First steps for success.

Getting to know continuous glucose monitoring (CGM).

The Animas® Vibe® System is approved for persons age 2 and older.
Important Safety Information

- The Animas® Vibe® Insulin Pump and CGM System is intended for the delivery of insulin and for continuous glucose monitoring (CGM) for the management of insulin-requiring diabetes. The Animas® Vibe® System’s CGM, which includes the Dexcom G4® PLATINUM Sensor and Transmitter, is indicated for detecting trends and tracking patterns in persons age 2 and older. The system is intended for single patient use and requires a prescription.

- **Contraindications:** Insulin pump therapy is not recommended for people unwilling or unable to test their blood glucose four to six times per day, unwilling or unable to see their healthcare professional regularly, or whose vision or hearing does not allow recognition of pump alerts, warnings, and alarms. The Animas® Vibe® Insulin Pump must be removed before MRI or CT scan, and the Dexcom G4® PLATINUM Sensor and Transmitter must be removed before MRI, CT scan, or diathermy treatment. Taking acetaminophen-containing medications while wearing the sensor may falsely raise sensor glucose readings.

- **Warnings:** Connecting to the pump before receiving the necessary training could result in serious injury or death. Younger children may inadvertently press the pump buttons and deliver insulin, which can lead to hypoglycemic events. Caregivers are responsible for helping to ensure safe and effective delivery of insulin to people in their care, including using the safety features on the Animas® Vibe® System to help prevent injury. CGM glucose readings are not to be used to make treatment decisions. The sensor and transmitter do not replace a blood glucose meter. The sensor and transmitter are not to be used during pregnancy or while on dialysis. Sensor placement is only approved for sites under the skin of the belly (abdomen) in adults and the belly or upper buttocks for ages 2 to 17 (pediatrics). Patients should seek professional medical help if a sensor breaks and no portion of it is visible above the skin, or if there is infection or inflammation. Any broken sensors or adverse events should be reported to Customer Service. Contact Customer Service at 1-877-937-7867 or visit [www.animas.com/importantssaftyinformation](http://www.animas.com/importantssaftyinformation) for detailed indications for use and safety information.
Welcome to the “First Steps for Success: Getting to Know CGM” training course.

If you have never experienced CGM before, this course is for you.

• Starting CGM can be an emotional experience.
• You are going to learn more about your body and your diabetes.
• The purpose of this course is to help you understand what to expect your first week on CGM and help make your first week a success.

Please note: We recommend that you insert your first Sensor and start your first Sensor session prior to taking this course. The Animas® Vibe® Insulin Pump and CGM System Owner’s Booklet provides you with a thorough understanding of the Animas® Vibe® System and how to get the most from it. Please read it carefully.
Expect the unexpected.

Your first week on CGM may be an emotional roller coaster. These are some common situations you may see your first week:

"I guess I took too much insulin."

"I didn't know pizza did this to me."

“3 hours in my target range!”
Watch and learn.

- Accept what comes your way and learn from CGM during this first week.
- Try not to be frustrated and remember this is the first step to helping you improve your glucose control.
- Your first week you may want to sit back, watch and learn. Try not to over react, especially when you see those high glucose values 1 hour after a meal and are tempted to “correct” and take more insulin.
- Watch and learn is the best course for you to learn on your CGM.

Consult your healthcare provider before making any adjustments to your insulin therapy. Do not use glucose readings from the Dexcom G4® PLATINUM Sensor and Transmitter to make treatment decisions, such as how much insulin to take. The BG value from your BG meter should be used for treatment decisions.
Taking the first steps.
Getting to know CGM.

In this course you will learn about:

• Calibration and accuracy
• Speed and direction
• Alert settings
• Troubleshooting
• New Sensor Session
Calibration basics.

• Your Sensor does not automatically know your glucose levels. Your blood glucose (BG) meter needs to teach your Sensor what your BG levels are.

• You do this by calibrating. Your Sensor needs to be calibrated at least once every 12 hours (after the initial startup calibration) to keep it on track.

• The accuracy of your Sensor glucose readings may be compromised unless you calibrate at least once every 12 hours.
What does that number really mean?

- Your BG meter reading and the CGM reading on your pump may not match. That is okay. Readings can be different and still be considered accurate.
- CGM readings from interstitial fluid are different than BG readings from a BG meter. There are differences in how glucose is measured in the blood versus how it is measured in the fluid below the skin. And there is a lag time between when glucose is absorbed into the blood versus when it is absorbed into the fluid below the skin.
- This is why you will continue to use a BG meter to make treatment decisions and to calibrate the Sensor.
Teaching your Sensor.

• Periodic BG values from a BG meter are used to calibrate the Sensor, which adjusts Sensor readings to your body’s current health status to help ensure the accuracy of the readings.

TIP: Do not calibrate if your BG is changing more than 2 mg/dL per minute.
Teaching your Sensor: Example 1.

Example 1: Here is an example of where the meter and CGM readings are “off.” Your meter reads 100 mg/dL and your CGM reads 204 mg/dL. How would you correct this?

Consult your healthcare provider before making any adjustments to your insulin therapy. Do not use glucose readings from the Dexcom G4® PLATINUM Sensor and Transmitter to make treatment decisions, such as how much insulin to take. The BG value from your BG meter should be used for treatment decisions.
Teaching your Sensor: Example 1.

**Answer:** In this situation, you should wash your hands and take a 2\textsuperscript{nd} fingerstick BG meter reading. If the value of your 2\textsuperscript{nd} fingerstick is within close range to the first, enter that number as the calibration value into your Insulin Pump. By taking a 2\textsuperscript{nd} fingerstick, you are confirming your meter reading is accurate before you calibrate.

1\textsuperscript{st} fingerstick: 100 mg/dL  
2\textsuperscript{nd} fingerstick: 106 mg/dL

Consult your healthcare provider before making any adjustments to your insulin therapy. Do not use glucose readings from the Dexcom G4\textsuperscript{®} PLATINUM Sensor and Transmitter to make treatment decisions, such as how much insulin to take. The BG value from your BG meter should be used for treatment decisions.
Teaching your Sensor: Example 1.

After entering the 106 mg/dL into the Animas® Vibe® Insulin Pump, the number shifts from 204 mg/dL to 138 mg/dL.

Consult your healthcare provider before making any adjustments to your insulin therapy. Do not use glucose readings from the Dexcom G4® PLATINUM Sensor and Transmitter to make treatment decisions, such as how much insulin to take. The BG value from your BG meter should be used for treatment decisions.
Teaching your Sensor: Example 2.

Example 2: Here is another example where the meter and CGM are “off.” Your meter reads 240 mg/dL and your CGM reads 104 mg/dL. How would you correct this?

Consult your healthcare provider before making any adjustments to your insulin therapy. Do not use glucose readings from the Dexcom G4® PLATINUM Sensor and Transmitter to make treatment decisions, such as how much insulin to take. The BG value from your BG meter should be used for treatment decisions.
Teaching your Sensor: Example 2.

Answer: In this situation, you should wash your hands and take a 2nd fingerstick. In this example there was something wrong with the 1st fingerstick. In this situation no action is needed. By taking the 2nd fingerstick, you are confirming your meter reading is accurate before you calibrate.

1st fingerstick: 240 mg/dL

2nd fingerstick: 100 mg/dL

Consult your healthcare provider before making any adjustments to your insulin therapy. Do not use glucose readings from the Dexcom G4® PLATINUM Sensor and Transmitter to make treatment decisions, such as how much insulin to take. The BG value from your BG meter should be used for treatment decisions.
Speed and direction.

Your trend graph provides information regarding the speed and direction of your glucose. It is not all about the number. A 95 mg/dL value going down is different than 95 mg/dL going up.

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Speed and direction: Example 1.

If you saw 95 mg/dL with two arrows pointing downwards and were about to exercise, what would you do?

Consult your healthcare provider before making any adjustments to your insulin therapy. Do not use glucose readings from the Dexcom G4® PLATINUM Sensor and Transmitter to make treatment decisions, such as how much insulin to take. The BG value from your BG meter should be used for treatment decisions.
Alert settings.

The default low and high alerts may not be the best fit for you. You should set your alerts at a level that you would want to take action.

Questions to ask yourself:

• What glucose level would you consider treating for a low glucose value, for instance, when taking rapid acting carbohydrate?

• What glucose level would you consider treating for a high glucose value, for instance, when taking insulin?

Tip: Set your low and high alerts at a level at which you would take action, for example when you would treat a high or a low glucose value, based on the recommendations of your HCP?
Alert settings.

• You may also want to adjust the default rise rate and fall rate alert settings in your Animas® Vibe® Insulin Pump. Remember, too many alerts during your first week on CGM may be frustrating.

• The rise rate and fall rate are both enabled and are set to alert you if your CGM readings begin to rise or fall at or faster than 3 mg/dL per minute. You may adjust these settings in the CGM setup menu.

• **For example:** If you do not want to get rise rate alerts at this time, change the Enable setting from Yes to No.

Consult your healthcare provider before making any adjustments to your insulin therapy. Do not use glucose readings from the Dexcom G4® PLATINUM Sensor and Transmitter to make treatment decisions, such as how much insulin to take. The BG value from your BG meter should be used for treatment decisions.
Extra protection when you are very low.

- An additional CGM Alarm will display/sound on your pump when your most recent CGM reading is at or below 55 mg/dL. This Alarm is fixed, and cannot be changed or disabled.
- You will be re-alerted every 30 minutes if your current reading remains at or below 55mg/dL. This can be your safety net to help avoid hypoglycemia.

**Tip:** The goal is to not be at 55 mg/dL. Set your low alert for a level where you will take action and not ignore it.
CGM Warning screens.

These CGM Warning screens will appear on pumps intended for pediatric patients (ages 2-17).

• Whenever the CGM Low (Glucose) Alert is set
• Anytime the current CGM reading is below the low user limit and/or below 55 mg/dL

<table>
<thead>
<tr>
<th>CGM Warning</th>
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<tbody>
<tr>
<td>In a pediatric clinical study, a significant number of low glucose events were not detected by CGM.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>CGM Warning</th>
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<tbody>
<tr>
<td>Do not rely solely on CGM alerts to detect low glucose</td>
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</tbody>
</table>

ANCO/G4/1017/0187
Troubleshooting.

- As with any device, things may go wrong. Here are some examples you may see your first week of using the Dexcom G4® PLATINUM Sensor with your Animas® Vibe® Insulin Pump.

  ![Graph showing unknown glucose reading](image1)

  **Unknown Glucose Reading (usually resolves itself)**

  ![Graph showing out of range](image2)

  **Out of Range (make sure pump is within 12 feet of Transmitter)**

- For more tips on troubleshooting, refer to the Animas® Vibe® System Owner's Booklet and Dexcom G4® PLATINUM Sensor and Transmitter Quick Start Guide.

ANCO/G4/1017/0187
New Sensor session.

Your Animas® Vibe® Insulin Pump will tell you when to change your Sensor. Sensor expiration notifications will begin to appear 6 hours before the end of your Sensor session.

- **At 6 hours**, find your new Sensor.
- **At 2 hours**, get your Sensor ready.
- **At 30 minutes**, plan for insertion of new sensor.
New Sensor session.

At 0 min, take off your Sensor and put on a new one.

**Reminder:** Do not throw out the Transmitter.

- If you are not able to change your Sensor immediately, that’s okay, just know you won't be getting any Sensor readings until you replace your Sensor.

- Start your new Sensor session and approximately 2 hours later do your initial Sensor calibration.
Course summary.

Thank you for viewing the “First Steps for Success: Getting to know CGM” training course. This course was designed to help you understand what to expect your first week on CGM.

To learn more about successfully using CGM, check out the “Next Steps for Success: More tips for using CGM” training course at www.animas.com