



GETTING STARTED WITH CONTINUOUS GLUCOSE MONITORING

FOR THE MINIMED™ 630G SYSTEM



WARNING: Do not use the Suspend on low feature until you have read the information in this Getting Started Guide and received instructions from your healthcare professional. The Suspend on low feature causes the pump to temporarily suspend insulin delivery for two hours when the sensor glucose reaches a set limit. Under some conditions of use, the pump can suspend again, resulting in limited insulin delivery. Prolonged suspension can increase the risk of serious hyperglycemia, ketosis, and ketoacidosis.

GETTING STARTED

Continuous Glucose Monitoring MiniMed 630G System

Section 1: Introduction to Continuous Glucose Monitoring.....	2
Section 2: Sensor Glucose (SG) and Blood Glucose (BG)	3
Section 3: Trends	4
Section 4: Personalized Alerts	5
Section 5: Connecting Your Pump and Transmitter	17
Section 6: Inserting and Starting the Sensor	19
Section 7: Calibration	29
Section 8: Reading the Sensor Display	33
Section 9: Sensor Alerts and Suspend	35
Section 10: Appendix	39
Training Handouts	41
Quick Reference Guide to Sensor Alerts	43
Quick Reference Guide for Using the Enlite Sensor and One-press Serter	45

Section 1: Welcome to Continuous Glucose Monitoring

Congratulations on your decision to use continuous glucose monitoring (CGM) and taking this important step to better glucose control.

Continuous glucose monitoring gives you a more complete picture of your glucose control. Using a sensor allows you to receive up to 288 sensor glucose readings every 24 hours, filling the gaps between your BG tests. CGM alerts notify you of high and low glucose values. Graphs and trend arrows show the speed and direction your glucose levels are moving. This CGM information is displayed on your insulin pump screen. Your pump is programmed to deliver the insulin that you need. When using the MiniMed 630G system with SmartGuard technology, the pump can also be set to automatically stop delivering insulin when sensor glucose reaches or falls below a low limit that you set.

The first step in using CGM is understanding the items included in your CGM system.

YOUR CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM INCLUDES 3 KEY ITEMS:

- 1 Transmitter*** GuardianLink transmitter connects to the glucose sensor and sends sensor glucose readings to your insulin pump.
- 2 Glucose sensor** The Enlite sensor measures glucose levels in the body.
- 3 Insulin pump** The MiniMed 630G insulin pump displays glucose readings.

Other items include: One-press sarter, Enlite overtape, Guardian Link charger, and watertight tester

Always use the components that were sent with your MiniMed 630G System.

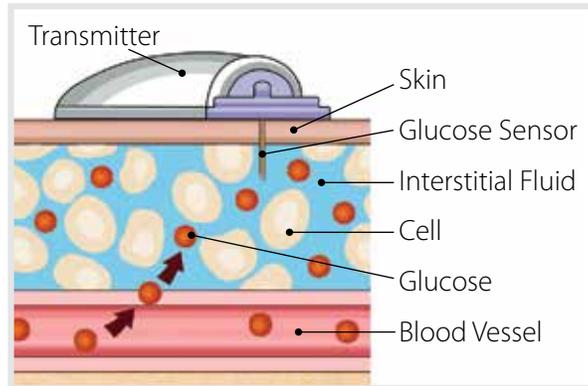


Drawings throughout this document are only generic representations of the system components.

* The transmitter must be within 6 feet (1.8 meters) of the insulin pump in order to communicate sensor readings.

Section 2: Sensor Glucose (SG) and Blood Glucose (BG)

Your **BG meter** measures glucose levels in your **blood**. The **glucose sensor** measures glucose in the fluid surrounding the cells of your tissue called **interstitial fluid**.



Glucose travels between these two areas (blood and interstitial fluid). Most of the time, it travels to your blood first, and then to your interstitial fluid. Because of how glucose moves, **your BG meter readings (BG) and sensor glucose readings (SG) will be close, but will rarely match exactly**. This difference is normal and should be expected.

When glucose levels are rising or falling quickly, you should expect to see an even **larger difference** between your BG meter readings and the sensor glucose readings.

Examples of times when this larger difference may occur include:

- After meals or taking a bolus of insulin
- During exercise
- When arrows appear on your pump screen as explained in the next section



WARNING: Do not make therapy treatment decisions based on sensor glucose values because sensor glucose and blood glucose values may differ. If your sensor glucose reading is low or high, or if you feel symptoms of low or high glucose, confirm your sensor glucose with your BG meter prior to making therapy decisions to avoid severe low or high glucose conditions.

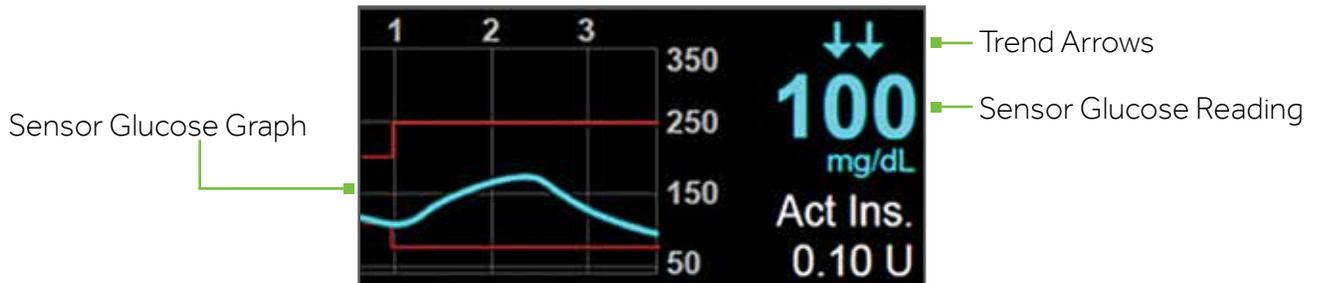
Section 3: Trends

When using CGM, you will want to focus on sensor glucose trends. These trends give insight into the direction and the speed that your glucose is changing. The sensor graph and trend arrows are used to show your trend information.



IMPORTANT: When using CGM, focus less on each individual glucose number and more on the direction and speed that your glucose is changing.

EXAMPLE OF SENSOR INFORMATION ON THE HOME SCREEN



By looking at the sensor information above, you can see that your current sensor glucose reading is 100 mg/dL. When you look at the graph, you can see that you are trending downward.

Furthermore, you see arrows above the number. These arrows indicate the rate that your glucose values are moving up or down:

↑ or ↓ - SG has been rising or falling by at least 1 but less than 2 mg/dL per minute over the last 20 minutes

↑↑ or ↓↓ - SG has been rising or falling by at least 2 but less than 3 mg/dL per minute over the last 20 minutes

↑↑↑ or ↓↓↓ - SG has been rising or falling by at least 3 or more mg/dL per minute over the last 20 minutes



NOTE: You may be likely to notice your glucose trending up or down after eating, giving a bolus, or when exercising.

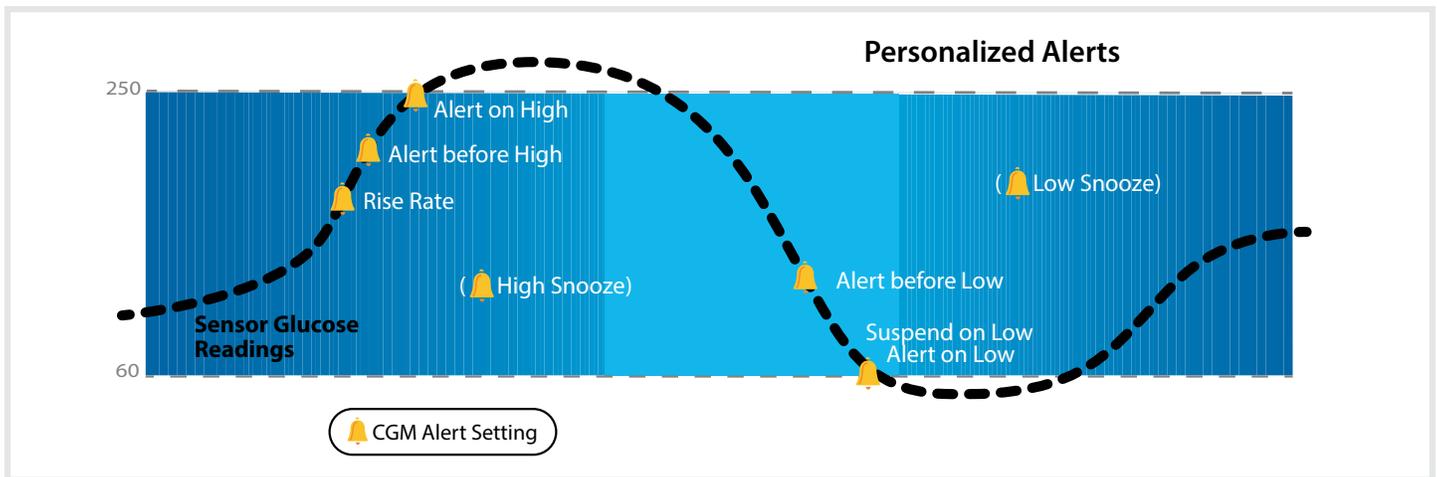
Section 4: Personalized Alerts

Your CGM alert and suspend settings are most beneficial if they are personalized for your needs. Settings will be entered into your pump during your CGM training. They can then be adjusted as you learn more from the information that wearing the sensor provides. Your healthcare professional will work with you to determine your initial settings and help with adjustments that need to be made.



NOTE: It is recommended to use values prescribed by your healthcare professional. Please make sure these are available at the time of your in-person training.

The graph below shows the different settings that can be personalized for both High and Low sensor glucose readings.



Turning Sensor Feature On

Before setting any of these sensor alerts, you must first turn the sensor feature on.



To turn on Glucose Alerts:

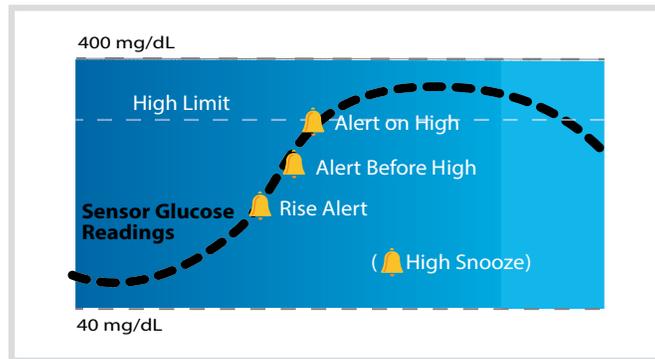
- 1) Press .
- 2) Select **Sensor Settings**.
- 3) Select **Sensor** to turn feature **On**.
You can now see the Sensor Settings menu options.



High Settings

Let's now look at the **High Settings**. These settings allow you to be alerted if your sensor glucose:

- is rising rapidly (**Rise Alert**)
- is approaching your high limit (**Alert before high**)
- has reached your high limit (**Alert on high**)



High Limit

The first step is to set the high (**Hi**) limit. The high limit can be set from 100 to 400 mg/dL. This is the value on which other high settings are based. You can set up to eight high limits for different time segments throughout the day or night.



NOTE: Your high limit is not the same as your glucose target. Your healthcare professional will help you determine the best setting so that you are alerted when needed while preventing unnecessary or inconvenient alerts.

Alert before High

When **Alert before high** is on, you will receive an alert any time the sensor glucose is predicted to reach your high limit, making you aware of a potential high before it occurs. This can help you to evaluate what has occurred and take any necessary action as directed by your healthcare professional.

Time before High

Time before high determines how many minutes before reaching the high limit that you will receive an Alert before high. This can be set from 5 to 30 minutes.

Alert on high

When the **Alert on high** is on, you will receive an alert any time your SG reading reaches or exceeds your high limit. This allows you to evaluate and treat if necessary as instructed by your healthcare professional.

ALERT ON HIGH...



Sara has been working hard to keep her glucose levels under control. Her healthcare professional has set her high limit at 225 mg/dL and instructed her to use the **Alert on high**. Now if her glucose reaches this limit, she tests her BG and takes insulin if necessary to help make sure her glucose levels return to her normal range.

Rise Alert

The **Rise Alert** will notify you when your glucose is rising rapidly. This alert can help you understand how much your glucose levels are affected by meals or, for example, when forgetting to give a bolus.

The Rise Alert can be set to alert if glucose is rising as follows:

- **↑** - SG is rising at a rate of 1 mg/dL per minute or more
- **↑↑** - SG is rising at a rate of 2 mg/dL per minute or more
- **↑↑↑** - SG is rising at a rate of 3 mg/dL per minute or more
- **Custom** - SG is rising at the rate that you set. This can be set from 1.0 to 5.0 mg/dL per minute

Snooze

The high **Snooze** is set for the amount of time that you want to wait to be reminded that an alert condition still exists. Once a high alert is received and cleared, you will be alerted again only if the high alert condition still exists after the snooze time you have set. The high snooze time can be set from 5 minutes to 3 hours.

SNOOZE...



Robert's healthcare professional instructed him to turn **Alert on high** on with a **Snooze** of 2 hours. If his sensor glucose reaches his high limit, he checks his BG and gives a bolus if he needs it. His pump will check again in 2 hours and alert him if he is still at or above his high limit.



REMEMBER: You can set up to 8 different time segments throughout the day and night. Each time segment can have different high limits and high alerts that work best for you during that time of day or night.



Setting up your High Settings:

- 1) Press .
- 2) Press  to **Sensor Settings** and press .



- 3) Press  to **High Settings** and press .

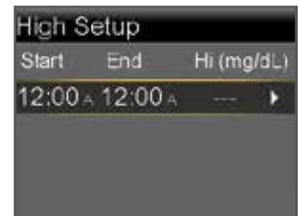


- 4) Select **High Settings** to turn **On**.

If you are changing settings that are already entered, press  to **Setup** and press .



- 5) Press  on the time segment.
If you are setting multiple time segments with different high limits and alerts, press  to set the first **End** time and press .
- In this example, only one time segment is set.*



- 6) Press  or  to set **Hi** limit and press .
- In this example, the limit is set to 250 mg/dL.*



- 7) Press  to continue onto the next screen.

PERSONALIZED ALERTS

8) Select each feature you wish to turn on. If a feature is on, select it again to turn it back off.



9) Once settings are selected, select **Next**.
In this example, the Alert on high has been turned on.



10) Select **Done**.



11) Verify that settings are correct and select **Save**.



12) If snooze time needs to be changed, press \checkmark to **Snooze** and press \circ .

13) Press \wedge or \vee to the correct time and press \circ .



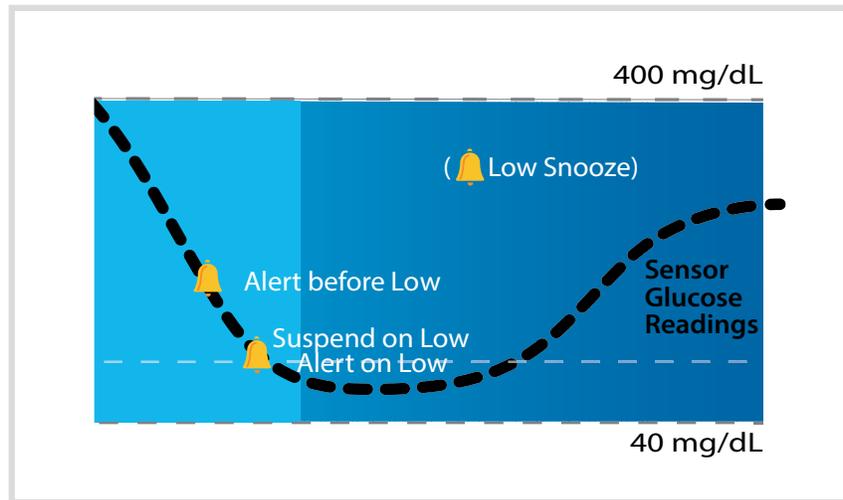
Your High Settings setup is now complete.



REMEMBER: Confirm your sensor glucose reading with a BG meter reading before making any treatment decision.

Low Settings

Let's now look at the Low Settings. You can choose to be alerted before and/or when you have reached your low limit. By using the SmartGuard suspend feature, you can also have insulin stopped when you reach the low limit that you have set. The low settings that can be chosen are shown here:



Low Limit

The first step is to set the low (**Lo**) limit. This can be set from 60 to 90 mg/dL. This is the value on which the other low settings are based. You can set up to eight low limits for different periods of the day or night.

Alert before Low

When **Alert before low** is turned on, you will be notified when your sensor glucose is predicted to reach your low limit in 30 minutes. The Alert before low can make you aware of potential low glucose levels even before they occur.

ALERT BEFORE LOW...



Alicia gets very busy at work and sometimes has low glucose readings. Her doctor has instructed her to turn her Alert before low on so she is notified 30 minutes before her sensor glucose reaches the low limit of 60 mg/dL that she has set.

Suspend on Low

When **Suspend on low** is turned on, your pump will temporarily stop delivering insulin if your sensor glucose has reached or fallen below your low limit. This keeps additional insulin from being delivered.



WARNING: Do not use the Suspend on low feature to prevent or treat low glucose. The Suspend on low feature is designed to suspend insulin delivery when you are unable to respond to the Suspend on low alarm. Always confirm your sensor glucose using your BG meter, and follow the instructions of your healthcare professional. Using Suspend on low to prevent or treat low glucose may result in prolonged hypoglycemia.

Additional information on the Suspend on low feature can be found in the Sensor Alerts and Suspend section on page 35 of this guide.

Alert on Low

When **Alert on low** is on, you will receive an alert any time your SG reading reaches or falls below your low limit. This allows you to test your BG and treat if necessary as instructed by your healthcare professional.



NOTE: If Suspend on low is turned on, Alert on low will automatically be set to on so you know that your glucose is at or below your low limit and insulin is being suspended.

SUSPEND ON LOW...



Sam has turned the Suspend on low feature on during the night. He knows that if his low limit is reached, he will be alerted and can check his glucose with his BG meter. If his BG is confirmed to be low, he can treat as directed by his healthcare professional. Sam knows that if he is ever unable to respond to the Suspend on low, that the pump will begin to siren and insulin delivery will be suspended for 2 hours.

Snooze

The low **Snooze** is set for the amount of time that you want to wait to be reminded that an alert condition still exists. Once a low alert is received and cleared, you will be alerted again only if the low alert condition still exists after the snooze time you have set. The low snooze time can be set from 5 minutes to 1 hour.

✓ Setting up your Low Settings:

In this example, we will set up multiple time segments with different alert and suspend settings.

- 1) Press .
- 2) Press  to **Sensor Settings** and press .



- 3) Press  to **Low Settings** and press .



- 4) Select **Low Settings** to turn **On**.

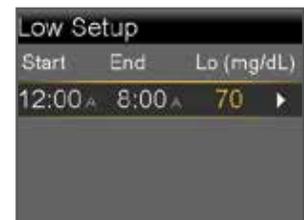
If you are changing settings that are already entered, press  to **Setup** and press .



- 5) Press  on the time segment. If you are setting only one time segment, press . If setting multiple time segments, press  to end of first segment, and press .
In this example, multiple times segments are set.



- 6) Press  or  to set **Lo** limit and press .



- 7) Press  to continue onto the next screen.

PERSONALIZED ALERTS

8) Select each feature you wish to turn on. If a feature is on, you can select it again to turn it back off. *In this example, Suspend on low has been turned on.*

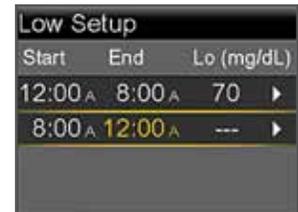


9) Once settings are selected, select **Next**.

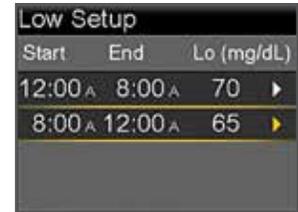


REMEMBER: When Suspend on low is turned on, Alert on low is automatically turned on.

10) Press **○** on the time segment.



11) Press **^** to the **End** time of the second segment and press **○**.



12) Press **^** or **v** to set **Lo** limit and press **○**.

13) Press **○** to continue onto the next screen.



14) Select each feature you wish to turn on. If a feature is on, you can select it again to turn it back off. *In this example, Alert before low and Suspend on low have been turned on.*



15) Select **Next**.



16) Select **Done**.

17) Verify that settings are correct and select **Save**.



18) If snooze time needs to be changed, press \blacktriangledown to **Snooze** and press \bigcirc .

19) Press \blacktriangle or \blacktriangledown to the correct time and press \bigcirc .



Your Low Settings setup is now complete.

Changing High or Low Settings

As you use CGM, you and your healthcare professional may find that changes need to be made to the existing settings. To make these changes:

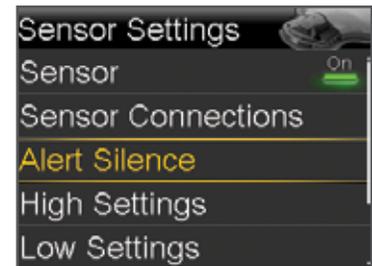
- 1) Press .
- 2) Press \blacktriangledown to **Sensor Settings** and press \bigcirc .
- 3) Press \blacktriangledown to either **High Settings** or **Low Settings**, and press \bigcirc .
- 4) Press \blacktriangledown to **Setup** and press \bigcirc .
- 5) Select **Edit**.
- 6) Select time segment you wish to change.
 - a. Change **End** time if necessary and press \bigcirc .
 - b. Change **Hi** or **Lo** limit if necessary and press \bigcirc .
 - c. Press \bigcirc when the arrow is highlighted to continue onto the next screen.
- 7) Select any feature that is off if you wish to turn it on. Select any feature that is on if you wish to turn it off.
- 8) Select **Next**.
- 9) When finished, select **Done**.
- 10) Verify settings are correct and select **Save**.

Alert Silence

The Alert Silence feature allows you to silence sensor alerts for a set period of time. If a sensor alert occurs when Alert Silence is on, a Sensor alert occurred message is displayed and the notification light flashes, but there is no beep or vibration. You can go to Alarm History in the History menu to see which sensor alert or alerts occurred. If you have not cleared the message when the Alert Silence period ends, the pump will beep and/or vibrate until cleared.

To set Alert Silence

- 1) Press .
- 2) Select **Sensor Settings**.
- 3) Select **Alert Silence**.
- 4) Select the alerts that you want to be silenced.
- 5) Press  to **Duration** and press .
- 6) Press  to set the time that you want alerts to be silenced and press .
- 7) Select **Begin**.



Alerts will automatically return to audio and/or vibrate at the end of the duration that you set.

SILENCING ALERTS...



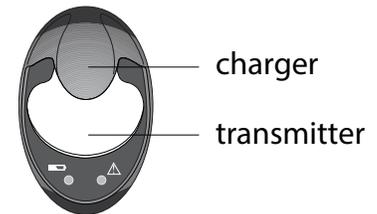
Sandra uses the **Alert Silence** feature when she is in class so that she does not disrupt her classmates if an alert occurs. She routinely looks at her pump to check for alerts, and can take action if necessary.

Section 5: Connecting your Pump and Transmitter

Before using the sensor for the first time, you will need to wirelessly connect the pump and transmitter so that they can communicate with each other. This allows the sensor information to be displayed on the pump screen.

To wirelessly connect your pump and transmitter:

- 1) Attach your transmitter to the charger and make sure it is fully charged.*



- 2) Press .
- 3) Select **Utilities**.
- 4) Select **Device Options**.
- 5) Select **Connect Device**.



Only one transmitter can be connected to the pump at one time. When you need to connect a new transmitter, you must first select Manage Devices, select the transmitter number and select Delete.

- 6) Select **Auto Connect**.
Steps for Manual Connect can be found in the MiniMed 630G User Guide.



- 7) Press .
- 8) Select **Continue**.



*See page 39 for more information on charging the transmitter.

CONNECTING YOUR PUMP AND TRANSMITTER

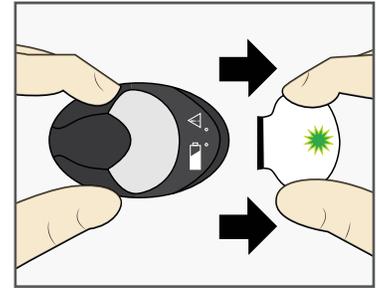
9) Make sure the transmitter is on the charger before proceeding. Now start the search processes on both devices:

a. Remove transmitter from charger

If green light on transmitter does not flash, reconnect to charger until fully charged.

b. Immediately select **Search** on the pump

The search can take up to 2 minutes.



10) Once device is found, confirm that the serial number (SN) shown on the pump is the serial number on the back of your transmitter.

*If you receive the **No devices found** message, place the transmitter back onto the charger. Then remove the transmitter from the charger and immediately select **Retry** on the pump.*



11) If SN matches, select **Confirm**.

12) Connection is now complete. The transmitter serial number will be displayed on the pump screen.

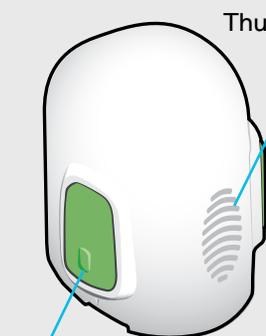


NOTE: These steps only need to be done as a first time set-up. You will not have to repeat with each new sensor you start.

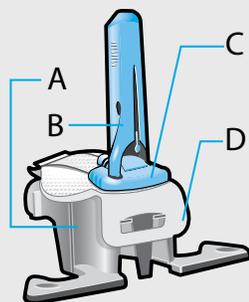
Section 6: Inserting and Starting the Sensor

Before you insert your sensor, gather all of your supplies:

ENLITE SYSTEM COMPONENTS*

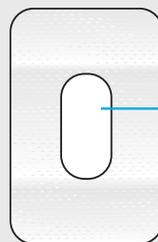


One-press Serter



Enlite Sensor & Pedestal

- A – Pedestal
- B – Needle Housing
- C – Sensor
- D – Clear Liner



Sensor Overtape

- A – Pre-cut Hole



Guardian 2 Link

*For more details, consult the individual User Guides sent within the box of each Enlite system component.

One-press serter is required in order to insert the sensor properly

Enlite sensor is individually packaged and comes attached to a plastic pedestal which is necessary for proper loading into the serter

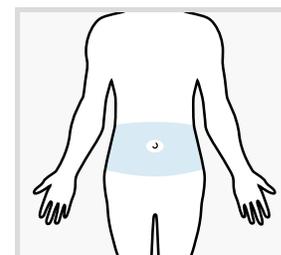
Sensor overtape is required to keep the sensor securely in place

Guardian Link transmitter is connected after the sensor is inserted and covered with the overtape

Selecting Your Site

Your sensor can be inserted in the abdomen.** The sensor insertion site should be at least:

- 2 inches from your navel
- 1 inch from your insulin pump infusion site
- 1 inch from any manual insulin injection site



**Clinical trials for glucose sensors were performed on sensors inserted in the gray shaded area shown in the image above.

INSERTING AND STARTING THE SENSOR

For best sensor glucose performance, avoid sites:

- Where clothing may rub or constrict (for example, your beltline)
- Where your body naturally bends a great deal which may cause the sensor to pull out
- That are scarred or have hardened tissue or stretch marks
- Where there is a great deal of motion or friction

Preparing Your Site

- Wash your hands with soap and water.
- Clean the selected site with an alcohol swab and allow the alcohol to dry. Do not use IV prep.

Inserting Your Sensor



1. Open the sensor package.

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



2a. Hold sensor by plastic pedestal.

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



Correct



Incorrect

2b. Tuck adhesive tab.

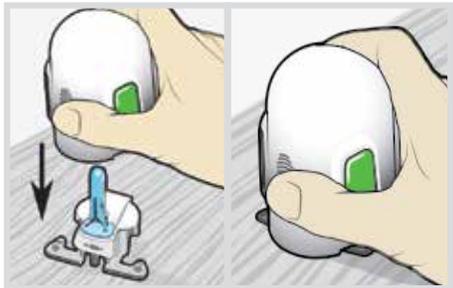
Make sure that the sensor's adhesive tab is tucked under the sensor connector and snaps.

INSERTING AND STARTING THE SENSOR



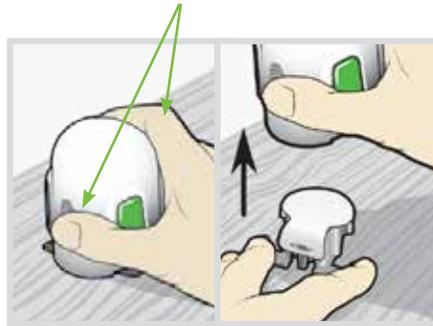
Correct

Incorrect



3. Load sensor into serter. Grip the serter exactly as shown **with your thumb placed 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.



4. Detach serter from pedestal.

To detach the serter from the pedestal, grip the serter as shown with thumb placed on 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.

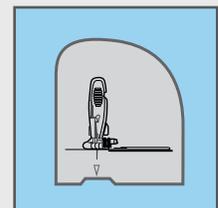
Warning: Do not detach the pedestal from the serter in mid-air as this may damage the sensor.



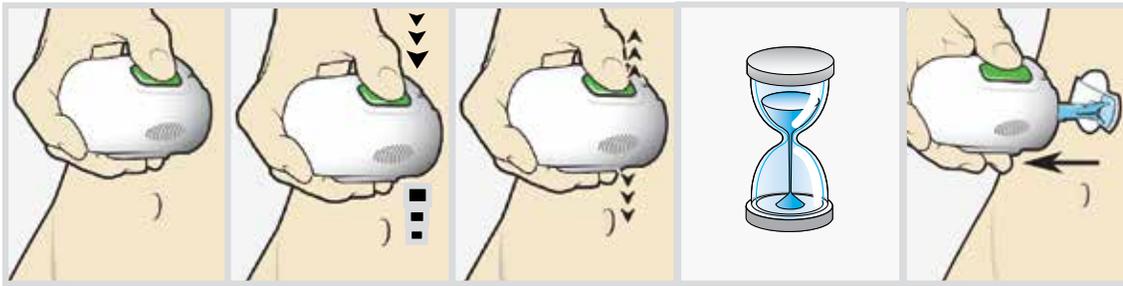
NOTE: The thumb print on the serter can be used for either left-handed or right-handed insertion.



NOTE: The sensor remains inside the serter after removing the pedestal. The arrow on both sides of serter indicate location of the sensor needle.



INSERTING AND STARTING THE SENSOR



5a. Place serter on body.

Hold the serter steadily against your cleaned insertion site, without pushing the serter too deeply into the skin.

5b. Insert sensor. Press and release the **bump** on both buttons at the same time. Do not pull the serter away from your body just yet.

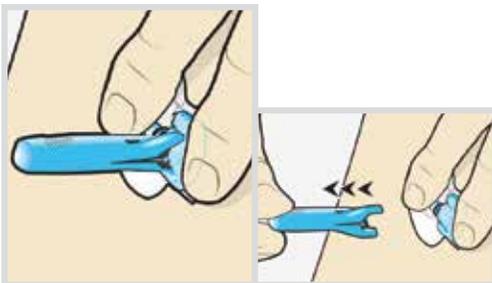
5c. Hold serter against body. Continue to hold the serter against your body to allow the adhesive time to stick to your skin.

5d. Remove serter from body.

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



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

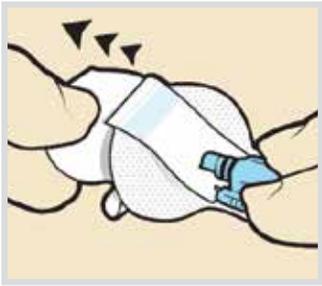


6. Remove needle housing.

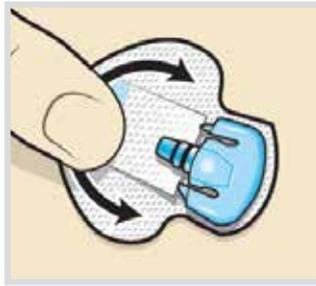
Gently hold the base of the sensor against the skin with one hand. With other hand, hold the needle housing **at the top** and slowly pull it straight away from the sensor.

Dispose of the needle housing in a sharps container.

INSERTING AND STARTING THE SENSOR

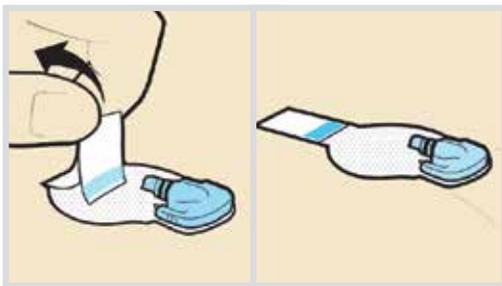


7a. Remove adhesive pad liner. Hold the sensor in place and gently remove the adhesive liner from under the adhesive pad. Do not remove the liner on the rectangular adhesive tab yet.



7b. Press entire adhesive pad to skin. Firmly press the adhesive against the skin and smooth the entire adhesive pad so that it sticks to your skin.

NOTE: The Enlite adhesive is pressure-sensitive. Continue applying pressure on the adhesive to ensure that the sensor remains inserted in the skin for the whole 6 days of wear.

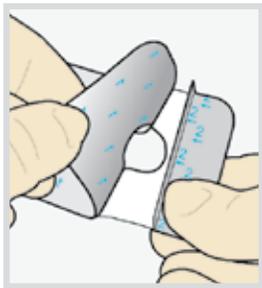


8a. Untuck adhesive tab. Untuck the adhesive tab from under the sensor connector.

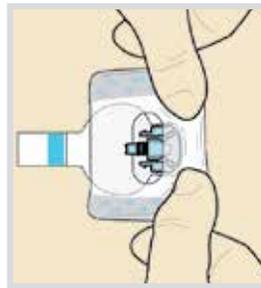
8b. Straighten adhesive tab. Straighten the adhesive tab so that it lies flat against your skin, but do not remove the adhesive liner yet.

Taping Your Sensor

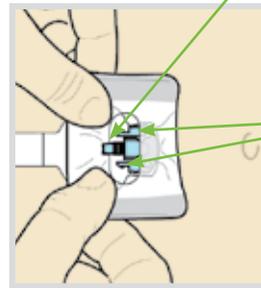
Before you connect the transmitter to your Enlite sensor it is very important that you properly secure the sensor against your skin using the sensor overtape.



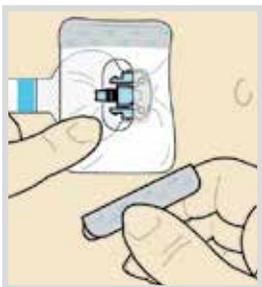
1. Remove adhesive liner 1. Remove the liner marked 1 from the overtape. Do not remove the two smaller liners marked 2 from the sides of the overtape.



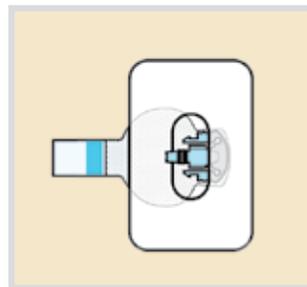
2. Apply overtape on sensor and skin. Important: Attach the overtape to both the sensor and the skin next to the sensor.



3. Apply overtape on adhesive pad. Stretch the remaining part of the overtape around the sensor connector so that the tape sticks to the curved adhesive pad and does not block the sensor connector or sensor snaps. **Continue to press the overtape to your skin to help ensure that it sticks securely.**



4. Remove liners 2. Remove the two liners marked 2 from the sides of the overtape and press the adhesive against the skin.



5. This image is an example of the overtape applied correctly. The sensor base and skin next to it are covered, but the sensor connector and snaps are uncovered and appear in the opening in the center of the overtape.



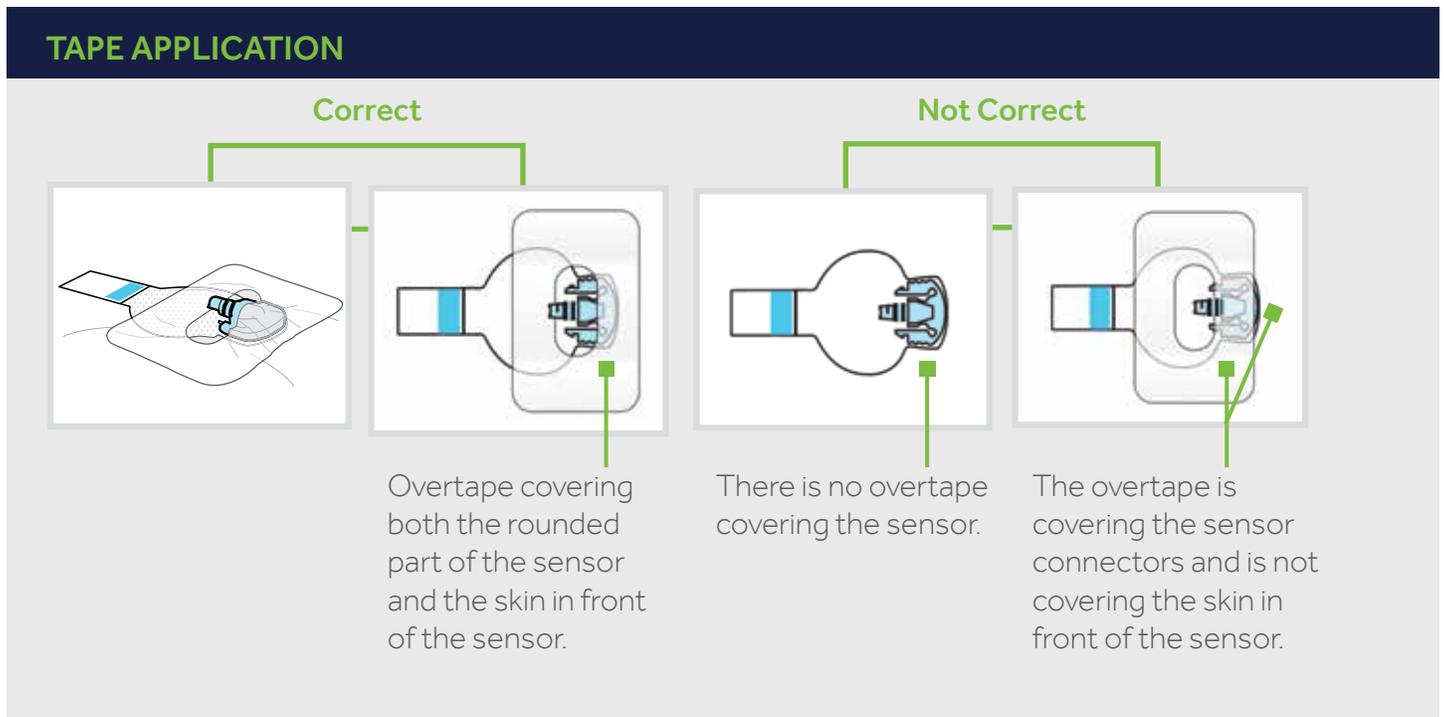
IMPORTANT: All Enlite tapes and adhesives stick best when you continue to apply pressure after putting them on your skin. Doing so helps the Enlite sensor stay securely placed and fully inserted.

INSERTING AND STARTING THE SENSOR

Checking Proper Tape Application

Properly applying the overtape is key to ensuring your success with the Enlite sensor. Due to the sensor's small size and flexible nature, the overtape helps to secure it from body motion or physical activity that can cause it to be pulled out.

The images below show both proper tape application and overtape placement that is not correct.

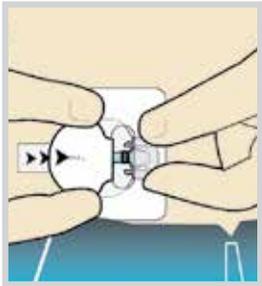


It is important to check your sensor site periodically to make sure the sensor is still secure and has not been pulled out. If the sensor has been pulled out, do not try to push it back into place as this will damage the sensor and it may no longer work properly. If this has occurred, remove the sensor and insert a new one.

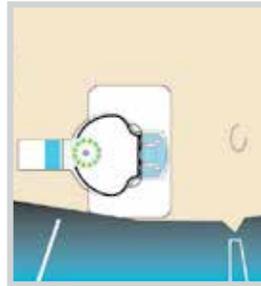
INSERTING AND STARTING THE SENSOR

Connecting your transmitter to your sensor

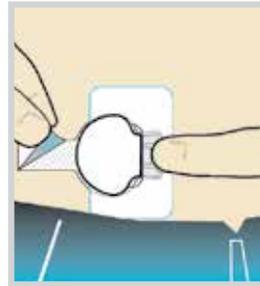
Before connecting the transmitter, make sure the **Sensor** feature is **On**. See page 5 if you need help with these steps.



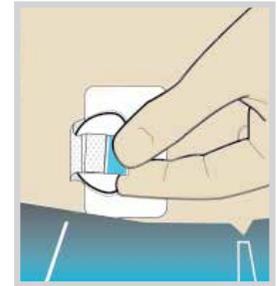
1. With one hand, hold the sensor in place. With the other hand, connect the transmitter to the sensor.



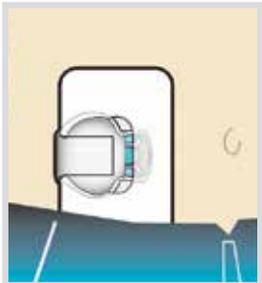
2. You may hear a faint "click" indicating that the transmitter and sensor are connected. Check for the green light on the transmitter to flash to confirm transmitter and sensor are connected and sensor is ready to be started.



3. Remove the paper on the adhesive tab.



4. Fold the adhesive tab over and onto the transmitter. **Be careful not to pull the adhesive tab too tightly or it may cause the transmitter to pull from the sensor connection.**



5. Press the adhesive onto the transmitter.



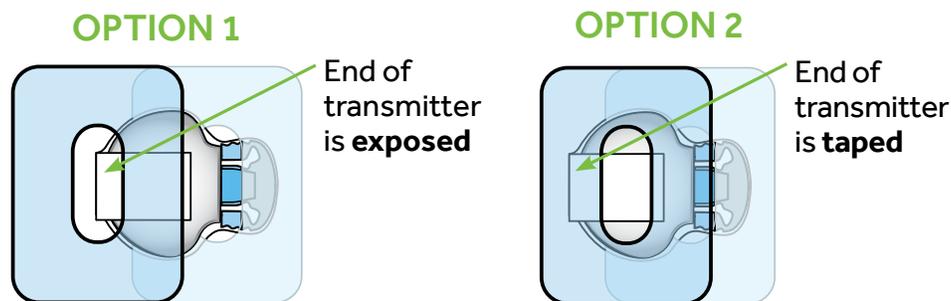
IMPORTANT: If you do not see a green light flashing on the transmitter after it is connected to the sensor, then disconnect the transmitter and place it back on the charger to ensure that it is fully charged. Then reconnect the transmitter to the sensor.

If for any reason you disconnect the transmitter from the sensor, wait 5 seconds before reconnecting it to the sensor.

Applying a second overtape

After connecting your transmitter to your sensor, apply a second piece of overtape using **Option 1** or **Option 2**.

If you have skin irritation due to moisture buildup, follow Option 1. If the transmitter catches on your clothes, follow Option 2.



Place the overtape so that the end of the transmitter is exposed through the hole in the tape.

Place the hole of the overtape over the center of the transmitter. Make sure the end of the transmitter is securely covered by the overtape.

It is very helpful to remember the order of these three steps when changing your sensor:

1. **Insert** the sensor.
2. **Tape** the sensor in place.
3. **Connect** the transmitter.
4. **Apply** second tape to secure transmitter.



NOTE: When your transmitter is connected to your sensor they form a water-tight seal to a depth of 8 feet (2.4 meters) for up to 30 minutes. You can shower and swim without removing them.

To help you during your sensor setup and insertions, a *Quick Reference Guide for Using the Enlite Sensor* is available in the *Training Handouts* section page 45.

Starting the Sensor

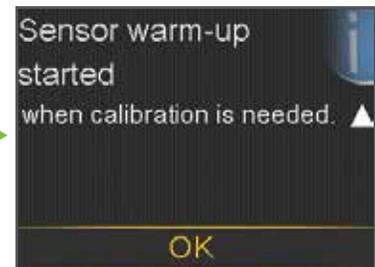
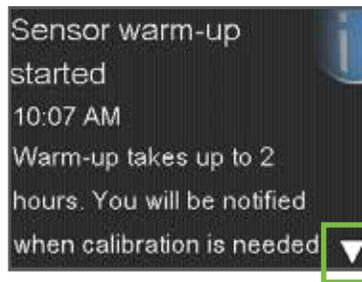
Once you have inserted the sensor and connected the transmitter, the pump and transmitter will begin to communicate.

Make sure your pump is on the Home screen so that the message below will be displayed when the sensor is ready to be started. *This typically takes less than a minute, but may take up to 10 minutes.*

- 1) Select **Start New Sensor**.



- 2) The **Sensor warm-up started** message will appear.
- 3) Press **▼** and then **○** to clear.



Warm up... will appear on the Home screen until sensor is ready for the first calibration.

*If 15 minutes have passed and the Warm up bar does not appear or it looks like it is not progressing, look in the **Quick Status** screen.*

*If you see the time of **Next cal** listed, the sensor is in Warm up.*



NOTE: The next time you connect a transmitter, you will see these screens. Select **Start New Sensor** if you have just inserted a new sensor. Select **Reconnect Sensor** if you have only disconnected and reconnected the transmitter.



Section 7: Calibration

Your continuous glucose monitoring system requires BG meter readings in order to provide you with sensor glucose readings. These BG meter readings are entered into the pump and are for sensor **calibrations**. Calibration is essential for optimal CGM performance. CGM does not eliminate the need for BG meter tests.

To calibrate, you must use a **fingerstick** blood sample to test your BG on your meter and then enter that value into your pump. The pump will accept BG meter readings between 40 mg/dL and 400 mg/dL.

After inserting a new sensor, a calibration is needed:

- 2 hours after you connect the transmitter to your sensor and start the **Warm up** period. Your pump will notify you with a **Calibrate now** alert when it is ready for its first calibration.
- Again within 6 hours (first day of inserting sensor only)
- Again every 12 hours

After the first day, the minimum number of calibrations required is one every 12 hours. However, calibrating 3-4 times a day is optimal and these can be done when it is convenient for you. To help you remember to calibrate, think 'before is best' - typically the best times to calibrate are before meals, before taking insulin, and before bedtime. Also check for arrows - calibrating when there are two or three arrows may decrease sensor accuracy until the next calibration.



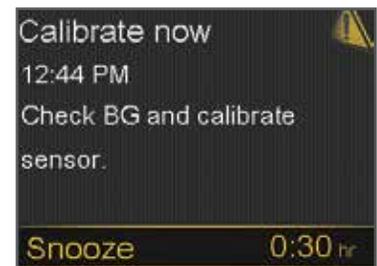
NOTE: Calibrate your sensor regularly to ensure that you continue to receive sensor glucose data.

Approximately two hours after starting a new sensor or any other time a calibration is necessary, you will receive a **Calibrate now** alert. If you cannot calibrate right away, for example, if you are driving or in a meeting, you can set the **Snooze** to remind you to calibrate in the time that you set. You can change the time if you desire, and press **O**.

If you plan to test BG and calibrate right away, simply select **Snooze**.

Once you select Snooze, **Calibration required** will appear on the Home screen until you enter a BG to calibrate.

You will not receive sensor glucose readings or sensor alerts and alarms until a calibration BG is entered.



Calibrating the Sensor

There are several different ways that you can enter a BG reading to calibrate the sensor.

✓ Calibrating by using the CONTOUR®NEXT LINK 2.4 Meter

When you use the compatible Bayer meter, you will see the meter value automatically displayed as shown here. Select one of the following options:

- 1) Select **Calibrate Sensor** to calibrate using the BG value.
- 2) Select **Bolus** to give a bolus or select **Done**.

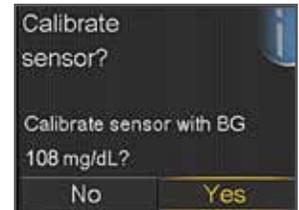


✓ Calibrating through the Bolus Wizard

You are able to calibrate when using the Bolus Wizard.

- 1) Select **Bolus** from the Home screen.
- 2) Select **Bolus Wizard**.
- 3) Enter your BG and Carbs as you normally would.
- 4) Select **Next**.
- 5) Select **Deliver Bolus**.

- 6) Press > and select **Yes** to calibrate sensor.



✓ Calibrating through Home Screen Graph

This short cut will make it easy to enter a calibration BG.

- 1) Select  to the sensor graph.
- 2) Press and hold .
- 3) Select **BG**.
- 4) Press  or  to enter BG value and press .
- 5) Select **Calibrate**.



✓ Calibrating through Sensor Settings

You can access the calibration screen through the Sensor Settings menu.

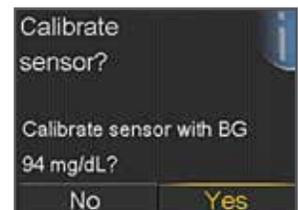
- 1) Press .
- 2) Select **Sensor Settings**.
- 3) Select **Calibrate Sensor**.
- 4) Select **BG**.
- 5) Press  or  to enter BG value and press .
- 6) Select **Calibrate**.



✓ Calibrating through Event Markers

You can also calibrate when using Event Markers.

- 1) Select .
- 2) Select **Event Markers**.
- 3) Select **BG**.
- 4) **Enter BG** value and press .
- 5) Select **Save**.
- 6) Select **Yes** to calibrate sensor.



Once you have entered a calibration BG, the Home screen will show you that the system is calibrating.

You will start seeing sensor glucose readings again in about 10-15 minutes.



NOTE: If you notice a large difference between your BG meter reading and sensor glucose readings, wash your hands and do another BG fingerstick test to help ensure a more accurate reading. Also check the sensor site and make sure the sensor oval tape is holding the sensor in place. If it is not, you will need to remove and insert a new sensor.

Wait at least 15 minutes in between calibration attempts.

Calibration Reminder

You can use the Calibration Reminder to give you notice before the next calibration is necessary. For example, let's say you calibrated at 7:00A and your reminder is set for 4 hours. Since your next calibration would be due at 7:00P (12 hours), you would receive a Calibration Reminder at 3:00P which is 4 hours before the calibration is due. This can help ensure you calibrate 3-4 times a day. The Calibration Reminder defaults On with a reminder time of 1:00 hour.

✓ To change the Calibration Reminder

- 1) Press .
- 2) Select **Reminders**.
- 3) Select **Calibration**.
- 4) Press  to **Time** and press .
- 5) Press  or  to desired time and press .
- In this example, the reminder is set for 4 hours.*
- 6) Select **Save**.



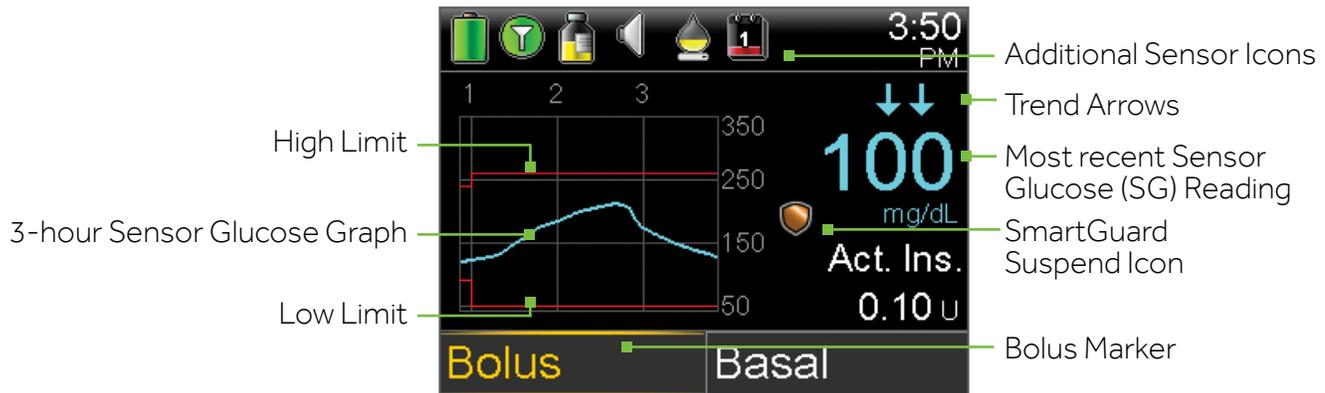
CALIBRATE BEFORE BED...



Pam does not want to be woken during the night by a **Calibrate now** alert so she tests her BG and calibrates her sensor before she goes to bed.

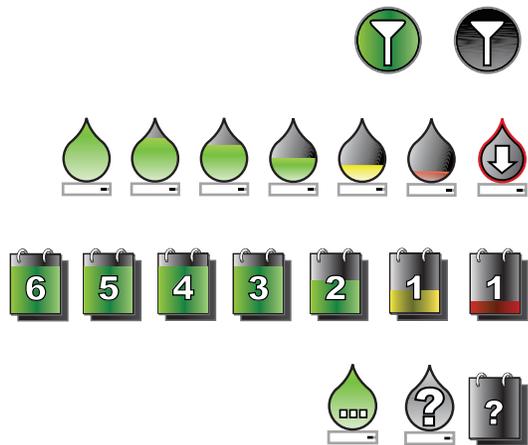
Section 8: Reading the Sensor Display

Once the sensor has started giving you sensor glucose readings, the Home screen will display them similar to what you see here.



Status Bar

In addition to the pump icons, you will see additional sensor icons on the Status Bar when using CGM.



Connection icon: shows radio frequency (RF) communication between the pump and sensor.

Calibration icon: represents the time left until next calibration is due. The icon empties as time decreases. Down arrow means calibration is needed.

Sensor Life icon: represents the number of days before sensor needs to be changed.

Additional icons: appear when the sensor is in warm up, pump and transmitter are out of range, system cannot be calibrated, or calibration or sensor age are unknown.

SmartGuard Suspend Icon

During any time segment when Suspend on low is set to on, you will see the suspend icon on the Home screen:



Suspend on low is on and ready. If insulin delivery is suspended, the icon will flash while insulin delivery is stopped



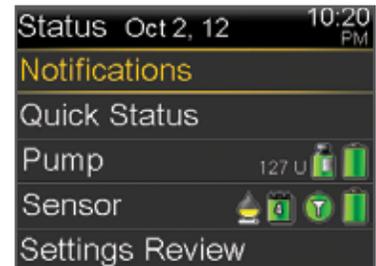
Suspend on low is on but is unavailable. This can be due to a recent suspend or when no SG values are available.

Sensor Status

You can go to the Sensor status menu to see, for example, when your next calibration is due, time left on your sensor, and battery life remaining on your transmitter.

- 1) From the Home screen, select the Status Bar.
- 2) Select **Sensor**.

You will also see additional sensor status information in **Notifications**, **Quick Status**, and **Settings Review** screens.



Current Sensor Value

The most current sensor reading is displayed on the Home screen. This is updated every 5 minutes. The sensor reads glucose values from 40 mg/dL to 400 mg/dL.



REMEMBER: One, two or three trend arrows may sometimes appear above the SG reading. These give you insight on the speed and direction that your sensor glucose is moving. See page 4 to review these arrows.

Sensor Graph

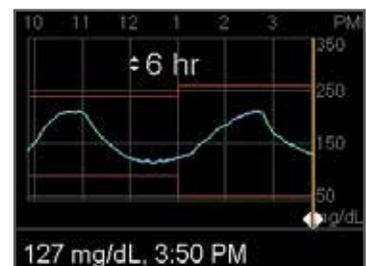
A graph that shows the last 3 hours of sensor glucose readings will always display on the Home screen. Your high and low glucose limits entered in your sensor settings will be shown in red.



Additional Sensor Graphs

In addition to the 3-hour graph, you can also view 6-hour, 12-hour and 24-hour glucose trend graphs. Blue squares at the bottom of the graph represent a bolus. A gold shaded area represents time when insulin was suspended due to a Suspend on low event. To access these graphs:

- 1) From the Home screen, press **O** on the sensor graph.
The first graph displayed is the 3-hour graph.
- 2) Press **<** to scroll back over the graph. Sensor values will be shown at the bottom of the graph.
- 3) Press **^** to see the 6-hour, 12-hour and 24-hour graphs.
- 4) Press **⬅** to return to the Home screen.



Section 9: Sensor Alerts and Suspend

Receiving alerts is a part of wearing CGM. We discussed some of these alerts earlier in Section 3: Personalized Alerts. There are other alerts that you will receive as well.

When a sensor alert or sensor suspend occurs:

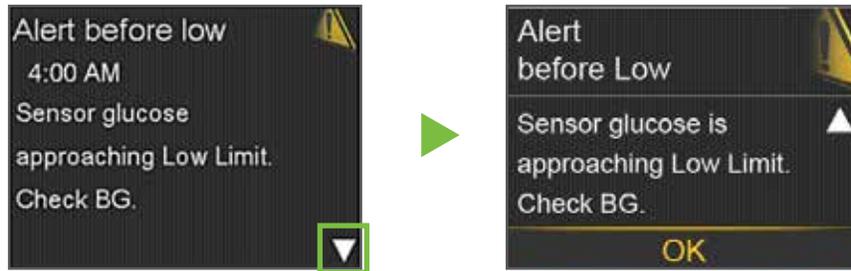
- notification light will flash
- the pump will beep or vibrate or both depending on your Audio Options setting
- the pump will display a message with a description of what is occurring

Follow these steps when you receive an alert:

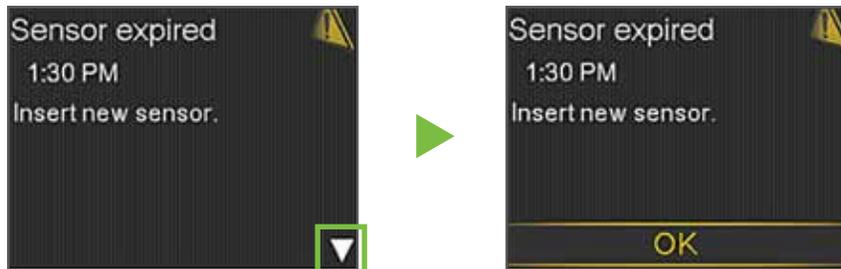
- 1) Read the text on the screen. Take any action necessary.
- 2) Press .
- 3) Press  on the desired option.

Sensor Alerts

This is an example of the **Alert below low** alert message:



This is an example of the **Sensor expired** alert message:



A table of the most common alerts that you can expect to receive when using CGM can be found in the Training Handouts section on page 43 of this guide.

Suspend on Low

When **Suspend on low** occurs, all insulin delivery is stopped immediately. Your pump alarms and the screen displays an alarm message like the one shown here. You can press  and  to clear the alarm. Insulin will remain suspended.

If the Suspend on low alarm is not cleared after 2 minutes:

- the pump will begin to siren
- this emergency message will appear on the pump screen

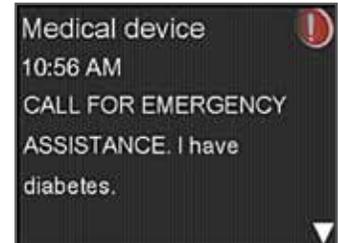
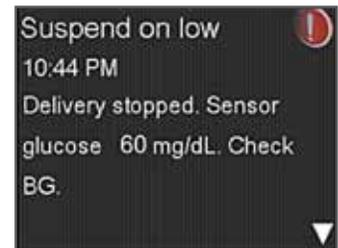
This will continue until the alarm is cleared.

If you clear the alarm within 2 hours:

- insulin will stay suspended for a maximum of 2 hours unless you manually resume insulin delivery
- basal insulin will then resume and will not suspend again for the duration of time determined by your Low Snooze setting
- after this time has passed, insulin will then be suspended again if sensor glucose is at or below the low limit

If you do not clear the alarm:

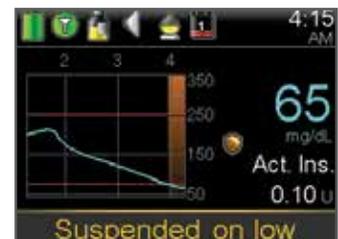
- insulin delivery will remain suspended for 2 hours
- basal insulin will then resume automatically and will not suspend again for 4 hours regardless of your sensor glucose value
- if you clear the alarm during the 4 hour period, the time before insulin can be suspended again will be reduced to equal the duration of your Low Snooze setting



Suspended on Low Home Screen

After the **Suspend on low** message is cleared and insulin delivery has stopped, the Home screen will display:

- **Suspended on low** at the bottom of the screen
- a shaded area to represent the time when insulin has been suspended
- a flashing SmartGuard suspend icon



WARNING: Suspend on low uses the sensor glucose value, not the blood glucose value, to automatically suspend all insulin delivery. Be aware that insulin could be suspended while your sensor glucose is at or below the low limit, but your blood glucose is above that limit. This could result in hyperglycemia. Likewise, your pump may not suspend even when your blood glucose is at or below the low limit. This could result in hypoglycemia. Always confirm your glucose using your BG meter and treat as directed by your healthcare professional.

Resuming Basal Insulin

There are two ways insulin can be restarted when Suspend on low occurs: automatic and manual resume.

Automatic Basal Resume

Basal insulin will automatically resume if insulin has been suspended for the maximum of 2 hours. You will always receive a **Basal delivery resumed** alert when this occurs.



NOTE: Any bolus that was delivering at the time the Suspend on low occurred will not restart. The basal pattern active at the time the Suspend on low occurred will restart. If a Temp Basal was running, the Temp Basal will not resume.

Manual Basal Resume

There may be times when you choose to resume basal insulin delivery yourself. You can simply take these steps to manually resume basal insulin delivery:

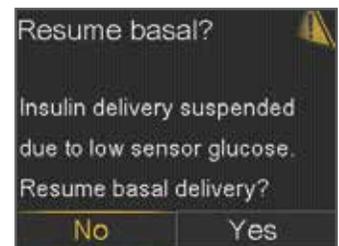
1) Select **Suspended on low**.



2) Press **∨** to **Resume Basal**.



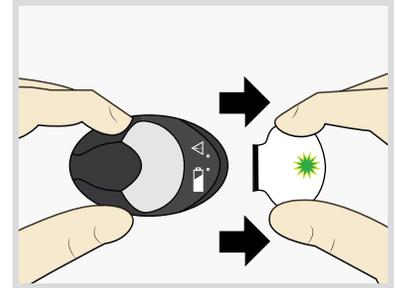
3) Press **>** to **Yes** and press **○**.



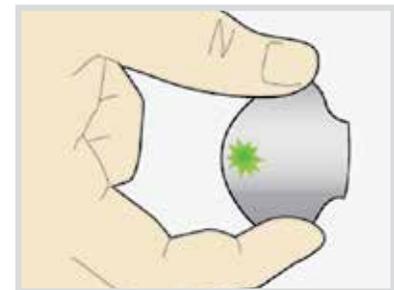
Section 10: Appendix

Charging and Storing the Guardian Link Transmitter

Charge the transmitter before each use. When the transmitter is charging, a green light will flash on the charger. This green light will turn off when the transmitter is completely charged. You will need to charge the transmitter after each sensor use. A fully charged transmitter can be used for a maximum of six days without recharging. It can take up to an hour to fully recharge.



When you remove the transmitter from the charger, a green light should flash on the transmitter. This indicates that it has enough battery power to be connected to the sensor. If you do not see the green flashing light on the transmitter place it back on the charger until it is fully charged.



Store the transmitter, charger, and test plug in a clean, dry location at room temperature. Although not required, you may store the transmitter on the charger. If the transmitter is not in use, you must charge it at least once every 60 days.

If you connect transmitter to charger and you see no lights on the charger: replace the battery in the charger.

While charging your transmitter you see a flashing red light on the charger: replace the battery in the charger.

While charging your transmitter you see a repeating pattern of quick red flashes followed by a long single red flash: replace the battery in the charger and fully charge the transmitter.

Refer to your Guardian Link transmitter and charger User Guides for more information.

X-rays, MRI, or CT Scan

If you are going to have an X-ray, MRI, CT scan, or other type of diagnostic imaging involving radiation exposure, remove your insulin pump, transmitter, and glucose sensor and place them outside of the testing area.

Going through Airport Security

Your monitor should not go through the x-ray machine that is used for carry-on or checked luggage. The full body scanner is also a form of x-ray. If you choose to go through the full body scanner, you will need to remove your sensor and transmitter prior to the scan. To avoid removing your devices, you should request an alternative screening process that does not use x-ray. Your CGM system (monitor, sensor, and transmitter) can withstand exposure to metal detectors and wands used at airport security checkpoints.



Traveling by Air

Your transmitter, sensor, and insulin pump are safe for use on U.S. commercial airlines and can be worn during flight. However, if airport security requests that you turn off your CGM device, then you must comply. It is advisable to check with the Transportation Safety Administration (TSA) for updates. International passengers should consult with their individual air carriers for international regulations.

If you need to temporarily stop wireless communication during the flight:

- 1) Press  and select **Utilities**.
- 2) Select **Airplane Mode**.
- 3) Select **Airplane Mode** to turn **On** and select **Save**.

The transmitter continues to measure glucose levels when in Airplane Mode.

To resume wireless communication:

- 1) Press  and select **Utilities**.
- 2) Select **Airplane Mode**.
- 3) Select **Airplane Mode** to turn **Off** and select **Save**.

When Airplane Mode is turned off and communication resumes, the transmitter will send up to 10 hours of sensor data to your pump.

If Airplane Mode was on for <6 hours, wait 15 minutes for sensor data to appear on pump screen.

If Airplane Mode was on for >6 hours, disconnect transmitter from the sensor and then reconnect it. Select Reconnect Sensor when it appears on the Home screen to begin warm up. The sensor data will appear on the pump. You will be asked to calibrate in 2 hours to resume sensor readings.



NOTE: It is important that you test your blood glucose (BG) more frequently while you are traveling. The routine hassle of travel, including stress, changes in time zones, schedules and activity levels, meal times and types of food, can all affect your diabetes control. Be extra attentive to monitoring your BG frequently, and be prepared to respond if needed.

Training Handouts

This section contains handouts that you can use during or after your training.

- The **Quick Reference Guide for Sensor Alerts** provides information about alerts that you might receive.
- The **Quick Reference Guide for Using the Enlite Sensor and One-press Serter** reminds you of the steps to take when inserting a new sensor.

Feel free to remove these handouts and keep them in a place where they are easily accessible.

Sensor Alerts

This table shows some of the most common alerts that you may receive when using CGM.



REMEMBER: To clear an alert, press **▼** and then press **○** on the desired option.

ALERT	REASON	STEPS TO TAKE
Alert on high	Sensor glucose value is equal to or higher than the high limit that you set.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat if necessary based on instructions from your healthcare professional and continue to monitor.
Alert on low	Sensor glucose value is equal to or lower than the low limit that you set.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat if necessary based on instructions from your healthcare professional and continue to monitor.
Alert before high	Sensor glucose reading is expected to reach the high glucose limit in the length of time you set for the Time before high.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat if necessary based on instructions from your healthcare professional and continue to monitor.
Alert before low	Sensor glucose reading is expected to reach the low glucose limit within 30 minutes.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat if necessary based on instructions from your healthcare professional and continue to monitor.
Rise Alert	Sensor glucose reading is increasing at a rate that is equal to or faster than the Rate Limit that you set.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat if necessary based on instructions from your healthcare professional and continue to monitor.

QUICK REFERENCE GUIDE FOR SENSOR ALERTS

ALERT	REASON	STEPS TO TAKE
Calibrate now	A calibration is needed in order to receive sensor glucose readings.	Enter BG value into your pump to calibrate.
Lost sensor signal	Communication between pump and transmitter has been lost for 30 minutes during or after warm-up.	Check that the sensor is still inserted in the skin and the transmitter and sensor are still connected. Move your pump closer to your transmitter.
Calibration not accepted	Your system was unable to use the BG meter readings you entered to calibrate your sensor.	Wait 15 minutes. Wash your hands and repeat the BG test. Use this value to calibrate again. If you receive a Calibration not accepted alert on your second calibration after 15 minutes, a Change sensor alert occurs
BG not received	The transmitter was unable to receive the calibration BG reading from the pump.	Move your pump closer to your transmitter and select OK. The pump will try sending the BG again.
Sensor expired	The sensor has reached the end of its useful life.	Remove the sensor and follow the instructions for inserting and starting a new sensor.
Change sensor	You have received two Calibration not accepted alerts in a row.	Remove the sensor and follow the instructions for inserting and starting a new sensor.
Cannot find sensor signal	The pump has not received a signal from the transmitter.	Disconnect and reconnect your transmitter and sensor and select OK.

For a complete list of Alerts and Alarms, refer to the MiniMed 630G System User Guide.

Inserting a New Sensor

Wash your hands and clean insertion site with alcohol.

1. **Open sensor package.**

Pull corner of paper covering to open sensor package.



2a. **Hold sensor by plastic pedestal.**

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



2b. **Tuck adhesive tab.**

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



Correct

Incorrect

3. **Load sensor into serter.** Grip serter exactly as shown **with thumb on serter thumb print.** **Do not hold green buttons.**

Push serter down onto pedestal until base of serter sits flat on table.



Correct

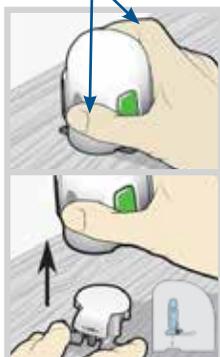


Incorrect

4. **Detach serter from pedestal.**

To detach serter from pedestal, grip serter as shown, with thumb on thumb print on serter. With other hand, place two fingers on pedestal arms and slowly pull serter straight up. **Note: Make sure that pedestal is firmly on table before pulling serter away.** **Warning: Do not detach pedestal from serter in mid-air as this may damage sensor.**

Fingers NOT holding green buttons



5a. **Place serter on body.**

Hold serter steadily against your cleaned insertion site, without pushing serter too deeply into skin.

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



5b. **Insert sensor.** Press and release bump on both buttons at same time.



5c. **Hold serter against body.**

Continue holding serter against body to allow adhesive time to stick to skin.

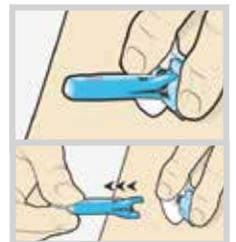


5d. **Remove serter from body.**

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



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



7a. **Remove adhesive pad liner.**

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



7b. **Press entire adhesive pad to skin.** Firmly press adhesive against skin and smooth entire adhesive pad so it sticks to skin. **Note: Enlite™ adhesive is pressure-sensitive. Continue applying pressure to ensure sensor remains inserted in skin for whole 6 days of wear.**



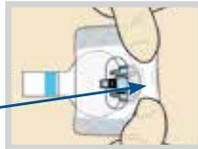
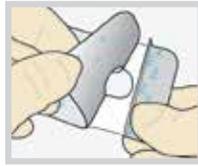
8a. **Untuck adhesive tab.** Untuck adhesive tab from under sensor connector.



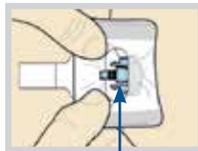
8b. **Straighten adhesive tab.** Straighten adhesive tab so it lies flat against your skin, but do not remove adhesive liner yet.

Taping the Sensor

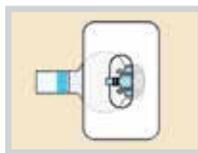
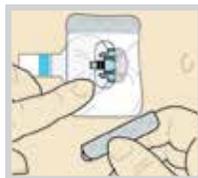
1. Remove liner marked 1 from overtape. Do not remove two smaller liners marked 2 from sides of overtape.
2. **Important: Attach overtape to both sensor and skin next to sensor.**
3. Stretch remaining part of overtape around sensor connector so that overtape sticks to curved adhesive pad and does not block sensor connector and snaps. **Continue to press overtape to your skin to help ensure that it sticks securely.**
4. Remove two liners marked 2 from the sides of the overtape and press adhesive against the skin.



Tape is over both sensor and skin



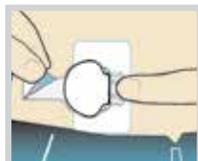
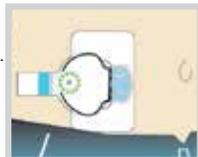
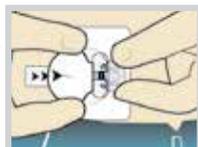
Connector and snaps in hole of tape



5. This image is an example of overtape applied correctly. Sensor connector and snaps are not covered and appear in opening of overtape.

Connecting the Transmitter

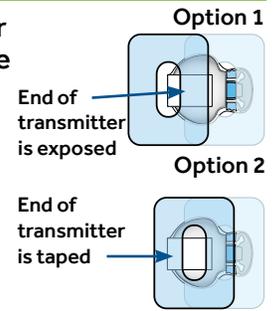
1. With one hand, hold sensor in place. With other hand, connect transmitter to sensor.
2. You will hear a faint "click" indicating that two components are connected. Check for a green light to flash on transmitter.
3. Remove liner on adhesive tab.
4. Fold adhesive tab over and onto transmitter. **Important: Be careful not to pull adhesive tab too tightly or it may cause transmitter to pull from sensor connector.**
5. Press adhesive onto transmitter.



Applying Second Overtape

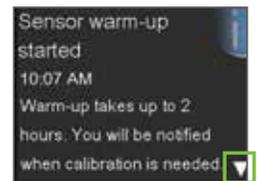
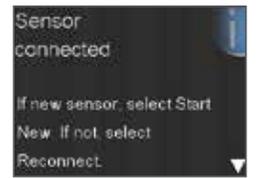
After connecting your transmitter to your sensor, apply second piece of overtape. Use Option 1 or Option 2.

If you have skin irritation due to moisture buildup, follow Option 1. If transmitter catches on your clothes, follow Option 2.



Starting the Sensor

1. Once **Sensor connected** message appears, press \checkmark . *This typically takes less than a minute, but may take up to 10 minutes.*
2. Select **Start New Sensor**.
3. **Sensor warm-up started** message will appear. Press \checkmark and then \circ to clear.

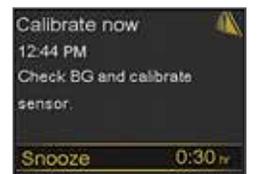


Warm up... will appear on the Home screen until sensor is ready for first calibration.



Calibrating

1. Select **Snooze**.
2. Pump will display this screen.
3. Test your BG and use it to calibrate sensor.
4. Once calibration BG is entered, this screen will display. You will begin receiving sensor glucose readings in 5 - 15 minutes.



For additional help calibrating, see the *Getting Started with Continuous Glucose Monitoring* page 29.

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