

## Getting Started with Continuous Glucose Monitoring

for the MiniMed® 530G with Enlite®



**WARNING:** The Threshold Suspend feature will cause the pump to temporarily suspend insulin delivery for two hours when the sensor glucose reaches a set threshold. Under some conditions of use the pump can suspend again resulting in very limited insuln delivery. Prolonged suspension can increase the risk of serious hyperglycemia, ketosis, and ketoacidosis. Before using the Threshold Suspend feature, it is important to read the Threshold Suspend information in this Getting Started Guide and the MiniMed 530G` System User Guide and discuss proper use of the Threshold Suspend feature with your healthcare provider.

Record safety information from your healthcare provider:			

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Please refer to the MiniMed 530G System User Guide for more information.

## Section 1: Continuous Glucose Monitoring System Components

#### Your MiniMed 530G with Enlite includes 3 key items:

**Glucose Sensor** The Enlite® sensor measures glucose levels in the body.

Transmitter

The MiniLink® transmitter connects to the glucose sensor and sends glucose readings to your insulin pump/CGM monitor.

It is recharged and stored in the MiniLink charger when not

in use.

3 Insulin Pump/CGM monitor The MiniMed® 530G insulin pump displays glucose readings.

Other items include: Enlite® serter and Enlite® sensor overtape



The transmitter must be within 6 feet of the insulin pump in order to communicate sensor readings. For more information, please see "Insulin pump and RF accessories" or "RF interference from other devices" sections in the MiniMed 530G System User Guide.



The Enlite sensor is approved for ages 16 years and older, those who are not pregnant, and those who are not on dialysis.

Refer to the MiniMed 530G System User Guide for more information.

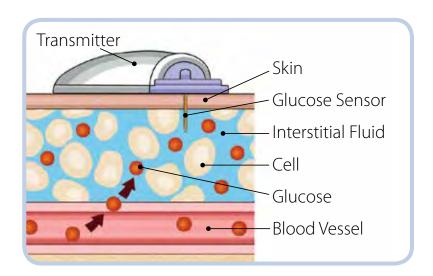
#### Section 2: Sensor Glucose and Blood Glucose

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

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

However, when glucose levels are rising or falling quickly, you should expect to see a *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 after taking a bolus of insulin
- When **↑** or **↓** arrows appear on your pump screen



**IMPORTANT** Sensor glucose is <u>not</u> the same as blood glucose. Your sensor glucose reading will rarely match your BG meter reading.

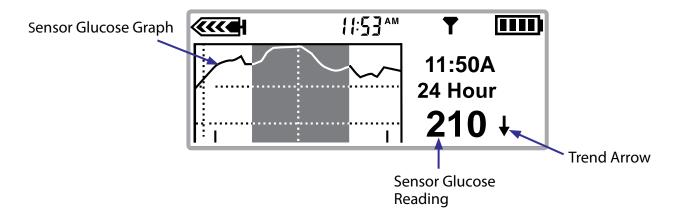
Sensor glucose values should not be used to make diabetes treatment decisions. Always confirm your blood glucose with a BG meter first.

If you "feel" that your glucose is high or low, but your sensor glucose does not match your symptoms, always test your blood glucose using your BG meter.

#### Section 3: Trends

When using CGM focus on what matters, the **trends** - the **direction** and the **speed** of the sensor glucose readings and graphs. **Pay less attention to each individual glucose number.** 

#### Example of a Sensor Glucose Trend Graph



Your insulin pump screen will display 3-hour, 6-hour, 12-hour, and 24-hour glucose trend graphs. The most current part of the graph appears on the far right side of the graph display.

There are times you may see one or two arrows next to your sensor glucose reading. Arrows indicate that your sensor glucose has been changing rapidly:

↑ or ↓ means your glucose has risen or fallen by 1-2 mg/dL per minute
↑ or ↓ means your glucose has risen or fallen by 2 or more mg/dL per minute



#### When might you see your glucose trending up or down?

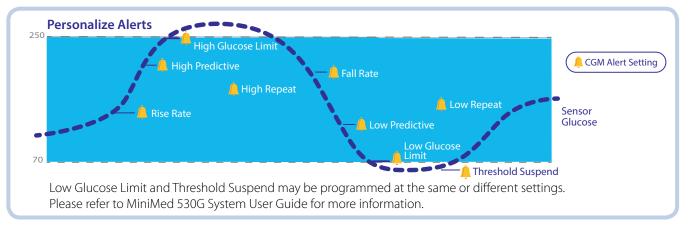
You may notice that after eating, giving a bolus, or when exercising your glucose may begin to rise or fall.

#### Section 4: Personalize Alarm and Alerts

Your CGM settings will be most beneficial to you if they are personalized for your needs. Personalizing alerts means that all or some settings will be programmed during your CGM training but can be changed to better meet your needs as you learn more about the information your CGM provides. Your healthcare provider will work with you and your trainer to determine your initial settings and help with adjustments.

#### There are five main categories of alarm and alerts that you can personalize:

- High and Low Glucose Alerts
- Predictive Alerts
- Rate of Change Alerts
- Threshold Suspend Alarm
- Calibration Alerts



#### **Low and High Glucose Alerts**

Low and high glucose alerts notify you when your sensor glucose readings have reached or moved below or above your programmed glucose limits. You can set up to eight customizable **Low and High Glucose Limits** for different periods of the day or night. You may set either the low or high limit or both. The Low Glucose Limit can be set from 40 to 390 mg/dL. The High Glucose Limit can be set from 50 to 400 mg/dL.

In order to temporarily silence or "snooze" repeated glucose alerts, the **High and Low Repeat** are set for the amount of time when you are reminded that your sensor glucose is still above or below your selected glucose limits. The Low Repeat can be set from 5 minutes to 1 hour. The High Repeat can be set from 5 minutes to 3 hours. High and Low Repeat will also apply to other CGM settings (Rate of Change and Predictive Alerts and Threshold Suspend alarm which are discussed next).

#### While sleeping...

Michael wants his CGM to alert him if his sensor glucose falls too low so his doctor instructed him to set his Low Glucose Limit to 80 mg/dL and leave his High Glucose Limit off to prevent too many alerts. During the day when he's awake his Low Glucose Limit is set to 70 mg/dL as he is able to sense when his glucose is low. Michael and his doctor agree that these settings work best for him.





#### To turn the SENSOR feature on:

- 1) From the Home Screen:

  Press (ACT) to open the Main Menu.
- 2) Press oto scroll to **Sensor** and press act.



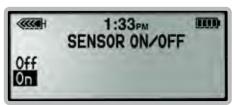
3) Press (ACT) to Edit Settings.



4) Press (ACT) to select **Sensor.** 



5) Press  $\bigcirc$  to scroll to **On** and press  $\bigcirc$  **ACT**.





#### To turn on Glucose Alerts:

- 1) From the Home Screen:
  - Press (Act) to open the Main Menu.
- 2) Press to scroll to **Sensor** and press (ACT).



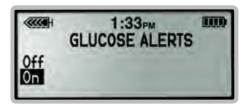
3) Press (ACT) to **Edit Settings.** 



4) Press 🔾 to scroll to **Glucose Alerts** and press 🕰.



5) Press 🔾 to scroll to **On** and press (ACT).



#### To set Low and High Glucose Limits:

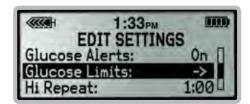
- From the Home Screen:
   Press (ACT) to open the Main Menu.
- 2) Press to scroll to **Sensor** and press (ACT).



3. Press 🔾 to scroll to **Edit Settings** and press ACT.

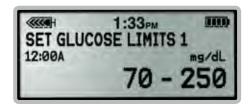


4) Press 🔾 to scroll to **Glucose Limits** and press 🖛.



5) Use  $\bigcirc$  and  $\bigcirc$  buttons to change the **Low Glucose limit** and press  $\bigcirc$ .

Then use  $\bigcirc$  and  $\bigcirc$  buttons again to change the **High Glucose limit** and press  $\bigcirc$ .



SET START TIME 2 appears with dashes flashing in the upper left part of the screen.

The flashing dashes indicate that the Start Time for the 2nd Low and High Glucose Limits need to be programmed here. Use and buttons to select the start time and AM/PM.

Then press ar.



7) Then repeat step 5 to set the Low and High Glucose Limit.



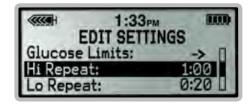
- From the Home Screen:
   Press (ACT) to open the Main Menu.
- 2) Press  $\bigcirc$  to scroll to **Sensor** and press  $\bigcirc$ .



3) Press 🔾 to scroll to **Edit Settings** and press 🕰.



4) Press  $\bigcirc$  to scroll to **High Repeat** and press  $\bigcirc$ 

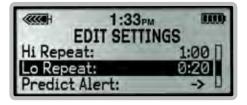


5) Use  $\bigcirc$  and  $\bigcirc$  buttons to set the **High Repeat** time and press  $\bigcirc$  **ACT**.



Repeat steps 1 to 3 if the screen has timed out and returned to the Home Screen.

Then press to scroll to **Low Repeat** and press (AT).



7) Use  $\bigcirc$  and  $\bigcirc$  buttons to set the **Low Repeat time** and press  $\bigcirc$ .





**REMEMBER:** Your Low and High Glucose Limits are not the same as your glucose target ranges. Initially, your healthcare provider may determine that it is best to set only the Low Glucose Limit in order to prevent frequent inconvenient alerts. You can still view your glucose readings on your pump even if your limits are not set.

#### **Predictive Alerts**

Predictive Alerts can warn you up to a half hour before you reach your chosen High or Low Glucose Limit. With Predictive Alerts you can be made aware of potential highs and lows even before they occur. You may set a Predictive Low, Predictive High, both or neither. The Predictive Alerts can be set from 5 to 30 minutes.

#### While at work...

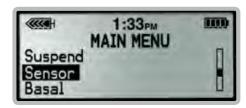
John is very busy and with customers all day. Sometimes he receives Low Sensor Glucose alerts while working. His doctor has decided that setting the Predictive Low Alert to 30 minutes can notify him 30 minutes before his sensor glucose value has reached his programmed Low Glucose Limit of 70 mg/dL.





#### **To set Predictive Alerts:**

- 1) From the Home Screen:
  Press (ACT) to open the Main Menu.
- 2) Press 🔾 to scroll to **Sensor** and press 🕰.



3) Press  $\bigcirc$  to scroll to **Edit Settings** and press  $\bigcirc$ .



4) Press to scroll to **Predictive Alert** and press (ACT).



5) Press oto scroll to **On** and press (ACT).



6) Use  $\bigcirc$  and  $\bigcirc$  buttons to set the Low Predictive time and press  $\bigcirc$ 



7) Repeat step 6 to set the High Predictive time.

#### **Rate of Change Alerts**

Rate of Change Alerts tell you when your glucose is changing rapidly. These alerts are useful for understanding how quickly your glucose levels are affected by meals, insulin, and physical activity (such as forgetting to bolus or giving yourself more insulin than you needed) and to recognize potentially dangerous sensor glucose changes before they become a problem. You can set a Fall Rate, Rise Rate, both or neither. The Rate of Change Alerts can be set from 1.1 to 5.0 mg/dL/minute.



**NOTE:** Your healthcare provider may determine that using the Rate of Change Alerts are more helpful when notifying you of extreme changes in your sensor glucose. Otherwise, setting the rate too low may cause you to receive too many alerts when you may not need them such as after every time you eat causing your sensor glucose values to rise quickly.

#### While exercising...

Mark sometimes experiences low glucose when he is playing tennis. His doctor has determined that using the Rate of Change Alert may be helpful. His doctor has instructed him to set his Fall Rate to 4 mg/dL/minute. Now when his pump notifies him that his sensor glucose is falling rapidly and is also trending towards his Low Glucose Limit of 70 mg/dL Mark is prepared to take action sooner.





#### To set Rate of Change Alerts:

- 1) From the Home Screen:

  Press (ACT) to open the Main Menu.
- 2) Press oto scroll to **Sensor** and press (ACT).



3) Press to scroll to **Edit Settings** and press (ACT).



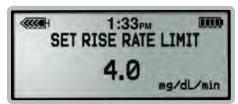
4) Press to scroll to **Rate Alerts** and press (ACT).



5) Use  $\bigcirc$  and  $\bigcirc$  buttons to set the **Fall Rate Limit** and press  $\bigcirc$  **ACT**.



6) Repeat step 5 to set the **Rise Rate Limit.** 



#### **Threshold Suspend**

The Threshold Suspend feature stops the pump's insulin delivery if your sensor reading has reached or fallen below your programmed suspend threshold. Threshold Suspend can be set from 60 to 90 mg/dL. **WARNING:** Threshold Suspend is not intended to be used to prevent or treat low glucose. Always confirm your blood glucose using your BG meter. Treat a confirmed low blood glucose with carbohydrates and according to your healthcare provider's instructions. If you are unable to respond to the Threshold Suspend alarm, insulin delivery will remain suspended for 2 hours unless you restart basal insulin delivery earlier.

Once the Threshold Suspend alarm is triggered, all insulin delivery will stop immediately and the pump will siren. The pump will continue to siren until the alarm is cleared by pressing (4), followed by (47). After clearing the alarm you will have the option to continue to suspend or restart basal insulin delivery.

#### If you do not clear the alarm:

- insulin delivery will remain suspended for 2 hours
- then basal insulin will restart automatically for 4 hours regardless of the sensor glucose value
- **NOTE:** Your standard basal rate or basal pattern will restart. Any programmed temporary basal will be cancelled.



**NOTE:** Any bolus that was delivering at the time of Threshold Suspend will not restart.

#### If you clear the alarm within 2 hours:

- you will have the option to continue to Suspend or Restart Basal insulin delivery
- if you choose to continue to suspend, the pump will remain suspended for 2 hours before restarting basal insulin
- once basal insulin is restarted, the pump will use the Low Repeat time that is set as the time frame to suspend again if the sensor glucose is still at or below the Suspend Threshold
- Any bolus that is delivering at the time of Threshold Suspend will not restart
- **NOTE:** If a temporary basal is delivering at the time of Threshold Suspend, then it will restart.

#### While sleeping...

Beth has set the Threshold Suspend feature to siren at a sensor glucose value of 60 mg/dL or below. If the siren awakens her she can check her glucose with her BG meter. If her BG is confirmed to be low, Beth will follow the recommendations of her healthcare provider to treat low blood glucose. Beth knows that if she is ever unable to respond to the Threshold Suspend siren, the pump will automatically suspend insulin delivery for 2 hours.



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



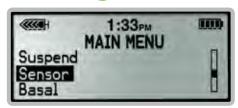
**IMPORTANT** When the Threshold Suspend alarm is triggered it will siren automatically even if you have set your pump's alert type to beep or vibrate. Your healthcare provider may instruct you to only turn on the Threshold Suspend feature at night before you go to bed and then turn it off in the day to avoid receiving the alarms during the day if you don't need them.



#### To set Threshold Suspend:

- 1) From the Home Screen:

  Press (ACT) to open the Main Menu.
- 2) Press 🔾 to scroll to **Sensor** and press 🕰.



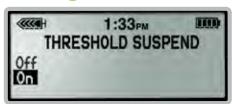
3) Press oto scroll to **Edit Settings** and press (ACT).



4) Press to scroll to **Threshold Suspend** and press (ACT).



5) Press  $\bigcirc$  to scroll to **On** and press  $\bigcirc$ 



6) Use  $\bigcirc$  and  $\bigcirc$  buttons to set the **Suspend Threshold** and press  $\bigcirc$  **ACT**.



#### **Calibration Alerts**

Calibration alerts remind you when a sensor calibration ("Meter BG Now" alert) is due. There are two types of calibration alerts. The **Cal Repeat** is the amount of time after a missed calibration when you are reminded that a calibration is needed. You can set your Cal Repeat from 5 minutes to 1 hour. The other is the **Cal Reminder** which is the amount of time until your next calibration is required. The Calibration Reminder is optional and can be set from 5 minutes to 6 hours.

#### To reduce inconvenient alerts...

Lynn has set her Cal Reminder to off. She used to have her Cal Reminder set to alert her one hour before her next calibration was due. However, Lynn has learned that with frequent calibrating throughout the day as part of her daily routine, she no longer needs the reminder and extra alert.





#### **To set Calibration Repeat:**

- 1) From the Home Screen:

  Press (ACT) to open the Main Menu.
- 2) Press  $\bigcirc$  to scroll to **Sensor** and press  $\bigcirc$



3) Press of to scroll to **Edit Settings** and press (ACT).



4) Press ( to scroll to **Cal Repeat** and press (AT).



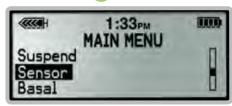
5) Use  $\bigcirc$  and  $\bigcirc$  buttons to set the **Calibration Repeat time** and press  $\bigcirc$  **ACT**.





#### To set Calibration Reminder:

- From the Home Screen:
   Press (ACT) to open the Main Menu.
- 2) Press (v) to scroll to **Sensor** and press (ACT).



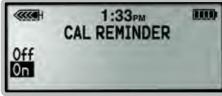
3) Press 🔾 to scroll to **Edit Settings** and press 🕰.



4) Press of to scroll to **Cal Reminder** and press (ACT).



5) Press ( to scroll to **On** and press (ACT).



6) Use ( and ( buttons to set the **Calibration Reminder time** and press ( act).





#### TIP: There are other alerts that can be customized...

The Alert Silence feature allows you to prevent beep or vibrate alerts for specific settings. You can silence high, low, both, or all sensor alerts. "ALERT SILENCE" will appear on your pump screen when an alert is triggered. Check your Sensor Alert History to see the specific alert.

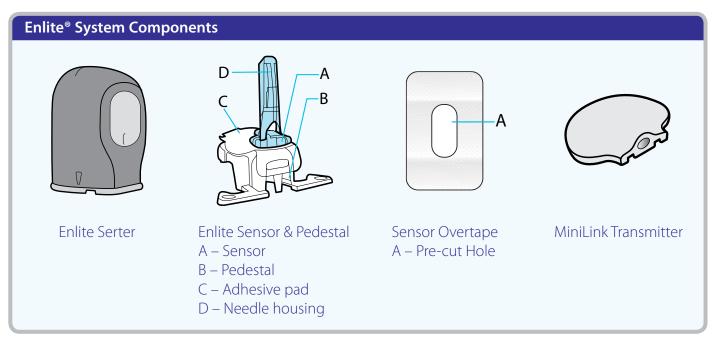


**REMEMBER:** Your healthcare provider may instruct you on:

• Waiting to turn on CGM alerts • Turning on only certain alerts
These alerts are meant to be adjusted as your knowledge of how to use CGM improves.

#### Section 5: Sensor Insertion

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



<sup>\*</sup>For more details on the Enlite System Components, consult the User Guides.

**Enlite serter** is required in order to insert the sensor properly and safely

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

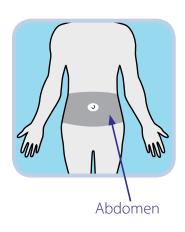
**Sensor overtape** is required to keep the sensor securely in place

MiniLink transmitter is connected after the sensor is inserted and covered with the overtape

#### **Selecting Your Site**

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

- 2 inches away from your navel
- 1 inch away from your insulin pump infusion site
- 1 inch away from any other insulin needle injection site (syringe, pen)



<sup>\*\*</sup> Clinical trials for glucose sensors were performed on sensors inserted in the shaded area shown

#### For best glucose sensor 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

#### **Preparing Your Site**

- Wash your hands
- 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.

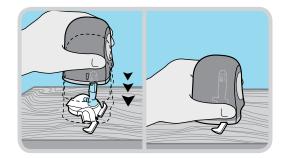
#### **Inserting Your Sensor**



1. Open the sensor package



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



3. 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.

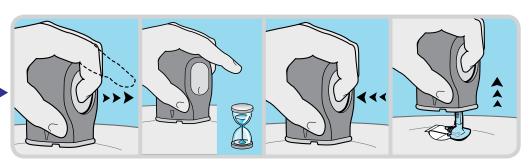


4. To detach the pedestal from the sensor, place two fingers on the pedestal arms and slowly pull the serter straight up. This step will also remove the paper backing from the sensor. The sensor will remain inside the serter after detaching the pedestal.

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



5. Place the base of the serter flat against your selected insertion site. The arrow on each side of the serter indicate the location of the sensor and needle.



6a. To insert the sensor, press the green button in and then release it. Then keep the serter flat against your body.

6b. While continuing to hold the serter against your body, wait 5 seconds in order to allow time for the pressure-sensitive adhesive to stick to your skin.

oc. In order to remove the serter, a SECOND BUTTON PUSH is required. Press and hold in the green button. Do not push the serter too hard against the skin or doing so may make it difficult to press and hold in the green button.

6d. While continuing to hold in the green button, slowly pull the serter away from your body.



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



8. Slowly pull the needle housing straight out, away from the sensor. Warning: If bleeding occurs at your sensor site (under/around/or on top of the sensor), apply steady pressure using sterile gauze or a clean cloth placed on top of the sensor for up to three minutes. If bleeding does not stop, then remove the sensor and apply steady pressure until the 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.

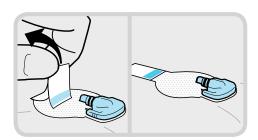


#### REMEMBER:

Inserting the sensor requires

#### 2 button presses:

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



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

#### **Taping Your Sensor**

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



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



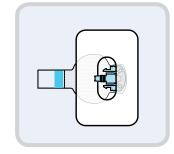
2. Important:
Attach the overtape to both the rounded part of the sensor and the skin in front of the sensor.



3. 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.



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



5. This image is an example of the overtape applied correctly.



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

**IMPORTANT** 

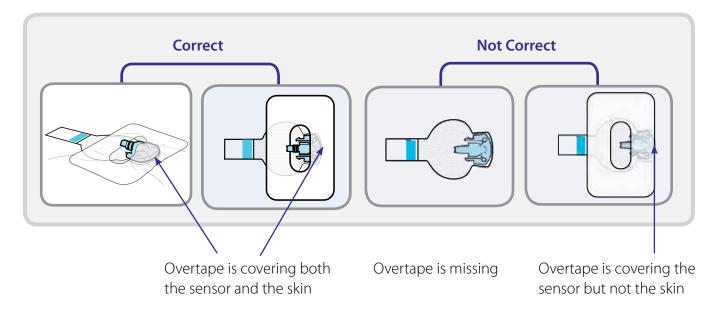


Properly applying the overtape is key to ensuring your success with the Enlite sensor. Due to the sensor's small size and flexible nature, the overtape helps to secure it from body motion or physical activity that can cause it to be pulled out.

#### **Checking Proper Tape Application**

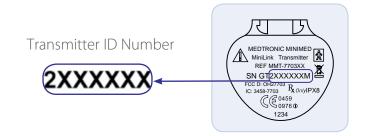
It is important to check your sensor site periodically to make sure the sensor is still secure and has not been pulled out. If the sensor has been pulled out, do not try to push it back into place as this will damage the sensor.

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



#### **Connecting Your Transmitter**

Before connecting your MiniLink® transmitter to your sensor, your transmitter ID must be entered into your pump in order to enable communication. Look on the back of your transmitter to locate the ID number.





#### To program the Transmitter ID into your pump:

- 1) From the Home Screen:

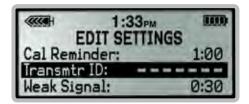
  Press (ACT) to open the Main Menu.
- 2) Press 🔾 to scroll to **Sensor** and press 🕰.



3) Press oto scroll to **Edit Settings** and press (ACT).



4) Press of to scroll to **Transmitter ID** and press of.



5) Use  $\bigcirc$  and  $\bigcirc$  buttons to enter each digit and press  $\bigcirc$ 

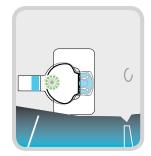


6) Repeat step 5 to enter each digit.

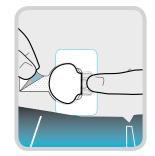
#### To connect your transmitter to your sensor:



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



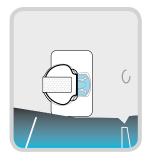
2. You will hear a faint "click" indicating that the two components are connected. Check for a green light to flash on the transmitter.



3. Remove the paper on the adhesive tab.



4. Fold the adhesive tab over and onto the transmitter. Important: Be careful not to pull the adhesive tab too tightly or it may cause the transmitter to bend or 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.



**Optional:** If you notice that the Enlite overtape is peeling, then you may want to add a second adhesive on top of the provided sensor overtape. This second adhesive can be used to cover the entire area including the transmitter.





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.

#### **Initializing the Sensor**

- From the Home Screen:
   Press (ACT) to open the Main Menu.
- 2) Press 🔾 to scroll to **Sensor** and press (ACT).



3) Press of to scroll to **Link to Sensor** and press (ACT).



4) Press (ACT) to select **New Sensor.** 



5) You will see a message that your sensor will be ready in 2 hours.

You will now see next to the time. Your sensor is now initializing and you will be alerted in about 2 hours to enter your first BG calibration before sensor glucose readings can be viewed.



A Quick Reference page is available in the back of this book to help guide you during your sensor insertions.

#### Section 6: Calibration

Your continuous glucose monitoring system requires BG meter readings in order to generate 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 readings.

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 to 400 mg/dL.

After inserting a new sensor, a calibration is needed:

- Approximately 2 hours after you connect the transmitter to your sensor and initialize your sensor. Your pump will notify you with a "METER BG NOW" alert when it is ready for its first calibration.
- Again within 6 hours (first day of inserting sensor only)
- Again every 12 hours

The minimum number of calibrations required is once every 12 hours (after the first day). The sensor's accuracy can be improved with 3 - 4 calibrations per day. \*Although not optimal, calibrations can be done at anytime providing you with the flexibility to calibrate at times that are convenient for you and to avoid needing to calibrate when it is less convenient such as during the night.

\*Note: Calibrating with \ightharpoonup or \frac{1}{4} displayed on the CGM screen may decrease sensor accuracy until the next calibration.



Calibrations are necessary in order to continue to receive sensor glucose readings, alerts, and Threshold Suspend alarms. Not calibrating properly can affect CGM performance.

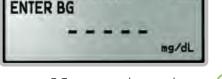
Approximately two hours after inserting a new sensor, a "METER BG NOW" alert will notify you that the pump is ready for your first calibration. Clear the alert by pressing (a), followed by (ar) and follow these steps:

#### There are two ways to calibrate:

Using your Bolus Wizard

- 1) Press B button
- 2) Use ( and ( buttons to enter BG meter value and press ( AT).
- 3) You will receive a message "BG to update sensor?" Press the 🔾 to select Yes and press 🕰





1:33PM

\*\*If you are using a linked meter, then your BG meter value will automatically appear on the pump screen. Then follow step 3 above.

Or

Using your Sensor Menu

- 1) From the Home Screen:

  Press (ACT) to open the Main Menu.
- 2) Press 🔾 to scroll to the Sensor menu and press 🕰.



3) Press (You will only see the option to Calibrate if your sensor and transmitter are connected and your sensor is ready for its first calibration).





Calibrating through your Sensor Menu can only occur if your pump's insulin delivery is not suspended.

After your first calibration, it will take about 10-15 minutes for sensor glucose readings to appear on your pump screen. To find when your next calibration is due press three times from the Home Screen to view the Sensor Status screen.

#### Calibrate before bed...

Pam knows she will not have to wake up in the middle of the night from a "METER BG NOW" alert if she tests her BG before bed and enters that value into her pump to calibrate her sensor.





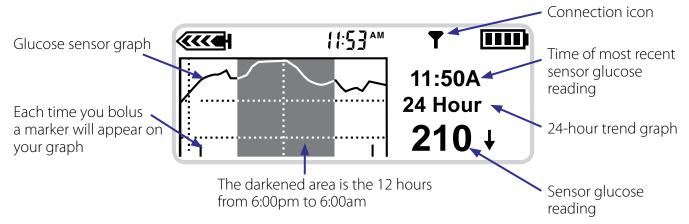
**IMPORTANT** If you notice a large difference between your BG meter reading and sensor glucose readings, do another BG fingerstick test after washing your hands. Then check the sensor site to ensure the sensor is still inserted in your skin. If there is still a large difference in glucose readings, then another calibration may be needed to bring the readings closer together again. Wait 15 minutes before entering another BG reading for a calibration.

#### **Reading the CGM Display**

Your pump displays 3-hour, 6-hour, 12-hour, and 24-hour glucose trend graphs. To view different trend graphs press (2).

Press once from the Home screen to display the most recently viewed graph. Press to display the other graphs.

The CGM will provide sensor glucose readings between 40 mg/dL and 400 mg/dL. If the sensor glucose reading falls below 40 mg/dL, then the screen will display "Below 40". If the sensor reading rises above 400 mg/dL, then the screen will display "Above 400".



Press  $\bigcirc$  to view individual sensor glucose readings on the graph. Press  $\bigcirc$  to return to the most recent sensor glucose reading. In order to view the different trend graphs, the most recent sensor glucose reading must be displayed first.

What the Sensor Connection Icons Mean			
<b>T</b>	Insulin pump indicates that the MiniLink® transmitter and insulin pump/CGM monitor are communicating properly.		
G	Pump/CGM monitor has not received a signal for more than 5–7 minutes. This is okay. The MiniLink transmitter stores up to 40 minutes of data and will send these readings to the insulin pump once a signal is re-established.		

#### Section 7: CareLink® Personal Software

CareLink Personal software is a free, web-based program that allows you to upload information from your insulin pump, CGM, and blood glucose meter, making it easier to understand your glucose patterns and trends.

CareLink Personal is an important part of your success with CGM as it will assist you and your health-care provider in tracking your glucose levels to see how they are affected by your insulin delivery, meals, and exercise routines. It provides you with a secure place to store your information and uncover glucose patterns that meter and logbooks alone cannot reveal. It also allows you and your healthcare provider to make more informed therapy decisions such as identifying which pump settings to change for better glucose control.

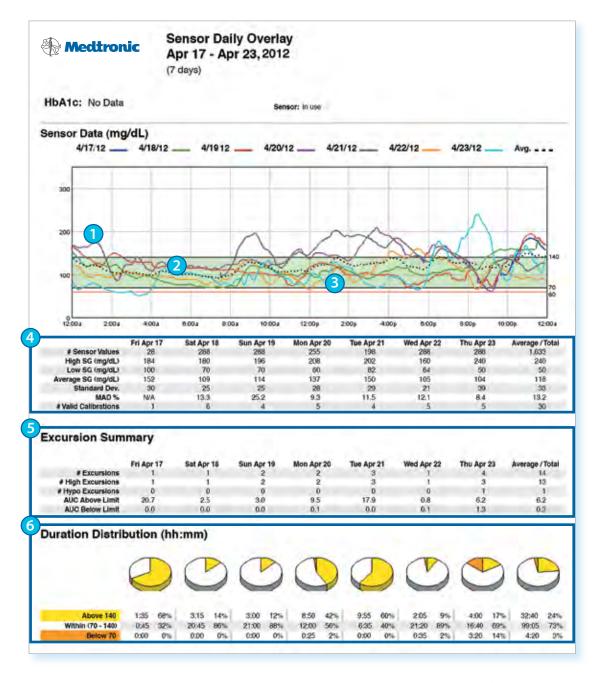
CareLink organizes your sensor and meter glucose readings, insulin usage, and carbohydrate intake into detailed reports with charts, tables, and graphs.

#### **Tips for Using CareLink Personal**

- Regularly upload your insulin pump using CareLink Personal (at least once/month)
- Review your data and look for patterns and trends
- · Discuss therapy adjustments with your healthcare provider

#### Let's get started by looking at one of the CareLink Personal Reports: Sensor Daily Overlay

- 1 Sensor readings for one day each day is shown with a different color.
- 2 Target glucose range the green shaded area represents the target glucose range set in the preferences section of CareLink® Personal and shows whether you are within your target for glucose control.
- 3 **Hypoglycemic threshold** the red line represents the low glucose indicator set in the preferences section. The default setting is 60 mg/dL.
- 4 Specific information regarding each day's sensor readings and calibrations.
- **Excursion Summary** shows the number and type of excursions outside the target glucose range.
- **Duration Distribution** shows the amount of time spent above, in, or below your target glucose range on a pie chart.



Do you see a pattern of low or high glucose values? Focus on resolving lows first.

- · Look at the overnight period first,
- Then, look at the time periods before meals (let's assume this patient eats at 7 AM, 12 noon, and 6 PM)
- Finally, look at the time periods after meals (2-3 hours after each meal)

#### **Getting started with CareLink® Personal**

To register and setup your free CareLink account visit: www.medtronicdiabetes.com/carelink

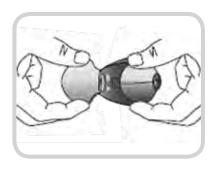
#### Section 7: Appendix

#### Charging and Storing the MiniLink® transmitter

Charge the transmitter before each use. When the transmitter is charging, a green light will flash on the charger. This green light on the charger will turn off when the transmitter is completely charged. A completely depleted transmitter battery will need up to 8 hours to recharge. The transmitter can be used for a maximum of 6 full days in between charges.



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 see red lights on the charger** that flash once every 2 seconds, then the AAA battery in the charger needs replacement. However, if you see a mix of quick and long flashes of red lights, then the transmitter battery is depleted and should be fully charged.

Note: Refer to your MiniLink® transmitter User Guide for more information.

#### Going for 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.

#### To turn off your CGM, simply:

- Go to: Home Screen > Main Menu > Sensor > Turn Off Sensor
- Keep the glucose sensor in place on your body, but disconnect the transmitter from the sensor and store it on the charger.

#### To turn on your CGM after the flight:

- 1) Reconnect your transmitter to your sensor
- Go to: Home Screen > Main Menu > Sensor > Edit Settings > Sensor: On
- 3) Go to: Home Screen > Main Menu > Sensor > Link to Sensor > Reconnect Old Sensor

In two hours you will be prompted by a "METER BG NOW" alert that a calibration is needed.







**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.

#### **Alerts and Alarms**

This table shows the possible alerts and alarms you may receive. To silence an alert, press (4), followed by (ACT).



WARNING: The Threshold Suspend feature cannot be used to prevent or treat hypoglycemia. Patients should always respond to the Threshold Suspend alarm when possible and perform a self-monitor blood glucose (fingerstick glucose test with a BG meter). Patients should follow the advice of their healthcare providers in treating hypoglycemia and hyperglycemia.

Alert/Alarm	What It Means	How to Respond
Weak Signal  1:33-4 O IIII  WEAK I  SIGNAL	There has been no communication between the pump and transmitter for the amount of time selected in the Weak Signal setting of the Sensor menu. Communication needs to be re-established or "Lost Sensor" alert will follow.	Move the pump closer to the transmitter/sensor site. To adjust the timing of this setting go to Home Screen > Main Menu > Sensor > Edit Settings > Weak Signal
Lost Sensor	Communication between pump	Check that the sensor is still inserted in the
LOST I SENSOR	and transmitter has stopped and sensor glucose readings will not be displayed.	skin. Check that the transmitter and sensor are still connected. To restart communication go to Home Screen > Main Menu > Sensor > Link to Sensor > Find Lost Sensor.
Meter BG Now  1:33  METER I BG NOW	A calibration is needed in order to receive sensor glucose readings	Test your BG with your meter and enter that BG value into your pump to calibrate. To adjust how often you want this alert to repeat after clearing it, go to Home Screen > Main Menu > Sensor > Edit Settings > Cal Repeat
Meter BG By  1:33- METER I BG BY 2:28-	A calibration is needed by the time that is shown on the alert screen	Test your BG with your meter and enter that BG value into your pump to calibrate by the time that is indicated on the alert screen. To adjust this setting go to Home Screen > Main Menu > Sensor > Edit Settings > Cal Reminder
Cal Error  1:33-4 CAL I ERROR	BG meter value that was entered as a calibration is too different compared with the sensor glucose readings	Wait at least 15 minutes. Wash hands and do another BG test with your meter and enter that value into the pump as a calibration
High SG  1:33 T HIGH I  250 MG/DL	Sensor glucose reading is equal to or higher than your programmed high glucose limit value	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat based on instructions from your healthcare provider. To adjust this setting go to Home Screen > Main Menu > Sensor > Edit Settings > Glucose Limits
Low SG  1:33 T BW 128 P LOW I 70 MG/DL	Sensor glucose reading is equal to or lower than your programmed low glucose limit value	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat based on instructions from your healthcare provider. To adjust this setting go to Home Screen > Main Menu > Sensor > Edit Settings > Glucose Limit

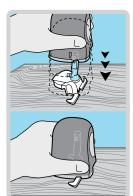
Alert/Alarm	What It Means	How to Respond
High Predicted  1:33 HIGH   PREDICTED	Sensor glucose reading is expected to reach your programmed high glucose limit in the length of time you selected for the high predicted alert	Do not treat your glucose based on SG. Confirm it using your BG meter and continue to monitor. Treat based on instructions from your healthcare provider. To adjust this setting go to Home Screen > Main Menu > Sensor > Edit Settings > Predict Alert
Low Predicted  1:33	Sensor glucose reading is expected to reach your programmed low glucose limit in the length of time you selected for your low predicted alert	Do not treat your glucose based on SG. Confirm it using your BG meter and continue to monitor. Treat based on instructions from your healthcare provider. To adjust this setting go to Home Screen > Main Menu > Sensor > Edit Settings > Predict Alert
Rise Rate  1:33 T RISE   RATE	Sensor glucose reading is increasing at a rate that is equal to or faster than your programmed rate alert setting	Do not treat your glucose based on SG. Confirm it using your BG meter and continue to monitor. Treat based on instructions from your healthcare provider. To adjust this setting go to Home Screen > Main Menu > Sensor > Edit Settings > Rate alerts
Fall Rate  1:33 FALL   RATE	Sensor glucose reading is decreasing at a rate that is equal to or faster than your programmed rate alert setting	Do not treat your glucose based on SG. Confirm it using your BG meter and continue to monitor. Treat based on instructions from your healthcare provider. To adjust this setting go to Home Screen > Main Menu > Sensor > Edit Settings > Rate alerts
Threshold Suspend  1:33-4 T IIII THRESH I SUSPEND	Your programmed Suspend Threshold has been reached and insulin delivery has stopped	Test your BG and treat based on instructions from your healthcare provider. Select to continue to Suspend or Restart Basal insulin delivery. To adjust this setting go to Home Screen > Main Menu > Sensor > Edit Settings > Threshold Suspend
Sensor End  1:33 SENSOR I END	Sensor has reached its maximum usage of 6 full days	Remove the sensor and follow the instructions for inserting and starting a new sensor
Sensor Error  1:33-4 SENSOR I ERROR	Sensor electrical signals are not within the expected range	Clear the alert and ignore it if it occurs during the two-hour sensor initialization. If the alert occurs repeatedly, then replace the sensor.
Change Sensor  1:33 CHANGE I SENSOR	The system has detected that the sensor may not be working properly. For more information, please see "Alarms and alerts" chapter, in the section "Alerts" of the MiniMed 530G User Guide.	If alert occurs after two "CAL ERROR" messages in a row, replace the sensor. If alert happens without two "CAL ERROR" screens, use the transmitter's tester to make sure the transmitter is working properly. If alert occurs during initialization, call Medtronic for assistance.

#### Part 1. Inserting a new Sensor

1. Hold sensor by pedestal and place on table.



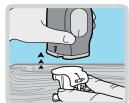
2. To load serter, push serter all the way down onto sensor and pedestal until serter sits on table.



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



3. To remove pedestal, place two fingers on pedestal arms and pull serter straight up.

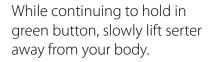


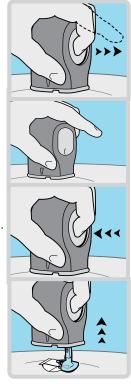
4. To insert sensor, press green button in and release it.



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

Press and **hold in** green button.

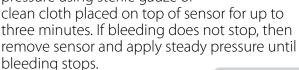




5. With one hand, hold sensor against your body. With other hand, hold needle housing at the tip.

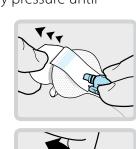
Pull needle housing straight out.

**Warning:** If bleeding occurs at sensor site (under/around/or on top of sensor), apply steady pressure using sterile gauze or



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







#### Part 2. Taping the Sensor

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



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

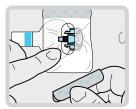


3. Apply rest of overtape, but do not block sensor connector with overtape. Press overtape to your skin for several seconds.



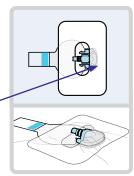
#### Taping the Sensor cont.

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



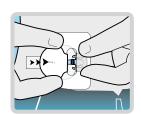
These images are examples of overtape applied correctly.

> Overtape covers both sensor and skin



#### Part 3. Connecting the Transmitter

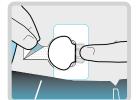
1. With one hand, hold sensor in place. With other hand, connect transmitter to sensor.



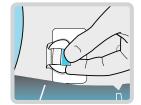
2. You will hear a faint "click" when the two components are connected. Check for green light to flash on transmitter.



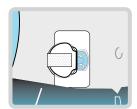
3. Remove paper on adhesive tab.



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

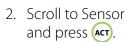


5. Press adhesive onto transmitter.



#### Part 4. Initializing the Sensor

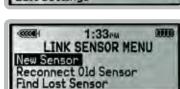
1. From Home Screen, press (ACT) to open Main Menu.





Sensor

- 4. Press (ACT) to select New Sensor
- 5. You will see a message that your sensor will be ready in 2 hours.



MAIN MENU

#### Part 5. Calibrating

Two hours after sensor has started, "METER BG NOW" alert will notify you for first calibration. There are two ways to calibrate:

- 1. Press Button
- 2. Enter BG meter value
- 1:33 PM ENTER BG

1:33pm

1:33pm

1:33pm

MAIN MENU

3. You will receive message "BG to update sensor?" Select "yes" and press (ACT).



BG TO UPDATE SENSOR?

- \*\*If you are using linked meter, your BG meter value will automatically appear on pump screen. Then follow step 3 above.
- 1. From Home Screen, press (ACT) to open Main Menu.
- 2. Scroll to the Sensor menu and press (ACT).



is ready for first calibration).

**Note:** Calibrating through Sensor Menu can only occur if pump's insulin delivery is not suspended.

#### **Quick Reference Guide for Threshold Suspend**

#### **Threshold Suspend**

Stops all insulin delivery when your sensor glucose reading has reached or fallen below your programmed Suspend Threshold (can be set between 60 – 90 mg/dL).

#### **Important Tips:**

- Threshold Suspend is not intended to be used to treat or prevent low blood glucose. Confirm your blood glucose using your BG meter. Then treat your confirmed low blood glucose using the "15-15 Rule" or as directed by your healthcare provider:
  - Take 15 grams of fast-acting carbohydrates (4 oz. orange juice, 3-4 glucose tabs) and wait 15 minutes. Then retest your blood glucose. If your blood glucose has not improved, then take another 15 grams of carbohydrates, wait 15 minutes, and retest.
- **Do not miss Calibrations.** Threshold Suspend requires that CGM is working. Calibrate before going to bed.
- **Avoid "Lost Sensor" alert.** Check that your sensor has not pulled out of your skin. Check that your transmitter and sensor are properly connected and communicating with your pump.
- **Check the battery.** Change the pump battery when you receive a "Low Battery" alert to avoid depleting the battery quickly during Threshold Suspend.
- Avoid nuisance alarms with the two-step response to the Threshold Suspend siren:
  - First, <u>clear</u> the alarm (press , followed by )
  - Then, <u>select</u> continue to "Suspend" or "Restart Basal" delivery

#### Two-step response to Threshold Suspend alarm:

When Threshold Suspend sirens all insulin delivery stops immediately.

**Step 1.** Press (a), followed by (Acr) to clear the alarm.



Step 2. Select to continue "Suspend" or "Restart Basal" delivery.



**NOTE:** If you have not cleared the alarm in 2 minutes, then another screen will appear: "I have diabetes, call for emergency assistance, to clear ESC then ACT"

If you select to continue "Suspend", then suspend will last two hours.\*



If you select "Restart Basal", then pump will only suspend again after the set Low Repeat time has passed and sensor glucose is still at or below the Suspend Threshold.



<sup>\*</sup> Note: If you decide to resume basal insulin delivery after you have selected "Suspend", press or show the THRESHOLD SUSPEND options screen again, and select "Restart Basal".

Notes	

Notes		

# www.medtronicdiabetes.com Medtronic Diabetes 18000 Devonshire Street Northridge, CA 91325 1.800.646.4633

**Medtronic**