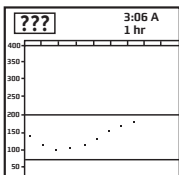




Sensor Troubleshooting

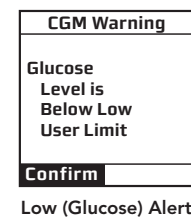
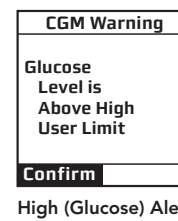
12:34 PM BG IOB 5.54U	BG Symbol on CGM Data/Trend screens Calibration needed. • Perform calibration.
CGM Warning Enter BG Confirm	
CGM Warning CGM Sensor Error 0, Insulin Delivery Continues Confirm	Sensor [ERR0] Sensor cannot calibrate. • Press ☺ . [ERR0] will appear on CGM Data/Trend screens. • Wait 15 minutes and then enter 1 fingerstick BG value. • If error continues, add additional fingerstick BG value. • If no CGM glucose readings appear, Sensor should be replaced.
CGM Warning CGM Sensor Error 1, Insulin Delivery Continues Confirm	Sensor [ERR1] Sensor is not calibrating correctly. • Press ☺ . [ERR1] will appear on CGM Data/Trend screens. • Wait 1 hour, and then enter 1 fingerstick value. • If no CGM glucose readings appear after 10 minutes, Sensor should be replaced.
CGM Warning Replace CGM Transmitter Low Battery Confirm	Transmitter Low Battery Transmitter battery is low. Transmitter will continue to work but with possible data gaps. • Press ☺ . Replace Transmitter.
CGM Warning CGM Failure, Insulin Delivery Continues, Call Service XXX-XXXXXXX XXXXXXXXXX Confirm	CGM Data Failure Pump and CGM are having a communication problem. • Press ☺ and contact Customer Support.
12:34 PM ??? IOB 5.54U 	[???] Symbol (Unknown CGM glucose readings) on CGM Data/Trend screens [???] usually resolves itself within several minutes, but may take up to several hours. • DO NOT calibrate. • Make sure Sensor Pod is sticking well to your body and nothing is rubbing against it. • Check that Transmitter is snapped in on both sides. • When you see a glucose reading or BG symbol on the CGM Data or Trend screen, enter fingerstick BG value for calibration.
CGM Warning CGM Sensor Failure, Insulin Delivery Continues Confirm	Sensor Failed Sensor has shut off before end of 7-day session. • Press ☺ . The Status Box on the CGM Data or Trend screen will be shaded completely gray. • Contact Customer Support. • Remove failed Sensor and insert new Sensor.
12:34 PM ANT IOB 5.54U CGM Warning Transmitter Out of Range Confirm	Out of Range Warning/[ANT] symbol on CGM Data/Trend screens Pump and CGM are not communicating or are outside of RF range. • Make sure the pump is within 12 feet of the Transmitter/Sensor Pod. • Wait 10 minutes. If no glucose reading appears, contact Customer Support.



Helpful Hints

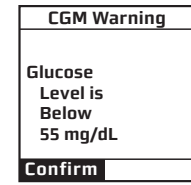
High/Low Glucose Alerts

- With High/Low Glucose Alerts, insulin delivery continues.
- If Alerts are not confirmed by pressing **☺** the Alert will repeat every 3 minutes.
- You can enable/disable and set Alert sounds based on your health care professional recommendations or your personal preferences.



Low Glucose Alarm

- The CGM has an automatic Low Glucose Alarm set at 55 mg/dL. You cannot disable this Alarm, or change the Alarm level or its re-alert settings. If this Alarm occurs:
• Press **☺** to confirm.
- You will be notified again in 30 minutes if your glucose reading is still at or below 55 mg/dL.



NOTE: In a pediatric clinical study, a significant number of low glucose events were not detected by CGM. Also in the pediatric study, larger differences were observed between CGM readings and actual blood glucose values, compared to those differences observed in the adult clinical study. Whenever you set your Low Glucose Limit, and whenever your current CGM reading falls below that limit and/or 55 mg/dL, a series of pump CGM Warning screens will be displayed to make you aware of these differences. Refer to the Owner's Booklet for complete information.

Calibration - What to do

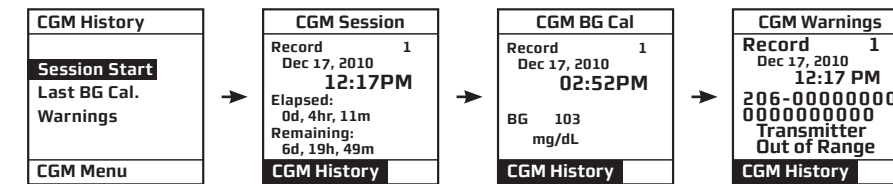
- Wash hands before each calibration.
- Use same BG meter for all calibrations.
- Quality-check BG meter to make sure your BG meter is giving accurate values for calibration.
- Entering the correct fingerstick BG value is critical to obtaining accurate Sensor readings. Use proper technique when performing a fingerstick test.
- Calibrate at any time as long as you see a CGM glucose reading or BG symbol (**BG**) on the CGM Data or Trend screen.
- Calibrate a minimum of once every 12 hours.
- Calibrate whenever your glucose levels are rising or falling¹.

Calibration - What NOT to do

- DO NOT calibrate when you see the **ANT** or **[???]** symbol on the CGM Trend or Data screen.
- DO NOT calibrate if your BG is higher than 400 mg/dL or lower than 40 mg/dL.
- DO NOT use sampling sites other than your fingertips to get BG values for calibration.

CGM History

- From the **CGM Menu**, you can access and review a history of CGM sessions, BG calibrations and CGM Warnings.



References

- Kamath A, Mahalingam A, Brauker J. Analysis of time lags and other sources of error of the Dexcom SEVEN continuous glucose monitor. Diabetes Technol Ther. 2009;11(11):689-695.



Important information

⚠ Warnings

- DO NOT use glucose readings from the G4 PLATINUM Sensor and Transmitter to make treatment decisions, such as how much insulin you should take. The Sensor and Transmitter do not replace a BG meter and BG values may differ from Sensor glucose readings. Using glucose readings from the Sensor and Transmitter to make treatment decisions can result in serious injury or death.
- Your Animas® Vibe™ System will not automatically make insulin adjustments based on the CGM readings.
- You should calibrate the CGM at least once every 12 hours.

CONTRAINDICATIONS

- Remove the Dexcom G4 PLATINUM Sensor and Transmitter prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT) Scan, or diathermy treatment. The Dexcom G4 PLATINUM Sensor and Transmitter have not been tested during MRI or CT Scans or with diathermy treatment. The magnetic fields and heat could damage the Sensor and Transmitter so that they might not record or transmit Sensor glucose readings or provide alerts, and you might miss a low or high blood glucose value.
- Taking medications containing acetaminophen while wearing the Sensor may falsely raise your Sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.



Frequently Asked Questions

What can the CGM do for me?

The CGM gives you a continuous picture of your glucose levels to help you detect trends and patterns in your glucose levels. Trends let you see where your glucose levels have been, which direction they are headed, and how fast they may be rising or falling.

Does the CGM replace my traditional BG meter?

No, it is meant to be used IN ADDITION TO your BG meter. When you use the CGM, you need to take two fingerstick tests with your BG meter to start/calibrate your Sensor session. You will also need to take at least 1 fingerstick test every 12 hours.

Should I make treatment decisions based on the results from my Animas® Vibe™ System?

You must take a fingerstick test with your BG meter and use that BG value to make any insulin or treatment decisions. Insulin dosing decisions should not be based solely on results from the CGM readings.

Is it okay if my CGM readings and fingerstick BG readings do not match exactly?

Yes. This is normal.

Is my Transmitter reusable?

Yes. DO NOT THROW AWAY YOUR TRANSMITTER. Your Transmitter is reusable.

How close do my pump and Transmitter have to be?

They need to be within 12 feet of each other at all times, including the Startup period and while you are sleeping.

If I confirm a CGM Alert/Alarm, does my insulin delivery continue?

Yes.

Do my CGM alerts and alarms get progressively louder if I do not confirm them the first time they sound?

No. The sound for the CGM alerts and alarms does not get progressively louder over time.

What is the warranty for my Animas® Vibe™ System?

The warranty for your pump is 4 years. The warranty for your Transmitter is 6 months.

What do I do if I see [???] instead of a glucose value?

Unknown CGM glucose readings ([???]) on the CGM Data and Trend screens are periods of time when the System does not understand the CGM glucose readings. This is usually temporary. Your CGM will normally correct itself, after which you will see CGM glucose readings again.

When I prime the pump, change the insulin cartridge, or when there is an occlusion alarm, do my CGM readings continue to be received and displayed on the pump?

Yes – CGM readings will continue to be received and displayed during these pump functions.

When I put my pump in Suspend mode, do my CGM readings continue to be received and displayed on the pump?

No – You will not receive CGM readings when your pump is in Suspend mode.

What do I do if I have questions?

Contact Customer Support.

Is the Animas® Vibe™ System water resistant?

Yes. Your pump is water resistant up to 12 feet for 24 hours. Your Sensor and Transmitter are water resistant up to 8 feet for 24 hours.

Dexcom G4 PLATINUM Sensor and Transmitter

Quick Start Guide

Part of the Animas® Vibe™ System

Review all Contraindications, Warnings, Precautions, and detailed procedures in the Animas® Vibe™ Owner's Booklet before using the Dexcom G4 PLATINUM Sensor and Transmitter.

You must take a fingerstick test (blood glucose test using a blood sample from your fingertip) with your BG meter and use that BG value to make any insulin or treatment decisions. Insulin dosing decisions should not be based solely on results from the Dexcom G4 PLATINUM Sensor and Transmitter.

- Get to Know Your Animas® Vibe™ System
- Set up Transmitter ID
- Set Alert Sounds & Levels
- Insert Sensor & Place Transmitter
- Start Sensor Session
- Calibrate
- CGM Trend & Data Screens
- End Sensor Session

Making the Animas® Vibe™ System part of your life

The Dexcom G4 PLATINUM Sensor and Transmitter are not a replacement for your traditional blood glucose (BG) meter. When you use the Dexcom G4 PLATINUM Sensor and Transmitter, you will see real-time continuous glucose readings on your Animas® Vibe™ Insulin Pump display every 5 minutes, for up to 7 days. These readings will help you detect trends and patterns in your glucose levels. This way, you can see where your glucose levels have been, which direction they are headed, and how fast they may be rising or falling.

This Quick Start Guide will help you set up the CGM part of your Animas® Vibe™ System. Before you begin or anytime you have questions, review the Animas® Vibe™ Owner's Booklet. You may also contact Customer Support.

NOTE: The CGM is optional with your Animas® Vibe™ Insulin Pump and is sold separately.



200 Lawrence Drive
West Chester, PA 19380 USA

Customer Support is available
24 hours a day, 7 days a week.
U.S. and Puerto Rico:
1 877 YES-PUMP (937-7867)
Visit us at www.Animas.com.

Consult Owner's Booklet

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P/N: 41031200 Rev. A 08/2015



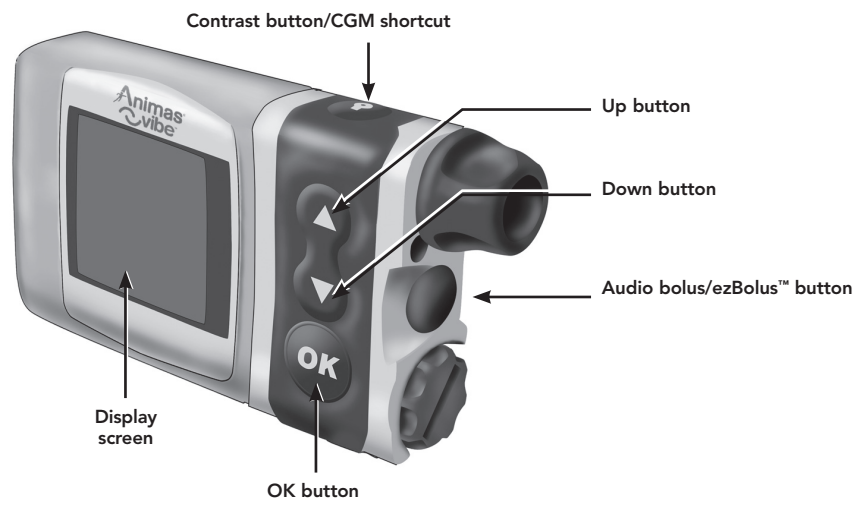
Dexcom, Inc.
6340 Sequence Drive
San Diego, CA 92121 USA

1 Get to Know Your Animas® Vibe™ System

Your Animas® Vibe™ System is comprised of:

- The Animas® Vibe™ Insulin Pump
- The Dexcom G4 PLATINUM Transmitter
- The Dexcom G4 PLATINUM Sensor and Applicator

The Animas® Vibe™ Insulin Pump



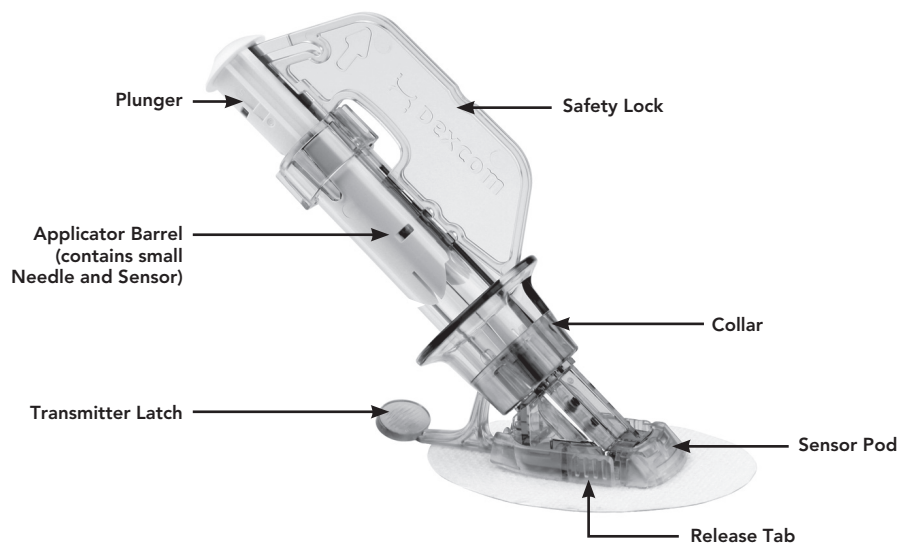
Dexcom G4 PLATINUM Transmitter (NOT DISPOSABLE)



Dexcom G4 PLATINUM Sensor (DISPOSABLE)



Sensor Applicator (DISPOSABLE)

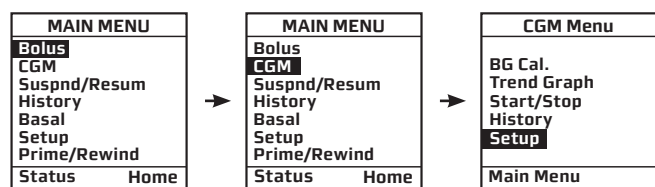


NOTE: If you have problems with your Sensor session, keep your Sensor until you speak with Customer Support.

2 Set up Transmitter ID

From the **MAIN MENU**:

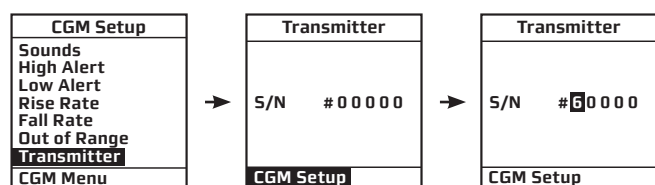
- Press **▼** to highlight **CGM** and Press **⏏**.
- Press **▼** to highlight **Setup** and press **⏏**.



Every time you begin using a new Transmitter you need to set the Transmitter ID. This allows your pump and Sensor to talk to each other. Your unique Transmitter ID number makes this possible. Be sure to remove the Transmitter from its tray when you are ready to use it. As soon as you remove it from the tray, it begins to use battery power. Wait 10 minutes for the Transmitter to turn on and be ready for use.

To Set Transmitter ID

- From the **CGM Setup** screen, press **▼** to highlight **Transmitter** and press **⏏**.



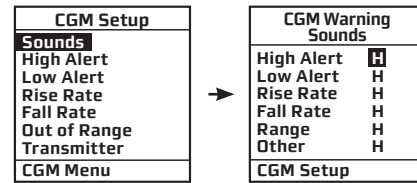
- Press **▲** to highlight the **S/N #**. The last digit will be highlighted. Use the **▲/▼** buttons to move to the first digit and press **⏏** to activate "Edit Mode". Use the **▲/▼** buttons to enter the first digit of your 5-digit ID number (found on underside of Transmitter).
- Press **⏏** after each digit is entered and repeat until the last digit is entered.
- CGM Setup** will be highlighted. Press **⏏** to return to **CGM Setup** screen.

3 Set Alert Sounds & Levels (optional)

You can set your pump to notify you when your CGM readings become too high or low (High/Low Alerts), or are rising or falling too quickly (Rise Rate/Fall Rate Alerts). You can also set your pump to let you know when your Transmitter is not within RF range of your pump (Out of Range Alert). Alerts can be enabled/disabled and set to default or customized levels. Customized levels should be based on your health care professional's recommendations and your personal preferences. Some Alerts (High/Low and Out of Range Alerts) also let you set a "snooze" period to re-alert you after a desired amount of time.

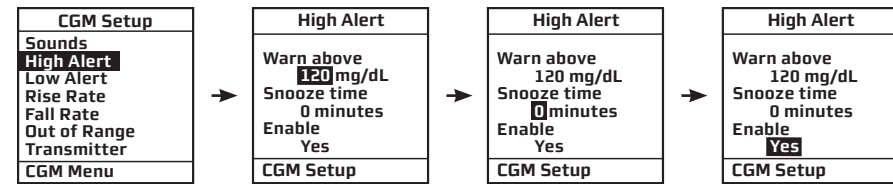
To Set Alert Sounds

- From the **CGM Setup** screen, **Sounds** will be highlighted. Press **⏏**.
- Highlight any Alert type. Press **⏏** to activate "Edit Mode". Use the **▲/▼** buttons to set the desired sound for the Alert (High - Medium - Low - Vibrate options). Press **⏏**.
- Scroll down to **CGM Setup**. Press **⏏** to return to **CGM Setup** screen.



To Set Alert Levels

- From the **CGM Setup** screen highlight any Alert type. Press **⏏**.
- Press **⏏** to activate "Edit Mode".
- Where applicable, set the level and snooze time, and choose to enable/disable the Alert. The default snooze time is 0 minutes (no snooze) and all Alerts are enabled.
- Scroll down to **CGM Setup**. Press **⏏** to return to **CGM Setup** screen.

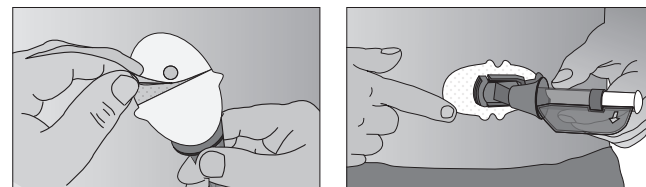


4 Insert Sensor & Place Transmitter

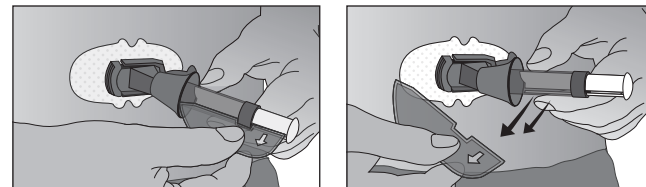
Before starting this step, you should have a Sensor, Sensor Applicator, the Transmitter, and alcohol wipes on hand.

To Insert the Sensor

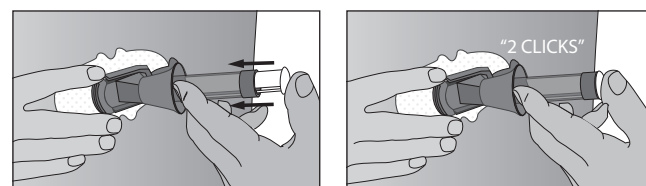
- Clean the placement site with alcohol. Let dry. The placement site should be on your belly (or upper buttocks in children and adolescents between the ages of 2 and 17), and out of the way of waistband or other areas where rubbing can occur. It should be at least 3 inches away from the insulin pump infusion site.
- Remove adhesive backing from bottom of Sensor Pod.
- Place Sensor horizontally, NOT vertically. Press your fingers firmly around adhesive to secure.



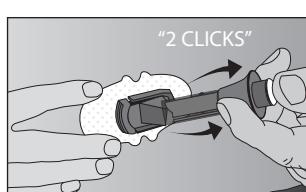
- Remove Safety Lock by pulling straight out (follow arrows in picture below). Save Safety Lock.



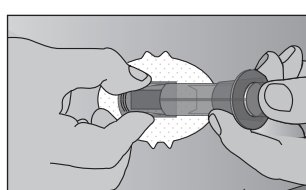
- Using your thumb and finger, it may help to pinch up on your skin at base of the Sensor Pod (use non-dominant hand).
- With dominant hand, place 2 fingers above collar (see picture below). Put your thumb on plunger and push down completely. You should hear 2 "clicks".



- Using your thumb as a base, place your 2 fingers below the collar and pull up completely. You should hear 2 "clicks".

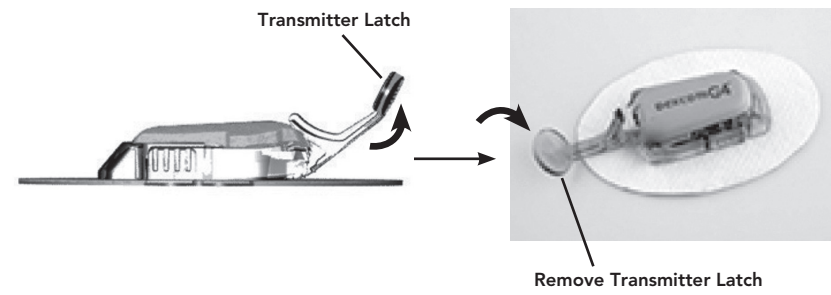


- Make sure the Transmitter Latch is flush against the skin. While still holding the Applicator Barrel, use your other hand to squeeze the ribbed Release Tabs on sides of the Sensor Pod. Rock the Applicator Barrel forward and lift up and away from your body.



To Place the Transmitter

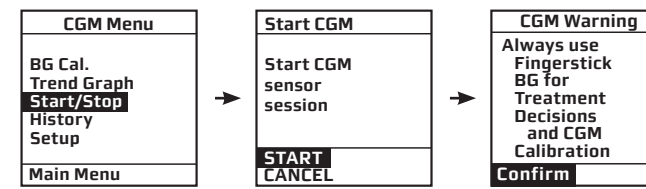
- Clean Transmitter with alcohol wipe. Let dry.
- Using your thumb and finger, pinch up on your skin at the base of the Sensor Pod. Place Transmitter in Sensor Pod (flat side down, thinner side away from Latch).
- Use a finger to hold Transmitter in place. With your other hand, move Transmitter Latch forward until you hear 2 "clicks".
- To remove Transmitter Latch, hold sides of Sensor Pod with one hand and Transmitter Latch with the other. Twist off Latch.



5 Start Sensor Session

To Start the Sensor Session

- From the **CGM Menu** screen, scroll down to highlight **Start/Stop**. Press **⏏**.
- START** will be highlighted. Press **⏏**. Confirm **CGM Warning** by pressing **⏏**.
- 2-hour Startup period will begin. Check your pump approximately 10 minutes after starting your Sensor session to make sure your pump and Transmitter are talking (ANT symbol should NOT appear on the CGM Trend screen).
- To show progression of the Startup period, a shaded box will appear on CGM Trend screens and gradually diminish over the 2 hours. No CGM data is displayed during the Startup period.

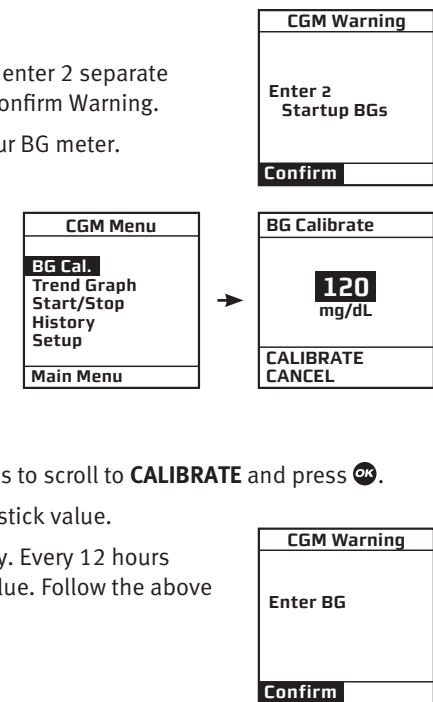


6 Calibrate

At the end of the 2-hour Startup period, calibrate your CGM by taking 2 fingerstick tests with your BG meter. BG values must be taken within 5 minutes of each other and then immediately entered in your pump. You will also need to calibrate daily with 1 fingerstick BG value at least once every 12 hours. Calibration values can be entered sooner or more often than every 12 hours if desired.

To Calibrate

- After the 2-hour Startup, you will be prompted to enter 2 separate fingerstick BG values in your pump. Press **⏏** to confirm Warning.
- Wash hands and perform fingerstick test with your BG meter.
- From **CGM Menu**, **BG Cal.** will be highlighted. Press **⏏**.
- NOTE:** 120 mg/dL is the default value that appears the first time you calibrate. Enter your actual fingerstick BG value for calibration.
- Use the **▲/▼** buttons to enter the BG value. Press **⏏**.
- CANCEL** will be highlighted. Use the **▲/▼** buttons to scroll to **CALIBRATE** and press **⏏**.
- Repeat above instructions to enter second fingerstick value.
- A minimum of 2 calibrations are needed each day. Every 12 hours you will be prompted to enter 1 fingerstick BG value. Follow the above instructions for entering a BG value.



7 CGM Trend & Data Screens

CGM Trend Screens

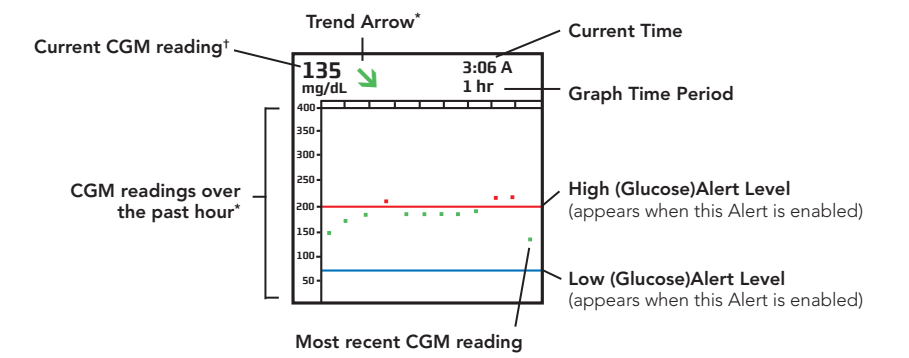
The CGM Trend screens provide a complete picture of your glucose status. CGM Trend screens include a graphical display of your CGM readings over a 1-3-6-12-24 hour time period, based on your preferred screen view. CGM Trend screens also provide information to assess the speed and direction of your glucose levels.

The CGM Data screen provides a snapshot of your current glucose status.

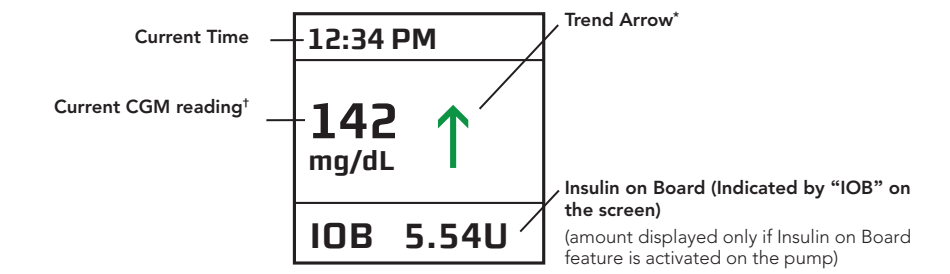
Access CGM Trend and Data Screens

- From the **CGM Menu** screen, press **▼** to highlight **Trend Graph**. Press **⏏**.
- Use the **▲/▼** buttons to scroll through the Trend screens and then the Data screens. Press **⏏** to return to the **CGM Menu** screen.
- When the pump is in sleep mode, you can access CGM Trend screens directly by pressing the Contrast/CGM Shortcut button (Ⓞ).

CGM Trend Screen



CGM Data Screen



* Trend Arrows (on CGM Data/Trend screens) and CGM readings (on CGM Trend screens) are color coded. An explanation of the Trend Arrows and the color coding appears below.
† A symbol may appear in place of your current CGM reading on CGM Data/Trend screens. Refer to the Animas® Vibe™ Owner's Booklet for more information.

Trend Arrows

Trend arrows can be used along with trend graphs to assess which direction your glucose levels are headed and how rapidly they are changing. You should not dose insulin based on trend arrow information.

↗	Rapidly rising: Your CGM glucose readings are rising more than 3 mg/dL each minute.
↗	Rising: Your CGM glucose readings are rising 2–3 mg/dL each minute.
↗	Slowly rising: Your CGM glucose readings are rising 1–2 mg/dL each minute.
→	Constant: Your CGM glucose readings are steady (not increasing/decreasing more than 1 mg/dL each minute).
↘	Slowly falling: Your CGM glucose readings are falling 1–2 mg/dL each minute.
↘	Falling: Your CGM glucose readings are falling 2–3 mg/dL each minute.
↘	Rapidly falling: Your CGM glucose readings are falling more than 3 mg/dL each minute.
⏏	No Rate of Change Information: The CGM cannot always calculate how fast your CGM glucose readings are rising or falling.

Trend Arrows and CGM glucose readings on CGM Data/Trend screens are color coded. See explanation below:

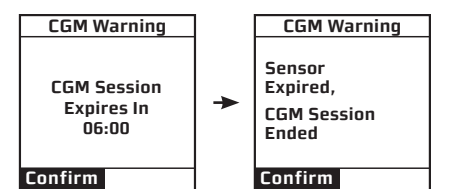
↗	Red arrows or data points mean your most recent CGM reading was at or above the High (Glucose) Alert limit set in the pump.
↗	Green arrows or data points mean your most recent CGM reading was between the High and Low (Glucose) Alert limit set in the pump.
↘	Blue arrows or data points mean your most recent CGM reading was at or below the Low (Glucose) Alert limit set in the pump.

8 End Sensor Session

The Sensor automatically shuts off after 7 days. Your pump will alert you 6 hours, 2 hours and 30 minutes before this happens. A final CGM Warning screen will appear when your Sensor session has ended.

Press **⏏** to confirm your Sensor session has ended.

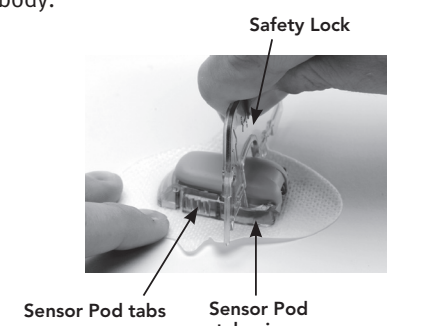
You can also stop your Sensor session at any time by choosing **Start/Stop** from **CGM Menu**.



To Remove the Sensor Pod and Transmitter

Loosen adhesive and peel Sensor Pod/Transmitter from body.

Place Sensor Pod/Transmitter on hard surface. Hold the rounded edge of the Safety Lock. Insert jagged edges of Safety Lock (from Sensor Applicator) so they "hug" the wide end of the Transmitter in the Sensor Pod.



Press Safety Lock down until you cannot press anymore and then pull up. The Transmitter will pop out of the Sensor Pod.

NOTE: If you did not keep the Safety Lock, you can use your fingers to spread out the back tabs of the Sensor Pod. The Transmitter will then pop out.

Keep Transmitter for next Sensor session.

