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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.



Changing the MiniMed Silhouette Infusion Set and Reservoir





The MiniMed Silhouette 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.



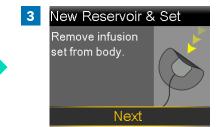
Follow these steps to change the infusion set and reservoir.



Wash hands with soap and water. On the pump, press 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.



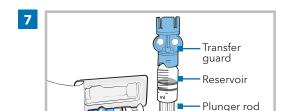


Follow the next steps to fill the new reservoir with insulin and to connect the new infusion set tubing.

Do not select **Next**

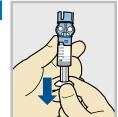


Fill the reservoir



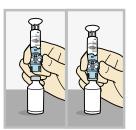
Remove the reservoir from the package. Make sure the insulin vial is at room temperature to reduce the risk of air bubbles





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





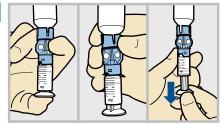
Wipe the top of the vial with isopropyl alcohol. Place the vial on a sturdy, flat surface. Firmly press the transfer guard onto the vial.





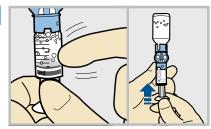
Push and hold the plunger down.





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.

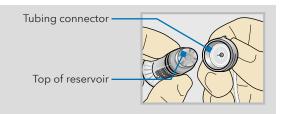
Note: The MiniMed Silhouette infusion set and reservoir can be used for up to three days. To avoid wasting insulin, fill the reservoir with enough insulin to last until the next infusion set change.





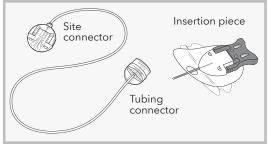
To avoid getting insulin on the top of the reservoir, flip the vial over again so the reservoir is on top. Hold the transfer guard and turn the reservoir counter-clockwise and remove the reservoir from the transfer quard.

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.

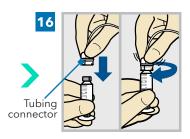


Connect the infusion set to the reservoir





Remove the infusion set tubing from the package.



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 🞒.



Select Next.





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.

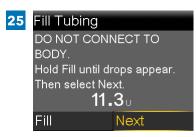
WARNING: Always confirm that the infusion set is disconnected from the body before loading the reservoir and filling the tubing. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.



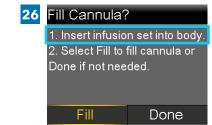


Select **Fill** and keep holding **O** until there are no air bubbles visible in the tubing, and there are drops at the end of the tubing.

Do not connect the infusion set to the body.

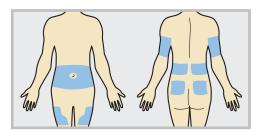


After drops appear, press 🛇 and select **Next**



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

Insert the Infusion Set



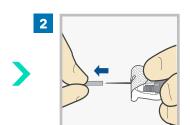
Choose an insertion site from the shaded areas. Clean the insertion site with alcohol or other antiseptic as directed by a healthcare professional.



Method 1: By Hand



Hold the insertion piece by the sides of the gray needle handle using thumb and middle finger.



Hold the tape with your forefinger and remove the needle guard.



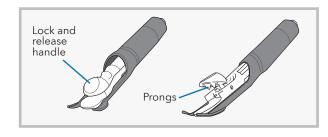
Pinch up skin at prepared site. Use other hand to insert needle at a 20-45 degree angle.





After it is inserted release the skin and hold inserted piece in place. Now go to the Removing introducer needle section on page 9.

Method 2: Using the serter





Use thumb to press down on the Lock & Release handle of the serter









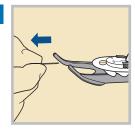
Method 2: Using the serter (cont.)







Use thumb to slide the Lock & Release handle back until you hear a click.



Gently pull off needle quard.



Rest arms of serter against skin so that it is at a 20-45 degree angle.









Press the white button at the top of serter to insert the infusion set.







Hold infusion set against skin with one hand. With the other hand press the Lock & Release handle to open serter. Then, slide serter back from infusion set.

Removing introducer needle

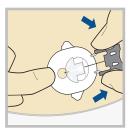






Peel paper from the front part of the adhesive and press adhesive securely to skin.





Squeeze arms on the gray needle handle and pull back to remove introducer needle. Dispose needle into a sharps container.



Dispose needle into a sharps container

skin. Press adhesive securely to skin.

Done







4



Connect tubing to body by sliding the site connector into the insertion piece on your skin.

Fill the cannula

Fill

Fill Cannula? 1. Insert infusion set into body 2. Select Fill to fill cannula or Done if not needed.

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

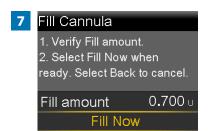
Note: Always verify that the amount shown in the Fill amount field is correct. The pump will remember the fill amount last used. Change the Fill amount if needed.





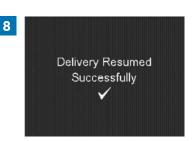
Select Fill amount and enter:

• 0.700 if using the 13 mm or 17 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.





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 **a**, 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.

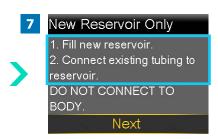


Select Rewind

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.



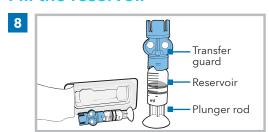


Follow the next steps to fill the new reservoir with insulin and to connect the new infusion set tubing.

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.



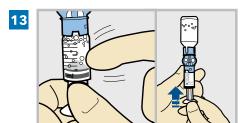
Wipe the top of the vial with isopropyl alcohol. Place the vial on a sturdy, flat surface. Firmly press the transfer guard onto the vial.



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 Silhouette 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.

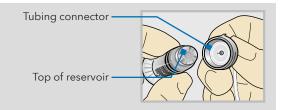




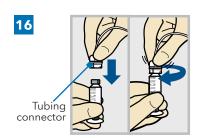


To avoid getting insulin on the top of the reservoir, **flip the vial over again so the reservoir is on top.** Hold the transfer guard and turn the reservoir counter-clockwise and remove the reservoir from the transfer guard.

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





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 ountil there are no air bubbles visible in the tubing, and there are drops at the end of the tubing.

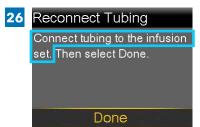
Do not connect the infusion set to the body.

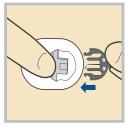


After drops appear, press 🛇 and select Next.



Reconnect the tubing to the infusion site







Connect tubing to body by sliding the site connector into the insertion piece on your skin.





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.



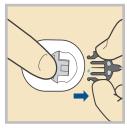


The MiniMed Silhouette infusion set can be used for up to three days. If only the infusion set needs to be changed before three full days of use, the New Set Only option may be used to change the infusion set. The reservoir must still be replaced within three days of use.



Disconnecting the infusion set from your body







2



Remove adhesive from skin. Peel the rest of the paper lifting the infusion set from the skin.

the insertion piece on your skin.

Disconnect tubing from body by sliding the site connector out of

Remove the old infusion set

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





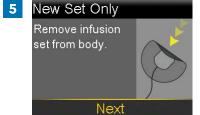


Wash hands with soap and water. On the pump, press 0 to go to the menu screen.



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

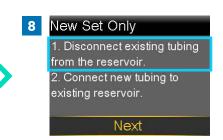
Do not connect the infusion set to the body.

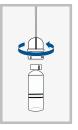
WARNING: Always confirm that the infusion set is disconnected from the body before rewinding the pump. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.







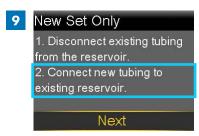




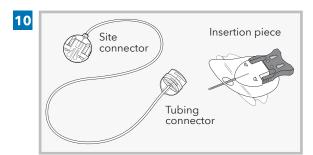
Disconnect the infusion set tubing connector from the reservoir and throw it away. Place the current reservoir on a clean surface. Do not throw away.

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

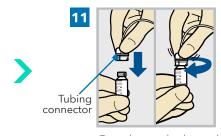
Connect the infusion set to the reservoir







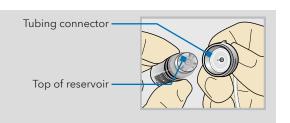
Remove the infusion set tubing from the package.



Gently push the tubing connector onto the reservoir.

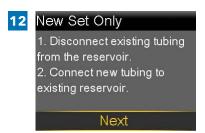
Turn the connector clockwise until it is locked into place.

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.

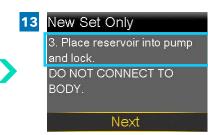




Place the reservoir into the pump



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.

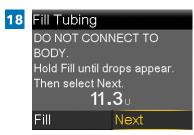
WARNING: Always confirm that the infusion set is disconnected from the body before loading the reservoir and filling the tubing. Failing to disconnect the infusion set from the body may result in an accidental infusion of insulin, and may cause hypoglycemia.



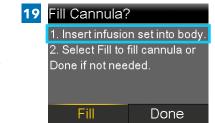


Select **Fill** and keep holding **O** until there are no air bubbles visible in the tubing, and there are drops at the end of the tubing.

Do not connect the infusion set to the body.

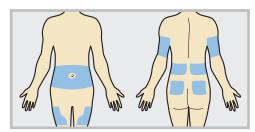


After drops appear, press 🛇 and select **Next**



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

Insert the Infusion Set



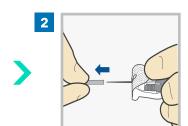
Choose an insertion site from the shaded areas. Clean the insertion site with alcohol or other antiseptic as directed by a healthcare professional.



Method 1: By Hand



Hold the insertion piece by the sides of the gray needle handle using thumb and middle finger.

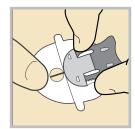


Hold the tape with your forefinger and remove the needle guard.



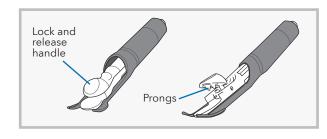
Pinch up skin at prepared site. Use other hand to insert needle at a 20-45 degree angle.

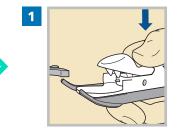




After it is inserted release the skin and hold inserted piece in place. Now go to the Removing introducer needle section on page 9.

Method 2: Using the serter





Use thumb to press down on the Lock & Release handle of the serter





Place the insertion piece inside serter and let go of the Lock & Release handle. The serter prongs should fit securely into the holes of the insertion piece.



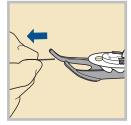
Method 2: Using the serter (cont.)







Use thumb to slide the Lock & Release handle back until you hear a click.



Gently pull off needle guard.





Rest arms of serter against skin so that it is at a 20-45 degree angle.







Press the white button at the top of serter to insert the infusion set.







Hold infusion set against skin with one hand. With the other hand press the Lock & Release handle to open serter. Then, slide serter back from infusion set.

Removing introducer needle

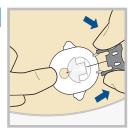






Peel paper from the front part of the adhesive and press adhesive securely to skin.





Squeeze arms on the gray needle handle and pull back to remove introducer needle. Dispose needle into a sharps container.



Dispose needle into a sharps container

skin. Press adhesive securely to skin.

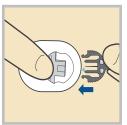
Done







4





Connect tubing to body by sliding the site connector into the insertion piece on your skin.

Fill the cannula

Fill

Fill Cannula? 1. Insert infusion set into body 2. Select Fill to fill cannula or Done if not needed.

> 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.



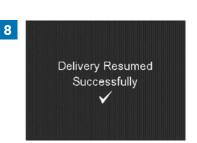
Select Fill amount and enter:

• 0.700 if using the 13 mm or 17 mm cannula. After entering the cannula fill amount, press 🔘

Fill Cannula 1. Verify Fill amount. 2. Select Fill Now when ready. Select Back to cancel. **0.700** u Fill amount Fill Now

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.



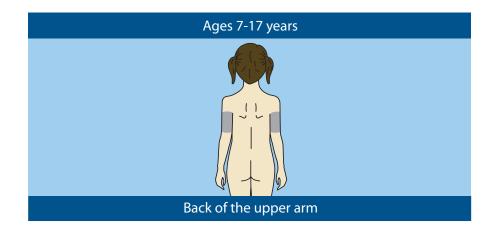


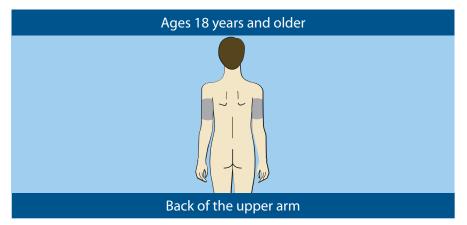
Insert the sensor

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

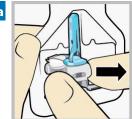
Wash hands with soap and water and clean the insertion site with alcohol.















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

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





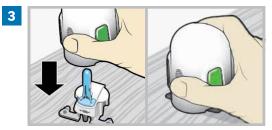


Correct

Incorrect

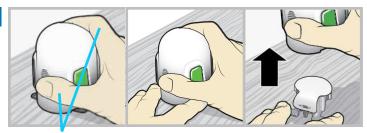
Note: Refer to the illustrations for correct and incorrect ways to hold the serter for loading.





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.

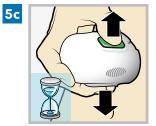
Note: Failing to hold the serter securely flat against the body may allow the serter to spring back after pressing buttons and result in improper insertion of the sensor.





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.



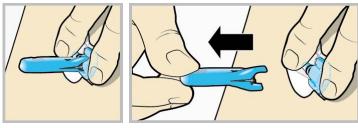
5a



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

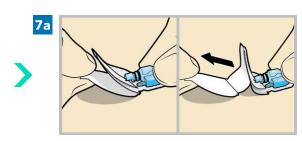






Remove the needle housing. Gently hold the base of the sensor against the skin with one hand. With the other hand, hold the needle housing at the top and slowly pull it straight away from the sensor. Dispose of the needle housing in a sharps container.

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.



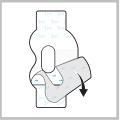


Straighten the adhesive tab. Straighten the adhesive tab so it lies flat against the skin, but do not remove the adhesive liner yet.



Tape the sensor





Remove the liner marked 1.

10

Note: Wait for the green

to flash. If the green light

light on the transmitter

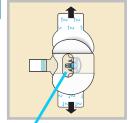
does not flash, refer to Troubleshooting section of the transmitter user quide.

Wide part of tape covers half of sensor base.

Apply the tape as shown and press down firmly.

Both sensor and skin are taped.

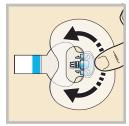




Connector and snaps in hole of tape.

Remove the liner marked 2 from each side.

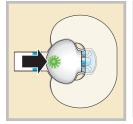
12



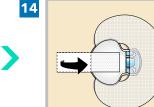
Smooth the tape.

Connect the transmitter





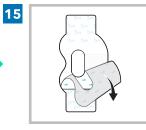
Connect the transmitter to the sensor.



Cover the transmitter with the adhesive tab

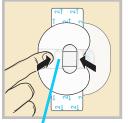
Note: Do not pull the tab too tightly.





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

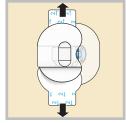




Wide part of tape covers end of transmitter and skin.

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





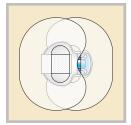
Remove the liner marked 2 from each side



Smooth the tape.

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



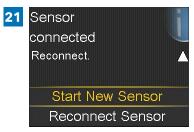


This image is an example of the tape applied correctly.

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.