pull the plunger back down to allow the reservoir to fill with the amount of insulin needed for 2-3 days.

Note: The MiniMed Mio Advance infusion set and reservoir can be used for up to three days. To avoid wasting insulin, fill the reservoir with enough insulin to last until the next infusion set change.



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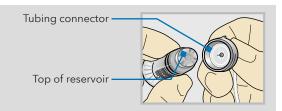
Changing the MiniMed Mio Advance Infusion Set and Reservoir

14



To avoid getting insulin on the top of the reservoir, **flip the vial over again so the reservoir is on top.** Hold the transfer guard and turn the reservoir counter-clockwise and remove the reservoir from the transfer guard.

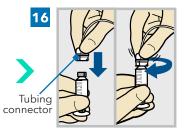
WARNING: Do not use the reservoir or infusion set if insulin or any liquid gets on the top of the reservoir or inside the tubing connector, as shown in the image. If insulin, or any other liquid, gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly fill the infusion set. This may result in the infusion of too little or too much insulin, and may result in hyperglycemia or hypoglycemia. If this occurs, start over with a new reservoir and infusion set.



Connect the infusion set to the reservoir

15 MiniMed Mio Advance infusion set Disconnect Top. Tubing button connector Raised Insertion arrows device indicating tubing Tubing direction White cap for site Cannulaconnector connector housing cannula

Remove infusion set from package. Remove the paper that holds the tubing together and unwind.



Gently push the tubing connector onto the reservoir.

Turn the connector clockwise until it is locked into place.



Tap the reservoir to move any air bubbles to the top. Push the plunger slightly to move the bubbles into the tubing.



Twist the plunger counter-clockwise to loosen it and to remove it.



Place the reservoir into the pump

Note: The backlight may have turned off. Press any button to turn the screen back on. Press © to go to the menu screen, and then select $\mathbf{\hat{\omega}}$.



Select Next.





Place the reservoir into the pump. **Do not** connect the infusion set to the body.

WARNING: Always confirm that the infusion set is disconnected from the body before placing the reservoir into the pump. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.







Turn the reservoir clockwise until the reservoir locks into place, and select **Next**.



Load the reservoir and fill the tubing

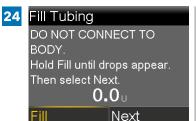


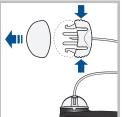


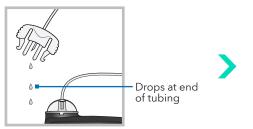


When the check mark appears, select **Next**.

WARNING: Always confirm that the infusion set is disconnected from the body before loading the reservoir and filling the tubing. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.





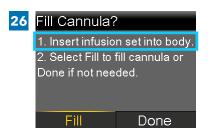


Select **Fill** and keep holding © until there are no air bubbles visible in the tubing, and there are drops at the end of the tubing.

Do not connect the infusion set to the body.



After drops appear, press and select **Next**.



Follow the next steps to insert the infusion set before filling the cannula.

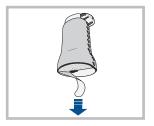


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Changing the MiniMed Mio Advance Infusion Set and Reservoir

Insert the infusion set

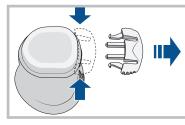






Remove the paper backing from the adhesive. Be careful not to touch the adhesive.







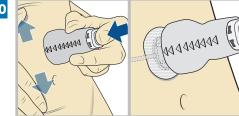
Remove the disconnect cover from the insertion device by gently squeezing the sides of the disconnect cover then pulling it away from the insertion device. Keep the disconnect cover for later use.



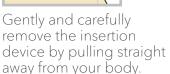


Choose an insertion site from the shaded areas. Clean the insertion site with alcohol or other antiseptic as directed by a healthcare professional.





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Stretch the skin until smooth. Place the insertion device in the desired location on your skin. The raised arrows indicate the direction to connect the tubing. Press the top button completely down to insert the infusion set.







Press the adhesive onto the skin with your finger. Replace the infusion set if the adhesive does not stick to the skin

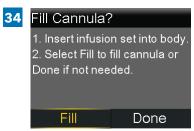




Gently hold the cannula housing steady with your finger. Then push the site connector straight into the cannula housing until you hear a click. **Note:** Remove the transfer guard from the vial and dispose of the transfer guard in an appropriate sharps container and in accordance with local laws.



Fill the cannula



After the infusion set is inserted into the body, select **Fill**.

Note: Always verify that the amount shown in the **Fill amount** field is correct. The pump will remember the fill amount last used. Change the **Fill amount** if needed.



Select Fill amount and enter:

• 0.600 if using the 6 mm or 9 mm cannula. After entering the cannula fill amount, press ©.



Select Fill Now.

The Home screen displays the insulin amount as insulin fills the cannula.



The reservoir and infusion set change is now complete.

Always check blood glucose one to three hours after changing the infusion set or reservoir.

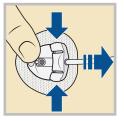


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Disconnecting and Reconnecting the MiniMed Mio Advance Infusion Set

Disconnecting the infusion set from your body

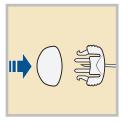
1



>

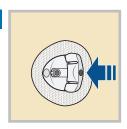
To disconnect, gently hold the cannula housing steady with your finger. Then squeeze the sides of the site connector and pull it out from the cannula housing.

2



Put the white cap on the site connector.

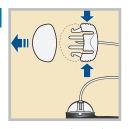
3



Put the disconnect cover on the cannula housing. Then push the cover into the cannula housing until you hear a click.

Reconnecting the infusion set to your body

1

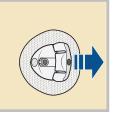


Remove the white cap from the site connector by squeezing the side of the site connector then pulling the white cap off. 2



Ensure there is no air in the tubing. ONLY if there is air in the tubing: Fill the tubing with insulin and watch for drops as instructed. Do not leave any air in the tubing.

3



Remove the disconnect cover by squeezing the sides and pulling away from the cannula housing. 4



Use your finger to gently hold the cannula housing steady. Push the site connector into the cannula housing until you hear a click.





The MiniMed reservoir can be used for up to three days. If the reservoir runs out of insulin and the infusion set has not been used for three full days, the New Reservoir Only option may be used to change the reservoir. The infusion set must still be replaced within three days of use.



Remove the old reservoir and rewind the pump

Follow these steps to change the reservoir and keep the current infusion set.





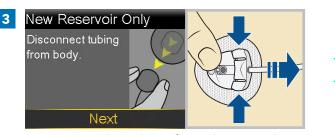
Wash hands with soap and water. On the pump, press 🔘 to go to the menu screen.



Reservoir & Set New Reservoir & Set New Reservoir Only New Set Only Fill Cannula

> Select 🗗, and then select New Reservoir Only.





Disconnect the tubing from the cannula housing. Do not remove the cannula housing from the body. Select Next.







Disconnect the infusion set tubing connector from the used reservoir. Place the tubing on a clean surface. Do not throw the tubing away.

Note: Dispose of the used reservoir in an appropriate container and in accordance with local laws.



Remove the used reservoir from the pump.



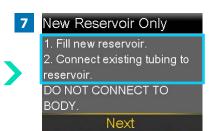
Rewind

Select Rewind

Do not connect the infusion set to the body.

WARNING: Always confirm that the infusion set is disconnected from the body before rewinding the pump. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.



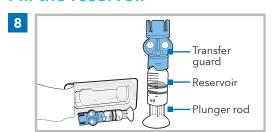


Follow the next steps to fill the new reservoir with insulin and to connect the new infusion set tubing.

Do not select **Next**.



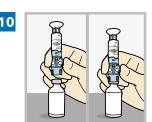
Fill the reservoir



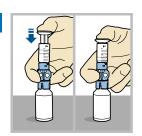
Remove the reservoir from the package. Make sure the insulin vial is at room temperature to reduce the risk of air bubbles.



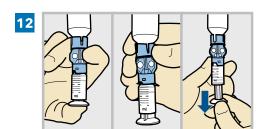
Pull the plunger down based on the planned 2-3 day insulin fill amount.



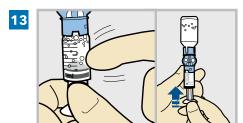
Wipe the top of the vial with isopropyl alcohol. Place the vial on a sturdy, flat surface. Firmly press the transfer guard onto the vial.



Push and hold the plunger down.



Keeping a thumb on the plunger, flip the vial over so the vial is on top. Release the thumb and pull the plunger down to fill the reservoir with insulin



Tap the reservoir to move air bubbles to the top of the reservoir. Push the plunger up to move air into the vial.



Pull the plunger back down to allow the reservoir to fill with the amount of insulin needed for 2-3 days.

Note: The MiniMed Mio Advance infusion set and reservoir can be used for up to three days. To avoid wasting insulin, fill the reservoir with enough insulin to last until the next infusion set change.

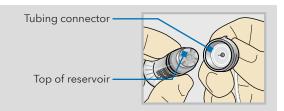




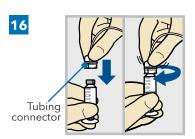


To avoid getting insulin on the top of the reservoir, **flip the vial over again so the reservoir is on top.** Hold the transfer guard and turn the reservoir counter-clockwise and remove the reservoir from the transfer guard.

WARNING: Do not use the reservoir or infusion set if insulin or any liquid gets on the top of the reservoir or inside the tubing connector, as shown in the image. If insulin, or any other liquid, gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly fill the infusion set. This may result in the infusion of too little or too much insulin, and may result in hyperglycemia or hypoglycemia. If this occurs, start over with a new reservoir and infusion set.



Connect the infusion set to the reservoir



Gently push the tubing connector onto the reservoir.

Turn the connector clockwise until it is locked into place.





Tap the reservoir to move any air bubbles to the top. Push the plunger slightly to move the bubbles into the tubing.





Twist the plunger counterclockwise to loosen it and to remove it.



Place the reservoir into the pump

Note: The backlight may have turned off. Press any button to turn the screen back on. Press 💿 to go to the menu screen, and then select 🗐



Select Next.



Place the reservoir into the pump. **Do not** connect the infusion set to the body.

WARNING: Always confirm that the infusion set is disconnected from the body before placing the reservoir into the pump. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.









Turn the reservoir clockwise until the reservoir locks into place, and select **Next**.



Load the reservoir and fill the tubing



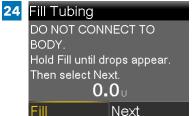


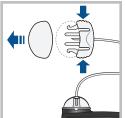


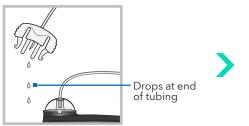
When the check mark appears, select **Next**.

WARNING: Always confirm that the infusion set is disconnected from the body before loading the reservoir and filling the tubing. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.









Select **Fill** and keep holding ① until there are no air bubbles visible in the tubing, and there are drops at the end of the tubing.

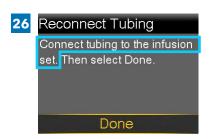
Do not connect the infusion set to the body.



After drops appear, press ⊙ and select Next.



Reconnect the tubing to the infusion site



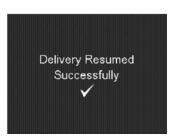




Use your finger to gently hold the cannula housing steady. Push the site connector into the cannula housing until you hear a click.



It is not necessary to fill the cannula because the infusion set was not changed. Select **Done**.



The reservoir change is now complete.

Always check blood glucose one to three hours after changing the reservoir.

Note: Remove the transfer guard from the vial and dispose of the transfer guard in an appropriate sharps container and in accordance with local laws.





The MiniMed Mio Advance infusion set can be used for up to three days. If only the infusion set needs to be changed before three full days of use, the New Set Only option may be used to change the infusion set. The reservoir must still be replaced within three days of use.



Remove the old infusion set

Follow these steps to change the infusion set and to keep the current reservoir.





Wash hands with soap and water. On the pump, press 🔘 to go to the menu screen.



Select **a**, and then select New Set Only.

Reservoir & Set

New Set Only Fill Cannula

New Reservoir & Set

New Reservoir Only





Remove the entire infusion set by loosening the adhesive and pulling the set away from the body. Select Next.





Remove the used reservoir from the pump.

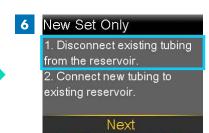


Select Rewind.

Do not connect the infusion set to the body.

WARNING: Always confirm that the infusion set is disconnected from the body before rewinding the pump. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.







Disconnect the infusion set tubing connector from the reservoir and throw away the used infusion set. Place the current reservoir on a clean surface. Do not throw away.

Note: Dispose of all parts of the infusion set, including the tubing, in an appropriate sharps container and in accordance with local laws



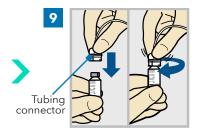
Connect the infusion set to the reservoir



Follow these steps to connect the infusion set to the reservoir.



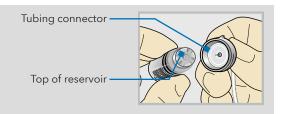
Remove infusion set from package. Remove the paper that holds the tubing together and unwind.



Gently push the tubing connector onto the reservoir.

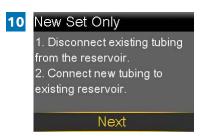
Turn the connector clockwise until it is locked into place.

Warning: Do not use the reservoir or infusion set if insulin or any liquid gets on the top of the reservoir or inside the tubing connector, as shown in the image. If insulin, or any other liquid, gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly fill the infusion set. This may result in the infusion of too little or too much insulin, and may result in hyperglycemia or hypoglycemia. If this occurs, start over with a new reservoir and infusion set.

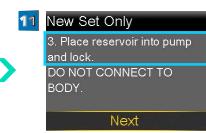




Place the reservoir into the pump



Select Next.





Place the reservoir into the pump. Do not connect the infusion set to the body.

WARNING: Always confirm that the infusion set is disconnected from the body before placing the reservoir into the pump. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.





Turn the reservoir clockwise until the reservoir locks into place, and select **Next**.



Load the reservoir and fill the tubing

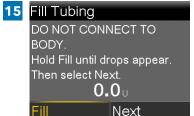


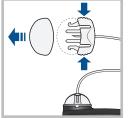
Select **Load** and hold ountil the check mark appears on the screen. Do not connect the infusion set to the body.

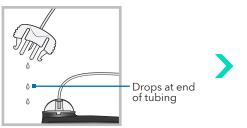


When the check mark appears, select **Next**.

WARNING: Always confirm that the infusion set is disconnected from the body before loading the reservoir and filling the tubing. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.

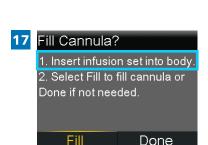




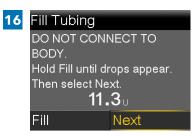


Select **Fill** and keep holding **(a)** until there are no air bubbles visible in the tubing, and there are drops at the end of the tubing.

Do not connect the infusion set to the body.



Follow the next steps to insert the infusion set before filling the cannula.

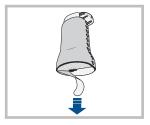


After drops appear, press 🛇 and select Next.



Insert the infusion set

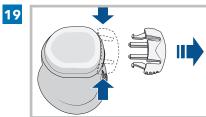






Remove the paper backing from the adhesive. Be careful not to touch the adhesive







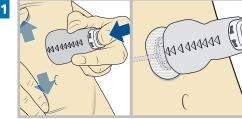
Remove the disconnect cover from the insertion device by gently squeezing the sides of the disconnect cover then pulling it away from the insertion device. Keep the disconnect cover for later use.





Choose an insertion site from the shaded areas. Clean the insertion site with alcohol or other antiseptic as directed by a healthcare professional.









Gently and carefully remove the insertion device by pulling straight

away from your body.

Stretch the skin until smooth. Place the insertion device in the desired location on your skin. The raised arrows indicate the direction to connect the tubing. Press the top button completely down to insert the infusion set.







Press the adhesive onto the skin with your finger. Replace the infusion set if the adhesive does not stick to the skin



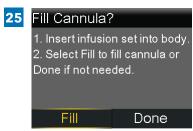


Gently hold the cannula housing steady with your finger. Then push the site connector straight into the cannula housing until you hear a click.

Note: Dispose of the insertion device in an appropriate sharps container and in accordance with vour local laws.



Fill the cannula



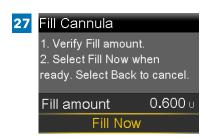
After the infusion set is inserted into the body, select Fill.

Note: Always verify that the amount shown in the Fill amount field is correct. The pump will remember the fill amount last used. Change the Fill amount if needed.



Select Fill amount and enter:

• 0.600 if using the 6 mm or 9 mm cannula. After entering the cannula fill amount, press ©.



Select Fill Now.

The Home screen displays the insulin amount as insulin fills the cannula.



The infusion set change is now complete.

Always check blood glucose one to three hours after changing the infusion set.



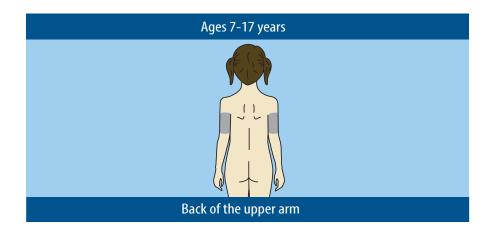


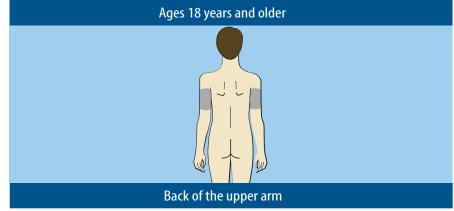
Insert the sensor

Choose an insertion site that has an adequate amount of subcutaneous fat. The Guardian 4 sensor has been studied and is approved for use in the following sensor insertion sites by persons of the following ages:

Approved Age	Sensor Insertion Site
7 and older	Arm

CAUTION: The Guardian 4 sensor is indicated for arm use only. Do not use 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.





Note: Assistance will likely be needed for sensor insertion into the back of the upper arm. Some users find it difficult to insert the sensor into their arm by themselves.



Insert a new sensor

Wash hands with soap and water and clean the insertion site with alcohol.











Open the sensor package.

Pull the corner of the paper covering to open the sensor package.

Hold the sensor by the plastic pedestal.

Remove the sensor with attached pedestal from the packaging by holding the pedestal only. Place the sensor with the pedestal on a clean, flat surface (such as a table).









Correct

Incorrect

Tuck the adhesive tab. Make sure that the sensor's adhesive tab is tucked under the sensor connector and snaps.

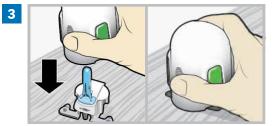




Incorrect

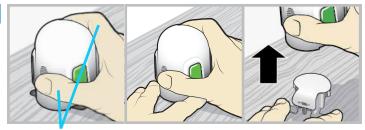
Note: Refer to the illustrations for correct and incorrect ways to hold the serter for loading.





Load the sensor into the serter. Grip the serter exactly as shown with a thumb on the thumb print on the serter. Do not hold the side buttons Push the serter down onto the pedestal until the base of the serter sits flat on the table.



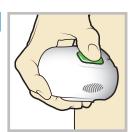


Fingers are NOT holding the side buttons.

Detach the serter from the pedestal. To detach the serter from the pedestal, grip the serter as shown with a thumb on the thumb print on the serter. With the other hand, place two fingers on the pedestal arms, and slowly pull the serter straight up.

Note: Make sure that the pedestal is firmly on the table before pulling the serter away.

CAUTION: Do not detach the pedestal from the serter in mid-air as this may damage the sensor.



Place the serter on the body. Hold the serter steadily against the cleaned insertion site without pushing the serter too deeply into the skin.

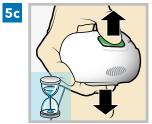
Note: Failing to hold the serter securely flat against the body may allow the serter to spring back after pressing buttons and result in improper insertion of the sensor.





Insert the sensor. Press the bump on both buttons and release them at the same time.





Hold the serter against the body. Continue holding the serter against the body for at least five seconds to allow the adhesive to stick to the skin.



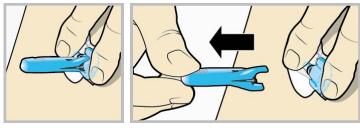
5a



Remove the serter from body. Slowly pull the serter away from the skin, making sure the buttons are not pressed.

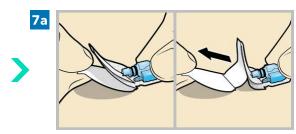






Remove the needle housing. Gently hold the base of the sensor against the skin with one hand. With the other hand, hold the needle housing at the top and slowly pull it straight away from the sensor. Dispose of the needle housing in a sharps container.

Note: An optional, liquid adhesive, such as Skin Tac™, may be used on the skin. Apply the adhesive and allow the skin to dry before removing the adhesive pad liner.



Remove the adhesive pad liner. Hold the sensor in place and gently remove the liner from under the adhesive pad.





Press the entire adhesive pad to the skin. Firmly press the adhesive pad against the skin and smooth the entire adhesive pad so it sticks to the skin.

Note: The sensor adhesive is sensitive to pressure. Continue applying pressure on the adhesive to ensure that the sensor remains inserted in the skin for 7 days of wear.





Untuck the adhesive tab. Untuck the adhesive tab from under the sensor connector.



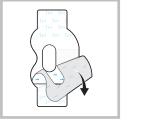


Straighten the adhesive tab. Straighten the adhesive tab so it lies flat against the skin, but do not remove the adhesive liner yet.



Tape the sensor





Remove the liner marked 1.



10

Note: Wait for the green

to flash. If the green light

light on the transmitter

does not flash, refer to Troubleshooting section of the transmitter user quide.

Wide part of tape covers half of sensor base.

Apply the tape as shown and press down firmly.

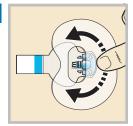
11



Connector and snaps in hole of tape.

Remove the liner marked 2 from each side.

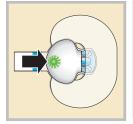
12



Smooth the tape.

Connect the transmitter

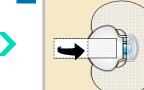




Connect the transmitter to the sensor.

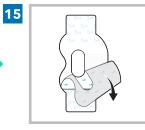


Both sensor and skin are taped.



Cover the transmitter with the adhesive tab

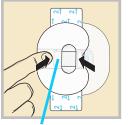
Note: Do not pull the tab too tightly.



To apply the 2nd tape, remove the liner marked 1



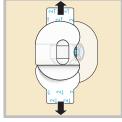




Wide part of tape covers end of transmitter and skin.

Rotate the 2nd tape and place the tape over the transmitter. Press down firmly.





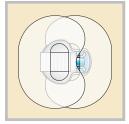
Remove the liner marked 2 from each side



Smooth the tape.

Note: Check the site regularly. Apply additional off-the-shelf tape if the sensor and the transmitter are not secure.



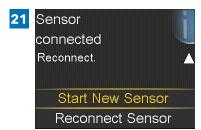


This image is an example of the tape applied correctly.

Connect the transmitter

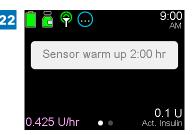


After Sensor connected message appears, press Q. The message typically takes less than a minute to appear, but may take up to 5 minutes



Select Start New Sensor.





Sensor warm up X:XX hr will appear on the Home screen. After the warm up is complete, the pump begins receiving SG readings.