

# **Getting Started**

WITH CONTINUOUS GLUCOSE MONITORING



let's get started!

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# 1.0 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. The MiniMed® 640G also includes SmartGuard™ technology, our latest advancement in diabetes management. By using the SmartGuard™ suspend by sensor features, insulin delivery can be automatically suspended and resumed based on your low limit.

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:

Guardian™ 2 Link
Transmitter\*

Medtronic Guardian™ 2 Link transmitter connects to the glucose sensor and sends glucose readings to your insulin pump.

2 **Glucose sensor** The Enlite™ sensor measures glucose levels in the body.

3 Insulin pump The MiniMed® 640G insulin pump displays glucose readings.

### Other items include:

Enlite<sup>™</sup> serter, Enlite<sup>™</sup> overtape, Guardian<sup>™</sup> 2 Link charger, and watertight tester

Always use the components that were sent with your MiniMed® 640G System.^





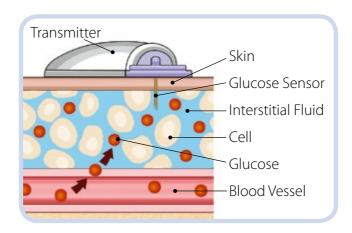


Drawings throughout this document are only generic representations of the system components.

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

# 2.0 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



**IMPORTANT:** Sensor glucose is not the same as blood glucose. Your SG and BG readings will be close to one another, but will rarely match exactly.

Sensor glucose values should not be used to make diabetes treatment decisions.

Always confirm your glucose value with a BG meter first.

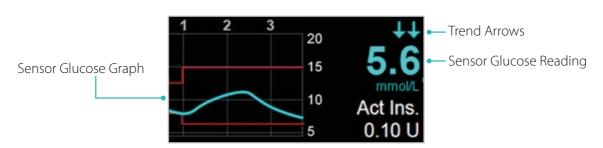
# 3.0 Trends

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 glucose reading is 5.6 mmol/L. 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 about 1-2 mmol/L over the last 20 minutes
- ↑↑ or ↓ SG has been rising or falling by about 2-3 mmol/L over the last 20 minutes
- ↑↑↑ or ↓↓↓ SG has been rising or falling by about 3 mmol/L over the last 20 minutes

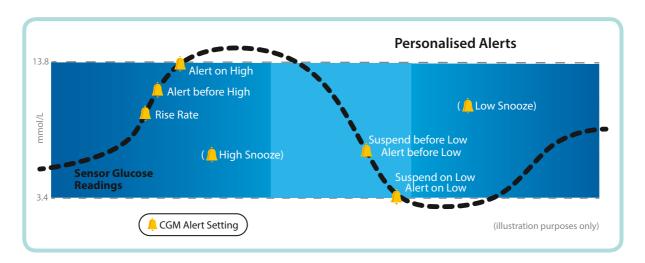


**Note:** You may be likely to notice your glucose trending up or down after eating, giving a bolus, or when exercising.

# **4.0** Personalised Alerts

Your CGM alert and suspend settings are most beneficial if they are personalised for your needs. Settings will be set 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.

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



# 4.1 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 (a).
- 2) Select **Sensor Settings.**
- Select **Sensor** to turn feature **On**.
   You can now see the Sensor Settings menu options.

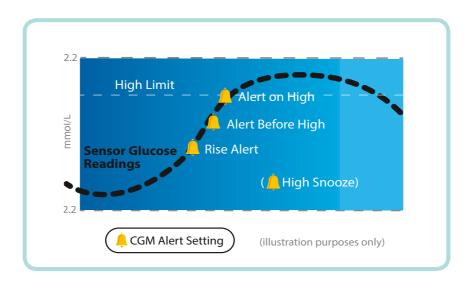




### 4.2 High Settings

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)



# 4.3 High Limit

The first step is to set the high (**Hi**) limit. The high limit can be set from 5.6 to 22.2 mmol/L. 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.



**Remember:** 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.

# 4.4 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.

# 4.5 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.

# 4.6 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 12.5 mmol/L 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.



### 4.7 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 about 1-2 mmol/L in the last 20 minutes
- **ff** SG is rising at a rate of about 2-3 mmol/L in the last 20 minutes
- 111 SG is rising at a rate of 3 or more mmol/L in the last 20 minutes
- **Custom** SG is rising at the rate that you set. This can be set from 0.050 to 0.275 mmol/L per minute

### 4.8 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  $\bigcirc$  to **Sensor Settings** and press  $\bigcirc$ .



3) Press to **High Settings** and press 0.



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

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

- 5) Press O 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 O. 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 13.8 mmol/L.
- 7) Press O to continue onto the next screen.







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

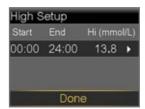


9) Once settings are selected, select **Next**.

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  $\bigcirc$  to **Snooze** and press  $\bigcirc$ .
- 13) Press  $\bigcirc$  or  $\bigcirc$  to the correct time and press  $\bigcirc$ .



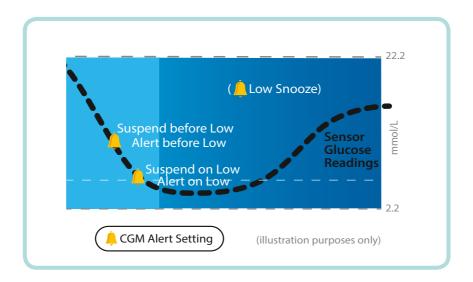
Your High Settings setup is now complete.



**Remember:** Sensor glucose values must be confirmed with a BG meter reading before diabetes treatment decisions can be made.

### 4.9 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. You can also use the SmartGuard™ suspend by sensor features that can automatically suspend insulin if you are approaching or have reached your low limit. The low settings that can be chosen are shown here:



### 4.10 Low Limit

The first step is to set the low (**Lo**) limit. This can be set from 2.8 to 5.0 mmol/L. This is the value on which the other low settings are based. You can think of this limit as the lowest sensor glucose value that you would like to avoid reaching. Furthermore, if you do reach it, you would like to spend as little time at or below it as possible. You can set up to eight low limits for different periods of the day or night.

### 4.11 Suspend before Low

When **Suspend before low** is on, your pump will temporarily stop delivering insulin if the sensor glucose value is approaching your low limit. This will keep you from getting additional insulin that would continue to lower your sensor glucose level.



**Note:** Insulin delivery will not be suspended if you are more than 3.9 mmol/L above your low limit.

### 4.12 Alert before Low

When **Alert before low** is set to on, you will receive an alert when you are approaching your low limit, making you aware of potential lows before they occur. Alert before low can be used with our without Suspend before low.

- If Suspend before low is on, you will be alerted when insulin is suspended
- If Suspend before low is off, you will be alerted when the sensor predicts you will reach your low limit in 30 minutes

You can also choose have the **Alert before low** off.

# Suspend before low...

Sam uses **Suspend before low** during the night. He knows that if his sensor glucose values are approaching his low limit, his insulin delivery will stop. He has the **Alert before low** set to off – he doesn't want to be alerted when this occurs. He is comfortable knowing the pump will stop insulin delivery and he will receive an **Alert on low** if he reaches his low limit.



# 4.13 Suspend on Low

When **Suspend on low** is set to 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.



**Note:** Only one suspend feature can be used during each time segment; you cannot turn both Suspend before low and Suspend on low on.

### 4.14 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 either Suspend on low or Suspend before 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.

# Suspend on low...

Alex's healthcare professional advised her to use the **Alert before low** and the **Suspend on low** during the daytime. If she receives an alert before she reaches her low, she tests her BG and treats with carb if necessary. In case her sensor glucose still reaches her low limit, she knows she will be alerted and her pump will suspend insulin.



### 4.15 Resume Basal Alert

In addition to suspending insulin delivery, the pump can also automatically resume delivery of basal insulin. If insulin has been suspended by either **Suspend before low** or **Suspend on low,** insulin delivery will automatically be resumed:

- if SG values are above the low limit and are trending upward
- after a maximum suspend time of 2 hours

When the Resume basal alert is on, you will be alerted when insulin is automatically resumed because SG values are above the low limit and trending upward. If the Resume basal alert is off, basal insulin will still resume, you just won't receive an alert.

If basal resumes after the maximum 2 hour suspend time, you will be alerted even if the Resume basal alert is off. It is important that you check your BG and ensure your glucose is at a safe level.

### 4.16 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.



**Note:** Additional details about the SmartGuard<sup>™</sup> suspend by sensor features can be found in the Training Handouts section on page 43 of this guide.



### **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 O.
- 3) Press  $\bigcirc$  to **Low Settings** and press  $\bigcirc$ .



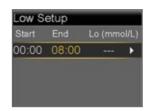
If you are changing settings that are already entered, press  $\bigcirc$  to **Setup** and press  $\bigcirc$ .

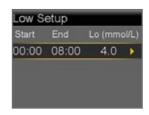
- 5) Press O on the time segment. If you are setting only one time segment, press O. If setting multiple time segments, press O to end of first segment, and press O. In this example, multiple times segments are set.
- 6) Press or to set **Lo** limit and press o.
- 7) Press (O) to continue onto the next screen.











- 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 before low has been turned on.*
- 9) Once settings are selected, select **Next**.



**Remember:** Only one Suspend feature can be used during each time segment. If either Suspend feature is turned on, Alert on low will automatically be turned on.

- 10) Press O on the time segment.
- 11) Press on to the **End** time of the second segment and press o.
- 12) Press  $\bigcirc$  or  $\bigcirc$  to set **Lo** limit and press  $\bigcirc$ .
- 13) Press (O) 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, Suspend on low, and Resume basal alert 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 to **Snooze** and press .
- 19) Press  $\bigcirc$  or  $\bigcirc$  to the correct time and press  $\bigcirc$ .





### 4.17 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 (1).
- 2) Press  $\bigcirc$  to **Sensor Settings** and press  $\bigcirc$ .
- 3) Press  $\bigcirc$  to either **High Settings** or **Low Settings**, and press  $\bigcirc$ .
- 4) Press oto **Setup** and press o.
- 5) Select Edit.
- 6) Select time segment you wish to change.
  - a. Change **End** time if necessary and press O.
  - b. Change **Hi** or **Lo** limit if necessary and press **O**.
  - c. Press (O) 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**.

### 4.18 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  $\bigcirc$  to **Duration** and press  $\bigcirc$ .
- 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.



# **5.0** Connecting your Pump and Guardian™ 2 Link Transmitter

Before using the sensor for the first time, you will need to wirelessly connect the pump and Guardian™ 2 Link 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 Guardian™ 2 Link transmitter:

Attach your Guardian™ 2 Link transmitter to the charger and make sure it is fully charged.\*



- Press (1). 2)
- 3) Select **Utilities**.
- 4) Select **Device Options.**
- Select Connect Device. 5)

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.

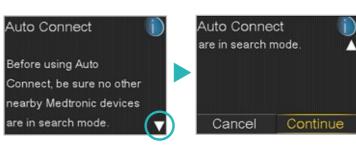


Select Auto Connect. 6)

Steps for Manual Connect can be found in the MiniMed® 640G User Guide.

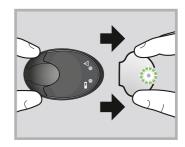


- Press 🔾 . 7)
- Select Continue.



<sup>\*</sup>See page 36 for more information on charging the transmitter.

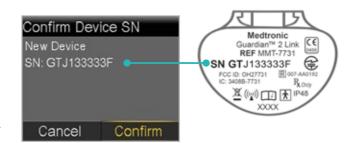
- 9) Make sure the Guardian<sup>™</sup> 2 Link transmitter is on the charger before proceeding. Now start the search processes on both devices:
  - a. Remove Guardian™ 2 Link transmitter from charger If green light on transmitter does not flash, reconnect to charger until fully charged.
  - b. Immediately 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 Guardian™ 2 Link 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.



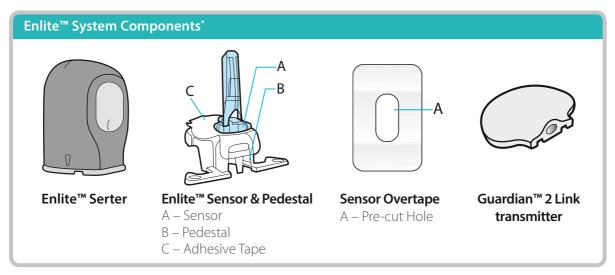
- 11) If SN matches, select **Confirm.**
- 12) Connection is now complete. The Guardian<sup>™</sup> 2 Link transmitter serial number will be displayed on the pump screen.



**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.

# **6.0** Inserting and Starting the Sensor

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



**Enlite™ 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

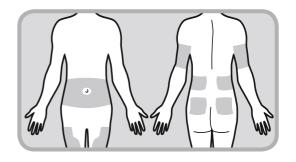
**Sensor overtape** is required to keep the sensor securely in place

Guardian™ 2 Link transmitter is connected after the sensor is inserted and covered with the overtape

# **6.1 Selecting Your Site**

Your sensor can be inserted in any of the shaded areas shown here.\*\* The sensor insertion site should be at least:

- 5 centimeters from your navel
- 2.5 centimeters from your insulin pump infusion site
- 2.5 centimeters from any manual insulin injection site



# 6.2 For best sensor glucose performance, <u>avoid</u> 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

### 6.3 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 or the sensor may not work properly.

<sup>\*</sup> For more details on the Enlite™ system components, consult the User Guides

<sup>\*\*</sup> Clinical trials for glucose sensors were performed on sensors inserted in these areas

# 6.4 Inserting Your Sensor

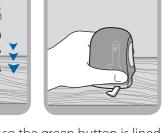


Open the sensor package.



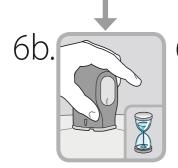
Remove the sensor with attached pedestal by holding the pedestal. Place the sensor/pedestal on a clean, flat surface (such as a table).





Hold the serter so the green button is lined up with the arms of the pedestal. To load the serter, carefully push the serter down on the sensor and pedestal until the base of the serter sits flat on the table.

Be careful not to force the serter too hard onto the sensor and pedestal or it may not load properly.



While continuing to hold the serter against your body, wait at least 5 seconds in order to allow time for the pressuresensitive adhesive to stick to your skin.



In order to remove the serter, a SECOND BUTTON PUSH is required. Press and **hold in** the green button.

Do not press the serter too hard against the skin. Doing so may make it difficult to press and hold in the green button.



While continuing to hold in the green button, slowly pull the serter away from your body.



With one hand hold the base of the sensor against your body. With the other hand, hold the needle housing at the tip. 4.



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

To detach the pedestal from the sensor, place two fingers on the pedestal arms and slowly pull the serter straight up.

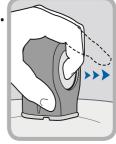
This step will also remove the paper backing from the sensor. The sensor will remain inside the loaded serter after detaching the pedestal.

5.



Place the base of the serter flat against your selected insertion site. The needle location is indicated by the arrows on the serter.

ba.



To insert the sensor, press the green button in (apply pressure towards bottom half of button where the ridge is located) and then release it. Then keep the serter flat against your body.

8.



Slowly pull the needle housing straight out, away from the sensor.



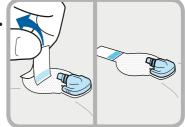
warning: If bleeding occurs at your sensor site, apply steady pressure using sterile gauze or a clean cloth for up to three minutes. If bleeding does not stop, remove the sensor and apply steady pressure until bleeding stops.

9



Carefully, remove the white paper that is located underneath the curved adhesive pad. Press the adhesive against the skin for several seconds to help ensure that it sticks to your skin.

10



Flip the adhesive tab so that it lies flat, but do not remove the paper backing yet.



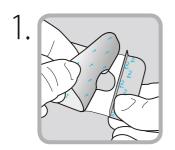
**Remember:** Inserting the sensor requires

### 2 button presses:

- 1. To insert the sensor
- **2.** To remove the serter after sensor insertion

# 6.5 Taping Your Sensor

Before you connect the Guardian™ 2 Link transmitter to your Enlite™ sensor it is very important that you properly secure the sensor against your skin using the sensor overtape.



Remove the large paper backing from the overtape. Do not remove the two smaller paper tabs on the sides of the overtape.





**IMPORTANT:** Attach the overtape to both the rounded part of the sensor and the skin in front of the sensor.



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.

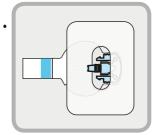
Press the overtape to your skin for several seconds to help ensure that it sticks securely.



**IMPORTANT:** All Enlite<sup>™</sup> tapes and adhesives stick best when you apply pressure for several seconds after putting them on your skin. Doing so helps the Enlite<sup>™</sup> sensor stay securely placed and fully inserted.



Remove the two paper tabs from the sides of the overtape and press the adhesive against the skin.



This image is an example of the overtape applied correctly.

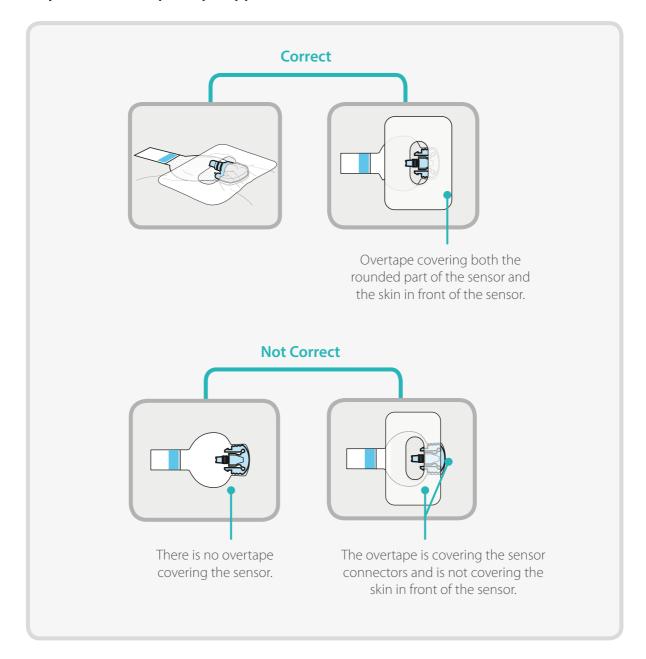


Properly applying the overtape is key to ensuring your success with the Enlite™ sensor. Due to the sensor's small size and flexible nature, the overtape helps to secure it from body motion or physical activity that can cause it to be pulled out.

### **Checking Proper Tape Application**

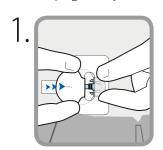
It is important to check your sensor site periodically to make sure the sensor is still secure and has not been pulled out. If the sensor has been pulled out, do not try to push it back into place as this will damage the sensor and it may no longer work properly.

### **Ways to Check Proper Tape Application**



# 6.6 Connecting your Guardian™ 2 Link transmitter to your sensor

Before connecting the Guardian<sup>™</sup> 2 Link transmitter, make sure the **Sensor** feature is **On**. See page 5 if you need help with these steps.



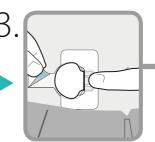
With one hand, hold the sensor in place. With the other hand, connect the transmitter to the sensor.



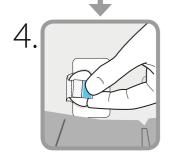
IMPORTANT: Connect the transmitter immediately after inserting the sensor



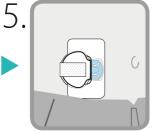
You will hear a faint "click" indicating that the transmitter and sensor are connected. Check for a green light to flash on the transmitter.



Remove the paper on the adhesive tab.



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.



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 ensure you followed the steps outlined in Section 5. Then reconnect the transmitter to the sensor. If you still do not see a green light flashing you will need to call the helpline (1800 777 808).

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



**Strongly Suggested:** Applying an additional piece of tape over the sensor as shown here helps to ensure the transmitter and sensor stay secure and connected during wear. The Enlite™ overtape or any other medical tape can be used.







Medical tape\*

<sup>\*</sup>A piece of Tegaderm $^{\text{m}}$  dressing cut in half is shown in this image as an example.

# Section 6 | Inserting and Starting the Sensor

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.



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

Notes			

### 6.7 Starting the Sensor

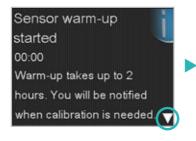
Once you have inserted the sensor and connected the Guardian™ 2 Link transmitter, the pump and transmitter will begin to communicate.

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.





### 7.0 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 2.2 mmol/L to 22.2 mmol/L.

After inserting a new sensor, a calibration is needed:

- Within 2 hours after you connect the Guardian<sup>™</sup> 2 Link 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.



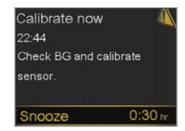
Calibrations are necessary in order to continue to receive sensor glucose readings, alerts, and alarms.

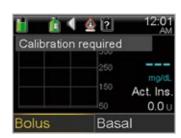
Approximately two hours after starting a new sensor or any other time a calibration is necessary, you will receive a **Calibrate now** alert. If you cannot calibrate right away, for example, if you are driving or in a meeting, you can set the **Snooze** to remind you to calibrate in the time that you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

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.





# 7.1 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 from Bayer

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

- Select **Calibrate Sensor** to calibrate using the BG value.
- If you plan to give a bolus using Bolus Wizard™ calculator, select Bolus. Select Yes to Calibrate Sensor? after bolus is delivered.
- Select **Done** if you wish to do neither.





### Calibrating through the Bolus Wizard™ calculator

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 (0).
- 3) Select **BG.**
- 4) Press or to enter BG value and press o.
- 5) Select Calibrate.



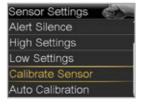




### **Calibrating through Sensor Settings**

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 o.
- 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 (O).
- 5) Select **Save.**

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 5-15 minutes.





6)

**IMPORTANT:** 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. Check the sensor site to ensure the sensor overtape is still holding the sensor in place. If there is still a large difference in glucose readings, another calibration may be needed to bring the readings closer together again.

### 7.2 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 07:00 and your reminder is set for 4 hours. Since your next calibration would be due at 19:00 (12 hours), you would receive a Calibration Reminder at 15:00 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  $\bigcirc$  to **Time** and press  $\bigcirc$ .
- 5) Press or to desired time and press . In this example, the reminder is set for 4 hours.
- 6) Select **Save.**



### How often you should calibrate...



DO calibrate approximately 3-4 times a day



**DON'T** use every BG reading to calibrate

### The best times to calibrate...



**DO** set up a calibration schedule



**DON'T** calibrate during rapid rates of change in glucose levels

### Entering a BG for calibration...



**DO** enter and accept the BG reading straight away



**DON'T** use an old BG reading or wait more than a minute before accepting as a calibration

### After a calibration error...



**DO** wait at least 15 minutes between calibrations



**DON'T** recalibrate immediately

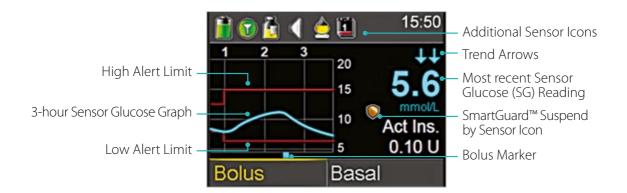
# Calibrate before bed...

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.



# 8.0 Reading the Sensor Display

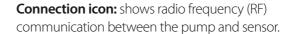
Once the sensor has started giving you sensor glucose readings, the Home screen will display them similar to what you see here:



### 8.1 Status Bar

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







**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 Guardian<sup> $\mathrm{IM}$ </sup> 2 Link transmitter are out of range, system cannot be calibrated, or calibration or sensor age are unknown.

# 8.2 SmartGuard™ Suspend by Sensor Icon

During any time segment when either Suspend before low or Suspend on low is set to on, you will see the Suspend by sensor icon on the Home screen:



Suspend before low or Suspend on low is on and ready. If either suspend becomes active, the icon will flash while insulin delivery is stopped.



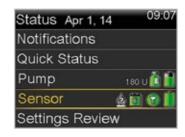
Suspend before low or Suspend on low is on but is unavailable. This can be due to a recent suspend or when no SG values are available.

### 8.3 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 Guardian<sup>m</sup> 2 Link 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.



### 8.4 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 2.2 mmol/L to 22.2 mmol/L.



**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.

# 8.5 Sensor Graph

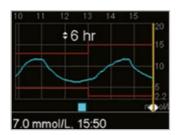
A graph that shows the last 3 hours of sensor glucose readings will always display on the Home screen. Your high and low limits entered in your sensor settings will be shown in red.



# 8.6 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 SmartGuard™ suspend by sensor events. To access these graphs:

- 1) Press 🔿 to the sensor graph.
- 2) Press (a). The first graph displayed is the 3-hour graph.
- 3) Press ( to scroll back over the graph. Sensor values will be shown at the bottom of the graph.
- 4) Press to see the 6-hour, 12-hour and 24-hour graphs.
- 5) Press ( to return to the Home screen.



# 9.0 Sensor Alerts and Suspend

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

When a sensor alert or sensor suspend occurs:

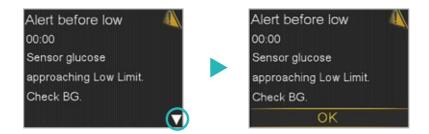
- the notification light will flash
- the pump will beep or vibrate or both depending on your Audio Options setting
- the pump will display a message with a description of what is occurring

Follow these steps when you receive an alert:

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

### 9.1 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 39 of this guide.

# 9.2 SmartGuard™: Suspend by Sensor

### **Suspend before Low**

When **Suspend before low** occurs, you will receive this alert message. Notice insulin delivery has stopped. The pump will beep and/or vibrate every minute until you press  $\bigcirc$  then  $\bigcirc$  to clear the alert. Insulin will remain suspended after the alert is cleared. If the alert is not cleared in 10 minutes, the pump will begin to siren.





If sensor glucose still reaches the low limit, you will receive an Alert on low to notify you.

### Suspend on Low

When **Suspend on low** occurs, you will receive this alarm message. Notice insulin delivery has stopped. The pump will continue to beep and/or vibrate every minute for 10 minutes until you press then (a) to clear the alert.

If the Suspend on low alarm is not cleared after 10 minutes:

- the pump will begin to siren
- this emergency message will appear on the pump screen Insulin will remain suspended for a maximum of 2 hours.

# Suspend on low 00:00 Delivery stopped. Sensor glucose 5.6 mmol/L. Check BG.



### Suspended by Sensor Home Screen

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

- Suspended before low or 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 by sensor icon



# 9.3 Resuming Basal Insulin

There are two ways insulin can be restarted when a suspend is active: automatic and manual resume.

#### **Automatic Basal Resume**

Basal rates will automatically resume if:

- SG vaules are above the low limit and are trending upward. If you have the **Resume** basal alert on, you will be alerted when this occurs.
- insulin has been suspended for the maximum of 2 hours. You will always receive a message and be alerted when this occurs.

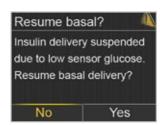
#### **Manual Basal Resume**

There may be times when you choose to resume basal insulin delivery yourself. Perhaps your healthcare professional has advised you to eat carbohydrate to bring your glucose level up and does not want insulin to continue to be suspended. You can simply take these steps to resume basal delivery:

- 1) Select Suspended before low.
- 2) Press oto Resume Basal.
- 3) Press  $\bigcirc$  to **Yes** and press  $\bigcirc$ .





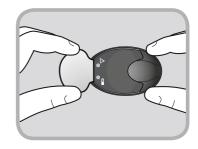


# 10.0 Other Useful Information

# 10.1 Charging and Storing the Guardian™ 2 Link Transmitter

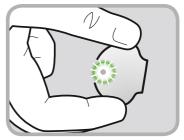
### Charge the Guardian™ 2 Link transmitter before each use.

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 Guardian™ 2 Link 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 Guardian™ 2 Link 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 Guardian™ 2 Link transmitter to charger and you see no lights on the charger: replace the battery in the charger.

While charging your Guardian™ 2 Link transmitter you see a flashing red light on the charger: replace the battery in the charger.

While charging your Guardian™ 2 Link transmitter you see a mix of short and long flashing red lights on the charger: replace the battery in the charger and fully charge the transmitter.

Refer to your Guardian™ 2 Link transmitter and charger User Guides for more information.

# 10.2 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, infusion set (if using a Medtronic Sure-T® set) and glucose sensor and place them outside of the testing area.



# 10.3 Traveling by Air

If you wear a CGM device, it is safe for use on commercial airlines. If questioned by airline personnel about the use of your device, please show them your airport information card. If they still request that you turn off your CGM device, you must comply.

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

- 1) Press 🗐 .
- 2) Select **Utilities.**
- 3) Select **Airplane Mode.**
- 4) Select **Airplane Mode** to turn **On.**
- 5) Select **Save.**

The Guardian<sup>™</sup> 2 Link transmitter continues to measure glucose levels when in Airplane Mode.

#### To resume wireless communication:

- 1) Press 🗐 .
- 2) Select **Utilities.**
- 3) Select **Airplane Mode.**
- 4) Select **Airplane Mode** to turn **Off.**
- 5) Select **Save.**

When Airplane Mode is turned off and communication resumes, the Guardian™ 2 Link transmitter will send up to 10 hours of sensor data to your pump.

If Airplane Mode was on for <6 hours:

1) Wait 15 minutes for sensor data to appear on pump screen

If Airplane Mode was on for >6 hours:

- 1) Disconnect transmitter from sensor and then reconnect it.
- 2) Select **Reconnect Sensor** when it appears on the pump screen to begin sensor warm-up.
- 3) The sensor data (up to 10 hours) will appear on the pump.
- 4) You will be asked to calibrate in 2 hours to resume sensor readings.

Always remember that it is important when traveling to be extra attentive to monitoring your glucose and prepared to respond if needed.

# Training Handouts

# **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** reminds you of the steps to take when inserting a new sensor.
- SmartGuard™ Suspend by Sensor Features provides further details about the suspend by sensor features.

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 silence an alert, press  $\bigcirc$  and then press  $\bigcirc$  on the desired option.

Alert	Reason	Steps to take
Alert on high High SG 14.6 mmol/L 12:00 AM High sensor glucose. Check BG.	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 Low SG 3.6 mmol/L 12:00 AM Low sensor glucose. Check BG.	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 High SG predicted 12:00 AM Sensor glucose approaching High Limit.	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 Low SG predicted 12:00 AM Sensor glucose approaching Low Limit.	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 Rise Alert 12:00 AM Sensor glucose rising rapidly.	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.

Alert	Reason	Steps to take
Calibrate now Calibrate now 12:00 AM Check BG and calibrate sensor. Snooze 0:30 hr	A calibration is needed in order to receive sensor glucose readings.	Enter BG value into your pump to calibrate.
Lost sensor signal Lost sensor signal 12:00 AM Move Pump closer to transmitter. May take 15 minutes to find 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 Calibration not accepted 12:00 AM Recheck BG and calibrate sensor. Snooze 0:30 hr	The BG meter value could not be used to calibrate; it was too different from the SG value.	Wash your hands and repeat the BG test. Use this value to calibrate again.
BG not received BG not received 12:00 AM Place pump close to transmitter. Select OK to resend BG to transmitter.	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 Sensor expired 12:00 AM Insert new sensor.	Sensor has reached it's maximum usage of 6 full days.	Remove the sensor and follow the instructions for inserting and starting a new sensor.
Change sensor Change sensor 12:00 AM Second calibration not accepted, Insert new 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 Cannot find sensor signal Disconnect and reconnect transmitter, then select OK. Notice if transmitter light	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® 640G System User Guide.

#### **Inserting a New Sensor**

Wash your hands and clean the insertion site with alcohol.

1. Hold sensor by pedestal and place on table.







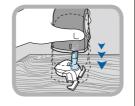
4. To insert sensor, press green button in (apply pressure towards bottom half of the button where the ridge is located) and release it.

Hold serter against body and wait at least 5 seconds to allow time for pressure-sensitive adhesive to stick to skin.

Press and **hold in** the green button.

While continuing to hold in the green button, slowly lift the serter away from your body.

















5. With one hand, hold the sensor against your body. With the other hand, hold the needle housing at the tip.

Slowly pull the needle housing straight out, away from the sensor.

Warning: If bleeding occurs at your sensor site, apply steady pressure using sterile gauze or a clean cloth for up to three minutes.

Remove white paper underneath curved adhesive pad. **Press entire adhesive to skin for several seconds.** 

Flip adhesive tab so it lies flat, but do not remove the paper backing yet.







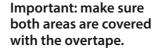


#### **Taping the Sensor**

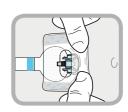
 Remove large paper backing from overtape.
 Do not remove two smaller paper tabs on sides of overtape.



2. Attach the overtape to both the rounded part of the sensor and the skin in front of the sensor.



 Apply rest of overtape, but do not block sensor connector with overtape. Press overtape to your skin for several seconds.



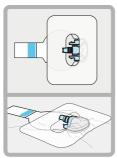


#### Taping the Sensor cont.

 Remove two paper tabs from sides of overtape. Press overtape against skin.



5. These images show overtape applied correctly.

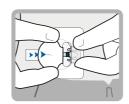


# Connecting the Guardian™ 2 Link Transmitter

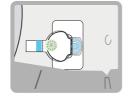


**IMPORTANT:** Connect the transmitter immediately after inserting the sensor

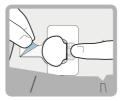
1. With one hand, hold sensor in place. With other hand, connect transmitter to sensor.



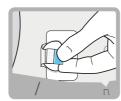
2. You will hear a faint "click" when the two components are connected. Check for green light to flash on transmitter.



3. Remove the paper on adhesive tab.



4. Fold adhesive tab over transmitter. **Be careful not to pull adhesive tab too tightly.** 



5. Press adhesive onto transmitter.

Apply additional tape over transmitter as needed.



#### **Starting the Sensor**



2. Select **Start New Sensor.** 



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



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



#### **Calibrating**

1. Select **Snooze.** 



2. Pump will display this screen.



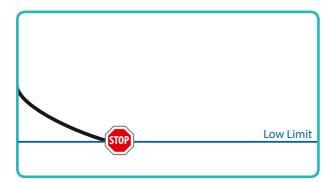
- 3. Test BG and use to calibrate the sensor. See this guide if you need help calibrating.
- 4. Once calibration BG is entered, this screen will display. You will begin receiving sensor glucose readings in 5-15 minutes.



The images below show additional detail about using the SmartGuard™ suspend by sensor features of your MiniMed® 640G System.^



### 1) Suspend on low event:

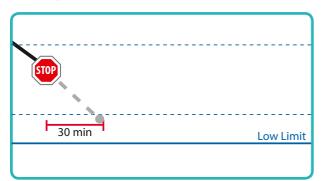


If sensor glucose (SG) reaches your low limit, insulin delivery will be stopped.

You will always receive a message and alarm when this occurs.

You will have 10 minutes to respond before the pump begins to siren and emergency message appears.

# 2) Suspend before low event:

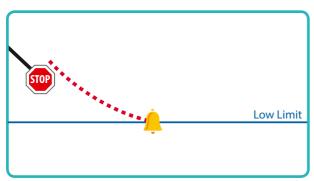


To help keep sensor glucose (SG) from reaching your low limit, insulin delivery will be stopped if SG is:

- at or within 3.9 mmol/L above the low limit
- predicted to be approaching the low limit in 30 minutes

If **Alert before low** is on, you will receive an alert when insulin is suspended.

# 3) Alert on low during Suspend before low:

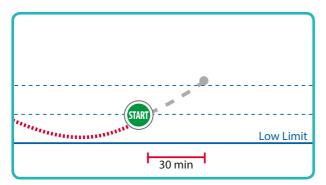


If insulin delivery has stopped due to **Suspend before low**, SG may still reach your low limit.

You will always be alerted when this occurs.

You will have 10 minutes to respond before the pump begins to siren.

# 4) Automatic basal resume based on sensor glucose (SG) value:

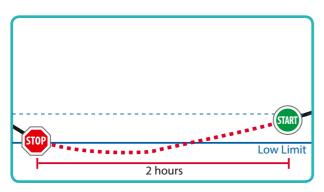


During **Suspend before low** or **Suspend on low**, basal insulin will automatically resume if:

- SG is above the low limit and trending upward
- insulin has been suspended by sensor for at least 30 minutes

If **Resume basal alert** is on, you will receive an alert when this occurs. Remember you can manually resume basal insulin at any time.

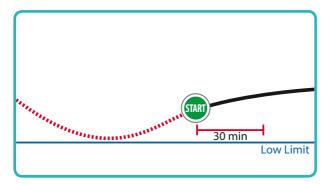
# 5) Automatic basal resume due to 2 hour maximum suspend:



During either **Suspend before low** or **Suspend on low**, if basal insulin is not resumed due to SG values, it will automatically resume after 2 hours.

You will always receive an alert when you reach the 2 hour maximum suspend time, even if the **Resume basal alert** is set to off. Remember you can manually resume basal insulin at any time.

# 6) Suspend by sensor unavailable:



Once basal insulin resumes following either a **Suspend before low** or a **Suspend on low**, there will be a period of time when suspend by sensor is unavailable.

This will most often be 30 minutes if you respond to the suspend alarm, but can be up to 4 hours. See the User Guide for more specific information about this unavailable period.

that's all, enjoy!





Medtronic Diabetes 24-hour toll free helpline (Australian landlines): **1800 777 808** 

#### www.medtronic-diabetes.com.au

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Please note: In contacting the Diabetes Toll Free, your personal and health information may be disclosed to an operator located outside Australia. ^Components sold separately. Automated insulin delivery is made possible through combining Medtronic insulin pump and continuous glucose monitoring technology.

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