

Congratulations on your decision to use the

REAL-Time Continuous Glucose Monitoring (CGM) system!

A solid understanding of CGM basics is essential to your success. Here's what we'll cover in this guide:

1 UNDERSTANDING CGM

Glucose Readings Blood glucose (BG) meter and sensor glucose readings

come from similar, but different, places in your body

Calibration A sensor needs BG meter readings to function properly

Settings Personalize and adjust your settings over time

2 STARTING-UP CGM

Step 1 – Inserting the Glucose Sensor

Step 2 – Programming Settings

Step 3 – Connecting the MiniLink® Transmitter

Step 4 – Calibrating

Step 5 – Reading the Display

3 APPLYING CGM IN YOUR LIFE

What is CareLink™ Therapy Management Software?

How do CareLink Software reports help me?

How do I sign up for CareLink Software?

Let's get started!

Your CGM system includes 3 key items:

Glucose Sensor Monitors your glucose.

MiniLink® transmitter The MiniLink transmitter connects to the glucose sensor and sends

glucose readings to your insulin pump. It is recharged and stored in the

MiniLink charger when not in use.

Insulin Pump Receives and displays glucose readings.

Other items include: Sen-serter® Insertion Device, test plug, IV-3000® adhesive tape and CareLink™ USB used to download your pump information to CareLink software on a computer.



Understanding CGM



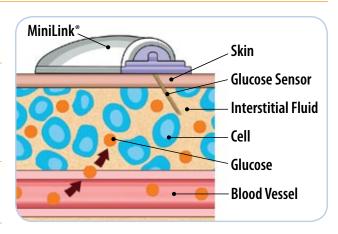
GLUCOSE READINGS

Your BG meter measures glucose (sugar) levels in your **blood**, and your glucose sensor measures glucose levels in the fluid surrounding the cells in your tissue, which is called **interstitial fluid**.

Most of the time, glucose travels first to your blood and then to your interstitial fluid.

Because of how glucose travels, your BG meter readings and sensor readings will rarely match exactly. This is normal and should be expected.

Usually your BG meter readings and your sensor readings will be very close.



However, when glucose levels are rising or falling quickly, you should **expect** to see a larger difference between your BG meter value and the sensor glucose reading. Examples of times when this may occur include:

- After meals or after insulin
- When ↑ or ↓ arrows appear on your pump screen

Use CGM to understand your glucose trends.



Focus on what matters: the direction and the speed of the sensor glucose change. Pay less attention to each individual glucose number.

Always rely on BG meter readings for therapy adjustments.



Your MiniMed Paradigm® REAL-Time System uses BG meter readings to make sure the glucose sensor maintains its accuracy over time. This is called **calibration**.

To calibrate you must check your BG on your meter and enter the value into the pump. Two methods are available to calibrate your sensor – through the Bolus Wizard® or the sensor menus. The preferred method is to use the Bolus Wizard, which may help prevent the stacking of insulin.

> ENTER BG > BG to update Sensor : YES or MAIN MENU > SENSOR > Enter Meter BG

When you calibrate is important.

- On day one of a new sensor, a calibration is needed:
 - approximately 2 hours after you connect the MiniLink® transmitter to your sensor (the system will notify you)
 - again within 6 hours
 - again within 12 hours
- After day one, calibrate **3–4 times a day** for optimal sensor accuracy
- A **minimum** of 1 calibration every 12 hours is required to receive sensor glucose readings

It's easy to remember when to calibrate. Think *Before is best*. The best times to calibrate are when glucose levels are least likely to be changing rapidly, such as:

- Before meals
- Before insulin
- **Before** bedtime
- When there are **no arrows on your insulin pump screen**

Tip:

Time your calibrations so you will not have to wake up in the middle of the night. Remember, you can calibrate early! For example, if it's 9pm and you know a calibration will be required by 3am, go ahead and calibrate before bed. This will start the 12 hour calibration clock over. To find out when your next calibration is due, press 4 times from the HOME screen.

If you notice a large difference between your BG meter and sensor glucose readings, calibration may be needed to bring them together again (remember, only calibrate if there are no arrows on your display).

Calibration is essential for optimal sensor performance. The glucose sensor performs best when calibrated 3–4 times per day.



CGM does **not** eliminate the need for BG meter readings (fingersticks).

You do not need to wait 6 hours (day one) and 12 hours to calibrate. You can calibrate early, as long as your glucose is stable.



SETTINGS

The MiniMed Paradigm® REAL-Time System allows you to customize alerts to help you improve glucose control. Your healthcare provider will work with you and your trainer to determine your initial alert settings.

Two alerts are the **High Glucose** alert and the **Low Glucose** alert. They notify you when your glucose has moved above or below your programmed glucose limits. For example, if your High alert is set at 250 mg/dL and your Low alert is set at 70 mg/dL, you will receive an alert every time your glucose goes above 250 or below 70.

In using CGM, where you place these settings will determine how often you are alerted. You will want to find a balance between the benefit of receiving these alerts and any inconvenience

that may be caused by receiving too many.

During the first several weeks on CGM, you and your healthcare provider may consider (i) waiting to turn these alerts on, (ii) turning on only the Low alert, or (iii) setting the High and Low alert very wide. As you learn more about your glucose patterns and how to use CGM, you can adjust your alert settings to meet your individual needs.



Your personalized CareLink™ reports help you and your healthcare provider see where to set your alerts over time.

The **Snooze** setting is the time the system waits after an alert and before it alerts again, if the situation is not resolved.

Setting	What It Does	Commonly Used Settings
High Snooze	The amount of time until you are reminded that your sensor glucose is still above your high alert setting	2 hrs – 3 hrs
Low Snooze	The amount of time until you are reminded that your sensor glucose is still below your low alert setting	20 min – 30 min
Cal Reminder	The amount of time until your next calibration	30 min – 1 hr
Alarm Snooze	The amount of time after you miss a calibration (Meter BG Now alarm) before you are reminded	1 hr
Missed Data	The amount of time before you are alerted if there is a weak signal	30 min

Remember, alerts are meant to be adjusted over time. Start wide and customize as you learn more about your glucose levels.



You can temporarily adjust your alert settings before bed to ensure that you get a good night's sleep. Remember to review your settings in the morning.

CareLink reports help you and your healthcare provider fine tune your settings.

2 Starting-Up CGM



STEP 1: GLUCOSE SENSOR INSERTION

Site Selection

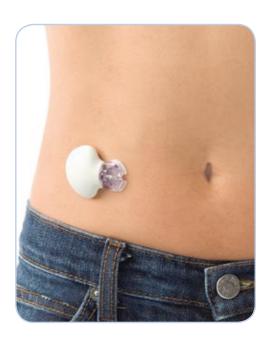
Choose a place on your body at least:

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

For best glucose sensor performance, avoid:

- Sites where clothing may rub or constrict (for example your beltline)
- Sites where your body naturally bends a great deal
- Sites that are scarred or have hardened tissue or stretch marks

Note: clinical trials for glucose sensors were performed on sensors inserted in the abdominal area.



Insertion

- Remove glucose sensor from package by holding the sensor base or tape. Do not hold the glucose sensor by the introducer needle handle.
- Using an alcohol swab, clean the selected site prior to insertion.
- Allow the alcohol to dry, then follow the steps outlined on page 7 to insert the glucose sensor.



Proper insertion is important for optimal glucose sensor performance and to prevent bleeding at the site.

Insertion:		_	
insertion.	1 Place the glucose sensor in the Sen-serter® Insertion Device until it fits snugly and the black o-rings on the sensor are no longer visible.		6 While holding the skin taut with two fingers, press the white button on top of the Sen-serter Insertion Device.
	2 Place your thumb on the back of the white tape and push the glucose sensor down until it locks.		7 Gently hold the glucose sensor in place and gently slide the Sen-serter Insertion Device away from the glucose sensor in a horizontal motion.
	3 While holding down the white tape, remove the clear tape.		3 Gently hold the glucose sensor in place and remove the white paper from the adhesive pad. Press adhesive against your skin.
	4 Gently remove the needle guard.		Hold the glucose sensor base with two fingers and gently remove the introducer needle at the same angle that it was inserted.
45°- 60°	Sest the Sen-serter Insertion Device legs flat on skin so that the Sen-serter Insertion Device sits at a 45–60 degree angle to your skin.		Wait 10–15 minutes before connecting the fully charged MiniLink® transmitter to the glucose sensor. Be sure to program your settings before connecting the MiniLink transmitter.



STEP 2: PROGRAMMING SETTINGS

A good time to program your glucose sensor settings into your insulin pump is after glucose sensor insertion, while the glucose sensor is still wetting with interstitial fluid.

Your healthcare provider will work with you and your trainer to determine your initial settings.

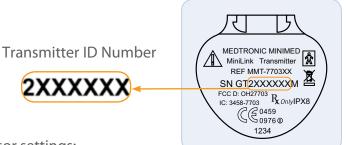
To turn the SENSOR feature on, go to:

HOME Screen > MAIN MENU > SENSOR > SENSOR SETUP > EDIT SETTINGS > Sensor: ON

After you have turned your SENSOR feature on, enter your MiniLink® transmitter ID:

HOME Screen > MAIN MENU > SENSOR > SENSOR SETUP > EDIT SETTINGS > Transmtr ID

• Use the and buttons to select each digit and press to enter. The seven-digit ID (or serial number) is located on the flat side of the MiniLink transmitter. Be sure to only select the numbers.



Follow these steps to personalize your sensor settings:

HOME Screen > MAIN MENU > SENSOR > SENSOR SETUP > Edit Settings

(see pages 4 and 5 for commonly used HIGH and LOW glucose alert and SNOOZE settings)

Remember!

Your High and Low glucose alerts are not the same as your target glucose ranges.

High and Low alerts are useful features of the system that are meant to be adjusted as your knowledge of the system improves.

Successful CGM usage involves optimizing your settings over time.



STEP 3: CONNECTING THE MINILINK® TRANSMITTER

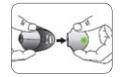
After the glucose sensor is inserted and your settings are entered, wait 10–15 minutes before connecting the MiniLink transmitter to the glucose sensor.

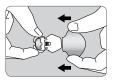
Once 10–15 minutes have passed, remove the MiniLink transmitter from the charger and wait 1 minute.

When you remove the MiniLink transmitter from the charger, a green light will flash on the transmitter. This indicates it has enough battery power to last at least 3 days and is ready to be connected to the glucose sensor.

After 1 minute, connect the MiniLink transmitter to the glucose sensor. Do not connect if the site is bleeding or if there is blood on the glucose sensor connection point.

A green light on the MiniLink transmitter will begin flashing when a good connection exists and the glucose sensor is "wet" (note: it may take up to 20 seconds for the MiniLink transmitter to flash).







Optional: IV-3000® adhesive can be used to tape down and secure your sensor and MiniLink.

If the MiniLink transmitter does not flash when connected to the glucose sensor:

Disconnect the transmitter and place it back in the charger to ensure it is fully charged.

Remove the transmitter from the charger (when fully charged) and wait 1 minute. After 1 minute connect the transmitter to the sensor and look for the flashing green light.

If you still do not see the transmitter flash, your sensor may simply need more time to wet. With the transmitter connected to the sensor, wait 2 hours and then perform the **Sensor Start** (see below).

Perform the **Sensor Start**: **HOME Screen** > **MAIN MENU** > **SENSOR** > **SENSOR START** > **New Sensor.** The system is ready approximately 2 hours after the MiniLink transmitter is connected to the glucose sensor and the green light flashes. This 2 hour period is called **initialization**.



STEP 4: CALIBRATING

METER BG NOW alarm will sound when the system is ready for you to enter a BG meter value for initial calibration. Remember, the preferred method is to use the Bolus Wizard.® Clear the alarm and follow either of these steps to enter a BG meter value:



Enter BG > BG to update Sensor : YES or MAIN MENU > SENSOR > Enter Meter BG

After you calibrate, it will take 10–15 minutes for sensor glucose readings to appear on your insulin pump screen.

After your initial calibration, another calibration will be required within 6 hours.

1 calibration every 12 hours is the minimum required to continue to receive glucose sensor readings after the first day.

Calibrate 3–4 times a day thereafter for optimal glucose sensor accuracy.

Remember!

The best times to calibrate the glucose sensor are when your glucose levels are least likely to be changing rapidly. Think *Before*: before meals, before bedtime, before insulin. Also, you do not need to wait until you are alerted to calibrate. You can calibrate at any time when your glucose is stable.

If you get a CAL ERROR on your insulin pump, don't worry. This is a feature of your system intended to ensure good performance.

- To avoid a CAL ERROR make sure you calibrate when your glucose is least likely to be changing rapidly
- If you get a CAL ERROR recalibrate if the BG is stable, otherwise wait 15–30 minutes before calibrating again

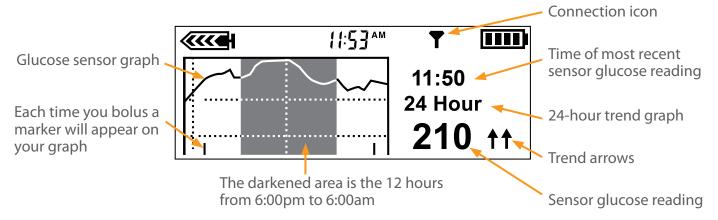
Tip:

The wireless transmission feature of linked BG meters should be turned OFF when using CGM. You should manually calibrate the system as outlined on page 3.



STEP 5: READING THE DISPLAY

Your insulin pump screen displays 3-hour and 24-hour glucose trend graphs. Press once from the HOME Screen to display the 3-hour trend graph. Press twice to display the 24-hour trend graph.



To view historical glucose sensor readings press the and buttons on your insulin pump. The 3-hour trend graph will display readings in 5 minute increments and the 24-hour trend graph will display readings in 20 minute increments.

What the Sensor Icons Mean				
↑ or ↓	Glucose has risen or fallen 20 to 40 points during the last 20 minutes.			
↑↑ or ↓↓	Glucose has risen or fallen 40 points or more during the last 20 minutes.			
T	Insulin pump indicates that the MiniLink® transmitter and insulin pump are communicating properly.			
	Pump 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 reestablished.			

3 Applying CGM in Your Life



WHAT IS CARELINK™ SOFTWARE?

CareLink software is a Web-based software that allows you to upload information from your MiniMed Paradigm® REAL-Time System to a secure online (internet) site for viewing.

CareLink software organizes all of your insulin pump and glucose sensor information into reports (charts, tables and graphs) that help you track glucose levels, insulin usage and carbohydrate intake over time.

With CareLink software, you can grant your healthcare provider online access – or just bring a copy of your CareLink reports to your appointments – so you and your provider can work together to determine the best therapy decisions and system settings to improve your outcomes.

Don't have a computer? Your healthcare provider may be able to download the reports at your next visit.



CareLink reports help you and your healthcare provider make decisions that improve your control and fit your lifestyle.



The combination of insulin pump therapy, continuous glucose monitoring and CareLink software provides you with the tools and information you need to *optimize* your therapy.



HOW DO CARELINK™ SOFTWARE REPORTS HELP ME?

CareLink software provides you with information you've never had before about your glucose trends and patterns. Take action and make simple changes to optimize your glucose control. CareLink software helps you answer questions like:

- Do I need to adjust my basal rate or use temporary basal rates to avoid going high or low at the same time every day?
- Am I accurately counting my carbs at meals?
- Are my carb ratios correct?
- Do I need to use the Dual Wave® or Square Wave® bolus functions for tighter control?
- Where should I set my high and low glucose alerts?



CareLink™ Software Tips

For best results using CareLink software, Medtronic Diabetes recommends:

- Finding a consistent time once a week to review your CareLink reports.
- Reviewing two CareLink reports to start: the Sensor Daily Overlay Report and the Daily Summary Report.
- Picking one or two simple adjustments to work on at a time when you review the past week's information in CareLink software.

Always remember to review and discuss your CareLink reports when you visit your healthcare provider. Note: some providers may use a different but similar version of CareLink software called "CareLink Pro" at their office.



HOW DO I SIGN UP FOR CARELINK SOFTWARE?

To sign up for your free CareLink software account visit: www.medtronicdiabetes.com/carelink

Set up a meeting with your Medtronic Diabetes trainer or your healthcare provider to learn more about how to use this valuable tool.

See the difference that the combination of insulin pump therapy, CGM and CareLink software can make in your life.



CGM and Medtronic Diabetes – giving you the confidence to live *your* life.

Appendix

- Menu Map
- MiniLink® Transmitter Tips
- Cleaning Your MiniLink Transmitter
- Other Useful Information

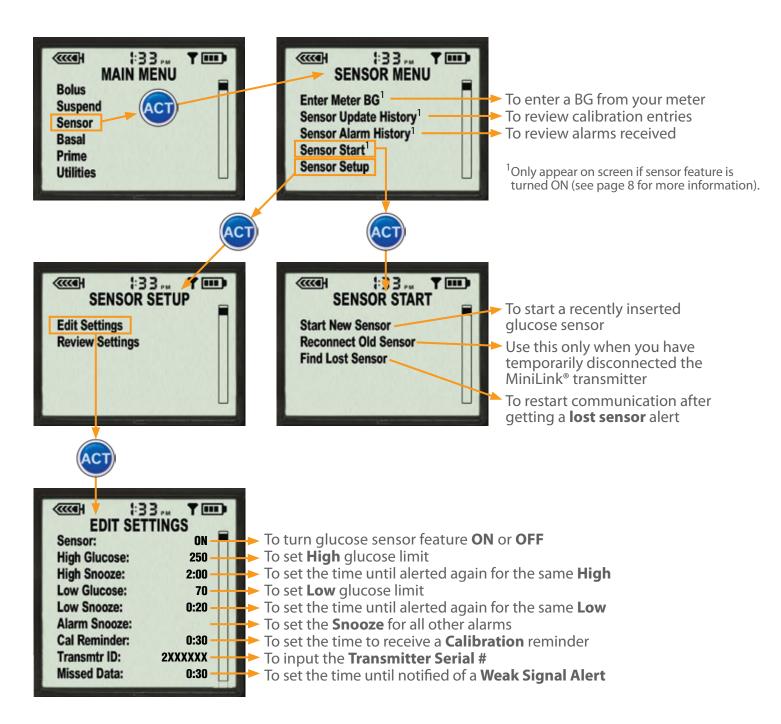
Tape Tips

X-rays, MRIs and CT scans

Air Travel

- Alarm/Alerts
- Notes

Appendix: Menu Map

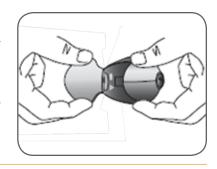


Appendix: MiniLink® Transmitter Tips

Fully charge the MiniLink transmitter before each use.

When the MiniLink transmitter is charging, a green light on the charger will flash.

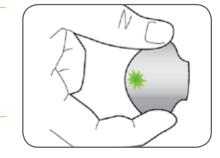
The green light on the charger will turn off when completely charged.



When you remove the MiniLink transmitter from the charger, a green light should flash on the MiniLink transmitter. This indicates it has enough battery power to last at least 3 days and is ready to be connected to the sensor.

Charging time:

- First time use, or for a completely depleted transmitter: up to 8 hours.
- Normal use: less than 20 minutes to fully recharge.



Always store the MiniLink transmitter in the charger when not in use (so that it retains optimal battery life).

• To preserve transmitter battery life during periods of infrequent usage, remove the MiniLink transmitter from its charger for at least 1 minute every 1-2 months.

Battery status for charger and MiniLink transmitter:

- The light on the charger will flash red once every 2 seconds if the AAA battery in the charger needs replacement.
- The light on the charger will quickly and repeatedly flash red over 2 second intervals if the MiniLink transmitter battery is depleted. This should rarely happen if the transmitter is recharged after each use.

Appendix: Cleaning Your MiniLink® Transmitter

Medtronic Diabetes does not recommend cleaning the MiniLink transmitter after each sensor use.

CAUTION: The MiniLink charger and test plug are not waterproof and should not be immersed in water.

If you feel that the MiniLink transmitter needs cleaning, follow these steps:

- Attach the test plug to the MiniLink transmitter to help prevent water, soap and sanitizer from damaging the connector pins inside the MiniLink transmitter. Do not expose the connector pins to liquids.
- Wipe the MiniLink transmitter with a dampened cloth and mild liquid soap.
- Remove the soap using warm tap water. Be sure not to let water enter the MiniLink transmitter connection point.
- Wipe the MiniLink transmitter surface with anti-bacterial hand sanitizer.
- Wipe the MiniLink transmitter with a dry cloth and air dry for three minutes.

Appendix: Other Useful Information

Tape Tips

It is highly recommended that you put a transparent dressing to secure the system in place and ensure that the sensor remains fully inserted underneath the skin. Seasonal climates, skin lotions/creams, trapped moisture or different clothing may affect your sensor tape adhesion or the way your body reacts to it. Here are some tips you may want to try:

- Cut a piece of IV-3000® in half and place it crossways so that it covers the glucose sensor and the part of the MiniLink® transmitter closest to the sensor connection. This secures the glucose sensor and MiniLink transmitter while allowing them to air dry.
- Try another type of tape from your local pharmacy or a simple Band-Aid® over the MiniLink transmitter.
- While the sensor and transmitter are safe to be worn in a hot tub, be careful as the adhesive may weaken.

X-rays, MRIs and CT scans

If you are going to have an X-ray, CT scan, MRI or other type of exposure to radiation, take off your insulin pump, BG meter, MiniLink transmitter and glucose sensor and remove them from the area.

Air Travel

The Federal Aviation Administration (FAA) requires that devices with radio frequency capabilities should not be used on an aircraft.

For the flight simply:

- 1) Go to: HOME Screen > MAIN MENU > SENSOR > SENSOR SETUP > EDIT SETTINGS > Sensor: OFF
- 2) Keep the glucose sensor in, but disconnect the MiniLink transmitter from the glucose sensor and store on the charger

Note: During this time you will have to manually check your BG

To reconnect after the flight:

- 1) Reconnect the MiniLink transmitter to the sensor
- 2) Go to: HOME Screen > MAIN MENU > SENSOR > SENSOR SETUP > EDIT SETTINGS > Sensor: ON
- 3) Go to: HOME Screen > MAIN MENU > SENSOR > SENSOR START > Reconnect Old Sensor Just like starting a New Sensor, there will be a two hour initialization period and a calibration will be needed.

Appendix: Alarm/Alerts

Alarm/Alert	What It Means	How to Respond
Weak Signal	The pump and MiniLink® transmitter are not communicating.	Reposition the insulin pump closer to the MiniLink transmitter.
Lost Sensor	Pump has not received a signal from the MiniLink transmitter for more than 40 minutes. If alarm occurs during initialization, the sensor is warming up and the alarm should be cleared.	Reposition the insulin pump closer to the MiniLink transmitter. Go to: HOME Screen > MAIN MENU > Sensor > Sensor Start > Find Lost Sensor.
Cal Error	BG entry is out of expected BG range.	Re-calibrate if BGs are stable. Wait 15 – 30 minutes if BG was entered at time of rapid glucose change.
Meter BG Now	A calibration is needed for the system to continue to provide sensor readings.	Make sure there are no arrows on the pump screen and enter new BG.
High	Glucose level is higher than or equal to your high glucose alert setting.	Treat as required based on BG meter reading. If this alarm becomes frequent, adjust the setting and/or Snooze setting for this alert.
Low	Glucose level is lower than or equal to your low glucose alert setting.	Treat as required based on BG meter reading. If this alarm becomes frequent, adjust the setting and/or Snooze setting for this alert.
Sensor End	The glucose sensor has been used for 72 hours.	Remove sensor and follow guide for new sensor start.
Bad Sensor	System has detected a possibly malfunctioning glucose sensor.	If alarm occurs during initialization, wait and perform a sensor start using the same sensor. Otherwise, call our 24-Hour HelpLine.
Sensor Error	Glucose sensor signals are either too high or too low.	Clear the alarm and ignore if this happens during initialization. If alarm happens more than 3 times in 24 hours, replace the glucose sensor.

Notes

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