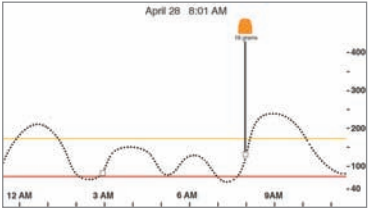


Enter Stress Event	
14	 <p>Turn to landscape.</p>

The receiver and app don't talk to one another. If you enter an Event only into the receiver, while the information will appear on Dexcom reports, you won't get an Event marker on your app's Trend screen.

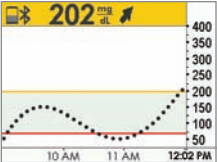
The app has Event markers on its screen, the receiver doesn't.

There may be times when you want or need to enter Events on the Dexcom G5 Mobile Receiver.

Enter Events: Dexcom G5 Mobile Receiver

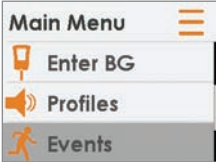

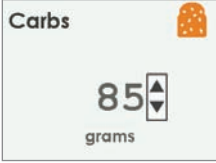
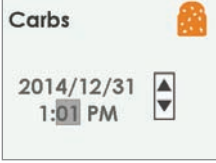
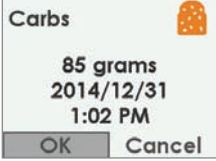
While the Event data is the same between display devices, the flow is not the same, including how to enter the Event's date and time. The following table reviews how to enter the same Carb/Stress Event data from the previous scenario: Carbs at 85, and a Stress Event.

Entering Events: Receiver



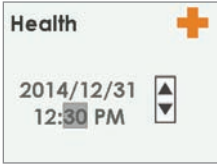
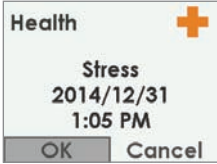
Step	What you see	What you do
Enter Carbs Event		
1		Default screen Press <i>Select</i> to go to Main Menu.

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(Continued from previous page)

Enter Carbs Event		
2	 The screenshot shows the 'Main Menu' with four options: 'Enter BG', 'Profiles', 'Events', and 'Events'. The 'Events' option is highlighted with a grey background.	<p>Press Down Arrow until <i>Events</i> is highlighted.</p> <p>Press Select.</p>
3	 The screenshot shows the 'Events' menu with four options: 'Carbs', 'Insulin', and 'Exercise'. The 'Carbs' option is highlighted with a grey background.	<p>Highlight <i>Carbs</i>.</p> <p>Press Select.</p>
4	 The screenshot shows the 'Carbs' entry screen with a large '85' and 'grams' below it. There are up and down arrow buttons next to the number.	<p>Add up all carb grams from lunch.</p> <p>Arrow up to "85."</p> <p>Press Select.</p>
5	 The screenshot shows the 'Carbs' entry screen with the date '2014/12/31' and time '1:01 PM'. There are left and right arrow buttons next to the date and time.	<p>Press Left/Right Arrows to change time and date.</p> <ul style="list-style-type: none">• Left: Backwards• Right: Forward <p>Press Select.</p>
6	 The screenshot shows the 'Carbs' entry screen with the text '85 grams', '2014/12/31', and '1:02 PM'. At the bottom, there are 'OK' and 'Cancel' buttons.	<p>Confirmation screen.</p> <p>Press Select.</p>

(Continued on next page)

Enter Health Event		
7		Press Down Arrow until <i>Health</i> .
8		Press Down Arrow to <i>Stress</i> . Press Select .
9		Press Left/Right Arrows to change time and date. <ul style="list-style-type: none">• Left: Backwards• Right: Forward Press Select .
10		Verify information is correct. Press Left/Right Arrows to highlight field. Press Up/Down Arrows to change numbers. Press Select to save.

10.4 Viewing Events

Events entered into your receiver can only be viewed on a Dexcom report; there are no markers on your receiver's screen.

On your smart device, turn to landscape to view your Event markers. A single small square marks all Events. Slide your finger across the screen or tap the square to get your Event's information.

Landscape	What it does	What you do
	<p>Landscape Only Show Event details.</p>	<p>Landscape Only</p> <ul style="list-style-type: none"> • Tap <i>square</i> • Slide finger across screen

Once you have allowed your Share Follower's access to your Trend screen, they too will be able to view your Events. See Part 5 for more information.

Summary

Now You Can:

- Define Event
- Describe each Event
- Create an Event
 - Dexcom G5 Mobile App
 - Dexcom G5 Mobile Receiver
- Recognize Event Markers on the Dexcom G5 Mobile App
 - Describe how Event Markers are different in portrait and landscape view
- Describe how to view Events entered via your receiver

What's Next?

In the next chapter, you will learn about your trend's Alarm and Alerts helping you monitor you glucose levels. You'll also learn how you know when your system loses its signal and stops communicating.

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Chapter 11

Next Steps:

Sensor Glucose Alarm and Alerts

11.1 Introduction

Monitoring your glucose trends is critical in managing your diabetes. But what happens if you're driving, in a meeting, at the movies, and can't or, don't want to, keep looking at your display device?

Dexcom's G5 Mobile CGM System understands there are times when you can't look at your receiver or smart device; however you still need to know of actionable glucose trends or if you're not getting your sensor glucose readings.

This chapter reviews the sensor glucose Alarm and Alerts based on your sensor glucose readings, allowing you to proactively manage your glucose trend levels and make sure your transmitter is communicating with your display device.

In the next chapter, you'll learn how to customize the Alarm and Alerts.

After this chapter you will be able to:

- Define an Alarm
- Define an Alert
- Identify the different types of Alerts
- Describe the difference between an Alarm and an Alert
- Recognize different Alarm/Alert prompts and sounds
- Determine signal loss is preventing you from getting an Alarm or Alert
- Describe recommended app settings
- Successfully clear an Alert notification
 - Dexcom G5 Mobile App
 - Dexcom G5 Mobile Receiver

Your trending information is one of the greatest benefits of the Dexcom G5 Mobile System. It's important to focus on your trends and rate of change arrows, rather than the exact number of your glucose reading

11.2 Safety Statements

The Alarm and Alerts were designed to keep you safe, helping you avoid severe lows and highs or from missing your readings. The following safety statements help ensure you get your Alerts and Alarm.

WARNING

Do: *Verify your smart device settings let you get Alarm and Alerts.*

To receive Alarm/Alerts you must:

1. **Make sure** Dexcom G5 Mobile App Notifications are **turned on** in *Settings* menu
2. **Verify** app hasn't been shut down.
3. **Adjust** volume so you can hear sounds.
4. **Turn Bluetooth** on.
5. **Turn off** *Do Not Disturb*.
6. **Keep** Dexcom G5 Mobile App running in the background.
7. **Restart** app after device is restarted.

Why: Your apps settings do not override phone settings.

Consequences: Missing severe low or high Alarm or Alerts.

WARNING

Don't: *Never assume the Dexcom G5 Mobile CGM System's Alarm/Alert vibrations are different from other vibrating apps.*

Do: *Look at your smart device and check if vibration is a Dexcom G5 Mobile CGM System Alarm or Alert.*

Why: Medical device apps don't have special priority over your smart device's features. You can't determine if the vibration is coming from your Dexcom G5 Mobile App or another app.

Consequences: Missing severe low or high Alarm or Alerts.

WARNING

Do: *Unplug headphones from your smart device when not in use.*

Why: If headphones are plugged in while not being used, you won't hear an Alarm or Alert.

Consequences: Missing severe low or high Alarm or Alerts.

PRECAUTION

Don't: *Never prevent communication between transmitter and display devices.*

Do: *Keep smart device and receiver within 20 feet of transmitter and away from obstructions.*

Why: If your transmitter display device(s) are more than 20 feet apart or are separated by an obstruction, they might not communicate.

Types of obstruction differ and not all types have been tested. Obstructions can include water, walls, metal, etc.

Water (e.g., swimming, surfing, bathing, etc.) can severely limit communication range.

Consequences: Missing severe low or high Alarm or Alerts.

PRECAUTION

Do: *Set smart device and receiver settings separately.*

Why: Settings are specific to each display device and don't carry over to other devices. If you set up one device and then use another, you won't get an Alarm or Alert.

Consequences: Missing severe low or high Alarm or Alerts.

PRECAUTION

Do: *Verify smart device and receiver are turned on.*

Why: Neither the receiver nor smart device will generate sensor glucose readings, Alarm or Alerts if turned off.

Consequences: Missing severe low or high Alarm or Alerts.

11.3 Alarm and Alerts

As part of managing your diabetes, you learned how to read your Trend screen and how to enter Events. In this chapter, you'll learn how Alarm and Alerts can keep you safe from severe lows or highs.

Depending on your display device, you can customize how you receive your Alarm or Alerts.

What Is an Alarm?

While there are a variety of Alerts, there is just one Alarm, the Urgent Low Alarm (Alarm) is set at 55 mg/dL. The Alarm will repeat every 5 minutes until you clear the Alarm (see Chapter 12 on how to customize the sounds). If you clear the Alarm and your sensor glucose readings do not go over 55 mg/dL in the next 30 minutes, you get another Alarm.

Unlike Alerts, the Urgent Low Alarm setting can't be changed or turned off. Think of it as a safety net: your glucose level is dangerously low—pay attention now!

What Are Alerts?

An Alert is a message telling you your glucose trend levels need attention.

Low/High glucose Alerts tell you when your sensor glucose readings are outside your target glucose ranges. Think of them as an FYI: You need to know what's happening, Rising/Falling Alerts tell you your glucose levels are changing quickly. Their default settings are Off (see Chapter 12 on how to turn them on).

Alerts message you with vibrations (vibrations not available on all smart devices), visual prompts, sounds, or a combination of all three.

Unlike the Alarm, you can customize your different Alert's target range (Chapter 12).

During your initial set up, you establish your low and high alert levels. As mentioned before, this chapter is a review of the Alarm and Alerts, recommended smart device settings and the receiver's default Alert settings.

Chapter 12 will show you how to change their settings: customize glucose levels prompts, how you are notified, and in some cases, how often you get notified. The following are the defaults.

Default Alerts

Low/High Alerts

Your Low/High Alerts have the same color coding as your Trend Graph screen:

1. Red: Glucose levels are below your low threshold.
 - a. Default setting of 80 mg/dL.
2. Gray: Glucose levels are within your high/low Alert levels.
 - a. No Alerts.
3. Yellow: Glucose levels are above your high threshold.
 - a. Default setting of 200 mg/dL.

Rise Rate/Fall Rate/Repeat/Signal Loss Alerts

Rise Rate and Fall Rate Alerts warn you when your glucose levels are changing rapidly, either down or up, and look similar to the rate of change arrows. Repeat Alerts let you know if your sensor glucose readings continue to be above or below your Alert levels.

Glucose Level Alerts

1. Rise Rate
 - a. Default setting is Off—No Alert.
 - b. Need to change settings to receive Rising Alert.
2. Fall Rate
 - a. Default setting is Off—No Alert.
 - b. Need to change settings to receive Falling Alert.
3. Repeat
 - a. Default setting is Off—No Alert.
 - b. Need to change settings to receive Repeat Alert.

Signal Loss Alert

Signal Loss tells you when you and the transmitter are too far from your display device or something is blocking your transmitter signal, causing you not to get sensor glucose readings. The default setting for Signal Loss is On.

Now you have the basics for Dexcom's G5 Mobile's Alarm/Alerts feature. Next, you will learn about each Alarm/Alert in more detail.

11.4 Alarm and Alerts Screens

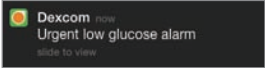
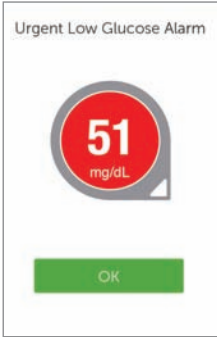

When you fall within an Alarm or Alert target range, your display device tells you. As mentioned in previous chapters you won't get any Alarm or Alerts within five minutes of calibration.

Let's first review how the information is presented visually across the devices. While the Alarm/Alerts prompts look different on the display devices, they reflect the same information.

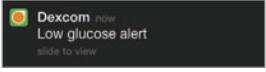

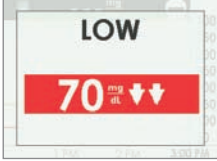
After prompts we'll separately review the vibration and audible Alarm/Alerts for app and receiver.

Alarm and Alerts look different based on your display device, but reflect the same information.

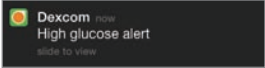


Urgent Low Glucose Alarm

Device	What you see	What it means
Smart Device: Lock Screen	 A notification on a black background with the Dexcom logo and text: "Dexcom Urgent low glucose alarm slide to view".	
Smart Device: In App	 A white screen titled "Urgent Low Glucose Alarm" showing a red circular gauge with the number "51" and "mg/dL" below it. A green "OK" button is at the bottom. Arrows on the gauge indicate the rate of change.	<p>Sensor glucose reading at or below 55 mg/dL.</p> <p>Shows last glucose value.</p> <p>Arrows reflect rate of change.</p> <p>Check BG meter to make treatment decisions.</p>
Receiver	 A screen with a red background and white text. It says "URGENT LOW" at the top, "53 mg/dL" in the middle with a red arrow pointing right, and "5:00 PM" at the bottom.	

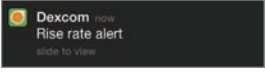


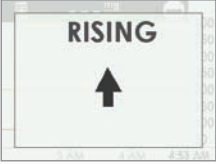

Low/High Glucose Alerts

Device	What you see	What it means
Smart Device: Lock Screen	 <p>A notification banner on a lock screen with the Dexcom logo, the text "Dexcom now Low glucose alert", and "slide to view".</p>	
Smart Device: In App	 <p>A screenshot of a mobile app showing a "Low Glucose Alert" with a large red circle containing the number "77" and "mg/dL" below it. A green "OK" button is at the bottom. Arrows on the sides indicate the rate of change.</p>	<p>Sensor glucose reading at or below your low Alert level.</p> <p>Shows most current sensor glucose reading.</p> <p>Arrows reflect rate of change.</p> <p>Can be set to repeat between 15 minutes to 4 hours.</p> <p>Check your BG meter to make any treatment decisions.</p>
Receiver	 <p>A screenshot of a receiver display showing "LOW" in large letters, with "70 mg/dL" and two downward-pointing arrows below it.</p>	


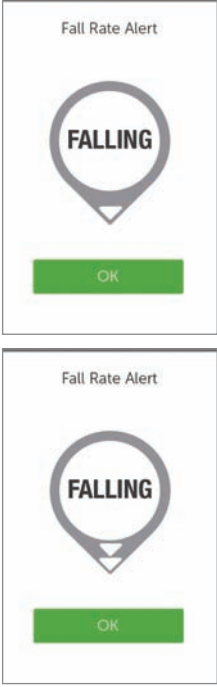

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Device	What you see	What it means
Smart Device: Lock Screen	 A black notification banner with the Dexcom logo on the left. The text reads: "Dexcom now High glucose alert slide to view".	<p>Sensor glucose reading at or above your high Alert level.</p> <p>Shows most current sensor glucose reading.</p> <p>Arrows reflect rate of change.</p> <p>Can be set to repeat between 15 minutes to 4 hours.</p> <p>Check BG meter to make treatment decisions.</p>
Smart Device: In App	 A white rectangular alert box with the title "High Glucose Alert" at the top. In the center is a large yellow circle containing the number "202" and "mg/dL" below it. At the bottom is a green button with the text "OK".	
Receiver	 A close-up of a receiver screen. At the top, it says "HIGH" in large black letters. Below that, a yellow bar contains the number "389" followed by "mg/dL" and two upward-pointing arrows. The bottom of the screen shows a time and date: "10:00 AM 1/24/14 4:50 AM".	

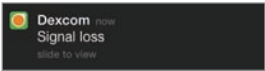

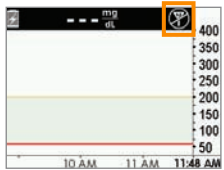
Rise Rate/Fall Rate Alerts

Device	What you see	What it means
Smart Device: Lock Screen	 <p>A notification card on a dark background with the Dexcom logo, the text "Rise rate alert", and "slide to view".</p>	
Smart Device: In App	  <p>Two screenshots of the in-app alert. The first shows a "Rising" alert with two upward-pointing arrows. The second shows a "Rising" alert with three upward-pointing arrows. Both screens have an "OK" button at the bottom.</p>	<p>Sensor glucose readings rising quickly.</p> <p>Number of arrows shows how fast (2 mg/dL/min; 3+ mg/dL/min).</p> <p>Check BG meter to make any treatment decisions.</p>
Receiver	  <p>Two screenshots of the receiver alert. The first shows "RISING" with one upward arrow. The second shows "RISING" with two upward arrows.</p>	

(Continued on next page)

Device	What you see	What it means
Smart Device: Lock Screen		
Smart Device: In App		<p>Sensor glucose readings falling quickly.</p> <p>Number of arrows shows how fast (2 mg/dL/min; 3+ mg/dL/min).</p> <p>Check BG meter to make any treatment decisions.</p>
Receiver		

Signal Loss Alert

Device	What you see	What it means
Smart Device: Lock Screen		<p>Your receiver and transmitter are not communicating.</p> <p>You will not receive Alarm/Alerts.</p> <p>Check BG meter to check your glucose and make any treatment decisions.</p>
Smart Device: In App		
Receiver		

11.5 App: Alarm/Alert Recommended Settings

The receiver is a stand-alone medical device and used solely to monitor your glucose trends.

The app cannot override the smart devices general settings.

The app can't override your smart device settings:

- When your smart device is on Silent, you'll still receive Alarms and Alerts visual prompts and messages, but not vibrations if you haven't adjusted your smart device settings
- Some smart devices don't have a Vibration feature, so you won't get any vibration notifications
- When your ringer's volume is low, you may not hear an Alarm or Alert
- When your smart device is in Do Not Disturb mode, you won't receive any Alarm/Alerts. The Dexcom G5 Mobile App can't override the Do Not Disturb setting
- If you don't enable your Dexcom G5 Mobile push Notifications settings during set up, you won't get any Alarm/Alerts
- Check in Settings under Notifications on how your Alarm/Alerts are prioritized

For information on smart device settings, see your smart device's instructions.

If you are concerned about missing an Alarm or Alert (e.g., due to smart device settings, app shutting off due to lack of storage, low smart device battery, etc.), bring your receiver with you.

11.6 Receiver: Default Beeps and Vibrations


The Dexcom G5 Mobile Receiver's Alarm/Alerts are vibrations and a beep, or a series of beeps, based on the Alarm or Alert. Beeps and vibrations are preprogrammed into the receiver, and unlike the smart device, the volume can't be changed.

In Chapter 12 you'll learn how to adjust the volume and intensity of your Alarm/Alerts.

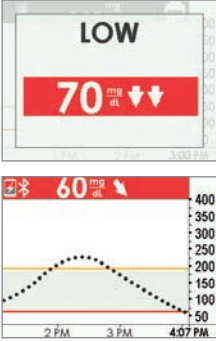
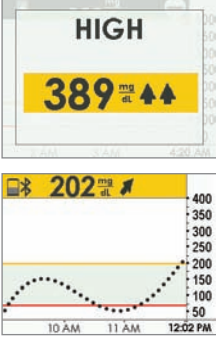
The following is a table of the receiver's default beep and vibration patterns. If you clear the Alert's initial vibration, you won't get any beeps or sounds unless you've turned on the Repeat Alert.

In the next section, you'll learn how to clear the Alarm/Alerts.

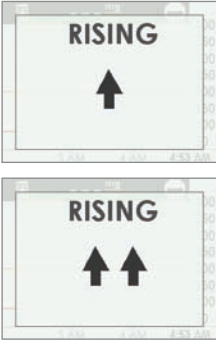
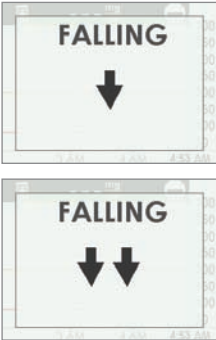
Urgent Low Glucose Alarm

What you see	Beeps and vibration
	<p>Initial Default Alert: Vibrates 4x's.</p> <p>After 5 Minutes: Vibrates/beeps 4x's every 5 minutes until cleared or sensor glucose readings go above Alarm level.</p> <p>After 30 Minutes: After clearing Alarm, continues to notify if sensor glucose readings remain at or below Alarm level.</p>

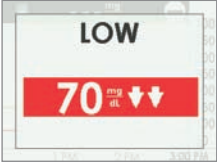

Low/High Glucose Alerts

What you see	Beeps and vibration
 <p>The top screen displays 'LOW' in large black letters. Below it, a red banner shows '70 mg/dL' with two downward-pointing arrows. The bottom screen shows a trend graph with a red horizontal line at 70 mg/dL. The y-axis ranges from 50 to 400 mg/dL. The x-axis shows time from 2 PM to 4:07 PM. A black dotted line represents the glucose trend, which is above the red alert line.</p>	<p>Initial Default Alert: Vibrates 3x's.</p> <p>After 5 Minutes: Vibrates/beeps 3x's every 5 minutes until cleared. Trend screen will continue to reflect Alert until sensor glucose readings go above Alert level.</p>
 <p>The top screen displays 'HIGH' in large black letters. Below it, a yellow banner shows '389 mg/dL' with two upward-pointing arrows. The bottom screen shows a trend graph with a yellow horizontal line at 389 mg/dL. The y-axis ranges from 50 to 400 mg/dL. The x-axis shows time from 10 AM to 12:02 PM. A black dotted line represents the glucose trend, which is below the yellow alert line.</p>	<p>Initial Default Alert: Vibrates 2x's.</p> <p>After 5 Minutes: Vibrates/beeps 2x's every 5 minutes until cleared. Trend screen will continue to reflect Alert until sensor glucose readings go below Alert level.</p>

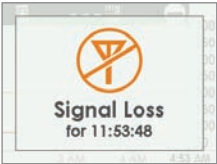
Rise Rate/Fall Rate Alerts

What you see	Beeps and vibration
	<p>Initial Default Alert: None/Off.</p> <p>After Setting Change: Vibrates 2x's, 2 sounds.</p> <p>After 5 Minutes: Vibrates/beeps 2x's every 5 minutes until cleared.</p>
	<p>Initial Default Alert: None/Off.</p> <p>After Setting Change: Vibrates 3x's.</p> <p>After 5 Minutes: Vibrates/beeps 3x's every 5 minutes until cleared or sensor glucose reading drops below Alert level.</p>

Low Repeat/High Repeat

What you see	Beeps and vibration
	<p>Initial Default Alert: None/Off.</p> <p>After Setting Change: Vibrates 3x's.</p> <p>After 5 Minutes: Vibrates/beeps 3x's every 5 minutes until cleared.</p> <p>Will re-alert if sensor glucose readings drop at or below 55 mg/dL.</p>
	<p>Initial Default Alert: None/Off.</p> <p>After Setting Change: Vibrates 2x's.</p> <p>After 5 Minutes: Vibrates/beeps 2x's every 5 minutes until cleared.</p>

Signal Loss Alert

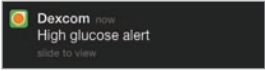

What you see	Beeps and vibration
	<p>Initial Default Alert: On.</p> <p>After Setting Change: Vibrates 1x.</p> <p>After 5 Minutes: Vibrates/beeps 1x every 5 minutes for a total of 6 times if not cleared.</p> <p>After 6 times it will not alert again.</p>

11.7 Clearing Alarm/Alerts

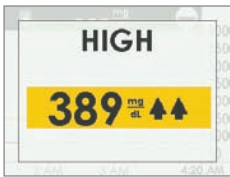
Alerts require you to acknowledge and clear them. How this is done depends on your display device. If using both display devices, you'll need to clear each separately.

Due to their medical importance, the Alarm is more persistent. Even after acknowledging and clearing an Alarm, if your sensor's glucose readings remain at or below 55 mg/dL, an Alarm will sound every 30 minutes until readings are above 55 mg/dL.

Clearing Your Smart Device

Device	What you see	What you do
Smart Device: Lock Screen	 A notification card on a lock screen. It features the Dexcom logo, the text "High glucose alert", and a "slide to view" indicator.	Slide <i>Alarm</i> or <i>Alert</i> to access app.
Smart Device: In App	 A "High Glucose Alert" dialog box. It shows a large "202 mg/dL" reading inside a circular graphic and a green "OK" button at the bottom.	Tap <i>OK</i> to accept Alarm or Alert.

Clearing Your Receiver

What you see	What you do
	<p>Press <i>Select</i>.</p>

Once cleared, you won't receive the same Alert unless you hit the Alert's target range again. Your Alarm will repeat even after clearing if your glucose levels do not return to your target range.

Summary

Now You Can:

- Define an Alarm
- Define an Alert
- Identify the different types of Alerts
- Describe the difference between an Alarm and an Alert
- Recognize different Alarm/Alert prompts and sounds
- Determine if signal loss is preventing you from getting an Alarm/Alert
- Describe recommended app settings
- Successfully clear an Alert notification
 - Dexcom G5 Mobile App
 - Dexcom G5 Mobile Receiver

What's Next?

Up to now, you have learned about the Alarm or Alert default settings. But what do you do if you want to decrease the High Alert glucose level threshold, or you want to continue getting a Low Alert notification if your glucose levels don't improve, even though you cleared the message?

How do you make your Alarm/Alerts fit your needs?

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Chapter 12

Next Steps:

On the Go With G5: Customizing Your Alarm and Alerts

12.1 Introduction

The receiver and app come with default glucose Alert level settings, but perhaps they don't reflect the glucose level that works best for you.

Perhaps you're in a meeting and can only clear an Alert, yet want to make sure your Alert repeats, or continues, until you're able to take corrective measures. Maybe you'd like to get a Rising/Falling glucose Alert, but their settings are off by default. How do you turn them on?

In this chapter, you'll learn how to personalize your Alarm and Alerts tones and glucose levels.

Afterwards, you will be able to:

- Customize your Low/High Alerts
 - Dexcom G5 Mobile App
 - Dexcom G5 Mobile Receiver
- Adjust Alarm sound notification
- Use receiver's Advanced Alerts
 - Low/High Repeat
 - Rise/Fall Alerts
 - Signal Loss

Each display device has customization options; however the setup flow is different. Before making any changes to your Alert levels, talk with your healthcare professional.

First, let's take a look at personalizing your app Alarm and Alerts, and then we'll review the same process for the receiver.

12.2 Safety Statement

WARNING

Do: If using both receiver and app for to get an Alarm or Alert, change settings in each display device.

Why: Any changes to the G5 Mobile app will not carry over to the receiver.

Consequences: Missing severe low or high Alarm or Alerts.

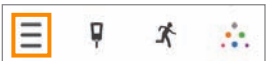
12.3 Changing App Alarm and Alerts

App Screen Overview

The Alerts Main Menu lists all customizable Alerts and Alarm and their current settings. Part of your initial set up included setting your Low/High Alerts. In this chapter, you'll learn how to change them.

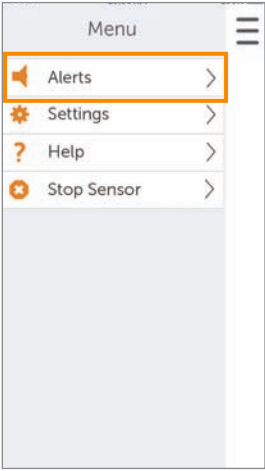
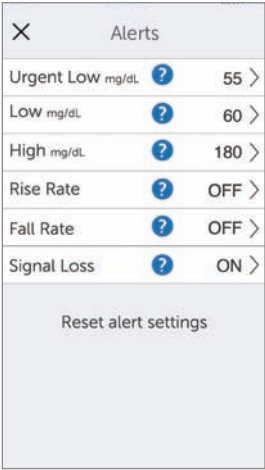
Before learning how to change your settings, let's review the app's Alerts Main Menu screen.

Customizing Alerts: App Alarm/Alerts Screen Overview

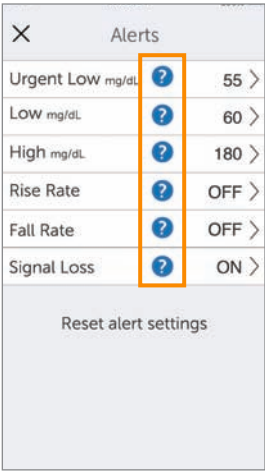
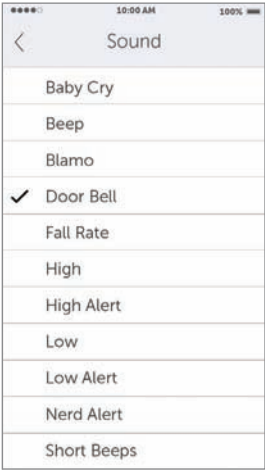
Step	What you see	What it means	What you do
1		Access Main Menu.	Tap <i>Main Menu</i> icon.

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Step	What you see	What it means	What you do
2	 A screenshot of a mobile application menu. The menu is titled "Menu" and has a hamburger icon on the right. It contains four items: "Alerts" with a speaker icon, "Settings" with a gear icon, "Help" with a question mark icon, and "Stop Sensor" with a red 'X' icon. The "Alerts" item is highlighted with an orange border.	Access Alerts Main Menu.	Tap Alerts.
3	 A screenshot of the "Alerts" settings screen. The screen has a close button (X) in the top left. It lists several alert settings: "Urgent Low mg/dL" with a value of 55, "LOW mg/dL" with a value of 60, "High mg/dL" with a value of 180, "Rise Rate" set to OFF, "Fall Rate" set to OFF, and "Signal Loss" set to ON. Each setting has a question mark icon and a right arrow. At the bottom, there is a "Reset alert settings" button.	All customizable Alarm and Alerts. Current Alert settings. All alerts have: <ul style="list-style-type: none">• On/Off switch• Notify me options• Sound options	Tap Alarm/Alert you want to change.

(Continued on next page)

Step	What you see	What it means	What you do
4		<p>“?” explains:</p> <ul style="list-style-type: none"> • Each Alarm/Alert • Message options • Recommended settings 	<p>Tap “?” for Alarm/Alert information.</p>
5		<p>Urgent Low Glucose Alarm:</p> <ul style="list-style-type: none"> • Preset at 55 mg/dL and cannot be changed • <i>Repeat</i> preset at 30 minutes and can't be changed • <i>Sound</i> is the only change option 	<p>Tap <i>Sound</i> to change sound.</p>

Steps to Customize App Alarm/Alerts





Although the results will vary depending on what Alarm or Alert you are customizing, the steps to change your Alarm or Alert are the same:

From app's Main Menu:

1. Tap *Alerts*.
2. Tap the *Alert* you want.
 - a. Tap *On* or *Off* switch to turn on desired Alerts.
3. Tap *Notify me*.
 - a. Change the Alert glucose level (mg/dL).
 - i. Scroll selection wheel, find your desired Alert level.
 - ii. Tap to highlight.
 - iii. Tap *Save*.
4. Tap *Repeat*.
 - a. Change the amount of time you want between your High/Low Alerts if your sensor glucose readings continue to be low or high.
 - i. Scroll selection wheel, find your desired Alert level.
 - ii. Tap to highlight.
 - iii. Tap *Save*.
5. Tap *Sound*.
 - a. Assign a different sound to each Alarm or Alert.
 - i. Scroll selection wheel, find your desired sound.
 - ii. Tap to highlight.
 - iii. Tap *back arrow*.

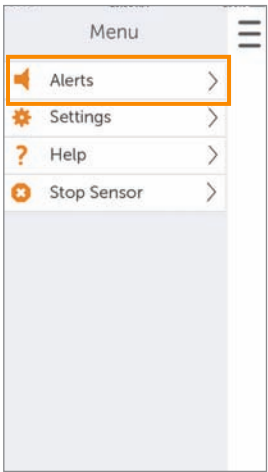
In this following example, we'll change the High Alert level from 200 mg/dL to 190 mg/dL, repeating every hour if you continue to stay high, with a Door Bell sound.

Customizing Alerts: App


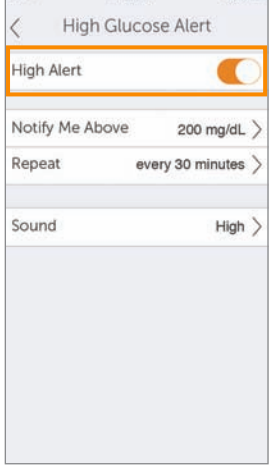
Step	What you see	What it means	What you do
Access Alerts' Main Menu			
1	   	Access Main Menu.	Tap <i>Main Menu</i> icon.

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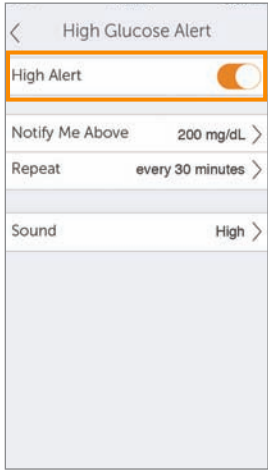
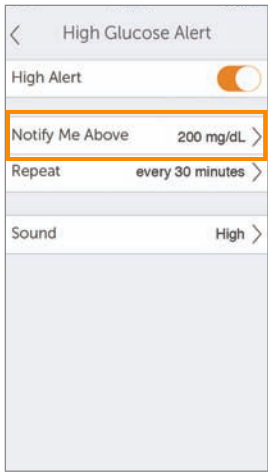
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Access Alerts' Main Menu		
2	 A screenshot of a mobile application's main menu. The menu is titled "Menu" and has a hamburger icon on the right. It contains four items: "Alerts" with a speaker icon, "Settings" with a gear icon, "Help" with a question mark icon, and "Stop Sensor" with a star icon. The "Alerts" item is highlighted with an orange border. Below the menu items is a large grey rectangular area. <p>Alerts</p> <p>Settings</p> <p>Help</p> <p>Stop Sensor</p>	Access Alerts Main Menu.
		Tap Alerts.

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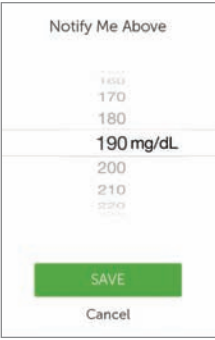
Changing an Alert			
3	 <p>The screenshot shows a list of alerts: Urgent Low mg/dL (55), LOW mg/dL (60), High mg/dL (180), Rise Rate (OFF), Fall Rate (OFF), and Signal Loss (ON). The 'High mg/dL' row is highlighted with an orange border. A 'Reset alert settings' button is at the bottom.</p>	<p>Access High Alert settings (mg/dL).</p>	<p>Tap <i>High mg/dL</i>.</p>
4	 <p>The screenshot shows the 'High Glucose Alert' settings. The 'High Alert' toggle is turned on (orange). Other settings include 'Notify Me Above' (200 mg/dL), 'Repeat' (every 30 minutes), and 'Sound' (High).</p>	<p>Shows High Alert options and current settings.</p>	<p>Check <i>High Alerts</i> is On.</p> <ul style="list-style-type: none">• On - Orange• Off - Gray

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Changing an Alert			
5	 A screenshot of the 'High Glucose Alert' settings screen. At the top, there is a back arrow and the title 'High Glucose Alert'. Below that is a 'High Alert' toggle switch, which is currently turned off (gray). This row is highlighted with an orange border. Underneath are three rows: 'Notify Me Above' with '200 mg/dL' and a right arrow; 'Repeat' with 'every 30 minutes' and a right arrow; and 'Sound' with 'High' and a right arrow. The bottom half of the screen is a light gray area.	Won't get Alerts if Off.	If Off: <i>On</i> Slide to On. <ul style="list-style-type: none">• On - Orange• Off - Gray
6	 A screenshot of the 'High Glucose Alert' settings screen, identical to the one above. In this screenshot, the 'High Alert' toggle switch is turned on (orange). The 'Notify Me Above' row, showing '200 mg/dL' and a right arrow, is highlighted with an orange border.	Change High Alert (mg/dL).	Tap <i>Notify Me Above</i> .

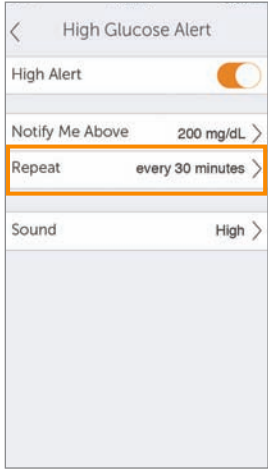
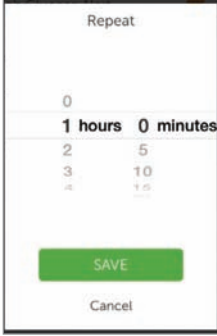
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Changing an Alert			
7		Change glucose level from current level (mg/dL).	Scroll selection wheel. Stop at 190.
8		Saves new High Alert glucose level (mg/dL). Returns to <i>High Glucose Alert</i> screen options. <i>Notify Me Above</i> set at 190 mg/dL.	Tap <i>Save</i> .

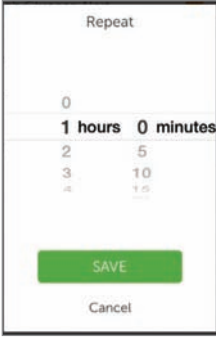
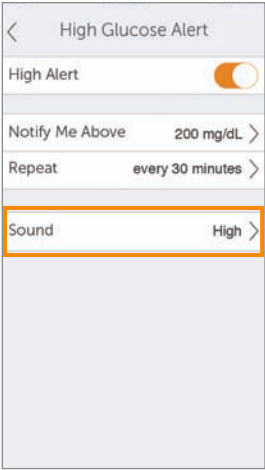
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Changing an Alert

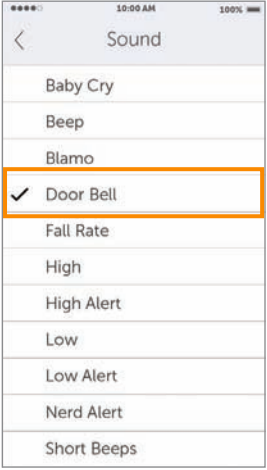
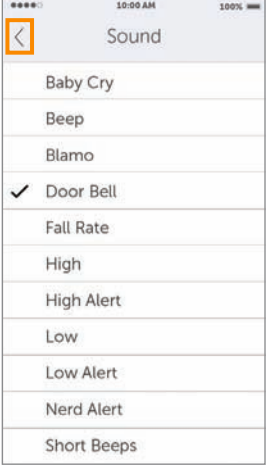
9		<p>Changes how often your High Alert repeats after initial Alert and confirmation.</p> <p>Repeats only if you are above your high glucose level.</p>	<p>Tap <i>Repeat</i>.</p>
10		<p>Changing the current repeat setting.</p> <p>Can select in five minute steps (range 15 minutes-4 hours).</p>	<p>Scroll selection wheel.</p> <p>Stop at 1 hour.</p>

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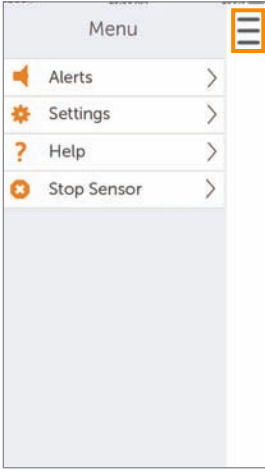
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Changing an Alert			
11		<p>Saves your new repeat timing.</p> <p>Returns to <i>High Glucose Alert</i> screen options.</p> <p><i>Repeat</i> shows how often you'll get notified.</p>	<p>Tap Save.</p>
12		<p>Customize Alert sound.</p>	<p>Tap Sound.</p>

(Continued on next page)

Changing an Alert			
13	 A screenshot of an iPhone's 'Sound' settings page. The page title is 'Sound' with a back arrow on the left. The list of options includes: Baby Cry, Beep, Blamo, Door Bell (which is selected with a checkmark and highlighted by an orange border), Fall Rate, High, High Alert, Low, Low Alert, Nerd Alert, and Short Beeps. The status bar at the top shows 10:00 AM and 100% battery.	Changes current sound setting.	Tap <i>Doorbell</i>. Tap <i>Sound</i> again to hear sound sample.
14	 A screenshot of the same iPhone 'Sound' settings page. In this view, the 'Door Bell' option is selected with a checkmark. The back arrow in the top left corner is highlighted with an orange square, indicating it should be tapped to return to the previous menu.	Saves your new Alert sound. Return to High Glucose Alert Menu.	Tap <i>Back Arrow</i>.

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Changing an Alert		
15		Return to Main Menu. Tap “X”.
16		Return to trend screen. Tap <i>Menu</i> icon Or Swipe right.

Any changes to the app will not carry over to the receiver. If using both, make the same changes in the receiver you made in your smart device. If you don't, you may miss an Alarm or Alert.

12.4 Changing Receiver Alarm and Alerts

You'll notice a flow difference between the app and the receiver when personalizing your Alarm/Alerts. With the app, all Alert adjustments are made from one screen, whereas in the receiver, you make changes in different screens.

Unlike the app, you change your receiver's tones (known as Profiles) through a number of different screens in the Profiles menu.

Profiles

Profiles determine the sound and volume of your Alarm and Alerts.

As mentioned in the previous chapter, the receiver uses a series of beeps/vibrations for an Alarm or Alert. The receiver doesn't have the same variety of tones as the app; however you can adjust their volume. While the receiver doesn't have a silent mode, selecting *Vibrate* will replace audible beeps with quiet vibrations. The only exception is the Alarm: the urgent low Alarm can't be turned off.

Changes made in *Profiles* are applied to all of the receiver's Alarm/Alerts. If you choose *Soft* (see next table), all Alerts are in Soft mode. In Chapter 10, you learned how many beeps each Alarm/Alert has.

Normal is the default setting for your receiver sound Profiles.







Attentive uses a rising or falling melody instead of beeps.

The receiver first vibrates when sending you an Alarm or Alert. If you clear the alert at the first vibration by pressing the *Select* button on your navigation wheel, you won't get any Alarm/Alert tones. If you would like to continue to get your Alarm or Alert after clearing, later in this chapter you'll learn about setting up Repeat Alerts.

HypoRepeat is very similar to the *Normal* Profile, but keeps repeating the fixed low alarm every 5 seconds until your sensor glucose value rises above 55 mg/dL or you confirm by pressing the *Select* button.

The next table lists the different sound Profiles, starting with the quietest, working its way up to the loudest.

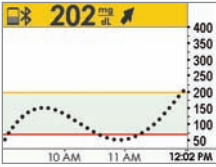

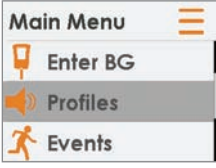
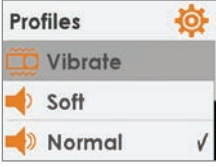
Alarm/Alert Sound Profiles

Icon	Profile name	Notification description
	Vibrate	Vibration only. Only sound is your receiver vibrating. Vibrate is not available for the Alarm.
	Soft	Lower volume beeps.
	Normal	Medium volume beeps. Default Profile.
	Attentive	No beeps. <ul style="list-style-type: none"> • Rising melody for High and Rising Alerts • Dropping melody for Low and Falling Alerts
	HypoRepeat	Medium volume beeps. Urgent low Alarm only. Repeats fixed low alarm every 5 seconds until sensor glucose reading rises above 55 mg/dL or is confirmed.
	Try It	Sample <i>Profile</i> setting before selecting.

After choosing your sound profile, changing it is just a few steps away! Change your *Profile* throughout the day depending on what lays ahead: In a meeting? Select *Vibrate*. Going to a ball game after work? Select *Attentive*.

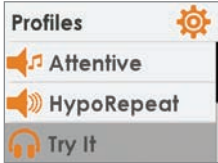
The next table shows how to change a sound Profile, then sample how it sounds.

Customizing Sound Profiles: Receiver

Step	What you see	What it means	What you do
1		Go to Main Menu.	Press <i>Select</i>.
2		Second Main Menu screen.	Press <i>Down Arrow</i>. <i>Profiles</i> on second screen.
3		Profiles adjusts volume of Alarm/Alerts.	Press <i>Up/Down Arrow</i>. Stop at <i>Profiles</i> . Press <i>Select</i>.
4		Choose sound <i>Profile</i> .	Press <i>Up/Down Arrow</i>. Stop at desired <i>Profile</i> . Press <i>Select</i>.

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Step	What you see	What it means	What you do
5		Selected <i>Profile</i> check marked.	Sample sound: Press Down Arrow. Stop at <i>Try It</i> . Press Select to have the sound play. Exit Profiles: Press Left Arrow.
6	N/A	Repeat as needed.	Repeat steps 2-5 to change Profile. To Exit: Press Left Arrow to <i>Main Menu</i> .

Profiles allow you to change your Alarm and Alerts tones. The Alerts menu gives you options for personalizing your glucose level Alerts, repeating Alerts, turning your Rising/Falling Alerts on and turning on your Signal Loss Alert.

Alerts Main Menu

Low/High Alert option lets you adjust your low/high glucose Alert level (mg/dL).

Advanced gives you options to turn on Low/High Repeat, Rise/Fall Alerts and Signal Loss Alert.

Low/High Repeat

In the previous chapter, you learned clearing an Alert stops it from repeating. If you want to continue to be re-alerted until your glucose levels are back in your target range, turn on the *Repeat* option.

Rise/Fall Rate

Your trend screen provides visual cues letting you know your sensor glucose readings are falling or rising rapidly.

Constantly looking at your screen may not be practical. You can customize your Rise/Fall Alert with vibrations or beeps letting you know when your glucose is rising or falling (2 mg/dL/min or 30 mg/dL up or down in 15 minutes) or rising or falling rapidly (3 or more mg/dL/min or 45 mg/dL or more up or down in 15 minutes).

The default setting for Repeat and Rise/Fall Rate is *Off*.

It's important you discuss your alert settings with your healthcare professional.

Signal Loss

Signal Loss Alert tells you when your transmitter and receiver aren't communicating. Set the Signal Loss and get alerted if your sensor glucose readings have stopped due to a signal loss anywhere from 20 to 200 minutes.

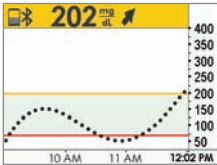
The default setting for Signal Loss is *On*.

Steps to Customize Receiver Alarm/Alerts

Using the same example from changing your app Alerts, let's change the receiver's High Alert notification level from 200 mg/dL to 190 mg/dL, repeating every 60 minutes.

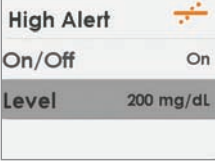
Follow the same steps turning on the Rise/Fall Alerts, and adjusting your Low Alerts.

Customizing Alerts: Receiver






Step	What you see	What it means	What you do
Change High Alert Level			
1		Go to Main Menu.	Press <i>Select</i>.

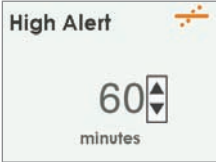

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Change High Alert Level			
2		Alerts option from the Main Menu.	Press Down Arrow. Stop at Alerts.
3		Enter Alerts menu option.	Press Select.
4		Alerts' option menu. Lists different Alerts: High/Low/Advanced (Repeat, Rise/Fall, Signal Loss) Alerts.	Press Up/Down Arrow. Stop at High Alert. Press Select.
5		Alert's current settings. Change your current High Alert level.	Press Down Arrow. Stop at Level. Press Select.
6		Current setting. Use Up/Down arrows to change your High Alert level (mg/dL).	Press Down Arrow. Stop at 190 mg/dL.

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Change High Alert Level			
7		Saves new High Alert level. Return to Alerts Menu.	Press Select. To exit: Press Left Arrow.
Turn Repeat On			
8		Alerts Menu. Choose Advanced to get to Repeat Alert.	Press Down Arrow. Stop at Advanced.
9		Enter Advanced Alert options.	Press Select on Advanced.
10		Main Advanced screen. Set Repeat Alerts. Turn On Rise/Fall Rate Alerts.	Arrow to High Repeat. Press Select.
11		Initial screen shows current repeat minutes. Change time frame in 5 minute increments.	Press Up/Down Arrow. Stop at 60 minutes.

Turn Repeat On			
12		Changed <i>Repeat</i> time for High Alert.	Press <i>Select</i>.
13		Changed completed. Return to <i>Alerts Menu</i> .	To exit: Press <i>Left Arrow</i>.

It doesn't matter which device you first use to customize your Alarm/Alert settings, key is making sure you make the same changes in both or you may miss an Alarm or Alert.

Summary

Now You Can:

- Customize your glucose trend Low/High level notifications
 - Dexcom G5 Mobile App
 - Dexcom G5 Mobile Receiver
- Adjust Alarm tones
- Set up receiver's Advanced Alerts
 - Low/High Repeat
 - Rise/Fall Rate
 - Signal Loss

What's Next?

Believe it or not, you are becoming a pro at using your Dexcom G5 Mobile CGM System! You've set up the app and receiver, started a session, calibrated, followed your glucose trends, paid attention to your Alarm/Alerts, prompts, and ended a session!

The next chapters begin our fourth part of the user guide: information you need to know, but unlike the previous chapters, typically not part of your day-to-day Dexcom G5 Mobile CGM System experience.

The next part, Part 4: Everything Else G5, reviews the technical specifications, the warranty, how to take care of the Dexcom G5 Mobile components, going through security when traveling, contacting the Help Desk, Troubleshooting information, and symbols on system components and packages.

4

EVERYTHING ELSE G5

- Warranty
- Maintenance
- Travel Tips
- Customer Service Contacts
- Technical Information
- Troubleshooting
- Package Symbols

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Chapter 13

Everything Else G5: Warranty: The Fine Print

13.1 Introduction

Sometimes stuff happens. Dexcom has you covered!

The following is our warranty information outlining what we do cover, what we don't and for how long. First the receiver's limited warranty information, then the transmitter's limited warranty information.

13.2 Receiver Warranty Information

Dexcom G5 Mobile CGM System's Limited Warranty

What's Covered and for How Long?

Dexcom, Inc. ("Dexcom") provides a limited warranty to the original purchaser ("you" or "Purchaser") that the Dexcom G5 Mobile Receiver (the "Receiver") is free from defects in material and workmanship under normal use ("Limited Warranty") for the period starting from the shipment date and continuing for a year following the shipment date ("Warranty Period"):

Dexcom G5 Mobile Receiver: **1 year** from shipment date

NOTE: If you received this Receiver as a replacement for an in-warranty Receiver, the Limited Warranty for the original Receiver shall continue for the Warranty Period on the original Receiver, but the replacement is not subject to any other warranty.

What's Not Covered?

This Limited Warranty is based on the Purchaser properly using the CGM system in accordance with the documentation provided by Dexcom. You are not permitted to use the CGM system otherwise. You understand that misusing the CGM system, improperly accessing it or the information it processes and transmits, "jailbreaking" your CGM system or cell phone, and taking other unauthorized actions may put you at risk, cause the CGM system to malfunction, is not permitted and voids your Limited Warranty.

This Limited Warranty does not cover:

1. Defects or damage resulting from accident, misuse, abuse, neglect, unusual physical, electrical or electromechanical stress, modification of any part of the product, or cosmetic damage.
2. Equipment with the ID number removed or made illegible.
3. All surfaces and other externally exposed parts that are scratched or damaged due to normal use.
4. Malfunctions resulting from the use of the Receiver in conjunction with accessories, ancillary products, and peripheral equipment, whether hardware or software, not furnished or approved by Dexcom.
5. Defects or damage from improper testing, operation, maintenance, installation, or adjustment.
6. Installation, maintenance, and service of products or services other than the CGM system (which may be subject to a separate limited warranty), whether provided by Dexcom or any other party; this includes your cell phone or smart device and your connection to the Internet.
7. Equipment which has been taken apart physically or which has had any of its software accessed in any unauthorized manner.
8. Water damage to the Receiver.
 - a. Receiver is not water resistant.
 - b. Do not get the receiver wet at any time.

Dexcom's Obligations Under the Limited Warranty

During the Warranty Period, Dexcom will replace, without charge to purchaser, any defective Dexcom G5 Mobile Receiver.

To return, you must send the Receiver to an authorized Dexcom Technical Support Department. Make sure you package the Receiver adequately for shipping.

The return package needs to include:

1. Receiver
2. Sales receipt or comparable substitute proof of sale showing the date of purchase
3. Receiver's Serial Number
4. Seller's name and address

Call Dexcom Technical Support Department for delivery information help:

- Toll free: **1.877.339.2664**
- Charges may apply: **1.858.200.0200**

Upon receipt, Dexcom will promptly replace the defective Receiver.

If Dexcom determines the Receiver isn't covered by this Limited Warranty, Purchaser must pay all shipping charges for the Receiver's return by Dexcom.

Limits on Dexcom's Warranty and Liability Obligations

The Limited Warranty described above is the exclusive warranty for the Receiver, and in lieu of all other warranties, expressed or implied, either in fact or by operation of law, statutory or otherwise.

Dexcom expressly excludes and disclaims all other warranties, including without limitation any warranty of merchantability, fitness for a particular purpose, or non-infringement, except to the extent prohibited by applicable law.

Dexcom shall not be liable for any special, incidental, consequential, or indirect damages, however caused, and on any theory of liability, arising in any way out of the sale, use, misuse, or inability to use, any Dexcom G5 Mobile CGM System or any feature or service provided by Dexcom for use with the Dexcom G5 Mobile CGM System.

These limits on Dexcom's warranty and liability obligations apply even if Dexcom, or its agent, has been advised of such damages and notwithstanding any failure of essential purpose of this Limited Warranty and the limited remedy provided by Dexcom.

This Limited Warranty is only provided to the original Purchaser and can't be transferred to anyone else, and states Purchaser's exclusive remedy.

If any portion of this Limited Warranty is illegal or unenforceable by reason of any law, such partial illegality or enforceability shall not affect the enforceability of the remainder of this Limited Warranty. This Limited Warranty will be enforced to the maximum extent permitted by law.

13.3 Transmitter Warranty Information

Dexcom G5 Mobile Transmitter Limited Warranty

What's Covered and for How Long?

Dexcom, Inc. ("Dexcom") provides a limited warranty to the original purchaser that the Dexcom G5 Mobile Transmitter is free from defects in material and workmanship under normal use for the period commencing on the date of first use by the original purchaser (the "Date of First Use") and expiring three (3) months thereafter; provided, that, the Date of First use occurs within five (5) months of the date of shipment (or disbursement) of the transmitter to the original purchaser.

NOTE: If you received this Transmitter as a replacement for an in-warranty Transmitter, the Limited Warranty for the original Transmitter shall continue for the Warranty Period on the original Transmitter, but the replacement is not subject to any other warranty.

What's Not Covered?

This Limited Warranty is based on the Purchaser properly using the CGM system in a timely manner and in accordance with the documentation provided by Dexcom. You are not permitted to use the CGM system otherwise. You understand that misusing the CGM system, improperly accessing it or the information it processes and transmits, “jailbreaking” your CGM system or cell phone, and taking other unauthorized actions may put you at risk, cause the CGM system to malfunction, is not permitted and voids your Limited Warranty.

This Limited Warranty does not cover:

1. Defects or damage resulting from accident, misuse, abuse, neglect, unusual physical, electrical or electromechanical stress, modification of any part of the product, or cosmetic damage.
2. Equipment with the ID number removed or made illegible.
3. All surfaces and other externally exposed parts that are scratched or damaged due to normal use.
4. Malfunctions resulting from the use of the Transmitter in conjunction with accessories, ancillary products, and peripheral equipment, whether hardware or software, not furnished or approved by Dexcom.
5. Defects or damage from improper testing, operation, maintenance, installation, or adjustment.
6. Installation, maintenance, and service of products or services other than the CGM system (which may be subject to a separate limited warranty), whether provided by Dexcom or any other party; this includes your cell phone or smart device and your connection to the Internet.
7. Equipment which has been taken apart physically or which has had any of its software accessed in any unauthorized manner.
8. Water damage to Transmitter.
 - a. Beyond specifications listed in Dexcom G5 Mobile CGM System's User Guide.
 - b. User Guide is included in the Dexcom G5 Mobile System's Receiver package.
 - c. Located on dexcom.com.

13.4 Dexcom's Obligations Under the Limited Warranty

During the Warranty Period, Dexcom will replace, without charge to purchaser, any defective Dexcom G5 Mobile Transmitter.

To return, you must send the Transmitter to an authorized Dexcom Technical Support Department. Make sure you package the Transmitter adequately for shipping.

The return package needs to include:

1. Transmitter
2. Sales receipt or comparable substitute proof of sale showing the date of purchase
3. Transmitter's Serial Number
4. Seller's name and address

Call Dexcom Technical Support Department for delivery information or help:

- Toll free: **1.877.339.2664**
- Charges may apply: **1.858.200.0200**

Upon receipt, Dexcom will promptly replace the defective Transmitter.

If Dexcom determines the Transmitter isn't covered by this Limited Warranty, Purchaser must pay all shipping charges for the Transmitter's return by Dexcom.

Limits on Dexcom's Warranty and Liability Obligations

The Limited Warranty described above is the exclusive warranty for the Transmitter, and in lieu of all other warranties, expressed or implied, either in fact or by operations of law, statutory or otherwise.

Dexcom expressly excludes and disclaims all other warranties, including without limitation any warranty merchantability, fitness for a particular purpose, or non-infringement, except to the extent prohibited by applicable law.

Dexcom shall not be liable for any special, incidental, consequential, or indirect damages, however caused, and on any theory of liability, arising in any way out of the sale, use, misuse, or inability to use, any Dexcom G5 Mobile CGM System or any feature or service provided by Dexcom for use with the Dexcom G5 Mobile CGM System.

These limits on Dexcom's warranty and liability obligations apply even if Dexcom, or its agent, has been advised of such damages and notwithstanding any failure of essential purpose of this Limited Warranty and the limited remedy provided by Dexcom.

This Limited Warranty is only provided to the original Purchaser and can't be transferred to anyone else, and states Purchaser's exclusive remedy.

If any portion of this Limited Warranty is illegal or unenforceable by reason of any law, such partial illegality or enforceability shall not affect the enforceability of the remainder of this Limited Warranty.

This Limited Warranty will be enforced to the maximum extent permitted by law.

Chapter 14

Everything Else G5:

How to Take Care of Your Dexcom G5 Mobile CGM System

14.1 Introduction

There are not a lot of moving parts in the Dexcom G5 Mobile CGM System, so maintenance is relatively simple: keep it clean, keep display device (s) dry and protected, use accessory parts, like the USB cable, etc., given to you with the system and store according to each piece's labeling instructions.

This chapter only covers Dexcom parts (sensor, transmitter, and receiver). Follow the manufacturer's instructions when caring for your smart device.

After this chapter, you will be able to:

1. Demonstrate proper maintenance
 - a. Sensor
 - b. Transmitter
 - c. Receiver
 - d. Charge receiver battery
2. Determine what accessories you may use
3. Identify the best storage methods
 - a. Sensor
 - b. Transmitter
 - c. Receiver
4. How to safely dispose of
 - a. Sensor
 - b. Transmitter
 - c. Receiver

14.2 Basic Maintenance

Sensor

1. Keep in sterile package until ready for use.
2. Check package label for expiration date.
 - a. Expiration date format is YYYY-MM-DD (year-month-day) format.
 - b. Don't use if sensor has expired.
 - i. May provide inaccurate sensor glucose readings.
 - ii. May be unsterile.

Transmitter

1. Keep in box until ready for use.
 - a. Check transmitter and don't use if damaged.
2. Transmitter is reusable, however only by the same person.
 - a. Never share transmitter with anyone.
3. Between uses, clean outside of the transmitter with damp cloth or alcohol wipes. Let dry before use or storage.
4. When not in use.
 - a. Protect transmitter by returning to its packaging or another safe place.
 - b. Store between 32° F-113° F.

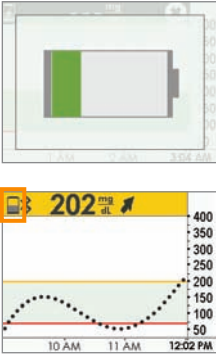

Receiver

1. Check receiver casing, if it's cracked or damaged, don't use.
 - a. May get an electric shock.
2. Keep receiver dry—it is only splash resistant.
 - a. Don't submerge in liquid.
 - b. Don't spill fluids on receiver.
3. Keep battery charged.
 - a. Only use Dexcom USB charging/download cable.
4. Keep the micro USB port cover closed if not using USB cable.
 - a. Prevents fluid from getting inside receiver.

Charging Receiver's Battery



The receiver's status bar lets you see its battery level and prompts you when the battery is getting low. While the receiver is being charged, you will continue to get your sensor glucose readings if the transmitter and receiver are within 20 feet of each other.

Each charge lasts approximately three days. If your receiver's battery was drained, after charging, you may need to reset its time and date. If this is required, the system tells you to reset and takes you to the time/date setting screens.

Step	What you see	What it means	What you do
1		Low Battery	Charge your battery.
2		Micro USB Port	Open <i>USB port door</i> . Plug <i>USB cable</i> into port for recharging.

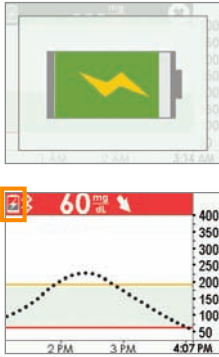
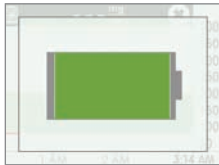

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Step	What you see	What it means	What you do
3		Micro USB Cable	<p>Plug into <i>receiver</i> to charge battery.</p> <p>Don't plug into a computer port to charge</p> <p>Don't use an external USB hub, it doesn't provide enough power to charge battery.</p> <p>Battery can only be charged using the adapter/wall charger.</p> <p>Charge battery before each new sensor session.</p>
4		Wall Charger	<p>Plug <i>USB cable</i> into <i>adapter/wall charger</i>.</p> <p>Plug wall charger into an electrical outlet to charge receiver's battery.</p> <p>Don't block access to the charger.</p>

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Step	What you see	What it means	What you do
5		Battery Charging	Keep charging until icons are solid.
6		Battery Charged	Unplug wall charger from outlet when fully charged.
6		USB Port Door	Remove USB cable from receiver. Close USB port door after removing USB cable to keep receiver clean and dry.

Accessories

1. Only use Dexcom-supplied parts (including cables and chargers).
 - a. Use of non-Dexcom supplied parts may affect safety and performance.
2. Insert cables only as directed.
 - a. Do not force cables in place.
3. Look at cables for signs of wear and tear. Do not use if worn or damaged.

There is no repair service available for any Dexcom G5 Mobile CGM System parts.

If you experience problems, call Dexcom Technical Support, available 24 hours, 7 days a week, toll free at **1.877.339.2664** or toll at **1.858.200.0200** to report the issue.

14.3 Storage

Storing your Dexcom G5 Mobile CGM System correctly helps prevent system failures.

Sensor

1. Keep the sensor in its sterile packaging until you are ready to use it.
2. Store at temperatures between 36° F-77° F.
 - a. Stored outside of this range may cause inaccurate sensor glucose readings.
 - b. May store in refrigerator if it's within this temperature range.
 - c. Sensors should not be stored in freezer.
3. Store at humidity levels between 15%-85% relative humidity.

Transmitter

1. Keep transmitter protected when not in use.
2. Store at temperatures between 32° F-113° F.
3. Store at humidity levels between 10%-95% relative humidity.

Receiver

1. Keep receiver protected when not in use.
2. Fully charge the battery before storing for over 3 months.
3. Store at temperatures between 32° F-104° F.
4. Store at humidity levels between 10%-95% relative humidity.

14.4 Checking App and Receiver Information

CHECKING YOUR APP & RECEIVER SOFTWARE VERSION

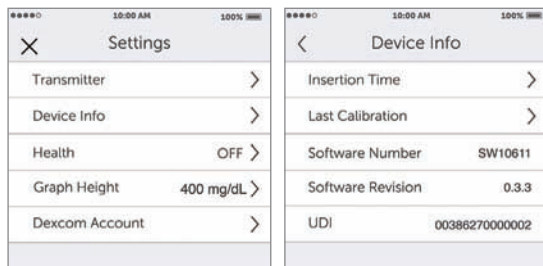
You can check your app or receiver for information about your CGM system at any time.

Receiver



1. From the Settings menu, **press Up or Down arrows** to scroll to “Device Info.”
2. **Press Select.** Information about your sensor session and system will show.

App



1. From Main Menu, **tap Settings.**
2. **Tap Device Info.**

Available Information

- Insertion Time
- Last Calibration
- Transmitter Battery
- Transmitter SN
- Serial Number
- Part Number
- Part Revision
- Software Number

14.5 System Disposal

Different municipalities have different requirements when throwing away electronics (receiver and transmitter) and parts that have come in contact with blood or other bodily fluids (sensor).

Consult your area's local waste management authorities for proper disposal instructions.

Taking care of your Dexcom G5 Mobile CGM System is pretty easy. In the next chapter, traveling with your Dexcom G5 Mobile CGM System, you'll learn how simple it is to see the world with your Dexcom G5 Mobile CGM System!

Chapter 15

Everything Else G5:

On the Go With Dexcom G5 Mobile CGM System: Getting Through Security

15.1 Introduction

Dexcom G5 Mobile can be a great travel companion; you can go through metal detectors, be handwanded, and even keep your receiver on during your flight.

This chapter only covers the Dexcom G5 Mobile CGM System. It doesn't cover steps you need to take when traveling with your smart device. See your smart device's instruction for use to learn how to travel with it.

After this chapter, you will be able to:

1. Explain proper procedure if you prefer a full body pat down.
2. Describe steps needed for a TSA officer to inspect Dexcom G5 Mobile CGM System components.
3. Identify when your display device(s) can be on during a flight.
4. Contact TSA directly with your security questions.

15.2 Going Through Security

Walk-Through Metal Detectors

Transmitter and Sensor

No worries about wearing your transmitter and sensor when going through security.

Go through walk-in metal detectors or, if you prefer, be handwanded without worrying about damaging your transmitter or sensor.

If you're concerned or uncomfortable about walking through the metal detector, the Transportation Security Administration (TSA) requests you tell the Security Officer you're wearing a continuous glucose monitor and want a full-body pat-down with a visual inspection of your sensor and transmitter.

Let the Security Officer know the sensor can't be removed because it's inserted under the skin.

X-Ray Machines

Receiver, Extra Sensors

Don't put your Dexcom G5 Mobile CGM System components through x-ray machines.

Before your screening process begins, ask the TSA Officer to perform a visual inspection of the receiver and your extra sensors. Place all Dexcom G5 Mobile components in a separate bag before handing over to the Security Officer.

For other medical supplies, such as medications, meters, and strips, check manufacturer's instructions or the TSA website.

Body Scanners

Use of AIT body scanners has not been studied and therefore we recommend hand-wanding or full body pat down and visual inspection in those situations.

In the Plane

You may keep the receiver on:

1. Before take-off
2. While in flight
3. After landing

The Dexcom G5 Mobile CGM System is safe for use on U.S. commercial airlines.

If you choose to use your smart device, the airlines request you put your smart devices in airplane mode. You can do this, but still keep your *Bluetooth* on and you will be able to receive sensor glucose information on your smart device.

Technical Information

The Dexcom G5 Mobile Transmitter is an M-PED with emission levels that meet RTCA/DO160, Section 21, Category M. Per FAA Advisory, Circular #91-21, 1B, dated 8/25/06.

Any M-PED that meets this standard in all modes may be used onboard the aircraft without any further testing by the operator.

This device can withstand exposure to common electrostatic (ESD) and electromagnetic interference (EMI).

Still Have Questions?

Visit the TSA's website if you have any questions or concerns at tsa.gov.

Email: TSA-ContactCenter@dhs.gov

Phone: Call 1.866.289.9673

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Chapter 16

Everything Else G5: Need Help? You're Not Alone!

Dexcom has two support teams to help you, each with their own specialty:

- Technical Support Team
- Patient Care Team

16.1 Dexcom Technical Support

Provides replacement units, resolves technical issues or takes product complaints.

Call your Dexcom Technical Support Team, 24 hours a day, 7 days a week, if something is wrong with your Dexcom G5 Mobile CGM System.

By Phone

Dexcom Technical Support Phone Numbers:

Toll Free: **1.877.339.2664**

Toll Call: **1.858.200.0200**

By Email

Email: TechSupport@dexcom.com

If you prefer to email, to help us help you best, include the following information in your email:

- Name of patient
- Date of Birth
- The technical issue you
- When the problem happened (date and time)
- Patient's address
- Patient's phone number
- Item SKU number and description (e.g., name of the device)
- Lot number and/or serial number(s) of affected devices (e.g., sensor)

What Can They Help Me With?

The Dexcom Technical Support Team helps you with all CGM system related issues as well as software related issues.

Dexcom Technical Support does not offer medical advice.

16.2 Patient Care Team



The Patient Care Team (PCT) is a group of Certified Diabetes Educators (CDE®) and Registered Nurses (RNs) offering you customer care and individualized education services around Dexcom CGM.

Your PCT provides education and support throughout your CGM experience, such as:

- Initial CGM Product Training
- Ongoing Dexcom product education (e.g., how to use a specific feature)
- How to maximize Dexcom CGM use
- Dexcom CGM reporting software and features
- How to review and understand Dexcom CGM reports

By Phone

Available Monday-Friday 5:30 am-8:00 pm PST (subject to change)

Toll Free: **1.877.339.2664**

Toll Call: **1.858.200.0200**

By Email

Email: patientcare@dexcom.com

If you prefer to email, to help us help you best, include the following information in your email:

- Name
- DOB
- Contact phone number
- Reason for inquiry or education needed

For additional Dexcom CGM education, check the Dexcom website:
dexcom.com/web-based-education

16.3 Sales Support Team

Inside Sales Support Team

For help with:

- First-time orders
- Re-orders
- Tracking shipments
- Locating a local Dexcom representative

By Phone

Dexcom Inside Sales Support Phone Numbers:

Toll Free: **1.877.339.2664**

Toll Call: **1.858.200.0200**

By Email

Dexcom Inside Sales Support Email: CustomerService@dexcom.com

By Fax

1.877.633.9266

16.4 Corporate

Dexcom Website:

Dexcom.com

Dexcom Address:

6340 Sequence Drive
San Diego, CA 92121

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Chapter 17

Everything Else G5:

Technical Information

17.1 Device Performance Characteristics

NOTE: We recommend that you review the information in this chapter with your healthcare professional to understand how well the Dexcom G5 Mobile CGM System performs.

The Dexcom G5 Mobile CGM System (the System) uses a glucose sensor to continuously measure and monitor your glucose levels. The sensor is “calibrated” using a commercially available blood glucose meter. Once calibrated, the System reports glucose readings up to every 5 minutes. The System was evaluated clinical studies in which System readings were compared to blood glucose values to assess its performance and how well the System readings compare to a laboratory test method that measures blood glucose values. Additionally, subjects performed self-monitoring blood glucose meter tests at home to assess the System performance in real use environment.

Although the performance characteristics of the System are presented in the following, there is no commonly accepted statistical approach for capturing performance of continuous glucose monitors (CGMs), such as the Dexcom G5 Mobile CGM System.

Clinical Study Overview

The System performance was evaluated in four separate prospective clinical studies. Two studies included adults, and two studies included pediatrics. In the following sections and tables, the studies will be identified as follows:

Adult Studies (18 years and older)

Original Adult Study: the Receiver included software version SW10050

Software 505 Adult Study: the Receiver included software version SW10505

Pediatric Studies (2 to 17 years)

Original Pediatric Study: the Receiver included software version SW10050

Software 505 Pediatric Study: the Receiver included software version SW10505

The Dexcom G5 Mobile CGM System incorporates the algorithm from software version SW10505 and has a new software number.

Overview of Adult Studies

The System performance for adults was evaluated in two separate prospective clinical studies:

Original Adult Study (software SW10050) and the **Software 505 Adult** Study (software SW10505).

Differences between the studies include the number of subjects enrolled, the number of Systems worn by each participant, the SMBG meter used, and the number of clinic days each subject participated in during the study. An overview of each study is provided here.

The **Original Adult** Study enrolled 72 subjects, and the **Software 505 Adult** Study enrolled 51 subjects. All subjects had Type 1 or Type 2 diabetes mellitus, and required insulin or oral medication to manage their diabetes. In the **Original Adult** Study, 83% of subjects had Type 1 diabetes, and 17% of subjects had Type 2 diabetes. In the **Software 505 Adult** Study, 86% of subjects had Type 1 diabetes, and 14% of subjects had Type 2 diabetes. Both studies included subjects greater than 18 years of age.

Subjects in both studies used the System for seven days. In the **Original Adult** Study, thirty-six subjects each wore 2 sensors; in the **Software 505 Adult** Study, all subjects wore 1 sensor only. Throughout the 7-day wear period, the sensor was calibrated with an average of 2 fingersticks per day (approximately once every 12 hours). In the **Original Adult** Study, subjects used the LifeScan® OneTouch® Ultra®2 meter and in the **Software 505 Adult** Study, subjects used Bayer's CONTOUR® NEXT USB meter.

In the **Original Adult** Study, all subjects were evaluated in a controlled clinic environment on all three clinic days: Day 1, Day 4, and Day 7 of the 7-day wear period. In the **Software 505 Adult** Study, subjects were evaluated in one of the three clinic days so there are fewer data samples than in the **Original Adult** Study. While using the System in the clinic, subjects had their blood glucose measured every 15 minutes with a reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the "YSI." Readings from the System were reported every 5 minutes and paired with YSI values in order to characterize how well the System readings agreed with laboratory standard blood glucose results. The remainder of the study took place at home, and the System performance was also paired with the comparative meter results, referred to as the "SMBG."

Overview of Pediatric Studies

The System performance for children and adolescents was evaluated in two separate prospective clinical studies: the **Original Pediatric** Study (SW10050) and the **Software 505 Pediatric** Study (SW10505). Differences between the studies include the number of subjects enrolled, the number of Systems worn by each participant, the SMBG meter used, the length of time subjects were evaluated in a controlled clinic environment and whether or not subjects ages 13-17 had their glucose levels intentionally manipulated during the study. An overview of each study is provided here.

The **Original Pediatric** Study enrolled 176 subjects, with 16% of subjects younger than 6-years old, and the **Software 505 Pediatric** Study enrolled 79 subjects, with 20% of subjects younger than 6-years old. All subjects had Type 1 or Type 2 diabetes mellitus and required insulin or oral medication to manage their diabetes. In the **Original Pediatric** Study, about 99% of subjects had Type 1 diabetes and 1% had Type 2 diabetes. In the **Software 505 Pediatric** Study, all subjects had Type 1 diabetes. Sensors were inserted in either the abdomen or upper buttocks.

Subjects in all studies used the System for seven days. In the **Original Pediatric** Study, all subjects wore 2 sensors; in the **Software 505 Pediatric** Study, all subjects wore 1 sensor only. Throughout

the 7-day wear period, the sensors were calibrated with an average of 2 fingersticks per day (approximately once every 12 hours), using self-monitoring blood glucose (SMBG) meter values. The **Original Pediatric** Study used the LifeScan® OneTouch® Verio® IQ meter; the **Software 505 Pediatric** Study used Bayer's CONTOUR® NEXT USB meter.

All subjects were evaluated in a controlled clinic environment on Day 1, Day 4 or Day 7 of the 7-day wear period. While using the System in the clinic, subjects provided at least two fingerstick measurements per hour, and subjects ages 6-17 also provided venous blood for comparison to a laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the "YSI." In the **Original Pediatric** Study, subjects' glucose levels were not intentionally manipulated during this study; in the **Software 505 Pediatric** Study, subjects ages 13-17 had their glucose levels intentionally manipulated during the clinic session. Readings from the System were reported every 5 minutes and paired with YSI values collected every 15 minutes in order to characterize how well the System readings agreed with laboratory standard blood glucose results. The remainder of the study took place at home, and the System performance was also paired with the comparative meter results, referred to as the "SMBG."

Table 1-A. System Agreement to YSI within CGM Glucose Ranges (Adult)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of Paired CGM-YSI	Percent Within 15/15% YSI	Percent Within 20/20% YSI	Percent Within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Original	9152	71%	82%	92%	3%
	Software 505	2263	86%	93%	98%	1%
40-60	Original	512	67%	78%	88%	6%
	Software 505	120	89%	94%	98%	0%
61-80	Original	781	73%	85%	94%	2%
	Software 505	226	91%	96%	99%	0%
81-180	Original	3853	67%	78%	91%	3%
	Software 505	738	84%	92%	98%	1%
181-300	Original	2784	72%	84%	93%	4%
	Software 505	798	86%	93%	98%	1%
301-350	Original	775	82%	91%	97%	2%
	Software 505	229	86%	94%	98%	1%
351-400	Original	447	74%	84%	91%	5%
	Software 505	152	80%	92%	97%	0%

¹CGM readings are within 40-400 mg/dL, inclusive.

²Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 1-B. System Agreement to YSI within CGM Glucose Ranges (Pediatric)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of Paired CGM-YSI	Percent Within 15/15% YSI	Percent Within 20/20% YSI	Percent Within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Original	2922	55%	68%	85%	7%
	Software 505	2262	81%	91%	96%	2%
40-60	Original	19	63%	74%	79%	21%
	Software 505	86	54%	74%	91%	3%
61-80	Original	76	61%	82%	92%	4%
	Software 505	142	77%	82%	90%	3%
81-180	Original	1155	56%	69%	84%	6%
	Software 505	805	78%	88%	97%	1%
181-300	Original	1380	55%	68%	85%	7%
	Software 505	957	89%	96%	99%	1%
301-350	Original	206	48%	62%	80%	11%
	Software 505	209	81%	91%	94%	5%
351-400	Original	86	48%	61%	79%	12%
	Software 505	63	64%	81%	83%	8%

¹CGM readings are within 40-400 mg/dL, inclusive.

²Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Agreement Relative to YSI

Agreement between the System and blood glucose values is characterized using paired System and YSI values. The System and YSI results were compared by pairing the YSI blood glucose value to a System glucose reading that occurred immediately after the YSI was collected.

The agreement of the System to blood glucose value was assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and greater than 40% of the YSI values. For readings less than or equal to 80 mg/dL the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 80 mg/dL the absolute percent difference (%) from the YSI values was calculated. The percentages of total readings within 15 mg/dL or 15%, 20 mg/dL

or 20%, 30 mg/dL or 30% or greater than 40 mg/dL or 40% are provided in Table 1-A and 1-B. The tables are categorized within CGM glucose ranges. When you see a CGM reading on your receiver, this table shows you how likely that reading matches your blood glucose level (measured by YSI in the study).

For example, in the **SW10505 Adult** Study (Table 1-A), the total number of data pairs considered in the analysis was 2263. Of these, 93% of the System readings fall within ± 20 mg/dL of the YSI blood glucose values ≤ 80 mg/dL and within $\pm 20\%$ of YSI blood glucose values > 80 mg/dL.

Table 2-A. Number and Percentage of YSI Values When CGM Readings are “LOW” or “HIGH” (Adult)

			YSI mg/dL					Total
CGM Readings	Study ¹	CGM-YSI Pairs	< 55	< 60	< 70	< 80	≥ 80	
“LOW”	Original	n	66	84	123	142	13	155
		Cumulative Percent	42%	54%	79%	92%	8%	
	Software 505	n	11	16	17	18	0	18
		Cumulative Percent	61%	89%	94%	100%	0%	
			YSI mg/dL					Total
CGM Readings	Study ¹	CGM-YSI Pairs	> 340	> 320	> 280	> 240	≤ 240	
“HIGH”	Original	n	189	220	238	246	2	248
		Cumulative Percent	76%	89%	96%	99%	1%	
	Software 505	n	40	43	45	45	0	45
		Cumulative Percent	89%	96%	100%	100%	0%	

¹Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 2-B. Number and Percentage of YSI Values When CGM Readings are “LOW” or “HIGH” (Pediatric)

			YSI mg/dL					Total
CGM Readings	Study ¹	CGM-YSI Pairs	< 55	< 60	< 70	< 80	≥ 80	
“LOW”	Original	n	0	0	0	0	13	13
		Cumulative Percent	0%	0%	0%	0%	100%	
	Software 505	n	3	5	10	15	1	16
		Cumulative Percent	19%	31%	63%	94%	6%	
			YSI mg/dL					Total
CGM Readings	Study ¹	CGM-YSI Pairs	> 340	> 320	> 280	> 240	≤ 240	
“HIGH”	Original	n	38	51	68	69	1	70
		Cumulative Percent	54%	73%	97%	99%	1%	
	Software 505	n	14	19	22	23	1	24
		Cumulative Percent	58%	79%	92%	96%	4%	

¹Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Agreement When CGM Reads “LOW” or “HIGH”

The System reports glucose readings between 40 and 400 mg/dL. When the System determines the glucose reading is below 40 mg/dL, it displays “LOW” in the Receiver Status Box. When the Dexcom G5 Mobile System determines that the glucose level is above 400 mg/dL, it displays “HIGH” in the Receiver Status Box. Because the System does not display glucose values below 40 mg/dL or above 400 mg/dL, the comparisons to the actual blood glucose levels (as determined by the YSI analyzer) when CGM is classified as “LOW” or “HIGH” are included separately in Table 2-A and 2-B. The tables include the numbers and the cumulative percentages when YSI values were less than certain glucose levels (for “LOW”), and when YSI values were greater than certain glucose levels (for “HIGH”).

For example, in the **Software 505 Adult** Study (Table 2-A), when the System displayed “LOW” (18 occasions), 100% (18 out of 18) of the YSI values were less than 80 mg/dL, and 94% (17 out of 18) of the YSI values were less than 70 mg/dL. When the System displayed “HIGH” (45 occasions), 100% (45 out of 45) of the YSI values were greater than 240 mg/dL, and 100% (45 out of 45) of the YSI values were greater than 280 mg/dL.

Table 3-A. Concurrence of CGM Readings and YSI Values (Original Adult Study)

CGM (mg/dL)	YSI (mg/dL) Row Percentage of Matched Pairs in each CGM Glucose Range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	6%	48%	37%	7%	1%	0%	0%	0%	0%	0%	0%	155
40-60	4%	49%	36%	11%	1%	0%	0%	0%	0%	0%	0%	512
61-80	0%	22%	51%	24%	1%	0%	0%	0%	0%	0%	0%	781
81-120	0%	2%	17%	66%	13%	1%	0%	0%	0%	0%	0%	1706
121-160	0%	0%	1%	25%	60%	13%	2%	0%	0%	0%	0%	1492
161-200	0%	0%	0%	2%	28%	53%	16%	2%	0%	0%	0%	1240
201-250	0%	0%	0%	0%	3%	21%	51%	21%	3%	1%	0%	1181
251-300	0%	0%	0%	0%	0%	4%	19%	49%	24%	3%	0%	1018
301-350	0%	0%	0%	0%	0%	0%	3%	28%	51%	16%	1%	775
351-400	0%	0%	0%	0%	0%	0%	3%	10%	43%	38%	7%	447
> 400	0%	0%	0%	0%	0%	0%	1%	6%	21%	57%	15%	248

Table 3-B. Concurrence of CGM Readings and YSI Values (Software 505 Adult Study)

CGM (mg/dL)	YSI (mg/dL) Row Percentage of Matched Pairs in each CGM Glucose Range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	6%	83%	11%	0%	0%	0%	0%	0%	0%	0%	0%	18
40-60	2%	74%	22%	3%	0%	0%	0%	0%	0%	0%	0%	120
61-80	0%	19%	68%	13%	0%	0%	0%	0%	0%	0%	0%	226
81-120	0%	0%	19%	72%	8%	1%	0%	0%	0%	0%	0%	347
121-160	0%	0%	0%	17%	72%	11%	0%	0%	0%	0%	0%	246
161-200	0%	0%	0%	0%	25%	59%	16%	0%	0%	0%	0%	286
201-250	0%	0%	0%	0%	0%	16%	70%	13%	1%	0%	0%	376
251-300	0%	0%	0%	0%	0%	2%	16%	61%	14%	7%	0%	281
301-350	0%	0%	0%	0%	0%	0%	2%	28%	59%	10%	1%	229
351-400	0%	0%	0%	0%	0%	0%	0%	4%	47%	45%	5%	152
> 400	0%	0%	0%	0%	0%	0%	0%	0%	20%	38%	42%	45

Table 3-C. Concurrence of CGM Readings and YSI Values (Original Pediatric Study)

CGM (mg/dL)	YSI (mg/dL) Row Percentage of Matched Pairs in each CGM Glucose Range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	0%	0%	0%	54%	31%	15%	0%	0%	0%	0%	0%	13
40-60	0%	21%	58%	16%	5%	0%	0%	0%	0%	0%	0%	19
61-80	0%	21%	45%	30%	4%	0%	0%	0%	0%	0%	0%	76
81-120	0%	1%	20%	66%	12%	1%	0%	0%	0%	0%	0%	338
121-160	0%	0%	1%	36%	54%	7%	1%	0%	0%	0%	0%	511
161-200	0%	0%	0%	4%	40%	48%	6%	1%	0%	0%	0%	596
201-250	0%	0%	0%	1%	9%	44%	41%	5%	0%	0%	0%	658
251-300	0%	0%	0%	0%	2%	7%	50%	36%	3%	0%	2%	432
301-350	0%	0%	0%	0%	0%	2%	18%	59%	21%	0%	0%	206
351-400	0%	0%	0%	0%	0%	0%	3%	28%	50%	16%	2%	86
> 400	0%	0%	0%	0%	0%	0%	1%	14%	41%	36%	7%	70

Table 3-D. Concurrence of CGM Readings and YSI Values (Software 505 Pediatric Study)

CGM (mg/dL)	YSI (mg/dL) Row Percentage of Matched Pairs in each CGM Glucose Range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	6%	25%	63%	6%	0%	0%	0%	0%	0%	0%	0%	16
40-60	0%	33%	60%	6%	1%	0%	0%	0%	0%	0%	0%	86
61-80	0%	8%	64%	26%	2%	0%	0%	0%	0%	0%	0%	142
81-120	0%	1%	15%	69%	13%	1%	1%	0%	0%	0%	0%	314
121-160	0%	0%	0%	15%	66%	18%	1%	0%	0%	0%	0%	313
161-200	0%	0%	0%	1%	18%	66%	15%	0%	0%	0%	0%	355
201-250	0%	0%	0%	0%	1%	17%	68%	14%	0%	0%	0%	444
251-300	0%	0%	0%	0%	0%	0%	26%	58%	16%	0%	0%	336
301-350	0%	0%	0%	0%	0%	0%	4%	40%	46%	9%	0%	209
351-400	0%	0%	0%	0%	0%	0%	3%	14%	62%	21%	0%	63
> 400	0%	0%	0%	0%	0%	0%	4%	13%	29%	38%	17%	24

Concurrence of System and Laboratory Reference

Table 3-A (Original Adult Study), 3-B (Software 505 Adult Study), 3-C (Original Pediatric Study) and 3-D (Software 505 Pediatric Study) are categorized by ranges of CGM glucose readings. These tables describe, for each range of CGM glucose readings, what percentage of paired YSI values were in the same glucose range (shaded) or in glucose ranges above and below the paired CGM readings. For example, based on the Software 505 Adult Study, when CGM readings are within 81 to 120 mg/dL, you can expect your blood glucose levels are within 81 to 120 mg/dL 72% of time.

Table 4-A. System Difference to YSI within CGM Glucose Ranges (Adult)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of Paired CGM-YSI	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	9152	2.9%	1.7%	13.3%	9.8%
	Software 505	2263	2.5%	2.4%	9.0%	7.0%
*40-60	Original	512	-10.0	-8.2	13.5	9.7
	Software 505	120	-3.3	-2.1	6.9	4.8
*61-80	Original	781	-2.4	-0.4	11.4	8.6
	Software 505	226	0.8	1.4	6.7	5.4
81-180	Original	3853	4.8%	3.0%	13.8%	9.8%
	Software 505	738	3.9%	4.1%	9.6%	8.2%
181-300	Original	2784	2.1%	0.0%	11.9%	9.2%
	Software 505	798	0.6%	0.4%	8.0%	6.1%
301-350	Original	775	3.8%	2.8%	9.8%	7.9%
	Software 505	229	4.1%	3.4%	8.0%	5.8%
351-400	Original	447	10.4%	7.7%	12.8%	9.1%
	Software 505	152	7.2%	6.3%	9.2%	7.2%

¹CGM readings are within 40 to 400 mg/dL, inclusive.

²Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

*For CGM ≤ 80 mg/dL, the difference and absolute difference in mg/dL are included instead of percent differences (%).

Table 4-B. System Difference to YSI within CGM Glucose Ranges (Pediatric)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of Paired CGM-YSI	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	2922	13.5%	11.6%	17.4%	13.5%
	Software 505	2262	1.8%	1.2%	10.4%	7.9%
*40-60	Original	19	-18.1	-9.1	19.2	9.1
	Software 505	86	-15.3	-13.2	16.1	13.2
*61-80	Original	76	-3.7	-2.3	13.4	10.6
	Software 505	142	-4.8	-1.0	11.8	7.7
81-180	Original	1155	11.9%	9.7%	17.0%	13.0%
	Software 505	805	1.9%	0.7%	10.6%	8.1%
181-300	Original	1380	14.8%	12.4%	17.4%	13.3%
	Software 505	957	2.2%	1.0%	8.1%	6.5%
301-350	Original	206	19.2%	15.9%	19.4%	15.9%
	Software 505	209	7.8%	6.5%	11.0%	7.9%
351-400	Original	86	18.5%	15.5%	19.1%	15.5%
	Software 505	63	14.9%	11.6%	15.2%	11.6%

¹CGM readings are within 40 to 400 mg/dL, inclusive.

²Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

*For CGM ≤ 80 mg/dL, the difference and absolute difference in mg/dL are included instead of percent differences (%).

Accuracy Relative to YSI

Accuracy between matched pairs was also estimated by calculating the percent difference between the System reading and the YSI value. For example, if the YSI value is 100 mg/dL and the System reading is 90 mg/dL, a 10% difference between the System and the YSI is reported. The System and YSI values were compared by pairing the System reading that fell immediately after the YSI value was collected.

In the example above, the System reading is less than the YSI value, so the percent difference reading is negative. The mean percent difference is the average of all positive and negative percent differences between the two devices; it tells you if the System reads higher or lower on average than the YSI within each glucose range.

Another estimate used to show the accuracy of the System is the absolute percent difference. The absolute percent difference tells you the percent difference or “distance” between the System and YSI values, but does not tell you whether the System is reading, on average, higher or lower than the YSI laboratory standard. The mean absolute percent difference is the average “distance” (regardless if positive or negative) between System readings and YSI values.

Accuracy measures in differences for both the **Original Adult** and **Software 505 Adult** Studies are summarized in Table 4-A. Accuracy measures in differences for both the **Original Pediatric** and **Software 505 Pediatric** Studies are summarized in Table 4-B. Table 4-A and 4-B are categorized within CGM glucose ranges.

For example, in the **Software 505 Adult** Study (Table 4-A), overall, on average, the System reads 2.5% different (Mean Percent Difference) than the reference and 9.0% absolute different (Mean Absolute Difference) than the reference values. The Median Percent Difference shows that half of the time the System reads 2.4% or less than the YSI blood glucose values and the Median Absolute Percent Difference shows that half of the time the System reads about 7.0% or less than the YSI blood glucose values.

Table 5-A. Hypoglycemia Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Adult)

Hypoglycemia Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	50%	50%	71%	29%
	Software 505	71%	29%	68%	32%
60	Original	64%	36%	75%	25%
	Software 505	85%	15%	83%	17%
70	Original	79%	21%	83%	17%
	Software 505	92%	8%	91%	9%
80	Original	87%	13%	86%	14%
	Software 505	95%	5%	90%	10%
90	Original	90%	10%	89%	11%
	Software 505	96%	4%	94%	6%

¹Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 5-B. Hypoglycemia Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Pediatric, Ages 6-17 Years)

Hypoglycemia Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	0%	100%	0%	100%
	Software 505	22%	78%	75%	25%
60	Original	11%	89%	25%	75%
	Software 505	42%	58%	78%	23%
70	Original	47%	53%	50%	50%
	Software 505	68%	32%	75%	25%
80	Original	55%	45%	55%	45%
	Software 505	86%	14%	91%	9%
90	Original	69%	31%	62%	38%
	Software 505	90%	10%	93%	7%
100	Original	75%	25%	62%	38%
	Software 505	91%	9%	93%	7%

¹Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 5-C. Hypoglycemia Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Pediatric, Ages 2-5 Years)

Hypoglycemia Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	3%	97%	57%	43%
	Software 505	25%	75%	100%	0%
60	Original	11%	89%	62%	38%
	Software 505	20%	80%	100%	0%
70	Original	29%	71%	77%	23%
	Software 505	20%	80%	100%	0%
80	Original	35%	65%	85%	15%
	Software 505	61%	39%	100%	0%
90	Original	51%	49%	89%	11%
	Software 505	78%	22%	100%	0%
100	Original	64%	36%	91%	9%
	Software 505	82%	18%	100%	0%

¹Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Low and High Glucose Alerts

The ability of the System to detect high and low glucose levels is assessed by comparing System results to YSI results at low and high blood glucose levels and determining if the alert may have sounded. The System and YSI values were compared by pairing the System reading that occurred immediately after the YSI value was collected. We suggest that you ask your doctor what alert settings would be best for you.

The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in Table 5-A, 5-B and 5-C. Table 5-A represents the hypoglycemia alert evaluation within 15 minutes of the YSI value in the adult studies. Table 5-B represents the alert evaluation within 15 minutes of the YSI value for a subset of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes.

Table 5-C represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric studies.

Hypoglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or below the alert setting within 15 or 30 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was above the alert setting within 15 or 30 minutes before or after the device alarmed.

For example, if you set the Low Glucose Alert to 70 mg/dL and your alarm sounds, how often can you expect your blood sugar to actually be low? In the **Software 505 Adult** Study (Table 5-A), when your alarm sounds, you can expect your blood sugar to be below 70 mg/dL approximately 92% of the time and above 70 mg/dL approximately 8% of the time within the 15 minute period before or after your alarm sounds.

Hypoglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hypoglycemia or how often it misses such an event. The Hypoglycemia Detection Rate is the % of time the blood glucose level was at or below the alert setting and device alarmed within 15 or 30 minutes before or after the blood glucose was at or below the alert settings. The Hypoglycemia Missed Detection Rate is the % of time the blood glucose was at or below the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood glucose was at or below the alert setting.

For example, if you set the Low Glucose alert to 70 mg/dL, how often will your alarm alert you if your blood glucose goes below 70 mg/dL? In the **Software 505 Adult** Study (Table 5-A), when your blood sugar goes below 70 mg/dL, you can expect your alarm to sound 91% of the time and not to sound approximately 9% of time within the 15 minute period before or after your blood sugar goes below 70 mg/dL.

Table 6-A. Hyperglycemia Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Adult)

Hyperglycemia Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	95%	5%	98%	2%
	Software 505	98%	2%	100%	0%
140	Original	94%	6%	97%	3%
	Software 505	97%	3%	99%	1%
180	Original	92%	8%	97%	3%
	Software 505	97%	3%	99%	1%
200	Original	92%	8%	97%	3%
	Software 505	96%	4%	98%	2%
220	Original	91%	9%	95%	5%
	Software 505	94%	6%	98%	2%
240	Original	91%	9%	94%	6%
	Software 505	93%	7%	95%	5%
300	Original	82%	18%	86%	14%
	Software 505	86%	14%	90%	10%

¹Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 6-B. Hyperglycemia Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Pediatric, Ages 6-17 Years)

Hyperglycemia Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	91%	9%	98%	2%
	Software 505	98%	2%	99%	1%
140	Original	87%	13%	99%	1%
	Software 505	97%	3%	98%	2%
180	Original	75%	25%	99%	1%
	Software 505	94%	6%	98%	2%
200	Original	71%	29%	98%	2%
	Software 505	94%	6%	97%	3%
220	Original	67%	33%	97%	3%
	Software 505	93%	7%	96%	4%
240	Original	62%	38%	96%	4%
	Software 505	88%	12%	94%	6%
300	Original	43%	57%	93%	7%
	Software 505	69%	31%	84%	16%

¹Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 6-C. Hyperglycemia Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Pediatric, Ages 2-5 Years)

Hyperglycemia Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	92%	8%	98%	2%
	Software 505	97%	3%	99%	1%
140	Original	90%	10%	98%	2%
	Software 505	98%	2%	100%	0%
180	Original	87%	13%	96%	4%
	Software 505	99%	1%	93%	7%
200	Original	85%	15%	96%	4%
	Software 505	98%	2%	93%	7%
220	Original	81%	19%	95%	5%
	Software 505	100%	0%	97%	3%
240	Original	80%	20%	95%	5%
	Software 505	99%	1%	98%	2%
300	Original	71%	29%	90%	10%
	Software 505	95%	5%	96%	4%

¹Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in Table 6-A, 6-B and 6-C. Table 6-A represents the hyperglycemia alert evaluation within 15 minutes of the YSI value in the adult studies. Table 6-B represents the alert evaluation within 15 minutes of the YSI value for a subset of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes. Table 6-C represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric studies.

Hyperglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or above the alert setting within 15 or 30

minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was below the alert setting within 15 or 30 minutes before or after the device alarmed.

For example, if you set the High Glucose alert to 200 mg/dL and your alarm sounds, how often can you expect your blood sugar to actually be high? In the **Software 505 Adult** Study (Table 6-A), when your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL approximately 96% of the time and not be above 200 mg/dL approximately 4% of the time within the 15 minute period before or after your alarm sounds.

Hyperglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hyperglycemia or how often it misses such an event. The Hyperglycemia Detection Rate is the % of time the blood glucose level was at or above the alert setting and the device alarmed within 15 or 30 minutes before or after the blood glucose was at or above the alert settings. The Hyperglycemia Missed Detection Rate is the % of time the blood glucose was at or above the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood glucose was at or above the alert setting.

For example, if you set your High Glucose alert to 200 mg/dL, how often will your alarm alert you if your blood glucose goes at or above 200 mg/dL? In the **Software 505 Adult** Study (Table 6-A), when your blood sugar goes above 200 mg/dL, you can expect your alarm to sound 98% of the time and not to sound approximately 2% of time within the 15 minute period before or after your blood sugar goes above 200 mg/dL.

Table 7-A. Percentage of System Readings¹ within YSI Values With Data Stratified in 2-Hour Increments After Calibration (Adult)

Time from Calibration	Study ²	Number of Paired CGM-YSI	Percent Within 15/15% YSI	Percent Within 20/20% YSI	Percent Within 30/30% YSI	Percent Greater than 40/40% YSI
0-2 hours	Original	1929	78%	88%	96%	2%
	Software 505	469	93%	97%	99%	0%
2-4 hours	Original	1516	69%	81%	91%	4%
	Software 505	389	90%	97%	99%	0%
4-6 hours	Original	1547	69%	79%	91%	5%
	Software 505	383	85%	91%	97%	2%
6-8 hours	Original	1520	68%	79%	92%	3%
	Software 505	380	79%	90%	97%	2%
8-10 hours	Original	1555	71%	82%	92%	4%
	Software 505	347	83%	92%	98%	0%
10-12 hours	Original	1068	65%	77%	91%	4%
	Software 505	295	80%	90%	98%	0%
12-14 hours	Original	17	65%	76%	82%	12%
	Software 505	0	--	--	--	--

¹CGM readings are within 40 to 400 mg/dL, inclusive.

²Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 7-B. Percentage of System Readings¹ within YSI Values with Data Stratified in 2-Hour Increments after Calibration (Pediatric)

Time from Calibration	Study ²	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent greater than 40/40% YSI
0-2 hours	Original	648	65%	75%	87%	7%
	Software 505	545	83%	91%	97%	1%
2-4 hours	Original	649	51%	67%	86%	7%
	Software 505	460	72%	89%	96%	2%
4-6 hours	Original	630	51%	61%	80%	10%
	Software 505	428	77%	88%	95%	2%
6-8 hours	Original	409	52%	68%	85%	5%
	Software 505	325	88%	92%	94%	3%
8-10 hours	Original	296	53%	69%	84%	7%
	Software 505	305	86%	93%	97%	1%
10-12 hours	Original	253	58%	74%	89%	5%
	Software 505	198	89%	94%	98%	0%
12-14 hours	Original	37	32%	38%	65%	22%
	Software 505	1	100%	100%	100%	100%

¹CGM readings are within 40 to 400 mg/dL, inclusive.

²Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Calibration Stability

The System must be calibrated every 12 hours. To demonstrate performance of the System over a 12-hour calibration period, Systems were evaluated to verify that performance remains consistent over the 12-hour calibration period. Systems were evaluated in 2-hour increments after calibration. Performance was estimated at each 2-hour interval and stratified by glucose values by calculating the percentage of System readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% and greater than 40 mg/dL or 40% of the YSI values in Table 7-A and 7-B.

Table 8-A. Sensor Stability Relative to YSI (Accuracy Over Time¹) - (Adult)

Day of Wear	Study ²	Number of Paired CGM-YSI	Mean Absolute Percent Differences	Median Absolute Percent Differences	Percent Within 15/15% YSI	Percent Within 20/20% YSI	Percent Within 30/30% YSI	Percent Greater than 40/40% YSI
Day 1	Original	3023	16.7%	13.2%	59%	71%	86%	6%
	Software 505	680	10.7%	7.9%	77%	84%	96%	2%
Day 4	Original	3108	11.4%	8.2%	77%	87%	95%	2%
	Software 505	777	8.0%	6.4%	89%	96%	99%	0%
Day 7	Original	3021	11.9%	8.9%	76%	87%	95%	2%
	Software 505	806	8.5%	7.2%	90%	97%	99%	0%

¹CGM readings are within 40 to 400 mg/dL, inclusive.

²Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 8-B. Sensor Stability Relative to YSI (Accuracy Over Time¹) - (Pediatric, Ages 6-17 Years)

Day of Wear	Study ²	Number of Paired CGM-YSI	Mean Absolute Percent Differences	Median Absolute Percent Differences	Percent Within 15/15% YSI	Percent Within 20/20% YSI	Percent Within 30/30% YSI	Percent Greater than 40/40% YSI
Day 1	Original	1016	21.2%	15.8%	48%	61%	78%	15%
	Software 505	740	12.7%	8.5%	75%	83%	91%	4%
Day 4	Original	810	16.0%	13.9%	52%	66%	87%	3%
	Software 505	795	8.1%	6.7%	89%	97%	100%	0%
Day 7	Original	1096	15.1%	11.3%	63%	76%	89%	4%
	Software 505	727	10.4%	8.4%	80%	91%	98%	1%

¹CGM readings are within 40 to 400 mg/dL, inclusive.

²Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 8-C. Sensor Stability Relative to SMBG (Accuracy Over Time¹) - (Pediatric, Ages 2-17 Years)

Day of Wear	Study ²	Number of Paired CGM-SMBG	Mean Absolute Percent Differences	Median Absolute Percent Differences	Percent Within 15/15% SMBG	Percent Within 20/20% SMBG	Percent Within 30/30% SMBG	Percent Greater than 40/40% SMBG
Day 1	Original	3216	18.8%	14.2%	53%	65%	81%	10%
	Software 505	893	14.8%	10.7%	64%	79%	91%	5%
Day 2	Original	2148	16.2%	12.4%	60%	74%	87%	6%
	Software 505	436	13.2%	10.4%	69%	81%	95%	3%
Day 3	Original	1977	15.2%	11.0%	63%	76%	89%	5%
	Software 505	441	13.8%	11.3%	66%	77%	91%	2%
Day 4	Original	2830	14.0%	10.9%	66%	79%	91%	4%
	Software 505	850	10.7%	8.5%	79%	91%	97%	1%
Day 5	Original	1768	15.4%	10.7%	67%	78%	90%	5%
	Software 505	374	11.4%	8.7%	74%	86%	96%	1%
Day 6	Original	1704	14.3%	9.8%	68%	79%	90%	4%
	Software 505	410	12.3%	9.2%	72%	80%	93%	2%
Day 7	Original	2675	12.4%	9.2%	72%	83%	94%	3%
	Software 505	860	11.3%	8.6%	79%	90%	96%	2%

¹CGM readings are within 40 to 400 mg/dL, inclusive.

²Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Sensor Stability

Relative to YSI

Sensors can be worn for up to 7 days. Performance was estimated by calculating the percentage of System readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% and greater than 40 mg/dL or 40% of the YSI values at the beginning (Day 1), middle (Day 4) and end (Day 7) of the System lifecycle. The average and median of the absolute percent differences are included in Table 8-A and 8-B showing consistent accuracy and sensor stability over the 7-day life of the sensor.

Relative to SMBG (Pediatric Study)

Performance was also estimated by calculating the percentage of system readings within various percentages of the SMBG values at each day of the sensor wear period (Table 8-C). The average and median of the absolute percent differences are included in the table.

Precision of System Readings

A subset of subjects wore two Systems at the same time. This was to look at how similarly two Systems function on the same subject (sensor precision). Precision was evaluated by comparing the glucose readings from the two Systems worn on the same subject at the same time.

In the **Original Adult** Study, 36 subjects wore two Systems. Results showed that System readings from the two sensors generally agreed with each other within 9% (absolute percent difference) with a 7% coefficient of variation. In the **Original Pediatric** Study, all subjects wore two Systems. Results showed that System readings from the two sensors generally agreed with each other within 10% (absolute percent difference) with a 7% coefficient of variation. Only one System was worn in the **Software 505 Adult** and **Software 505 Pediatric** Studies so precision data was not collected.

Sensor Life

Sensors may be worn for up to 7 days (168 hours). To estimate how long a sensor will work over 7 days, all sensors worn were evaluated to determine how many days/hours of readings each sensor provided.

In the **Original Adult** Study, 108 sensors were evaluated. Ninety-four percent (94%) of the sensors lasted until Day 7 (145-168 hours). There were 6 (6%) sensors that ended early, four of which lasted more than 3 days.

In the **Software 505 Adult** Study, 51 sensors were evaluated. Ninety-eight percent (98%) of the sensors lasted until Day 7 (145-168 hours). There was 1 (2%) sensor that ended early, which lasted until day 5 of the sensor wear.

In the **Original Pediatric** Study, 351 sensors were evaluated. Eighty-five percent (85%) of the sensors lasted until Day 7 (145-168 hours).

In the **Software 505 Pediatric** Study, 77 sensors were evaluated. Ninety-four percent (94%) of the sensors lasted until Day 7 (145-168 hours).

Table 9-A. Number of Readings Provided by Each Sensor Over 7-Days (Adult)

% of Total Possible Readings Provided	Study ¹	Total Readings Provided (Min-Max)	% of Systems Providing That Number of Readings
0-25%	Original	167-491	2%
	Software 505	0	0%
26-50%	Original	719-914	4%
	Software 505	856-856	2%
51-75%	Original	1267-1267	1%
	Software 505	1253-1253	2%
76-100%	Original	1811-1992	94%
	Software 505	1497-1992	96%

¹Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 9-B. Number of Readings Provided by Each Sensor Over 7-Days (Pediatric)

% of Total Possible Readings Provided	Study ¹	Total Readings Provided (Min-Max)	% of Systems Providing That Number of Readings
0-25%	Original	103-427	3%
	Software 505	60-223	4%
26-50%	Original	569-954	3%
	Software 505	877-891	3%
51-75%	Original	1006-1484	9%
	Software 505	1131-1342	3%
76-100%	Original	1518-1992	86%
	Software 505	1623-1990	91%

¹Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 10-A. System Readings Within Wear Days (Adult)

Statistic	Study ¹	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days ²
Mean	Original	98%	98%	98%	98%	97%	99%	95%	97%
	Software 505	98%	99%	98%	98%	96%	99%	97%	98%
Median	Original	100%	100%	100%	100%	100%	100%	100%	100%
	Software 505	99%	100%	100%	100%	100%	100%	100%	100%
Standard Deviation	Original	5%	3%	9%	8%	10%	3%	11%	8%
	Software 505	3%	2%	8%	11%	15%	2%	13%	9%

¹Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

²A total of 108 sensors were included with the **Original** Study and 51 sensors were included with the **Software 505** Study.

Table 10-B. System Readings within Wear Days (Pediatric)

Statistic	Study ¹	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days ²
Mean	Original	97%	96%	96%	95%	94%	94%	92%	95%
	Software 505	96%	96%	95%	96%	93%	95%	93%	95%
Median	Original	99%	99%	99%	99%	99%	99%	98%	99%
	Software 505	99%	98%	99%	99%	97%	97%	98%	98%
Standard Deviation	Original	6%	10%	9%	12%	14%	14%	17%	12%
	Software 505	9%	6%	12%	10%	15%	7%	12%	11%

¹Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

²A total of 108 sensors were included with the **Original** Study and 77 sensors were included with the **Software 505** Study.

Number of Readings Provided

The System is capable of providing a reading up to every 5 minutes, or up to 288 readings per day. For a variety of reasons, the System may not display a glucose reading and readings are “skipped.” Table 9-A and 9-B estimate the number of readings you can expect to receive from the System over the entire 7-day period after calibration. Table 10-A and 10-B show the number of readings you can expect to receive from the System within each system wear day.

For the **Software 505 Adult** Study (SW10505), 96% of Systems provided between 1,497 and 1,992 valid glucose readings (or more than 75% of the expected number of readings) as seen in Table 9-A. Adjusted within each system wear-day, the System in the **Software 505 Adult** Study provided an average of 98% of all expected glucose readings (288) as seen in Table 10-A.

Table 11-A. System Agreement to SMBG Within CGM Glucose Ranges (Adult)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of Paired CGM-SMBG	Percent Within 15/15% SMBG	Percent Within 20/20% SMBG	Percent Within 30/30% SMBG	Percent Greater than 40/40% SMBG
Overall	Original	7508	69%	81%	94%	2%
	Software 505	2992	77%	87%	96%	1%
40-60	Original	731	75%	84%	92%	4%
	Software 505	221	73%	80%	87%	7%
61-80	Original	968	78%	86%	95%	1%
	Software 505	336	77%	85%	95%	1%
81-180	Original	3141	65%	78%	93%	2%
	Software 505	1362	74%	85%	96%	1%
181-300	Original	1960	68%	81%	94%	3%
	Software 505	826	80%	90%	97%	1%
301-350	Original	450	77%	88%	98%	1%
	Software 505	161	83%	93%	99%	0%
351-400	Original	258	75%	85%	95%	2%
	Software 505	86	90%	93%	98%	1%

¹CGM readings are within 40 to 400 mg/dL, inclusive.

²Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 11-B. System Agreement to SMBG Within CGM Glucose Ranges (Pediatric)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of Paired CGM-SMBG	Percent Within 15/15% SMBG	Percent Within 20/20% SMBG	Percent Within 30/30% SMBG	Percent Greater than 40/40% SMBG
Overall	Original	16318	64%	76%	89%	5%
	Software 505	4264	73%	84%	94%	2%
40-60	Original	487	44%	55%	68%	19%
	Software 505	240	54%	71%	86%	7%
61-80	Original	1340	59%	70%	85%	7%
	Software 505	399	64%	76%	92%	2%
81-180	Original	7084	62%	74%	90%	5%
	Software 505	1650	72%	84%	95%	2%
181-300	Original	5627	69%	80%	90%	5%
	Software 505	1526	79%	89%	97%	2%
301-350	Original	1176	65%	77%	90%	4%
	Software 505	319	72%	83%	94%	2%
351-400	Original	604	58%	72%	86%	6%
	Software 505	130	69%	79%	86%	8%

¹CGM readings are within 40 to 400 mg/dL, inclusive.

²Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

Table 12-A. System Difference to SMBG Within CGM Glucose Ranges (Adult)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of Paired CGM-SMBG	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	7508	-0.4%	-1.4%	14.0%	11.0%
	Software 505	2992	-2.6%	-2.7%	11.3%	8.6%
*40-60	Original	731	-9.3	-8.0	11.7	8.0
	Software 505	221	-10.3	-6.0	13.0	8.0
*61-80	Original	968	-1.0	1.0	10.7	8.0
	Software 505	336	-4.0	-2.0	10.1	7.0
81-180	Original	3141	1.4%	0.0%	14.2%	11.0%
	Software 505	1362	-2.6%	-3.1%	11.4%	8.9%
181-300	Original	1960	-0.7%	-2.8%	13.0%	10.3%
	Software 505	826	-1.4%	-2.0%	9.5%	7.4%
301-350	Original	450	-0.7%	-2.6%	10.5%	8.6%
	Software 505	161	-0.0%	0.0%	8.3%	6.0%
351-400	Original	258	5.0%	3.0%	11.9%	8.6%
	Software 505	86	3.9%	3.2%	8.1%	6.7%

¹CGM readings are within 40 to 400 mg/dL, inclusive.

²Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

*For CGM ≤ 80 mg/dL, the differences in mg/dL are included instead of percent differences (%).

Table 12-B. System Difference to SMBG Within CGM Glucose Ranges (Pediatric)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of Paired CGM-SMBG	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	16318	2.2%	0.9%	15.3%	11.1%
	Software 505	4264	-0.7%	-1.1%	12.5%	9.5%
*40-60	Original	487	-22.1	-17.0	23.9	18.0
	Software 505	240	-15.9	-14.0	16.9	14.0
*61-80	Original	1340	-11.8	-8.0	17.0	11.0
	Software 505	399	-7.8	-6.0	13.7	10.0
81-180	Original	7084	1.1%	-1.0%	15.4%	11.4%
	Software 505	1650	-1.2%	-2.6%	12.1%	9.5%
181-300	Original	5627	5.7%	3.4%	13.5%	9.5%
	Software 505	1526	1.7%	0.9%	10.1%	7.7%
301-350	Original	1176	9.6%	7.2%	14.2%	10.4%
	Software 505	319	6.7%	5.9%	11.8%	8.9%
351-400	Original	604	12.7%	10.2%	16.1%	11.9%
	Software 505	130	12.0%	8.9%	15.7%	10.6%

¹CGM readings are within 40 to 400 mg/dL, inclusive.

²Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505).

*For CGM ≤ 80 mg/dL, the differences in mg/dL are included instead of percent differences (%).

Agreement and Accuracy Relative to SMBG

Agreement between the System and blood glucose values is also characterized using paired System and SMBG results (Table 11 to 12). The System and SMBG values were compared by pairing the comparative SMBG value to a System glucose reading that occurred immediately after the SMBG was collected. These results characterize the performance subjects expect during real-time use of the System in their daily diabetes management when comparing the System readings to their home blood glucose meter results. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 80 mg/dL, the absolute percent difference (%) from the SMBG values was calculated. The percentages of total readings within

15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% or greater than 40 mg/dL or 40% were then calculated.

For example, if the System reads 100 mg/dL, it is between 81-180 mg/dL range and you can expect the System readings to be within 20% of the SMBG values 85% of the time for the **Software 505 Adult** Study, as seen in Table 11-A.

Overall, the System in the **Software 505 Adult** Study reads, on average, 2.6% lower (Mean Percent Difference) than SMBG values and 11.3% absolute different (Mean Absolute Percent Difference) than the SMBG values. The Median Percent Difference shows that half of the time the System reads lower in 2.7% or less than the SMBG values and the Median Absolute Percent Difference shows that half of the time the System reads about 8.6% or less different than SMBG values, as seen in Table 12-A.

Adverse Events

No serious adverse events or device-related serious adverse events occurred during the studies. Mild to moderate skin irritation, such as erythema or edema, occurred at the sensor needle insertion area or around the adhesive area. No infection, bruising, or bleeding occurred at the sensor needle insertion area or the adhesive area.

17.2 Product Specifications

User is the single use operator in the home environment.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Do not touch the metal connectors on the bottom of the transmitter and other open connectors on the receiver, charging cable and charger.

Sensor Product Specifications

Glucose Range	40-400 mg/dL
Sensor Life	Up to 7 days
Calibration	Commercially available blood glucose meter
Calibration Range	40-400 mg/dL
Storage Condition	Temperature: 36° F-77° F Humidity: 15%-85% RH
Sterilization	Sterile by radiation

Transmitter Product Specifications

Part Number	9438-06
Dimensions (Including Sensor Pod)	Length: 1.5 inches Width: 0.9 inches Thickness: 0.5 inches
Weight (Including Sensor Pod)	0.4 ounces
Power Supply	Silver oxide batteries (not replaceable)
Operational Conditions	Ambient temperature is 10° C-42° C (50° F-107.6° F) Equilibrium temperature of less than 0.5° C (0.9° F) above ambient Humidity: 10%-95% RH
Storage Conditions	Temperature: 32° F-113° F Humidity: 10%-95% RH
Operating Altitude	-1300 feet to 13800 feet
Limited Warranty	3 months
Moisture Protection	IP28: Protection against insertion of large objects and immersion in water for up to 8 feet for 24 hours
Protection Against Electrical Shock	Type BF applied part

Transmitter Performance Characteristics

Parameter	Performance Characteristic
TX/RX Frequencies	2.402-2.480 GHz
Bandwidth	1.02 MHz
Maximum Output Power	1.0 mW EIRP
Modulation	Gaussian Frequency-Shift Keying
Data Rate	1 Mbps
Data Communication Range	20 feet

The Dexcom G5 Mobile CGM System is safe for use on U.S. commercial airlines. The Dexcom G5 Mobile CGM System is an M-PED with emission levels that meet RTCA/DO160, Section 21, Category M. Per FAA Advisory, Circular #91-21, 1B, dated 8/25/06, any M-PED that meets this standard in all

modes may be used onboard the aircraft without any further testing by the operator. This device can withstand exposure to common electrostatic (ESD) and electromagnetic interference (EMI).

Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

The transmitter (P/N 9438-06) is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

Transmitter Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Receiver Product Specifications

Part Number	MT22719
Reading Frequency	Every 5 minutes
Dimensions	Length: 4.0 inches Width: 1.8 inches Thickness: 0.5 inches
TX/RX Frequencies	2.402-2.480 GHz
Bandwidth	1.22 MHz
Maximum Output Power	2.5 mW EIRP
Modulation	Gaussian Frequency-Shift Keying
Data Rate	1 Mbps

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Weight	2.4 ounces
Receiver Input	5V DC, 1A
Power Supply	MT21255
Communication Range	20 feet
Memory Storage	30 days of glucose data 7 days of tech support data
Re-Chargeable Battery Use	3 days
Charging Time	3 hours wall outlet The device behaves normally while being charged Do not hold the receiver while charging for over a minute There are no risks to connecting any part of the system to an MSO (Multiple Socket Outlet)
Storage/Operating Conditions	Temperature: 32° F-104° F Humidity: 15%-95% RH, (Storage 10%-95% RH)
Operating Altitude	-1300 feet to 13800 feet
Medium Priority Alarm Audible Output	50 dBa at 1 meter
Moisture Protection	IP22: Vertically falling drops Protection against insertion of large objects and dripping water
Limited Warranty	1 year
Control Classification	Class II equipment

No cleaning methods are recommended or tested for the receiver. The warranty life of the receiver is 1 year. The service life for the accessories is noted to be up to one year. If you have difficulty reading your receiver in bright sunlight, you may need to seek a shady location. Do not connect the receiver to any equipment not specified in IFU.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The receiver (MT22719) is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the receiver should ensure that it is used in such an environment.

Receiver Electromagnetic Immunity Specifications


Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11 IEC 60601-1-11	0% U_T for 1 cycle 0% U_T for 0.5 cycle at 8 phase angles 70% U_T (30% dip in U_T) for 25 cycles 0% U_T for 250 cycles	0% U_T for 1 cycle 0% U_T for 0.5 cycle at 8 phase angles 70% U_T (30% dip in U_T) for 25 cycles 0% U_T for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Dexcom G5 Mobile System is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the Dexcom G5 Mobile System should ensure that it is used in such an environment.

System Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6 (Receiver only)	3 Vrms 150 kHz to 80 MHz	6 Vrms	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF IEC 61000-4-3	10 V/m at 80 MHz to 2700 MHz (AM Modulation)	10 V/m	Recommended Separation Distance $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Dexcom G5 MOBILE System is used exceeds the applicable RF compliance level above, the Dexcom G5 MOBILE System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Dexcom G5 MOBILE System.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Dexcom G5 Mobile System is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the Dexcom G5 Mobile System should ensure that it is used in such an environment.

Electromagnetic Emissions Specifications

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The Dexcom G5 Mobile System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Dexcom G5 Mobile System is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Receiver

The receiver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the receiver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the receiver as recommended in the next table, according to the maximum output power of the communications equipment. Portable and mobile RF equipment include: baby monitors, *Bluetooth* wireless headsets, wireless routers, microwave ovens, laptops with internal Wi-Fi adapters, GSM cell phones, RFID scanners and hand-held security metal detector often used by security screeners.

Minimum Recommended Distance Between Other RF Transmitters and the Dexcom Transmitter/Receiver

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 P^{1/2}$	80 MHz to 800 MHz $d = 1.2 P^{1/2}$	800 MHz to 2.5 GHz $d = 2.3 P^{1/2}$
0.01	0.12	0.12	0.23

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Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 P^{1/2}$	80 MHz to 800 MHz $d = 1.2 P^{1/2}$	800 MHz to 2.5 GHz $d = 2.3 P^{1/2}$
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in feet can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

USB Charging/Download Cable* Specifications

Part Number	MT20655
Input/Output	5V DC, 1A
Type	USB A to USB micro B
Length	3 feet

*The power supply/charger can be connected to the USB charging/download cable for charging using an AC power outlet. Misuse of the USB cable can present a strangulation risk. Isolation of system is by unplugging charger from wall.

Power Supply/Charger Specifications

Part Number	MT21255
Class	II
Input	AC Input 100-240 Vac, 50/60Hz, 0.2A, 0.2A rms at 100 Vac
DC Output	5V DC, 1A (5.0 Watts)

17.3 FCC Requirements

The transmitter and receiver covered by this user guide have been certified under FCC ID:

- G5 Mobile Transmitter: PH29715
- G5 Mobile Receiver: PH29496

Although the transmitter and receiver have been approved by the Federal Communications Commission, there is no guarantee that they will not receive interference or that any particular transmission from either device will be free from interference.

Compliance Statement (Part 15.19)

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Warning (Part 15.21)

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. No modification of the equipment is allowed as it could create an unsafe condition.

FCC Interference Statement (Part 15.105 (b))

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult the dealer or an experienced radio/TV technician for help.

This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population/uncontrolled exposure.

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Chapter 18

Everything Else G5:

Troubleshooting

18.1 Introduction

Sensor pod not sticking? Prompt won't go away? Not getting your sensor glucose readings? Don't know when to replace your transmitter? This chapter will help you figure it out!

Troubleshooting sections are categorized by function or system component. The solutions here are meant to be brief and not all inclusive, some have audible prompts, and others don't. When more detailed answers or preventative measures are in a chapter, you'll get a brief explanation here, and then get directed to the applicable chapter and section.

After looking at the troubleshooting chapter, are you still not sure what to do? Or maybe your problem is hardware (e.g., receiver or transmitter failure).

If your problem is not found here, follow the steps listed on your app screen, or call Technical Support.

Please call the Dexcom Technical Support Team, 24/7, toll free at **1.877.339.2664** or toll at **1.858.200.0200** if any of these errors continue and the instructions don't resolve the issue.

18.2 Safety Statements

Following are the Safety Statements for the Troubleshooting chapter.

WARNING

Do: *Calibrate at least once every 12 hours.*

Why: Calibrating less often than every 12 hours might cause inaccurate sensor glucose readings.

Consequences: Missing severe low (hypoglycemia) or high (hyperglycemia) Alarm or Alerts.

PRECAUTION

Do: Enter the exact BG value displayed on your BG meter within five minutes of a carefully performed fingerstick measurement.

Why: Entering the wrong blood glucose values, or waiting more than five minutes before entry, might affect sensor accuracy.

Consequences: You may miss a severe low or high glucose events.

PRECAUTION

Don't: Never prevent communication between transmitter and display devices.

Do: Keep smart device and receiver within 20 feet of transmitter and away from obstructions.

Why: If your transmitter display device(s) are more than 20 feet apart or are separated by an obstruction, they might not communicate.

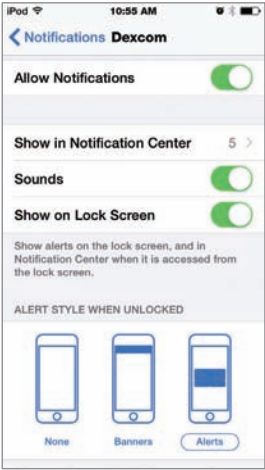

Types of obstruction differ and not all types have been tested. Obstructions can include water, walls, metal, etc.

Water (e.g., swimming, surfing, bathing, etc.) can severely limit communication range.

Consequences: Missing severe low or high Alarm or Alerts.



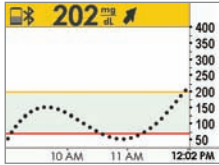
18.3 Troubleshooting

No Alarm/Alerts

Device	What you see	Problem	What you do
<p>Smart Device: In App</p>		<p>Not receiving Alerts</p>	<p>See Chapter 11.</p> <p>Check <i>Alarm/Alerts</i>, sound and/or vibrations for notifications are on.</p> <p>Check your smart device is not on mute (if applicable).</p>
<p>Receiver</p>			


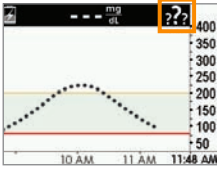

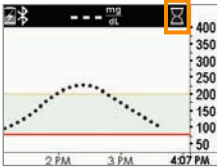
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Sensor Glucose Readings


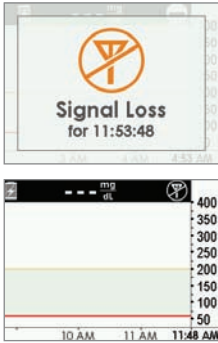


Device	What you see	Problem	What you do
BG Meter			See Chapter 7. Differences are not uncommon.
Smart Device: In App			Readings from different body fluids reflect different numbers: Meter - from blood Sensor - from interstitial fluid
Receiver		Sensor readings and BG meter glucose values often don't show the same	20/20 Rule If the meter shows 80 or less, CGM should read within ± 20 points. If the meter shows 80 or above, the CGM should read $\pm 20\%$. Example: a 202 mg/dL sensor reading and a 188 mg/dL glucose meter value = a 7% difference (this is still considered accurate). Outside of 20/20 rule: Calibrate again.

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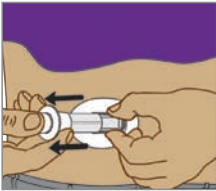

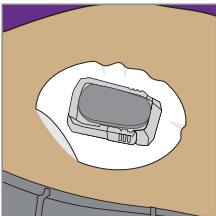
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Device	What you see	Problem	What you do
Smart Device: In App		Not getting sensor glucose readings	See Chapter 9. <i>Don't</i> calibrate. Wait for more prompts. System may correct problem itself and continue to provide sensor glucose readings.
Receiver			3 hours since last sensor reading: call Technical Support (see Section 16.1).
Smart Device: In App		Not getting sensor glucose readings	See Chapter 9. Wait System will often resolve itself.
Receiver			If this continues for an extended period of time, call Technical Support to report error (see Section 16.1).




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Device	What you see	Problem	What you do
Smart Device: In App			<p>See Chapter 9. <i>Don't</i> calibrate.</p> <p>Wait 10 minutes.</p>
Receiver		<p>System display device and transmitter not communicating</p>	<p>Move display device and transmitter within 20 feet of each other without obstruction.</p> <p>Wait another 10 minutes.</p> <p>App (if not resolved):</p> <ol style="list-style-type: none"> 1. Go to <i>Settings</i>. 2. Tap <i>Bluetooth</i>. 3. Turn <i>Bluetooth Off</i> and <i>On</i>.
Smart Device: In App			<p>See Chapter 7.</p> <p>Wait up to 2 hours.</p>
Receiver		<p>No sensor glucose readings</p>	<p>System is counting down to when you do your initial calibration.</p>

Applicator

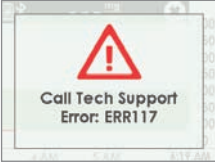
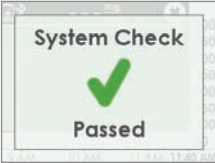

Picture	Problem	What you do
	<p>Safety lock stuck</p>	<p>See Chapter 6.</p> <p>Pull <i>safety lock</i> straight out:</p> <ul style="list-style-type: none"> • Away from your body • Follow direction of safety lock <i>Up Arrow</i>
	<p>Collar won't pull up</p>	<p>See Chapter 6.</p> <p>Use force when pulling the collar up.</p> <p>Check <i>white plunger</i> is completely down—flush to the applicator barrel.</p>
	<p>Can't remove transmitter latch</p>	<p>See Chapter 6.</p> <p>Don't pull it straight off.</p> <p>Hold <i>sensor pod</i> with one hand.</p> <p>Twist <i>transmitter latch</i> with other hand to break transmitter latch off.</p>
	<p>Sensor pod won't stick</p>	<p>See Chapter 6.</p> <p>Put medical tape over sensor pod's white adhesive patch (e.g., Blenderm).</p> <p>Don't place tape over the transmitter.</p>

Hardware Error




Device	What you see	Problem	What you do
Receiver		Won't turn on: Battery dead	See Chapter 4. Charge <i>receiver</i> using electrical outlet, not computer/laptop. Full charge may take up to five hours.
Receiver		After full charge session: Won't turn on	See Chapter 4. Reset <i>receiver</i> . Connect <i>receiver</i> to <i>charger</i> . Insert end of paper clip into small circular hole on receiver's back. Push down on paper clip. Receiver will vibrate. Processing screen appears. Charge <i>receiver</i> .
Receiver		Receiver Low Battery	See Chapter 4. Charge <i>receiver</i> .

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Device	What you see	Problem	What you do
Receiver		Corrupted database	See Chapter 16. Write down error code. Contact Dexcom Technical Support (see Section 16.1). Check BG value using BG meter. Prompt: Vibrates one time for four seconds and four beeps.
Receiver		System Recovery	See Chapter 16. Do nothing. Receiver is able to continue to work and recover from an error. App: Tap OK to clear Alert. Receiver: Press Select to clear Alert.
Smart Device: In App		No <i>Bluetooth</i>	See Chapter 5. Go to smart device's <i>Settings</i> . Make sure <i>Bluetooth</i> is On. If problem persists, please contact device's manufacturer.

Calibration Error




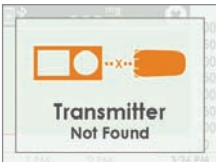
Device	What you see	Problem	What you do
BG Meter		System will not accept calibration if outside of the 40-400 mg/dL range	See Chapter 7. Wait until your glucose is between 40-400 mg/dL. Calibrate only when your BG meter values are between 40-400 mg/dL.
Smart Device: In App		System didn't accept recent calibration (see Sensor Glucose Readings troubleshooting for a possible reason)	See Chapter 7. Wait 15 minutes. Enter 1 calibration. If error screen still appears enter 1 more BG meter value.
Receiver		No sensor glucose readings will be displayed until error is resolved	Wait 15 minutes. If no sensor glucose readings appear on the display, the sensor needs to be replaced. Call Technical Support to report error (see Section 16.1). App: Follow same instructions. Tap question mark to get more information.

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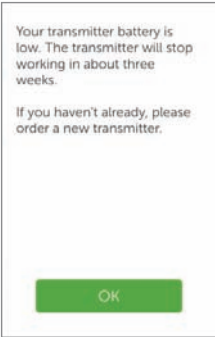
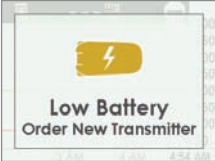
Device	What you see	Problem	What you do
Smart Device: In App		System didn't accept recent calibration	See Chapter 7. Wait 15 minutes. Enter 1 BG meter value. Wait 15 more minutes. If error screen still appears enter 1 more BG meter value. Wait 15 minutes.
Receiver			If no sensor glucose readings appear on the display, the sensor needs to be replaced. Call Technical Support (see Section 16.1) to report error.

Transmitter Error:

Device	What you see	Problem	What you do
Smart Device: In App		Transmitter not working	See Chapter 16. Contact Technical Support to report issue (Section 16.1). Start checking BG value using BG meter.
Receiver		Sensor session automatically stopped No sensor glucose readings displayed	App: Tap OK to clear Alert. Receiver: Press Select to clear. Will not re-alert once cleared. Order new transmitter.
Smart Device: In App			See Chapter 6. Check Transmitter SN in display device is correct. If wrong: Stop sensor session.
Receiver		Pairing Failed	Re-Enter correct transmitter SN. App: Menu > Trans SN > Enter correct SN Receiver: Settings > Trans SN > Enter correct SN If correct: Call Tech Support (see Chapter 16).

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Device	What you see	Problem	What you do
Smart Device: In App	 A screenshot of a mobile application interface. The text reads: "Your transmitter battery is low. The transmitter will stop working in about three weeks. If you haven't already, please order a new transmitter." Below the text is a green button with the text "OK".	Transmitter Low Battery	See Chapter 16. App: Tap <i>OK</i> to clear Receiver: Press <i>Select</i> to clear. Will not re-alert once cleared. Order new transmitter.
Receiver	 A screenshot of a receiver's display. It shows a yellow battery icon with a lightning bolt, indicating low battery. Below the icon, the text reads: "Low Battery" and "Order New Transmitter".		















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Chapter 19

Everything Else G5: Symbols on Package Labels

















The following symbols may be found on the sensor, transmitter, and receiver package labels. These symbols tell you about the proper and safe use of the Dexcom G5 Mobile System.

Some of these symbols may not have meaning in your region, and are listed for informational purposes only. This table shows what each symbol means.

	Use By Date		Batch/Lot Number
	Caution		Part/Catalog Number
	Date of Manufacture		Sterile by Radiation
	Do Not Reuse		Temperature Limitation
	Serial Number		IP28: Protection Against Insertion of Large Objects and Immersion in Water
	Class II Equipment		IP22: Protection Against Insertion of Large Objects and Dripping Water
	Alternating Current		Direct Current

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	Type BF Applied Part		Authorized Representative in the European Community
	Manufacturer		Non-Ionizing Radiation
	Humidity Limitation		Marking Certifies Device Meets European Council Directive 93/42/EEC
	European Union WEEE Directive 2012/19/EU		Do Not Use if Package is Damaged
	Electrical Equipment Designed Primarily for Indoor Use		Ship By Date
	Input		Prescription Required
	Keep Dry		MR Unsafe
	Refer to Instruction Manual/Booklet		<i>Bluetooth</i>

5

SHARING IS CARING

- Dexcom Share

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Chapter 20

Sharing Is Caring:

Dexcom Share

20.1 Learning About Dexcom Share

Glossary

Airplane Mode	A setting on a smart device where wireless features are disabled in order to comply with airline regulations.
Application or App	A software program, such as the Dexcom G5 Mobile App and the Dexcom Follow App, designed to run on a smart device.
App Store	Internet store for downloading applications to a smart device.
Blood Glucose Meter	A device used to measure how much glucose is in the blood.
BG Value	The measurement of glucose in the blood.
Bluetooth	<i>Bluetooth</i> wireless technology allows devices to wirelessly communicate with each other.
Default	A manufacturer's preset option for a device setting.
Delay	Amount of set time that passes before a notification is sent to a Follower.
Dexcom Share Cloud	A secure online storage server where Dexcom Share feature information is stored and then shared with Followers.
Dexcom Follow App	Gets the Sharer's glucose information and prompt data from the Dexcom Share Cloud.
Dexcom G5 Mobile/G4 PLATINUM Sensor	The Dexcom G5 Mobile System part that includes an applicator and sensor wire.

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Dexcom G5 Mobile System	CGM system made of a sensor, transmitter, and smart device/receiver.
Dexcom G5 Mobile Transmitter	The Dexcom G5 Mobile System part that wirelessly sends glucose information to the Dexcom G5 Mobile App.
Dexcom G5 Mobile App	Receives glucose information from the Dexcom G5 Mobile Transmitter. Sends glucose information to the Dexcom Cloud using an Internet connection.
Dexcom Share	Secondary notification using the following parts: <ul style="list-style-type: none">• Dexcom G5 Mobile System• <i>Bluetooth</i> wireless technology• Sharer's smart device• Dexcom G5 Mobile App• Internet• Follower's smart device• Dexcom Follow App
Do Not Disturb	A setting on a smart device where all incoming calls, alerts, and notifications are silenced. Do Not Disturb can be set to specific times and can be set to allow exceptions (people who can disturb you).
Follower	A person that gets the Sharer's shared information in the Dexcom Follow App.
Follow Dashboard™	On the Dexcom Follow App, the Follow Dashboard shows the glucose information of up to five (5) Sharers.
Follower's Smart Device	Runs the Dexcom Follow App.
Hyperglycemia	High BG. Same as "high." The default high alert in the Dexcom G5 Mobile CGM System is set to 200 mg/dL. Consult your healthcare professional to determine the appropriate hyperglycemic setting for you.

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Hypoglycemia	<p>Low BG. Same as “low.”</p> <p>The default low alert the Dexcom G5 Mobile CGM System is set to 80 mg/dL.</p> <p>Consult your healthcare professional to determine the appropriate hypoglycemic setting for you.</p>
Invite/Follow Invitation Email	<p>An email request for a person to download the Dexcom Follow App and get the Sharer’s shared information.</p>
Jailbroken	<p>The removal of limitations set by the manufacturer on a smart device.</p> <p>Do not use jailbroken smart devices with Dexcom Share.</p>
mg/dL	<p>Milligrams per deciliter. The standard unit of measure for sensor glucose information in the United States.</p>
Mobile Data Connections	<p>Cellular networks, such as 3G, 4G and LTE™, used by a smart device to access the Internet.</p>
No More Data prompt	<p>Prompts the Follower when the Sharer is unable to share glucose information.</p>
Not Sharing	<p>When the Sharer chooses to temporarily not share glucose data with the Follower.</p>
Obstruction	<p>An object that stops the wireless communication between devices, such as wall thickness or radio waves.</p>
Profile	<p>Located in Follow Dashboard and displays the Sharer’s glucose information, trend arrow and profile picture.</p>
Prompt	<p>A visual message that appears on the screen of the Follower’s smart device. Prompt may also include a sound, depending on the smart device’s settings.</p>
Range	<p>Maximum distance two devices can communicate wirelessly without obstruction.</p>

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Real-Time CGM	Data the Sharer receives on the Dexcom G5 Mobile App. Although your Dexcom Follow App might be similar to what you see on your app, it cannot be considered real-time because there are layers of communication between the Dexcom G5 Mobile App and the Dexcom Follow App.
Repeat	Amount of time the Follower chooses before they wish to receive a repeated notification.
Sensor Glucose Reading	A glucose measurement taken by the Dexcom G5 Mobile System.
Sharer	The person who uses the Dexcom G5 Mobile System.
Sharing	The act of electronically transmitting glucose information from the Sharer's smart device to the Follower's smart device.
Simultaneous Voice and Data	The ability to make a phone call and access the Internet on the same cellular connection at the same time.
Smart Device	A smart device is a cordless electronic device (unless charging), mobile (easily transportable), connected (via Wi-Fi, 3G, 4G, etc.) that can operate the Dexcom G5 Mobile App or the Dexcom Follow App. Examples of smart devices are smartphones or tablets. For a list of compatible smart devices, see dexcom.com/compatibility .
Standard Home Glucose Monitoring	Self-monitoring of BG using blood taken from the finger and a BG meter.
Trend Arrow	The arrow next to the Sharer's glucose value, located on the Sharer's profile on the Dexcom Follow App. This is the same trend arrow that is found on the Dexcom G5 Mobile Receiver.
Trend Graph	Displays the pattern of the Sharer's glucose information.

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Wi-Fi or Wireless Internet	A wireless technology that allows electronic devices access to the Internet. These networks can include your home Internet or one found at a public location.
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20.2 Dexcom Share Overview

Dexcom Share is a feature within the Dexcom G5 Mobile App. It allows for remote monitoring from one person, the Sharer, of Dexcom G5 Mobile CGM data to another person, the Follower.

Dexcom Share includes:

- Dexcom G5 Mobile CGM System
- Sharer's smart device
- Dexcom G5 Mobile App
- Internet connection
- Follower's smart device
- Dexcom Follow App

You cannot use the Share feature with Dexcom G5 Mobile Receiver.

Once the Sharer activates the Share feature in their Dexcom G5 Mobile App, the smart device transfers sensor glucose readings to the Dexcom Share Cloud using either Wi-Fi or a cellular data plan. Then, the sensor glucose readings are sent from the Dexcom Share Cloud to the Follower's smart device using Wi-Fi or the Follower's cellular data plan.

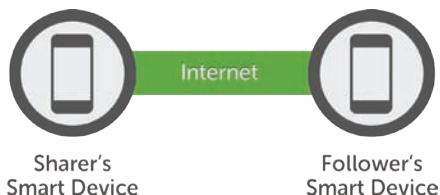










Figure 10. Sharing

The Sharer must be within 20 feet of their smart device in order to send data to their Follower or it will not work.

Dexcom Share Parts

	<p>Sharer's smart device*¹</p>
	<p>Follower's smart device*¹</p>
	<p>Dexcom G5 Mobile App</p>
	<p>Dexcom Follow App</p>
	<p>Dexcom G5 Mobile Transmitter*</p>
	<p>Dexcom G5 Mobile/G4 PLATINUM Sensor*</p>
	<p>Internet/Wi-Fi or mobile data service/3G/4G/LTE*</p>
	<p><i>Bluetooth</i></p>

*Must be purchased separately.

¹A list of compatible devices can be found at dexcom.com/compatibility.

Conditions Affecting Use

Once sharing is active, make sure the Share's and Follower's smart device settings are not altered.

Make sure the Sharer's and Follower's smart devices have:

- Enough battery power to maintain sharing
- Sharer's smart device has Internet connection
- Notifications turned on. If turned off, Follower won't receive any notifications
- Follower's smart device has an Internet connection

Dexcom recommends charging the smart device when sharing.

20.3 Risks and Benefits

Risks

Dexcom Share is a feature of the Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) System. The main risks involved with using the feature Dexcom Share are based on misunderstanding its purpose.

Remember that the Dexcom Share in the Dexcom G5 Mobile CGM System is a secondary notification feature, not a real-time remote monitoring system.

With using the Dexcom Share feature, there are 3 distinct parts of glucose monitoring:

1. **Blood glucose meter** - use this to make any treatment decisions.
2. **Dexcom G5 Mobile CGM System** - use the Dexcom G5 Mobile CGM System to complement, but not replace, information obtained from the blood glucose meter. It detects glucose trends and tracks glucose patterns.
3. **Dexcom Share** - this is an optional add-on to the Dexcom G5 Mobile CGM System that can share glucose information and notifications with up to five (5) other people. Shared sensor glucose readings and information can add another level of awareness.

Using the wrong glucose information for treatment decisions could lead to low or high glucose. Blood glucose values from a blood glucose meter may differ from the information displayed on Dexcom Follow App. All treatment decisions should be made using a blood glucose value from your meter, not the glucose information displayed on the Dexcom Follow App.

Followers who are concerned by notifications on the Dexcom Follow App should contact the patients and remind them to check their blood glucose with a blood glucose meter

before driving a car or making any treatment decisions, such as taking insulin or eating fast-acting carbohydrates.

Sharers should not rely on Followers to notify them about low or high glucose.

Any problems with smart device(s), *Bluetooth*, wireless Internet connection, mobile data connection, Dexcom Share Cloud or not being in the communication range could cause data to not be shared with the Follower. In addition, if the Delay setting is too long, the Follower might not be aware of glucose level changes in a reasonable time. Therefore, the Dexcom Share feature should be used only to give a secondary level of awareness and should not be expected to always communicate and transfer sensor glucose readings and information.

Benefits

Patients usually respond when their continuous glucose monitoring (CGM) systems alert them.

However, experts advise that an additional CGM alert to another person may be helpful in increasing the detection of low glucose or high glucose values, especially at night. The Dexcom Share feature enables this additional awareness, even when the Sharer and Follower are not in the same place.

The Dexcom Share feature may provide improved quality of life and greater peace of mind to patients, their caregivers and their support team by allowing the Dexcom G5 Mobile Continuous Glucose Monitoring System Alerts, Alarms and trend graphs to be checked remotely.

20.4 Safety Statement

Intended Use

The purpose of Dexcom Share Direct Secondary Displays is to notify another person, the Follower, of the patient's Dexcom Continuous Glucose Monitoring (CGM) System sensor glucose information.

The Secondary Displays is intended for providing secondary notification of a continuous glucose monitoring system and does not replace real time continuous glucose monitoring (Dexcom G5 Mobile System) or standard home blood glucose monitoring. The Dexcom Share Direct Secondary Displays is not intended to modify or analyze data received from the continuous glucose monitor system. Nor is it intended to instruct, or to transmit information to the continuous glucose monitor system.

The Dexcom Share Direct Secondary Displays is not intended to serve as a replacement for a primary display device for a continuous glucose monitoring system. The Dexcom Share Direct Secondary Displays is not intended to receive information directly from the sensor or transmitter of a continuous glucose monitoring system.

Important User Information

Please review the indications, contraindications, warnings, precautions, cautions and other important information in the Dexcom G5 Mobile System User Guide. Dexcom Share is a feature of the Dexcom G5 Mobile System.

If you do not have the Dexcom G5 Mobile System User Guide, you can view it on dexcom.com or call **1.877.339.2664** to request a copy. Availability hours: Monday-Friday, 6am-6pm PST. Please contact your healthcare professional during hours the line is unavailable.

Contraindications

Do not bring the smart device (e.g., mobile phone, tablet computer) into a room containing medical equipment such as Magnetic Resonance Imaging (MRI), Computed Tomography (CT), or diathermy.

These smart devices have not been tested with this equipment. Exposure to these types of equipment could heat and damage the smart devices so that they are unable to send or receive glucose information.

Warnings

Dosing decisions should not be made based on this device. The user should follow instructions on the continuous glucose monitoring system.

This device is not intended to replace self-monitoring practices advised by a physician. Dexcom Share does not work alone. Dexcom Share does not replace the Dexcom G5 Mobile System and requires Share to be turned “On” to communicate glucose information to the Follower.

You cannot use Dexcom Share to make treatment decisions, such as how much insulin to take. Dexcom Share does not replace a blood glucose meter. Always use the values from a blood glucose meter for treatment decisions.

Blood glucose values may differ from the sensor glucose information. Using the sensor glucose information for treatment decisions could lead to low or high blood glucose values.

Precautions

Do not use Dexcom Share as the main source of CGM glucose trend information. Use the Dexcom G5 Mobile Receiver as the main device to track sensor glucose information, notifications and alarms.

At times, the patient will be unable to share data using Dexcom Share, and the Follower might miss helping the patient in the event of low or high blood glucose values. Do not rely solely on the Follower to alert the patient of low or high glucose events or other important information. At times, the Follower may not receive data, and the patient will not be notified of this fact.

When using Dexcom Share, make sure Share is turned “On.” If not, the patient will be unable to share data, and the Follower might miss helping the patient in the event of low or high blood glucose values. If the patient’s smart device does not have a connection or loses the connection, the patient will be unable to share data, and the Follower might miss helping the patient in the event of low or high blood glucose values.

Do not use Dexcom Share unless both the patient’s and Follower’s smart devices have active Internet connections in order to share data. If either the patient or the Follower does not have a connection, loses their connection, turns off the connection (“Airplane Mode”) or if the smart device is in Do Not Disturb mode, the patient will be unable to share data and the Follower might miss helping the patient in the event of low or high blood glucose values. To check this, make sure that the Follower’s smart device can receive text messages. Follow notifications and text messages work by a similar process.

Make sure the patient’s and Follower’s smart devices have charged batteries or are connected to electrical outlets. If the smart device shuts down due to low battery, the patient will be unable to share data, and the Follower might miss helping the patient in the event of low or high blood glucose values.

If the patient’s smart device is powered off or restarted, make sure the Dexcom G5 Mobile App is reopened after the smart device is turned back on in order to resume sharing. If the G5 Mobile App is not reopened, the patient will be unable to share data, and the Follower might miss helping the patient in the event of low or high blood glucose values.

Do not turn off sounds in the Follower’s smart device at any time that he or she wants Follow notifications to be heard. The smart device settings override the Dexcom Follow App, and all notifications will be silent even if the Follower has selected a Dexcom Follow App notification sound. If the smart device has a vibrate feature and vibrate is On, the Dexcom Follow App notifications will only vibrate.

Check the delay settings on the patient’s smart device to make sure they are not too long. The Follower will not receive notifications until after the time period in the delay has passed, and the Follower might miss helping the patient in the event of low or high blood glucose values if the delay is too long.

The patient should not choose to “Not Share” with the Follower at any time when he or she wants the Follower to get notifications. During the time the patient chooses to “Not Share,” the Follower will not receive notifications and might miss helping the patient in the event of low or high blood glucose values.

Check the Dexcom Follow App’s trend graph if the Follower’s smart device has been off or if there is no data connection (e.g., Internet/Wi-Fi or mobile data service/3G/4G/LTE is lost, connection is turned off in Airplane Mode, or smart device touch is placed in Do Not Disturb mode). When the smart device is turned back on, the Follower will only receive the most recent notification and might miss helping the patient in the event of prior low or high blood glucose values.

Sharers and Followers should check whether their cellular service carriers support voice and data at the same time (simultaneous voice and data). If their carriers do not support simultaneous voice and data, the Dexcom G5 Mobile App may not be able to share glucose readings and the Dexcom Follow App may not be able to receive notifications or glucose readings during phone calls. Dexcom Share will resume sharing after the phone call has ended, and the Follower will receive any waiting notifications after the phone call has ended.

20.5 Setting up Dexcom Share

Dexcom Share Description

What Dexcom Share does:

- Connects your smart device with your Follower’s smart device via either a Wi-Fi or mobile data connection (connect to Wi-Fi through a secured network to maintain data security)
- Invites and sends Followers your setting recommendations
- Displays the status of your smart device, and the Dexcom Share Cloud
 - Confirms your sensor glucose readings are being shared with your Follower(s)



What Dexcom Share does not do:

- Let you know when the Follower is not receiving your sensor glucose readings and information

Tips

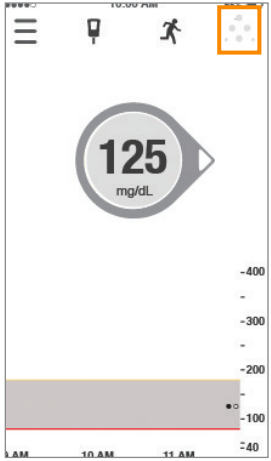

- Read the rest of the Dexcom G5 Mobile CGM System User Guide before using Dexcom Share
- Always confirm information with a BG meter before making treatment decisions
- Check the status screen after turning Dexcom Share “On” on the smart device to make sure it is working

Installing the Dexcom G5 Mobile App

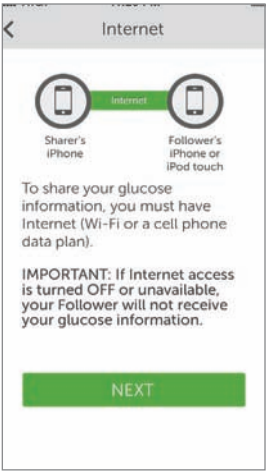

Step	What you see	What you do
1		<p>Download the Dexcom G5 Mobile App from your app store.</p> <p>See your smart device's user manual for instructions.</p> <p>Download the Dexcom G5 Mobile App to use Dexcom Share.</p>
2		<p>Launch the Dexcom G5 Mobile App.</p> <p>Setup your smart device (see the Dexcom G5 Mobile User Guide) before sharing.</p> <p>Once your App has set up, activate Dexcom Share.</p>

A series of screens walk you through Dexcom Share's features highlighting important information.

Activating Your Share Feature


Step	What you see	What it means	What you do
1	 <p>The image shows a smartphone home screen with a large circular glucose reading of 125 mg/dL. In the top right corner, there is a square icon with a grid of dots, which is the Dexcom Share icon. The icon is currently gray, indicating that the Share feature is not activated. Other icons like a menu, location, and walking person are visible at the top.</p>	<p>Activates Dexcom Share. If Dexcom Share icon is gray, your Share feature has not been turned on.</p>	<p>Tap <i>Dexcom Share icon</i> in the upper right corner of your smart device's home screen.</p>
2	 <p>The image shows the Dexcom Share Welcome Screen. At the top is the 'DEXCOM SHARE' logo. Below it, the text reads: 'Welcome! Dexcom Share allows you the Sharer, to send your information to another person, the Follower. For complete information see your User Guide.' At the bottom, there is a green button labeled 'NEXT' and a 'Cancel' option below it.</p>	<p>Dexcom Share Welcome Screen.</p>	<p>Read screen. Tap <i>Next</i> when done.</p>

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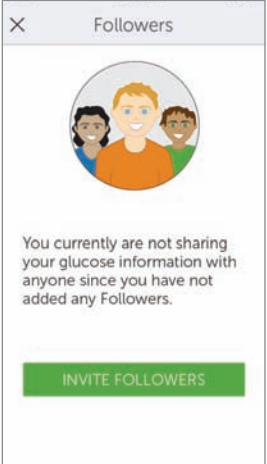
Step	What you see	What it means	What you do
3	 <p>Internet</p> <p>Sharer's iPhone</p> <p>Follower's iPhone or iPod touch</p> <p>To share your glucose information, you must have Internet (Wi-Fi or a cell phone data plan).</p> <p>IMPORTANT: If Internet access is turned OFF or unavailable, your Follower will not receive your glucose information.</p> <p>NEXT</p>	Message about Internet access.	Tap <i>Next</i> .
4	 <p>Sharing</p> <p>Colored Logo</p> <p>Glucose Value</p> <p>To make sure you are sharing, you must see BOTH a colored logo and a glucose value.</p> <p>If you are not sharing, the logo will turn gray with a red badge.</p> <p>NEXT</p>	How to know you are sharing your data.	Tap <i>Next</i> .

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Step	What you see	What it means	What you do
5	 <p>Sharing</p> <p>There will be times when your Follower cannot see your glucose information.</p> <p>An example: Follower is in a remote area with no Internet access. Your Dexcom G5 Mobile should always be the primary source of glucose information.</p> <p>LET'S GET STARTED</p>	How to know your Follower is not getting your sensor data.	Tap <i>Let's Get Started</i> to move on and invite your Followers.

Inviting Followers

Step	What you see	What you do
1		<p>Tap <i>Invite Followers</i> to set up your Followers.</p>


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Step	What you see	What you do
2	 <p>The screenshots show the 'Add a Follower' screen. The top screenshot shows the form with a keyboard open. The bottom screenshot shows the form with a green 'NEXT' button at the bottom.</p>	<p>Enter the Follower's nickname and email address. Confirm Follower's email address. The Follower will get a Follow Invitation email. Make sure the Follower can access this email account from their smart device. Tap Next.</p>

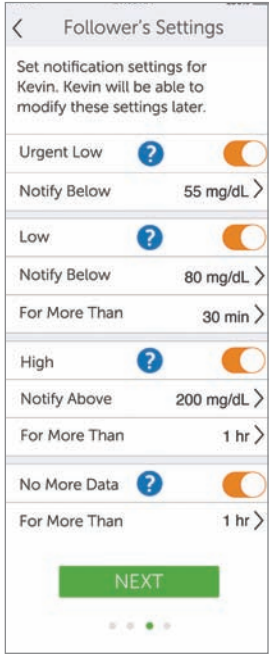
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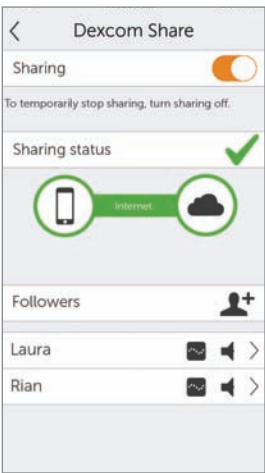
Step	What you see	What you do
3		<p>Tap <i>Allow Trend Graph View's On/Off switch</i> if you want Follower to see your trend graph.</p> <p>Tap Next.</p> <p>Turned Off: Follower sees only your sensor glucose reading and trend arrow.</p> <p>Turned On: Follower sees your sensor glucose reading, trend arrow and trend graph.</p>

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Step	What you see	What you do
4	 <p>The screenshot shows the 'Follower's Settings' screen. At the top, it says 'Set notification settings for Kevin. Kevin will be able to modify these settings later.' Below this are four sections, each with a toggle switch and a 'For More Than' setting:</p> <ul style="list-style-type: none">Urgent Low: Toggle is on (orange), 'Notify Below' is 55 mg/dL.Low: Toggle is on (orange), 'Notify Below' is 80 mg/dL, 'For More Than' is 30 min.High: Toggle is on (orange), 'Notify Above' is 200 mg/dL, 'For More Than' is 1 hr.No More Data: Toggle is on (orange), 'For More Than' is 1 hr. <p>At the bottom, there is a green 'NEXT' button and three dots indicating the current step.</p>	<p>Choose if your Follower gets your urgent low, low and high sensor glucose Alarm/Alerts.</p> <p>Choose if you want your Follower to get prompts if they are not receiving your sensor glucose readings.</p> <p>Select what Alarms/Alerts your follower gets and how long you are low/high or not sharing data (for example, if you want your Follower to know when your glucose is above 200 mg/dL for more than 2 hours, you can set up in the Follower Settings Menu).</p> <p>Tap <i>Save</i> for each Follower Setting “Save.”</p> <p>Tap <i>Next</i> when done.</p>

(Continued on next page)

Step	What you see	What you do
5		<p>Before Follower invitation is sent, review the Summary screen.</p> <p>Tap <i>Send Invitation</i>.</p> <p>After sending invitation, you cannot adjust the Follower's settings.</p>
6		<p>To add more Followers:</p> <p>Tap <i>Followers</i> tab on the Share Status screen.</p> <p>Invite up to a total of five (5) Followers.</p>

20.6 Using Dexcom Share

Dexcom Share Status

You can look at the Dexcom Share icon on your home screen to see if Dexcom Share is working. After turning Dexcom Share on, check its status.

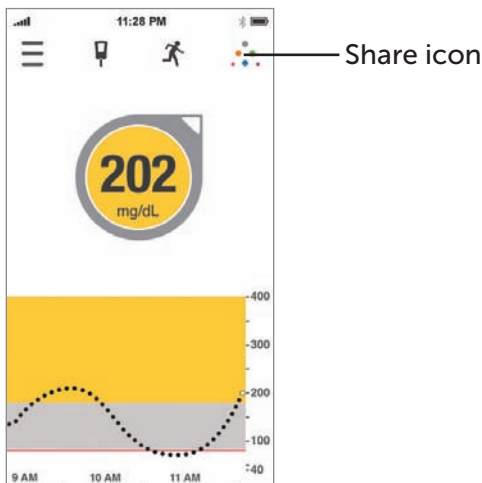





Figure 11. Dexcom G5 Mobile App Home Screen

Dexcom Share Status Icons

Status Tab	What it is
	The Share icon is in color when Dexcom Share is sending sensor glucose readings and information.
	The Share icon is gray with a red circle when Dexcom Share is not working. The sharer should tap on the grayed out Share icon when it is not working to get further information about the error.

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Status Tab	What it is
	<p>The Share icon is light gray when Dexcom Share has not been activated.</p> <p>The sharer should tap the light gray icon to get started using Dexcom Share.</p>

When a device or connection is not working, Dexcom Share will not work. The Sharer will not be able to send their sensor glucose readings and data to their Follower.

Troubleshooting Status Issues

Dexcom Share's status bar is a useful tool. It can help identify if there is a problem and Dexcom Share is not working. The following table provides troubleshooting tips for the Share status bar.

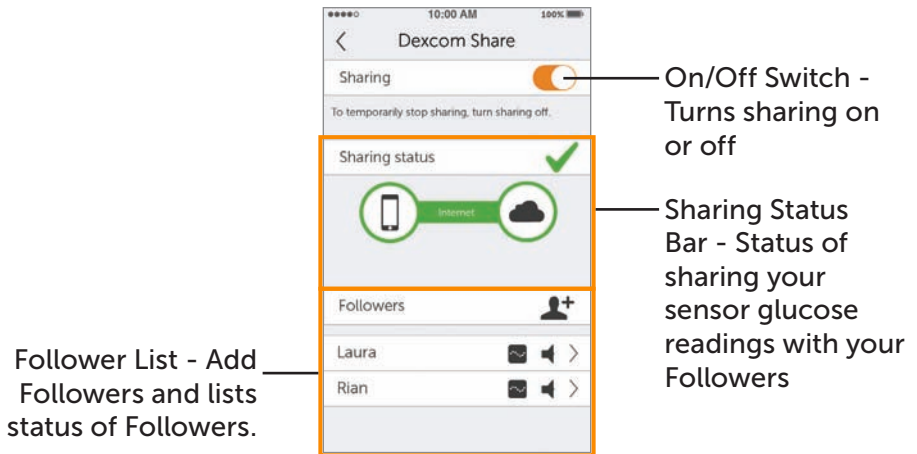
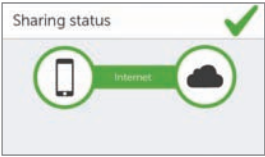
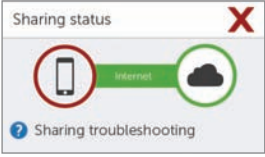


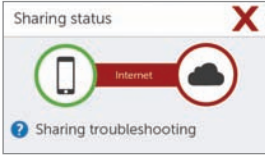
Figure 12. Dexcom Share Screen

NOTE: Whether or not Dexcom Share is working and the Followers are receiving glucose Alarm/Alerts, you must always refer to your Dexcom G5 Mobile display device for your sensor glucose readings and alerts.

All treatment decisions must be based on your BG value from your BG meter.

What you see	What it means	What you do
 <p>Sharing status</p>	<p>Green Check: All connections are working</p>	<p>N/A.</p>
 <p>Sharing status</p> <p>Sharing troubleshooting</p>	<p>Issue with:</p> <ul style="list-style-type: none"> • Sharer's CGM data • Your smart device 	<p>The Sharer should make sure:</p> <ul style="list-style-type: none"> • There is a glucose value on the smart device • Transmitter is in range of the smart device • Tap on blue “?” to learn more about how to troubleshoot this issue • The Sharer should allow up to 10 minutes for their status to turn green and a green check mark to appear <p>If the Sharer continues to see this, the Sharer should turn off Share and then turn it back on.</p>

(Continued on next page)

What you see	What it means	What you do
 A screenshot of a mobile device's sharing status notification. At the top, it says "Sharing status" with a red "X" icon. Below this is a diagram showing a smartphone icon connected to a cloud icon labeled "Internet". The smartphone icon is inside a green circle, and the cloud icon is inside a red circle with a white "X". At the bottom left, there is a blue question mark icon and the text "Sharing troubleshooting".	<p>Issue with:</p> <ul style="list-style-type: none">• Sharer's Internet connection• Dexcom Share Cloud	<p>The Sharer should make sure:</p> <ul style="list-style-type: none">• Their Wi-Fi or cellular connection is ON• They are in an area that has cellular reception• They are not on a voice call• They can access the web via a browser• Check later or follow up with their Internet connectivity provider• Tap on blue "?" to learn more about how to troubleshoot this issue


Follower List

The Followers list allows the Sharer to manage their Followers.

In the Follower list you can:

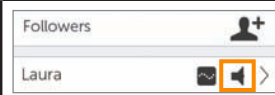

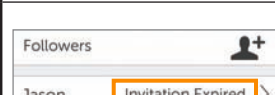
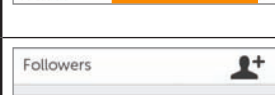

- Invite a new Follower
- See the status of Followers you have invited
- Glance at what options your current Followers have

Icon/Status

What you see	What it means
 A screenshot of a mobile device's Followers list. The title "Followers" is at the top. Below it is a list item for "Laura". To the right of "Laura" is a person icon with a plus sign, which is highlighted with an orange square. Below the name "Laura" are icons for a speech bubble, a speaker, and a right-pointing arrow.	<p>Invite a new Follower.</p>

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What you see	What it means
	Follower is set to get prompts from their Sharer.
	Follower is able to view their Sharer's trend graph.
	Follower did not accept their Sharer's Follow Invitation email within 7 days. The Sharer can invite their Follower again by pressing on the + icon in the top right corner of the screen.
	Follower has been sent a Follow Invitation email but has not accepted it yet.
	Sharer stopped sharing with Follower. Follower will not get any of the Sharer's glucose information, Alarm/Alerts, or trend graph updates.

Editing/Removing Followers

Tap on a Follower to edit the Follower's profile (nickname or ability to view trend graph) or remove a follower. Remove a follower by tapping "Remove Follower." Once removed, they won't get glucose information or Alarm/Alerts.

NOTE: The Sharer cannot change any Follower settings after the Follow Invitation email is sent.

Stop Sharing

The Sharer can swipe the On/Off switch to temporarily stop glucose information and Alarm/Alerts from being sent to Followers. Sharing stops until the Sharer turns the On/Off Switch back on.

For reasons of safety and intended use, the Follower will get a message telling them their Sharer's data was set to *Not Sharing*. The Follower's dashboard will show the Sharer has stopped sharing glucose information.

20.7 Dexcom Follow App

Dexcom Follow App Description

The Dexcom Follow App is a separate App from the Dexcom G5 Mobile App. Your Followers only need to download and install the Dexcom Follow App.

What the Dexcom Follow App does:

- Allows Follower to view the Sharer's glucose information
- Allows Follower to get Alerts and Alarms
- Allows the Follower to view the Sharer's trend graph

What the Follower app does not do:

- Provide treatment advice
- Interact with the Dexcom G5 Mobile App

Receiving Dexcom Follow Invitation Email

After getting the Sharer's Follow invitation by email, the Follower sets up their smart device.

Glucose Alarm and Alerts

A glucose prompt is a visual message saying "Glucose notification from [Sharer's name]" that appears on the screen of the Follower's smart device. The prompt may include sounds, depending on their smart devices settings.

Types of prompts your Followers get:

- Low Sensor Glucose Reading
- Urgent Low Sensor Glucose Reading (< 55 mg/dL)
- High Sensor Glucose Reading

Your Follower can change some of the initial settings to fit their needs. The Follower cannot change your permission settings to see your Trend Graph.

Sharer Status Changes That Notify the Follower

Some Sharer status changes will prompt your Followers.

- **Not Sharing** - Sharer decides to temporarily stop sharing
- **Removed by Sharer** - Sharer removes Follower
- **No More Data** - Prompt Sent when active glucose sharing is stopped for any reason, other than the Sharer turning Share “Off”
 - The Follower should contact the Sharer for more information about the data interruption

The Follower Dashboard



Figure 13. Follower Dashboard

If you don't allow your Follower to see your Trend Graph, they will only see your glucose reading and trend arrow.

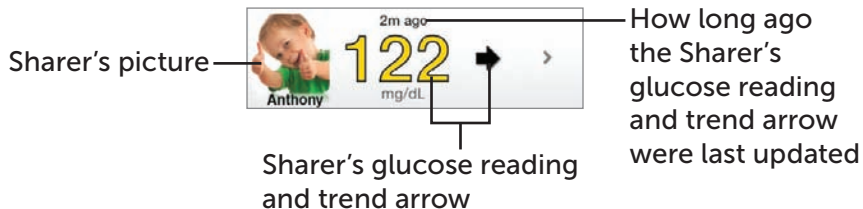


Figure 14. Follower Information

If you choose to have your Follower see your Trend Graph, they see:

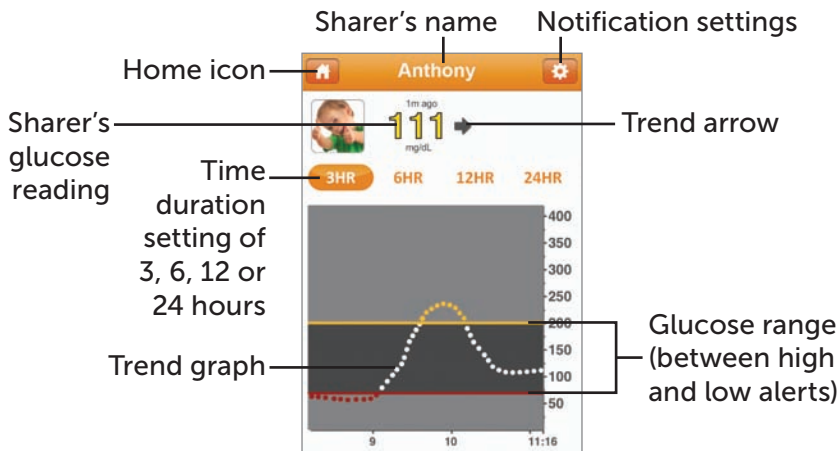


Figure 15. Follower Information With Trend Graph

20.8 Troubleshooting

Dexcom Share Troubleshooting

Troubleshooting Status - See the Troubleshooting Status Issues portion of Section 20.6.

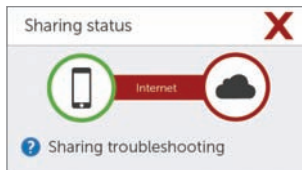


Figure 16. Sharing Status Troubleshooting

Sharing Checklist

To share, you need to:

Make sure your smart device works with the Dexcom G5 Mobile App. To see a list of supported smart devices and operating systems, go to: dexcom.com/compatibility

- The Dexcom G5 Mobile App is open or running in the background
- Smart device has an active Internet connection (Wi-Fi, 3G, 4G, LTE). The Sharer can check to see if the Internet connection is working by trying to open a web page on the Sharer's smart device
- If on a phone call using your smart device, your CGM information may not upload into the Share Cloud while on your call
- Airplane Mode turned off
- Do Not Disturb is turned off
- Smart device sound is on in order to hear prompts
- Smart device is sufficiently charged or charging
- Smart device is within 20 feet of the transmitter
- Smart device has 35 MB of available memory
- Refer to the smart device user manual for further instructions

Tips

- Read the Dexcom G5 Mobile CGM System User Guide before using the Dexcom Share feature
- Always confirm information with a BG meter before you make treatment decisions

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