

### CONTINUOUS GLUCOSE MONITORING SYSTEM

User Guide

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Dexcom G5x Mobile System User Guide

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Glossary

## **GETTING STARTED**

- Glossary
- Getting Started
- Indications for Use and Safety Statement
- Risks and Benefits

Dexcom G5x System User Guide Glossary

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### Glossary

A1C	Blood test used to diagnose type 1 or 2 diabetes and to gauge how well you're managing your diabetes. The A1C test result reflects your average blood sugar level for the past two to three months.
Accessory Device	Hardware, connected to your smart device by <i>Bluetooth</i> , you use to get easy access to some of its features. For example, <i>Bluetooth</i> headset, Apple watch, or smart watch. Also called wearables.
Alternative Site Testing	Using a blood sample from non-fingertip (alternative) sites such as the palm, forearm, or upper arm for meter readings. Do not use alternative site testing to calibrate the Dexcom G5 <sup>®</sup> x CGM System (G5x), only use fingerstick measurement.
Арр	A self-contained program or piece of software designed to fulfill a particular purpose; an application, especially as downloaded by a user to a smart or mobile device. The Dexcom G5® Mobile app (app) was developed as a display for continuous glucose monitoring.
Apple Watch®	Accessory device for iPhone®.
Blood Glucose (BG)	An abbreviation of blood glucose. Blood glucose
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	(BG) value is the amount of glucose in the blood measured by a BG meter.
Blood Glucose Meter/Meter/BG Meter	A medical device used to measure how much glucose is in the blood.
Calibration	A comparison or measurement between your meter's fingerstick BG values and the sensor's interstitial fluid glucose readings. Although blood and interstitial fluids are similar, glucose concentration is higher in your blood. Calibration allows alignment between your sensor and meter readings.
	When you calibrate, you take a fingerstick measurement from your meter then enter the value into your receiver or smart device. The system uses that value to verify that the sensor glucose reading is on track.
Continuous Glucose Monitoring (CGM)	A system that uses a sensor inserted under the skin to check glucose levels in interstitial fluid. A transmitter sends sensor glucose readings to a display device.
	Users must confirm glucose levels with a BG meter before making a change in treatment.
Contraindication	A safety statement outlining specific situations where the system should not be used because it may be harmful to you. The risk of use clearly outweighs any possible benefit.

Glossary

Hyperglycemia	High BG. Same as "high" or high blood sugar. Hyperglycemia is characterized by an excess of glucose in the bloodstream.
	It's important to treat hyperglycemia. If left untreated, hyperglycemia can lead to serious complications.
	The default High Glucose Alert in the G5x is set to 200 mg/dL. Consult your healthcare professional to determine the appropriate hyperglycemic setting for you.
Hypoglycemia	Low BG. Same as "low" or low blood sugar. Hypoglycemia is characterized by a low level of glucose in the bloodstream.
	It's important to treat hypoglycemia. If left untreated, hypoglycemia can lead to serious complications.
	The default Low Glucose Alert in the G5x is set to 80 mg/dL. Consult your healthcare professional to determine the appropriate hypoglycemic setting for you.
Indications	A condition making a particular treatment or procedure advisable. How, for what purposes, and under what circumstances you should use the G5x. Indications let you know who should use the G5x and when.

Glossary

IP	The International Electrotechnical Commission (IEC) is a nonprofit, non-governmental, international organization created to produce safety standards for electronics. One of the safety standards it designed is the Ingress Protection (IP) Marking, which classifies and rates how protected an electronic device is against dust, water, accidental contact, etc.
	IP ratings are numerical, with the number based on the conditions the electronic device comes across.
	An IP22 rating lets you know your electronic device won't allow you to stick your fingers in it and won't get damaged or be unsafe during specific testing with water dripping down.
	An IP28 rating tells you your electronic device won't let you stick your fingers in it and is safe for long-term immersion in liquid up to a specified pressure.
Jailbroken	The removal of limitations and security measures set by the manufacturer on a smart device. The removal poses a security risk, and data may become vulnerable.
	Do not use, install, or run the Dexcom G5 Mobile app on a jailbroken smart device. The app may not work correctly on a jailbroken smart device.
Landscape	When your smart device is oriented sideways.
mg/dL	Milligrams per deciliter. The standard unit of measure for glucose readings in the United States.

Glossary

Portrait	When your smart device is oriented vertically.
Precaution	A safety statement regarding any special care to be exercised by you or your healthcare professional for the safe and effective use of the G5x.
RF	Radio-frequency (RF) transmission used to send glucose information from the transmitter to the receiver or smart device. Also used to send calibration data from the receiver or smart device to the transmitter.
Safety Statement	A statement of the intended uses of G5x and relevant warnings, precautions, and contraindications.
Sensor Session	The seven-day monitoring period after inserting a new sensor. During this time frame, your glucose is being monitored and reported every five minutes, with data being sent to your display device(s).
Smart/Mobile Device	Electronic device that can be wirelessly connected to networks over Wi-Fi, <i>Bluetooth</i> , or a cellular data connection (3G, 4G, etc. Examples are smartphones, tablets, and smart watches.
Today View	Swipe down to access information and notifications on your iPhone, iPad®, and iPod®.
Warning	A safety statement letting you know the following feature has important hazard information.
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Glossary

Glossary

### Chapter 1

Getting Started:

### Beginning Your Dexcom G5<sup>®</sup>x Continuous Glucose Monitoring System (G5x) Journey

### **1.1 Introduction**

Welcome to the G5x family!

We are excited you chose us to partner with you in your journey to manage your diabetes. As a continuous glucose monitoring (CGM) device, the G5x allows you to break free from constant fingersticks. But how do you use the G5x? What are its features? Do you need to avoid anything?

Where do you even begin?

This chapter is the first step to answering these and many other questions.

After this chapter, you will be able to:

- Describe different training resources
- Locate tutorials about using the G5x in your diabetes management
- Find G5x's step-by-step instructions
- Recall how to use the user guide
- Explain why you need a Dexcom<sup>®</sup> account

We have numerous resources available to help you get the most out of your G5x. Between our self-paced training resources and our friendly and knowledgeable Dexcom customer support teams, help is always available.

### First Things First - Learning How to Learn

Knowing about the G5x is your first step in creating a successful CGM experience. Before using it, learn about it.

You have numerous self-paced resources, helping you get to know the G5x:

- 1. Tutorials
- 2. Getting Started Guide

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Beginning Your Dexcom G5x Continuous Glucose Monitoring System (G5x) Journey

#### 3. User Guide

No matter which resource(s) you select, make sure you review them prior to using your new CGM system.

### 1.2 Self-Paced Resources

#### **Tutorials**

Along with step-by-step instructions, our tutorials illustrate how real-time CGM can assist in your daily diabetes management. The following is a list of tutorials and how to access them.

#### **Online Tutorials**

#### First Steps With Your Dexcom CGM

Designed for those who have never used a Dexcom CGM. This tutorial covers what to expect in your first week and includes links to step-by-step videos on how to insert your sensor, calibrations, ending a sensor session, etc.

#### Next Steps With Your Dexcom CGM

Just finished First Steps or already familiar with how a CGM can benefit you? This tutorial covers looking at trends and introduces some advanced features including our reporting tools.

#### Accessing Online Tutorials:

From dexcom.com homepage, click Support.

Once you have viewed the online tutorials, you should be pretty comfortable with what CGMs do and how the G5x can help you.

#### **Offline Tutorials**

You don't need to be tied to the Internet to view our instructional tutorials, they're also available offline.

#### Accessing Offline Tutorials:

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Beginning Your Dexcom G5x Continuous Glucose Monitoring System (G5x) Journey

USB Card in the receiver package.

#### Guides

#### Getting Started Guide (GSG)

The G5x GSG complements the tutorials by providing the same step-by-step instructions in a booklet form or within the app.

One of the great things about the GSG is you can use it in conjunction with the videos, taking notes as you go!

#### Accessing the GSG:

Booklet in the receiver package.

Both the tutorial and the GSG give you a brief look at the G5x. But what if you want more detailed information?

#### User Guide

Your G5x reference book!

This user guide gives you the most extensive overview of the system, detailing features, important safety information, and so much more.

To download an eBook of the user guide or request a printed user guide, visit dexcom.com/guides.

The G5x user guide is grouped into six separate parts:

Part 1: Getting Started

- Glossary
- · Getting Started
  - Learning how to learn about the G5x
  - Registering at dexcom.com
- · Indications for Use and Safety Statement
- Risks and Benefits

Part 2: *Let's G5x! The Basics* Dexcom G5x System User Guide

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Beginning Your Dexcom G5x Continuous Glucose Monitoring System (G5x) Journey

- Introduction to the G5x
- Initial Setup
- Starting a Sensor Session: Inserting the Sensor and Attaching Transmitter
- Calibration
- Ending a Sensor Session and Transmitter Session

Part 3: Next Steps - Getting the Most out of Your G5x

Once you are up and running, how you can maximize the G5x features:

- Reading Trend Graph Screens and Recognizing Trends
- Events
- Alarm and Alerts
- Sounds for Alarm, Alerts, and System Messages

**Part 4:** Everything Else G5x

- Warranty
- G5x Maintenance
- Travel Tips
- Customer Service Contacts
- Technical Information
- Troubleshooting
- Symbols on Package Labels

At the end of your G5x user guide, Part 5, is the user guide for Dexcom  $Share^{\mathbb{B}_{TM}}$ .

#### Part 5: Sharing Is Caring

- Dexcom Share
  - What Is Dexcom *Share*?
  - Setting Up Dexcom Share
  - How to Use Dexcom Share

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Beginning Your Dexcom G5x Continuous Glucose Monitoring System (G5x) Journey

- Your Followers
- Troubleshooting

#### Part 6

• Index for G5x System and Dexcom *Share* 

#### How to Use Your User Guide

All chapters in the G5x user guide are laid out the same way:

The beginning of each chapter lists what you'll be able to do after you have finished, after that, any applicable safety statements you need to know, followed by the chapter's content. At the end, there's a recap of what was covered and what's in the next chapter.

### 1.3 Your Dexcom Account

You'll need a username and password to set up the G5 Mobile app (app) and for reordering.

If you haven't already done so, go to dexcom.com and set up your own account.

Or, if you prefer, the app walks you through creating your log-in credentials as part of your initial app setup.

#### Summary

Now You Can:

- · Describe different training resources
- Locate tutorials about using the G5x
- Find step-by-step instructions for the G5x
- Recall how to use the user guide
- Explain why you need a Dexcom<sup>®</sup> account

#### What's Next?

Now you are familiar with how to use this user guide and where to go for help.

Throughout the user guide you'll see color-coded boxes containing Safety Statements. The next chapter, Indications for Use and Safety Statement, lists all Safety Statements along with how to read and interpret them. Dexcom G5x System User Guide

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Next you'll learn about when and how to use the G5x safely.

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Beginning Your Dexcom G5x Continuous Glucose Monitoring System (G5x) Journey

### Chapter 2

Getting Started:

### Indications for Use and Safety Statement

### 2.1 Introduction

We want the G5x to be a valuable tool in your diabetes management. Like any system, there are steps to take to get the most out of it. As excited as you are about getting started, did you know if you just took Tylenol<sup>®</sup>, maybe you should wait? Did you know taking Tylenol is contraindicated?

In this chapter, you'll learn about some key areas that might prevent you from having the best CGM experience, or, if you're not careful, might even harm you or the system. You'll even learn what a contraindication is!

### 2.2 Important User Information

Each part of your system has instructions including indications, contraindications, warnings, precautions, and other important user information. Please review the instructions for each part of the system in this user guide before using the G5x.

This chapter is important to read. It helps you use the G5x safely and covers:

- What is a Safety Statement?
  - Telling the difference between an indication and a contraindication
  - Explaining why warnings are so important
  - Defining precautions
- How to read a chapter's Safety Statement
- Overview of Safety Statements

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Let's start with definitions, look at a Safety Statement example used throughout the User Guide, and then review the Safety Statements broken down into the system's components.

#### Safety Statement

A Safety Statement is a brief statement of the G5x's indications, relevant warnings, precautions, or its contraindications (when to avoid using it). The Safety Statements are meant to keep you and the system safe while using the G5x:

#### 1) Indications

How, for what purposes, and under what circumstances you should use the G5x. Indications let you know who should use the G5x and when. Indications are the who, what, and why of the G5x.

#### 2) Contraindications

Contraindications let you know when *not* to use the G5x. If used during these situations, you may hurt yourself or the system; the risk of use clearly outweighs the benefit.

#### 3) Warning

Important hazard information: Describes serious or life-threatening circumstances to stay away from while using the G5x, their consequences, and how to avoid danger.

#### 4) Precaution

Special steps you need to take while using the G5x, preventing minor or moderate injury to either you or the system.

### 2.3 Safety Statements

This user guide presents Safety Statement two ways:

1. In this chapter's Overview of Safety Statements

Dexcom G5x System User Guide

- o Lists all Safety Statements
- o Includes a section reviewing how the statements are formatted
- 2. Within each chapter
  - Lists only those statements applicable to that specific chapter

### Chapter's Safety Statements

Each chapter will list all applicable indications, contraindications, warnings, and precautions.

Some chapters will have multiple Safety Statements; others have none. Safety Statements are located toward the front so you can keep them in mind as you learn about that chapter's topic. The same statement may be repeated throughout the user guide. It's important to recognize which factors could prevent the system from working correctly, or even harm you.

Within chapters, each color-coded Safety Statement is in a box, broken down into four sections:

- 1. Type of statement
  - a. Bold and color-coded
    - WARNING-Red
    - PRECAUTION-Blue
    - INDICATION-Green
    - CONTRAINDICATION-Purple
- 2. Do's/Don'ts
  - a. An action you should or should not take
  - b. Italicized
- 3. Why
  - a. A statement of the potential harm
- 4. Consequences
  - a. What could happen if you don't follow the instructions

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The following is an example of a chapter's Safety Statement and how to read

#### Warning

it.

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

Since this is a **Warning**, you know it covers important safety information. Italics are the **Do/Don't** steps to follow: *Calibrate at least once every 12 hours*. Below the italics is a statement explaining **Why** you need to follow the steps: Calibrating less often than every 12 hours might cause inaccurate sensor glucose readings. And finally what happens, or the **Consequences**, if you don't: Missing a severe low (hypoglycemia) or high (hyperglycemia) glucose event.

### 2.4 Overview of Safety Statements

This section provides a review of Safety Statements containing the same elements described above (type of Safety Statement, an action, a statement of potential harm, and consequences) but listed in a narrative, not boxed, format. Here you'll learn what indications and contraindications are and what to do to keep you safe and the system in proper working order.

Safety Statements are broken down into two major categories. First, general CGM system Warnings which review warnings and precautions you take with most CGM systems—and second, Hardware/Software Warnings and Precautions which list warnings and precautions specific to the G5x components.

### Indications and Contraindications Indications

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What are the G5x indications? Well, in technical terms, the indications are:

The Dexcom G5x Continuous Glucose Monitoring (CGM) System (G5x) is a glucose monitoring system indicated for detecting trends and tracking patterns in persons (age 2 years and older) with diabetes. The system is intended for single patient use and requires a prescription.

The system is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The system aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the system results should be based on the trends and patterns seen with several sequential readings over time.

#### In Layman's Terms

But what does that mean? Indications are the who, what, and why of the G5x.

#### Who

The G5x is a single patient use device (meaning you can't share the components with others) for people age 2 years and older with diabetes.

#### What

The G5x is a prescription-only glucose-monitoring device. G5x tracks your glucose patterns and detects trends. Working with your home blood glucose (BG) meter, the system is meant to complement, not replace, your BG meter.

#### Why

The CGM system's trend and pattern information, its glucose Alarm/Alerts, combined with your meter's actual BG value, can help you manage your diabetes.

By identifying low and high glucose level periods, the G5x allows you to take action when needed and create long-term management strategies with your healthcare professional. Using trend information to see your highs and lows helps you stay inside your target range.

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The G5x's trend and pattern information is based on a series of sensor glucose readings taken over a period of time.

Work with your healthcare professional and create a game plan on how to best use your trend and pattern information in managing your diabetes.

#### Contraindications

Contraindications let you know when *not* to use the G5x; you may hurt yourself or damage the system. Remember, if used during certain situations, the risk of use may clearly outweigh any potential benefit. Within the chapters, contraindications are in purple boxes.



MRI/CT/Diathermy

Don't wear the system (sensor, transmitter, and receiver) before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.

The system hasn't been tested during MRI, CT scans, or with diathermy treatment. Magnetic fields and heat could damage the components, stopping sensor glucose readings or Alarm/Alert notifications. Without sensor glucose readings or Alarm/Alert notifications, you might miss a severe low or high glucose event.

#### **Medications**

Taking medications with acetaminophen (such as Tylenol or Excedrin<sup>®</sup> Extra Strength) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and is different for each person.

### 2.5 General CGM System Warnings

### Warnings

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Warnings outline important hazard information, describing any serious and/or life-threatening situations, their consequences, how to avoid danger while using the system and how to protect the G5x from harm.

#### **Review Training Materials**

Thoroughly review the training materials included with your system before using.

Incorrect use could lead you to misunderstand system information or might affect its performance and you might miss a severe low or high glucose event.

#### **Treatment Decisions**

The system does not replace your BG meter.

When making treatment decisions, such as the amount of insulin you need, only use your BG value. Don't use the G5x sensor glucose readings because they can be different from your BG value. If sensor glucose readings are used in determining treatments, it could result in you missing a severe low or high glucose event.

#### Don't Ignore Low/High Symptoms

If your sensor glucose readings don't match your symptoms, measure your BG with a fingerstick. You may miss a severe low or high glucose event.

#### Who Shouldn't Use

The system was not evaluated for the following persons:

- Pregnant women
- Persons on dialysis

Do not use the Dexcom G5x System in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Sensor glucose readings may be inaccurate in critically ill patients.

The system's accuracy hasn't been tested in people falling into these groups and sensor glucose readings may be inaccurate, resulting in missing a severe low or high event.

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### 2.6 Calibration Warning and Precautions

Calibration is the process of making sure your sensor continues to be accurate. Your sensor doesn't automatically know what your glucose levels are—you have to teach your system what a given BG value is by entering in a KNOWN glucose value from your BG meter.

### Warning

#### Calibrate on Schedule

Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate, resulting in you missing a severe low or high glucose event.

#### Precautions

#### Be Accurate, Be Quick

Enter the exact BG value displayed on your BG meter within five minutes of a fingerstick.

Entering the wrong BG values, or waiting more than five minutes before entry, might affect sensor performance, resulting in you missing a severe low or high event.

#### Significant Glucose Rate Changes

Don't calibrate when your BG is changing at a significant rate: more than 2 mg/dL per minute.

Look for rate of change arrows on your display device screen and don't calibrate when you see:

- A single arrow, pointing up
  - Rising 2-3 mg/dL each minute
- Two arrows pointing up
  - Rising more than 3 mg/dL each minute
- Single arrow pointing down
  - Falling 2-3 mg/dL each minute

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- Two arrows pointing down
  - Falling more than 3 mg/dL each minute

Calibrating during a significant rise/fall of your BG may affect accuracy of sensor glucose readings, resulting in you missing a severe low or high glucose event.

#### Fingerstick Only

Only use fingerstick measurements from your BG meter for calibration.

Alternative site BG values from your arms, palm of your hand, etc., may be different and less accurate than your fingerstick BG values. Using alternative sites for calibration might affect sensor performance, resulting in you missing a severe low or high glucose event.

#### Prior to Startup Calibration: Data/Alarm/Alert

After starting a new sensor session, until completing your startup calibrations you won't receive any sensor information such as readings, Alarm or Alerts. Without these, you may miss a severe low or high glucose event.

Continue to take fingerstick measurements during a new sensor warmup period.

Now that we have reviewed common CGM Safety Statements, let's focus on the G5x components.

# 2.7 System/Hardware/Software Warnings and Precautions

In this section, you will learn how to safely use the G5x's hardware and software. Some sections have either Precautions or Warnings, others will have both.

#### Sensor/Transmitter Holder Warnings and Precautions

### Warnings Sensor Breaking Off

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On rare occasions, the sensor wire may break or detach from the transmitter holder.

Within 24 hours of experiencing a broken sensor wire, please call our 24/7 Technical Support department, toll free at **1.888.738.3646** 

If a sensor wire breaks under the skin with no portion of it visible, don't remove it. Contact your healthcare professional if you have redness, swelling, or pain at the insertion site.

#### Placement

Do not insert the sensor component of the system in a site other than the belly/abdomen (ages 2 years and older) or the upper buttocks (ages 2 to 17 years). The placement and insertion of the sensor component of the system is not approved for other sites.

The system has not been tested in other areas and may not work properly if inserted in other areas.

#### Storage

During a sensor's shelf life, store it between  $36^{\circ}$  F- $86^{\circ}$  F. While you don't need to keep your sensor in a refrigerator, you can as long as the refrigerator is between  $36^{\circ}$  F- $86^{\circ}$  F.

Never store sensors and/or sensor packages in a freezer.

Storing the sensor incorrectly might cause the sensor glucose readings to be incorrect, resulting in you missing a severe low or high glucose event.

#### Precautions

#### **Expiration Date**

Don't use expired sensors. Before inserting, always check the package label for the expiration date using the YYYY-MM-DD format.

If past the expiration date, don't use because the sensor glucose readings might not be accurate, resulting in you missing a severe low or high glucose event.

#### Sensor Package

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Don't use sensor if its sterile package has been damaged or opened. Using a non-sterile sensor might cause infection.

#### Clean and Dry Before Using

Before opening the sensor package, wash your hands with soap and water, then dry. If your hands are dirty while inserting the sensor, you may contaminate the insertion site and get an infection.

Before sensor insertion, clean the skin with alcohol wipes to prevent infections. Don't insert the sensor until the cleaned insertion site is dry, and free from any lotions or perfumes.

If your insertion site is not clean and completely dry, you run the risk of infection or the transmitter holder not sticking and falling off.

#### Sensor Placement

Don't insert the sensor where bones are close to the skin's surface (for example, over your ribs or hip bones). If you insert the sensor in these areas, you may feel excessive pain or damage your sensor.

Don't remove the safety guard before placing the applicator on the skin. If you remove the safety guard first, you may accidentally deploy the needle and hurt yourself. Change the site where you place the sensor with each new insertion. Using the same site too often might not allow the skin to heal, causing scarring or skin irritation.

Sensor placement is important. Choose a site:

- · At least 3 inches from insulin pump infusion set or injection site
- · Away from waistband, scarring, tattoos, irritation
- Unlikely to be bumped or pushed

Insertion in these areas might affect sensor performance, resulting in you missing a severe low or high glucose event.

### Transmitter Warnings and Precautions

### Warnings

#### Inspect Transmitter

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If your transmitter is damaged or cracked in any way, don't use it. Damaged components could create an electrical safety hazard or malfunction, which might cause electrical shocks.

#### Choking

The transmitter is small and may pose a choking hazard. Don't put it in your mouth or allow children to play with it.

#### Precautions

#### **Reusable: Don't Throw Away**

When ending a session, don't throw away the transmitter.

The transmitter is reusable and can be used in multiple sensor sessions. Keep using it until the system notifies you the transmitter battery is about to expire.

#### **Don't Share Your Transmitter**

Never share your transmitter with another person. The system is a prescription-only medical device and is meant, or indicated, for your use only.

Your transmitter is tied to *your* readings. If used by someone else, your reports, Alarm and Alerts, etc., would be wrong, resulting in you missing a severe low or high glucose event.

### **System Precautions**

Next are precautions for the receiver, transmitter, sensor, and the system.

#### Precautions

#### Use Correct Transmitter, Receiver, and Sensor

The G5x transmitter must be used with the G5x Sensor and is not interchangeable with the Dexcom G5®Mobile/G4<sup>®</sup> PLATINUM Sensor. The G5x transmitter is compatible with the G5 Mobile receiver.

The G5x transmitter and receiver are not compatible with the Dexcom G4 PLATINUM CGM System's transmitter and receiver.

#### System Accuracy

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System accuracy may be affected when your glucose is changing at a significant rate such as during exercise or after a meal.

Significant glucose rise/fall rates:

- Rising 2-3 mg/dL each minute
- · Rising more than 3 mg/dL each minute
- Falling 2-3 mg/dL each minute
- Falling more than 3 mg/dL each minute

#### **Airport Scanners**

Be aware of airport body scanners and baggage x-rays when you travel. Do not place any part of the G5x system in the baggage x-ray machine or body scanner. Ask for visual inspection instead:

- Baggage x-ray machine: Instead of putting any part of your G5x through the baggage x-ray, ask the TSA officers to visually inspect it.
- Body scanner: When you are wearing your G5x, request handwanding or full-body pat-down and visual inspection instead of going through the Advanced Imaging Technology (AIT) body scanner. AIT is also called millimeter wave scanner.

The system has not been tested in x-rays or AIT body scanners, and it is unknown if exposure to x-rays or AIT body scanners can affect the system performance and result in you missing a severe low or high glucose event.

It is safe to wear the system through the walk-through metal detector or handwanding. If you are unsure of whether the airport scanner is a metal detector, an AIT body scanner or an x-ray, ask the TSA officer or request hand-wanding or full-body pat-down.

### **Receiver and Smart Device Precautions**

The Dexcom receiver and your smart device share some warnings and precautions.

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### Precautions

#### **Communication Range**

Do not separate the transmitter from the receiver or smart device by more than 20 feet. The transmission range from the transmitter to receiver or smart device is up to 20 feet without obstruction.

Types of obstruction differ and not all have been tested. Obstructions can include water, walls, metal, etc. If your transmitter and display device(s) are more than 20 feet from each other or are separated by an obstruction, they might not communicate, resulting in you missing a severe low or high glucose event.

As with any wireless device, water in reducing the communication distance. This applies to the transmitter and display devices. Take special care when swimming, taking a bath, or getting into a hot tub.

#### Setting Alarm/Alert Notifications

When using both a receiver and a smart device, you must set your settings separately in each. If you set up one device and then use another, you might not get an Alarm or Alerts, causing you to miss a severe low or high glucose event.

Using an accessory device (like a smart watch) might override your smart device sounds. Alarms or Alerts might vibrate or be heard on the accessory instead of your smart device. After connecting any accessories, make sure that the smart device settings allow you to continue receiving Alarms or Alerts on the smart device.

#### Is It On?

If the receiver or smart device is turned off (Shut Down), it will not display sensor data, information, Alarm or Alerts. Make sure they are turned on; otherwise you won't get sensor glucose readings or Alarm or Alerts, causing you to miss a severe low or high glucose event.

### **Smart Device Warnings**

Next are warnings for just your smart device.

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### Warnings

#### **Smart Device Settings**

The app can't override your smart device's internal settings. Also, accessory devices (like a smart watch or other wearable smart devices) might override your smart device's Alerts and Alarm.

To receive Alarm or Alerts you must:

- 1. Make sure app Notifications are turned on in the Setting's menu.
- 2. Verify app hasn't been shut down.
- 3. **Turn** *Bluetooth*<sup>®</sup> on.
- 4. **Turn off** *Do Not Disturb* (if available on your smart device).
- 5. **Restart** app after device is restarted.
- 6. Set *Volume* at a level you can hear.
- 7. Do not close app, always run app in the background.
- 8. **Make sure** accessory devices do not override your smart device settings.

If your settings are incorrect, you might miss a severe low or high glucose event.

App Alarm/Alert vibrations aren't any different from other vibrating apps on your smart device. Medical device apps, like this app, don't have any special priorities over your smart device's features. G5 Mobile app notifications or Alerts may sound or feel the same as notifications from another app. The only way to know is to look at the screen.

#### Did You Miss an Alarm or Alert?

An Alarm or Alert can't be heard through your smart device's speakers if headphones are plugged in.

Make sure you unplug your headphones when you are done using them, otherwise you might not hear an Alarm or Alert, causing you to miss a severe low or high glucose event.

### **Receiver Warning and Precaution**

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### Warning

#### Don't Use Damaged Goods

If your receiver is damaged or cracked, don't use it. This could create an electrical safety hazard or malfunction, causing possible electrical shocks.

#### Avoid Strangulation

Use USB cable only as directed and store safely. Misuse of the USB cable can present a strangulation risk.

#### Precaution

#### **Test Receiver**

If your receiver gets wet or dropped, make sure the speaker and vibrations still work. To check, either plug it in, turn it on, or go to the *Profiles* menu and select *Try It*. If it doesn't vibrate and beep, contact Technical Support.

If the vibration motor and/or speaker on your receiver aren't functioning properly you may miss a severe low or high Alarm/Alert. Use the app on your smart device until this issue is resolved

#### Keep Receiver Clean and Dry

Keep the USB port cover on the receiver closed whenever the USB cable is not attached and do not submerge in water.

If dirt or water gets into the USB port, the receiver could become damaged and stop displaying readings or providing Alerts; you might miss a severe low or high glucose event.

#### Caution

U.S. law restricts the sale of the G5x to sale by or on order of a physician.

#### Summary

Now You Can:

Define a Safety Statement
Dexcom G5x System User Guide

- Explain the difference between an indication and a contraindication
- Describe the importance of warnings
- Describe what a precaution is
- Correctly read a chapter's Safety Statement
- Provide an overview of Safety Statements by category

#### What's Next?

In our next chapter, you will learn about the risks and benefits of using the G5x.

Dexcom G5x System User Guide
# Chapter 3

Getting Started:

# **Risks and Benefits**

When using any medical device, there are risks and benefits. In this chapter, you'll learn what they are so you can better understand the pros and cons of CGM and the G5x.

First, let's review some possible risks.

# 3.1 Risks

There are some risks with using real-time CGM.

# Not Receiving Alarm/Alerts

If you aren't getting your CGM Alarm/Alerts, you run the risk of not knowing you are having a severe glucose low or high.

Some hardware issues preventing Alarm/Alerts:

- Alert function is turned off
- Transmitter or display device is out of range
- Display device isn't showing sensor glucose readings
- · Display device battery is dead
- Unable to hear Alarm/Alerts or feel vibration
- Speaker or vibration motor not working
- App not running in the background
- Smart device is on *Do Not Disturb* or Silent Mode

See Troubleshooting in Chapter 18 or recommended settings in Chapter 11 for more information.

# **Different Devices May Give Different Numbers**

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The sensor glucose reading can be different from your meter's BG value.

If the sensor's glucose reading is higher than your meter's BG value, you may miss a Low Alert. As an example, your last sensor glucose reading was 82 mg/dL, whereas your meter BG value shows 78 mg/dL. If your Low Alert is set at 80 mg/dL, you won't receive an alert because the sensor glucose reading is 82 mg/dL.

If you're not receiving an Alarm/Alert, and not taking fingerstick measurements, you may be unaware of low or high glucose levels.

### Sensor Insertion Risks

Inserting the sensor and wearing the adhesive patch might cause infection, bleeding, pain, or skin irritations (for example, redness, swelling, bruising, itching, scarring, or skin discoloration). The chance of this happening is low. The G5x uses a different applicator than older systems. The G5x clinical studies showed slight redness and swelling occurring only in a few patients. Different people may have different skin sensitivity to the sensor adhesive. If skin irritation is seen, follow up with your healthcare professional on ways or tips to reduce or avoid sensor site irritation.

With any sensor, if you don't follow the instructions for sensor insertion, there is a chance you may mistakenly insert the sensor before you are ready. Be careful to ensure you place the sensor on your sensor insertion site **before** taking off the safety guard. **After** placing the applicator on the body, fold and break the safety guard.

The safety guard can be a choking hazard. Carefully throw it away, especially if around children.

During Dexcom's G5x clinical studies, no sensor wires broke; however, there is a remote chance a sensor wire could break or detach and remain under your skin. Sterile broken sensor wires usually don't pose a significant medical risk.

If a sensor wire breaks off or detaches and remains under your skin, contact your healthcare professional and call Dexcom's Technical Support toll free, 24/7, at **1.888.738.3646** or toll at **1.858.200.0200** within 24 hours.

Those are the risks, let's now review the benefits!

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# 3.2 Benefits

Daily habits impact your BG levels. With the G5x, you can track how your exercise, carbs, stress levels, medication, or illness influences your glucose levels.

# **Knowing Your Trends**

Providing sensor glucose readings every five minutes, for up to seven days, the G5x helps you detect trends and patterns. Trend information reveals where your glucose is now, where it's been, where it's heading, and how fast it's changing.

Understanding your trends allows you to take proactive action, helping you avoid dangerously low or high glucose values.

Using Dexcom *Share* (see Part 5) allows friends and family, your Followers, to monitor your glucose activity, adding another layer of support and peace of mind.

# Simplified Sensor Insertion

The redesigned G5x sensor applicator allows you to insert a sensor with fewer steps while using just one hand. Fewer steps simplify the insertion process.

# Helping Your Diabetes Management

Wearing the G5x on a consistent and ongoing basis helps you manage your diabetes. The Alarm/Alerts features (see Chapter 11) keep you aware of your glucose levels. Alerts notify you when your glucose goes outside your target range or is rapidly falling or rising, letting you take action before you get too low or too high. The Urgent Low Glucose Alarm lets you know when you are dangerously or urgently low, going below 55 mg/dL. By taking corrective measures, you reduce the time spent in your low/high range, while increasing time in your target range (Garg, S. Z., 2006) (Battelino, T., 2011).

Real-time CGM can help improve your A1C as well as improve the quality of your glucose control. If you are at or below 7%, using a CGM such as the G5x helps reduce hypoglycemia (Tamborlane, W. V., 2008).

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Lowering your A1C, increasing your time in your target range while decreasing time in low/high BG range is believed to reduce your risk of diabetes-related complications (Ohkubo, Y., 1995).

In some cases, patients perceived an increase in their quality of life and peace of mind when using real-time CGM (Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, 2010).

### What's Next?

You've read the Safety Statements, reviewed the risks and benefits; now let's take a look at Dexcom's G5x!

### **References:**

Battelino, T., Phillip, M., Bratina, N., Nimri, R., Oskarsson, P., & Bolinder, J. (2011). Effect of Continuous Glucose Monitoring on Hypoglycemia in Type 1 Diabetes. *Diabetes Care*, 34(4), 795-800.

Garg, S., Zisser, H., Schwartz, S., Bailey, T., Kaplan, R., Ellis, S., & Jovanovic, L. (2006). Improvement in Glycemic Excursions With a Transcutaneous, Real-Time Continuous Glucose Sensor: A Randomized Controlled Trial. *Diabetes Care*, 29(1), 44-50.

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group (2010). Quality-of-Life Measures in Children and Adults With Type 1 Diabetes. *Diabetes Care*, 33(10), 2175-2177.

Ohkubo, Y., Kishikawa, H., Araki, E., Miyata, T., Isami, S., Motoyoshi, S., & Shichiri, M. (1995). Intensive Insulin Therapy Prevents the Progression of Diabetic Microvascular Complications in Japanese Patients With Non-insulindependent Diabetes Mellitus: A Randomized Prospective 6-year Study. *Diabetes Research and Clinical Practice*, 28(2), 103-117.

Tamborlane, W. V., Beck, R. W., Bode, B. W., Buckingham, B., Chase, H. P., Clemons, R., ... & Xing, D. (2008). Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes. *The New England Journal of Medicine*, 359(14), 1464-1476.

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# 2

# LET'S G5x! THE BASICS

- Introduction to the G5x
- Initial Setup
- Starting a Sensor Session: Inserting the Sensor and Transmitter
- Calibration
- Ending a Sensor Session and Transmitter Session

Dexcom G5x System User Guide

# Chapter 4

Let's G5x! The Basics:

What Is the G5x?

# 4.1 System Description

Now it's time to get an overview of the the Dexcom G5x. After this chapter, you'll be able to:

- Explain the G5x
- Describe options to view trends
- Locate your historical readings
- Recognize system components
- Explain each part's function

# 4.2 Safety Statement

While you can use the G5 Mobile receiver with the G5x, you can't use the sensor or transmitter from previous generations. If the transmitter or sensor box says "G5 Mobile" or "G4 PLATINUM," don't use them with the G5x.

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### Warning

Don't: The system was not evaluated for the following persons:

- Pregnant women
- Persons on dialysis

Don't use the system in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Sensor glucose readings may be inaccurate in critically ill patients.

**Consequences:** The system's accuracy hasn't been tested in people falling into these groups, and sensor glucose readings may be inaccurate, resulting in missing a severe low or high event.

### Precaution

**Do**: The G5x transmitter must be used with the G5x Sensor and is not interchangeable with Dexcom the G5®Mobile/G4<sup>®</sup> PLATINUM Sensor. The G5x transmitter is compatible with the G5 Mobile receiver.

**Why:** The G5x transmitter and G5 receiver are not compatible with the Dexcom G4 PLATINUM CGM System's transmitter and receiver.

**Consequences:** Missing a severe low (hypoglycemia) or high (hyperglycemia) glucose event.

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### G5x-Compatible Components

G5x System Components	Components Not Compatible with G5x
G5x Sensor	G5 Mobile/G4 PLATINUM Sensor
G5x Transmitter	G5 Mobile Transmitter
G5 Mobile Receiver	G4 PLATINUM Transmitter
G5 Mobile App	G4 PLATINUM Receiver with Share
	G4 PLATINUM Receiver

# 4.3 The G5x

The G5x is a medical device you use on yourself. It allows you to continually see your sensor glucose readings, updated every five minutes for up to 7 days, without the bother of taking constant fingerstick measurements. A single-use sensor inserted under your skin measures your sensor glucose readings. A reusable transmitter sends your data to your display device.

The G5x provides personalized trend Alerts, notifying you to proactively react when your glucose levels are getting too low or too high. Dexcom provides web-based reports reflecting your glucose trends and patterns. Share the reports with your healthcare professional when developing your diabetes management treatment plans.

Some users of the G5x System may need a caregiver involved in their care. Please consult your physician for guidance.

# **Options to View Your Trends**

The G5x transmitter works with a number of display devices, giving you flexibility to use what's best for you, your situation, or your lifestyle.

1. Receiver

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2. G5 Mobile app (app) on your smart device

While the system works with different smart devices, they're not interchangeable during a sensor session, so before starting one, select which smart device you want to use and stick with it throughout your session. You can't use multiple smart devices at the same time, but you can combine the receiver with a smart device during a session.

The G5x is the first CGM system where a smart device acts as a receiver. For a list of current devices and operating systems, go to: dexcom.com/compatibility.

Chapter 5 covers how to set up your smart device with the app.

The primary difference between the receiver and app is not the information they give you, but how that information is presented. The following are some of the shared CGM data and system information features.

# Tracking Real-Time CGM Data

The receiver and app give you the ability to track your glucose trends in a number of different ways. Each device's home screen opens to your glucose trend screen.

### Viewing Glucose Levels

The receiver and app share many of the same glucose-monitoring features. Your glucose values are color-coded to highlight what zone you are in, allowing you, at a glance, to see what your levels are.

Color-coded glucose levels:

- Red Low
- Gray Within your target range
- Yellow High

### Trend Arrows

Glucose levels are not just about the numbers. The G5x includes trend arrows so you know the speed and direction of your glucose, allowing you to proactively react before your glucose gets too high or too low.

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# Alarm/Alerts

Being warned when your glucose value is too high or too low, falling or rising too quickly, or trending toward a severe low or high is very important. Warnings in the form of Alerts or an Alarm help you avoid getting too low or too high. Alarm and Alert notifications help keep you aware of your glucose trends and are made up of a combination of sounds, vibrations, and screens.

There are a number of Alerts, but only one Alarm: when your glucose level dips below 55 mg/dL. Some customization options are available and are part of the setup process for the receiver and smart device.

In Chapter 11, you can learn more about the Alarm and Alerts feature.

### Viewing Your Glucose Values

The G5x allows you to see your last 1-3-6-12-24 hours of your sensor glucose readings. On the receiver, from the home screen, **press** *Up/Down Arrows* to view. On a smart device, **hold upright** in *portrait* mode to see the most recent three hours; **turn sideways** to *landscape* mode to view your glucose levels over the last 1-3-6-12-24 hours.

Go to Chapter 9 to learn more about viewing your glucose trends.

# 4.4 What's New to the G5x?

Dexcom's G5x has features not found in our previous generations. They include:

- G5x sensor applicator
- Redesigned transmitter and transmitter holder

# G5x Sensor Applicator

Inserting a sensor has never been easier! The redesigned G5x sensor applicator allows you to insert a sensor with just one hand. Just peel away the adhesive's backing, place the applicator on your body, fold and break off the safety guard, and push the applicator's button. For detailed steps on sensor insertion, see Chapter 6.

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# Redesigned G5x Transmitter Holder and Transmitter

The redesigned transmitter and its holder enjoy a lower profile. The transmitter snaps into the newly designed holder and, with its new breakaway feature, snaps out for easy transmitter removal. For more information on how to attach the transmitter, go to Chapter 6. After a sensor session has ended, see Chapter 8 for its removal.

# 4.5 System Information

The receiver and app also keep you informed on the system's status. Technical notifications provide information about your sensor session and about the system's hardware. Each chapter provides a table of the notifications, system, and error messages applicable to its subject. As an example, the calibration chapter will review all calibration messages you may see.

Now that you know what the G5x does and what's new, let's open your G5x packages, see what's inside, and review each item.

# 4.6 System Components

# Package

The G5x comes to you in a number of boxes; after opening, keep the packaging until you are no longer using its contents.

### G5x System Component Packaging



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Single use sensor(s)
Sold separately.
Comes in a sterile pack.
Insert

Transmitter	-	
	Transmitter package	
Contan	Reusable transmitter	
Receiver		
and a second sec	Receiver package	
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Receiver
Receiver's USB charging and download cable

Receiver		
	AC power adapter	
	Welcome Card	

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# **Overview of System Components**

This section is meant as a quick overview of each part; specifics for each are found in following chapters. For detailed product specifications and technical information, please go to Chapter 17.

The G5x is comprised of four key parts:

1. Applicator with single use sensor

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- 2. Reusable transmitter
- 3. Rechargeable receiver
- 4. G5 Mobile app

G5x optional:

Dexcom Share

### Sensor Applicator Overview

After removing the backing from the adhesive patch on the back of the sensor applicator, place the applicator on your skin and remove the safety guard. Push the orange button to insert the sensor wire and release the transmitter holder.

The sensor wire is made of silver and platinum with polymer membranes. Once inserted, the thin and flexible wire measures your glucose levels in the fluid between your cells (interstitial fluid) for up to seven days.

This section is meant as a quick overview. More information on using and inserting the applicator, sensor, and sensor wire can be found in Chapter 6.



What it's called	What it does	
Applicator		
Applicator	Contains small insertion needle and sensor wire.	
	Inserts sensor wire under the skin.	
	Disposable, for single use only.	
	Removed after insertion.	
	Keeps all moving parts in place before insertion.	
Safety Guard	Prevents accidental sensor insertion.	
	Fold and break to remove.	
Button	Press to insert sensor wire and release transmitter holder.	

## Applicator and Transmitter Holder

Transmitter Holder

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Transmitter Holder	Holds sensor wire and transmitter in place. Water resistant when transmitter is properly installed. Discarded after sensor session.
Adhesive Patch	Keeps transmitter holder attached to your skin.
	Measures glucose levels in the fluid between your cells (interstitial fluid).
Sensor Wire	Attached to transmitter holder once inserted under skin.
	Discarded with holder after session.

### Transmitter Overview



Figure 2. G5x Transmitter Front and Back

Please Note: Pictures above are representational only; your transmitter may look different.

Snapping into the transmitter holder, the gray plastic transmitter wirelessly sends your glucose information to your display devices–receiver and/or smart

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device. If you have a new transmitter, open the package when you are ready to use it.

Transmitter features:

•

- Reusable
  - Do not discard after sensor session.
  - Only for you, don't share transmitter.
- Water resistant
- Can transmit data to your display devices for up to 20 feet
   Range is less if you are in or under water.
  - Battery lasts approximately three months
    - Receiver or smart device notifies you when battery is running low.
- Transmitter's serial number is on the back

More transmitter features and insertion information are in Chapter 6.

Now that you are familiar with the sensor applicator and transmitter, let's review the receiver.

### Receiver

The receiver is a small hand-held device. Your receiver, along with your smart device, shows your sensor glucose readings, trend graphs, and trend arrows, and notifies you when your glucose is too high or too low or if there is something you should be aware of or need to do.

The receiver is neither water resistant nor waterproof and can get damaged if moisture gets inside, so keep it away from any liquids and very high humidity as well as dirt and dust. Keeping the micro USB port closed helps prevent damaging fluids and dust from getting inside the receiver. If your receiver does get wet or dirty, test it to make sure the speaker and vibrations still work (see Chapter 12).

If your receiver isn't charged, see Chapter 14 for charging your receiver's battery.

If you want to use the receiver along with a smart device, you need to set them up separately.

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Remember, you can't use a combination of smart devices during a sensor session; select just one.

### **Receiver Overview**

What you see	What it's called	What it does
	Receiver	Provides data about your glucose trends via screen display, sounds, and vibration.
	Micro USB Port	Plug USB cable into port for recharging.
	USB Port Door	<b>Close</b> <i>USB port door</i> after removing <i>USB cable</i> to keep receiver clean and dry.
		Plug into <i>receiver</i> to charge battery.
Devcom GSv Svetam User Guida	Micro USB Cable	Don't plug into a computer port to charge.
		Battery can only be charged using the adapter/wall charger.

What you see	What it's called	What it does
		Plug USB cable into adapter/wall charger.
	Wall Charger	<b>Plug</b> <i>wall charger</i> into an electrical outlet to charge receiver's battery.
		Don't block access to the charger.
	Display Screen	Shows sensor glucose readings, trend graphs and arrows, Alarm/Alerts, sensor session status.
		Change settings on Menu screen.
	Speaker	Allows you to hear your Alarm/Alerts sounds.
	Navigation Wheel	Arrows and button to help you navigate through the receiver's menu options and choose features.
	Select Button	Press to select menu option.

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What you see	What it's called	What it does
	Left Arrow	<b>Press</b> to go back to last item/screen or home screen.
	Right Arrow	<b>Press</b> to highlight next item.
	Up/Down Arrows	Press to scroll up or down to select menu items or set values. Press to scroll back and forth from the 3-hour trend graph to the 1-6-12-24 views.

# 4.7 Smart Device Overview

The app was created to work with your smart device, giving you even more options in monitoring your glucose trends and patterns. The app is similar to all other apps.

This user guide is not meant to show you how to use your smart device. Please contact your smart device support or read your smart device's user guide for assistance.

## Summary

Now You Can:

• Explain the G5x Dexcom G5x System User Guide

- Describe options to view trends
- Locate your historical readings
- Recognize system components
- Explain each part's function

### **Next Steps**

Your next step in getting started with the G5x is selecting how to continuously receive your sensor glucose readings: using the app, the receiver, or a combination.

Our next chapter helps you set up both!

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# **Chapter 5**

Let's G5x! The Basics:

# Set Up Your Display Devices

# 5.1 Introduction

In the previous chapter, you received a high level overview of the G5x and learned you can monitor your glucose levels with different display devices. Now it's time to set up your app and your receiver.

After this chapter, you will be able to:

- Create a Dexcom username and password
- Download the app
- Set up the app with the recommended settings
- Successfully set up your receiver

# 5.2 Safety Statement

While you can use the G5 Mobile receiver with the G5x, you can't use the sensor or transmitter from previous generations. If the transmitter or sensor box says "G5 Mobile" or "G4 PLATINUM," don't use them with the G5x.

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### Precaution

**Do:** The G5x transmitter must be used with the G5x Sensor and is not interchangeable with the Dexcom G5® Mobile/G4<sup>®</sup> PLATINUM Sensor. The G5x transmitter is compatible with the G5 Mobile receiver.

**Why:** The G5x transmitter and G5 receiver are not compatible with the Dexcom G4 PLATINUM CGM System's transmitter and receiver.

**Consequences:** Missing a severe low (hypoglycemia) or high (hyperglycemia) glucose event.

### G5x-Compatible Components

G5x System Components	Components Not Compatible with G5x
G5x Sensor	G5 Mobile/G4 PLATINUM Sensor
G5x Transmitter	G5 Mobile Transmitter
G5 Mobile Receiver	G4 PLATINUM Transmitter
G5 Mobile App	G4 PLATINUM Receiver with Share
	G4 PLATINUM Receiver

# 5.3 Why Different Monitoring Methods?

Your convenience!

By offering two separate monitoring systems, the app or receiver, you can choose to monitor your glucose levels in the handiest method at that moment. Forgot your receiver at home? Use your smart device! Battery died on your smart device? Smart device memory full? Your receiver has you covered!

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With the exception of Dexcom *Share*, the primary difference between the two monitoring systems is not the data itself, but how it's presented.

The next section walks you through the initial setup for the app. To set up the receiver, go to Section 5.5. If you want to use both the app and the receiver, you need to setup each individually.

Once you have completed the initial setup, you're one step closer to beginning your sensor session!

# 5.4 App

Before starting your first sensor session, pick the smart device you want to use. As mentioned in the previous chapter, you can use the receiver with one smart device during a session; however, you can't use multiple smart devices during the same session.

While your smart device can have the app installed, part of your initial setup is entering the transmitter's serial number (SN). If by accident you enter the SN into more than one smart device, the system warns you and you won't be able to complete the setup process.

# Suggested Smart Device Settings

*Bluetooth* is designed for wireless communication between devices (unlike Wi-Fi<sup>®</sup>, which wirelessly connects devices to the Internet). Your transmitter communicates to your app via *Bluetooth*<sup>®</sup> Smart! Before beginning, **make** sure your smart device's *Bluetooth* is available and turned on.

Refer to your smart device's user guide if you have questions on how to change your smart device settings.

- While checking your *Bluetooth* settings, check to see *Silent* and *Do Not Disturb* are off. Your app does not override these settings; if you have them on, you will miss Alarm/Alerts
- After verifying all your settings are correct, there is one more thing to check. Make sure your smart device's *Volume* is loud enough for you to hear any Alarm/Alerts
- Make sure your smart device settings allow your Alarm/Alerts to always show on your lock screen

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- For information on how to set the above settings, see your smart device's user guide. Once you have verified your smart device's settings are right, the next step is installing the app
- The app needs to be open and running in the background. This may drain your smart device's battery; make sure you check its battery is charged
- Don't change your smart device's time because it can make the time on the trend screen wrong and the app may stop displaying data

If your smart device is broken or lost, use your receiver until it's fixed or replaced.

# App Installation

Installing the app is easy! Simply download the Dexcom G5 Mobile app from your smart device's store. However, if your smart device has been jailbroken, do not install the app.

For information on how to install an app, see your smart device's user guide.

# **Initial App Setup**

Setting up your app is easy! You'll need your Dexcom account *username* and *password*, along with your *transmitter box*. Once inside, simply follow the setup wizard instructions. The setup wizard walks you through safety information, recommended settings, entering transmitter SN, setting your high/low glucose levels, and receiving CGM notifications.

Your initial setup will require a Dexcom username and password. You can create them by **tapping** *Sign Up* within the app, or by going to dexcom.com.

From Your Web Browser:

- 1. Go to dexcom.com.
- 2. Click My Account at top right of page
  - If no *My Account*, click green menu bars at top left
    Click *My Account*
- 3. Click Create a Dexcom Account

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But what if you are unclear about a step?

The app has notifications allowing you to get more information. If you are unsure of something during your initial setup process, look at the screen for additional information notifications. Informational notifications include, but aren't limited to: *I don't understand, Learn More,* or *Question Mark*. **Tap** your *informational notification* to get more information.

To close out of the information notification, tap the X in the upper right-hand corner.

### **Initial App Setup**

Step	What you see	What you do
Introduc	ctory Screens	
1		<b>Tap</b> <i>app</i> icon to open app.

Introductory Screens

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### Setting Up Your App Alarm/Alerts and Basic Settings

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# Setting Up Your App Alarm/Alerts and Basic Settings

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Setting Up Your App Alarm/Alerts and Basic Settings

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Connecting/Pairing Transmitter With App

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# Connecting/Pairing Transmitter With App Dexcom G5x System User Guide

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Set up Your Display Devices



If you have any issues setting up the G5 Mobile app, <u>always contact Technical</u> Support (available 24/7) at:

- <u>TechSupport@dexcom.com</u>
- Toll free: 1.888.738.3646
- Toll call: 1.858.200.0200

If you are having problems with your smart device, contact your smart device's support line.

After completing your initial app setup, set up the receiver or go to Chapter 6 to start your initial sensor session.

### 5.5 Dexcom Receiver

In the previous chapter, you learned about the receiver's components. The following is a refresher to help in your initial setup.

#### **Display Screen:**

Trend screen

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Menu selection screen

#### Navigation Wheel:

- Select
  - Button in the middle of the navigation wheel
    - Center button does not say "Select"
  - Press to:
    - Turn on receiver
    - Select options/features
    - Accept changes
    - Move forward through menus/features
- Up/Down
  - Scroll through trend screens
  - o Highlight menu items
  - Change values
- Left
  - $\circ$   $\,$  Go back to last item or screen
- Right
  - o Go to next item or screen

## Initial Setup of the Dexcom Receiver

Press *Select* to turn receiver on.

The first screen you see is the startup screen with ascending green bars. Once complete, a setup wizard guides you through the initial setup steps. Don't be worry if your receiver buzzes or makes other sounds during this process.

After your initial setup is complete, you won't see the setup wizard again. Your settings can always be adjusted using menu options.

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How you complete your initial setup differs between the receiver and your smart device; however, the data is the same.

#### Setup Wizard Notifications:

- Time/Date
- Transmitter Serial Number
  - o Back of transmitter
  - Back of transmitter's box
- Setting Low Glucose Alert
- Setting High Glucose Alert

Before starting a session, you may want to check the receiver's battery level. If it is less than half, go to Chapter 4 for charging instructions.

#### **Initial Receiver Setup**

Step	What you see	What you do	
Initial S	Screens		
		Press Select to turn receiver on.	
2	Dexcom.	Wait.	
Time/Date			

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Time/Date			
3b	Time/Date 2015/04/10 1:Ⅲ PM	<ul> <li>Press Up/Down Arrow to change hour.</li> <li>Press Right Arrow.</li> <li>Press Up/Down Arrow to change minutes.</li> <li>Press Right Arrow.</li> <li>Press Up/Down Arrow to select AM/PM.</li> <li>Press Select to save and close.</li> <li>NOTE: After initial setup, if battery is drained, receiver will vibrate once and you will need to reset date and time.</li> </ul>	
Transn	nitter		
4a	om GS <sup>TM</sup> Mobile Transmitter Kit (Retail) STT-RF-001 12345789 m <sup>1</sup> Colored State Martmannn Martmannnn Martmannnnn	Turn transmitter box upside down to locate SN number. For information on how to pair transmitter after initial setup, see Chapter 8.	

Set up Your Display Devices

4b	4000N4	If transmitter package isn't available: • SN is on transmitter's back
4c	Transmitter SN ¥# 4000N4€	Press <i>Up/Down Arrows</i> to select and enter transmitter SN. Press <i>Right Arrow</i> to move to next digit. Press <i>Select</i> to save and close.

Setting Low Alert			
5a	Low Alert	System default is at 80 mg/dL. <b>Press</b> <i>Select</i> to save at present levels and close.	
5b	Low Alert	To change value: <b>Press</b> <i>Up/Down Arrows</i> to change value at 5 mg/dL increments. <b>Press</b> <i>Select</i> to save and close.	
Setting	l High Alert		

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6a	High Alert 200♥ mg/dL	System default is at 200 mg/dL. <b>Press</b> <i>Select</i> to save at present levels and close.
6b	High Alert 210♥ mg/dL	To change value: <b>Press</b> <i>Up/Down Arrows</i> to change value at 10 mg/dL increments. <b>Press</b> <i>Select</i> to save and close.

These steps are enough to get you going; **now you can** start your sensor session!

#### Summary

Now You Can:

- Create a Dexcom username and password
- Download the Dexcom G5 Mobile app
- Set up app with the recommended settings
- Successfully set up your receiver

#### What's Next?

Now that you have completed setting up your app and/or the receiver, your next step is starting a sensor session.

No matter what monitoring method you choose, starting a sensor session is the same:

- 1. Inserting the sensor.
- 2. Attaching the transmitter.
- 3. Pairing the transmitter to your device.

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Set up Your Display Devices

- 4. Two-hour sensor warmup.
- 5. Startup calibrations.

Set up Your Display Devices

# Chapter 6

Let's G5x! The Basics:

## Starting a Sensor Session: Inserting Sensor, Attaching Transmitter, and Starting Your Session

# 6.1 Introduction

Now that your display devices are set up, you're ready to begin a sensor session. If this is your first time inserting a sensor, you may want to watch the G5x sensor insertion video to get a better understanding of the process.

There are three ways to get the sensor insertion video:

- 1. Through the app
- 2. On the USB card in your receiver package
- 3. Online at dexcom.com:
  - a. Top of page, click Support

After inserting the sensor, start the sensor warmup on your smart device and receiver. The sensor warmup takes approximately two hours; during this time your body is getting used to the new sensor, allowing for more accurate sensor glucose readings. Once the two-hour sensor warmup has passed, you enter two back-to-back fingerstick measurements to calibrate the sensor's glucose readings with your fingerstick measurements (Calibration is covered in the next chapter).

Make sure you give yourself enough time to finish the startup session. Remember your smart device's *Bluetooth* needs to pair with the transmitter, adding up to 30 minutes to your wait time. Good news is you don't need to sit around waiting: as long as you have your display device near, you can go about your day running errands, gardening, personalizing the G5x settings, whatever you choose during that time frame.

Keep your display device(s) handy during the warmup period–it shows how much time has passed, notifying you with beeps and an icon when your sensor session is ready for its startup calibrations.

After this chapter you will be able to:

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- Identify sensor applicator features
- Properly prepare for sensor insertion
- · Choose the best location to insert your sensor
- · Correctly insert your sensor
- Prepare transmitter for placement
- Correctly attach transmitter to transmitter holder
- Outline what happens during the sensor warmup
- Identify countdown icon

## 6.2 Safety Statements

Following are some important Precautions and Warnings to review; we want to make sure you and the system are safe before starting a sensor session.

#### Warning

**Don't:** If a sensor breaks under the skin with no portion visible above the skin, don't remove it.

**Do:** Contact your healthcare professional if you have redness, swelling, or pain at the insertion site.

Within 24 hours of experiencing a broken sensor wire, please call our 24/7 Technical Support department:

Email: TechSupport@dexcom.com

Toll free: 1.888.738.3646

Toll call: 1.858.200.0200

Why: Sensors may fracture on rare occasions.

#### MRI with broken wire

For patients undergoing an MRI with a retained wire broken off from a G5x sensor, in-vitro MRI testing did not detect any safety hazards. There was no significant migration or heating of the wire and imaging artifacts were limited to the area around the wire.

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#### Warning

**Don't**: Insert the sensor component of the system in a site other than the belly/abdomen (ages 2 years and older) or the upper buttocks (ages 2 to 17 years).

Why: The placement and insertion of the sensor component of the system is not approved for other sites.

**Consequences:** The system has not been tested in other areas and may not work properly if inserted in other areas.

#### Warning

Do: During a sensor's shelf life, store it between 36° F-86° F.

Why: Storing the sensor incorrectly might cause the sensor glucose readings to be incorrect.

Never store sensors and/or sensor packages in the freezer.

Consequences: Missing a severe low or high glucose event.

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#### Warning

Don't: Use the system sensor glucose readings for treatment decisions.

**Do:** When making treatment decisions, such as the amount of insulin you need, only use your BG value from your BG meter.

**Why:** Since they measure your glucose from different body fluids, sensor glucose readings can be different from your meter's BG values.

**Consequences:** If sensor glucose readings are used in determining treatments, it could result in you missing a severe low or high glucose event.

#### Precaution

**Don't:** Insert the sensor where bones are close to the skin's surface (for example, over your ribs or hip bones).

**Why:** If you insert the sensor in these areas, you may feel excessive pain or damage your sensor.

#### Precaution

**Do:** Change the site where you place the sensor with each new insertion. Sensor placement is important. Choose a site:

- At least 3 inches from insulin pump infusion set or injection site
- Away from waistband, scarring, tattoos, irritation
- Unlikely to be bumped or pushed

Why: Using the same site too often might not allow the skin to heal. Also, insertion in these areas might affect sensor performance.

Consequences: Missing a severe low or high glucose event.

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#### Precaution

Don't: Use sensor if its sterile package has been damaged or opened.

Why: Make sure the sterile sensor pack has not been damaged or previously opened. If opened or damaged, sensor may be unsterile.

**Consequences:** Using a non-sterile sensor might cause an infection.

#### Precaution

**Don't:** *Don't remove the safety guard before placing the applicator on the skin.* 

**Why:** If you remove the safety guard first, you may accidentally deploy the needle and hurt yourself.

#### Precaution

Don't: Get dirt or water in the receiver's USB port or submerge in water.

Why: If dirt or water gets into the USB port, the receiver could become damaged and stop displaying readings or providing Alerts.

Consequences: You might miss a severe low or high glucose event.

#### 6.3 Prepping for Sensor Insertion

Before inserting a sensor, make sure you have everything you need. Some items are included in your G5x packages, others are not.

#### Included in Your G5x Packages

For sensor insertion, you need the sensor and transmitter.

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#### Sensor Applicator

#### **Inside Sensor Box**

What you see	What it is
	Sterilized applicator and sensor tray with important label information.
$\neg \leq$	Check expiration date.
50	Do not use if it is past the expiration date.
	Open when ready to use.
	Single use sensor applicator.

Knowing what each applicator piece does helps you successfully insert your sensor. Chapter 4, Section 4.6 gave you an overview of the sensor applicator.



#### Figure 3. G5x Sensor Applicator and Transmitter Holder

The following table reviews the sensor applicator components in order of use.

Sensor Applicator C	Components
---------------------	------------

Order of Use	Name	What it does
1	Adhesive Patch	Keeps transmitter holder securely on your skin.
2	Safety Guard	Prevents applicator from inserting sensor wire before you are ready.
3	Applicator	Inserts sensor under your skin.
4	Transmitter Holder	Holds sensor wire in place under skin. Holds transmitter.

#### Transmitter

#### Transmitter Box

What you see	What it is	
Descore Q5 Mobile Transmitter K4 (Retail) Transmitter K4 (Retail) Tra	Bottom of box with important label information. Keep box until transmitter battery dies. Please Note: Picture is representative only; your transmitter box may look different.	

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Reusable transmitter.

Please Note: Picture is representative only; your transmitter may look different.

In the previous chapter, you entered your transmitter SN into your display devices and made sure your smart device and/or receiver connected with the transmitter. You won't be able to start a sensor session if your transmitter isn't paired with your receiver and/or smart device.

#### Not included in packages:

- 1. Alcohol wipes
- 2. Your BG meter
- 3. Your test strips

Before starting, check your BG meter; make sure it's in good working order following manufacturer's directions and the meter's date and time match your display device's date and time.

Make sure test strips haven't expired and work with your meter.

Before removing the sensor applicator from its sterile pack, determine the best place to insert your sensor.

# 6.4 Choosing Your Insertion Site

Choose a place on your belly (or if user is between the ages of 2 and 17, upper buttocks) to insert the sensor; the site should be either above or below your belt line. The best areas are usually flat, "pinchable," and free from where rubbing can occur (along the waistband, seat belt strap, or where you lie when sleeping).

For more help on ideal sensor insertion sites, contact your healthcare professional.

#### **Insertion Sites**



Calibration



Do:

- Remove the sensor applicator and attached transmitter holder from its sterile pack only at time of use
- Place at least 3 inches from your insulin pump infusion set or injection site
- If needed, shave the area so adhesive patch sticks securely
- Make sure area is clean and free of lotions, perfumes, medications

#### Don't:

- · Never use same site repeatedly for sensor insertion
- Never use same site for 2 sensor sessions in a row

If you have concerns about the transmitter holder not sticking, before inserting your sensor, you can make the sensor site stickier to help ensure the transmitter holder does not peel up.

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### **Optional Site Preparation**

Use optional skin adhesives (Mastisol<sup>™</sup>, SkinTac<sup>™</sup>) as part of your insertion site preparation to help keep your transmitter holder attached. Apply the skin adhesive after you selected and cleaned your insertion site. Create an empty sideways oval, making sure you don't get any skin adhesive inside the oval. . Let the oval dry based on skin adhesive manufacture's instructions. Once dry, your skin may feel slightly sticky.

See Step 3 in the next table for directions.

**NOTE:** Contact your healthcare professional for specific questions regarding the use of medical tape, barrier wipes, and/or other adhesives as it relates to your use of Dexcom CGM.

# 6.5 Inserting Your Sensor

You've collected all of the needed items to begin a sensor session, viewed the tutorials, reviewed the sensor applicator, and prepped the transmitter holder site. You're now ready to insert your sensor!

#### **Inserting Sensor**

Step	Picture	What you do
Prepar	ation	
1		Wash and dry your hands.

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2		<b>Clean</b> <i>insertion site</i> with alcohol wipe. Let dry.
3	0	Optional Step: Skin Adhesive Create a empty sideways <i>oval</i> on the skin
		<ul> <li>Do not get any skin adhesive inside the oval</li> </ul>
		<ul> <li>Let skin adhesive dry (see manufacturer's instructions)</li> </ul>
		<ul> <li>Insert sensor on clean skin at the center of the oval</li> </ul>



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5	Place hand over <i>pack's</i> opening
6	<b>Gently roll</b> <i>pack</i> so applicator falls out and rests in the palm of your hand. <b>Closely inspect</b> <i>sensor applicator</i> , to check it has not been damaged.



Calibration

Inserting Sensor Wire and Transmitter Holder		
8		Place <i>applicator</i> horizontally, not vertically, on skin. Firmly press down, sticking <i>adhesive</i> <i>patch</i> to your skin.
9		Fold and break <i>safety guard.</i> Throw <i>safety guard</i> away.
10	Au Au	Push button to insert sensor.

Calibration



You have successfully inserted the sensor! Now the transmitter holder and sensor wire are attached to your body.

#### Having problems?

If it's the first time inserting a sensor, you may have questions or need help. If you do, please contact Technical Support (available 24/7) at:

- TechSupport@dexcom.com
- Toll free: 1.888.738.3646
- Toll call: 1.858.200.0200

The next step is attaching your transmitter to the transmitter holder.

# 6.6 Attaching Your Transmitter

Now that you have inserted your sensor, you need to attach your transmitter.

Since the transmitter is reusable, you don't need a new one every time you start a sensor session. Keep your current session's transmitter box. The bottom label has important information you may need after you've attached the transmitter. Once the transmitter has been attached, you can't remove it Dexcom G5x System User Guide

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until your session is over. Chapter 8 reviews when and how to remove your transmitter.

Before attaching your transmitter, check you've entered the correct transmitter SN into your display device. Chapter 5 covers entering transmitter's SN number during initial setup. See Chapter 8 for pairing your transmitter after the startup wizard

Step	Picture	What you do
1		Remove <i>transmitter</i> from box only when you are ready to insert it. Keep box. Get alcohol wipe.
2		Wipe back of <i>transmitter</i> with alcohol wipe.
		Let dry for 2-3 minutes.
		Do not let the back of transmitter touch your skin.
		Do not scratch transmitter's back; this can harm the waterproof seal.
		Do not touch metal dots on transmitter's bottom.

#### Attaching Transmitter

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Step	Picture	What you do
4	A CONTRACTOR	<b>Press</b> down firmly on <i>round end</i> of the transmitter until it clicks into place.
5	OF	<b>Move fingers</b> around top of <i>adhesive patch</i> three times to secure tape.

You're almost done starting your sensor session!

Inserting the sensor, attaching the transmitter, and the two-hour sensor warmup are the same, regardless of whether you use the receiver or app. Dexcom G5x System User Guide

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The remaining steps vary from app to receiver:

- 1. Letting your device know you need to start the sensor warmup.
- 2. Following your warmup countdown.

# 6.7 Loose Transmitter Holder

The transmitter holder should be able to stay on your skin using its own adhesive.

If the patch peels up, use medical tape (such as Blenderm<sup>™</sup>, Tegaderm<sup>™</sup>, Smith & Nephew IV3000<sup>®</sup>, 3M<sup>™</sup> tape) for extra support.

- · Tape over white adhesive patch on all sides for even support
- Don't tape over the transmitter or any plastic parts of the transmitter holder
- Don't tape under transmitter holder
- Don't leave any substance on the skin where you insert the sensor



Figure 4. The Right Way to Use Tape for Extra Support Image is representational only. Your transmitter may look different.

# 6.8 Starting Your Sensor Session

If you choose to use both the receiver and the app, each system requires individual setups (see Chapter 5).

After pairing the transmitter to your display device(s), inserting your sensor, and attaching the transmitter to the transmitter holder, your next step is telling

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your device(s) you want to start a sensor session. Transmitters are reusable; pairing is required only when using a new transmitter.

During the warmup period, neither device will provide any sensor glucose readings. Your sensor glucose readings begin after the two-hour sensor warmup has passed and you entered the two startup calibration BG values into either the smart device or the receiver.

We'll first review starting the sensor session for the app.

#### Dexcom App: Starting a Session

Step	What you see	What you do
1	Tar to the risor Par Successful	<b>Wait</b> for <i>Pair Successful</i> notification. <b>Tap</b> green checkmark in black square.
2	Tap to start 2-hour sensor warmup	Tap sensor warmup circle to start your two-hour sensor warmup. NOTE: You will NOT get any sensor glucose readings, Alarm/Alerts during your two-hour sensor warmup period.

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Step	What you see	What you do
4	Dexcom now Enter first BG meter value alide to view	Locked screen. <i>Startup calibration</i> notification tells you when warmup is complete. Chapter 7 covers calibrating.



#### Receiver: Starting a Session

Step	What you see	What you do
1	NEXTEM	Press Select to turn on receiver.

Step What you see What you do
-------------------------------

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	<sup>mg</sup> O. 400	Make sure <i>receiver</i> and <i>transmitter</i> are connected/paired before starting sensor session.
		<b>Check</b> <i>receiver</i> 10 minutes after starting for <i>Bluetooth</i> icon.
	350	Solid: Connected/paired
2	200	Blinking: Searching/not paired
	100 50 10 ÅM 11 ÅM 1224 PM	Don't start a sensor session until they are paired.
		Once connected/paired:
		Press Select to go to the Main Menu
3	Main Menu Trend Graph Start Sensor Enter BG	Press Down Arrow to highlight Start Sensor.
		Press Select to start new sensor session.
		<b>NOTE:</b> After sensor starts, <i>Start Sensor</i> option disappears.
4	Start Sensor	<i>"Start Sensor"</i> progress bar confirms two- hour sensor warmup. Keep your receiver within 20 feet during the warmup period.

Calibration



Step	What you see	What you do
6	■*	Wait. Screen provides countdown of the two- hour sensor warmup.
7		Sensor warmup is complete. You're ready to calibrate!

# 6.9 Receiver Bluetooth Tips

Your transmitter and receiver begin communicating once you start a sensor session. After approximately 30 minutes, if the *Bluetooth* symbol is solid, and not blinking, your transmitter and receiver are talking to each other.

- If blinking, Bluetooth is looking for your transmitter
  - Make sure your transmitter and receiver are within 20 feet of each other

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• Don't start a sensor session until they are paired.

If the *Bluetooth* icon isn't on the receiver and the Signal Loss icon appears in the receiver's upper right corner of the status bar, they're not communicating.

Step	What you see	What you do
1		<ul> <li>Check correct transmitter SN is in receiver.</li> <li>SN is on the label on bottom of transmitter box</li> <li>Press Select to go to Main Menu.</li> </ul>
2	Main Menu Alerts Settings Shutdown	Press Down Arrow to Settings. Press Select.
3	Settings Time/Date Transmitter Device Info	<b>Press</b> <i>Down Arrow</i> to <i>Transmitter</i> . <b>Press</b> <i>Select</i> .

No Communication Between Transmitter and Receiver

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Step	What you see	What you do
4	Transmitter <b>Y</b> <b>Y</b> i Transmitter Info	Press Select.
5	Transmitter     Yi       Transmitter SN:     400384       AB:     10000001       Activated on:     11/11/2014       Transmitter Battery:     0K	<ul> <li>Check correct transmitter SN is in receiver.</li> <li>SN is on the label on bottom of transmitter box</li> <li>Compare SN in receiver to SN on transmitter box.</li> <li>If correct, call our 24/7 Technical Support department, toll free at 1.888.738.3646 or toll at 1.858.200.0200 for help.</li> <li>Press Select to exit screen.</li> <li>Press Left Arrow twice to go to Main Menu.</li> </ul>
If Wror	ng SN Entered	
6	Main Menu       Ξ         ➡ Alerts       Settings         ➡ Settings       Shutdown	Press Left Arrow twice to go to Main Menu.

Calibration

Step	What you see	What you do
7	Main MenuImage: SettingsImage: SettingsImage: Stop Sensor	If sensor session has started, to correct the transmitter SN, you must stop the sensor session. <b>Press</b> <i>Down Arrow</i> to <i>Stop Sensor</i> . <b>Press</b> <i>Select</i> .
8	Stop Sensor 🕄 Stop Sensor OK Cancel	Press Select to stop session.
If Wron	ng SN Entered	
9	Stop Sensor 🕄	Wait for sensor session to end.
10	Main Menu       ■         ▲ Alerts       ♦         ♦       Settings         ♦       Shutdown	From <i>Main Menu</i> : <b>Press</b> <i>Down Arrow</i> to <i>Settings.</i> <b>Press</b> <i>Select</i> .

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Step	What you see	What you do
11	Settings Time/Date Transmitter Device Info	<b>Press</b> <i>Down Arrow</i> to <i>Transmitter</i> . <b>Press</b> <i>Select</i> .
12	Transmitter <b>Y</b> <del>Y</del> # Transmitter SN <b>Y</b> i Transmitter Info	Highlight <i>Transmitter SN.</i> Press <i>Select</i> .
13	Transmitter SN ¥#	Enter correct SN using <i>Up/Down Arrow</i> . Press <i>Up/Down Arrow</i> to select and enter transmitter SN. Press <i>Right Arrow</i> to move to next digit. Press <i>Select</i> to save and close. Press <i>Left Arrow</i> twice to return to <i>Main</i> <i>Menu</i> .
14	Main Menu Trend Graph Start Sensor Enter BG	Start Sensor Session. <b>Press</b> <i>Up/Down Arrow</i> to highlight <i>Start</i> <i>Sensor.</i> <b>Press</b> <i>Select.</i>

# 6.10 Sensor Session Warmup

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The sensor takes about two hours to adjust to your body. While you are in the sensor warmup period, you can customize your settings. Chapter 12 steps you through how to personalize your G5x display devices.

Once the sensor warmup is complete, you're ready to enter your startup calibrations! The next chapter shows you how.

#### Summary

#### Now You Can:

- Identify sensor applicator features
- Properly prepare for sensor insertion
- Choose the best location to insert your sensor
- Correctly insert your sensor
- Prepare transmitter for placement
- Properly attach transmitter to transmitter holder
- Outline sensor warmup
- Identify countdown icon

#### What's Next?

The next chapter guides you through the calibration steps.

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# Chapter 7

Let's G5x! The Basics:

# Calibration

## 7.1 Introduction

In the previous chapter, you learned how to insert your sensor, transmitter, and start a new sensor session. You're now ready to begin your last step before getting your sensor glucose readings: Calibration.

This chapter reviews not just your startup calibration, but also update calibrations required throughout your sensor session.

After this chapter, you will be able to:

- Calibration overview
  - o Define calibration
  - Explain the importance of calibration
  - o Identify steps to ensure a successful calibration
- Recognize steps in taking accurate BG measurement
  - o Identify the correct BG site for calibrations
  - Prepare finger for fingerstick measurement
- · Determine if you should/should not calibrate
  - Recognize when you can enter a fingerstick measurement for calibration
  - Recognize when you shouldn't enter a fingerstick measurement for calibration
  - Determine if you need to calibrate outside of the normal calibration requirements
- Initiate startup calibration
- Perform update calibrations

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- Correctly enter your fingerstick measurement
  - o In the app
  - o In the receiver
- Identify calibration errors

# 7.2 Safety Statements

### Contraindication

**Don't:** *Take medications containing acetaminophen while wearing the sensor.* 

**Why:** Taking medications with acetaminophen (such as Tylenol or Excedrin Extra Strength) while wearing the sensor may falsely raise your sensor glucose readings. The level of sensor inaccuracy:

- 1. Depends on amount of acetaminophen active in your body.
- 2. May be different for each person.

**Consequences:** Without correct readings you might miss a severe low or high glucose event.

### Warning

Don't: Use the system sensor glucose readings for treatment decisions.

**Do:** When making treatment decisions, such as the amount of insulin you need, only use your BG value from your BG meter..

**Why:** Since they measure your glucose from different body fluids, sensor glucose readings can be different from your meter's BG values.

**Consequences:** If sensor glucose readings are used in determining treatments, it could result in you missing a severe low or high glucose event.

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### Warning

Do: Calibrate at least once every 12 hours.

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

**Consequences:** Missing severe low (hypoglycemia) or high (hyperglycemia) glucose event.

### Precaution

**Do:** Look for rate of change arrows on your display device screen. Trend arrows help you determine if you can calibrate now or should wait.

**Don't:** Calibrate when your BG is changing at a significant rate: more than 2 mg/dL per minute.

Don't calibrate when you see:

- A single arrow, pointing up

   Rising 2-3 mg/dL each minute
- Two arrows pointing up
  - Rising more than 3 mg/dL each minute
- Single arrow pointing down
  - Falling 2-3 mg/dL each minute
- Two arrows pointing down

   Falling more than 3 mg/dL each minute

**Why:** Calibrating during a significant rise/fall of your BG may affect accuracy of sensor glucose readings.

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

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#### Precaution

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

**Why:** Entering the wrong BG values, or waiting more than five minutes before entry, might affect sensor performance.

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

#### Precaution

**Do:** Only use fingerstick measurements from your BG meter for calibration.

**Don't:** Use alternative site BG values from your arms, palm of your hand, etc.

**Why:** Alternative site BG values may be different and less accurate than your fingerstick BG values.

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

### 7.3 Calibration Overview

### What Is a Calibration?

As you learned earlier, the sensor glucose readings come from measuring the glucose fluids found between your cells (interstitial fluids). Although blood and interstitial fluids are similar, sensor glucose readings can be different between your fingerstick and your CGM. Calibration provides a comparison, or measurement, between your meter's fingerstick measurement and the sensor's glucose readings, allowing alignment between the sensor and meter.

Your BG meter "teaches" the sensor your glucose values through calibration. Just like a clock can need adjusting–calibrations allow your CGM to adjust to your body.

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### Why Is Calibrating Important?

Calibrations are a must to make sure the CGM system is performing at its best.

By calibrating when the system notifies you that a calibration is due, the G5x uses your meter's BG value to make sure the sensor glucose readings remain accurate throughout your session.

### How Do I Calibrate?

Take a fingerstick measurement from your meter, and simply enter the meter's BG value into one of your display devices. This chapter lets you know what precautions you need to take before taking your BG meter value, then entering your data. Up to now, you needed to enter information such as Alerts, transmitter SN, etc., separately for the receiver and smart device. Calibration is different. You only need to enter calibrations into one device.

Don't enter your BG values into both devices: enter into either your app or the receiver. If you enter your meter's BG value into your receiver, it takes about five minutes for your sensor glucose readings to begin. In approximately ten minutes, you can view the readings in the other display device.

### How Often Do I Calibrate?

There are three primary "must do" calibration events, each with its own notifications:

- 1. Two startup calibrations once your warmup session is complete.
- 2. Update calibrations done twice daily, once every 12 hours.
- 3. When you're notified.

If you receive a calibration notification outside of your scheduled calibration schedule, either the system doesn't accept your most recent calibration or your meter's BG value is very different from the sensor's glucose reading.

Don't worry about keeping track of the time between calibrations; the system will notify you when you are ready for another.

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Now that you have an overview of calibration, let's review some contraindications, warnings, and precautions you need to know and follow before you calibrate.

# 7.4 When to Calibrate

Calibrating on a regular schedule aligns your sensor glucose readings with your meter's BG values. Without calibrations, your sensor may be inaccurate, and as a result, so will your display device's sensor glucose readings, Alerts, and notifications, etc.

There are important times when you *must* calibrate:

- 1. Startup Calibration: two hours after you insert your sensor.
- 2. 12 Hour Update Calibration: every 12 hours after two-hour startup calibration.
- 3. When system notifies you.

With calibration notifications, your sensor and display device help you keep your calibration schedule on track. If your BG values are not between 40-400 mg/dL, the system won't accept your calibration. Wait until you are within the 40-400 mg/dL range before entering your BG values.

### Startup Calibration: Sensor Startup Completed

- 1. At notifications (see next table) enter two back-to-back fingerstick measurements into just one device.
- 2. No need to do startup calibrations twice.
  - a. Calibration data flows between the receiver and your app.
  - b. Five minute reporting delay between devices.
- 3. First update calibration is 12 hours after your startup calibration.

### **Update Calibration**

Enter an update calibration every 12 hours after your initial calibration. Below is a sample calibration schedule. As you can see from the calendar's BG meters, you:

1. Inserted your sensor and entered initial two calibrations on Monday at 10  $\ensuremath{\mathsf{AM}}$  .

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- 2. Entered update calibrations at 10 PM that night.
- 3. For the rest of the seven-day sensor period, you enter update calibrations at 10 AM and 10 PM.

	MON	TUE	WED	THU	FRI	SAT	SUN
8 AM							
10 AM	+	6	•	•	6	6	•
10 PM		•	•	•	•	•	•

Figure 5. Example Minimum Calibration Schedule During Seven-Day Sensor Session

Update calibrations are typically 12 hours since your last calibration; however, they can be sooner. As an example, if you know your next calibration is due at 10 PM, but you want to go to bed at 9 PM, you can do the calibration before bedtime, resetting the 12-hour count down.

- 1. Enter one fingerstick measurement at least every 12 hours.
- 2. Display devices provide calibration prompts.
- 3. You may be prompted to enter additional fingerstick measurements as needed.

## 7.5 Calibration Notifications

### Sensor Session Startup Calibration Notifications

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Once your two-hour sensor warmup is complete, your display device tells you it's time to enter the first of your two back-to-back startup calibrations. Once the system has accepted your BG values, your glucose readings begin. If you don't enter your BG values right away, the system reminds you every 15 minutes. Remember, use only your BG meter for calibrations, and never enter values from your CGM.

Device	What you see	What it	What you
First Calibration		IIIeans	uu
Smart Device: Lock Screen	Dexcom now Enter first BG meter value elide to view		
Smart Device: In App	Why two meter values? Steps: 1. Wash and dry your hands 2. Take a fingerstick with your meter 3. Tap the green circle above and promptly enter the exact value from your meter	Sensor warmup is complete. Ready for first of two startup calibrations.	Follow steps in Section 7.6 and 7.7. Immediately prepare for next calibration.

#### **Startup Calibration Notifications**

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Receiver			
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Receiver			
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Your sensor glucose readings begin in approximately five minutes once the device(s) accepts your calibrations.

## **Update Calibration Notifications**

Once your startup calibration is done, your update calibration schedule begins.

The steps to enter your update calibrations are the same as your startup calibration, including only entering values in one display device. The only difference is, with update calibrations, enter your BG meter value just once.

The default BG value is your current reading if available or 120 mg/dL.

Like the reminders you received with your startup calibration, if you don't enter your BG meter values right away, the system notifies you every 15 minutes.

#### Device What it means What you do What you see Smart Enter update Follow steps Dexcom now Enter new BG meter value **Device: Lock** calibration. in Section 7.6 Screen and 7.7 to If message calibrate. doesn't go away: Immediately Smart prepare for Device: System didn't In App next accept calibration calibration.

#### **Update Calibration Notifications**

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Receiver		<ul> <li>BG values are very different from sensor glucose readings</li> </ul>	
----------	--	---	--

**Tap** *Message* to clear notification on your smart device. To clear a notification on your receiver, **press** *Select*.

### Sound/Vibration Notifications

In case you can't look at your screen, both the smart device and receiver provide, with the exception of your regular 12-hour update calibration, beep/vibration notifications to let you know it's time to calibrate or if there was a system calibration error.

For more information on setting your sound/vibration notifications and how to clear them, please see Chapter 9.

#### **Smart Device**

Calibration notifications will Alert you with a triple beep if your smart device is not on *Silent* or *Do Not Disturb*.

#### Receiver

The receiver Alerts you with an initial vibration for calibration notifications. If not cleared, you receive a vibrate/beep every five minutes until confirmed.

# 7.6 Preparing for Calibration

Your sensor depends on you to help make its sensor glucose readings accurate. If you don't prepare properly for the calibration, your sensor may not provide you with the most accurate sensor glucose readings.

### Nine Steps to Successful Calibration:

#### Do:

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- 1. Wash and dry your hands before staking a fingerstick measurement.
- 2. Always use the same meter you routinely use to measure your BG.
  - a. BG meter and strip accuracy vary between meter brands.
  - b. Switching within a session might cause sensor glucose readings to be less accurate.
- 3. Follow meter's instructions exactly when taking your fingerstick measurement.
- 4. Verify test strips are current and, if required, coded correctly with meter.
- 5. Check: Is *Bluetooth* on?
  - a. If off, can't calibrate
- 6. Use fingerstick BG values only.
  - a. Other sites are not as accurate.
    - b. Must enter within five minutes of taking BG meter value.
    - c. Enter exact BG value from your meter for each calibration.

Don't:

- 7. Don't take acetaminophen-containing medication during your session (for example, Tylenol).
  - a. See your healthcare professional to better understand how long acetaminophen is active in your body.
- Don't calibrate if your BG values are under 40 mg/dL or over 400 mg/dL.
  - a. If BG value is outside of this range, receiver doesn't understand these values and won't calibrate.
    - i. You must wait until your BG is in the range to calibrate.
- 9. Don't calibrate if trend arrows are going straight up or down
  - a. Glucose is changing too quickly for an accurate calibration.

Be safe--if BG is low, first treat low blood sugar, and then calibrate.

# 7.7 Ready? Set? Calibrate!

You've followed the nine steps above, have a valid BG value from your meter, and your display device keeps alerting you: Calibrate! Calibrate! Calibrate!

#### Remember:

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You don't have to take a fingerstick measurement for each display device when calibrating. Once you enter the reading into one, data is pushed to the other within ten minutes.

Next are steps to enter your calibrations using the app, followed by the steps for entering your calibrations into the receiver.

Step	What you see	What you do	Additional Info
1	P     P     X     Tap to enter your first BG meter value     P     Why two meter values?     Steps     Why two meter values?     Steps     Wash and dry your hands     Take a fingerstick with your     meter     Take a fingerstick with your     meter     Tap the green circle above and     promptly enter the exact value     from your meter	Tap circle.	Startup calibration: Enter two back-to-back meter BG values. Update calibration: Enter one meter BG value.

Startup Calibration in the App

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Step	What you see	What you do	Additional Info
2	Enter BG Meter Value Enter BG Meter Value mg/dL Cancel 1 2 3 4 5 6 and 5 6 an	<b>Enter</b> meter's <i>BG</i> <i>value</i> using number pad. <b>Tap</b> <i>Save</i> .	Double-check your numbers. Entering wrong values, or values taken more than five minutes ago, can affect the sensor's accuracy.
3	Is this correct? 125 mg/dL BAVE Cancel	Verify value is correct. Tap Save. If not correct: Tap Cancel. Reenter correct value.	

Calibration

Step	What you see	What you do	Additional Info
4	The provide the second Big meter values Why two meter values? Steps: 1. Wash and dry your hands 2. Take a fingerstick with your meter 3. Tay the green clircle above and promptly enter the exact value from your meter	<b>Tap</b> <i>circle</i> to enter your second BG value. Follow steps 2-3 and enter second reading.	
5	ų	Meter icon has no calibration notification. Calibration accepted.	Your calibration was successful.

Calibration

Step	What you see	What you do	Additional Info
6	E P A .	Wait for next calibration notification in 12 hours.	Default Home trend screen. Calibration accepted.

### Startup Calibration With Your Receiver

Step	What you see	What you do	Additional Info
1		Press <i>Select</i> to turn on receiver. Press <i>Select</i> again for Main Menu.	You won't see calibration notifications when receiver screen is black.

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Step	What you see	What you do	Additional Info
2	Main Menu Trend Graph Start Sensor Enter BG	Press Up/Down Arrow. Highlight Enter BG. Press Select.	
3	Enter BG	Press Up/Down Arrow to change numbers. Stop at meter's BG value. Press Select.	Sensor default reading is 120 mg/dL. If sensor glucose reading is within the last 15 minutes, screen will show sensor's actual reading.
4a	Enter BG 120 mg/dL 2:41 PM OK Cancel	Verify BG value is correct. If correct: <b>Press</b> <i>Select</i> .	If Select is not pressed: • Receiver times out • BG level isn't recorded

Calibration

Step	What you see	What you do	Additional Info
4b	Enter BG 127 mg/dL 2:42 PM OK Cancel	Verify BG value is correct. If incorrect: <b>Press</b> <i>Right Arrow</i> to <i>Cancel.</i> <b>Press</b> <i>Select.</i> <b>Reenter</b> BG value.	Cancel and reenter BG value. Fingerstick measurement must be within the last five minutes.
5	Enter BG	Wait.	"Thinking" screen. BG value is accepted.
6		Immediately take another meter reading. Enter meter's BG value.	First calibration accepted. Time for second calibration.

Calibration

Step	What you see	What you do	Additional Info
7	2 150 mg ↓ 400 350 250 200 150 2 ÅM 3 ÅM 4 ÅM 434 ÅM	Wait for next calibration notification in 12 hours.	Default trend screen. Calibration(s) accepted.

# 7.8 Calibration Errors

Before or during your calibration process, your display device may show error notifications. If the notifications don't go away after 15 minutes, refer to Chapter 18, Troubleshooting.

### **Calibration Error Notifications**

Device	What you see	What it means	What you do
Smart Device: In App	Enter new BG meter value after 11:43PM 2		Wait 10-15 minutes.
Receive r	Enter BG in 15min	Sensor can't calibrate now.	Retake fingerstick measurement at notification. Enter BG value.

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Device	What you see	What it means	What you do
Smart Device: In App	Enter new BG meter value ?	System didn't	Additional calibration needed immediately.
Receive r		accept recent calibration.	Calibrate. No sensor glucose readings.

Approximately five minutes after entering your second BG meter value, your display device(s) will start providing sensor glucose readings and glucose level trends. While each display device may have different ways of presenting sensor glucose readings and trends, the meanings are the same.

Fingerstick measurements entered into one device will be available in the other approximately ten minutes after entering data.

#### Summary

Now You Can:

- Calibration overview
  - o Define calibration
  - Explain the importance of calibration
  - o Identify steps to ensure a successful calibration
- Recognize steps required to take accurate BG measurements
  - o Identify the best BG site for calibrations
  - Prepare finger for fingerstick measurement
- Determine if you should/should not calibrate

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- o Recognize when you can enter BG meter values
- o Recognize when you should not enter BG meter values
- Determine if you need to calibrate outside of the normal calibration guidelines
- Initiate startup calibration
  - Perform update calibrations
- · Correctly enter your fingerstick measurement
  - o App
  - o Receiver
- Identify calibration errors

#### What's Next?

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In the next chapter, you'll learn how to end a typical seven-day sensor session, what to do if you need to end your sensor session early, along with how to remove the transmitter and determining if you need to replace it.

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# Chapter 8

Let's G5x! The Basics:

### Ending Your Sensor Session and Transmitter Session

### 8.1 Introduction

G5x sensor sessions last seven days. This chapter reviews what you should expect when your session is about to expire, and removing the sensor and transmitter. It also covers how to determine if you need to end your session early.

After this chapter, you will be able to:

- Identify replace sensor notifications at the end of a seven-day sensor session
- · Recognize when you have to end a sensor session early
- Successfully end a sensor session early
  - Identify how you can prevent sensor session failures
- Remove your transmitter holder with transmitter attached
- Separate transmitter from its holder
- Determine if transmitter can be used for another sensor session
- Pair a new transmitter

To keep up with your glucose trends, it's important to begin a new sensor session as quickly as possible. After a sensor session ends, the sensor stops taking your sensor glucose readings. You won't get your trends, nor will you get any Alarm or Alerts.

Before stopping a session and removing the transmitter and its holder, review the following safety statements to make sure you don't harm yourself.

# 8.2 Safety Statements

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Ending Your Sensor Session and Transmitter Session

#### Warning

**Don't:** If a sensor breaks under the skin with no portion visible above the skin, don't remove it.

**Do:** Contact your healthcare professional if you have redness, swelling, or pain at the insertion site.

Within 24 hours of experiencing a broken sensor wire, please call our 24/7 Technical Support department:

Email: TechSupport@dexcom.com

Toll free: 1.888.738.3646

Toll call: **1.858.200.0200** 

Why: Sensors may fracture on rare occasions.

#### MRI with broken wire

For patients undergoing an MRI with a retained wire broken off from a G5x sensor, in-vitro MRI testing did not detect any safety hazards. There was no significant migration or heating of the wire and imaging artifacts were limited to the area around the wire.

### Precaution

Don't: When ending a session, don't throw away the transmitter.

**Do:** Keep using it until the system notifies you the transmitter battery is about to expire.

Why: The transmitter is reusable and can be used in multiple sensor sessions.

### 8.3 Ending Your Sensor Session

There are different ways your session might end.

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**Ending Your Sensor Session and Transmitter Session** 

The most common is your sensor's typical seven-day time frame ended. The second is ending the sensor session early. You may end a session early based on a personal decision, or, on rare occasions, the receiver or app detects sensor issues and notifies you to end the session.

Let's review ending a normal session first; later in this chapter we'll review the notifications for ending the session early.

## Ending Your Seven-Day Sensor Session

Just like other notifications, your sensor session ending notifications need clearing:

• App

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- Tap screen
- Receiver
  - Press Select

End of Seven-Day Sensor Session Notifications

### **Ending Sensor Session Notifications**

Device	What you see	What it means
At Six Hours		

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Ending Your Sensor Session and Transmitter Session

Device	What you see	What it means
Smart Device: Lock Screen	5       1       O       O         Monday, April 14       Monday, April 14       O       Dexcom       Sensor session ends at 11:08AM         Sensor session ends at 11:08AM       Sensor session ends at 11:08AM       Sensor session ends at 11:08AM	
Smart Device: In App	Your sensor session will end in six hours. You will not receive alerts or alarms after this time, unless you replace your sensor.	Notifications begin when sensor session has only six hours left. Clock will count down until session has ended. Continue to get sensor glucose readings.
Receiver	Replace Sensor Soon 06:00:00	

Device	What you see	What it means	
At Two Hours			
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OF compression, OCR, web optimization using a watermarked evaluation copy of CVISION PDFCompressor

Device	What you see	What it means
Smart Device: Lock Screen	Monday, April 14 Dexcorn Sensor session ends at 11:08AM alco to view	
Smart Device: In App	Your sensor session will end in two hours. You will not receive alerts or alarms after this time, unless you replace your sensor.	Two hours remain on your current sensor session. Continue to get sensor glucose readings.
Receiver	Replace Sensor Soon 02:00:00	

Device	What you see	What it means	
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Ending Your Sensor Session and Transmitter Session

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Ending Your Sensor Session and Transmitter Session

Device	What you see	What it means
Session Ended		
Smart Device: Lock Screen	Dexcom now Replace sensor now wide to view	
Smart Device: In App	Reptace sensor now. You will not receive alerts or alarms after this time, unless you reptace your sensor 2 Sensor removal 3 Sensor insertion	Session has ended. App Tap screen's "?" for steps to: • Remove sensor • Insert new sensor Receiver Press <i>Select</i> to clear.
Receiver	Replace Sensor Now 00:00:00	

Ending Your Sensor Session and Transmitter Session

Device	What you see	What it means		
Session Stopped	Session Stopped			
Smart Device: Lock Screen	N/A	Sensor session has stopped. App		
Smart Device: In App	Tap to start 2-hour sensor warmup	<ul> <li>No sensor glucose readings</li> <li>Notifications for new session</li> </ul>		
		No sensor glucose readings		
	■**********************************	<ul> <li>Straight line on trend graph</li> </ul>		
Receiver	200 150 100 1 PM 2 PM 328 PM	<ul> <li>Dashed lines on status bar</li> </ul>		

### Sound/Vibration Notifications

In case you can't look at your screen, both the smart device and receiver provide beep/vibration notifications to remind you your sensor session will end in 30 minutes, it has just ended, or your sensor failed and you need to start a new session. Remember, if your smart device is on *Silent* or *Do Not Disturb*, you won't get any sound notifications.

For more information on setting your sound/vibration notifications, please see Chapter 9.

#### **Smart Device**

Your smart device notifications you with a triple beep. If not cleared, you receive the triple beep twice, five minutes apart.

#### Receiver

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The receiver alerts you with an initial vibration notification. If not cleared, you receive a vibrate/beep twice, five minutes apart.

Once a sensor session has expired, you are ready to start your new session! If you're not sure what to do, the app will provide instructions, or you can refer to the Getting Started Guide, online tutorials, or Chapter 6 in this user guide.

### **Ending Your Sensor Session Early**

For personal reasons, you may want to force quit a sensor session early (for example, you're getting an MRI and need to remove all parts of the system).

Or, occasionally, the app or receiver may detect something is wrong with your sensor and let you know it's stopping the current session.

This may be caused by a number of reasons:

- 1. Unresolved calibration issues.
- 2. Error symbol does not go away.
- 3. Wait symbol does not go away.
- 4. Sensor is coming out of the body (for example, the adhesive is peeling off).

You'll receive error notifications leading to a new sensor session. If you see error notifications, before stopping a sensor session early, always contact Technical Support (available 24/7) at:

- Email: TechSupport@dexcom.com
- Toll free: 1.888.738.3646
- Toll call: 1.858.200.0200

When your display device has system errors, you may not receive any sensor glucose readings and you should not calibrate.

#### Notifications to End Sensor Session Early

#### System Notifications

Device	What you see	What it means
Device	What you see	What it means

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Device	What you see	What it means	
Smart Device: Lock Screen	Dexcom now Replace sensor now elide to view		
Smart Device: In App	Sensor Failed. Replace sensor now. You will not receive alerts or alarms after this time, unless you replace your sensor. (?) Sensor removal help (?) Sensor insertion help	Sensor issues detected. Session ends automatically. No: • Sensor Glucose Readings • Alarm/Alerts Replace sensor.	
Receiver	Sensor Failed Replace Sensor		

Device	What you see	What it means
Smart Device: Lock Screen	Signal loss side to view	Wait up to three hours while the system autocorrects.

Ending Your Sensor Session and Transmitter Session

Device	What you see	What it means
Smart Device: In App		Check transmitter—is it properly inserted into transmitter holder? Make sure you haven't taken acetaminophen. If not corrected after 3 hours:
Receiver		Contact Dexcom Technical Support
Smart Device: Lock Screen	Signal loss elide to view	
		system autocorrects.
Smart Device:	2??	Check transmitter—is it properly inserted into transmitter holder?
In App		Make sure you haven't taken acetaminophen.
	2	If not corrected after 3 hours:
Receiver	300 250 200 150 100 50	Contact Dexcom     Technical Support

The G5x knows when a typical seven-day sensor session is over, automatically ending the session in each display device. However, if you need to end the session early, you need to let the system know by manually stopping the sensor session.

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Ending Your Sensor Session and Transmitter Session

While the end result is the same (ending a sensor session), the steps differ between the app and receiver. If you're using both, no need to stop the sensor session in each: the other display will see the session has stopped.

Let's first look at how to end a sensor session in the app, then the receiver.

App: Ending a Sensor Session Early

Step	What you see	What it means	What you do
1	<u>.</u> * ₽ Ξ	Access Main Menu.	T <b>ap</b> <i>Main Menu</i> icon.

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Ending Your Sensor Session and Transmitter Session

Step	What you see	What it means	What you do
3	<ul> <li>Stop Sensor</li> <li>Are you sure you want to stop your sensor?</li> <li>You will not neceive alerts or alarms after you stop your sensor, unless you replace your sensor, unless you replace</li> <li>Sensor removal</li> <li>Sensor insertion</li> </ul>	Blue ? icons provide additional information.	Tap Stop Sensor.
4	Tap to start 2-hour sensor warmup	Confirms sensor session has ended. Ready for new session.	Remove sensor. Insert new sensor. Tap green circle when ready for new session.

### Receiver: Ending a Sensor Session Early

Step	What you see	What it means	What you do
1	202 m ≠ 400     350     350     200     150     10 Am 11 Am 12:52 PM	Go to Main Menu.	Press Select.

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Ending Your Sensor Session and Transmitter Session

Step	What you see	What it means	What you do
2	Main Menu 📃 Alerts Settings U Shutdown	Ends sensor session. During session, <i>Stop Sensor</i> option appears.	Press Down Arrow to Stop Sensor. Press Select.
3	Stop Sensor 🙁	Thinking screen.	Wait
4	Stop Sensor 🕄 Stop Sensor	Confirms you want to stop sensor. Return to Main Menu.	Press Select.
5	Main Menu Trend Graph Start Sensor Enter BG	Ready to start a new session. Not in active session, <i>Start Sensor</i> option appears.	Remove sensor. Insert new sensor. Press Select to Start Sensor when ready for new session.

# Temporarily Shut Down Receiver

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Ending Your Sensor Session and Transmitter Session

To save on its battery, you can temporarily shut down the receiver. When shut down, your receiver and transmitter no longer communicate and you will not get any Alarm or Alerts although your sensor session remains active.

Shutting down the receiver does not extend your sensor session past the seven days; it only stops the receiver from communicating with the transmitter. Your sensor session will stop seven days after you started the session.

Step	What you see	What it means	What you do
1	202	Go to Main Menu.	Press Select.
2	Main Menu Alerts Settings U Shutdown	Ends sensor session. During session, <i>Stop Sensor</i> option appears.	Press Down Arrow to Stop Sensor. Press Select.
3	Shutdown () Shutdown?	Confirms you want to shut down. Shuts down receiver.	Press Select.

#### **Receiver: Temporary Shutdown**

**Press** *Select* to turn the receiver back on. It may take up to 20 seconds for the receiver to turn on.

#### Preventing Sensor Failures Dexcom G5x System User Guide

Ending Your Sensor Session and Transmitter Session
Sensor failures can happen when your display device doesn't receive your sensor's glucose readings. While it is rare to have a sensor failure, there are preventative steps you can take.

#### Help prevent sensor failures by checking:

- 1. Sensor hasn't expired.
- 2. Transmitter is snapped securely into its holder.
- 3. Transmitter holder isn't dislodged or adhesive isn't peeling.
- 4. Nothing is rubbing against transmitter holder (for example, seat belts).
- 5. You selected a good insertion site (see Chapter 6).
- 6. Insertion site is clean and dry before sensor insertion.

## 8.4 Remove Sensor, Transmitter, and Transmitter Holder

The app and receiver are ready for a new session! However, before you can start a new sensor session, you need to end the current sensor session, and remove the old sensor and transmitter.

#### **Removing Transmitter Holder and Sensor**

Think of the transmitter as being part of the transmitter holder. Do not remove the transmitter before removing the transmitter holder from your body.

To remove the transmitter holder:

- 1. Gently peel transmitter holder adhesive patch from skin.
  - a. Sensor wire comes out with transmitter holder.
- 2. Separate the transmitter from the transmitter holder.
- Discard the transmitter holder following your local waste management regulations for disposing of blood-contacting parts (sensor and transmitter holder).

## **Removing Transmitter From Its Holder**

Remember, your transmitter is reusable, don't throw it away until its battery has died. With a battery life of 90 days, use the same transmitter over a number of sensor sessions. You'll receive notifications as it nears the end of its battery life.

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Ending Your Sensor Session and Transmitter Session

Before reusing the transmitter in your new sensor session, remove it from the old transmitter holder.

Step	Picture	What you do
1	and a second second	<b>Grasp</b> end of <i>adhesive patch</i> . <b>Peel</b> <i>adhesive patch</i> up and away from your body like a bandage, removing <i>sensor</i> , <i>transmitter</i> , and its <i>holder</i> . NOTE: Do not remove the transmitter while
	CARTER	the adhesive patch is on your skin.
2		Hold <i>transmitter holder</i> in your hand. Bend and break <i>latch</i> , releasing the transmitter.

Removing Sensor, Transmitter,	and Transmitter Holder
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Ending Your Sensor Session and Transmitter Session

Step	Picture	What you do
3		Hold <i>ridged side</i> Pull <i>transmitter</i> straight out
4		Keep <i>transmitter</i> to use with next sensor.
5		Throw away adhesive patch, transmitter holder, and sensor following your local guidelines for disposal of blood-contacting components.

After removing your sensor and taking the transmitter out of the transmitter holder, you're ready to begin a new sensor session. The transmitter's battery is good for up to three months. If you haven't received your final seven-day transmitter battery life warning, you can reuse the transmitter for your next session.

Remember:

1. Never use same spot repeatedly for sensor insertion.

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Ending Your Sensor Session and Transmitter Session

2. Never use same site for 2 sensor sessions in a row.

## 8.5 End of Transmitter Battery

How do you know if your transmitter's battery will last through your next session?

System messages help you determine if your transmitter's battery will last through your next seven-day session. Starting at three weeks prior to the end of its battery life, the messages count down the transmitter's battery until it has only seven days. If the transmitter battery has seven days or less remaining, you won't be able to start a new session.

#### Device What you see What it means Smart Dexcom now Your transmitter will stop working in about three weeks **Device: Lock** Screen Your transmitter battery is low. The transmitter will stop working in about three Transmitter battery will expire in weeks. three weeks. If you haven't already, please order a new transmitter. Smart Device: In App

#### **Transmitter Battery Messages**

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**Ending Your Sensor Session and Transmitter Session** 

Device	What you see	What it means
Receiver	Low Battery Order New Transmitter Days Left: 22	



Ending Your Sensor Session and Transmitter Session

Device	What you see	What it means
Smart Device: Lock Screen	Dexcom now Transmitter battery critically low side to view	
Smart Device: In App	Your current transmitter will stop working in about one week. This is the last sensor session with your current transmitter. If you haven't already, please order a new transmitter.	Transmitter battery will expire in one week. Order a new transmitter.
Receiver	Low Battery Order New Transmitter	

To make sure you have a transmitter that's ready for a new sensor session, you may want to reorder a new one at.dexcom.com/order, by calling Customer Service (see Section 16.1), or through the channels you used before, at your first low battery notification.

## Sound/Vibration Notifications

In case you can't look at your screen, both the smart device and receiver provide beep/vibration notifications to tell you your transmitter's battery is low or the transmitter failed. Remember, if your smart device is turned on to Silent or Do Not Disturb, you won't get any sound notifications. Dexcom G5x System User Guide

**Ending Your Sensor Session and Transmitter Session** 

For more information on setting your sound/vibration notifications and how to clear them, please see Chapter 9.

#### Smart Device

Your smart device notifies you with a triple beep. If not cleared, you receive the triple beep twice, five minutes apart.

#### Receiver

The receiver alerts you with an initial vibration notification. If not cleared, you receive a vibrate/beep twice, five minutes apart.

#### 8.6 Pair New Transmitter

Once the transmitter battery has died, before starting a new sensor session, you need to pair your new transmitter with your display device(s). In Chapter 5 you learned how to pair your transmitter using the set up wizard. But how do you pair a new transmitter once your display device is setup?

Pair the transmitter before inserting the sensor, putting the transmitter in the transmitter holder, and starting a new sensor session.

Арр		
Step	Picture	What you do
1	<u>.</u> * * ⊒	Tap <i>Menu</i> icon

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Ending Your Sensor Session and Transmitter Session

Step	Picture	What you do
5b	Cake Photo of Barcode Using your iPhone, take a photo of the barcode found on the bottom of the transmitter box.	<b>Center</b> longest barcode within green brackets. <b>Tap</b> <i>Take Photo</i>
5c	Take Photo of Barcode     In 43210     See User's Guide for Symbol Meaning     any smaller for the photo of Barcode     Single Control of Barcode     S	Check mark confirms successful transmitter SN scan.

Ending Your Sensor Session and Transmitter Session

Step	Picture	What you do
6a	Cake Photo of Barcode Using your iPhone, take a photo of the barcode found on the bottom of the transmitter box.	If unable to use app's scanning device: <b>Tap</b> <i>Enter transmitter SN by hand</i> .
6b	Enter Transmitter SN Enter transmitter SN Where is the transmitter SN? SAVE Cancel 1 2 3 Cancel 1 2 4 5 Cancel 1 2 4 5 Cancel 1 2 4 5 Cancel 2 4 5 Cancel 2 7 2 7 2 7 2 7 2 7 2 7 2 7 2 7	<b>Use</b> keyboard to enter transmitter SN. <b>Confirm</b> correct SN . <b>Tap</b> <i>Save</i> .

Ending Your Sensor Session and Transmitter Session

Step	Picture	What you do
7	Now connecting your iPod touch to your iPod touch to your transmitter twill take up to 30 minutes for your uransmitter using Bluetooth.	<b>Wait</b> up to 30 minutes for smart device and transmitter to connect.
8	Bluetooth Pairing Request           Your Dexcom Transmitter would like to pair with your iPhone.           Cancel         Pair	At notification, <b>Tap</b> <i>Pair</i> to pair app with smart device.
9	E P X	Before inserting the transmitter into its holder and starting a new sensor session, make sure your smart device and transmitter are paired

Ending Your Sensor Session and Transmitter Session

#### Receiver

Step	Picture	What you do
1		Press Left Arrow twice to go to Main Menu.
2	Main Menu = Alerts Settings U Shutdown	<b>Press</b> <i>Down Arrow</i> to <i>Settings.</i> <b>Press</b> <i>Select.</i>
3	Settings 🔅 Time/Date Transmitter Device Info	<b>Press</b> <i>Down Arrow</i> to <i>Transmitter</i> . <b>Press</b> <i>Select</i> .
4	Transmitter     Y       Y# Transmitter SN       Yi Transmitter Info	Highlight <i>Transmitter SN.</i> Press <i>Select.</i>
5a	Om Q5 <sup>th</sup> Mobile Transmitter Ki (Retail) ST1-RF-001 (Constraints Ki (Retail) 12355789 (constraints Ki (Retail)) 12355789 (constraints Ki (Reta	Turn transmitter box upside down to locate SN number.

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Ending Your Sensor Session and Transmitter Session

Step	Picture	What you do
5b	4000N4	If transmitter package isn't available: • SN is on transmitter's back
6	Transmitter SN ¥#	<ul> <li>Enter correct SN using Up/Down Arrow.</li> <li>Press Up/Down Arrow to select and enter transmitter SN.</li> <li>Press Right Arrow to move to next digit.</li> <li>Press Select to save and close.</li> <li>Press Left Arrow twice to return to Main Menu.</li> </ul>
7	400 350 350 200 10 ÅM 11 ÅM 1224 PM	<ul> <li>Make sure receiver and transmitter are connected/paired.</li> <li>Check receiver 10 minutes after starting for <i>Bluetooth</i> icon.</li> <li>Solid: Connected/paired</li> <li>Blinking: Searching,/not paired</li> <li>Don't insert the transmitter into its holder or start a new sensor session until they are paired.</li> </ul>

#### Summary

Now You Can:

Identify replace sensor notification at the end of a seven-day sensor session

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Ending Your Sensor Session and Transmitter Session

- Recognize when you have to end a sensor session early
- Successfully end a sensor session early
- · Identify how you can prevent sensor session failures
- Remove your transmitter holder with transmitter attached
- Separate transmitter from transmitter holder
- Determine if transmitter can be used for another sensor session
- Pair new transmitter

#### What's Next?

Congratulations, you have the basics down!

You can set up your app and receiver, start a sensor session, calibrate, as well as end your sensor session and know when to replace your transmitter.

But the G5x can do much more!

In the next part, Part 3: Next Steps, you will learn how to get the most out of your G5x.

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Ending Your Sensor Session and Transmitter Session



# NEXT STEPS - GETTING THE MOST OUT OF YOUR G5x

- Reading Trend Graph Screens and Recognizing Trends
- Events
- Alarm and Alerts
- Sounds for Alarm, Alerts, and System Messages

Dexcom G5x System User Guide Home Screen, Rate of Change Arrows, and Errors

## Chapter 9

Next Steps:

## Home Screen, Rate of Change Arrows, and Errors

## 9.1 Introduction to Home Screens

In the previous chapter, you learned about calibrations: why they are important and how to do them. Within five minutes of your final startup calibration your sensor glucose readings begin!

In this chapter, you'll learn three things. First, reading the home screen, second, identifying your sensor glucose readings and trends: What do they mean? What's the best way to use trend information? And third, what you do if you aren't getting your sensor glucose readings.

The purpose of this chapter isn't to tell you how to react to your trends but to help you recognize where your glucose was and where it's going. Your healthcare professional can help you with your questions on what actions to take based on your glucose trends.

After this chapter, you'll be able to:

- Recognize home screen icons
- Locate sensor glucose reading
- Explain sensor glucose target range
- Recognize the importance of gray, yellow, and red colors
- Identify Low/High Glucose Alert levels on your trend graph
- · Describe when you receive a High or Low sensor glucose reading
- Change trend graph views
- Cite differences between rate of change arrows
- Recognize error messages

## 9.2 Safety Statements

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Home Screen, Rate of Change Arrows, and Errors

Take a moment and read the safety statements. If not followed, your sensor glucose readings and trends may be less accurate, and you may miss important High or Low Glucose Alerts.

#### Contraindication

Don't: Take medications with acetaminophen while wearing the sensor.

**Why:** Taking medications with acetaminophen (such as Tylenol or Excedrin Extra Strength) while wearing the sensor may falsely raise your sensor glucose readings. The level of sensor inaccuracy:

- Depends on amount of acetaminophen active in your body.
- May be different for each person.

**Consequences:** Without correct readings you might miss a severe low or high glucose event.

#### Warning

**Don't:** Use the system sensor glucose readings for treatment decisions.

**Do:** When making treatment decisions, such as the amount of insulin you need, only use your BG value from your BG meter..

**Why:** Since they measure your glucose from different body fluids, sensor glucose readings can be different from your meter's BG values.

**Consequences:** If sensor glucose readings are used in determining treatments, it could result in you missing a severe low or high glucose event.

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#### Warning

Don't: Ignore symptoms of high and low glucose.

**Do:** If your sensor glucose readings don't match your symptoms, measure your BG with a fingerstick.

**Why:** Your sensor glucose readings may not be accurately reading your glucose.

**Consequences:** You may miss a severe low (hypoglycemia) or high (hyperglycemia) glucose event.

#### Precaution

**Do:** When using both a receiver and a smart device, you must set your settings separately in each.

**Why:** If you set up one device and then use another device with different settings, you might not get an Alarm or Alerts.

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

#### Precaution

**Do:** After connecting any accessories, make sure that the smart device settings allow you to continue receiving Alarm or Alerts on the smart device.

**Why:** Using an accessory device (like a smart watch) might override your smart device sounds.

**Consequences:** Alarm or Alerts might vibrate or be heard on the accessory instead of your smart device causing you to miss severe low or high glucose event.

## 9.3 Overview of Home Screen

Regardless of your display device, the home screen shows your current sensor glucose value, glucose trend, rate of change arrow, and CGM system
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Home Screen, Rate of Change Arrows, and Errors

status. While the screen does look different between the receiver, smart devices, along with the Apple Today View, and Apple Watch the information and color-coding are the same.

No matter how you hold it, the receiver's view does not change. The app, however, has two ways to view data based on how you hold your smart device:

- 1. Vertically in portrait: 3-hour trend information with task bar.
- 2. Horizontally in landscape: 1, 3, 6, 12, or 24-hour trend information without task bar.

This section first familiarizes you with the app's home screen, the Apple Today View, then the receiver's home screen, and last with the Apple Watch home screen. In other chapters, you'll see how to use the icons or use the navigation wheel to enter data or make system changes.

#### App Home Screen

The app's home screen has two main sections:

- 1. Status/Task Bar
  - a. Status Bar reflects status of smart device's system.
    - i. Battery, Bluetooth, etc.
  - b. Task Bar allows you to change settings, enter data, etc.
- 2. Glucose Information
  - a. Reflects sensor glucose readings and trends.



Figure 6. Example App Home Screen on Smart Device

#### App Task Bar

Арр	Name	What it means	What you do	
Status Bar: Informatio	n Only			
Displays signal strength, time, Bluetooth, and battery level.Time: Check smart device and receiver show same time.Status BarStatus BarChanges are made using smart device settings, not in the app.Time: Check smart device and receiver show same time.May look different depending on your smart device/carrier.Battery: App can use up battery-Check you are charged.				
Task Bar: Complete Tasks				

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Арр	Name	What it means	What you do
	Main Menu	Goes to other options.	Tap Main Menu icon to access: Alerts Settings Help Start/Stop Sensor
≣ 🛱 🛪 🔅	BG Meter with red circle and number	Calibration Notification.	<b>Tap</b> <i>icon</i> and enter fingerstick BG value (see Chapter 7).
	BG Meter without red circle	No need to calibrate.	Do nothing.
	Event	Enter different events capturing activities affecting your glucose.	Tap <i>icon</i> to enter data for: • Carbs • Insulin • Exercise • Health (See Chapter 10).

Home Screen, Rate of Change Arrows, and Errors

Арр	Name	What it means	What you do
≡ ₽ ≭ ⊡	Dexcom <i>Share</i>	Dexcom <i>Share</i> is available only on the app. Gray icon means <i>Share</i> is not active.	<b>Tap</b> <i>icon</i> to activate (see Part 5).
≡ ₽ x	Dexcom Share	Once activated, Dexcom <i>Share</i> icon is colored.	<b>Do nothing.</b> <b>Tap</b> <i>icon</i> to access Dexcom Share.

#### **Glucose Information**

App: Portrait	App: Landscape	What it means
11:28 PM	1 HR 3 HR 6 HR 24 HR	Home Screen In Landscape mode, Tap the <i>trend view</i> you want to see at the top of the screen: 1, 3, 6, 12, or 24-hour historical trend views.

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App: Portrait	App: Landscape	What it means
■ 11:28 PM = P A 2002 mg/dL 400 	1 HPR 3 HPR 50 HPR 24 HPR 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	Number: Most recent sensor glucose reading. Shown in milligrams per deciliter (mg/dL). • Yellow: At or above target • Gray: Within range • Red: At or below target
N/A	April 20 2.42 AM	Historical Readings Turn smart device to <i>Landscape</i> mode. Tap <i>time</i> shows time frame's sensor glucose reading. Slide finger across screen to view rest of day's sensor glucose readings.

Home Screen, Rate of Change Arrows, and Errors

App: Portrait	App: Landscape	What it means
11:28 PM E P X 2002 mg/dL 100 9 AM 10 AM 11 AM 11 AM 10 AM 11 AM 10 AM 1	N/A	Rate of Change Arrow Direction and number of arrows show sensor glucose change rate.
Image: state sta	1149) 3169 0149 123491 24149. 	Sensor Glucose Reading Range Shows between 40- 400 mg/dL.

Home Screen, Rate of Change Arrows, and Errors

App: Portrait	App: Landscape	What it means
tt:28 PM ∃ ↓ AAA PAM 10 AAA 11 AAA	1 HB1 3 HB1 0 HB1 12 HB1 24 HB1 999 380 13 PM 1 PM 2PM 99 13 PM 994	Within Glucose Range and Alert Levels • Yellow: High Alert level • Gray: Within range • Red: Low Alert level
→d1       11:28 PM       0         Ξ       P       ★          QQQ2       mg/dL       -200         -200       -200       -100         DAM       10 AM       11 AM       40	11492 0.1491 0.1491 121491 241493 499 388 499 499 499 499 499 499 499 499 499 4	Trend Graph Time Frame Default is most recent 3 hours. Turn smart device to <i>Landscape</i> mode for most recent 1, 3, 6, 12, and 24-hour readings.

Home Screen, Rate of Change Arrows, and Errors

## Apple Today View Widget

Check your CGM on your smart device without opening the app, even when the smart device is locked. Swipe down from the top edge of your smart device to find the Dexcom widget in your Today view; the widget installs when you install the app. (See your smart device instructions for customizing your Today view.)

#### Apple Today View

Apple Today View	Name	What it does	What you do
Glucose Information			
Saturday, October 24%	Glucose Information	Displays your glucose information: Current glucose number Direction your glucose is heading Graph of glucose trend	Review and take appropriate action.

Dexcom G5x System User Guide

Home Screen, Rate of Change Arrows, and Errors

Apple Today View	Name	What it does	What you do
Saturday, October 249: Bar Bar Bar Centor	Sensor Glucose Reading	Shows most recent sensor glucose reading. Color of circle changes: • Yellow: At or above target • Gray: Within target range • Red: At or below target	Take appropriate action.
Concertant	Trend Arrow	Shows direction and speed your glucose is changing.	Review and take appropriate action based on fingerstick BG value. (See Chapter 9)

Home Screen, Rate of Change Arrows, and Errors

Apple Today View	Name	What it does	What you do
Apple Today View	Name Historical Readings	<ul> <li>What it does</li> <li>Graph of your recent glucose readings between 40 and 400 mg/dL.</li> <li>Glucose target range Alert settings:</li> <li>Yellow Line: High Alert setting</li> <li>Gray: Target range</li> <li>Red Line: Low Alert setting or, if that's disabled, 55 mg/dL (largert Law)</li> </ul>	What you do Review and take appropriate action based on fingerstick BG value. (See Chapter 9)
		Glucose Alarm)	

## **Receiver Home Screen**

This section gets you familiar with the receiver's home screen. In other chapters, you'll see how to enter data or make system changes.

Dexcom G5x System User Guide

Home Screen, Rate of Change Arrows, and Errors

## **Receiver Home Screen**

Unlike your smart device screens, the receiver's screen is not interactive; all notifications are for information only. To make changes or enter data in the receiver, **press** *Select* and go to the Main Menu.

The receiver's home screen has two main sections:

- 1. Status Bar
  - a. Reflects glucose trends, readings, status of receiver's system (e.g., battery level).
- 2. Glucose Information Trend Graph
  - a. Reflects sensor glucose readings and trends.

This section will get you familiar with the receiver's home screen. In other chapters, you'll see how to use the navigation wheel to enter data or make system changes.



Figure 7. Home Screen on Receiver

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Home Screen, Rate of Change Arrows, and Errors

#### Status Bar

Receiver	Name	What it does	What you do
202 ma 400 350 350 220 50 50 10 ÅM 11 ÅM 1202 PM	Status Bar	Provides at-a- glance information about the receiver, system, or you. Icons will change based on current data.	Review and take appropriate action.
■ 202 m / 400 350 300 220 150 10 ÅM 11 ÅM 1202 PM	Battery	Shows battery level.	When low, <b>plug</b> <i>micro USB</i> <i>cable</i> into receiver. <b>Plug</b> <i>USB</i> into the adapter and then into electrical outlet.
202 m 400 350 350 200 10 Åm 11 Åm 1202 PM	Bluetooth	Shows <i>Bluetooth</i> connection is working.	Do nothing. Receiver's <i>Bluetooth</i> is always on.

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Receiver	Name	What it does	What you do
202 × 1 350 350 350 250 250 100 100 ÅM 11 ÅM 1202 PM	Sensor Glucose Reading	Shows most recent sensor glucose reading. Color of status bar changes: • Yellow: At or above target • Gray: Within target range • Red: At or below target	Take appropriate action.
202 m ▲ 400 350 300 250 150 10 AM 11 AM 1202 PM	Trend Arrow	Shows direction and speed your glucose is changing.	Review and take appropriate action based on fingerstick BG value.
202 2 2 300 250 250 150 10 ÅM 11 ÅM 1202 PM	Status Area	Far right. Error icons and calibration notifications.	Take appropriate action.

Home Screen, Rate of Change Arrows, and Errors

#### **Glucose Information**

Receiver	What it does
202 m ≠ 400     350     300     250     200     150     10 AM     11 AM     12202 PM	Home screen.
■         202         10         400           350         300         210           200         210         150           10 ÅM         11 ÅM         1202 PM	Number: Most recent sensor glucose reading. Shown in milligrams per deciliter (mg/dL). Color of status bar changes: • Yellow: At or above target • Gray: Within target range • Red: At or below target
202	Historical Readings Default is most recent 3 hours. Press <i>Up/Down Arrows</i> to access 1, 3, 6, 12, or 24- hour trend views.
202 m ≠ 400 350 350 300 250 10 ÅM 11 ÅM 1202 PM	Rate of Change Arrow Direction and speed of your glucose changes.

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Receiver	What it does	
■ 202 <sup>ma</sup> # 400 350 350 250 150 10 ÅM 11 ÅM 1202 PM	Sensor Glucose Reading Range Shows between 40-400 mg/dL.	
■ 202 m / 400 350 300 250 200 150 100 ÅM 11 ÅM 1202 PM	<ul> <li>Glucose target range Alert settings.</li> <li>Yellow: High Alert setting</li> <li>Gray: Target range</li> <li>Red: Low Alert setting</li> </ul>	

Now that you're familiar with the basic layout of the trend graph screen, can locate readings, identify color-coding, and view time frames, let's take a closer look at the rate of change arrows.

## Apple Watch Home Screen

This section gets you familiar with the Apple Watch home screen.

Like your smart device, your Apple Watch has a touchscreen.

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#### Apple Watch

Receiver	Name	What it does	What you do
DEXCOM 10:09 125 + Lat reg/dL	Apple Watch Home Screen	Displays your glucose information: Current glucose number Direction your glucose is heading Graph of glucose trend	Review and take appropriate action.
DEXCOM 10:09 With With With 10:09 With Wi	Sensor Glucose Reading	Shows most recent sensor glucose reading.	Take appropriate action.

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Home Screen, Rate of Change Arrows, and Errors

Receiver	Name	What it does	What you do		
DEXCOM 125 C Law Individual	Trend Arrow	Shows direction and speed your glucose is changing.	Review and take appropriate action based on fingerstick BG value. (See Chapter 9)		
DEXCOM 10:09 125 + War mg/dL	Historical Readings	Graph of your recent glucose readings between 40 and 400 mg/dL. Glucose target range Alert settings: • Yellow: High Alert setting • Gray: Target range • Red: Low Alert setting or, if that's disabled, 55 mg/dL (Urgent Low Glucose Alarm)	Review 3-hour trend graph; no other views are available. Take appropriate action based on fingerstick BG value. (See Chapter 9)		
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Home Screen, Rate of Change Arrows, and Errors
# 9.4 Rate of Change Arrows

Not sure of how your sensor glucose readings are trending?

Rate of change arrows show the speed and direction of your glucose trends based on the last several sensor glucose readings. Arrows and the trend graph help you know when to take action before you are too high or too low.

However, before doing anything, think about your most recent insulin dosing, food intake, overall trend graph, and current BG value. **Don't overreact to the arrows**. Remember the arrows don't reflect your latest reading: they reflect a combination of recent readings.

Арр		
	•	Steady
		Changing:
		<ul> <li>Less than 1 mg/dL each minute</li> </ul>
		Up to 15 mg/dL in 15 minutes
	<b>X</b>	Slowly Rising or Falling
$\bigcirc$		Changing:
		<ul> <li>1-2 mg/dL each minute</li> </ul>
		Up to 30 mg/dL in 15 minutes
		Rising or Falling
$\bigcirc$	★ ↓	Changing:
		<ul> <li>2-3 mg/dL each minute</li> </ul>
		Up to 45 mg/dL in 15 minutes

## **Rate of Change Arrows**

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	<b></b>	Rapidly Rising or Falling
A	-	Changing:
		<ul> <li>More than 3 mg/dL each minute</li> </ul>
		More than 45 mg/dL in 15 minutes
System can direction of		System can't calculate the speed and direction of your glucose change.

There are a number of reasons why you may not get rate of change arrows:

- You just started your sensor session
- No sensor glucose readings over the last few minutes

# 9.5 Error Messages

Sometimes the transmitter or sensor isn't communicating with the display device, causing you not to get your sensor glucose readings or rate of change arrows. Each device notifies you when there is an issue; however, the notifications look different.

Before the system can move forward, you need to address the error.

## Арр

1. If screen is locked:

a. Swipe message to go to app.

- 2. Within app:
  - a. Read message.
    - i. Tap Question Marks for more information and follow steps as appropriate.

## Receiver

1. Press Select to clear message.

You will not get any sensor glucose readings or rate of change arrows on either display device until the error is resolved. Check with your BG meter to monitor your glucose during these error periods.

# **Error Messages**

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What you see		What you do		
Bluetooth Is Out	Bluetooth Is Out of Range			
Smart Device: Lock Screen	Dexcom non     Signal loss     store to view			
Smart Device: In App	Signal Loss	Make sure there are no obstructions, such as a wall or water between your transmitter and your display device. Move within 20 feet of display device.		
Receiver	Signal Loss for 01:22:10	Wait up to 30 minutes while transmitter restores communication.		
Bluetooth Off				
Smart Device: Lock Screen	Dexcom non Bluetooth is off store to view			
Smart Device: In App	Bluetooth is off ?	Smart device: 1. Exit app. 2. Tap Settings. 3. Tap Bluetooth. 4. Turn Bluetooth on.		
Receiver	N/A; <i>Bluetooth</i> is always on.			
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Home Screen, Rate of Change Arrows, and Errors

What you see		What you do	
Not Getting Sens	or Glucose Reading		
Smart Device: Lock Screen	N/A		
Smart Device: In App	N/A	Within 20 feet of your display device?	
Receiver		<ul> <li>Period?</li> <li>Outside of your calibration schedule?</li> <li>In a sensor session?</li> </ul>	
System Found To	emporary Sensor Issu	le	
Smart Device: Lock Screen	N/A	Don't calibrate. System may correct problem on its	
Smart Device: In App	???	own and display sensor glucose readings again. If notification stays for three hours: • Contact Technical Support (see Section 16.1).	

Home Screen, Rate of Change Arrows, and Errors

What you see		What you do	
Receiver	400 350 300 220 10 AM 11 AM 11/8 AM		
Transmitter and S	Sensor Not Communi	cating	
Smart Device: Lock Screen Smart Device: In App	N/A	Wait three hours while the transmitter tries to fix the error. Do not enter calibrations during this time. Make sure your transmitter is properly inserted into the transmitter holder. If not corrected:	
Receiver	400 350 250 250 100 100 50 2 PM 3 PM 407 PM	<ul> <li>Contact Technical Support (see Section 16.1)</li> <li>Remove sensor</li> <li>Insert new sensor</li> </ul>	
Calibration Requ	ired		
Smart Device: Lock Screen	Dexcom now Signal loss editor to see	Error in calibrating. Verify you did not enter a BG reading outside the range of 40-400	

Home Screen, Rate of Change Arrows, and Errors

What you see		What you do
Smart Device: In App	Enter new BG meter value	mg/dL. Enter another BG meter value.
Receiver		
Calibration Error		
Smart Device: Lock Screen Smart Device: In App	N/A Enter new BG meter value after 11:43PM 2	Wait 15 minutes. Enter a BG meter value. If error screen still appears, enter one more BG meter value. Wait 15 minutes. If no sensor glucose readings appear on the display, the sensor needs to be replaced
Receiver	Enter BG in 15min	Contact Technical Support (available 24/7) at: • TechSupport@dexcom.co m • Toll free: 1.888.738.3646 • Toll call: 1.858.200.0200

Home Screen, Rate of Change Arrows, and Errors

What you see		What you do	
Display Devices	and Transmitter Not C	Communicating	
Smart Device: Lock Screen	Dexcom tous Signal loss stide to view	App/Receiver Wait 10 minutes.	
Smart Device: In App	Signat Loss	Move display device and transmitte within 20 feet of each other without obstruction (walls or water). Wait up to 30 minutes.	
Receiver	Signal Loss for 01:22:10	<ul> <li>In app (if not resolved):</li> <li>Tap Settings.</li> <li>Tap Bluetooth.</li> <li>Turn Bluetooth Off and On.</li> </ul>	

If error messages don't go away after you followed necessary steps, and you aren't getting sensor glucose readings, contact Technical Support (see Section 16.1).

## Now You Can:

- Recognize home screen icons
- Locate sensor glucose reading
- Explain glucose target range
- Recognize the importance of gray, yellow, and red colors
- Identify Low/High Glucose Alert setting lines
- Describe when you receive a high or low sensor glucose reading
- Change trend graph hours view
- Cite differences between rate of change arrows

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Home Screen, Rate of Change Arrows, and Errors

Recognize error messages

### What's Next?

By now you have a pretty good understanding of how your trends look on the different display devices, but did you know what you do can affect your trends and patterns? It's important to track actions or well-being to better understand that what you do or how you feel can change your trends.

In the next chapter, you will learn how to enter Events into your G5x.

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Home Screen, Rate of Change Arrows, and Errors

# Chapter 10

Next Steps:

# Daily Events Affect Your Glucose Trends and Patterns

# **10.1 Introduction**

Your daily activities can impact your glucose trends and patterns. In the previous chapter, you learned how to read your glucose trend screens; in this chapter, you learn how to enter situations, or "Events." By tracking Events, you can determine how certain actions or circumstances affect your glucose levels.

After this chapter, you'll be able to:

- Define Event
- Describe each Event
- Create Events
  - o App
  - o Receiver
- Recognize Event markers on app
  - Describe how Event markers are different in portrait and landscape view
- Describe how to view Events entered via your receiver
- View Event markers on your smart device

# 10.2 What Is an Event?

Did you take a walk after lunch today? Did you go to happy hour with your coworkers and have a beer? Are you feeling stressed? Did you catch your kid's sniffles? How much insulin did you take for your dinner meal? These are all Events that can raise or lower your blood sugar.

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Sensor Glucose Alarm and Alerts

An Event is an action or situation affecting your glucose levels. With the G5x, you have the ability to enter your daily Events, helping you track their effect on your glucose trends. Once entered into the smart device or receiver, Events can be viewed in Dexcom reports. The reports help you review how each Event influenced your glucose trends. You can use the reports with your healthcare professional to create a game plan in managing your diabetes.

Even though they differ on how to enter an Event and time, the app and receiver have the same Event categories and subcategories. Later in this chapter, you'll learn how to enter Events in each device.

# **Event Categories**

There are four main Event categories:

- 1. Carbs
- 2. Insulin
- 3. Exercise
- 4. Health

The fourth category, Health, has more options:

- Illness
- Stress
- Feel High
- Feel Low
- Cycle
- Alcohol

The following table provides more detail on each type of Event.

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Sensor Glucose Alarm and Alerts

# **Events Menu**

Device	What you see	What it means	What you do
Carbs			
Smart Device: In App	Carbs Event Carbs Event Carbs Event Cancel Cancel 1 2 3 Carbs Cancel 1 2 3 Carbs Cancel 7 8 9 Carbs Cancel	How many grams did you just eat? Receiver's screen reflects last number entered.	Enter Carb grams per snack or meal, up to 250 grams.
Receiver	Carbs		

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Device	What you see	What it means	What you do
Insulin			
Smart Device: In App	Image: State of the state	Receiver's screen reflects last number entered.	Enter insulin units for each dose, up to 250 units. Can't enter type of insulin, only dosage.
Receiver	Insulin 10.00 Units		

Sensor Glucose Alarm and Alerts

Device	What you see	What it means	What you do
Exercise			
Smart Device: In App	MESSAR     MASS AN        Exercise       Intensity	Default is 30 minutes.	Select each exercise's intensity level and duration. Enter intensity and duration. Type of exercise isn't an option.
Receiver	Exercise Type 👫 ++ Light ++ Medium ++ Heavy		

Sensor Glucose Alarm and Alerts

Device	What you see	What it means	What you do
Health			
Smart Device: In App	Health Event Ster.	General well- being.	Enter different health Events (see following Health Events Menu table).
Receiver	Health + Illness Stress High Symptoms		

Sensor Glucose Alarm and Alerts

Device	What you see	What it means	What you do
Event Time			
Smart Device: In App	Events     Jates Imm       Carbs     >       Insulin     >       Fearcise     >       Health     >	Event time.	For each separate Event, enter date/time Event began.
Receiver	Health 2014/12/31 12:30 PM		

As mentioned in the last table, Health has a series of Events. Tell the system how you are feeling, if you had a drink, if you're having low or high BG symptoms, etc. You select the Event: no amounts are entered, just date and time.

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## Health Events Menu

Device	What you see	What it means
Health Main M	lenu	
Smart Device: In App	Health Event Mess Mess Mess Mess Mess Mess Mess Mes	Use Health Main Menu to access selections.
Receiver	Events     A       Insulin     Insulin       Insulin     Health	

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Device	What you see	What it means	
Health Main	Health Main Menu		
Smart Device: In App	Health Event See	Illness Have a cold, flu, or any other temporary illness affecting your well- being? Stress Are you under stress? Feeling anxious? High Symptoms Feel high BG symptoms?	
Receiver	Health Illness Stress High Symptoms Health Low Symptoms Cycle Alcohol	Low Symptoms Feel low BG symptoms? Cycle Have you started your menstrual cycle? Alcohol Had a glass of wine, beer, or cocktail?	

You can have multiple Events in a single day, or even during the same time frame and enter them all in at the same time. As an example, you're running late because of traffic (Stress) and quickly swing by a drive-thru to get lunch (Carbs of 85 grams).

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Sensor Glucose Alarm and Alerts

For your convenience (and safety!), no need to stop everything and enter your Events as they are happening. When you have a moment, you can enter your Events retroactively in your app or receiver.

Events are entered as individual occurrences: don't enter daily totals, enter each Event separately.

In the next section, you will learn how to enter Events, first in your smart device, then in your receiver.

# **10.3 Entering Events**

You probably will enter Events in the display device you use most often; however, you should know how to enter Events into each.

First, let's look at how to enter Events in a smart device, then in the receiver.

When using Dexcom Share, you can allow your Followers to see your Event entries. For more Dexcom Share information, please see Part 5.

# **Entering Events: Smart Device**

In the app, Events are just a tap away! The Event icon, a running man, is on the app's home screen task bar in portrait mode (remember, you don't have the task bar in landscape).

Entering Events for the Carbs, Insulin, Exercise, and Health categories follows the same steps. If you can enter a Carbs Event, you can enter an Insulin Event. To enter Events, we'll use the above scenario. The following table shows how to enter Carbs (drive-thru lunch) and Stress (traffic jam) Events.

## **Entering Events: App**



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Enter C	Carbs Event		
	Event Time	Now >	
	Non-Amariana To Tue Apr 28, 11	21	
	Wed Apr 29 12	22 AM	
	Today 1	23 PM	
5	Fri May 1 2	24	Scroll and select date and time.
Ŭ	Sat May 2 3 monotone (2 3	25	Tap Done.
	DONE		
	Cancel		
	Cancer		

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Enter Health Event - Stress			
7	Ē	*	Tap Events icon.

Sensor Glucose Alarm and Alerts



Sensor Glucose Alarm and Alerts

Enter H	lealth Event - Stress	
9	IPed ♥     4:30 PM     ● # ■●+       Health Event     Health Event       Illness     ✓       Stress     ✓       Feel High     ✓       Feel Low     ✓       Cycle     ✓       Alcohol     ✓	Tap Stress. Tap Done.
10	Prid *       t29 PM         X       Events         Carbs       >         Carbs       >         Insulin       >         X       Exercise         X       Exercise         X       Exercise         X       Event Stress         Event Time       Now         DONE         Cancel	Tap Event Time.
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Sensor Glucose Alarm and Alerts

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, but the receiver doesn't.

However, there may be times when you want or need to enter Events on the receiver.

# **Entering Events: 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 Carbs/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	202 ma x     400     350     300     50     10 λM     11 λM     1202 PM	Default screen <b>Press</b> <i>Select</i> to go to Main Menu.
2	Main Menu Enter BG Profiles Kevents	<b>Press</b> <i>Down Arrow</i> until <i>Events</i> is highlighted. <b>Press</b> <i>Select</i> .

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Enter 0	Enter Carbs Event			
5	Carbs 2014/12/31 1:01 PM	<ul> <li>Press Left/Right Arrows to change time and date.</li> <li>Left: Backwards</li> <li>Right: Forward</li> <li>Press Select.</li> </ul>		
6 Carbs 6 85 grams 2014/12/31 1:02 PM OK Cancel		Confirmation screen. <b>Press</b> <i>Select</i> .		
Enter Health Event - Stress				

Sensor Glucose Alarm and Alerts



Enter H	Enter Health Event - Stress			
	Health 🕂	<b>Press</b> <i>Left/Right Arrows</i> to change time and date.		
9	2014/12/31 12:30 PM	<ul><li>Left: Backward</li><li>Right: Forward</li></ul>		
		Press Select.		
		Verify information is correct.		
10	10 Stress 2014/12/31 1:05 PM	<b>Press</b> <i>Left/Right Arrows</i> to highlight field.		
10		Press Up/Down Arrows to change numbers.		
	ou ourou	Press Select to save.		

# **10.4 Viewing Events**

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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 entered on your smart device. Slide your finger across the screen or tap the square to get your Event's information.

### App: Viewing Events

Landscape	What it does	What you do
April 28 8.01 AM	Landscape Only Show Event details.	Landscape Only Slide finger across screen.

Once your Share Follower's access 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
  - App
  - Receiver
- Recognize Event markers on the app
  - Describe how Event markers are different in portrait and landscape view

# What's Next?

In the next chapter, you will learn about how your Alarm and Alerts help you monitor your 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?

The G5x understands there are times when you can't look at your receiver or smart device; however, you still need to know critical 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 notifications and sounds
- Determine if signal loss is preventing you from getting an Alarm or Alert
- Describe recommended app settings
  - Successfully clear an Alert
    - App
    - Receiver

Your trending information is one of the greatest benefits of the G5x. It's important to focus on your trends and rate of change arrows, rather than the exact number of your glucose reading.
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# 11.2 Safety Statements

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

# Warning

**Do:** Verify that your smart device's internal settings let you receive Alarm and Alerts.

To receive Alarm/Alerts you must:

- 1. **Make sure** Dexcom G5 Mobile app Notifications are **turned on** in your smart device settings
- 2. Verify app hasn't been shut down
- 3. Turn Bluetooth on
- 4. **Turn off** *Do Not Disturb* (if available on your smart device)
- 5. **Restart** app after device is restarted
- 6. Set Volume at a level you can hear
- 7. Do not close app, always run app in the background
- 8. Make sure accessory devices do not override your smart device settings

**Why:** The app cannot override your smart device's internal settings. Also, accessory devices (like a smart watch or other wearable smart devices) might override your smart device's Alarm, Alerts, and notification settings.

**Consequences:** If your settings are incorrect, you might miss a severe low or high glucose Alarm or Alerts.

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### Warning

**Don't:** Assume the app Alarm/Alert vibrations are different from other vibrating apps on your smart device.

**Do:** Look at the screen of your smart device and check to see if the sound or vibration is from the G5 Mobile app.

**Why:** Medical device apps, like this app, don't have any special priorities over your smart device's features. App notifications or alerts may sound or feel the same as notifications from another app.

**Consequences:** You might miss a severe low or high glucose event.

## Warning

**Do:** Make sure you unplug your headphones from your smart device when you are done using them.

**Why:** An Alarm or Alert can't be heard through your smart device's speakers if headphones are plugged in.

**Consequences:** You might not hear an Alarm or Alert, causing you to miss a severe low or high glucose event.

### Precaution

**Don't:** Separate the transmitter from the receiver or smart device by more than 20 feet.

**Why:** The transmission range from the transmitter to receiver or smart device is up to 20 feet without obstruction. If your transmitter and 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 have been tested. Obstructions can include water, walls, metal, etc.

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As with any wireless device, water is often the biggest culprit in reducing communication distance. This applies to the transmitter and display devices. Take special care when swimming, taking a bath, or getting into a hot tub.

Consequences: Missing a severe low or high glucose event.

# Precaution

**Do:** When using both a receiver and a smart device, you must set your settings separately in each.

**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 device with different settings, you might not get an Alarm or Alerts.

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

# Precaution

**Do:** After connecting any accessories, make sure that the smart device settings allow you to continue receiving Alarm or Alerts on the smart device.

**Why:** Using an accessory device (like a smart watch) might override your smart device sounds.

**Consequences:** Alarm or Alerts might vibrate or be heard on the accessory instead of your smart device, causing you to miss severe low or high glucose event.

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#### Precaution

Do: Make sure the receiver and smart device are turned on.

**Why:** If the receiver or smart device is turned off (Shut Down), it will not display sensor information, Alarm or Alerts.

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

# 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 Glucose 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 don't go over 55 mg/dL in the next 30 minutes, you get another Alarm.

Unlike Alerts, the Urgent Low Glucose 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).

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

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

During your initial setup, you establish your Low/High Glucose 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 notifications, how you are notified, and in some cases, how often you get notified. The following are the defaults.

# **Default Alerts**

### Low/High Glucose Alerts

Your Low/High Glucose 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 Low/High Glucose 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 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.

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Sensor Glucose Alarm and Alerts

- 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 the G5x Alarm/Alerts features. 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 will tell 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 notifications look different on the display devices, they reflect the same information.

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

### Urgent Low Glucose Alarm

Device	What you see	What it means

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Sensor Glucose Alarm and Alerts

Smart Device: Lock Screen	Dexcom now Urgent low glucose alarm side to view	
Smart Device: In App	Urgent Low Glucose Alarm	Sensor glucose reading at or below 55 mg/dL. Shows last glucose value. Arrows reflect rate of change. Check BG meter to make treatment decisions.
Receiver	URGENT LOW 53 ≈ →	

# Low/High Glucose Alerts

Device	What you see	What it means
Smart	Dexcom now	Sensor glucose reading at or
Device:	Low glucose alert	below your Low Glucose Alert
Lock Screen	silde to view	level.

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Sensor Glucose Alarm and Alerts
	Low Glucose Alert	Shows most current sensor glucose reading. Arrows reflect rate of change.
Smart	77	Can be set to repeat between 15 minutes to 4 hours.
Device: In App	mg/dL	Check your BG meter to make any treatment decisions.
	OK	
		-
Baasiyar	LOW	
Receiver		

Device	What you see	What it means
Smart Device: Lock Screen	Dexcom now High glucose alert side to view	Sensor glucose reading at or above your High Glucose Alert level.

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Sensor Glucose Alarm and Alerts

	High Glucose Alert	Shows most current sensor glucose reading. Arrows reflect rate of change.
Smart		Can be set to repeat between 15 minutes to 4 hours.
Device: In App	OK	Check BG meter to make treatment decisions.
		-
	HIGH	
Receiver	389 ** **	

#### **Rise Rate/Fall Rate Alerts**

Device	What you see	What it means
Smart Device: Lock Screen	Dexcom now     Rise rate alert     side to view	Sensor glucose readings rising quickly.

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Sensor Glucose Alarm and Alerts



Device	What you see	What it means
Smart Device: Lock Screen	Dexcom now     Fall rate alert     side to view	Sensor glucose readings falling quickly.

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Sensor Glucose Alarm and Alerts



#### Signal Loss Alert

Device	What you see	What it means
Smart Device: Lock Screen	Signal loss side to view	Your display device and transmitter are not communicating.

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Sensor Glucose Alarm and Alerts



# 11.5 App: Alarm/Alert Recommended Settings

The receiver is a standalone medical device and used solely to monitor your glucose trends.

The app can't override your smart device's general settings:

- When your smart device is on Silent, you'll still receive Alarm/Alerts visual notifications 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 app can't override the Do Not Disturb setting
- If you don't enable your G5 push Notifications settings during setup, 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.

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Sensor Glucose Alarm and Alerts

If you are concerned about missing an Alarm or Alert (for example, 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 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
URGENT LOW	Initial Default Alert: Vibrates 4 times. After 5 Minutes: Vibrates/beeps 4 times every 5 minutes until cleared or sensor glucose readings go above Alarm level.
0 AUC 9 AUC 457 AM	After 30 Minutes: After clearing Alarm, continues to notify if sensor glucose readings remain at or below Alarm level.

#### Low/High Glucose Alerts

What you see	Beeps and vibration

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Sensor Glucose Alarm and Alerts



#### **Rise Rate/Fall Rate Alerts**

 What you see
 Beeps and vibration

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#### Low Repeat/High Repeat

What you see Beeps and vibration

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LOW 70 at ***	Initial Default Alert: None/Off. After Setting Change: Vibrates 3 times. After 5 Minutes: Vibrates/beeps 3 times every 5 minutes until cleared. Will re-Alert if sensor glucose readings drop at or below 55 mg/dL.
HIGH 389 <sup>ma</sup> 44	Initial Default Alert: None/Off. After Setting Change: Vibrates 2 times. After 5 Minutes: Vibrates/beeps 2 times every 5 minutes until cleared.

#### Signal Loss Alert

What you see

Beeps and vibration

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Sensor Glucose Alarm and Alerts



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

#### **Clearing Your Smart Device**

Device	What you see	What it means
Smart Device: Lock Screen	Dexcom now High glucose alert elde to view	Slide Alarm or Alert to access app.

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#### **Clearing Your Receiver**

What you see	What you do
HIGH 389≅▲▲	Press Select.

Once an Alert is 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 notifications and sounds

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- Determine if signal loss is preventing you from getting an Alarm/Alert
- Describe recommended app settings
- Successfully clear an Alert on
  - App
  - 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 Glucose Alert setting, or you want to continue getting a Low Glucose Alert 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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Sensor Glucose Alarm and Alerts

# Chapter 12

Next Steps:

# On the Go With G5x: 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.

After this chapter you will be able to:

- Customize your glucose trend Low/High Glucose Alert notifications

   App
  - 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

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On the Go With G5x: Customizing Your Alarm and Alerts

#### Precaution

**Do:** When using both a receiver and a smart device, you must set your settings separately in each.

**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 device with different settings, you might not get an Alarm or Alerts.

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

#### Precaution

**Do:** After connecting any accessories, make sure that the smart device settings allow you to continue receiving Alarm or Alerts on the smart device.

**Why:** Using an accessory device (like a smart watch) might override your smart device sounds.

**Consequences:** Alarm or Alerts might vibrate or be heard on the accessory instead of your smart device, causing you to miss severe low or high glucose event.

## 12.3 Changing Alarm and Alerts

#### App Screen Overview

The Alerts Main Menu lists all customizable Alarm and Alerts and their current settings. Part of your initial setup included setting your Low/High Glucose 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.

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On the Go With G5x: Customizing Your Alarm and Alerts

### Customizing Alerts: App Alarm/Alerts Screen Overview

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

Step	What you see	What it means	What you do
· · · · ·			· · · · · · · · · · · · · · · · · · ·

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Step	What you see	What it means	What you do
2	Menu     E       Alerts     >       Settings     >       Help     >       Stop Sensor     >	Access Alerts Main Menu.	Tap Alerts.
3	X     Alerts       Urgent Low mg/at.     2     55       Low mg/at.     2     60       High mg/at.     2     180       Rise Rate     2     OFF       Fall Rate     2     OFF       Signal Loss     2     ON   Reset alert settings	All customizable Alarm and Alerts. Current Alert settings. All Alerts have: • On/Off switch • Notify me options • Sound options	Tap <i>Alarm/Alert</i> you want to change.

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On the Go With G5x: Customizing Your Alarm and Alerts

Step	What you see		What it means	What you do
4	X     Alerts       Urgent Low mg/at     2       Low mg/at     2       High mg/at     2       Rise Rate     2       Fall Rate     2       Signal Loss     2       Reset alert setting	55 > 60 > 180 > OFF > OFF > ON >	<ul> <li>"?" explains:</li> <li>Each Alarm/Alert</li> <li>Message options</li> <li>Recommended settings</li> </ul>	<b>Tap</b> "?" for Alarm/Alert information.
5	<ul> <li>Sound</li> <li>Sound</li> <li>Baby Cry</li> <li>Beep</li> <li>Blarno</li> <li>✓ Door Bell</li> <li>Fall Rate</li> <li>High</li> <li>High Alert</li> <li>Low</li> <li>Low Alert</li> <li>Nerd Alert</li> <li>Short Beeps</li> </ul>	100% mm	Urgent Low Glucose Alarm: 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	<b>Tap</b> <i>Sound</i> to change sound.

# Steps to Customize App Alarm/Alerts

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On the Go With G5x: Customizing Your Alarm and Alerts

Although the results will vary depending on the Alarm or Alert you are customizing, the steps to change your Alerts 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.
  - Change the amount of time you want between your High/Low Glucose 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	Access Alerts Main Menu		
1	<u>.</u> . ⊁ ₽ Ξ	Access Main Menu.	<b>Tap</b> <i>Main Menu</i> icon.

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On the Go With G5x: Customizing Your Alarm and Alerts

Step	What you see	What it means	What you do
2	Menu Alerts > Settings > Help > Stop Sensor >	Access Alerts Main Menu.	Tap Alerts.

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3	X     Alerts       Urgent Low mg/at     2     55       Low mg/at     2     60       High mg/at     2     180       Rise Rate     2     OFF       Fall Rate     2     OFF       Signal Loss     2     ON	Access High Alert settings (mg/dL).	Tap High mg/dL.
4	✓       High Glucose Alert         High Alert       ●         Notify Me Above       200 mg/dL >         Repeat       every 30 minutes >         Sound       High >	Shows High Alert options and current settings.	<b>Check</b> <i>High Alert</i> is On. • On - Orange • Off - Gray

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5	<ul> <li>✓ High Glucose Alert</li> <li>High Alert</li> <li>Notify Me Above 200 mg/dL &gt;</li> <li>Repeat every 30 minutes &gt;</li> <li>Sound High &gt;</li> </ul>	Won't get Alerts if Off.	If Off: <b>Slide</b> to <i>On.</i> • On - Orange • Off - Gray
6	✓ High Glucose Alert High Alert Notify Me Above 200 mg/dL > Repeat every 30 minutes > Sound High >	Change High Alert (mg/dL).	Tap Notify Me Above.

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On the Go With G5x: Customizing Your Alarm and Alerts

7	Notify Me Above	Change glucose level from current level (mg/dL).	<b>Scroll</b> selection wheel. <b>Stop</b> at 190 mg/dL.
8	Notify Me Above	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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On the Go With G5x: Customizing Your Alarm and Alerts

9	High Glucose Alert       High Alert       Notify Me Above     200 mg/dL >       Repeat     every 30 minutes >       Sound     High >	Changes how often your High Alert repeats after initial Alert and confirmation. Repeats only if you are above your high glucose level.	Tap Repeat.
10	Repeat 0 1 hours 0 minutes 2 5 3 10 5AVE Cancel	Change the current repeat setting. Can select in 5- minute steps (range 15 minutes-4 hours).	<b>Scroll</b> selection wheel. <b>Stop</b> at 1 hour.

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On the Go With G5x: Customizing Your Alarm and Alerts

11	Repeat 0 1 hours 0 minutes 2 5 3 10 5AVE Cancel	Saves your new repeat timing. Returns to <i>High</i> <i>Glucose Alert</i> screen options. <i>Repeat</i> shows how often you'll get notified.	Tap Save.
12	High Glucose Alert       High Alert       Notify Me Above     200 mg/dL >       Repeat     every 30 minutes >       Sound     High >	Customize Alert sound.	Tap Sound.

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On the Go With G5x: Customizing Your Alarm and Alerts

13	Sound Baby Cry Beep Blamo Door Bell Fall Rate High High Alert Low Low Alert Nerd Alert Short Beeps	Change current sound setting.	Tap <i>Door Bell.</i> Tap <i>Sound</i> again to hear sound sample.
14	Sound Baby Cry Beep Blamo Door Bell Fall Rate High High Alert Low Low Alert Nerd Alert Short Beeps	Saves your new Alert sound. Returns to <i>High Glucose Alert</i> Menu.	Tap back arrow.

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15	Alerts       Urgent Low mg/at.       Low mg/at.       Aligh mg/at.       Aligh mg/at.       Fall Rate       Signal Loss       Reset alert sett	55 > 60 > 180 > OFF > OFF > ON >	Return to Main Menu.	Тар <i>"Х"</i> .
16	Menu Alerts Settings Help Stop Sensor	> > >	Return to trend screen.	<b>Tap</b> <i>Menu</i> icon Or <b>Swipe</b> 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.

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On the Go With G5x: Customizing Your Alarm and Alerts

# 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 Glucose 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 11, 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 Alarm/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 Urgent Low Glucose 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.

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On the Go With G5x: Customizing Your Alarm and Alerts

#### Alarm/Alert Sound Profiles: Receiver

lcon	Profile name	Notification description
~~~~	Vibrate	Vibration only.
		Only sound is your receiver vibrating.
~~~		Vibrate is not available for the Urgent Low Glucose Alarm.
	Soft	Lower volume beeps.
- 11		Medium volume beeps.
	Normal	Default Profile.
		No beens
	Attentive	Rising melody for High and Rising Alerts
		Dropping melody for Low and Falling Alerts
		Medium volume beeps.
		Urgent Low Glucose Alarm only.
<b></b> )))	HypoRepeat	Repeats Urgent 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.

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On the Go With G5x: Customizing Your Alarm and Alerts

After choosing your sound Profile, changing it is just a few steps away! Change your Profile throughout the day depending on what lies 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.

Step	What you see	What it means	What you do
1	202 m ≠ 400     350     350     250     150     10 Am     11 Am     1202 PM	Go to Main Menu.	Press Select.
2	Main Menu Trend Graph Start Sensor Enter BG	Access second Main Menu screen.	<b>Press</b> <i>Down Arrow.</i> <i>Profiles</i> on second screen.
3	Main Menu Enter BG Profiles Kevents	Profiles adjusts volume of Alarm/Alerts.	Press Up/Down Arrow. Stop at Profiles. Press Select.
4	Profiles ♥ Vibrate ♥ Soft ♥ Normal ♥	Choose sound Profile. Check mark shows current Profile.	Press Up/Down Arrow. Stop at desired Profile. Press Select.

#### **Customizing Sound Profile: Receiver**

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On the Go With G5x: Customizing Your Alarm and Alerts

Step	What you see	What it means	What you do
5	Profiles Attentive HypoRepeat Try It	Hear selected Profile.	To sample sound: <b>Press</b> <i>Down Arrow.</i> <b>Stop</b> at <i>Try It.</i> <b>Press</b> <i>Select</i> to play the sound. To exit Profiles: <b>Press</b> <i>Left Arrow</i> to <i>Main Menu.</i>
6	N/A	Repeat as needed.	Repeat steps 2-5 to change Profile. To exit Profiles: Press Left Arrow to Main Menu.

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 on your Rise/Fall Alerts, 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

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On the Go With G5x: Customizing Your Alarm and Alerts

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 Alert and get notified 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	
Chang	Change High Alert Level			

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On the Go With G5x: Customizing Your Alarm and Alerts

Step	What you see	What it means	What you do
1	202 m²      300     300     250     100     1	Go to Main Menu.	Press Select.
2	Main Menu Profiles Fvents Alerts	Alerts option from the Main Menu. Enter Alerts menu option.	Press Down Arrow. Stop at Alerts. Press Select.
3	Alerts High Alert Low Alert Advanced	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.

Change High Alert Level					
4	High Alert On/Off On Level 200 mg/dL	Alert's current settings. Change your current High Alert level.	Press <i>Down Arrow.</i> Stop at <i>Level.</i> Press <i>Select.</i>		

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5	High Alert	Current setting. <b>Use</b> <i>Up/Down</i> arrows to change your High Alert level (mg/dL).	<b>Press</b> <i>Down Arrow.</i> <b>Stop</b> at 190 mg/dL.
6	High Alert 190♥ mg/dL	Saves new High Alert level. Return to Alerts Menu.	<b>Press</b> <i>Select.</i> To exit: <b>Press</b> <i>Left Arrow.</i>
Turn C	n Repeat		
7	Alerts High Alert Low Alert Advanced	Alerts Menu. Choose <i>Advanced</i> to get to Repeat Alert.	Press Down Arrow. Stop at Advanced.

Turn On Repeat				
8	Alerts     ◀       → High Alert       → Low Alert       ☆ Advanced	Enter Advanced Alert options.	Press Select on Advanced.	

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On the Go With G5x: Customizing Your Alarm and Alerts

9	Advanced & High Repeat Low Repeat Rise Rate	Main Advanced screen. Set Repeat Alerts. Turn on Rise/Fall Rate Alerts.	<b>Arrow</b> to <i>High</i> <i>Repeat.</i> <b>Press</b> <i>Select.</i>
10	High Alert	Initial screen shows current repeat minutes. Change time frame in 5-minute increments.	Press <i>Up/Down</i> <i>Arrow.</i> Stop at 60 minutes.
11	High Alert	Changed <i>Repeat</i> time for High Alert.	Press Select.
12	Advanced High Repeat Low Repeat Rise Rate	Change completed. Return to <i>Alerts Menu.</i>	To exit: <b>Press</b> <i>Left Arrow</i> .

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

#### Summary

Now You Can:

G5x System User Guide

On the Go With G5x: Customizing Your Alarm and Alerts

- Customize your glucose trend Low/High Alerts in
  - App
  - Receiver
- Adjust Alarm Profiles
- 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 G5x! You've set up the app and receiver, started a session, calibrated, followed your glucose trends, paid attention to your Alarm/Alerts notifications, 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 G5x experience.

The next part, Part 4: Everything Else G5x, reviews the technical specifications, the warranty, how to take care of the G5x components, going through security when traveling, contacting the Help Desk, Troubleshooting information, and symbols on system components and packages.

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On the Go With G5x: Customizing Your Alarm and Alerts



# **EVERYTHING ELSE G5x**

- Warranty
- G5x Maintenance
- Travel Tips
- Customer Service Contacts
- Technical Information
- Troubleshooting
- Symbols on Package Labels

Dexcom G5x System User Guide
Warranty: The Fine Print
# Chapter 13

Everything Else G5x:

## 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

#### G5x'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 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 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

Dexcom G5x System User Guide Warranty: The Fine Print

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.
- 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 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.

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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: **1.888.738.3646**
- Toll call: 1.858.200.0200

Upon receipt, Dexcom will 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 G5x or any feature or service provided by Dexcom for use with the G5x.

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.

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Warranty: The Fine Print

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

G5x Transmitter Limited Warranty

#### What's Covered and for How Long?

Dexcom, Inc. ("Dexcom") provides a limited warranty to the original purchaser that the G5x 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:

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Warranty: The Fine Print

- 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.
- Defects or damage from improper testing, operation, maintenance, installation, or adjustment.
- 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 G5 Mobile's user guide.
  - b. Your options to get the user guide:
    - i. Download or view: dexcom.com/guides
    - ii. Online request form to receive free printed copy: dexcom.com/guides
    - iii. Request a free copy by mail
    - iv. Request a free copy by phone: Toll free: 1.888.738.3646 Toll call: 1.858.200.0200
    - v. 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 G5x transmitter.

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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: 1.888.738.3646
- Toll call: 1.858.200.0200

Upon receipt, Dexcom will replace the defective transmitter.

If Dexcom determines this Limited Warranty doesn't cover the transmitter, 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 G5x or any feature or service provided by Dexcom for use with the G5x.

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. Dexcom G5x System User Guide

Warranty: The Fine Print

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.

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Warranty: The Fine Print

# Chapter 14

Everything Else G5x:

# How to Take Care of Your G5x

# 14.1 Introduction

There are not a lot of moving parts in the G5x, so maintenance is relatively simple:

- Keep it clean
- Keep display device(s) dry and protected
- Use accessory parts, like the USB cable, etc., included with the system
- Store according to each piece's instructions

This chapter covers only 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 applicator
  - b. Transmitter
  - c. Receiver
  - d. Receiver battery
  - e. Accessories
- 2. Identify the best storage methods
  - a. Sensor applicator
  - b. Transmitter
  - c. Receiver
- 3. Check app and receiver information
- 4. Safely dispose of system components
  - a. Sensor
  - b. Transmitter
  - c. ReceiverX

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How to Take Care of Your Dexcom G5x Mobile CGM System

# 14.2 Safety Statements

Following are some important Warnings and Precautions to review. This information helps you take care of your system so it can take care of you.

## Warning

Do: Inspect your transmitter.

Don't: Use your transmitter if it is damaged or cracked in any way.

**Why:** Damaged components could create an electrical safety hazard or malfunction.

**Consequences:** Electrical safety hazard or malfunction could cause electrical shocks.

# Warning.

Don't: Use your receiver if it is damaged or cracked in any way.

**Why:** Damaged components could create an electrical safety hazard or malfunction.

**Consequences:** Electrical safety hazards or malfunctions could cause electrical shocks.

## Precaution

**Don't:** Never get dirt or water in the receiver's USB port or submerge in water.

Why: If dirt or water gets into the USB port, the receiver could become damaged and stop displaying readings or providing Alerts.

**Consequences:** You might miss a severe low or high glucose event.

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How to Take Care of Your Dexcom G5x Mobile CGM System

#### Precaution

**Don't:** Use expired sensors. Before inserting, always check the package label for the expiration date using the YYYY-MM-DD format.

Why; If past the expiration date, the sensor glucose readings might not be accurate.

Consequences: Missing severe low or high glucose event.

#### Precaution

Don't: Share your transmitter with another person.

**Why:** The system is a prescription-only medical device and is meant, or indicated, for your use only.

**Consequences:** Your transmitter is tied to *your* readings. If used by someone else, your reports, Alarm and Alerts, etc., would be wrong, resulting in you missing a severe low or high glucose event.

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#### **Precaution**

**Do:** If your receiver gets wet or dropped, make sure the speaker and vibrations still work.

*To check, either plug it in, turn it on, or go to the Profiles menu and select Try It. If it doesn't vibrate and beep, contact Technical Support.* 

**Why:** If your receiver gets wet or dropped, the speaker and vibrations may not work.

**Consequences**: If the vibration motor and/or speaker on your receiver aren't functioning properly you may miss a severe low or high Alarm/Alert. Use the app on your smart device until this issue is resolved

# 14.3 Basic Maintenance

14.2 Basic Maintenance

#### Sensor Applicator

- 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 past expiration date.
    - i. May provide inaccurate sensor glucose readings.
    - ii. May be unsterile.

#### Transmitter

1. Keep in box until ready for use.

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- a. Check transmitter and don't use if damaged.
- Transmitter is reusable, but only by the same person.
   a. Never share transmitter with anyone.
- 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 it 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. Do not open it. There are no serviceable parts inside.
  - 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 notifications 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.

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#### **Charging Receiver Battery**

Step	What you see	What it means	What you do
1	СО2 стородици и собрание и собра	Low Battery	Charge your battery.
2		Micro USB Port	Open USB port door. Plug USB cable into port for recharging.

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

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Step	What you see	What it means	What you do	
5	60 m 400 350 2 FM 3 FM 407 PM	Battery Charging	Keep charging until battery icon is solid.	
6		Battery Charged	Disconnect <i>wall</i> <i>charger</i> from outlet when fully charged.	
7		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 cable and charger).
  - a. Use of non-Dexcom supplied parts may affect safety and performance.
- 2. Insert cable only as directed.
  - a. Do not force cable in place.

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3. Look at cable for signs of wear and tear. Do not use if worn or damaged.

There is no repair service available for any G5x parts.

If you experience problems, report the issue to Technical Support (available 24/7) at:

- TechSupport@dexcom.com
- Toll free: 1.888.738.3646
- Toll call: 1.858.200.0200

## 14.4 Storage

Storing your G5x correctly helps prevent system failures.

#### Sensor Applicator

- 1. Keep the sensor applicator in its sterile packaging until you are ready to use it.
- 2. Store at temperatures between 36° F-86° F.
  - a. Storing 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 10%-90% 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.

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How to Take Care of Your Dexcom G5x Mobile CGM System

# 14.5 Checking app and Receiver Information

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

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How to Take Care of Your Dexcom G5x Mobile CGM System

CHECKING VERSION	OUR APP & RECEIVER SOFTWARE
You can check y system at any tir	our app or receiver for information about your CGM ne.
Receiver	
Settings 🔅	Device Info
Time/Date	Part #:
	Part Rev: 19
Transmitter	SW #: SW10617
2 Device Info	SW Rev: 4.0.1.030
1. From the	e Settings menu, <b>press</b> <i>Up</i> or <i>Down arrows</i> to scroll to
"Device	Info."
2. Press 3	Select. Information about your sensor session and system
will show	v ș
App	
****0 10:00 AM 500X IIII	www. (and har (and and
× Settings	C Device Info
Transmitter	Insettion Time
Health OFF )	Last Calorizon 2
Graph Height 400 mg/dL >	Software Relation 0.3.3
Dexcom Account	UDI 00086270000002
1. From Ma 2. Tap De	ain Menu, <b>tap</b> <i>Settings.</i> <i>vice Info</i> .
Available Inf	ormation
<ul> <li>Insertior</li> </ul>	1 Time
<ul> <li>Last Cal</li> </ul>	ibration
<ul> <li>Transmi</li> </ul>	tter Battery
<ul> <li>Transmi</li> </ul>	tter Serial Number
Part Nur	nder
<ul> <li>Part Rev</li> </ul>	vision
<ul> <li>Software</li> </ul>	e Number

# 14.5 System Disposal

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How to Take Care of Your Dexcom G5x Mobile CGM System

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 G5x is pretty easy. In the next chapter, "On the Go With G5x: Getting Through Security" you'll learn how simple it is to travel the world with your G5x!

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How to Take Care of Your Dexcom G5x Mobile CGM System

# Chapter 15

Everything Else G5x:

# On the Go With G5x: Getting Through Security

## **15.1 Introduction**

G5x 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 covers only the G5x. It doesn't cover steps you need to take when traveling with your smart device. See your smart device's instructions for use to learn how to travel with it.

After this chapter, you will be able to:

- Explain proper procedure if you prefer a full-body pat-down
- Describe steps needed for a TSA officer to inspect G5x components
- Identify when your display device(s) can be on during a flight
- Contact TSA directly with your security questions

# 15.2 Safety Statement

G5x System User Guide

On the Go With Dexcom G5x Mobile CGM System: Getting Through Security

#### Precaution

**Don't:** Place any part of the G5x in the baggage x-ray machine or body scanner.

**Do:** Ask for visual inspection instead:

- Baggage x-ray machine: Instead of putting any part of your G5 Mobile through the baggage x-ray, ask the TSA officer to visually inspect it.
- Body scanner: When you are wearing your G5 Mobile, request handwanding or full-body pat-down and visual inspection instead of going through the Advanced Imaging Technology (AIT) body scanner. (AIT is also called millimeter wave scanner.)

**Why:** The system has not been tested in x-rays or AIT body scanners, and it is unknown if exposure to x-rays or AIT body scanners can affect the system performance.

It is safe to wear the system through the walk-through metal detector or handwanding. If you are unsure of whether the airport scanner is a metal detector, an AIT body scanner or an x-ray, ask the TSA officer or request hand-wanding or full body pat-down.

**Consequences:** Missing a severe low (hypoglycemia) or high (hyperglycemia) glucose event.

# 15.3 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.

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On the Go With Dexcom G5x Mobile CGM System: Getting Through Security

If you're concerned or uncomfortable about walking through the metal detector, the Transportation Security Administration (TSA) requests you tell the Security Officer that 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 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 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 advanced imaging technology (AIT) body scanners, like millimeter wave scanners, has not been studied, and we therefore recommend hand-wanding or full-body pat-down and visual inspection in those situations.

#### In the Plane

To use your smart device, receiver, or both to get sensor glucose information while in the plane:

- Smart device: When you switch to airplane mode, keep *Bluetooth* on
- Receiver: Keep receiver on

Contact your airline for their policies.

## **Technical Information**

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On the Go With Dexcom G5x Mobile CGM System: Getting Through Security

The G5x System is an M-PED (Medical-Portable Electronic Device) which meets the FAA RTCA/DO-160 edition G section 21, Category M. It can be used on aircraft according to the directions provided by the operator of the aircraft.

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 discharge (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@tsa.dhs.gov

Phone: 1.866.289.9673

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On the Go With Dexcom G5x Mobile CGM System: Getting Through Security

# Chapter 16

Everything Else G5x:

# Need Help? You're Not Alone!

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

- Dexcom Technical Support Team
- Dexcom Patient Care Team
- Dexcom Sales Support Team

# 16.1 Dexcom Technical Support Team

The Dexcom Technical Support Team helps you with all CGM system-related issues as well as software-related issues. They provide replacement units, resolve technical issues and take product complaints.

Dexcom Technical Support does not offer medical advice.

# 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
- Patient's date of birth
- Description of technical problem
- When the problem happened (date and time)
- Patient's address
- Patient's phone number
- Item SKU number and description (for example, name of the device)
- Lot number and/or serial number(s) of affected device(s) (for example, sensor)
- · Your preferred contact method and information so Dexcom can reach

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Need Help? You're Not Alone!

you if needed. For example: by phone 555-555-5555 after 5 PM Pacific Time

#### By Phone

Available 24 hours a day, 7 days a week

Dexcom Technical Support phone numbers:

- Toll free: 1.888.738.3646
- Toll call: 1.858.200.0200

# 16.2 Dexcom Patient Care Team



The Dexcom Patient Care Team is a group of Certified Diabetes Educators (CDE<sup>®</sup>) and Registered Nurses (RNs) offering you customer care and individualized a cround Devcem CCM

education services around Dexcom CGM.

Your Dexcom Patient Care Team provides education and support throughout your CGM experience, such as:

- Initial CGM product training
- Ongoing Dexcom product education (for example, 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 Email

Email: patientcare@dexcom.com

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Need Help? You're Not Alone!

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

- Name of patient
- · Patient's date of birth
- Contact phone number
- Reason for inquiry or education needed

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

#### By Phone

Available Monday-Friday 5:30 AM-8:00 PM PST (subject to change)

Toll Free: 1.888.738.3646

Toll Call: 1.858.200.0200

# 16.3 Dexcom Sales Support Team

## Inside Sales Support Team

#### For help with:

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

#### By Internet

Dexcom online store: dexcom.com/order

#### By Email

Email: CustomerService@dexcom.com

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Need Help? You're Not Alone!

# By Phone

Dexcom Inside Sales Support phone numbers: Toll Free: 1.888.738.3646 Toll Call: 1.858.200.0200

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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Need Help? You're Not Alone!

# Chapter 17

Everything Else G5x:

## **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 G5 Mobile performs.

The G5 Mobile (the System) uses a glucose sensor to continuously measure and monitor your glucose levels. The sensor is "calibrated" using a commercially available BG meter. Once calibrated, the System reports glucose readings up to every 5 minutes. The System was evaluated in clinical studies in which System readings were compared to BG values to assess its performance and how well the System readings compared to a laboratory test method that measures BG values. Additionally, subjects performed selfmonitoring BG meter tests at home to assess the System performance in a 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 G5 Mobile.

## **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)

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Original Pediatric Study: the receiver included software version SW10050

Software 505 Pediatric Study: the receiver included software version SW10505

The G5 Mobile 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<sup>®</sup> OneTouch<sup>®</sup> Ultra<sup>®</sup>2 meter and in the Software 505 Adult Study, subjects used Bayer's CONTOUR<sup>®</sup> 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 BG measured every 15 minutes with a reliable laboratory method, the Yellow Dexcom G5x System User Guide 281

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Springs Instrument 2300 STAT Plus<sup>™</sup> 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 BG 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 BG (SMBG) meter values. The Original Pediatric Study used the LifeScan<sup>®</sup> OneTouch<sup>®</sup> Verio<sup>®</sup> IQ meter; the Software 505 Pediatric Study used Bayer's CONTOUR<sup>®</sup> 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

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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 BG 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."

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# Table 1-A. System Agreement to YSI Within CGM GlucoseRanges (Adult)

CGM Glucose Range <sup>1</sup> (mg/dL)	Study <sup>2</sup>	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%
Overall	Software 505	2263	86%	93%	98%	1%
40.60	Original	512	67%	78%	88%	6%
40-60	Software 505	120	89%	94%	98%	0%
61.90	Original	781	73%	85%	94%	2%
01-80	Software 505	226	91%	96%	99%	0%
01 100	Original	3853	67%	78%	91%	3%
81-180	Software 505	738	84%	92%	98%	1%
101 000	Original	2784	72%	84%	93%	4%
181-300	Software 505	798	86%	93%	98%	1%
001.050	Original	775	82%	91%	97%	2%
301-350	Software 505	229	86%	94%	98%	1%
351-400	Original	447	74%	84%	91%	5%
	Software 505	152	80%	92%	97%	0%

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

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

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# Table 1-B. System Agreement to YSI Within CGM GlucoseRanges (Pediatric)

CGM Glucose Range <sup>1</sup> (mg/dL)	Study <sup>2</sup>	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%
Overall	Software 505	2262	81%	91%	96%	2%
40.60	Original	19	63%	74%	79%	21%
40-60	Software 505	86	54%	74%	91%	3%
61.80	Original	76	61%	82%	92%	4%
01-80	Software 505	142	77%	82%	90%	3%
01 100	Original	1155	56%	69%	84%	6%
01-100	Software 505	805	78%	88%	97%	1%
101 200	Original	1380	55%	68%	85%	7%
181-300	Software 505	957	89%	96%	99%	1%
201 250	Original	206	48%	62%	80%	11%
301-350	Software 505	209	81%	91%	94%	5%
251 400	Original	86	48%	61%	79%	12%
351-400	Software 505	63	64%	81%	83%	8%

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

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

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#### Agreement Relative to YSI

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

The agreement of the System to BG 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 BG 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  $\pm$  20 mg/dL of the YSI BG values  $\leq$  80 mg/dL and within  $\pm$  20% of YSI BG values > 80 mg/dL.

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

# Table 2-A. Number and Percentage of YSI Values When CGM Readings Are "LOW" or "HIGH" (Adult)

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

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

# Table 2-B. Number and Percentage of YSI Values When CGMReadings Are "LOW" or "HIGH" (Pediatric)

<sup>1</sup>Both 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 System determines that the glucose level is above 400 mg/dL, it displays "HIGH" in the Receiver Status Box.

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Because the System does not display glucose values below 40 mg/dL or above 400 mg/dL, the comparisons to the actual BG 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.

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	R	ow Per	centag	e of Ma	YS atched	Pairs i	n Each	CGM	Glucos	e Ran	ge	
CGM (mg/dL)	< 40	40- 60	61- 80	81- 120	121- 160	161- 200	201- 250	251- 300	301- 350	351- 400	> 400	Number of Paired CGM-YSI
< 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-A. Concurrence of CGM Readings and YSI Values (Original Adult Study)

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

	Ro	ow Per	centag	e of Ma	YS atched	il (mg/o Pairs i	iL) n Each	CGM	Glucos	e Ran	ge	
CGM (mg/dL)	< 40	40- 60	61- 80	81- 120	121- 160	161- 200	201- 250	251- 300	301- 350	351- 400	> 400	Number of Paired CGM-YSI
< 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

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

	YSI (mg/dL) Row Percentage of Matched Pairs in Each CGM Glucose Range											
CGM (mg/dL)	< 40	40- 60	61- 80	81- 120	121- 160	161- 200	201- 250	251- 300	301- 350	351- 400	> 400	Number of Paired CGM-YSI
< 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

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

	Ro	ow Per	centag	e of Ma	YS atched	il (mg/o Pairs i	dL) n Each	CGM	Glucos	se Ran	ge	
CGM (mg/dL)	< 40	40- 60	61- 80	81- 120	121- 160	161- 200	201- 250	251- 300	301- 350	351- 400	> 400	Number of Paired CGM-YSI
< 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

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Adult Study, when CGM readings are within 81 to 120 mg/dL, you can expect your BG levels are within 81 to 120 mg/dL 72% of time.

Table 4-A.	System	Difference	to YS	SI Within	CGM	Glucose	Ranges
(Adult)							

CGM Glucose Range <sup>1</sup> (mg/dL)	Study <sup>2</sup>	Number of Paired CGM-YSI	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
0	Original	9152	2.9%	1.7%	13.3%	9.8%
Overall	Software 505	2263	2.5%	2.4%	9.0%	7.0%
*40.60	Original	512	-10.0	-8.2	13.5	9.7
40-60	Software 505	120	-3.3	-2.1	6.9	4.8
*01.00	Original	781	-2.4	-0.4	11.4	8.6
*61-80	Software 505	226	0.8	1.4	6.7	5.4
01 100	Original	3853	4.8%	3.0%	13.8%	9.8%
61-160	Software 505	738	3.9%	4.1%	9.6%	8.2%
101 200	Original	2784	2.1%	0.0%	11.9%	9.2%
181-300	Software 505	798	0.6%	0.4%	8.0%	6.1%
201 250	Original	775	3.8%	2.8%	9.8%	7.9%
301-350	Software 505	229	4.1%	3.4%	8.0%	5.8%
251 400	Original	447	10.4%	7.7%	12.8%	9.1%
351-400	Software 505	152	7.2%	6.3%	9.2%	7.2%

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

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

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

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

CGM Glucose Range <sup>1</sup> (mg/dL)	Study <sup>2</sup>	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%
Overall	Software 505	2262	1.8%	1.2%	10.4%	7.9%
*40.60	Original	19	-18.1	-9.1	19.2	9.1
40-60	Software 505	86	-15.3	-13.2	16.1	13.2
*61.90	Original	76	-3.7	-2.3	13.4	10.6
*61-80	Software 505	142	-4.8	-1.0	11.8	7.7
01 100	Original	1155	11.9%	9.7%	17.0%	13.0%
01-100	Software 505	805	1.9%	0.7%	10.6%	8.1%
101 200	Original	1380	14.8%	12.4%	17.4%	13.3%
181-300	Software 505	957	2.2%	1.0%	8.1%	6.5%
201 250	Original	206	19.2%	15.9%	19.4%	15.9%
301-350	Software 505	209	7.8%	6.5%	11.0%	7.9%
251 400	Original	86	18.5%	15.5%	19.1%	15.5%
331-400	Software 505	63	14.9%	11.6%	15.2%	11.6%

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

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

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

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#### 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 BG values and the Median Absolute Percent Difference shows that half of the time the System reads about 7.0% or less than the YSI BG values.

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

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

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

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

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

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Table 5-C. Hypoglycemia Alert and Detection Rate Evaluation inReference to SMBG 30 Minutes Before and After (Pediatric, Ages2-5 Years)

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

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

## Low and High Glucose Alerts

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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 BG 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 hypoglycemic 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 BG 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 BG 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.

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#### 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 BG level was at or below the Alert setting and device alarmed within 15 or 30 minutes before or after the BG was at or below the Alert settings. The Hypoglycemia Missed Detection Rate is the % of time the BG was at or below the Alert setting, but the device did not alarm within 15 or 30 minutes before or after the BG 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 BG 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.

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

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

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

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

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

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Table 6-C. Hyperglycemia Alert and Detection Rate Evaluation inReference to SMBG 30 Minutes Before and After (Pediatric, Ages2-5 Years)

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

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

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### 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 BG 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 BG 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 BG level was at or above the Alert setting and the device alarmed within 15 or 30 minutes before or after the BG was at or above the Alert settings. The Hyperglycemia Missed Detection Rate is the % of time the BG was at or above the Alert setting, but the device did not alarm within 15 or 30 minutes before or after the BG was at or above the Alert setting.

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For example, if you set your High Glucose Alert to 200 mg/dL, how often will your Alarm Alert you if your BG 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.

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		Percent	Percent	Percent	Percent
With Data Stratified in	n <mark>2-Hour I</mark>	ncrement	ts After C	alibratio	n (Adult)
Table 7-A. Percentag	e of Syste	m Readii	ngs <sup>1</sup> With	in YSI Va	alues

Time from Calibration	Study <sup>2</sup>	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%
0-2 110015	Software 505	469	93%	97%	Percent Within 30/30%         Great 40/4 YSI           96%         29           96%         29           99%         09           99%         09           99%         09           99%         09           99%         09           99%         09           99%         09           99%         09           99%         09           99%         09           99%         09           99%         09           99%         09           99%         09           99%         09           99%         09           97%         29           92%         39           99%         09           99%         09           98%         09           98%         09           98%         09           98%         124	0%
2.4 hours	Original	1516	69%	81%	91%	4%
2-4 110015	Software 505	389	90%	97%	Percent Within 30/30% YSI         C           96%         1           96%         1           99%         1           91%         1           99%         1           99%         1           99%         1           99%         1           99%         1           99%         1           99%         1           99%         1           97%         1           92%         1           92%         1           98%         1           98%         1           98%         1           82%         1            1	0%
1.6 hours	Original	1547	69%	79%	91%	5%
4-0 110015	Software 505	383	85%	91%	97%	2%
6 9 hours	Original	1520	68%	79%	92%	3%
0-8 HOUIS	Software 505	380	79%	90%	97%	2%
9 10 hours	Original	1555	71%	82%	92%	4%
8-10 Hours	Software 505	347	83%	92%	98%	0%
10.12 hours	Original	1068	65%	77%	91%	4%
10-12 hours	Software 505	295	9       78%       88%       96%       2%         9       93%       97%       99%       0%         6       69%       81%       91%       4%         9       90%       97%       99%       0%         7       69%       79%       91%       5%         8       85%       91%       97%       2%         0       68%       79%       91%       5%         0       68%       79%       92%       3%         0       79%       90%       97%       2%         0       68%       79%       92%       3%         0       79%       90%       97%       2%         5       71%       82%       92%       4%         7       83%       92%       98%       0%         8       65%       77%       91%       4%         5       80%       90%       98%       0%         6       5%       76%       82%       12%	0%		
12 14 hours	Original	17	65%	76%	82%	12%
12-14 110015	Software 505	0				

<sup>&</sup>lt;sup>1</sup>CGM readings are within 40 to 400 mg/dL, inclusive.

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

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# Table 7-B. Percentage of System Readings<sup>1</sup> Within YSI ValuesWith Data Stratified in 2-Hour Increments After Calibration(Pediatric)

Time from Calibration	Study <sup>2</sup>	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
0.0 h a	Original	648	65%	75%	87%	7%
0-2 nours	Software 505	545	83%	91%	Percent within 30/30% YSI 37% 37% 36% 36% 36% 35% 35% 35% 34% 34% 34% 34% 39% 39% 39% 39% 39% 39% 39% 39% 39% 39	1%
0.4 hours	Original 649 51% 67% 86%		86%	7%		
2-4 nours	Software 505	460	72%	89%	Percent within 30/30% YSI 87% 97% 86% 96% 80% 95% 85% 94% 84% 97% 89% 98% 65% 100%	2%
4.01	Original	630	51%	61%	80%	10%
4-6 nours	Software 505	428	77%	88%	Percent within 30/30% YSI 37% 97% 36% 96% 96% 95% 85% 94% 84% 97% 89% 98% 65% 100%	2%
0.0 h a	Original	409	52%	68%	85%	5%
6-8 nours	Software 505	325	88%	92%	94%	3%
0.40 h a	Original	296	53%	69%	84%	7%
8-10 nours	Software 505	305	86%	93%	97%	1%
40.401	Original	253	58%	74%	89%	5%
10-12 hours	Software 505	198	89%	94%	98%	0%
40.441	Original	37	32%	38%	65%	22%
12-14 nours	Software 505	1	100%	100%	100%	0%

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

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

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### 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 Time	э1
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#### - (Adult)

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

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

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

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Table 8-B. Sensor Stabilit	y Relative to	YSI (Accuracy	Over Time <sup>1</sup> )
- (Pediatric, Ages 6-17 Ye	ars)		

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

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

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

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Table 8-C. Sensor Stability Relative to SMBG (Accuracy Over
Time <sup>1</sup> ) - (Pediatric, Ages 2-17 Years)

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

<sup>1</sup>CGM readings are within 40 to 400 mg/dL, inclusive. Dexcom G5x System User Guide

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

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#### 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

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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

% of Total Possible Readings Provided	of Total Possible Study <sup>1</sup> adings Provided		% of Systems Providing That Number of Readings	
0.25%	Original	167-491	2%	
0-25%	Software 505	0	0%	
	Original	719-914	4%	
20-30 %	Software 505	856-856	2%	
E1 7E%	Original	1267-1267	1%	
51-75%	Software 505	1253-1253	2%	
76 100%	Original	1811-1992	94%	
76-100%	Software 505	1497-1992	96%	

## Days (Adult)

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

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% of Total Possible Readings Provided	Study <sup>1</sup>	Total Readings Provided (Min-Max)	% of Systems Providing That Number of Readings
0.25%	Original	103-427	3%
0-25%	Software 505	60-223	4%
00 50%	Original	569-954	3%
20-30 %	Software 505	877-891	3%
E1 7E%	Original	1006-1484	9%
51-75%	Software 505	1131-1342	3%
76 100%	Original	1518-1992	86%
76-100%	Software 505	1623-1990	91%

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

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

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Statistic	Study <sup>1</sup>	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days <sup>2</sup>
	Original	98%	98%	98%	98%	97%	99%	95%	97%
Mean	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%

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

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

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

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Statistic	Study <sup>1</sup>	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days <sup>2</sup>
	Original	97%	96%	96%	95%	94%	94%	92%	95%
Mean	Software 505	96%	96%	95%	96%	93%	95%	93%	95%
	Original	99%	99%	99%	99%	99%	99%	98%	99%
Median	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%

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

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

<sup>2</sup>A 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 1497 and 1992 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. Dexcom G5x System User Guide

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Table 11-A.	System Agreem	ent to SMBG	Within CGM	Glucose
Ranges (Ad	ult)			

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

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

<sup>2</sup>Both sets of study data are presented and are labeled as **Original** (SW10050) or **Software 505** (SW10505). Dexcom G5x System User Guide

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## Table 11-B. System Agreement to SMBG Within CGM GlucoseRanges (Pediatric)

CGM Glucose Range <sup>1</sup> (mg/dL)	Study <sup>2</sup>	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	16,318	64%	76%	89%	5%
Overall	Software 505	4264	73%	84%	94%	2%
40.60	Original	487	44%	55%	68%	19%
40-60	Software 505	240	54%	71%	86%	7%
	Original	1340	59%	70%	85%	7%
01-80	Software 505	399	64%	76%	92%	2%
01 100	Original	7084	62%	74%	90%	5%
01-100	Software 505	1650	72%	84%	95%	2%
191 200	Original	5627	69%	80%	90%	5%
181-300	Software 505	1526	79%	89%	97%	2%
201 250	Original	1176	65%	77%	90%	4%
301-350	Software 505	319	72%	83%	94%	2%
251 400	Original	604	58%	72%	86%	6%
351-400	Software 505	130	69%	79%	86%	8%

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

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

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

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

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

<sup>2</sup>Both 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 (%).

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## Table 12-B. System Difference to SMBG Within CGM GlucoseRanges (Pediatric)

CGM Glucose Range <sup>1</sup> (mg/dL)	Study <sup>2</sup>	Number of Paired CGM- SMBG	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
	Original	16,318	2.2%	0.9%	15.3%	11.1%
Overall	Software 505	4264	-0.7%	-1.1%	12.5%	9.5%
	Original	487	-22.1	-17.0	23.9	18.0
*40-60	Software 505	240	-15.9	-14.0	16.9	14.0
	Original	1340	-11.8	-8.0	17.0	11.0
*61-80	Software 505	399	-7.8	-6.0	13.7	10.0
	Original	7084	1.1%	-1.0%	15.4%	11.4%
81-180	Software 505	1650	-1.2%	-2.6%	12.1%	9.5%
	Original	5627	5.7%	3.4%	13.5%	9.5%
181-300	Software 505	1526	1.7%	0.9%	10.1%	7.7%
	Original	1176	9.6%	7.2%	14.2%	10.4%
301-350	Software 505	319	6.7%	5.9%	11.8%	8.9%
	Original	604	12.7%	10.2%	16.1%	11.9%
351-400	Software 505	130	12.0%	8.9%	15.7%	10.6%

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

<sup>2</sup>Both 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 (%). Dexcom G5x System User Guide

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#### Agreement and Accuracy Relative to SMBG

Agreement between the System and BG 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 that subjects expect during realtime use of the System in their daily diabetes management when comparing the System readings to their home BG 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.

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# **17.2 Product Specifications**

The G5x is intended for single patient use in the home environment and requires a prescription.

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 BG meter
Calibration Range	40-400 mg/dL
Storage /Operational/Transport Conditions	Temperature: 36° F-86° F Humidity: 10%-90% RH
Sterilization	Sterile by radiation

### **Transmitter Product Specifications**

Part Number	9445-01
Dimensions (Including Transmitter Holder)	Length: 1.5 inches Width: 0.9 inches Thickness: 0.5 inches
Weight (Including Transmitter Holder)	0.3 ounces

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Part Number	9445-01	
Power Supply	Lithium manganese dioxide/Organic electrolyte battery (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 /Transport Conditions	Temperature: 32° F-113° F Humidity: 10%-95% RH	
Operating Altitude	-1300 feet to 13,800 feet	
Limited Warranty	3 months	
Moisture Protection Against submersion in water		
Protection Against Electrical Shock	Type BF applied part	

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### **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 G5x CGM System is safe for use on U.S. commercial airlines.

The G5x System is an M-PED (Medical-Portable Electronic Device), which meets the FAA RTCA /DO-160 edition G section 21, Category M. It can be used on aircraft according to the directions provided by the operator of the aircraft.

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

### Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The transmitter (P/N 9445-01) 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.

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### 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/Operational/Tra nsport Conditions	Temperature: 32° F-104° F Humidity: 15%-95% RH, (Storage 10%-95% RH)
Operating Altitude	-1300 feet to 13,800 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 1 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

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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.

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% $U_{\rm T}$ for 1 cycle 0% $U_{\rm T}$ for 0.5 cycle at 8 phase angles 70% $U_{\rm T}$ (30% dip in Ut) for 25 cycles 0% $U_{\rm T}$ 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.

### **Receiver Electromagnetic Immunity Specifications**

**NOTE:** U<sub>T</sub> is the a.c. mains voltage prior to application of the test level.

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### 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.

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
Radiated RF IEC 61000-4-3	10 V/m at 80 MHz to 2700 MHz (AM Modulation)	10 V/m	should be at least 30%. 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 <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup> . Interference may occur in the vicinity of equipment marked with the following symbol:

### System Electromagnetic Immunity Specifications

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

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**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 G5 Mobile System is used exceeds the applicable RF compliance level above, the 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 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 G5 Mobile System is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the G5 Mobile System should ensure that it is used in such an environment.

Immunity Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The 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 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.

#### **Electromagnetic Emissions Specifications**

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### 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

Rated Maximum	Separation Distance According to Frequency of Transmitter (m)			
Output Power of Transmitter (W)	150 kHz to 80 MHz d = 1.2 P <sup>%</sup>	80 MHz to 800 MHz d = 1.2 P <sup>½</sup>	800 MHz to 2.5 GHz d = 2.3 P <sup>%</sup>	
0.01	0.12	0.12	0.23	
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	

### and the Dexcom Transmitter/Receiver

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 manufacturer.

**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

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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
Туре	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 disconnecting charger from wall.

### **Power Supply/Charger Specifications**

Part Number	MT21255
Class	П
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:

- G5x Transmitter: PH29588
- 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.

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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:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

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 G5x:

# Troubleshooting

## **18.1 Introduction**

Transmitter holder not sticking? Notification 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 notifications, 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 (for example, receiver or transmitter failure).

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

If any of these errors continue and the instructions don't resolve the issue, please contact Technical Support (available 24/7) at:

- TechSupport@dexcom.com
- Toll free: 1.888.738.3646
- Toll call: 1.858.200.0200

# 18.2 Safety Statements

Following are the Safety Statements for the Troubleshooting chapter.

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#### Warning

Do: Calibrate at least once every 12 hours.

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

**Consequences:** Missing severe low (hypoglycemia) or high (hyperglycemia) glucose event.

### Precaution

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

**Why:** Entering the wrong BG values, or waiting more than five minutes before entry, might affect sensor performance.

Consequences: Missing a severe low or high glucose event.

#### Precaution

**Don't:** Separate the transmitter from the receiver or smart device by more than 20 feet.

**Why:** The transmission range from the transmitter to receiver or smart device is up to 20 feet without obstruction. If your transmitter and 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 have been tested. Obstructions can include water, walls, metal, etc.

As with any wireless device, water is often the biggest culprit in reducing communication distance. This applies to the transmitter and display devices. Take special care when swimming, taking a bath, or getting into a hot tub.

Consequences: Missing a severe low or high glucose event.

## 18.3 Troubleshooting

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Troubleshooting

### No Alarm/Alerts

Device	What you see	Problem	What you do
Smart Device: In app	Pod © 1005 M 0 0 0 Notifications Dexcom Allow Notifications 0 0 Show in Notification Center 0 0 Sounds 0 Show on Lock Screen Brew alarts as the lock stream, and if minification Center when it is scienced for the science of the science of the science of the science of the science of the science of the science of the science of the science of the science of the science of the science of the science of the science of the science of the science of the science of the science of the s	Not receiving Alarm/Alerts	See Chapter 11. Check Alarm/Alerts, sound and/or vibrations notifications are turned on. Check your smart device is not on Silent or Do Not
Receiver	High Alert On/Off On Level 200 mg/dL		Disturb (if applicable).

### Sensor Glucose Readings

Device	What you see	Problem	What you do
BG Meter	188	Sensor readings and BG meter glucose values often don't show the same numbers.	See Chapter 7. Differences are not uncommon. Readings from different body fluids reflect different numbers:
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Troubleshooting

Device	What you see	Problem	What you do
	000		Meter - from blood
Smart			Sensor - from interstitial fluid
Device:	<b>ZUZ</b> mg/dL		20/20 Rule:
	In app		If the meter shows 80 or less, CGM should read within ± 20 points.
Receiver			If the meter shows 80 or above, the CGM should read $\pm$ 20%.
	202 ♥ ≠ 400 300 250 10 AM 11 AM 12 52 PM		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.

Device	What you see	Problem	What you do
Smart Device: In app	???	Not getting sensor glucose readings.	See Chapter 9. Wait. System will often resolve itself. Check transmitter–is it properly inserted into

Troubleshooting

Device	What you see	Problem	What you do
			the transmitter holder? Make sure you haven't
Receiver			Don't calibrate. Use BG meter for BG reading.
	10 10 AM 11 AM 1148 AM		If this continues for more than 3 hours, contact Technical Support (see Chapter 16.:
			See Chapter 9.
Smart			Wait
Device: In app	2		System will often resolve itself.
		Not getting	Check transmitter-is it properly inserted into transmitter holder?
		sensor glucose readings.	Make sure you haven't taken acetaminophen.
Dessiver			Don't calibrate.
Receivel	200 150 2 PM 3 PM 407 PM		If this continues for more than 3 hours, call Technical Support (see Chapter 16):

Troubleshooting

Device	What you see	Problem	What you do
Smart Device: In app	Signal Loss		See Chapter 9. <i>Don't</i> calibrate. Verify display device and transmitter are within 20 feet of each
Receiver	Signal Loss for 11:53:48	System display device and transmitter not connecting. No sensor readings, Alarm/Alerts or notifications until error is fixed.	other without obstruction. Wait up to 30 minutes. Don't calibrate. Use BG meter for BG reading. More than 30 minutes? App (if not resolved): • Go to Settings. • Tap Bluetooth. • Turn Bluetooth. • Turn Bluetooth Off and On. App/Receiver: If this continues for more than 3 hours, contact Technical Support (see Chapter 16).
Smart Device: In app	Sensor warmup	No sensor glucose readings	See Chapter 7. Wait up to 2 hours. System is counting down to when you do your startup calibration.

Troubleshooting

Device	What you see	Problem	What you do
Receiver			

# Applicator

Picture	Problem	What you do
R CO	Can't push in orange button.	After placing on body, make sure safety guard is removed. Fold and break away guard.
	Hurts when the needle fires.	Make sure your application site is not directly over a bone. Use an area of your belly with less scar tissue or irritation.
	Smaller adhesive patch won't come off.	Lift up the tab of the label.

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Troubleshooting

Picture	Problem	What you do
	Transmitter holder won't stick.	See Chapter 6. <b>Put</b> medical tape over transmitter holder's white adhesive patch (e.g., Blenderm). <b>Don't</b> place tape over the transmitter.

Troubleshooting

Picture	Problem	What you do
	Applicator doesn't come off after pushing button	<ul> <li>Don't panic!</li> <li>Remove applicator and adhesive patch: <ol> <li>Gently pull applicator up until you see adhesive patch</li> <li>Using your finger or thumb, hold front edge of patch and peel from skin</li> <li>While holding adhesive patch's front edge, gently rock back applicator, away from your body.</li> </ol> </li> <li>Check insertion site to make sure the sensor isn't left on the skin.</li> <li>Don't try to reuse applicator.</li> <li>Call Customer Service. <ol> <li>Toll free: 1.888.738.3646</li> <li>Toll call: 1.858.200.0200</li> </ol> </li> </ul>

Troubleshooting

### Hardware Error

Device	What you see	Problem	What you do
Receiver	BRUAR	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. <b>Reset</b> <i>receiver</i> . <b>Connect</b> <i>receiver</i> to <i>charger</i> . <b>Insert</b> end of paper clip into small circular hole on receiver's back. <b>Push down</b> on paper clip. Receiver will vibrate. Processing screen appears. <b>Charge</b> <i>receiver</i> .
Receiver		Receiver low battery.	See Chapter 4. Charge receiver.

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Troubleshooting

Device	What you see	Problem	What you do
			See Chapter 16.
Receiver			Write down error code. (Screen may show other codes.)
			Call Technical Support:
	Call Tech Support Error: ERR117	Corrupted database.	<ul> <li>Toll free: 1.888.738.36 46</li> </ul>
			<ul> <li>Toll call: 1.858.200.02 00</li> </ul>
			<b>Notification:</b> Vibrates one time for four seconds and four beeps.
	System Check Passed	System recovery.	See Chapter 16.
			Do nothing.
Receiver			Receiver is able to continue to work and recover from an error.
			app: <b>Tap</b> <i>OK</i> to clear Alert.
			Receiver: <b>Press</b> <i>Select</i> to clear Alert.

Troubleshooting

Device	What you see	Problem	What you do
	Smart Device: In app	No Bluetooth.	See Chapter 5.
Smort		No sensor	Go to smart device's Settings.
Smart Device: In app		readings, Alarm/Alerts	<b>Make sure</b> <i>Bluetooth</i> is On.
		or notifications until error is fixed.	If problem persists, please contact device's manufacturer.

## **Calibration Error**

Device	What you see	Problem	What you do
			See Chapter 7.
BG	406	System will not accept calibration if	Wait until your glucose is between 40-400 mg/dL.
Meter		outside of the 40-400 mg/dL range.	Calibrate only when your BG meter values are between 40-400 mg/dL.
Smart Device: In app	Enter new BG meter value after 11:43PM 2	System didn't accept recent calibration (see Sensor Glucose Readings troubleshooting	See Chapter 7. <b>app:</b> <b>Tap</b> <i>question mark</i> to get more information. OR Follow instructions

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Troubleshooting

Device	What you see	Problem	What you do
Receiver	Enter BG in 15min	for a possible reason). No sensor readings, Alarm/Alerts or notifications until error is fixed.	below. app/Receiver: Wait 15 minutes. Enter 1 calibration. If error screen still appears enter 1 more BG meter value. Wait 15 minutes. If no sensor glucose readings display on the smart device or receiver, the sensor needs to be replaced. Contact Technical Support (see Section 16.1) to report error:

Device	What you see	Problem	What you do
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Troubleshooting

Device	What you see	Problem	What you do
Smart Device: In app	11.28 AM В АМ 11.28 AM 11.28 AM Enter new 8G meter value 200 -400 -300 -400 -3	System didn't accept recent calibration.	See Chapter 7. <b>Wait</b> 15 minutes. <b>Enter</b> 1 BG meter value. <b>Wait</b> 15 more minutes. If error screen still appears enter 1 more BG meter value. <b>Wait</b> 15 minutes. If no sensor glucose readings appear on the
Receiver			<ul> <li>display, the sensor needs to be replaced.</li> <li>Call Technical Support (see Section 16.1) to report error: <ul> <li>TechSupport@dex com.com</li> <li>Toll free: 1.888.738.3646</li> <li>Toll call: 1.858.200.0200</li> </ul> </li> </ul>

## **Transmitter Error**

Device	What you see	Problem	What you do

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Troubleshooting

F compression, OCR, web optimization using a watermarked evaluation copy of CVISION PDFCompresso

Device	What you see	Problem	What you do
Smart Device: In App	Pair new transmitter 2	Transmitter not working.	See Chapter 16. Make sure transmitter is snapped into sensor pod Contact Technical
Receiver	Transmitter Failed Replace Transmitter	Sensor session automatically stopped. No sensor readings, Alarm/Alerts or notifications until transmitter is replaced	<ul> <li>TechSupport@dex com.com</li> <li>Toll free: 1.888.738.3646</li> <li>Toll call: 1.858.200.0200</li> <li>Use BG meter for BG reading.</li> <li>You won't get additional Alerts after clearing.</li> </ul>

Device	What you see	Problem	What you do
Smart Device: In App	Transmitter not found ?	Pairing failed Transmitter and sensor not connected.	See Chapter 6. Sensor may not be inserted correctly. Insert a new sensor. For a replacement,

Troubleshooting

Device	What you see	Problem	What you do
Receiver	Transmitter Not Found	No sensor readings, Alarm/Alerts or notifications until transmitter is paired.	<ul> <li>contact Tech Support at:</li> <li>TechSupport@dex com.com</li> <li>Toll free: 1.888.738.3646</li> <li>Toll call: 1.858.200.0200</li> </ul>

Device	What you see	Problem	What you do
Smart Device: In App	Your transmitter battery is low. The transmitter will stop working in about three weeks. If you haven't already, please order a new transmitter.	Transmitter Low Battery	See Chapter 16. Contact Technical Support: • TechSupport@dex com.com • Toll free: 1.888.738.3646 • Toll call: 1.858.200.0200

Troubleshooting

Device	What you see	Problem	What you do
Receiver	Low Battery Order New Transmitter		

Troubleshooting

# Chapter 19

Everything Else G5x:

# 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 G5x 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.

2	Alternating Current	EC REP	Authorized Representative in the European Community
LOT	Batch/Lot Number	*	Bluetooth
	Caution		Class II Equipment
$\mathbb{Z}$	Date of Manufacture		Direct Current
$\bigotimes$	Do Not Reuse		Do Not Use If Package Is Damaged
	Electrical Equipment Designed Primarily for Indoor Use		European Union WEEE Directive 2012/19/EU

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Symbols on Package Labels

<b>%</b>	Humidity Limitation	$\rightarrow$	Input
IP22	IP22: Protection Against Insertion of Large Objects and Dripping Water	IP28	IP28: Protection Against Insertion of Large Objects and Immersion in Water
Ť	Keep Dry		Manufacturer
	Marking Certifies Device Meets European Council Directive 93/42/EEC	MR	MR Unsafe
((()))	Non-Ionizing Radiation	Rx Only	Prescription Required
	Refer to Instruction Manual/Booklet	SN	Serial Number
SB	Ship By Date	STERILER	Sterile by Radiation
	Temperature Limitation	Ŕ	Type BF Applied Part
$\sum_{i=1}^{n}$	Use By Date		

Symbols on Package Labels

Symbols on Package Labels



# SHARING IS CARING

• Dexcom Share<sup>®</sup>

G5x System User Guide

Sharing is Caring

# 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	A wireless technology that 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.

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Dexcom Follow App	Gets the Sharer's glucose information and notification data from the Dexcom <i>Share</i> Cloud.	
Dexcom G5 Mobile App	Receives glucose information from the G5x transmitter. Sends glucose information to the Dexcom Cloud using an Internet connection.	
Dexcom G5x Sensor	The Dexcom G5x System part that includes an applicator and sensor wire.	
Dexcom G5x System	CGM system made of a sensor, transmitter, and smart device/receiver.	
Dexcom G5x Transmitter	The G5x System part that wirelessly sends glucose information to the app.	
Dexcom Share	A secondary notification system using the following parts:	
	• G5x	
	Bluetooth wireless technology	
	Sharer's smart device	
	• Арр	
	Internet	
	Follower's smart device	
	Dexcom Follow app	
Dexcom <i>Share</i> Cloud	A secure online storage server where Dexcom <i>Share</i> feature information is stored and then shared with Followers.	

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Sharing is Caring

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.	
G5 Mobile/G4 PLATINUM Sensor	G5 Mobile part that includes an applicator and sensor wire.	
G5 Mobile System	CGM system made of a sensor, transmitter, and smart device/receiver.	
G5 Mobile Transmitter	G5 Mobile part that wirelessly sends glucose information to the G5 Mobile app.	
G5 Mobile App	Receives glucose information from the G5 transmitter. Sends glucose information to the Dexcom <i>Share</i> Cloud using an Internet connection.	

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Hyperglycemia	High BG. Same as "high."
	The default High Glucose Alert in the G5x is set to 200 mg/dL.
	Consult your healthcare professional to determine the appropriate hyperglycemia setting for you.
Hypoglycemia	Low BG. Same as "low."
	The default Low Glucose Alert in the G5x is set to 80 mg/dL.
	Consult your healthcare professional to determine the appropriate hypoglycemic setting for you.
Invite/Follow Invitation Email	An email request for a person to download the Dexcom Follow app and get the Sharer's shared information.
Jailbroken	The removal of limitations set by the manufacturer on a smart device.
	Do not use jailbroken smart devices with Dexcom <i>Share</i> .
mg/dL	Milligrams per deciliter. The standard unit of measure for sensor glucose information in the United States.
Mobile Data Connections	Cellular networks, such as 3G, 4G, and LTE <sup>™</sup> , used by a smart device to access the Internet.
No More Data Notification	Notifies the Follower when the Sharer is unable to share glucose information.

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Notification	A visual message that appears on the screen of the Follower's smart device. Notifications may also include a sound, depending on the smart device's settings.
Not Sharing	When the Sharer chooses to temporarily not share glucose data with the Follower.
Obstruction	An object that stops the wireless communication between devices, such as wall thickness or radio waves.
Profile	Located in Follow Dashboard and displays the Sharer's glucose information, trend arrow, and profile picture.
Range	Maximum distance two devices can communicate wirelessly without obstruction.

Real-Time CGM	Data the Sharer receives on the G5 Mobile app. Although your Dexcom Follow app might be similar to what you see on your G5 Mobile 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 he/she wishes to receive a repeat notification.
Sensor Glucose Reading	A glucose measurement taken by the G5x.
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Sharer	The person who uses the Dexcom Share app	
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 cordless (unless charging), mobile (easily transportable), connected (via Wi-Fi, 3G, 4G, etc.) electronic device that can operate the 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 receiver.	

Sharing is Caring

Trend Graph	Displays the pattern of the Sharer's glucose information.
Wi-Fi or Wireless Internet	A technology that allows electronic devices to wirelessly access the Internet. These networks can include your home Internet or one found at a public location.

# 20.2 Dexcom Share Overview

Dexcom *Share* is a feature within the G5 Mobile app. It allows for remote monitoring of G5x data from one person, the Sharer, to another person, the Follower.

Dexcom Share includes:

- G5x CGM System
- Sharer's smart device
- App
- Internet connection
- Follower's smart device
- Dexcom Follow app

You cannot use the *Share* feature with the receiver.

Once the Sharer activates the *Share* feature in their 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.

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Figure 8. Sharing

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

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Sharing is Caring

### Dexcom Share Parts

	Sharer's smart device* <sup>1</sup>	
	Follower's smart device* <sup>1</sup>	
	G5 Mobile app	
	Dexcom Follow app	
	G5x transmitter*	
	G5x sensor*	
(((-	Internet/Wi-Fi or mobile data service/3G/4G/LTE*	
*	Bluetooth	

\*Must be purchased separately. <sup>1</sup>A list of compatible devices can be found at dexcom.com/compatibility.

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# **Conditions Affecting Use**

Once sharing is active, make sure the Sharer'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
- An active Internet connection
- Notifications turned on. If turned off, Follower won't receive any notifications

Dexcom recommends charging the smart device while sharing.

# 20.3 Risks and Benefits

### Risks

Dexcom *Share* is a feature of the G5x. The main risks involved with using the Dexcom *Share* feature are based on misunderstanding its purpose.

Remember that the Dexcom *Share* feature in the G5x is a secondary notification feature, not a real-time remote monitoring system.

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

- 1. BG meter-use this to make any treatment decisions.
- G5x–Use the G5x to complement, but not replace, information obtained from the BG meter. It detects glucose trends and tracks glucose patterns.
- Dexcom Share—This is an optional add-on to the G5x 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. BG values from a BG meter may differ from the information displayed on the Dexcom Follow app. All treatment decisions should be made using a BG value from your meter, not the glucose information displayed on the Dexcom Follow app.

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Followers who are concerned by notifications on the Dexcom Follow app should contact Sharers and remind them to check their BG with a BG 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 notify 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 G5x 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

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continuous glucose monitoring (G5x) or standard home BG monitoring. The Dexcom *Share* Direct Secondary Displays is not intended to modify or analyze data received from the continuous glucose monitoring system, nor is it intended to instruct, or to transmit information to the continuous glucose monitoring 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 G5x user guide. Dexcom *Share* is a feature of the G5x.

If you do not have the G5x user guide, you can view it on dexcom.com or call **1.888.738.3646** to request a copy. Availability hours: Monday-Friday, 6 AM-6 PM 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

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replace G5x 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 BG meter. Always use the values from a BG meter for treatment decisions.

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

#### Precautions

Do not use Dexcom *Share* as the main source of CGM glucose trend information. Use the Dexcom 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 BG values. Do not rely solely on the Follower to notify 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 BG 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 BG 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 BG 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

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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 BG values.

If the patient's smart device is powered off or restarted, make sure the app is reopened after the smart device is turned back on in order to resume sharing. If the 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 BG 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 BG 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 BG 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 (for example, 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 BG 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 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.

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# 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:

• Lets you know when the Follower is not receiving your sensor glucose readings and information

#### Tips

- Read the rest of the G5x 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 App

Step	What you see	What you do
------	--------------	-------------

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Step	What you see	What you do	
1		Download the G5 Mobile app from your app store. See your smart device's user manual for instructions. Download the app to use Dexcom <i>Share</i> .	
2	• • • • •	Launch the app. Set up your smart device (see Chapter 5) before sharing. Once your app has been set up, activate Dexcom <i>Share</i> .	

A series of screens walk you through the Dexcom *Share* features, highlighting important information.

## Activating Your Share Feature

|--|

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Step	What you see	What it means	What you do
1	E P ★	Activates Dexcom <i>Share</i> . If Dexcom <i>Share</i> icon is gray, your <i>Share</i> feature has not been turned on.	<b>Tap</b> <i>Dexcom Share</i> <i>icon</i> in the upper right corner of your smart device's home screen.
2	Records Under Control of Control	Dexcom <i>Share</i> Welcome Screen.	<b>Read</b> screen. <b>Tap</b> <i>Next</i> when done.

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Step	What you see	What it means	What you do
3	Internet           Image: State Sta	Message about Internet access.	Tap Next.
4	Sharing Colored Col	How to know you are sharing your data.	Tap Next.

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Step	What you see	What it means	What you do
5	Sharing     S	How to know your Follower is not getting your sensor data.	Tap Let's Get Started to move on and invite your Followers.

## **Inviting Followers**

Step	What you see	What you do
1	Followers     Followers     four currently are not sharing your glucose information with any cost added any Followers.     INVITE FOLLOWERS	<b>Tap</b> <i>Invite Followers</i> to set up your Followers.

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Step	What you see	What you do
2	Add a Follower Enter your Follower's information. Follower's email address Invitation will be sent to this address Confirm email address Confirm email address Confirm email address Add a Follower Next Follower's nickname Follower's nickname Follower'	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.

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Step	What you see	What you do
3	Contract Craph View Set trend graph access for Kevin. Allow Trend Graph View When switched off, Kevin will only be able to see your current glucose value and not your trend graph. NEXT	Slide Allow Trend Graph View's On/Off switch if you want Follower to see your trend graph. Tap Next. Turned Off: Follower sees only your sensor glucose reading and trend arrow. Turned On: Follower sees your sensor glucose reading, trend arrow, and trend graph.

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Step	What you see	What you do
4	✓       Follower's Settings         Set notification settings for         Kevin, Kevin will be able to         modify these settings later.         Urgent Low       ②         Notify Below       55 mg/dL >         Low       ③       ✓         Notify Below       80 mg/dL >         For More Than       30 min >         High       ③       ✓         Notify Above       200 mg/dL >         For More Than       1 hr >         No More Data       ②       ✓         NEXT       ●       ●	<ul> <li>Choose if your Follower gets your Urgent Low, Low, and High Glucose Alarm/Alerts.</li> <li>Choose if you want your Follower to get notifications if they are not receiving your sensor glucose readings.</li> <li>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 notifications in the Follower's Settings menu).</li> <li>Tap Save for each Follower Setting "Save."</li> <li>Tap Next when done.</li> </ul>

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# 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.



### Dexcom Share Status Icons

Status tab	What it is
••••	The <i>Share</i> icon is in color when Dexcom <i>Share</i> is sending sensor glucose readings and information.

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Status tab	What it is
• • •	The <i>Share</i> icon is dark gray with a red circle when Dexcom <i>Share</i> is not working. The Sharer should tap on the dark gray <i>Share</i> icon when <i>Share</i> is not working to get further information about the error.
• • •	The <i>Share</i> icon is light gray when Dexcom <i>Share</i> has not been activated. The Sharer should tap the light gray icon to get started using Dexcom <i>Share</i> .

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

#### Troubleshooting Status Issues

The Dexcom *Share* 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.

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**NOTE:** Whether or not Dexcom *Share* is working and the Followers are receiving glucose Alarm/Alerts, you must always refer to your G5x display device for your sensor glucose readings and Alerts.

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

Dexcom Share Status Issues

What you see	What it means	What you do
Sharing status	Green check mark: All connections are working.	N/A.

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What you see	What it means	What you do
Sharing status	Issue with: • Sharer's CGM data • Sharer's smart device	<ul> <li>The Sharer should:</li> <li>Verify there is a glucose value on the smart device</li> <li>Be sure the transmitter is in range of the smart device</li> <li>Tap on blue "?" to learn more about how to troubleshoot this issue</li> <li>Allow up to 10 minutes for their status to turn green and a green check mark to appear</li> <li>If the Sharer continues to see this, the Sharer should turn off <i>Share</i> and then turn it back on.</li> </ul>

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What you see	What it means	What you do
Sharing status	Issue with: • Sharer's Internet connection • Dexcom <i>Share</i> Cloud	<ul> <li>The Sharer should:</li> <li>Verify their Wi-Fi or cellular connection is ON</li> <li>Be sure they are in an area that has cellular reception</li> <li>Not be on a voice call</li> <li>Be sure they can access the web via a browser</li> <li>Check later or follow up with their Internet connectivity provider</li> <li>Tap on blue "?" to learn more about how to troubleshoot this issue</li> </ul>

# **Followers List**

The Followers list allows the Sharer to manage his/her Followers.

In the Followers list the Sharer can:

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

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#### Icon/Status

What you see	What it means
Followers	Invite a new Follower.
Followers	Follower is set to get notifications from Sharer.
Followers	Follower is able to view Sharer's trend graph.
Followers Jason Invitation Expired >	Follower did not accept Sharer's Follow Invitation email within 7 days. Sharer can invite Follower again by tapping on the + icon in the top right corner of the screen.
Followers Brian Invited	Follower has been sent a Follow Invitation email but has not accepted it yet.
Followers  Patty  Removed	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, the Follower won't get glucose information or Alarm/Alerts.

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

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

#### What the Follower app does not do:

- Provide treatment advice
- Interact with the G5 Mobile app

# Receiving Dexcom Follow Invitation Email

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

## **Glucose Alarm and Alerts**

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

Types of notifications the Follower gets:

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

Followers can change some of the initial settings to fit their needs. Followers cannot change the Sharer's permission settings to see the trend graph.

# Sharer Status Changes That Notify the Follower

Some Sharer status changes will notify the Follower:

- Not Sharing-Sharer decides to temporarily stop sharing
- Removed by Sharer-Sharer removes Follower
- No More Data-Active glucose sharing is stopped for any reason, other than the Sharer turning Share "Off"
  - Follower should contact Sharer for more information about the data interruption

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The Follower Dashboard



If the Sharer doesn't allow the Follower to see the trend graph, he/she will only see the glucose reading and trend arrow.



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If you choose to have your Followers see your trend graph, they see:

# 20.8 Troubleshooting

# Dexcom Share Troubleshooting

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



Figure 14. Sharing Status Troubleshooting

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# **Sharing Checklist**

#### To share, make sure:

- Your smart device works with the G5 Mobile app
  - To see a list of supported smart devices and operating systems, go to: dexcom.com/compatibility
- The app is open or running in the background
- Your smart device has an active Internet connection (Wi-Fi, 3G, 4G,
  - LTE)
    - Check to see if the Internet connection is working by trying to open a web page on the 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 is turned off
- Do Not Disturb is turned off
- Smart device sound is on in order to hear notifications
- 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 G5x user guide before using the Dexcom Share feature
- Always confirm information with a BG meter before you make treatment decisions

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pagination is wrong)

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