Dexcom®

User Guide

for Dexcom G5® Mobile Continuous Glucose Monitoring (CGM) System

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1

GETTING STARTED

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

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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 *Bluetooth*, you use to get easy access to some of its features. For example, *Bluetooth* 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® Mobile CGM System (G5 Mobile). Only use fingerstick measurement.
App	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 G5 Mobile app was developed as a display for continuous glucose monitoring.
Apple Watch®	Accessory device for iPhones®.
Blood Glucose (BG) Value	An abbreviation of blood glucose. Blood glucose (BG) value is the amount of glucose in the blood measured by a BG meter.

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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 G5 Mobile should not be used because it may be harmful to you. The risk of use clearly outweighs any possible benefit.

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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 G5 Mobile 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 G5 Mobile 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. Indications let you know who should use the G5 Mobile and when.

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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 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.

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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 G5 Mobile.
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 G5 Mobile 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, *Bluetooth*, 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. Describes serious and life threatening

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	circumstances of using the G5 Mobile, their consequences, and how to avoid the hazard.

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Chapter 1

Getting Started:

Beginning Your Dexcom G5® Mobile Continuous Glucose Monitoring (CGM) System Journey

1.1 Introduction

Welcome to the Dexcom G5 Mobile CGM System (G5 Mobile) 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 G5 Mobile System allows you to break free from constant fingersticks. But how do you use the G5 Mobile? 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 G5 Mobile in your diabetes management
- Find G5 Mobile System's step-by-step instructions
- Recall how to use the User Guide
- Explain why you need a Dexcom® account

We have numerous resources available to help you get the most out of your G5 Mobile. 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

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Knowing about the G5 Mobile 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 G5 Mobile:

1. Tutorials
2. Getting Started Guide
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 (see Chapter 10.4).

Accessing Online Tutorials:

From dexcom.com homepage, **click** *Support*.

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Once you have viewed the online tutorials you should be pretty comfortable with what CGMs do and how the G5 Mobile 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:

- USB card in the receiver package

Written Mobile Resources

Getting Started Guide (GSG)

The G5 Mobile 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 G5 Mobile. But what if you want more detailed information?

User Guide

Your G5 Mobile encyclopedia!

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 G5 Mobile user guide is grouped into six separate parts:

Part 1: *Getting Started*

- Glossary

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- Getting Started
    - Getting more information about the G5 Mobile
    - Registering at dexcom.com
- Indications for Use and Safety Statement
- Risks and Benefits

Part 2: *Let's G5! The Basics*

- Introduction to the G5 Mobile
- Initial Setup
- Starting a Sensor Session: Inserting the Sensor & Attaching the Transmitter
- Calibration
- Ending a Sensor Session & Transmission Session

Part 3: *Next Steps - Getting the Most out of Your G5 Mobile*

Once you are up and running, how you can maximize the G5 Mobile features:

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

Part 4: *Everything Else G5*

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

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At the end of your G5 Mobile user guide is the Dexcom *Share*® user guide.

Part 5: *Sharing Is Caring*

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

Part 6

- Index for G5 Mobile and Dexcom *Share*

How to Use Your User Guide

All chapters in the G5 Mobile 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, it shows 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 and for reordering supplies.

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

Or, if you prefer, the G5 Mobile app walks you through creating your login credentials as part of your initial app setup.

Summary

Now You Can:

- Describe different training resources

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- Locate tutorials about using a real-time CGM in your diabetes management
- Find G5 Mobile step-by-step instructions
- Recall how to use the user guide
- Explain why you need a Dexcom 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.

Next you'll learn about when and how to use the G5 Mobile safely.

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Chapter 2

Getting Started:

Indications for Use and Safety Statement

2.1 Introduction

We want the G5 Mobile System 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 that if you just took Tylenol®, 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 system.

This chapter is important to read. It helps you use the system 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. Then we'll 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 system's indications, contraindications (when to avoid using it), relevant warnings, and precautions. The Safety Statements are meant to keep you and the system safe while using the system:

1) **Indications**

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

2) **Contraindications**

   Contraindications let you know when *not* to use the system. 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 system, their consequences, and how to avoid danger.

4) **Precaution**

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

2.3 Safety Statements

This user guide presents Safety Statements two ways:

1. In this chapter's Overview of Safety Statements
   - Lists all Safety Statements
   - Includes a section reviewing how the statements are formatted
2. Within each chapter

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- Lists only those statements applicable to that specific chapter

Chapter's Safety Statements

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

Some chapters will have multiple Safety Statements; others have none. Safety Statements are located toward the beginning 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
      - **INDICATION-Green**
      - **CONTRAINDICATION-Purple**
      - **WARNING-Red**
      - **PRECAUTION-Blue**
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 it.

> **Warning**
>
> **Do:** *Calibrate at least once every 12 hours*
>
> **Why:** Calibrating less often than every 12 hours might cause inaccurate sensor glucose readings
>
> **Consequences:** Missing severe low (hypoglycemia) or high (hyperglycemia) Alarm or Alerts

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) Alarm or Alerts.

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 system components.

Indications and Contraindications

Indications

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

The Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) System 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 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 system.

Who

The system 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 system is a prescription-only glucose monitoring device. system tracks your glucose patterns and detects trends. Working with your home 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 system 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 system'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 system; 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

Do not wear the system (sensor, transmitter, and receiver) during 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® 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

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 system from harm.

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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 system 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 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.

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

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

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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 Initial Calibration: Data/Alarm/Alert

After starting a new sensor session, until completing your initial 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 system components.

2.7 System/Hardware/Software Warnings and Precautions

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

Sensor/Sensor Pod Warnings and Precautions

Warnings

Sensor Breaking Off

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

Within 24 hours of experiencing a broken sensor wire, please call our 24/7 Technical Support department, toll free at **1.888.738.3646** or toll at **1.858.200.0200**.

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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 system sensor 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° F-77° F. While you don't need to keep your sensor in a refrigerator, you can as long as the refrigerator is between 36° F-77° 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

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

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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 sensor pod not sticking and falling off.

Sensor Placement

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

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.

Precaution

Reusable: Don't Throw Away

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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

Different generations' transmitters and receivers aren't interchangeable with each other.

The Dexcom G5 Mobile CGM System transmitter and receiver are not compatible with the Dexcom G4® PLATINUM CGM System's transmitter and receiver. The Dexcom G5 Mobile CGM System won't work if you mix receiver and transmitter components from different generations, resulting in you missing a severe low or high glucose event.

You can use a Dexcom G4® PLATINUM Sensor with the Dexcom G5 Mobile CGM System. Before using the sensor, make sure the sensor label says "Dexcom G5 Mobile/G4 PLATINUM Sensor", or "Dexcom G4 PLATINUM Sensor".

System Accuracy

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

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- 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 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 system through the baggage x-ray, ask the TSA officer to visually inspect it.
- Body scanner: When you are wearing your system, request hand-wanding or full-body pat-down and visual inspection instead of going through the Advanced Imaging Technology (AIT) body scanner (also called a 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 for the walk-through metal detector or hand-wanding. 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 receiver and your smart device share some precautions.

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

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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 is often the biggest culprit in reducing communication distance. This applies to the transmitter and display devices. Take special care when swimming, getting into a pool, bathtub, shower, etc.

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. Alarm 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 Alarm 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.

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 *Settings* menu.

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2. **Verify** app hasn't been shut down.
3. **Turn on** *Bluetooth*.
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. 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 connected.

Make sure you disconnect 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 Precautions

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

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

Precautions

Test Receiver

Shortly after the receiver is powered on or plugged in to charge, it should briefly vibrate and beep. If this doesn't happen, it may mean the vibration motor and/or speaker are not functioning properly. Please retry. If it still doesn't vibrate and beep, contact Technical Support.

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 *Sounds* 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 is not 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

Do not get dirt or water in the USB port 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 system to sale by or on order of a physician.

Summary

Now You Can:

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

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- 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 system.

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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 G5 Mobile System.

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 and display device are 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 (Chapter 18.3) or recommended settings in Chapter 11 for more information.

Different Devices May Give Different Numbers

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

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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 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 G5 Mobile uses the same sensor as the previous CGM system—the Dexcom G4 PLATINUM. The Dexcom G4 PLATINUM System clinical studies and compliance data showed slight redness and swelling occurring only in a few patients.

During Dexcom's G4 PLATINUM System's clinical study, 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 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!

3.2 Benefits

Daily habits impact your BG levels. With the G5 Mobile, you can track how your exercise, carbs, stress levels, medication, or illness influence your glucose levels.

Knowing Your Trends

Providing sensor glucose readings every five minutes, for up to seven days, the G5 Mobile helps you detect trends and patterns. Trend information reveals

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where your glucose is now, where it has 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.

Helping Your Diabetes Management

Wearing the G5 Mobile 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 G5 Mobile System helps reduce hypoglycemia (Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group et al, 2008).

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 the G5 Mobile!

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2

LET'S G5! THE BASICS

- Introduction to the G5 Mobile
- Initial Setup
- Starting a Sensor Session: Inserting the Sensor & Attaching the Transmitter
- Calibration
- Ending a Sensor Session & Transmitter Session

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Chapter 4

Let's G5! The Basics:

What's the G5 Mobile?

4.1 Introduction

Now it's time to get an overview of the G5 Mobile.

After this chapter, you'll be able to:

- Explain the G5 Mobile
- Describe options to view trends
- Locate your historical readings
- Recognize system components
- Explain each part's function

4.2 Safety Statement

If you've used the Dexcom G4 PLATINUM CGM System, you might still have its transmitter or receiver. While you can use the sensors across the different generations (look for "G5 Mobile," "G4 PLATINUM," or "Dexcom G5 Mobile/G4 PLATINUM" on the sensor's package), you can't mix the transmitter or receiver between the two systems.

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Warning

Don't: *The G5 Mobile was not evaluated for the following persons:*

- *Pregnant women*
- *Persons on dialysis*

Do not use the Dexcom G5 Mobile 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

Don't: *Never mix Dexcom G5 Mobile's transmitter or receiver with Dexcom G4 PLATINUM's transmitter or receiver.*

Why: The G5 Mobile's transmitter and receiver are not compatible with the Dexcom G4 PLATINUM CGM System's transmitter and receiver. The G5 Mobile won't work if you mix receiver and transmitter components from different generations.

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

Only the components in the table below are compatible with each other within the G5 Mobile System.

G5 Mobile System Components	Sensor	Transmitter	Display Device	
			Receiver	App
Brand Name	G5 Mobile/G4	G5 Mobile	Dexcom	G5

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	PLATINUM Sensor	Transmitter	Receiver	Mobile App
Part Number(s)	9500-27	9438-06	MT22949	SW10611

4.3 The G5 Mobile

The G5 Mobile 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. Your sensor glucose readings are measured by a single use sensor inserted under your skin. A reusable transmitter sends your data to your display device.

The G5 Mobile provides personalized trend Alerts, prompting 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 G5 Mobile System may need a caregiver involved in their care. Please consult your physician for guidance.

Options to View Your Trends

The G5 Mobile 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
2. G5 Mobile 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.

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The G5 Mobile 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 G5 Mobile 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.

View 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 G5 Mobile 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.

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 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.

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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 G5 Mobile allows you to see your last 1-3-6-12-24 hours of your sensor glucose readings. On the receiver, from the home screen, **tap** *graph* 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 G5 Mobile?

Dexcom's G5 Mobile has features not found in our previous generations. They include:

- G5 Mobile app for your smart device and Apple® Watch
- Touchscreen receiver
- Software updates
    - Dexcom *Share* in the G5 Mobile app

G5 Mobile App

You now have an option for how you view your information and enter data. After downloading the app, you can monitor your glucose and enter information from your smart device.

Check your CGM information on your wrist! The G5 Mobile app supports Apple Watch. Use it to discreetly see your glucose information.

Touchscreen Receiver

With the new touchscreen receiver, your sensor glucose readings, calibrations, events, menu options, etc. are accessible by just a tap or two.

Share Your Data

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Through secure wireless connections, Dexcom *Share* allows your loved ones to view your sensor glucose readings, trends, and data by your loved ones from a smart device. Activate Dexcom *Share* by tapping on the app's *Share* icon, follow a few simple steps, then invite up to five people to connect with you.

After downloading the Dexcom Follow® app, the invited person becomes your Follower. As a Follower, he or she can watch your sensor glucose readings, trends, and receive Alarm/Alerts when your glucose is low or high.

You determine what your Follower can see. Based on what you allow, your Followers can receive your Alarm or Alerts and view your trends. Followers can pick and choose, or turn off, the data they receive, including the Alarm/Alerts, trends, and messages. The *Share* feature in the G5 Mobile app is different from the Dexcom *Share* app used with other systems.

For more information about Dexcom *Share* and instructions for use, go to Part 5.

> **NOTE:** Review all Dexcom *Share* System warnings, precautions, contraindications, indications, and detailed procedures in Part 5.

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 prompts, 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 G5 Mobile does and what's new, let's open your G5 Mobile packages, see what's inside, and review each item.

4.6 System Components

Package

The G5 Mobile comes to you in a number of boxes; after opening, keep each box until you are no longer using its contents.

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Throughout this guide, all images are representational. Your product may look slightly different.

Sensor Box	
	Single use sensor(s)

Transmitter Box	
	Reusable transmitter
Receiver Box	
	Receiver Two extra colored cases
	Receiver's USB charging and download cable

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	AC power adapter
	Welcome card
	Getting Started Guide
	Training Tutorial USB 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 G5 Mobile is comprised of four key parts:

1. Single use sensor
2. Reusable transmitter
3. Rechargeable receiver
4. G5 Mobile app
    a. Downloaded to your smart device

G5 Mobile optional:

Dexcom *Share*

Sensor Overview

For your safety, the sensor is packaged in a sterile sealed pack. When you first open the pack, your sensor looks like one item; however, it's actually three: sensor applicator, sensor pod, and sensor wire.

The applicator helps you insert the sensor wire inside the sensor pod under your skin. After inserting the sensor wire, remove the applicator. The sensor wire stays in the sensor pod with the pod attached to your skin by adhesive.

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.

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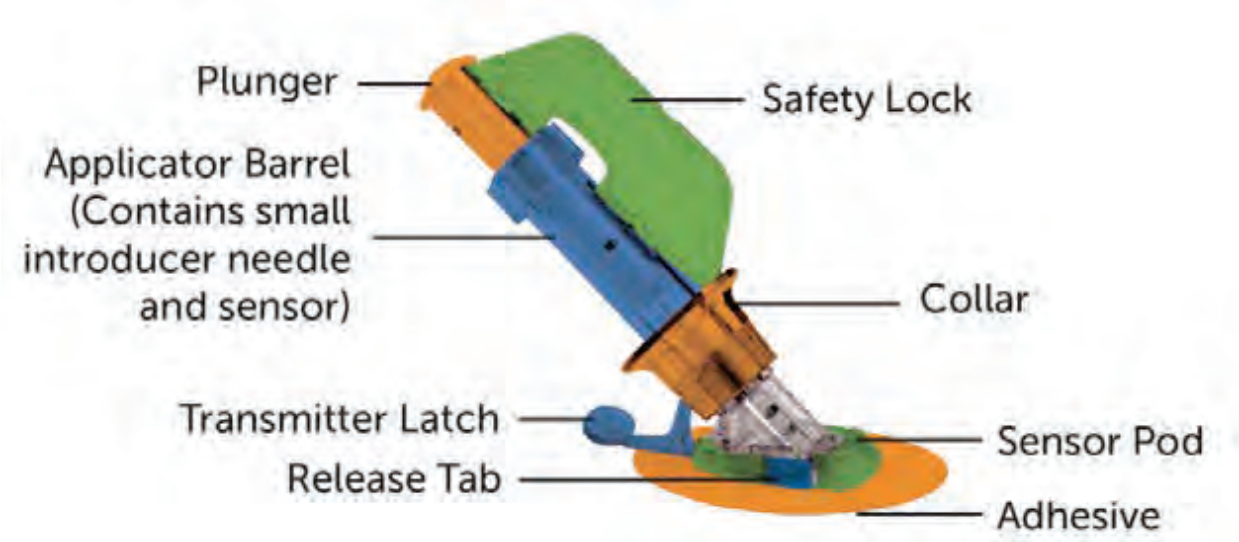


Figure 1. G5 Mobile Sensor Applicator and Pod

Applicator and Sensor Pod

What it's called	What it does
Applicator	
Applicator Barrel	Contains small insertion needle and sensor wire. Inserts sensor wire under the skin. Disposable, for single use only. Removed after insertion.
Safety Lock	Keeps all moving parts in place before insertion. Prevents accidental sensor insertion. Tool to remove transmitter after sensor session. Put in transmitter box after removal to use later.
Collar	Collar removes insertion needle.
Plunger	Inserts sensor wire into your body.
Transmitter Latch	Securely snaps transmitter into sensor pod.

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Sensor Pod	
Sensor Pod	Holds transmitter and sensor wire. Water resistant when transmitter is properly installed. Discarded after sensor session.
Adhesive Patch	Keeps sensor pod attached to your skin.
Transmitter Cradle	Holds transmitter in place during sensor session.
Sensor Wire	Wire measures glucose levels in fluid in between your cells. Attached to sensor pod. Discarded with pod after session.

Transmitter Overview



Figure 2. G5 Mobile Transmitter Front and Back
Image is representational only. Your transmitter may look different.

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

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- Battery lasts approximately three months
    - Receiver or smart device prompts 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 and transmitter, let's review the receiver.

Receiver

The receiver is a small hand-held device. Your receiver, as well as your smart device, shows your sensor glucose readings, trend graphs, and trend arrows and alerts 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. If your receiver does get wet or dirty, test it to make sure the speaker and vibrations still work (see Chapter 12).

The small hole on the back of the receiver is not to be used to reset the receiver. Do not push anything through the hole.

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

You can change the protective case. Just take off the black one and put on one of the colored ones. Be sure to line up the cover's speaker holes with the receiver speaker.

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

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

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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
	Micro USB Cable	**Plug** into *receiver* to charge battery Don't plug into a computer port to charge Battery can only be charged using the adapter/wall charger
	Wall Charger	**Plug** *USB cable* into *adapter/wall charger* **Plug** *wall charger* into an electrical outlet to charge receiver's battery

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What you see	What it's called	What it does
	Display Screen	Shows sensor glucose readings, trend graphs and arrows, Alarm/Alerts, sensor session status. Change settings on Menu screen.
	Charging Indicator	Turns on when receiver is being charged.
	Speaker	Allows you to hear your Alarm/Alerts sounds.
	Power and Wake-up Button	Press and hold button for two seconds to turn it on. Press briefly to wake it up.

4.7 Smart Device Overview

The G5 Mobile 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.

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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 G5 Mobile
- 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 G5 Mobile is selecting how to continuously receive your sensor glucose readings: the G5 Mobile app, the receiver, or a combination.

Our next chapter helps you set up both!

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Chapter 5

Let's G5! The Basics:

Set Up Your Display Devices

5.1 Introduction

In the previous chapter, you received a high level overview of the G5 Mobile and learned you can monitor your glucose levels with different display devices. Now it's time to set up your G5 Mobile app and your receiver.

After this chapter, you will be able to:

- Determine which display device(s) you'll use
- Create a Dexcom username and password
- Download the G5 Mobile app
- Set up the G5 Mobile app with the recommended settings
- Successfully set up your receiver

5.2 Safety Statement

If you've used the Dexcom G4 PLATINUM CGM System, you might still have its transmitter or receiver. While you can use the sensors across the different generations (look for the Dexcom G5 Mobile/G4 PLATINUM Sensor package), you can't mix the transmitter or receiver between the two systems.

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Precaution

Don't: *Never mix G5 Mobile's transmitter or receiver with Dexcom G4 PLATINUM's transmitter or receiver.*

Why: The G5 Mobile's transmitter and receiver are not compatible with the Dexcom G4 PLATINUM CGM System's transmitter and receiver. The G5 Mobile won't work if you mix receiver and transmitter components from different generations.

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

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!

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 Chapter 5.5. If you want to use both the G5 Mobile app and the receiver, you need to set up each individually.

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

5.4 G5 Mobile 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

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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®, which wirelessly connects devices to the Internet). Your transmitter communicates to your app via *Bluetooth*® 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
- 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 G5 Mobile 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 receiver until it's fixed or replaced.

G5 Mobile App Installation

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

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

Initial G5 Mobile 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** green *Get Started* tab or the three green bars, then "Get Started."
3. **Click** green *Get Started* button on the page.
4. **Fill out** *User account* screen.
5. **Click** the green *Create New Account* button towards the bottom of the screen.

But what if you are unclear about a step?

The G5 Mobile app has prompts allowing you to get more information. If you are unsure of something during your initial setup process, look at the screen for additional information prompts. Informational prompts include, but aren't limited to: *I don't understand, Learn More,* or *Question Mark*. **Tap** your *informational prompt* to get more information.

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

Initial App Setup

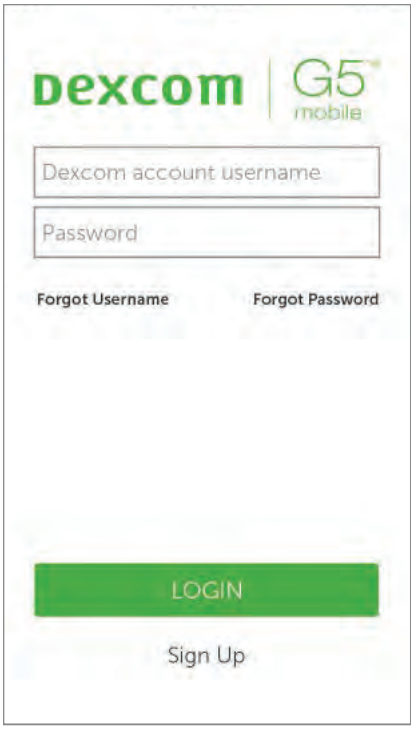
Step	What you see	What you do
Introductory Screens		

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Step	What you see	What you do
1		**Tap** *G5 Mobile app* icon to open app.

Introductory Screens		
2		**Swipe** through introductory screens or **tap** *Log In*.

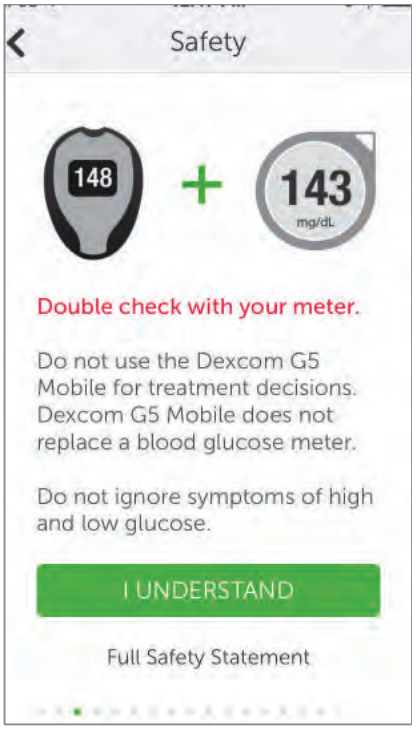
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3		**Enter** existing *username* and *password* OR Need a Dexcom username and password? **Tap** *Sign Up.* **Complete** *Username/Password* fields. **Tap** *Login* once.

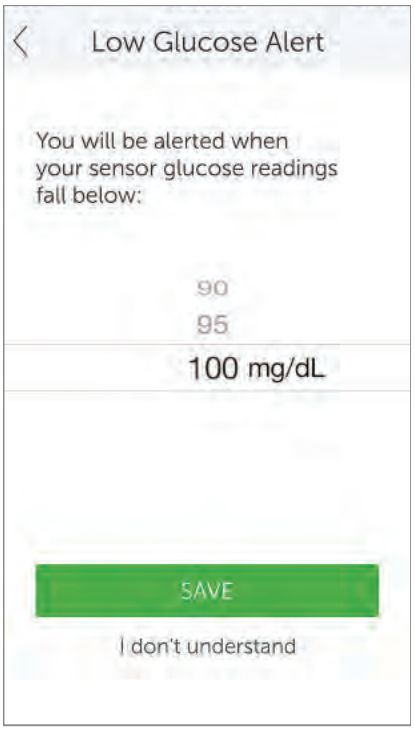
Introductory Screens

4		**Tap** *Let's Get Started*.

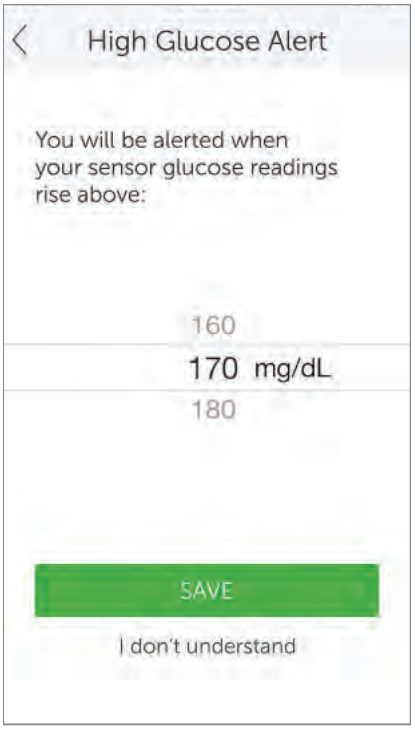
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5		The next screens are the Terms of Use, safety warnings, contraindications, and the recommended settings. Once each screen is read, **tap** the *appropriate answer* to move forward. **Tap** *Full Safety Statement* or, when available, *I don't understand* to get more information.

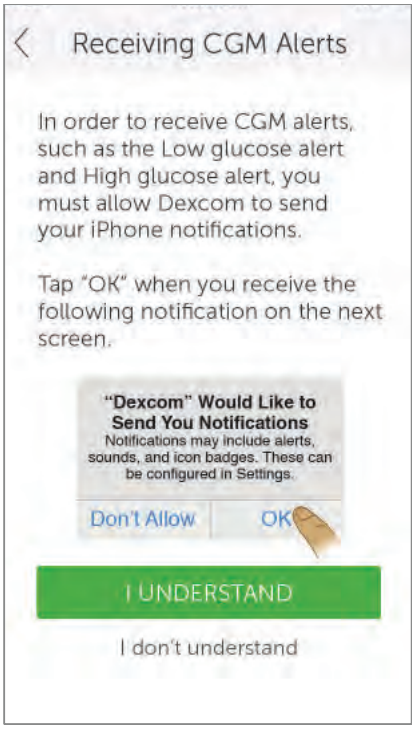
Setting Up Your App Alarm/Alerts and Basic Settings

6		**Set** your Low Glucose Alert. Default is 80 mg/dL. Scroll to select another amount. **Tap** *Save* to move forward. Once your Low Glucose Alert is set, you'll receive an Alert if your glucose dips below your set amount.

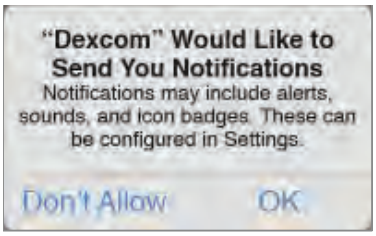
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7		**Set** your High Glucose Alert. Default is 200 mg/dL. **Scroll** to select another amount. **Tap** *Save* to move forward. Once your High Glucose Alert is set, you'll receive an Alert if your glucose rises above your set amount.

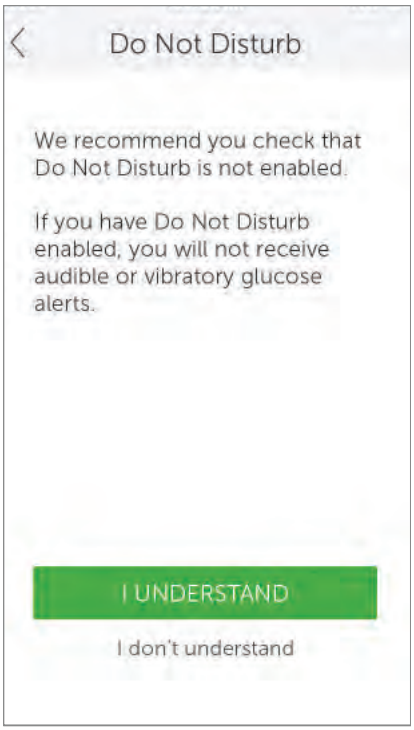
Setting Up Your App Alarm/Alerts and Basic Settings

8a		Make sure you get your Alarm/Alerts notifications. **Tap** the *appropriate response* to move forward and set your notifications.

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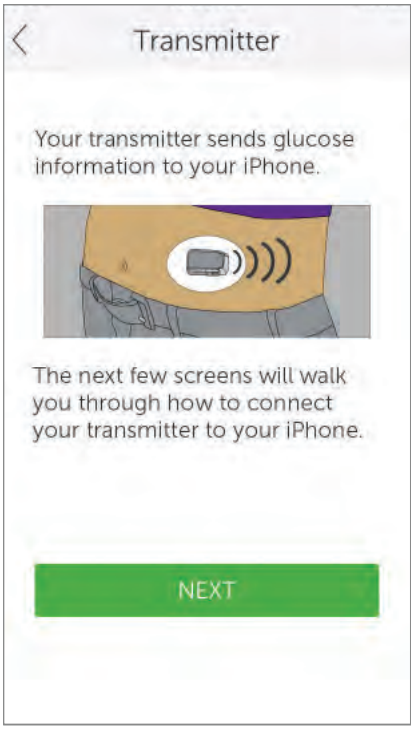
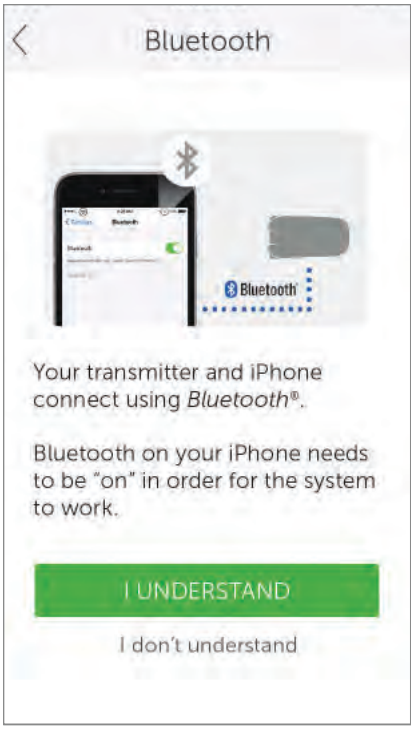
8b		**Tap** *OK* to receive Alarm/Alerts notifications.

Setting Up Your App Alarm/Alerts and Basic Settings

9		The next screens provide suggestions for device volume, *Do Not Disturb*, and other basic settings. **Tap** *appropriate answer* to move forward.

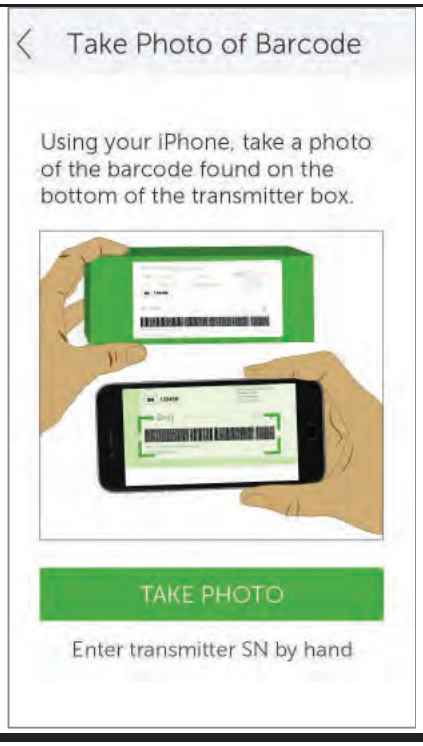
Connecting/Pairing Transmitter With App

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10		**Tap** *Next*.
11		**Verify** *Bluetooth* is on. The app will check to see if *Bluetooth* is turned "on."

Connecting/Pairing Transmitter With App

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12a		**Get** your transmitter box. **Turn** transmitter box **upside down** on a flat surface with barcodes facing up. For information on how to pair transmitter after initial setup, see Chapter 8.
12b		**Center** longest barcode within green brackets. **Tap** *Take Photo*.

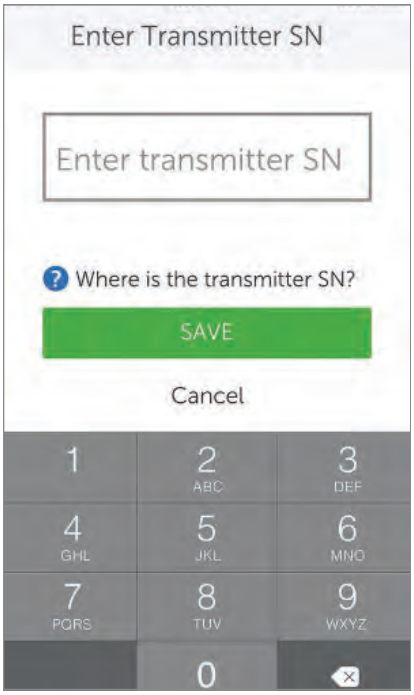
Connecting/Pairing Transmitter With App

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12c		Check mark confirms successful transmitter SN scan.
13a		If unable to use app's scanning device: **Tap** *Enter transmitter SN by hand*.

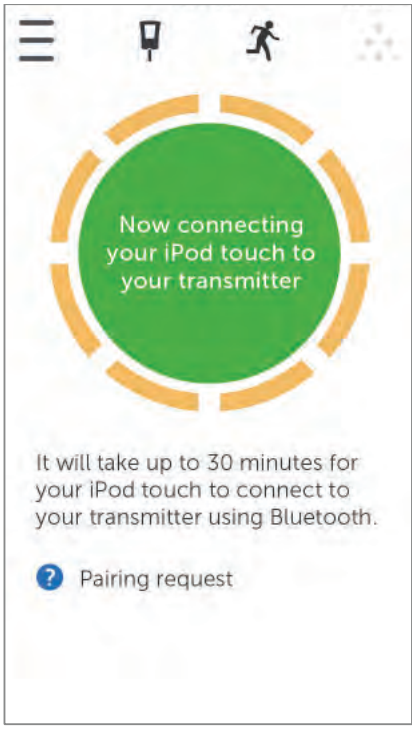
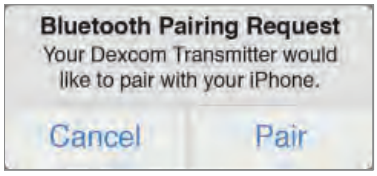
Connecting/Pairing Transmitter With App

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13b		**Use** keyboard to enter transmitter SN. **Confirm** correct SN . **Tap** *Save*.
14		Insert sensor and attach transmitter following video's instructions. See Chapter 6 for more information.

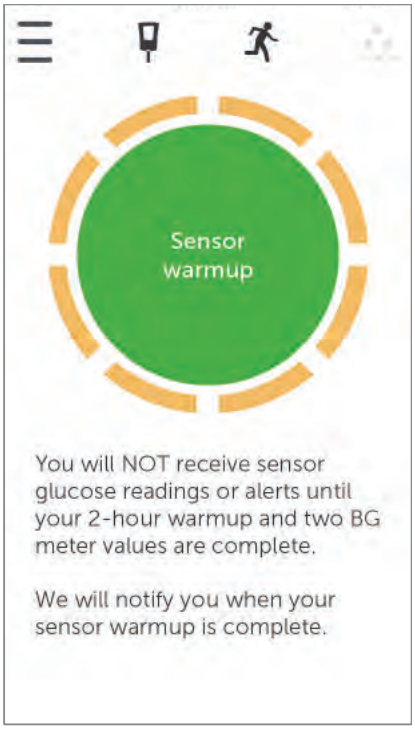
Connecting/Pairing Transmitter With App

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15		**Wait** up to 30 minutes for smart device and transmitter to connect. (This screen is skipped for smart devices.)
16		At prompt, **Tap** *Pair* to pair app with smart device.

Connecting/Pairing Transmitter With App		
17		Make sure your transmitter and smart device have paired before starting your sensor session

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18		**Tap** the *Sensor warmup* circle to start your two-hour sensor warmup. When you see the sensor warmup timer, your initial setup is complete. Congratulations!

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

- TechSupport@dexcom.com
- 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 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 bar, meter, and events icons

Initial Setup of the Receiver

Press and hold *power button* for two seconds 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. Your receiver has a touchscreen. Be sure your fingers are dry when you touch it. Don't be alarmed 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.

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

Setup Wizard Prompts:

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

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1		**Press** and hold *power button* for two seconds to turn receiver on. **Wait** for the Dexcom screen to appear.
2		**Wait.** Within 20 seconds, receiver will beep and vibrate briefly to show the speaker and vibration motor are working.
3		Tap *OK*.
Date/Time		
4a		The green box shows what is selected. Tap *up/down arrow* to change year. Tap *month* to select it. Tap *up/down arrow* to change month. Tap *day* to select it. Tap *up/down arrow* to change day.

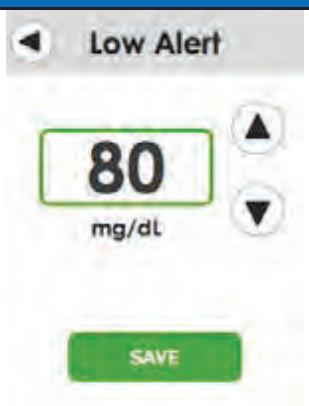
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4b		**Tap** *hour* to select it. **Tap** *up/down arrow* to change hour. **Tap** *minutes* to select them. **Tap** *up/down arrow* to change minutes. **Tap** *AM/PM* to select it. **Tap** *up/down arrow* to change between AM and PM. **Tap** *Save* to save and close. **NOTE:** After initial setup, if battery is drained, receiver will vibrate once and you will need to reset date and time.

Transmitter		
5a		**Turn** *transmitter box* **upside down** to locate SN number. For information on how to pair transmitter after initial setup, see Chapter 8.
5b		If transmitter package isn't available: • SN is on transmitter's back

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5c		**Tap** *up/down arrows* to select and enter transmitter SN. **Tap** *number* to select it. To choose a letter, tap up from 9 or down from 0. **Tap** *Save* to save and close.

Setting Low Alert		
6a		System default is set at 80 mg/dL. **Tap** *Save* to save at present levels and close.
6b		To change value: **Tap** *up/down arrows* to change value at 5 mg/dL increments. **Tap** *Save* to save and close.
Setting High Alert		

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7a		System default is set at 200 mg/dL. **Tap** *Save* to save at present levels and close.
7b		To change value: **Tap** *up/down arrows* to change value at 10 mg/dL increments. **Tap** *Save* 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 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:

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1. Inserting the sensor.
2. Attaching the transmitter.
3. Pairing the transmitter to your device.
4. Two-hour sensor warmup.
5. Initial calibrations.

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Chapter 6

Let's G5! The Basics:

Starting a Sensor Session: Inserting Sensor, AttachingTransmitter, 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 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: **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 G5 Mobile 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 initial calibrations.

After this chapter you will be able to:

- 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 sensor
- Outline what happens during the sensor warmup
- Identify countdown icon

6.2 Safety Statements

Following are some important Warnings and Precautions 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: *Seek professional medical help if you have symptoms of infection or inflammation (for example,, redness, swelling or pain) at the insertion site.*

If your sensor breaks under your skin, report it to Technical Support (available 24/7) as soon as possible:

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 G5 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 G5 Mobile 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 G5 Mobile sensor 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: *Store sensor between 36° F-77° F during its shelf life.*

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

Never store sensors in the freezer.

Consequences: If stored outside of 36° F-77° F, your sensor glucose readings may not be accurate, resulting in you missing a severe low or high glucose event.

Warning

Don't: *Never use the G5 Mobile sensor glucose readings for treatment decisions.*

Do: *Only use BG values from your BG meter for treatment decisions (for example, how much insulin to take).*

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

Consequences: Using sensor glucose readings for treatment decisions could result in you missing a severe low or high event.

Precaution

Do: *Select sensor insertion site with care.*

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: Insertion in these areas might affect sensor performance.

Consequences: Inaccurate sensor glucose readings may result in you missing a severe low or high event.

Precaution

Do*: Check sensor package before opening.*

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

Consequences: Using an unsterile sensor may cause an infection.

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.

6.3 Prepping for Sensor Insertion

Before inserting a sensor, make sure you have everything you need. Some items are included in the G5 Mobile's packages, others are not.

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Included in Your G5 Mobile Packages

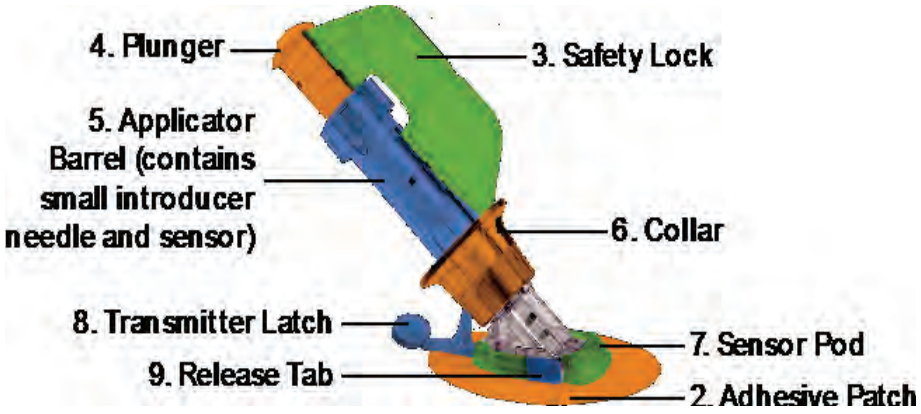
For sensor insertion, you need the sensor and transmitter.

Sensor Applicator

Inside Sensor Box

What you see	What it is
	Sterilized sensor pack with important label information. **Check** *expiration date.*
	Single use sensor applicator.

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



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Figure 3. G5 Mobile Sensor Applicator and Pod

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

Order of Use	Name	What it does
1	Sensor Pack	Sterilized for your protection. Open to remove applicator and sensor.
2	Adhesive Patch	Holds the sensor/transmitter in place on your skin.
3	Safety Lock	Prevents plunger from inserting sensor until you are ready.
4	Plunger	Inserts sensor wire into your body.
5	Applicator Barrel	Contains small insertion needle and sensor wire. Disposable, for single use only.
6	Collar	Collar removes insertion needle. Helps remove applicator barrel once sensor wire is inserted.

Order of Use	Name	What it does
7	Sensor Pod	Holds sensor wire in place under skin. Holds transmitter.
8	Transmitter Latch	Locks transmitter into sensor pod.
9	Release Tab	Allows you to remove applicator barrel from sensor pod.

Transmitter

Transmitter Box

What you see	What it is
	Bottom of box with important label information. Keep box until transmitter battery dies.
	Reusable transmitter.

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 out of its sterile pack, determine the best place to insert your sensor.

6.4 Choosing Your Insertion Site

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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 waist band, seat belt strap or where you lie when sleeping).

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

Insertion Sites

Location	Where it is
	Front of body (belly area) for ages 2 years and above.
	If user is between the ages of 2 years and 17: Back of body (Upper buttocks)

Do:

- Remove the sensor and applicator from its sterile pack only at time of use
- Place at least 3 inches from your insulin pump infusion set or injection site

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- 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 sensor pod not sticking, before inserting your sensor, you can make the sensor site stickier to help ensure the sensor pod does not peel.

Optional Site Preparation

Use optional skin adhesives (Mastisol™, SkinTac™) as part of your insertion site preparation to help keep your sensor pod 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 manufacturer's instructions. Once dry, your skin may feel slightly sticky.

See Step 3 in the next table for directions.

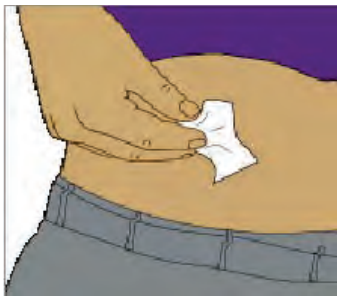
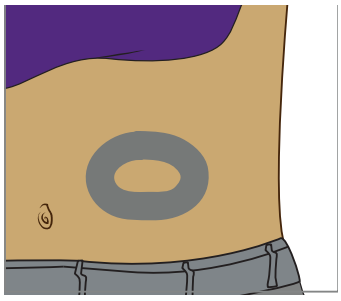
NOTE: Contact your healthcare professional for specific questions regarding the use of medical tape, barrier wipes, and/or other adhesives as it relates to your use of Dexcom CGM.

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 sensor pod site. You're now ready to insert your sensor!

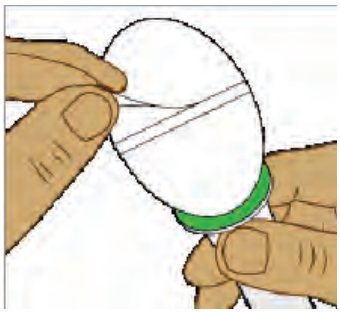
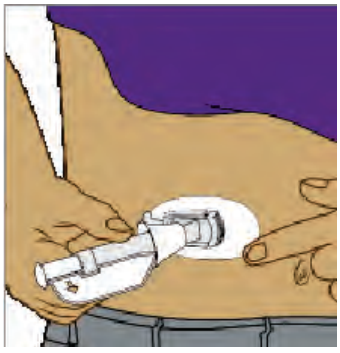
Step	Picture	What you do
Preparation		

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1		**Wash** and **dry** your hands.
2		**Clean** *insertion site* with alcohol wipe. Let dry.
3		**Optional Step: Skin Adhesive** **Create** an *empty, sideways oval* on the skin • Do not get any skin adhesive inside the oval • Let skin adhesive dry (see manufacturer's instructions) • Insert sensor on clean skin at the center of the oval

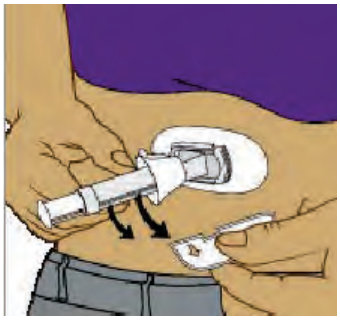
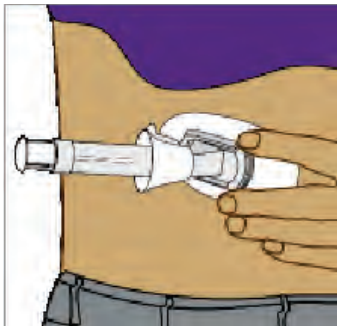
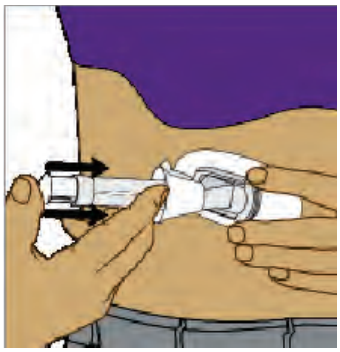
Preparation

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4		**Check** *pack*: Is it damaged or already opened? **Remove** *sensor applicator* from sterile pack. **Closely inspect** *sensor*, check it hasn't been damaged. **Keep** *sensor packaging* until sensor session is complete.
Attaching Sensor Pod		
5		**Pull** *adhesive backing tabs.* **Don't touch** *sticky adhesive patch.*
Inserting Sensor Wire		
6		**Place** *sensor* horizontally, not vertically, on skin. **Move** fingers around *the adhesive patch* several times to secure tape.

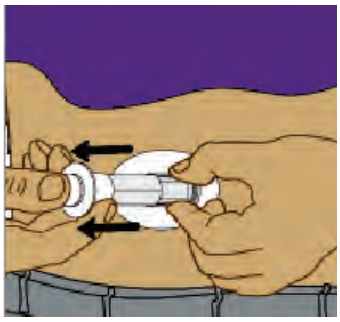
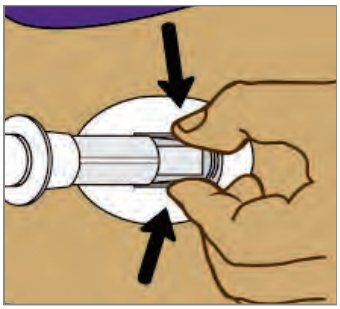
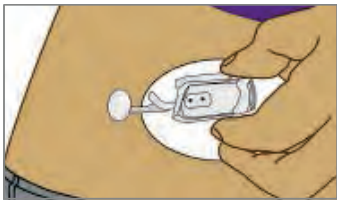
Preparation

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7		**Hold** *applicator barrel.* **Pull** *safety lock* out.
8		**Place** fingers of one hand on edges of *adhesive patch*. **Pinch** up your skin at the tips of the *white adhesive.*
9		**Place** two fingers directly *above* collar to steady applicator barrel. **Place** thumb on the *white plunger*. **Push** *plunger* completely down the applicator barrel. You should hear 2 clicks. **NOTE:** Finger placement is important for correct insertion.

Removing Applicator and Collar

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10		**Move** two fingers from *above* collar to *below* collar. Keeping your thumb as a base on the white plunger. **Pull** *collar* all the way back towards your thumb. You should hear 2 clicks. **NOTE:** Finger placement is important for correct removal.
11		**Hold** *transmitter latch* down against your body. **Squeeze** *ribbed release tabs* on the sides of sensor pod.
12a		**Move** *applicator barrel* forward and out, away from your body. Follow local ordinances when disposing the applicator.
12b		What's left? 1. Sensor pod 2. Transmitter latch

You have successfully inserted the sensor!

At this point, you should have two items attached:

1. The sensor pod
2. The transmitter latch

Having problems?

If it's the first time inserting a sensor, you may have questions or need help. If you do, please contact your 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 sensor pod.

6.6 Attaching Your Transmitter

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

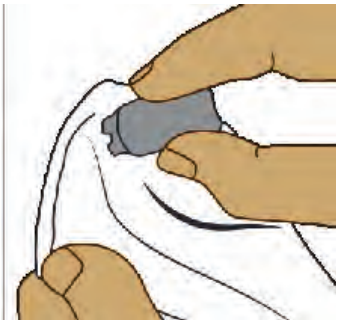
Since the transmitter is reusable, you don't need a new one every time you start a sensor session. Keep your current session's transmitter box. The bottom label has important information you may need after you've attached the transmitter. Once the transmitter has been attached, you can't remove it until your session is over. Chapter 8 reviews when and how to remove your transmitter.

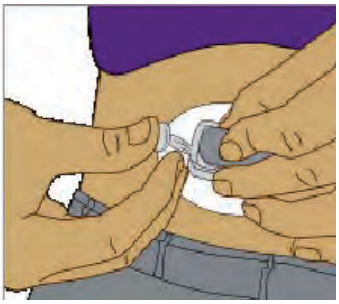
Before attaching your transmitter, check you've entered the correct transmitter SN into your display device. Chapter 5 covers entering transmitter's SN number during initial setup. See Chapter 8 for pairing your transmitter after the startup wizard

Attaching Transmitter

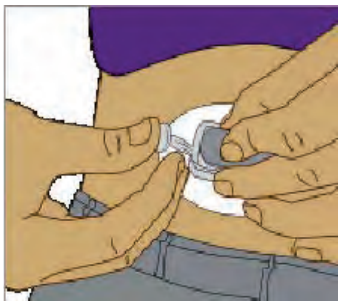
Step	Picture	What you do

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1		**Remove** *transmitter* from box. **Keep** box. **Save** *safety latch* from sensor applicator (helps remove transmitter once sensor session is over). **Get** alcohol wipe.
2		**Wipe** *back of transmitter* with alcohol wipe. **Let dry** for 2-3 minutes. **Don't** let the back of transmitter touch your skin. **Don't** scratch transmitter's back, this can harm the waponproof seal.
3		Flat side down. **Slide** *transmitter's small end* under the sensor pod lip located in front of pod's ribbed tabs, away from *transmitter latch*.

Step	Picture	What you do
4		**Keep** finger on *transmitter* holding it in place. Push *transmitter latch* up and forward over the transmitter's wide end with your other hand. You should hear 2 clicks.

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5		**Is transmitter secure?** Before removing transmitter latch, verify transmitter is securely in place. Make sure none of the transmitter's sides popped out of the sensor pod. If not completely snapped in, you may have a bad connection and it won't be water tight.
6		**Hold** *sensor pod sides* with one hand. **Twist** *latch* **away** from your body with other hand. **Remove** *latch*. **Don't** remove *transmitter* while sensor pod is attached to skin.

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.

No matter which display device you use, you'll insert the sensor and attach the transmitter only once during your seven-day sensor session.

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 Sensor Pod

The sensor pod should stay on your skin using its own adhesive.

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

- Tape over white adhesive patch on all sides for even support

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- Don’t tape over the transmitter or any plastic parts of the sensor pod
- Don’t tape under sensor pod
- Don’t leave any substance on the skin where you insert the sensor

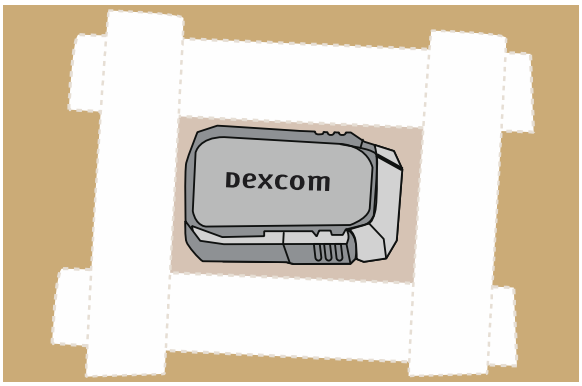


Figure 4. The Right Way to Use Tape for Extra Support

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

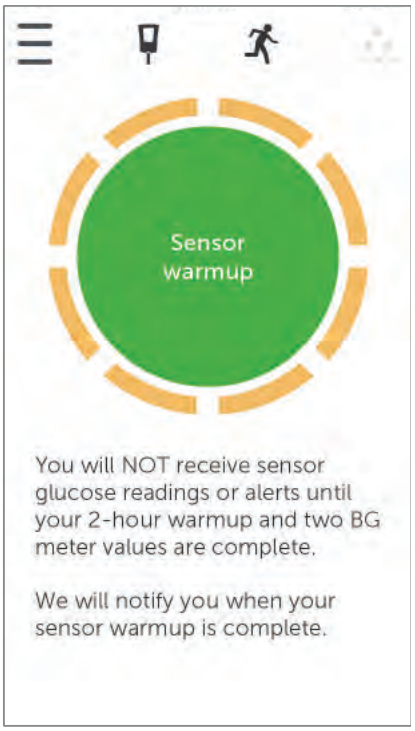
During the warmup period, neither device will provide any sensor glucose readings. Your sensor glucose readings begin after the two-hour sensor warmup has passed and you entered the initial two calibration BG values into either the smart device or the receiver.

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

Dexcom App: Starting a Session

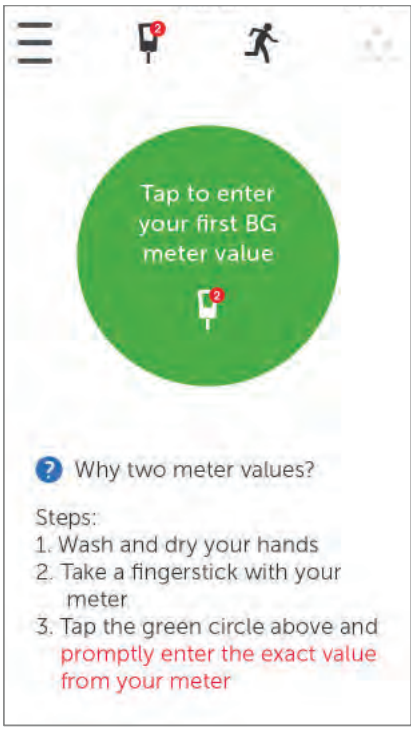
Step	What you see	What you do

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1		**Wait** for *Pair Successful* . **Tap** *green checkmark* in black square.
2		**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.
3		**Wait.** Screen provides countdown to sensor warmup. The orange dashes darken as the countdown moves forward. **Keep** *smart device* within 20 feet of transmitter during the sensor warmup period.

Step	What you see	What you do

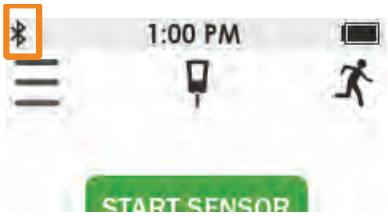
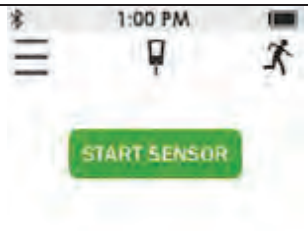
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4		Locked screen. *Initial calibration* prompt tells you when warmup is complete. Chapter 7 covers calibrating.
5		*Initial calibration* prompt tells you when warmup is complete. Sensor warmup is complete. You're ready to calibrate!

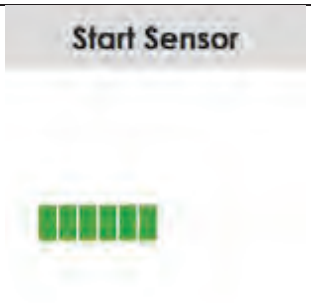
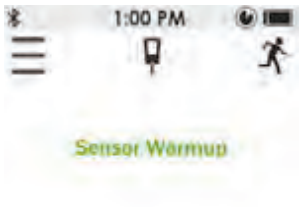
Receiver: Starting a Session

Step	What you see	What you do

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1		**Turn on receiver:** • **Press and hold** *power button* for two seconds to turn receiver on • Within 20 seconds, receiver will beep and vibrate briefly to show the speaker and vibration motor are working **Wake up receiver:** • **Press** *power button* briefly to wake up receiver
2		**Make sure** *receiver* and *transmitter* are connected/paired before starting sensor session. **Check** *receiver* 10 minutes after starting for *Bluetooth* icon. • Solid: Connected/paired • Blinking: Searching/not paired Don't start a sensor session until they are paired.
3		**Tap** *Start Sensor*.

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4		**Thinking screen**
5		Receiver returns to the trend graph screen. *Sensor Warmup* confirms two-hour sensor warmup. Keep your receiver within 20 feet during the warmup period **NOTE:** After sensor starts, *Start Sensor* option disappears from Main Menu and *Stop Sensor* appears.
6		**Wait.** In the upper right corner, icon shows countdown of the two-hour sensor warmup.
7		Sensor warmup is complete. You're ready to calibrate!

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

If the *Bluetooth* icon is blinking and *Signal Loss* displays, your transmitter and receiver are not communicating.

No Communication Between Transmitter and Receiver

Step	What you see	What you do
1		Tap OK. Verify display device and transmitter are within 20 feet of each other without obstruction. Wait up to 30 minutes. Don't calibrate. Use BG meter for BG reading. No sensor glucose readings display until error is fixed. More than 30 minutes? Contact Technical Support (available 24/7) at: • TechSupport@dexcom.com • Toll free: 1.888.738.3646 • Toll call: 1.858.200.0200

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6.10 Sensor Session Warmup

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 G5 Mobile's display devices.

Once the sensor warmup is complete, you're ready to enter your initial 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 sensor
- 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 G5! The Basics:

Calibration

7.1 Introduction

In the previous chapter, you learned how to insert your sensor, attach your 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 initial calibration, but also update calibrations required throughout your sensor session.

After this chapter, you will be able to:

- Calibration overview
    - Define calibration
    - Explain the importance of calibration
    - Identify steps to ensure a successful calibration
- Recognize steps in taking accurate BG measurement
    - 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 the 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
    - App
    - Receiver
- Identify calibration errors

7.2 Safety Statements

Contraindication

Don't: *Never take any medications containing acetaminophen during your sensor session.*

Why: Taking medications with acetaminophen (such as Tylenol or Excedrin Extra Strength) while wearing your sensor may falsely raise sensor glucose readings. 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 glucose event.

Warning

Don't: *Never use the G5 Mobile sensor glucose readings for treatment decisions.*

Do: *Only use BG values from your BG meter for treatment decisions (for example, how much insulin to take).*

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

Consequences: Using sensor glucose readings for treatment decisions 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 inaccurate sensor glucose readings.

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

Precaution

Do: *Look at trend arrows before calibrating. Trend arrows help you determine if you can calibrate now or should wait.*

Don't: *Never calibrate if your BG is changing at a significant rate, typically more than 2 mg/dL per minute.*

Never 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 significant rise/fall of 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 carefully performed fingerstick measurement.*

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

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: *Never use alternative site BG values such as blood from palms, forearms, etc.*

Why: Alternative site BG values are different from a fingerstick BG value and may not reflect most recent BG value.

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.

Why Is Calibrating Important?

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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 G5 Mobile 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 display device. 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 display 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 prompts:

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

If you receive a calibration prompt 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 prompt you when you are ready for another.

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.

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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 prompts, etc.

There are important times when you *must* calibrate:

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

With calibration prompts, 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.

Initial Calibration: Sensor Startup Completed

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

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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.

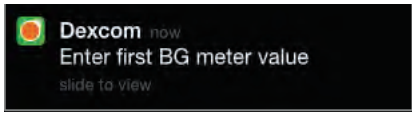
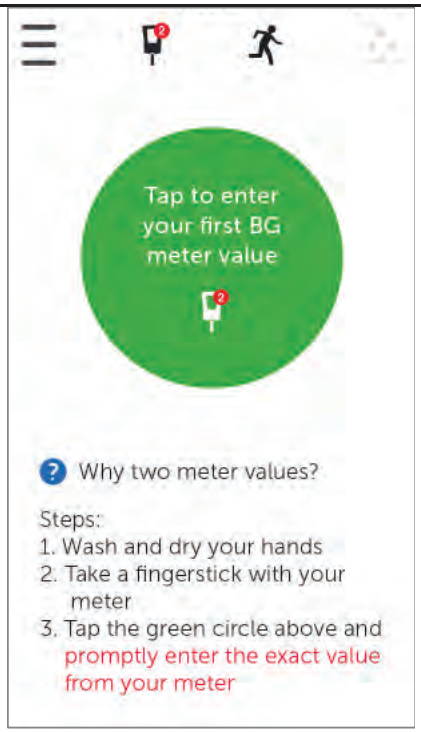
7.5 Calibration Prompts

Sensor Session Startup Calibration Prompts

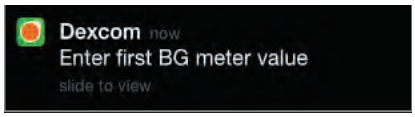
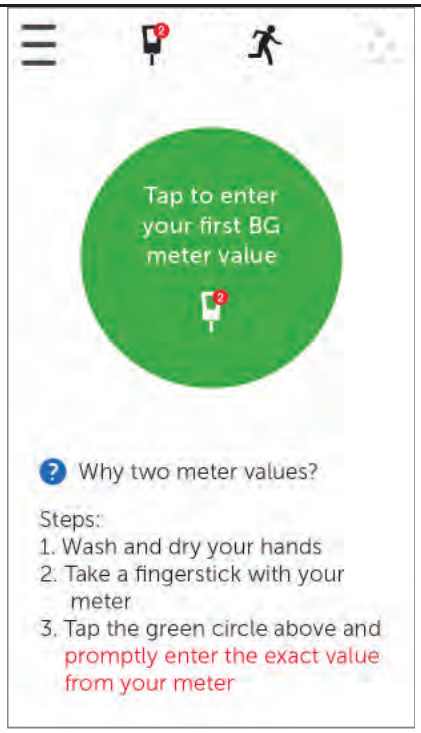
Once your two-hour sensor startup is complete, your display device tells you it's time to enter the first of your two back-to-back startup calibrations. Once the system has accepted your BG values, your glucose readings begin. If you don't enter your BG values right away, the system reminds you every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

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Startup Calibration Prompts

Device	What you see	What it means	What you do
First Calibration			
Smart Device: Lock Screen		Sensor warmup is complete. Ready for first of two initial calibrations.	Follow steps in Chapters 7.6 and 7.7. Immediately prepare for next calibration.
Smart Device: In App			
Receiver			

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Device	What you see	What it means	What you do
Second Calibration			
Smart Device: Lock Screen		Sensor accepted first calibration. Ready for second BG meter value.	Follow steps in Chapters 7.6 and 7.7. Next calibration in 12 hours.
Smart Device: In App			
Receiver			

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

Update Calibration Prompts

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

The steps to enter your update calibrations are the same as your initial 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 initial calibration, if you don't enter your BG meter values right away, the system prompts you every 15 minutes.

Update Calibration Prompts

Device	What you see	What it means	What you do
Smart Device: Lock Screen		Enter update calibration. If prompt doesn't go away: • System didn't accept calibration • BG values are very different from sensor glucose readings	Follow steps in Chapters 7.6 and 7.7. Immediately prepare for next calibration.
Smart Device: In App			
Receiver			

Tap *Message* to clear prompt on your smart device; to clear a prompt on your receiver, **Tap** *OK*.

Sound/Vibration Prompts

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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 prompts 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 prompts and how to clear them, please see Chapter 9.

Smart Device

Calibration prompts 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 prompts. 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:

1. Wash and dry your hands before taking 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?
6. Use fingerstick BG values only.
    a. Other sites are not as accurate.
    b. Must enter within five minutes of taking BG meter value.

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c. Enter exact BG value from your meter for each calibration.

Don't:

1. 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.
2. 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.
3. 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 eight steps above, have a valid BG value from your meter, and your display device keeps alerting you: Calibrate! Calibrate! Calibrate!

Remember:

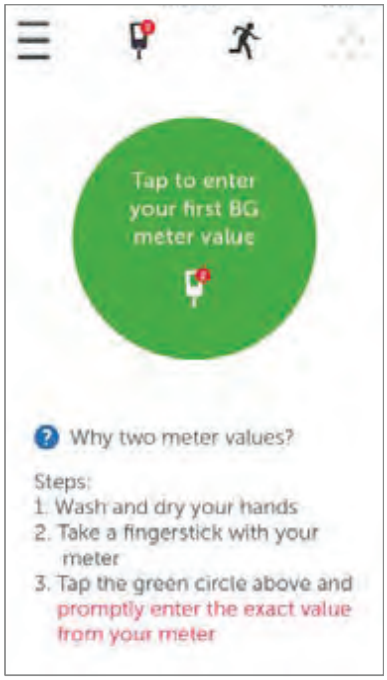
You don't have to take a fingerstick measurement for each display device when calibrating; once you enter the reading into one, data is pushed to the other within ten minutes.

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

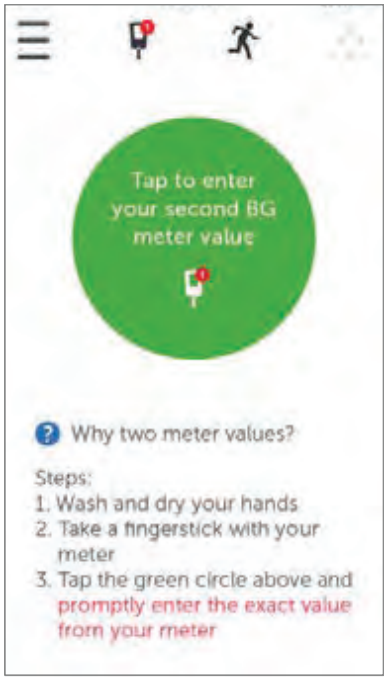
Initial Calibration With Your G5 Mobile app

Step	What you see	What you do	Additional Info

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Step	What you see	What you do	Additional Info
1		**Tap** *circle*.	**Initial calibration:** Enter two back-to-back meter BG values. **Update calibration:** Enter single meter BG value.
2		**Enter** meter's *BG value* using number pad. **Tap** *Save*.	Double-check your numbers. Entering wrong values, or values taken more than 5 minutes ago, can affect the sensor's accuracy.

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Step	What you see	What you do	Additional Info
3		**Verify** value is correct. **Tap** *Save*. If not correct: **Tap** *Cancel*. **Reenter** correct value.	
4		**Tap** *circle* to enter your second BG value. Follow steps 2-3 and enter second reading.	
5		Meter icon has no calibration prompt. Calibration accepted.	Your calibration was successful.

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Step	What you see	What you do	Additional Info
6		**Wait** for next calibration prompt in 12 hours.	Default Home Trend screen. Calibration accepted.

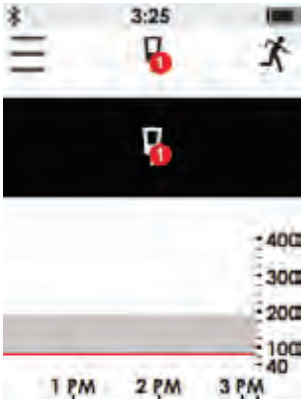
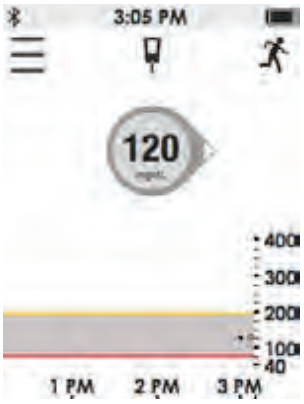
Initial Calibration With Your Receiver

Step	What you see	What you do	Additional Info
1		**Press** *power button* briefly to wake up receiver. **Tap** *OK*.	You won't see calibration prompts when receiver screen is black.

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Step	What you see	What you do	Additional Info
2		**Tap** *up/down arrows* to change numbers. **Stop** at meter's BG value. **Tap** *Done*.	Sensor default reading for initial calibration is 120 mg/dL.
3a		Verify BG value is correct. If correct: **Tap** *Save*.	If *Save* is not tapped: • Receiver times out • BG level isn't recorded
3b		Verify BG value is correct. If incorrect: **Tap** *Cancel*. **Reenter** BG value.	Cancel and reenter BG value. Fingerstick measurement must be within the last five minutes.

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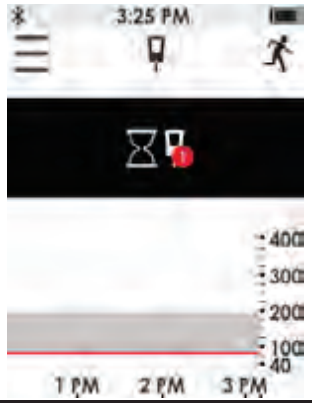
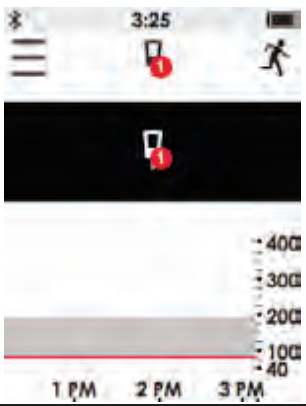
Step	What you see	What you do	Additional Info
4		**Wait.**	Thinking screen. BG value is accepted.
6		Immediately take another meter reading. **Enter** meter's BG value.	First calibration accepted. Time for second calibration.
7		**Wait** for next calibration prompt in 12 hours.	Default Trend screen. Calibration(s) accepted.

7.8 Calibration Errors

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

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Troubleshooting.

Device	What you see	What it means	What you do
Smart Device: In App		Sensor can't calibrate now.	**Wait** 5 minutes. **Retake** fingerstick measurement at prompt. **Enter** BG value.
Receiver			
Smart Device: In App		System didn't accept recent calibration.	Additional calibration needed immediately. **Calibrate**. No sensor glucose readings.
Receiver			

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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
    - Define calibration
    - Explain the importance of calibration
    - Identify steps to ensure a successful calibration
- Recognize steps required to take accurate BG measurements
    - Identify the best BG site for calibrations
    - Prepare finger for fingerstick measurement
- Determine if you should/should not calibrate
    - Recognize when you can enter BG meter values
    - 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
    - App
    - 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 removing the transmitter and determining if you need to replace it.

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Chapter 8

Let's G5! The Basics:

Ending Your Sensor Session and Transmitter Session

8.1 Introduction

G5 Mobile 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 prompts 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 sensor pod with transmitter attached
- Separate transmitter from sensor pod
- 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 sensor pod and transmitter, review the following safety statements to make sure you don't harm yourself.

8.2 Safety Statements

Warning

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

Do: *Seek professional medical help if you have symptoms of infection or inflammation (for example, redness, swelling or pain) at the insertion site.*

If your sensor breaks under your skin, report it to Technical Support (available 24/7) as soon as possible:

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 G5 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

Do: *Keep Transmitter until it's battery life has ended.*

Why: Transmitter is reusable.

- Use for multiple sessions

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8.3 Ending Your Sensor Session

There are different ways your session might end.

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 prompts you to end the session.

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

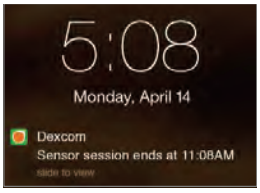
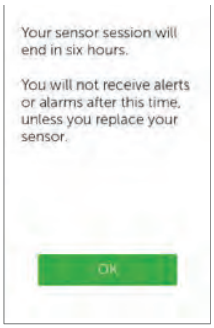
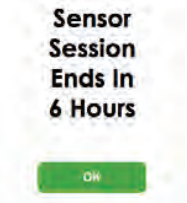
Ending Your Seven-Day Sensor Session

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

- App
  - o **Tap** *screen*
- Receiver
  - o **Tap** *OK*

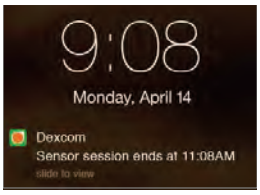
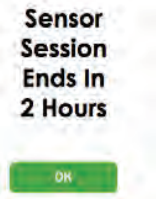
End Seven-Day Sensor Session Prompts

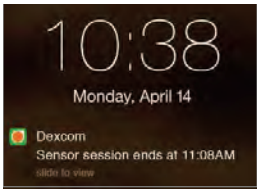
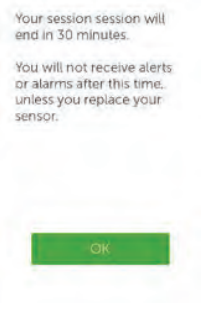
Ending Sensor Session Prompts

Device	What you see	What it means
At Six Hours		
Smart Device: Lock Screen		Prompts begin when sensor session has only six hours left. Clock will countdown until session has ended. Continue to get sensor glucose readings.
Smart Device: In App		
Receiver		

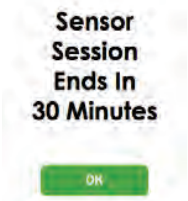
Device	What you see	What it means
At Two Hours		

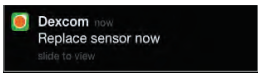
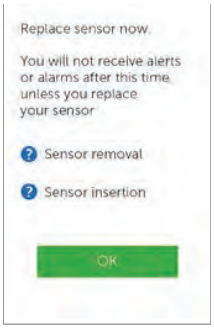
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Device	What you see	What it means
Smart Device: Lock Screen		Two hours remain on your current sensor session. Continue to get sensor glucose readings.
Smart Device: In App		
Receiver		

Device	What you see	What it means
At Thirty Minutes		
Smart Device: Lock Screen		Thirty minutes remain. Continue to get sensor glucose readings.
Smart Device: In App		

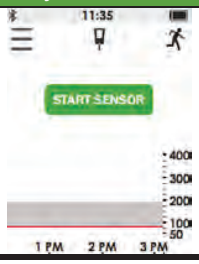
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Device	What you see	What it means
Receiver		

Device	What you see	What it means
Session Ended		
Smart Device: Lock Screen		Session has ended. **App** **Tap** screen's *"?"* for steps to: • Remove sensor • Insert new sensor **Receiver** **Tap** *OK* to clear.
Smart Device: In App		
Receiver		

Device	What you see	What it means
Session Stopped		
Smart Device: Lock Screen	N/A	Sensor session has stopped. **App** • No sensor glucose readings • Prompts for new session **Receiver**
Smart Device: In App		

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Device	What you see	What it means
Receiver		• Straight line o No sensor glucose readings

Sound/Vibration Prompts

In case you can't look at your screen, both the smart device and receiver provide beep/vibration prompts 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 prompts.

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

Smart Device

Your smart device prompts 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 prompt. 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 go to Chapter 6 in the 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 sensor pod).

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).

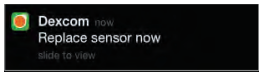
You'll receive error prompts leading to a new sensor session. If you see error prompts, before stopping a sensor session early, always contact Technical Support (available 24/7) at:

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

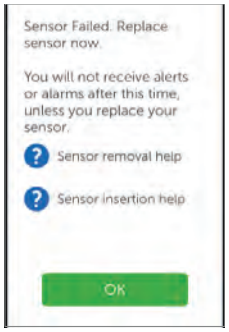
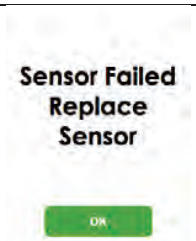
When your display device has system errors, you may not receive any sensor glucose readings and you should not calibrate.

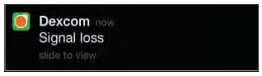
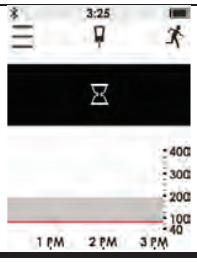
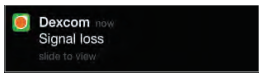
Prompts to End Sensor Session Early

System Prompts

Device	What you see	What it means
Smart Device: Lock Screen		Sensor issues detected. Session ends automatically.

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Device	What you see	What it means
Smart Device: In App		No: • Sensor Glucose Readings • Alarm/Alerts Replace sensor.
Receiver		

Device	What you see	What it means
Smart Device: Lock Screen		Wait up to three hours while the system autocorrects. Check transmitter–is it properly inserted into sensor pod? Make sure you haven't taken acetaminophen. If not corrected after 3 hours: • Contact Dexcom Technical Support
Smart Device: In App		
Receiver		
Smart Device: Lock Screen		Wait up to three hours while the system autocorrects. Check transmitter–is it properly inserted into sensor pod? Make sure you haven't taken acetaminophen. If not corrected after 3 hours: • Contact Dexcom Technical Support
Smart Device: In App		
Receiver		

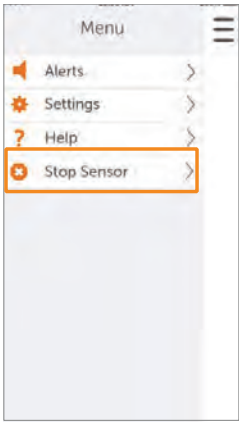
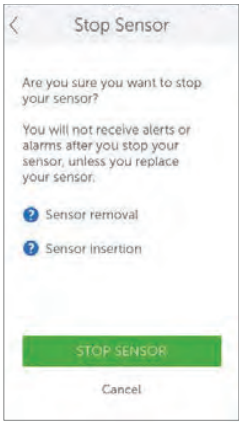
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The G5 Mobile knows when a typical seven-day sensor session is over, automatically ending the session in each display device. However, if you need to end the session early, you need to let the system know by manually stopping the sensor session.

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.

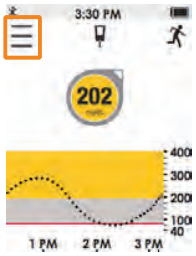
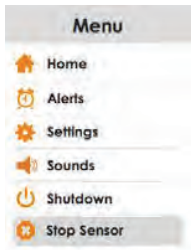
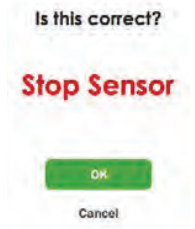
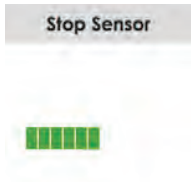
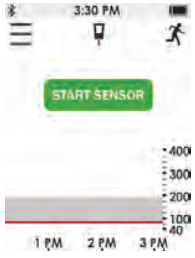
App: Ending a Sensor Session Early

Step	What you see	What it means	What you do
1		Access Main Menu.	**Tap** *Main Menu* icon.
2		Ends sensor session. During session: • *Stop Sensor* option appears Not in active session: • *Start Sensor* option appears	**Tap** *Stop Sensor*.
3		Blue "?" icons provide additional information.	**Tap** *Stop Sensor*.
4		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

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Step	What you see	What it means	What you do
1		Go to Main Menu.	**Tap** *Menu*.
2		Ends sensor session. During session, *Stop Sensor* option appears.	**Tap** *Stop Sensor*.
3		Do you want to stop the sensor?	**Tap** *OK*.
4		Thinking screen.	**Wait.**
5		Ready to start a new session. Not in active session, *Start Sensor* option appears.	**Remove** sensor. **Insert** new sensor. **Tap** *Start Sensor* when ready for new session.

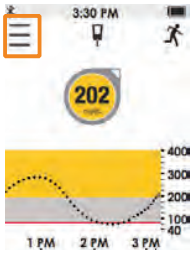
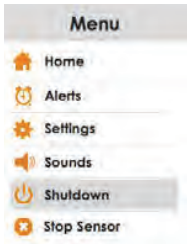
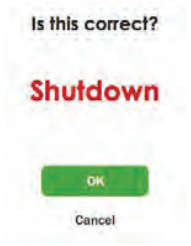
Temporarily Shut Down Receiver

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.

Receiver: Temporary Shutdown

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Step	What you see	What it means	What you do
1		Go to Main Menu.	**Tap** *Menu*.
2		Turns off receiver.	**Tap** *Shutdown*.
3		Confirms you want to shut down. Shuts down receiver.	**Tap** *OK*.

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

Preventing Sensor Failures

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 in sensor pod.
3. Sensor pod isn't dislodged or adhesive isn't peeling.
4. Nothing is rubbing against sensor pod (for example, seat belts, etc.).
5. You selected a good insertion site (see Chapter 6).
6. Insertion site is clean and dry before sensor insertion.

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.

8.4 Remove Sensor Pod and Transmitter

Remove Sensor Pod

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

To remove the sensor pod:

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

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Remove Transmitter From Sensor Pod

Remember that the transmitter is reusable–do not throw away. It lasts 90 days and can be used in multiple sensor sessions. Keep using it until the system notifies you the transmitter battery is about to expire.

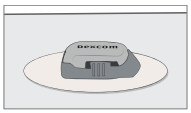
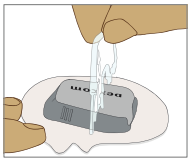
Before reusing the transmitter in your new sensor session, remove it from the old sensor pod.

You can detach transmitter two ways:

1. Use safety lock (see With Safety Lock table). You removed this from the applicator barrel at the beginning of the session.

2. Manually spread out tabs holding transmitter in sensor pod (see Without Safety Lock table).

With Safety Lock

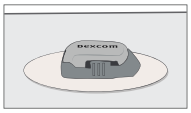
Step	Picture	What you do
1		**Grasp** end of *adhesive patch*. **Peel** *adhesive patch* up and away from your body to remove *sensor pod* and *transmitter*.
2		**Put** *sensor pod* on flat surface.
3		**Place** *safety latch's* jagged edge: Over transmitter's wide edge In between open slots on sensor pod's sides
4		**Lift up** *safety latch*.

After removing your sensor, and taking the transmitter out of the sensor pod, you're ready to begin a new sensor session. The transmitter's battery is good 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.

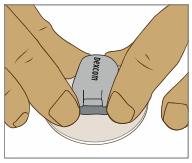
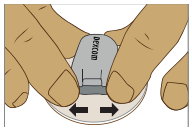
Remember:

1. Never use same spot repeatedly for sensor insertion.
2. Never use same site for 2 sensor sessions in a row.

Without Safety Lock

Step	Picture	What you do
1		**Grasp** end of *adhesive patch*. **Peel** *adhesive patch* up and away from your body to remove *sensor pod* and *transmitter*.
2		**Put** *sensor pod* on flat surface.

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Step	Picture	What you do
3		**Grasp** *sensor pod's* wide end with two hands and place fingers in sides' open slots.
4		**Pull** *tabs* away from transmitter.

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 countdown 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.

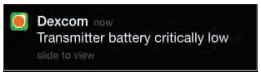
Transmitter Battery Messages

Device	What you see	What it means
Smart Device: Lock Screen		Transmitter battery will expire in three weeks. Order a new transmitter.
Smart Device: In App		
Receiver		

Device	What you see	What it means
Smart Device: Lock Screen		Transmitter battery will expire in two weeks. Order a new transmitter.

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Device	What you see	What it means
Smart Device: In App		
Receiver		

Device	What you see	What it means
Smart Device: Lock Screen		Transmitter battery will expire in one week. Order a new transmitter.
Smart Device: In App		
Receiver		

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 Chapter 16.1), or through the channels you used before, at your first low battery prompt.

Sound/Vibration Prompts

In case you can't look at your screen, both the smart device and receiver provide beep/vibration prompts 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 prompts.

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

Smart Device

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

Receiver

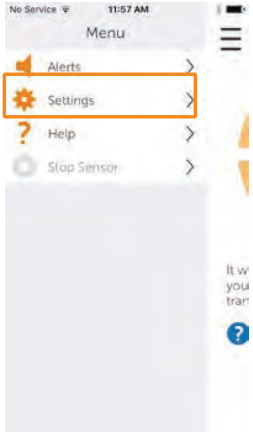
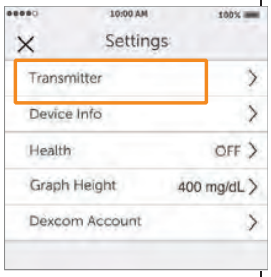
The receiver alerts you with an initial vibration prompt. If not cleared, you receive a vibrate/beep twice, five minutes apart.

8.6 Pair New Transmitter

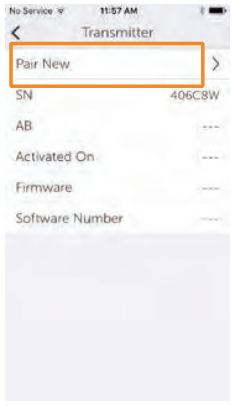
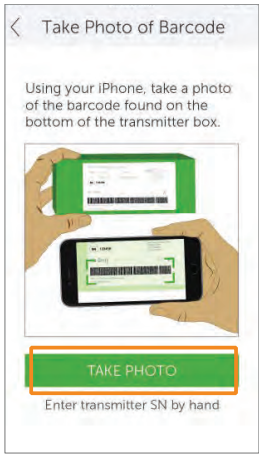
After the transmitter battery has died and before starting a new sensor session, you need to pair your new transmitter with your display device(s). In Chapter 5 you learned how to pair your transmitter using the set up wizard. But how do you pair a new transmitter once your display device is set up?

Part of pairing the transmitter is entering it's SN into your display device, inserting the sensor, and attaching the transmitter. After the transmitter and display device are paired,start a new sensor session.

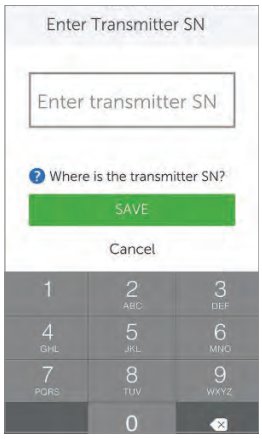
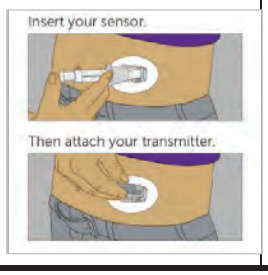
App

Step	What you see	What you do
1		**Tap** *Menu*
2		**Tap** *Settings*
3		**Tap** *Transmitter*

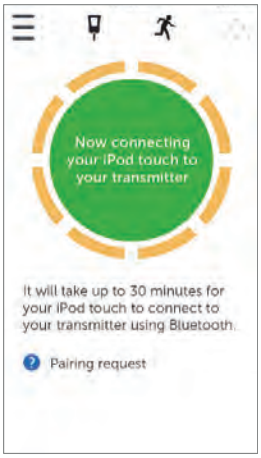
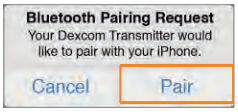
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Step	What you see	What you do
4		**Tap** *Pair New*
5a		**Turn** transmitter box **upside down** on a flat surface with barcodes facing up. (If you don't have the box, go to step 6a.)
5b		**Center** longest barcode within green brackets. **Tap** *Take Photo*
5c		Check mark confirms successful transmitter SN scan.

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Step	What you see	What you do
6a		Or, if you don't have the box, find the SN on the back of the transmitter and type it in. **Tap** *Enter transmitter SN by hand*.
6b		**Use** keyboard to enter transmitter SN. **Confirm** correct SN . **Tap** *Save*.
7		**Insert** sensor and **attach** transmitter. See Chapter 6 for more information.

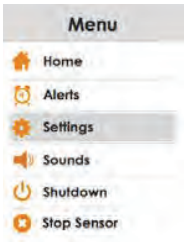
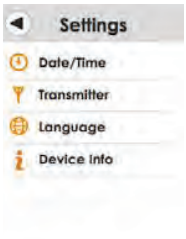
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Step	What you see	What you do
8		**Wait** up to 30 minutes for smart device and transmitter to connect.
9		At notification, **Tap** *Pair* to pair app with smart device.
10		Before starting a new sensor session, make sure your smart device and transmitter are paired

Receiver

Step	What you see	What you do
1		**Press** and hold the *power button* for 2 seconds to turn receiver on.
2		**Tap** *Menu* **icon**

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Step	What you see	What you do
3		**Tap** *Settings*
4		**Tap** *Transmitter*
5		**Tap** *Transmitter SN*.
6a	8 	**Turn** *transmitter box* **upside down** to locate SN number.
6b		If transmitter package isn't available, SN is also on back of transmitter
6c		**Tap** *up/down arrows* to select and enter transmitter SN. **Tap** *number* to select it. To choose a letter, tap up from 9 or down from 0. **Tap** *Save* to save and close.

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Step	What you see	What you do
7		Insert sensor and attach transmitter. See Chapter 6 for more information.
8		**Make sure** *receiver* and *transmitter* are connected/paired. **Check** *receiver* 10 minutes after starting for *Bluetooth* icon. • Solid: Connected/paired • Blinking: Searching,/not paired Don't start a new sensor session until they are paired.

Summary

Now You Can!

- Identify replace sensor prompts 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 sensor pod with transmitter attached
- Separate transmitter from sensor pod
- Determine if transmitter can be used for another sensor session
- Pair a 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 G5 Mobile can do much more.

In the next part, Part 3: Next Steps, you will learn how to get the most out of your G5 Mobile.

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3

NEXT STEPS - GETTING THE MOST OUT OF YOUR G5 MOBILE

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

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Chapter 9

Next Steps - Getting the Most out of Your G5 Mobile:

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 entering your two initial calibrations 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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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: *Never take any medications containing acetaminophen during your sensor session.*

Why: Taking medications with acetaminophen (such as Tylenol or Excedrin Extra Strength) while wearing sensor may falsely raise sensor glucose readings. Level of 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 event.

Warning

Don't: *Never use the G5 Mobile sensor glucose readings for treatment decisions.*

Do: *Only use BG values from your BG meter for treatment decisions (for example, how much insulin to take).*

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

Consequences: Using sensor glucose readings for treatment decisions could result in you missing a severe low or high glucose event.

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Warning

Don't: *Never ignore symptoms of high and low glucose.*

Do: *Measure your BG with a fingerstick measurement if sensor glucose readings don't match your symptoms.*

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

Consequences: Using sensor glucose readings for treatment decisions could result in having severe low (hypoglycemia) or high (hyperglycemia) events.

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 Alarm or Alerts.

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 status. While the screen does look different between the receiver, smart device, Apple Today View, and Apple Watch, the information is the same.

The G5 Mobile app has two ways to view data based on how you hold your smart device:

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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.

To change between the 1, 3, 6, 12, or 24-hour trend information in the receiver, tap the graph.

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 to enter data or make system changes.

App Home Screen

The app's home screen has two main sections:

1. Task Bar
    a. Allows you to change settings, enter data, etc.
2. Glucose Information
    a. Reflects sensor glucose readings and trends.



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Figure 6. Example App Home Screen on Smart Device

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App Task Bar

App	Name	What it means	What you do
Task Bar: Complete Tasks			
	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 Prompt.	**Tap** *icon* 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** *icon* to enter data for: • Carbs • Insulin • Exercise • Health (See Chapter 10).

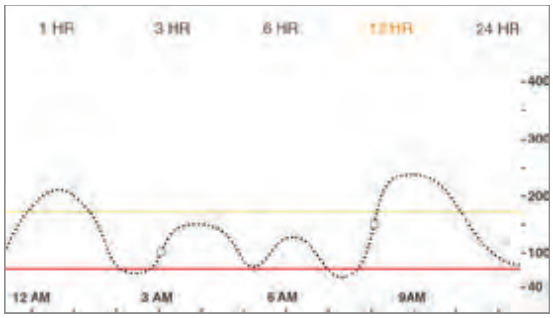
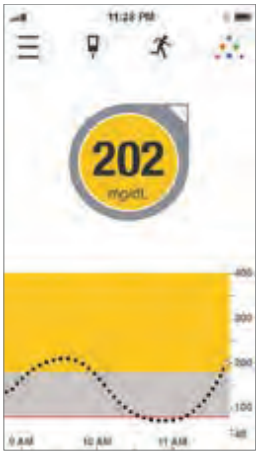
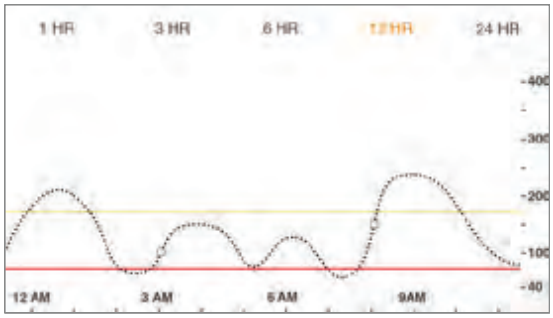
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App	Name	What it means	What you do
	Dexcom *Share*	Dexcom *Share* is available only on the app. Gray icon means *Share* is not active.	**Tap** *icon* to activate (see Part 5).
	Dexcom *Share*	Once activated, Dexcom *Share* icon is colored.	**Do nothing.** **Tap** *icon* to access Dexcom *Share*.

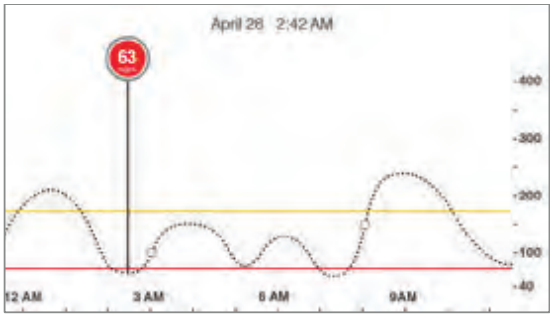
App Glucose Information

App: Portrait	App: Landscape	What it means
Glucose Information: Review		

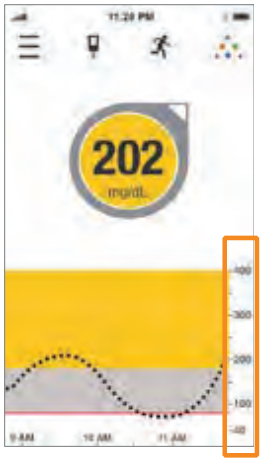
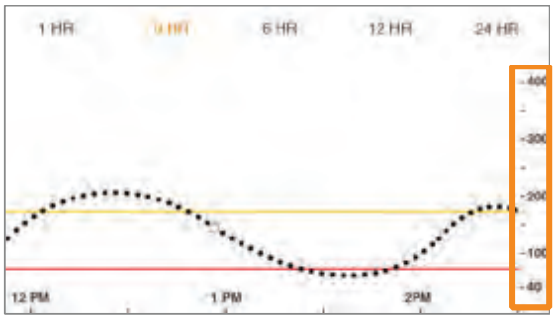
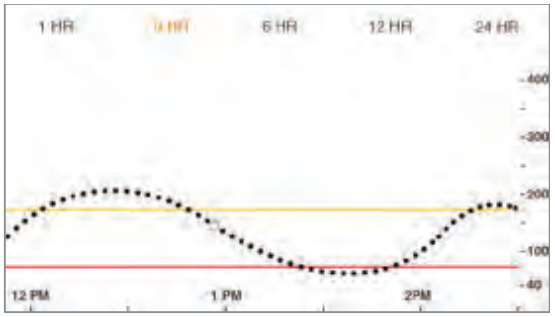
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App: Portrait	App: Landscape	What it means
		**Home Screen** In Landscape mode, **Tap** the *trend view* you want to see at the top of the screen: 1, 3, 6, 12, or 24-hour historical trend views.
		**Number:** Most recent sensor glucose reading. Shown in milligrams per deciliter (mg/dL). • Yellow: At or above target • Gray: Within range • Red: At or below target

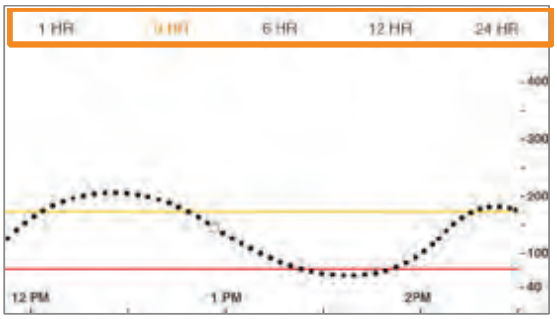
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App: Portrait	App: Landscape	What it means
N/A		**Historical Readings** **Turn** smart device to *Landscape* mode. **Tap** *time*: shows time frame's sensor glucose reading. Slide finger across screen to view rest of day's sensor glucose readings.
	N/A	**Rate of Change Arrow** Direction and number of arrows show sensor glucose change rate.

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App: Portrait	App: Landscape	What it means
		**Sensor Glucose Reading Range** Shows between 40-400 mg/dL.
		**Within Glucose Range and Alert Levels** • Yellow: High Alert level • Gray: Within range • Red: Low Alert level or, if that's disabled, 55 mg/dL (Urgent Low Glucose Alarm)

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App: Portrait	App: Landscape	What it means
		**Trend Graph Time Frame** Default is most recent 3 hours. **Turn** smart device to *Landscape* mode for most recent 1, 3, 6, 12, and 24-hour readings.

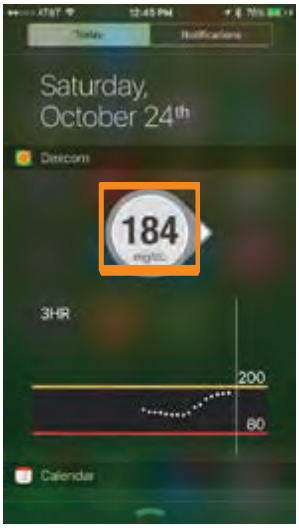
Apple Today View Widget

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 Apple mobile 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			

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

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Apple Today View	Name	What it does	What you do
	Trend Arrow	Shows direction and speed your glucose is changing.	Review and take appropriate action based on fingerstick BG value. (See Chapter 9)

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

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.

Like your smart device, your receiver has a touchscreen..

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The receiver's home screen has three sections:

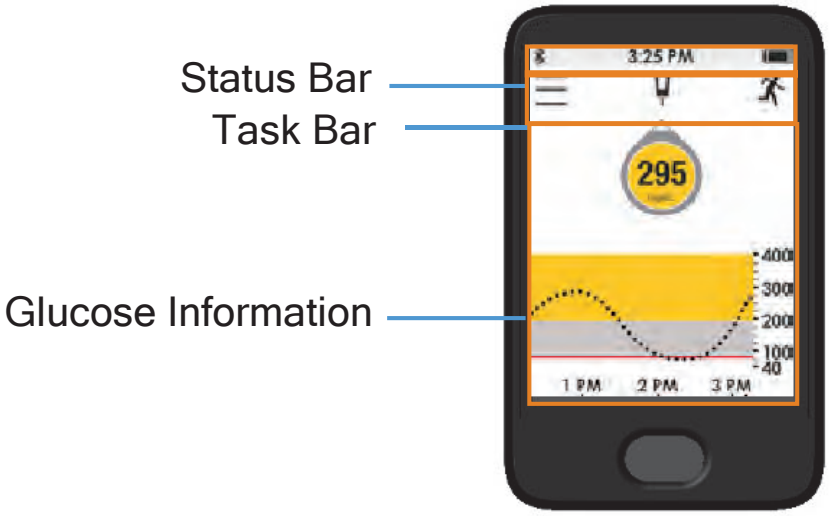


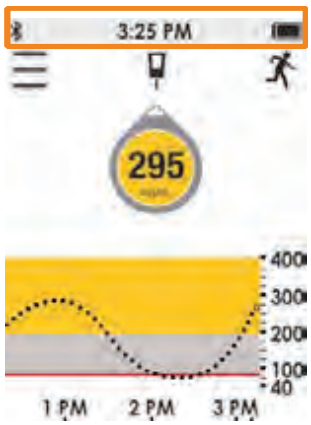
Figure 7. Home Screen on Receiver

- Status Bar: Shows Bluetooth status, system time, and battery level.
- Task Bar: Tap icons to go to the Main Menu, enter your BG numbers, or record Events.
- Glucose Information: Shows your sensor glucose readings and trends.

Receiver Status Bar

Receiver	Name	What it does	What you do
Status Bar: System Information			

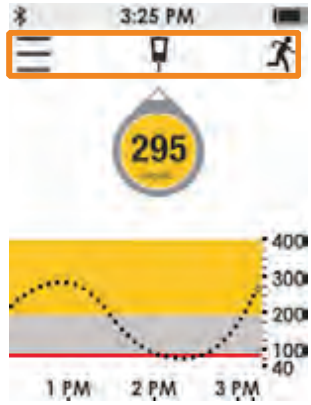
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Receiver	Name	What it does	What you do
	Status Bar	At-a-glance receiver information. Icons change based on what's happening.	Review and take appropriate action.
	*Bluetooth*	Shows *Bluetooth* is connected.	Do nothing. Receiver's *Bluetooth* is always on. If blinking, move receiver closer to transmitter.
	*Time*	Shows system time.	Do nothing. To change, go to Settings.

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Receiver	Name	What it does	What you do
	Battery	Shows battery level.	When low, **plug** *micro USB cable* into receiver. **Plug** *USB* into the adapter and then into electrical outlet (see Chapter 14).

Receiver Task Bar

Receiver	Name	What it does	What you do
Task Bar: Complete Tasks			
	Task Bar	Goes to the Main Menu, enter BG meter values, and record Events.	**Tap** applicable *icon*.

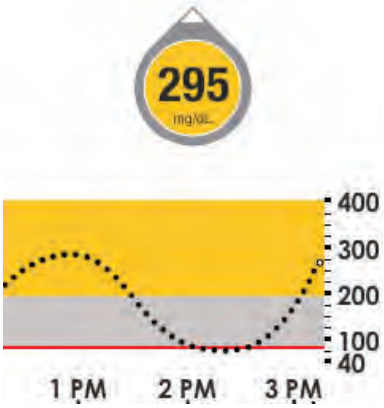
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Receiver	Name	What it does	What you do
	Main Menu	Goes to other options.	**Tap** *Main Menu* icon to access: • Alerts • Settings • Sounds • Shutdown • Start/Stop Sensor
	BG Meter with red circle and number	Calibration Prompt.	**Tap** *icon* and enter fingerstick BG value (see Chapter 7).
	BG Meter without red circle	No need to calibrate.	Do nothing.

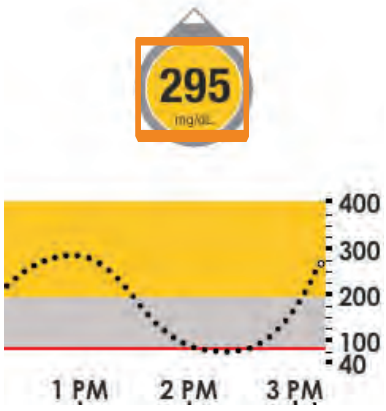
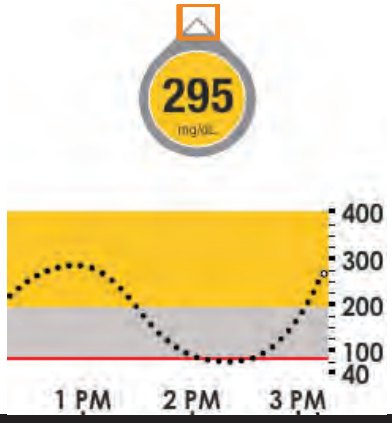
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Receiver	Name	What it does	What you do
	Events	Enter different events, capturing activities affecting your glucose.	**Tap** *icon* to enter data for: • Carbs • Insulin • Exercise • Health (See Chapter 10).

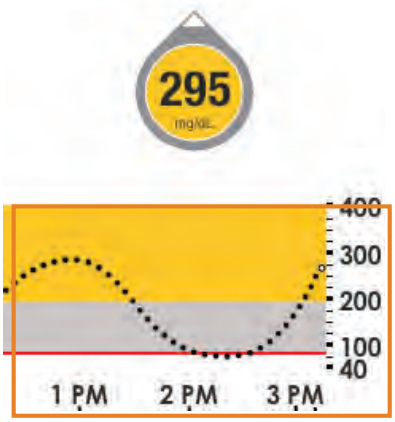
Receiver Glucose Information

Receiver	Name	What it does	What you do
Glucose Information: Review			
	Glucose Information	Displays your glucose information: • Current glucose number • Direction your glucose is heading • Graph of glucose trend	Review and take appropriate action.

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Receiver	Name	What it does	What you do
	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.
	Trend Arrow	Shows direction and speed your glucose is changing.	Review and take appropriate action based on fingerstick BG value. (See Chapter 9)

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Receiver	Name	What it does	What you do
	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)	**Tap** *graph* for 1, 3, 6, 12, or 24-hour trend views.

Now that you're familiar with the basic layout of the trend graph screen and 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.

Apple Watch

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Receiver	Name	What it does	What you do
	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.
	Sensor Glucose Reading	Shows most recent sensor glucose reading.	Take appropriate action.

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Receiver	Name	What it does	What you do
	Trend Arrow	Shows direction and speed your glucose is changing.	Review and take appropriate action based on fingerstick BG value. (See Chapter 9)
	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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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.

Rate of Change Arrows

Change Arrows	What your glucose is doing
	Steady Changing: • Less than 1 mg/dL each minute • Up to 15 mg/dL in 15 minutes
	Slowly Rising or Falling Changing: • 1-2 mg/dL each minute • Up to 30 mg/dL in 15 minutes
	Rising or Falling Changing: • 2-3 mg/dL each minute • Up to 45 mg/dL in 15 minutes

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Change Arrows	What your glucose is doing
	Rapidly Rising or Falling Changing: • More than 3 mg/dL each minute • More than 45 mg/dL in 15 minutes
N/A	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(s), causing you to not 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.

App

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.

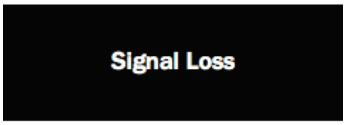
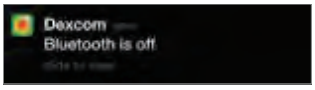
Receiver

1. **Tap** *OK* to clear message.

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

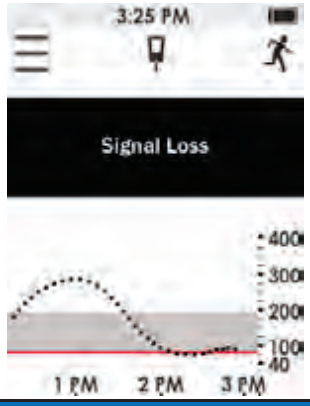
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Error Messages

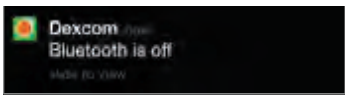
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<tr><td>Smart Device:
Lock Screen</td><td> 
</td><td rowspan="3">Make sure there are no obstructions, such as a wall or water between your transmitter and your display device.
Move within 20 feet of display device.
Wait up to 30 minutes while transmitter restores communication.</td></tr>
<tr><td>Smart Device:
In App</td><td> 
</td></tr>
<tr><td>Receiver</td><td> 
</td></tr>
<tr><td colspan="3">Bluetooth Off</td></tr>
<tr><td>Smart Device:
Lock Screen</td><td> 
</td><td rowspan="2">Smart device:
1. Exit app.
2. Tap Settings.
3. Tap Bluetooth.
4. Turn Bluetooth on.</td></tr>
<tr><td>Smart Device:
In App</td><td> 
</td></tr>
</table>

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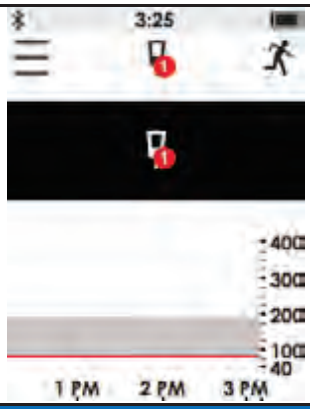
<table>
<tr><td>Receiver</td><td>N/A; Bluetooth is always on.</td><td></td></tr>
<tr><td colspan="3">Not Getting Sensor Glucose Reading</td></tr>
<tr><td>Smart Device: Lock Screen</td><td>N/A</td><td rowspan="3">Check–Are you:
Within 20 feet of your display device?
In your two-hour warmup period?
Outside of your calibration schedule?
In a sensor session?</td></tr>
<tr><td>Smart Device: In App</td><td>N/A</td></tr>
<tr><td>Receiver</td><td> 


</td></tr>
<tr><td colspan="3">System Found Temporary Sensor Issue</td></tr>
<tr><td>Smart Device: Lock Screen</td><td>N/A</td><td>Don’t calibrate.
System may correct problem on its</td></tr>
</table>

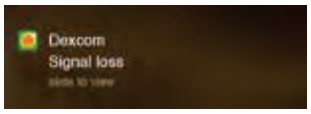
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Smart Device: In App		own and display sensor glucose readings again. If prompt stays for three hours: Contact Technical Support (see Chapter 16.1).
Receiver		
Transmitter and Sensor Not Communicating		
Smart Device: Lock Screen	N/A	Wait three hours while the transmitter tries to fix the error. Do not enter calibrations during this time. Make sure your transmitter is properly inserted into the sensor pod. If not corrected: • Contact Technical Support (see Chapter 16.1) • Remove sensor • Insert new sensor
Smart Device: In App		
Receiver		
Calibration Required		
Smart Device: Lock Screen		Error in calibrating. Verify you did not enter a BG

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Smart Device: In App		reading outside the range of 40-400 mg/dL. Enter another BG meter value
Receiver		
Calibration Error		
Smart Device: Lock Screen	N/A	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.
Smart Device: In App		

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<table>
<tr><td>Receiver</td><td> 
</td><td>Contact Technical Support (available 24/7) at:
TechSupport@dexcom.com
Toll free: 1.888.738.3646
Toll call: 1.858.200.0200</td></tr>
<tr><td colspan="3">Display Devices and Transmitter not Communicating</td></tr>
<tr><td>Smart Device: Lock Screen</td><td> 
</td><td rowspan="3">App/Receiver:
Wait 10 minutes.
Move display device and transmitter within 20 feet of each other without obstruction (walls or water).
Wait up to 30 minutes.
In app (if not fixed):
Tap Settings.
Tap Bluetooth.
Turn Bluetooth Off and On.Tap OK
Tap Settings.Turn Bluetooth Off and On.</td></tr>
<tr><td>Smart Device: In App</td><td> 
</td></tr>
<tr><td>Receiver</td><td> 
</td></tr>
</table>

If error messages don’t go away after you followed necessary steps, and you

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aren't getting sensor glucose readings, contact Technical Support (see Chapter 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
- Recognize error messages

What's Next?

By now you have a pretty good understanding 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 G5 Mobile.

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Chapter 10

Next Steps - Getting the Most out of Your G5 Mobile:

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
    - App
    - Receiver
- Recognize Event markers on the 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 co-workers 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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An Event is an action or situation affecting your glucose levels. With the G5 Mobile, 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:

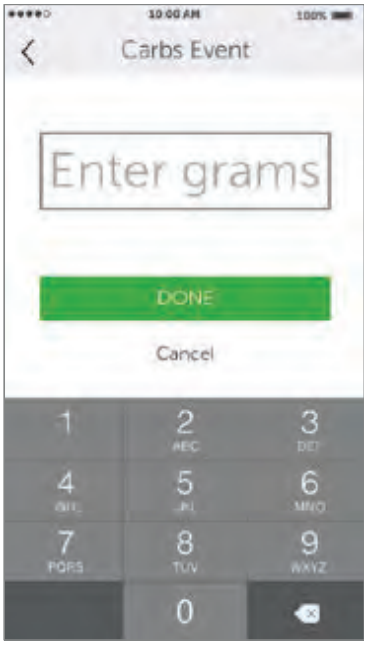
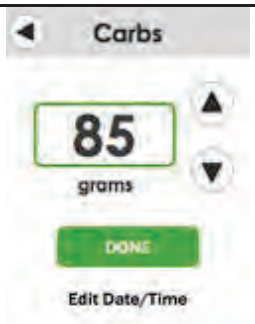
- Illness
- Stress
- Feel High
- Feel Low
- Cycle
- Alcohol

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

Events Menu

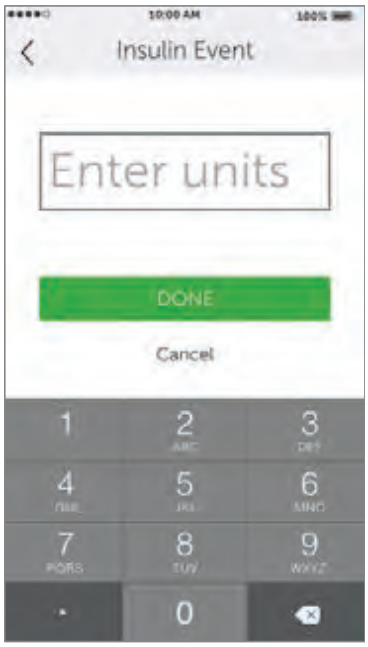
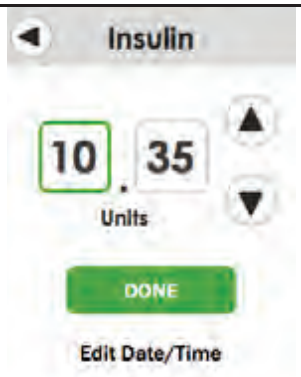
Device	What you see	What it means	What you do
Carbs			

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Device	What you see	What it means	What you do
Smart Device: In App		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			

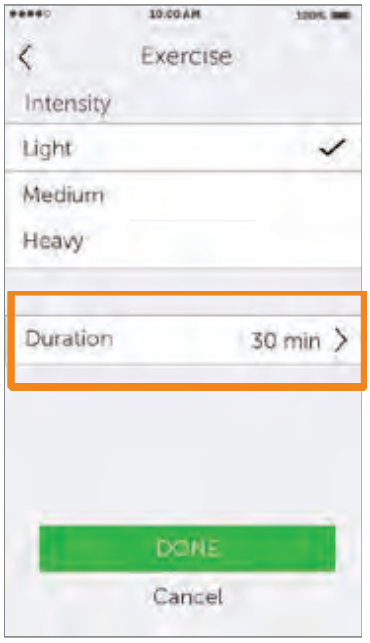
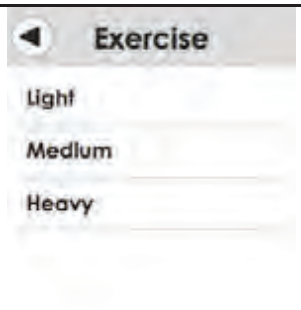
Device	What you see	What it means	What you do
Insulin			

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Device	What you see	What it means	What you do
Smart Device: In App		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			

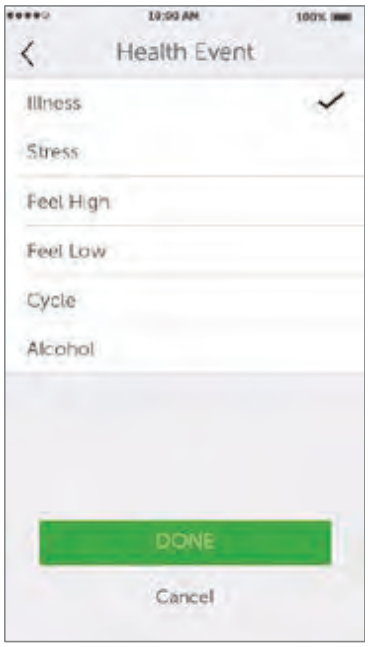
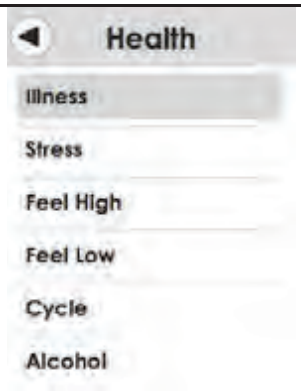
Device	What you see	What it means	What you do
Exercise			

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Device	What you see	What it means	What you do
Smart Device: In App		Default is 30 minutes.	Select each exercise's intensity level and duration. Enter intensity and duration. Type of exercise isn't an option.
Receiver			

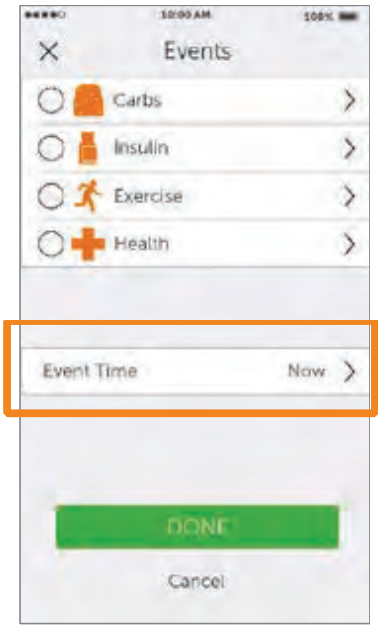
Device	What you see	What it means	What you do
Health			

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Device	What you see	What it means	What you do
Smart Device: In App		General well-being.	Enter different health Events (see following Health Events Menu table).
Receiver			

Device	What you see	What it means	What you do
Event Time			

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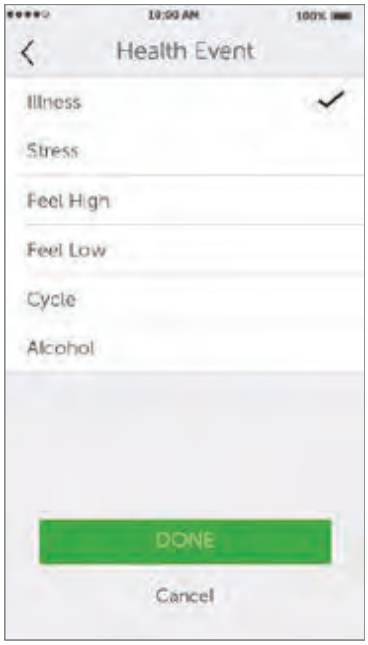
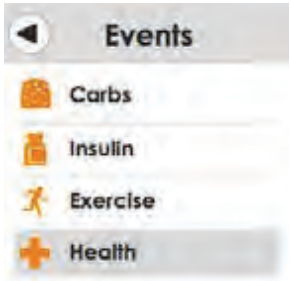
Device	What you see	What it means	What you do
Smart Device: In App		Event time.	For each separate Event, enter date/time Event began.
Receiver			

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.

Health Events Menu

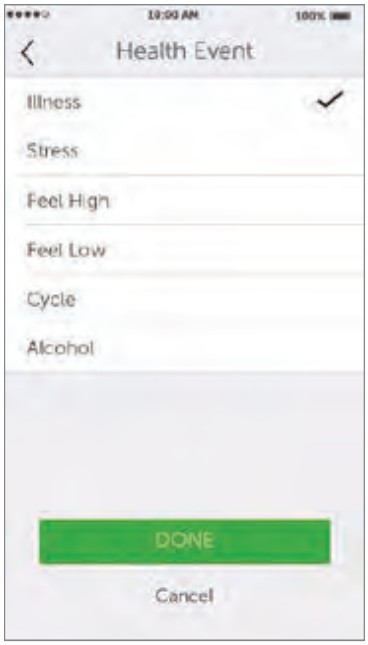
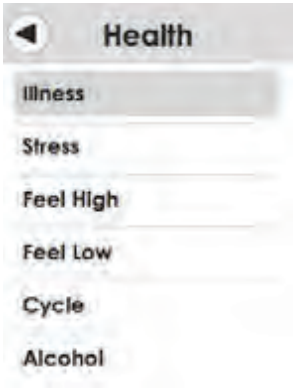
Device	What you see	What it means
Health Main Menu		

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Device	What you see	What it means
Smart Device: In App		Use Health Main Menu to access selections.
Receiver		

Device	What you see	What it means
Health Main Menu		

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Device	What you see	What it means
Smart Device: In App		**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? **Low Symptoms** Feel low BG symptoms? **Cycle** Have you started your menstrual cycle? **Alcohol** Had a glass of wine, beer, or cocktail?
Receiver		

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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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 meant to be 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.

Enter Events: Smart Device

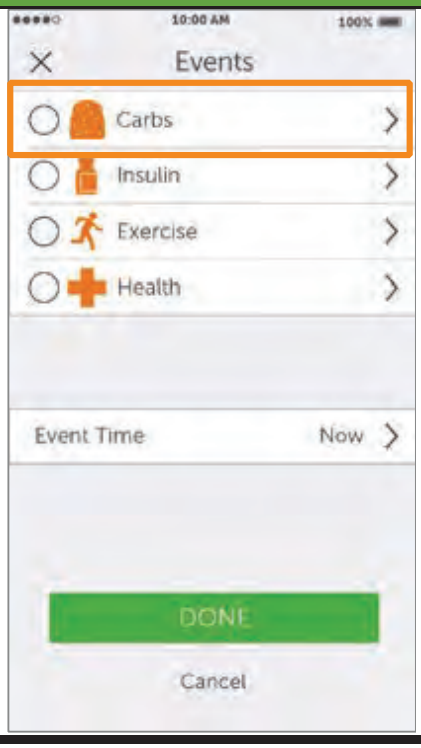
In the G5 Mobile app, Events are just a tap away! The Event icon, a running man, is on the app's home screen's task bar in portrait mode (remember, you don't have the task bar in landscape).

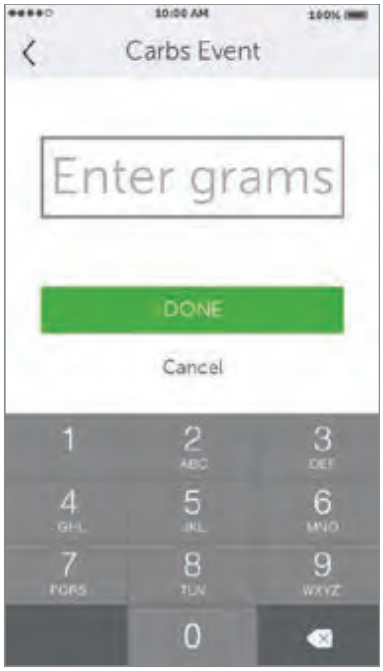
Entering Events for the Carbs, Insulin, Exercise, and Health categories follows the same steps. If you can enter a Carbs Event, you can enter an Insulin Event. To enter Events, we'll use the above scenario. The following table shows how to enter Carbs (drive-thru lunch) and Stress (traffic jam) Events.

Entering Events: G5 Mobile App

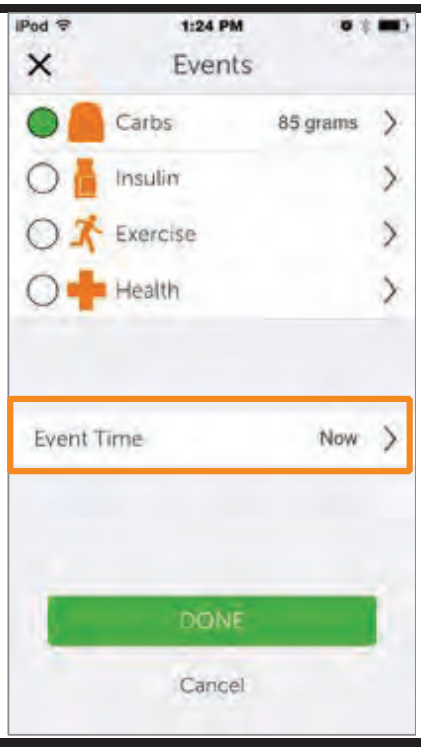
Step	What you see	What you do
Enter Carbs Event		
1		**Tap** *Events* icon.

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Step	What you see	What you do
2		**Tap** *Carbs*.

Enter Carbs Event		
3		Using the above example, add up all carb grams from lunch. **Enter** "85" using keypad. **Tap** *Done*.

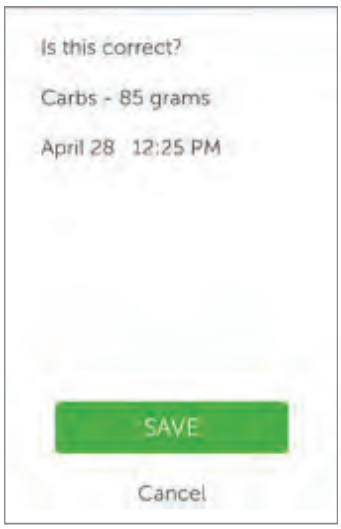
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4		Tap *Event Time*.

Enter Carbs Event

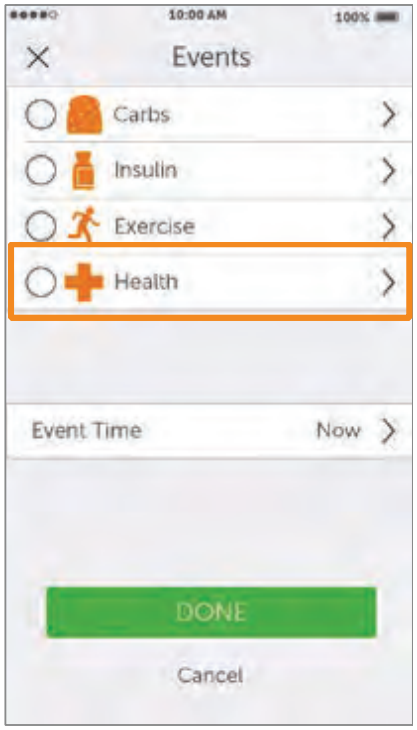
5		**Scroll** and **select** date and time. **Tap** *Done*.

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6		**Tap** *Save* or *Cancel*.

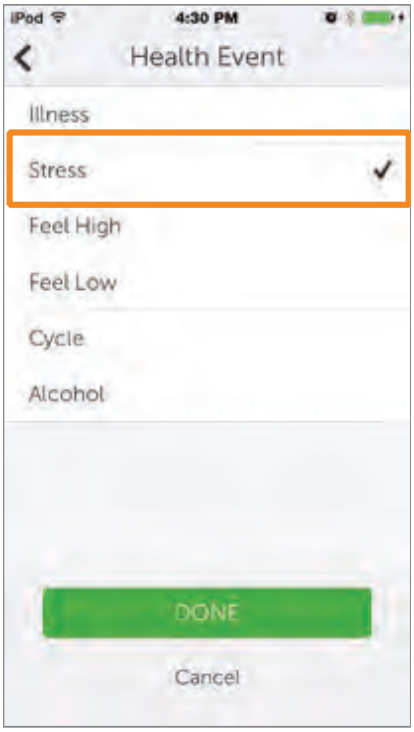
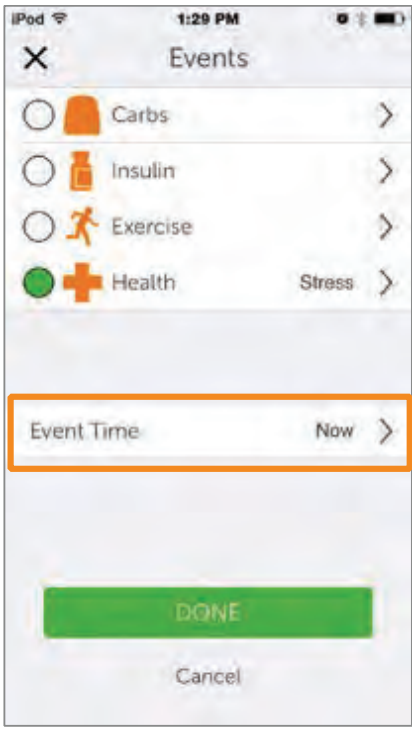
Enter Stress Event		
7		**Tap** *Events* icon.

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8		Tap *Health*.

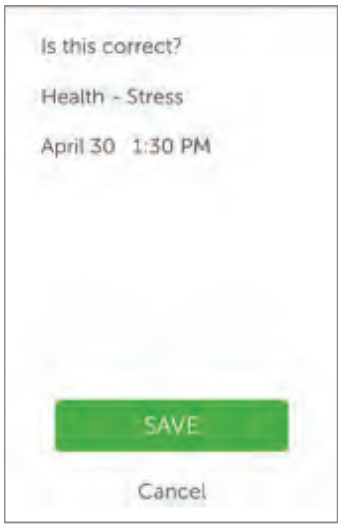
Enter Stress Event

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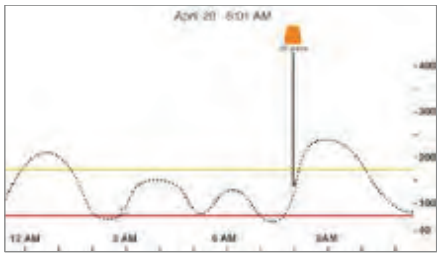
9		**Tap** *Stress*. **Tap** *Done*.
10		**Tap** *Event Time*.

Enter Stress Event

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11		**Scroll** and **select** date and time. **Tap** *Done.*
12		**Tap** *Save* or *Cancel.*

View Events

13		**Trend graph shows events.** **Turn** to landscape to see more.

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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.

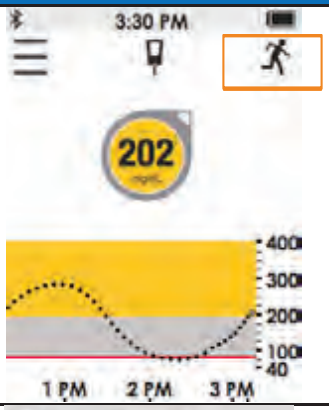
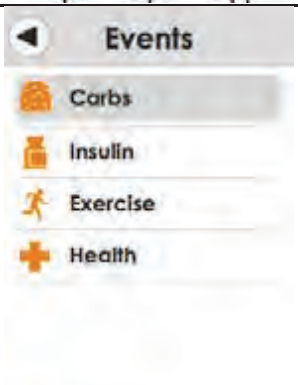
The app has Event markers on its screen, but the receiver doesn't.

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

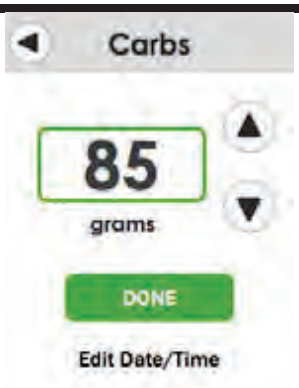
Enter Events: Receiver

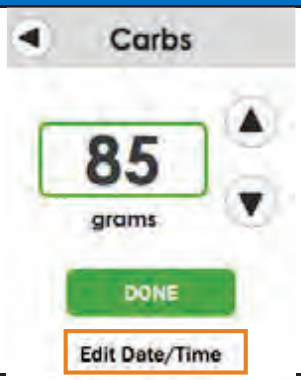
While the Event data is the same between display devices, the flow is not the same, including how to enter the Event's date and time. The following table reviews how to enter the same Carbs/Stress Event data from the previous scenario: Carbs at 85, and a Stress Event.

Entering Events: Receiver

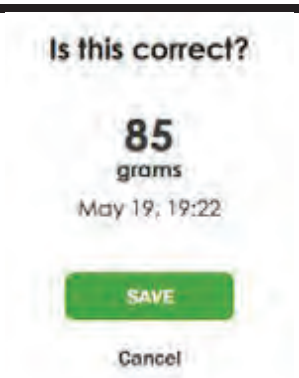
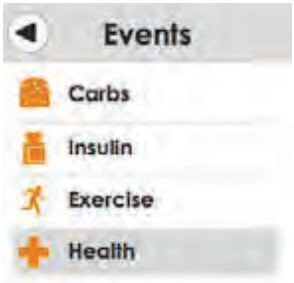
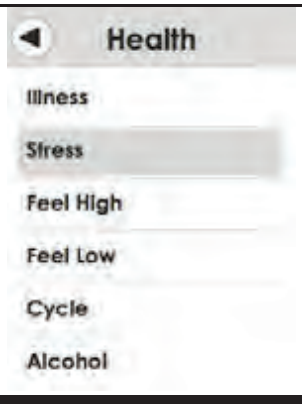
Step	What you see	What you do
Enter Carbs Event		
1		Default screen **Tap** *Events* icon.
2		**Tap** *Carbs.*

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3		Add up all carb grams from lunch. For example, 85. Tap *arrow* to “85.” Tap *Done.*

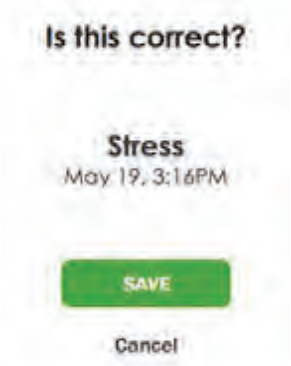
Enter Carbs Event		
4		Tap *Edit Date/Time*
5		Tap *year/month/day* box to select date. Tap *up/down arrow* to change hour. Tap *Minutes* to select them. Tap *up/down arrow* to change minutes. Tap *AM/PM* to select it. Tap *up/down arrow* to change between AM and PM. Tap *Done* to save and close.

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6		Confirmation screen. **Tap** *Save*.
Enter Health Event		
7		**Tap** *Health.*
8		**Tap** *Stress*

Enter Health Event

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9		**Tap** *year/month/day* box to select date. **Tap** *up/down arrow* to change hour. **Tap** *minutes* to select them. **Tap** *up/down arrow* to change minutes. **Tap** *AM/PM* to select it. **Tap** *up/down arrow* to change between AM and PM. **Tap** *Done* to save and close.
10		**Tap** *Save.*

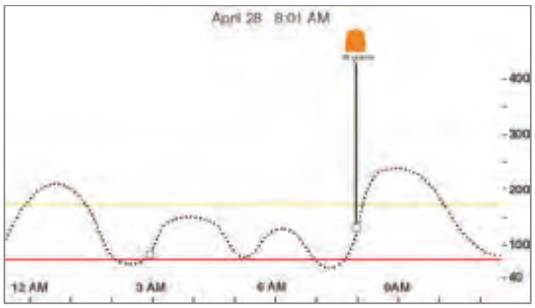
10.4 Viewing Events

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

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

Landscape	What it does	What you do

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	Landscape Only Shows Event details.	Landscape Only **Tap** *square.* Slide finger across screen.

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

Summary

Now You Can:

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

What's Next?

In the next chapter, you will learn about your trend's Alarm and Alerts helping you monitor 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 - Getting the Most out of Your G5 Mobile:

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 or at the movies and can't, or don't want to, keep looking at your display device?

The G5 Mobile 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 prompts 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 G5 Mobile. 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 your smart device settings let you get Alarm and Alerts.*

To receive Alarm/Alerts you must:

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

Why: Your app's settings do not override phone settings.

Consequences: Missing severe low or high glucose Alarm or Alerts.

Warning

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

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

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

Consequences: Missing severe low or high glucose Alarm or Alerts.

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Warning

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

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

Consequences: Missing severe low or high glucose Alarm or Alerts.

Precaution

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

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

Why: If your transmitter 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 types have been tested. Obstructions can include water, walls, metal, etc.

Water (for example, when swimming, surfing, bathing, etc.) can severely limit communication range.

Consequences: Missing severe low or high glucose Alarm or Alerts.

Precaution

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

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

Consequences: Missing severe low or high glucose Alarm or Alerts.

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Precaution

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

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

Consequences: Missing severe low or high glucose Alarm or Alerts.

11.3 Alarm and Alerts

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

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

What Is an Alarm?

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

Unlike Alerts, the Urgent Low 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 prompts, 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 prompts, 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/Signal Loss Alerts

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

Glucose Level Alerts

1. Rise Rate
    a. Default setting is Off–No Alert.

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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 G5 Mobile's 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 tells you. As mentioned in previous chapters, you won't get any Alarm or Alerts within five minutes of calibration.

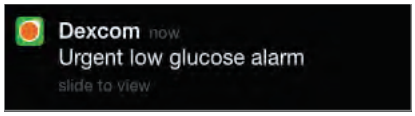
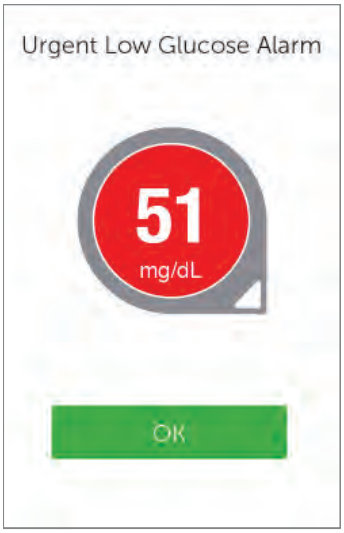
Let's first review how the information is presented visually across the devices. While the Alarm/Alerts prompts look different on the display devices, they reflect the same information.

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

Urgent Low Glucose Alarm

Device	What you see	What it means

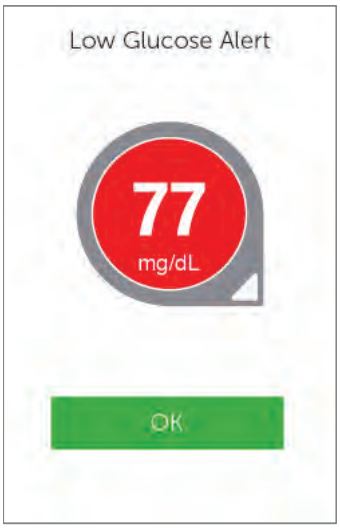
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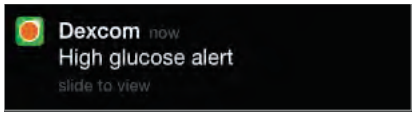
Smart Device: Lock Screen		Sensor glucose reading at or below 55 mg/dL. Shows last glucose value. Arrows reflect rate of change. Check BG meter to make treatment decisions.
Smart Device: In App		
Receiver		

Low/High Glucose Alerts

Device	What you see	What it means
Smart Device: Lock Screen		Sensor glucose reading at or below your low Alert level. Shows most current sensor

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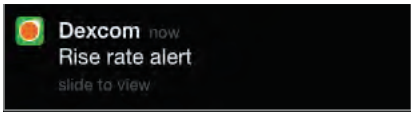
Smart Device: In App		glucose reading. Arrows reflect rate of change. Can be set to repeat between 15 minutes to 4 hours. Check your BG meter to make any treatment decisions.
Receiver		

Device	What you see	What it means
Smart Device: Lock Screen		Sensor glucose reading at or above your high Alert level. Shows most current sensor

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Smart Device: In App		glucose reading. Arrows reflect rate of change. Can be set to repeat between 15 minutes to 4 hours. Check BG meter to make treatment decisions.
Receiver		

Rise Rate/Fall Rate Alerts

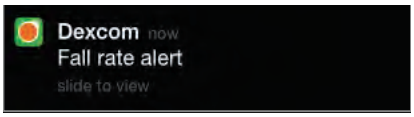
Device	What you see	What it means
Smart Device: Lock Screen		Sensor glucose readings rising quickly.

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Smart Device: In App	 	Number of arrows shows how fast (2 mg/dL/min; 3+ mg/dL/min) glucose is rising. Check BG meter to make any treatment decisions.

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Receiver		

Device	What you see	What it means
Smart Device: Lock Screen		Sensor glucose readings falling quickly.

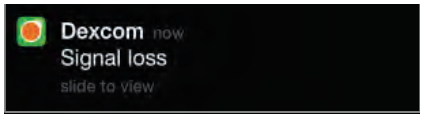
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Smart Device: In App	 	Number of arrows shows how fast (2 mg/dL/min; 3+ mg/dL/min) glucose is falling. Check BG meter to make any treatment decisions.

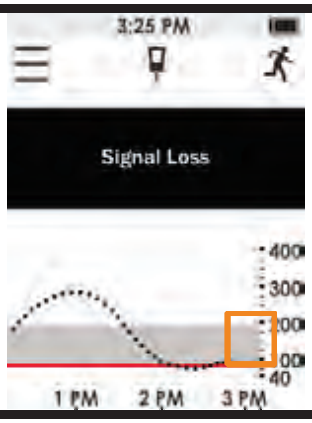
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Receiver		

Signal Loss Alert

Device	What you see	What it means
Smart Device: Lock Screen		Your receiver and transmitter are not communicating. You will not receive glucose readings or Alarm/Alerts. Check BG meter to
Smart Device: In App		

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Receiver		check your glucose and make any treatment decisions.

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 settings:

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

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

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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
	**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. **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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	**Initial Default Alert:** Vibrates 3 times. **After 5 Minutes:** Vibrates/beeps 3 times every 5 minutes until cleared or sensor glucose readings rises above Alert level. Trend screen will continue to reflect Alert until sensor glucose readings go above Alert level.
	**Initial Default Alert:** Vibrates 2 times. **After 5 Minutes:** Vibrates/beeps 2 times every 5 minutes until cleared.or sensor glucose readings go below Alert level. Trend screen will continue to reflect Alert until sensor glucose readings go below Alert level.

Rise Rate/Fall Rate Alerts

What you see	Beeps and vibration

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	**Initial Default Alert:** None/Off. **After Setting Change:** Vibrates 2 times, 2 sounds. **After 5 Minutes:** Vibrates/beeps 2 times every 5 minutes until cleared or sensor glucose reading rises rate drops below Alert level.
	**Initial Default Alert:** None/Off. **After Setting Change:** Vibrates 3 times. **After 5 Minutes:** Vibrates/beeps 3 times every 5 minutes until cleared or sensor glucose reading fall rate rises above Alert level.

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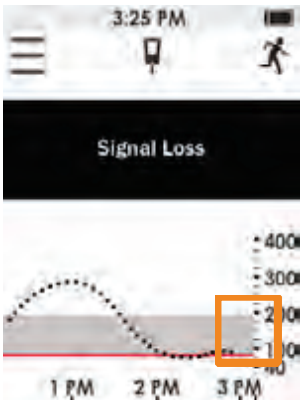
Low Repeat/High Repeat

What you see	Beeps and vibration
	**Initial Default Alert:** None/Off. **After Setting Change:** Vibrates 3 times. **After 5 Minutes:** Vibrates/beeps 3 times every 5 minutes until cleared or sensor glucose reading rises above Alert level. Will re-alert if sensor glucose readings drop at or below 55 mg/dL.
	**Initial Default Alert:** None/Off. **After Setting Change:** Vibrates 2 times. **After 5 Minutes:** Vibrates/beeps 2 times every 5 minutes until cleared or sensor glucose reading drops below Alert level.

Signal Loss Alert

What you see	Beeps and vibration

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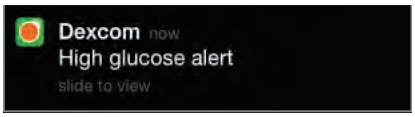
	**Initial Default Alert:** On. **After Setting Change:** Vibrates 1 time. **After 5 Minutes:** Vibrates/beeps 1 time every 5 minutes for a total of 6 times if not cleared. After 6 times it will not alert again.

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, an 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		**Slide** *Alarm* or *Alert* to access app.

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Smart Device: In App		**Tap** *OK* to accept Alarm or Alert.

Clearing Your Receiver

What you see	What you do
	**Tap** *OK.*

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

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- Describe the difference between an Alarm and an Alert
- Recognize different Alarm/Alert prompts and sounds
- Determine if signal loss is preventing you from getting an Alarm/Alert
- Describe recommended app settings
- Successfully clear an Alert
    - 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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Chapter 12

Next Steps - Getting the Most out of Your G5 Mobile:

On the Go With G5: Customizing Your Alarm and Alerts

12.1 Introduction

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

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

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

After this chapter you will be able to:

- Customize your glucose trend Low/High Alerts prompts
    - App
    - Receiver
- Adjust Alarm sound prompts
- Set up other 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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Warning

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

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

Consequences: Missing severe low or high Alarm or Alerts.

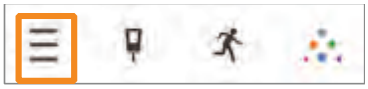
12.3 Changing App Alarm and Alerts

App Screen Overview

The Alerts Main Menu lists all customizable Alerts and 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.

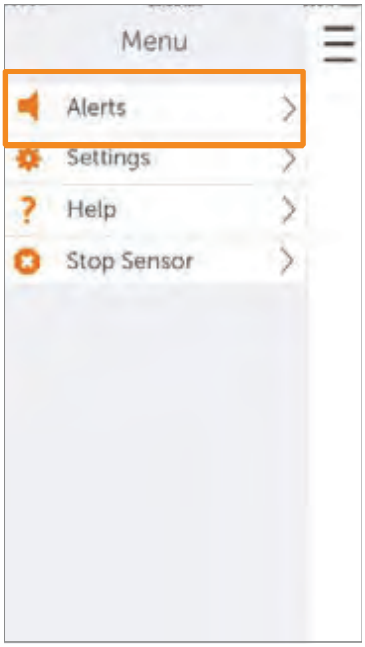
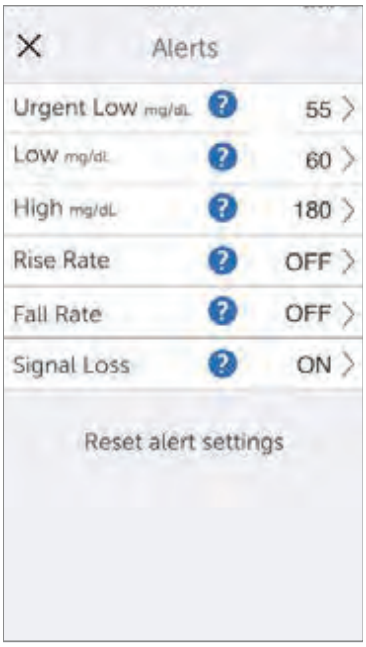
Before learning how to change your settings, let's review the app's Alerts Main Menu screen.

Customizing Alerts: App Alarm/Alerts Screen Overview

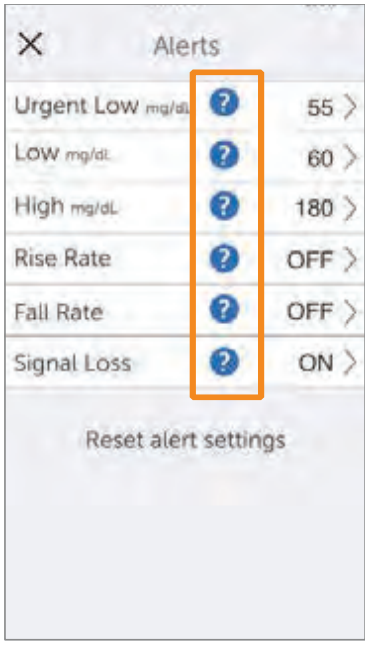
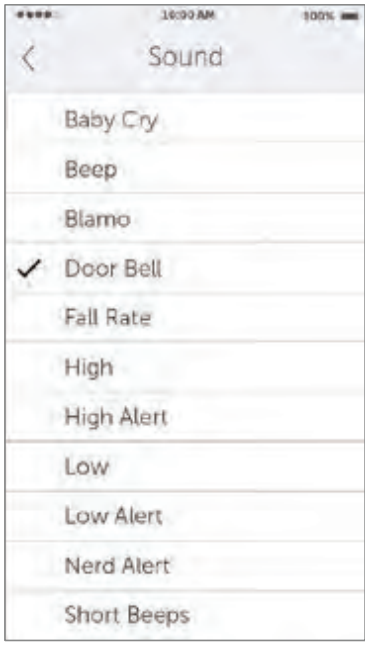
Step	What you see	What it means	What you do
1		Access Main Menu.	**Tap** *Main Menu* icon.

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		Access Alerts Main Menu.	**Tap** *Alerts*.
3		All customizable Alarm and Alerts. Current Alert settings. All Alerts have: • *On/Off* switch • *Notify me* options • *Sound* options	**Tap** *Alarm/Alert* you want to change.

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Step	What you see	What it means	What you do
4		"?" explains: • Each Alarm/Alert • Message options • Recommended settings	**Tap** *"?"* for Alarm/Alert information.
5		Urgent Low Glucose Alarm: • Preset at 55 mg/dL and cannot be changed • *Repeat* preset at 30 minutes and can't be changed • *Sound* is the only change option	**Tap** *Sound* to change sound.

Steps to Customize App Alarm/Alerts

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

From app's Main Menu:

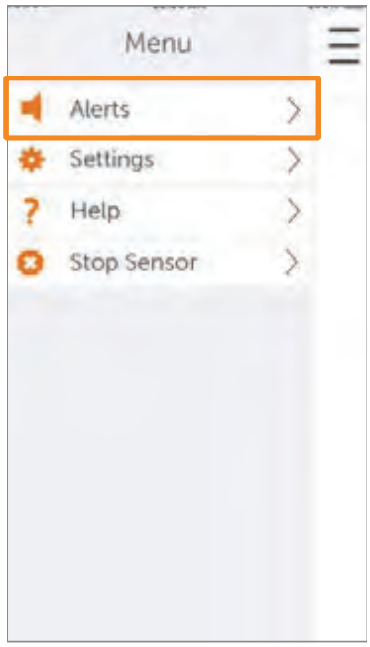
1. **Tap** *Alerts*.
2. **Tap** the *Alert* you want.
    a. **Tap** *On* or *Off* switch to turn on desired Alerts.
3. **Tap** *Notify me*.
    a. Change the Alert glucose level (mg/dL).
        i. **Scroll** selection wheel, find your desired Alert level.
        ii. **Tap** to highlight.
        iii. **Tap** *Save*.
4. **Tap** *Repeat*.
    a. 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

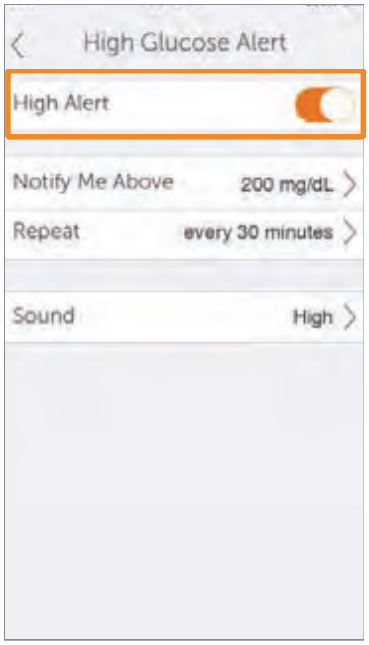
Step	What you see	What it means	What you do
Access Alerts Main Menu			
1		Access Main Menu.	**Tap** *Main Menu* icon.

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Step	What you see	What it means	What you do
2		Access Alerts Main Menu.	**Tap** *Alerts.*

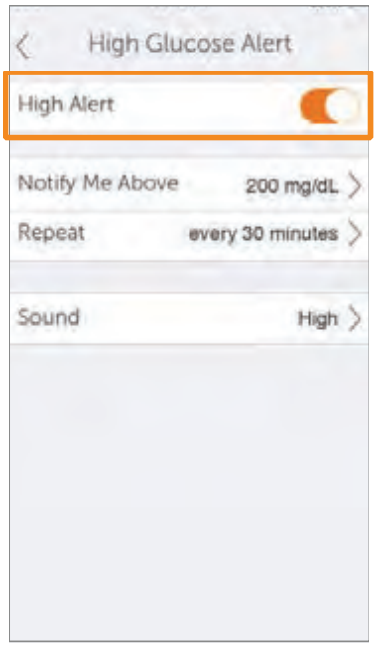
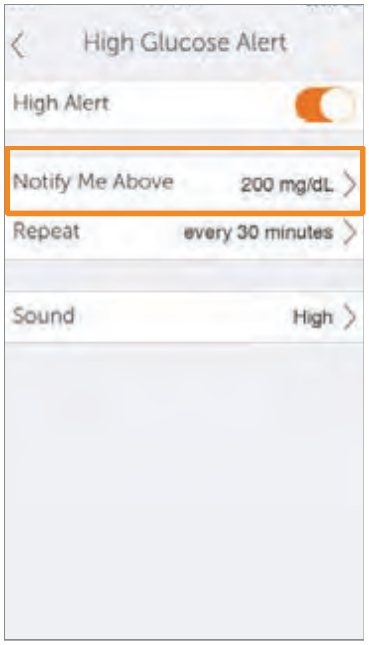
Changing an Alert

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3		Access High Alert settings (mg/dL).	**Tap** *High mg/dL.*
4		Shows High Alert options and current settings.	**Check** *High Alert* is On. • On - Orange • Off - Gray

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5		Won't get Alerts if Off.	If Off: **Slide** to *On*. • On - Orange • Off - Gray
6		Change High Alert (mg/dL).	**Tap** *Notify Me Above*.

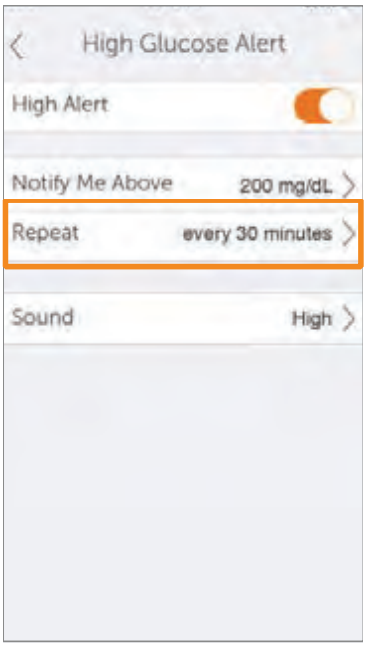
Changing an Alert

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

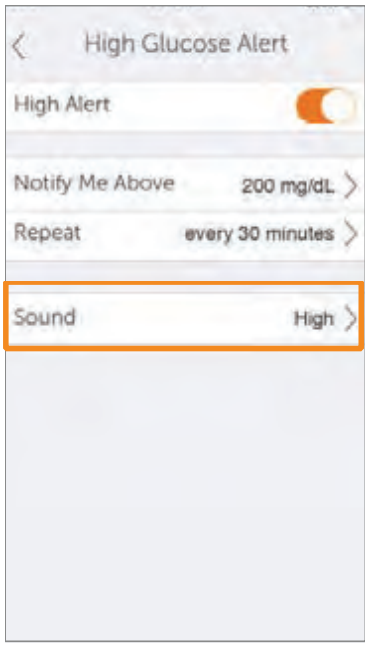
Changing an Alert

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9		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		Changing the current repeat setting. Can select in 5-minute steps (range 15 minutes-4 hours).	**Scroll** *selection wheel.* **Stop** at 1 hour.

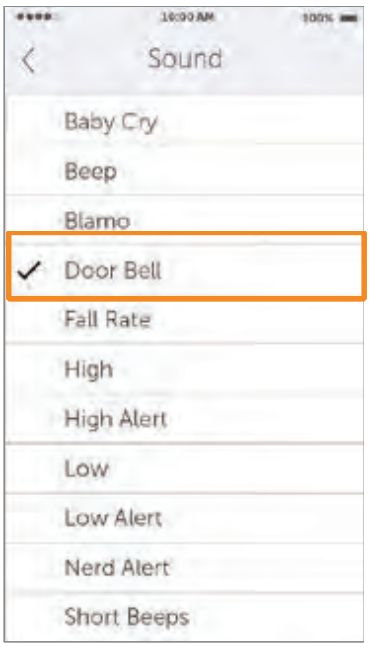
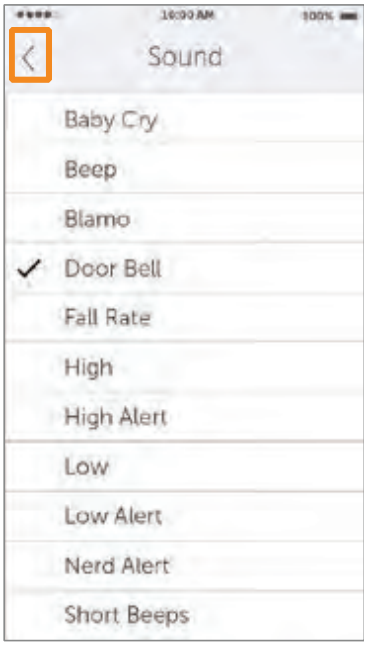
Changing an Alert

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11		Saves your new repeat timing. Returns to *High Glucose Alert* screen options. *Repeat* shows how often you'll get notified.	**Tap** *Save.*
12		Customize Alert sound.	**Tap** *Sound.*

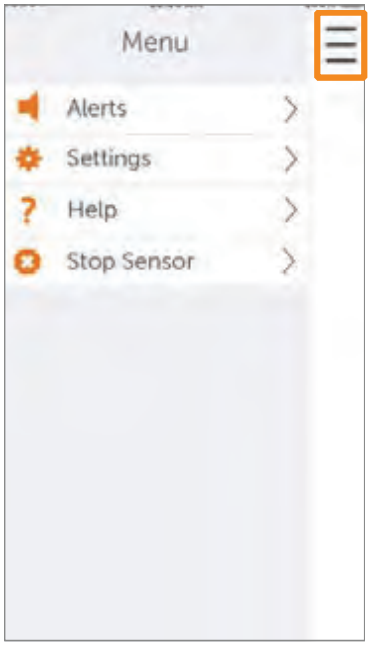
Changing an Alert

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13		Changes current sound setting.	**Tap** *Door Bell.* **Tap** *Sound* again to hear sound sample.
14		Saves your new Alert sound. Return to *High Glucose Alert* Menu.	**Tap** *back arrow.*

Changing an Alert

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15		Return to Main Menu.	**Tap** *"X".*
16		Return to trend screen.	**Tap** *Menu* icon Or **Swipe** right.

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

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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 sounds) in the Sounds menu.

Sounds

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

Normal is the default setting for your receiver sounds.

Attentive uses a rising or falling melody instead of beeps.

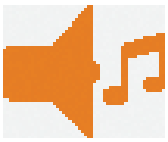
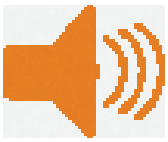
The receiver first vibrates when sending you an Alarm or Alert. If you clear the Alarm/Alert at the first vibration, you won't get any Alarm/Alert tones. If you would like to continue to get your Alarm or Alert after clearing, later in this chapter you'll learn about setting up Repeat Alerts.

HypoRepeat is very similar to the *Normal* sound, 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 tapping *OK* on your screen.

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

Alarm/Alert Sounds

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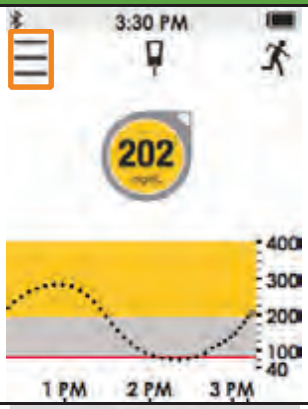
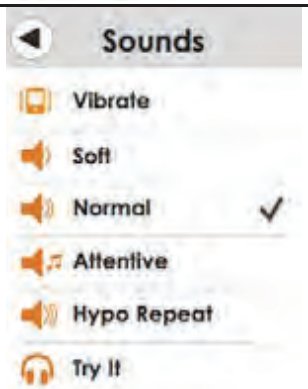
Icon	Sound Name	Sound Description
	Vibrate	Vibration only. Only sound is your receiver vibrating. Vibrate is not available for the Urgent Low Glucose Alarm.
	Soft	Lower volume beeps.
	Normal	Medium volume beeps. Default Sound.
	Attentive	No beeps. Rising melody for High and Rising Alerts Dropping melody for Low and Falling Alerts
	HypoRepeat	Medium volume beeps. Urgent Low Glucose Alarm only. Repeats Urgent Low Glucose Alarm every 5 seconds until sensor glucose reading rises above 55 mg/dL or is confirmed.
	Try It	Sample sound setting before selecting. This does not select your sound. To select your sound, use the *Sounds* menu.

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

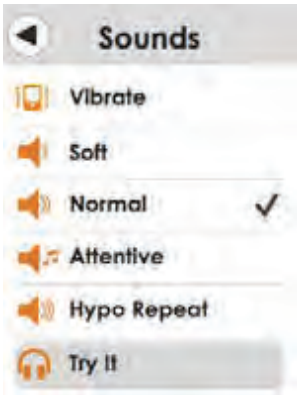
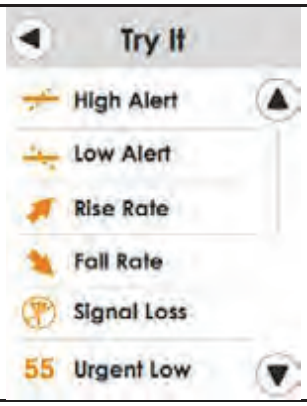
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The next table shows how to change your Sound, then hear a sample of it.

Customizing Alert Sounds: Receiver

Step	What you see	What it means	What you do
1		Go to Main Menu.	**Tap** *Menu* icon.
2		Change your Sounds.	**Tap** *Sounds.*
3		Choose one. Selected Sound is check marked.	**Tap** *your choice.*

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Step	What you see	What it means	What you do
4		Hear your Sound.	Sample Sound: **Tap** *Try It* to hear selected Sound. Exit Sound: **Tap** *left arrow*.
5		Hear Sound for each Alarm/Alert.	**Tap** the *Alarm/Alert* to hear. To Exit: **Tap** *left arrow.*
6	N/A	Repeat as needed.	**Repeat** steps 2-5 to change Sound.

In the previous chapter, you learned clearing an Alert stops it from repeating. If you want the Urgent Low Glucose Alarm to repeat until your glucose levels are back above 55 mg/dL, turn on the *Hypo Repeat* option.

Alerts Menu

The Alerts menu gives you options for personalizing your glucose level Alerts and turning on your Rising/Falling and Signal Loss Alerts.

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Low and High

Adjust your Low and High Glucose Alert levels (mg/dL) along with turning on and setting the time for the Repeat prompt.

Rise and Fall Rates

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 and Fall Rate Alerts 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 is *Off* for Repeat, Rise Rate, and Fall Rate.

It's important that 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 alerted if your sensor glucose readings have stopped due to a signal loss lasting anywhere from 20 to 200 minutes.

The default setting for Signal Loss is *On*.

Steps to Customize Receiver Alarm/Alerts

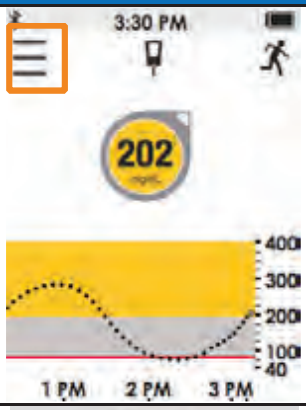
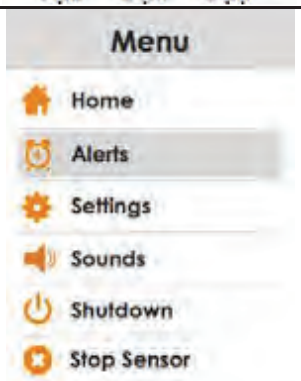
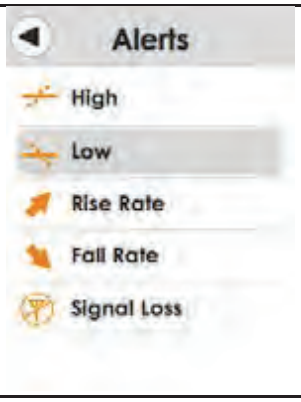
Using the same example from changing your app Alerts, let's change the receiver's High Alert level from 200 mg/dL to 190 mg/dL, repeating every 60 minutes.

Follow these same steps for turning on the Rise/Fall Rate Alerts and adjusting your Low Alerts.

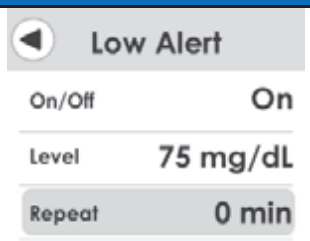
Customizing Alerts: Receiver

Step	What you see	What it means	What you do

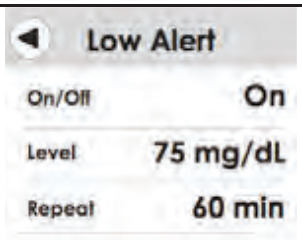
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Step	What you see	What it means	What you do
Change Low Alert Level			
1		Go to Main Menu.	**Tap** *Menu* icon.
2		Alerts option from the Main Menu.	**Tap** *Alerts.*
3		Alert's current settings. Change your current Low Alert level.	**Tap** *Low.*

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4		Current setting.	**Tap** *Level.*
5		Saves new Low Alert level. Return to Alerts Menu.	**Tap** *up/down arrows* to change number. To save and exit: **Tap** *Save.*
Turn On Repeat			
6		Current setting is updated.	**Tap** *Repeat* to have the Alert keep prompting you.
7		Initial screen shows current repeat minutes. Change time frame in 15-minute increments.	**Tap** *up/down arrows.* **Stop** at 60 minutes.

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8		Changed *Repeat* time for Low Repeat Alert.	**Tap** *Save.*
9		Change completed. Return to *Alerts Menu.*	To exit: **Tap** *left arrow*.

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:

- Customize your glucose trend Low/High Glucose Alerts
  - App
  - Receiver
- Adjust Alarm sound
- Set up other Alerts
  - Low/High Repeat
  - Rise/Fall Rate

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- Signal Loss

What's Next?

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

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

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

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4

EVERYTHING ELSE G5

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

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Chapter 13

Everything Else G5:

Warranty: The Fine Print

13.1 Introduction

Sometimes stuff happens. Dexcom has you covered!

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

13.2 Receiver Warranty Information

G5 Mobile'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 G5 Mobile receiver (the "receiver") is free from defects in material and workmanship under normal use ("Limited Warranty") for the period starting from the shipment date and continuing for a year following the shipment date ("Warranty Period"):

G5 Mobile receiver: **1 year** from shipment date

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

What's Not Covered?

This Limited Warranty is based on the Purchaser properly using the CGM system in accordance with the documentation provided by Dexcom. You are not permitted to use the CGM system otherwise. You understand that misusing the CGM system, improperly accessing it or the information it

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processes and transmits, “jailbreaking” your CGM system or cell phone, and taking other unauthorized actions may put you at risk, cause the CGM system to malfunction, is not permitted and voids your Limited Warranty.

This Limited Warranty does not cover:

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

Dexcom’s Obligations Under the Limited Warranty

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

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

The return package needs to include:

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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
- Charges may apply: 1.858.200.0200

Upon receipt, Dexcom will promptly replace the defective receiver.

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

Limits on Dexcom's Warranty and Liability Obligations

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

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

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

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

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

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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

G5 Mobile Transmitter Limited Warranty

What's Covered and for How Long?

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

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

What's Not Covered?

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

This Limited Warranty does not cover:

1. Defects or damage resulting from accident, misuse, abuse, neglect, unusual physical, electrical or electromechanical stress, modification of any part of the product, or cosmetic damage.

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2. Equipment with the ID number removed or made illegible.
3. All surfaces and other externally exposed parts that are scratched or damaged due to normal use.
4. Malfunctions resulting from the use of the transmitter in conjunction with accessories, ancillary products, and peripheral equipment, whether hardware or software, not furnished or approved by Dexcom.
5. Defects or damage from improper testing, operation, maintenance, installation, or adjustment.
6. Installation, maintenance, and service of products or services other than the CGM system (which may be subject to a separate limited warranty), whether provided by Dexcom or any other party; this includes your cell phone or smart device and your connection to the Internet.
7. Equipment which has been taken apart physically or which has had any of its software accessed in any unauthorized manner.
8. Water damage to transmitter.
    a. Beyond specifications listed in 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 G5 Mobile transmitter.

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

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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**
- Charges may apply: **1.858.200.0200**

Upon receipt, Dexcom will promptly replace the defective transmitter.

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

Limits on Dexcom's Warranty and Liability Obligations

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

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

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

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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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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Chapter 14

Everything Else G5:

How to Take Care of Your G5 Mobile

14.1 Introduction

There are not a lot of moving parts in the G5 Mobile, 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
    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. Receiver

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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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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: *Check for the receiver to briefly vibrate and beep shortly after you power on or plug in to charge. If it doesn't, please retry. If it still doesn't vibrate and beep, contact Technical Support.*

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

Use the app on your smart device until this issue is resolved.

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

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

14.3 Basic Maintenance

Sensor

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

Transmitter

1. Keep in box until ready for use.
    a. Check transmitter and don't use if damaged.
2. Transmitter is reusable, but only by the same person.
    a. Never share transmitter with anyone.
3. Between uses, clean outside of the transmitter with damp cloth or alcohol wipes. Let dry before use or storage.
4. When not in use

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a. Protect transmitter by returning to its packaging or another safe place.
b. Store between 32° F-113° F.

Receiver

1. Check receiver casing; if it's cracked or damaged, don't use.
    a. May get an electric shock.
    b. Don't open it. There are no serviceable parts inside.
2. Keep receiver dry–it is only splash resistant.
    a. Don't submerge in liquid.
    b. Don't spill fluids on receiver.
3. Use case to protect receiver from bumps and falls.
    a. When putting case on, make sure the speaker holes align with receiver's speaker.
4. Keep battery charged.
    a. Only use Dexcom USB charging/download cable.
5. Do not push anything into the small hole on the back of the receiver.

Charging Receiver's Battery

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

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

Step	What you see	What it means	What you do

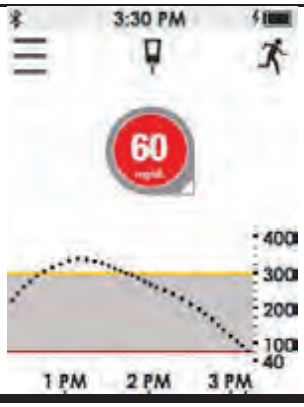
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Step	What you see	What it means	What you do
1		Low Battery	Charge your battery.
2		Micro USB Port	**Plug** *USB cable* into port for recharging.

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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.

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Step	What you see	What it means	What you do
5		Within 6 seconds, receiver will beep and vibrate briefly to show the speaker and vibration motor are working. *Receiver vibrates and beeps on plug-in* displays for 10 seconds, then home screen.	**Tap** *Continue* or wait 10 seconds. If receiver doesn't vibrate and beep, retry. If it still doesn't, call Technical Support. Use app until issue is fixed. Keep charging until home screen displays with battery icon filled in. The charge indicator turns on while the battery is charging.
6		Battery Charged	**Unplug** *wall charger* from outlet when fully charged.

Accessories

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

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damaged.

There is no repair service available for any G5 Mobile 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 G5 Mobile correctly helps prevent system failures.

Sensor

1. Keep the sensor in its sterile packaging until you are ready to use it.
2. Store at temperatures between 36° F-77° F.
    a. 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 15%-85% relative humidity.

Transmitter

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

Receiver

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

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14.5 Checking App and Receiver Information

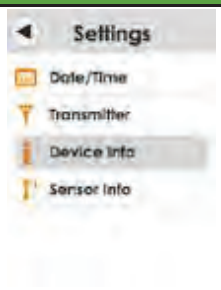
You can check your app or receiver for information about your CGM system at any time.

Check CGM System Settings: App

Step	What you see	What it means	What you do
1		Settings menu	**Update:** • Insertion date and time • Last calibration date, time, and value • Transmitter battery life • Transmitter SN • Receiver SN • Receiver battery life • Part number • Part revision • Software number
2		Device information menu	Check: • Insertion time • Last calibration • Software number and revision

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Check CGM System Settings: Receiver

Step	What you see	What it means	What you do
1		Settings menu	**Tap** *Device Info*
2		Device Information menu	Check: • Transmitter SN • Part number and revision • Firmware and Software numbers • Transmitter battery life

14.6 System Disposal

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

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

Taking care of your G5 Mobile is pretty easy. In the next chapter, "On the Go With G5 Mobile: Getting Through Security," you'll learn how simple it is to travel the world with your G5 Mobile!

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Chapter 15

Everything Else G5:

On the Go With G5 Mobile: Getting Through Security

15.1 Introduction

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

This chapter covers only the G5 Mobile. It doesn't cover steps you need to take when traveling with your smart device. See your smart device's instructions 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 G5 Mobile components
- Identify when your display device(s) can be on during a flight
- Contact TSA directly with your security questions

15.2 Safety Statements

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Precaution

Don't: *Never bring the G5 (sensor applicator, transmitter, and receiver) into an AIT body scanner (airport body scanner).*

Never put any part of the G5 in the baggage x-ray machine.

Do: *Request hand-wanding or full-body pat-down and visual inspection instead.*

Why: The system has not been tested in AIT scanners.

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

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 hand-wanded without worrying about damaging your transmitter or sensor.

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

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

X-Ray Machines

Receiver, Extra Sensors

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

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

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

Body Scanners

Use of 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

The G5 Mobile System is an M-PED (Medical-Portable Electronic Device) that 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

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Phone: 1.866.289.9673

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Chapter 16

Everything Else G5:

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

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 it 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 devices (for example, sensor)
- Your preferred contact method and information so Dexcom can reach you if needed. For example: by phone 555-555-5555 after 5 PM Pacific Time

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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®) and Registered Nurses (RNs) offering you customer care and individualized 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

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:

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dexcom.com/web-based-education.

By Phone

Available Monday-Friday 5:30 AM-8:00 PM PST (subject to change)

Dexcom Patient Care Team phone numbers:

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

By Phone

Dexcom Inside Sales Support phone numbers:

Toll free: **1.888.738.3646**

Toll call: **1.858.200.0200**

By Fax

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1.877.633.9266

16.4 Corporate

Dexcom Website:

Dexcom.com

Dexcom Address:

6340 Sequence Drive

San Diego, CA 92121

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Chapter 17

Everything Else G5:

Technical Information

17.1 Device Performance Characteristics

NOTE: We recommend that you review the information in this chapter with your healthcare professional to understand how well the 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 self-monitoring 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)

Original Pediatric Study: the receiver included software version SW10050

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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® OneTouch® Ultra®2 meter and in the Software 505 Adult Study, subjects used Bayer's CONTOUR® NEXT USB meter.

In the Original Adult Study, all subjects were evaluated in a controlled clinic environment on all three clinic days: Day 1, Day 4, and Day 7 of the 7-day wear period. In the Software 505 Adult Study, subjects were evaluated in one of the three clinic days so there are fewer data samples than in the Original Adult Study. While using the system in the clinic, subjects had their BG measured every 15 minutes with a reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the "YSI." Readings from the system were reported every 5 minutes and paired with YSI values in order to characterize how well the

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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® OneTouch® Verio® IQ meter; the Software 505 Pediatric Study used Bayer’s CONTOUR® NEXT USB meter.

All subjects were evaluated in a controlled clinic environment on Day 1, Day 4 or Day 7 of the 7-day wear period. While using the system in the clinic, subjects provided at least two fingerstick measurements per hour, and subjects ages 6-17 also provided venous blood for comparison to a laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the “YSI.” In the Original Pediatric Study,

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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 Glucose Ranges (Adult)

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

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

[2] *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 Glucose Ranges (Pediatric)

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

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

[2] *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 ± 20 mg/dL of the YSI BG values ≤ 80 mg/dL and within ± 20% of YSI BG values > 80 mg/dL.

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

			YSI mg/dL					Total
CGM Readings	Study[1]	CGM-YSI Pairs	< 55	< 60	< 70	< 80	≥ 80	
"LOW"	Original	n	66	84	123	142	13	155
		Cumulative Percent	42%	54%	79%	92%	8%	
	Software 505	n	11	16	17	18	0	18
		Cumulative Percent	61%	89%	94%	100%	0%	

			YSI mg/dL					Total
CGM Readings	Study[1]	CGM-YSI Pairs	> 340	> 320	> 280	> 240	≤ 240	
"HIGH"	Original	n	189	220	238	246	2	248
		Cumulative Percent	76%	89%	96%	99%	1%	
	Software 505	n	40	43	45	45	0	45
		Cumulative Percent	89%	96%	100%	100%	0%	

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

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

			YSI mg/dL					Total
CGM Readings	Study[1]	CGM-YSI Pairs	< 55	< 60	< 70	< 80	≥ 80	
"LOW"	Original	n	0	0	0	0	13	13
		Cumulative Percent	0%	0%	0%	0%	100%	
	Software 505	n	3	5	10	15	1	16
		Cumulative Percent	19%	31%	63%	94%	6%	

			YSI mg/dL					Total
CGM Readings	Study[1]	CGM-YSI Pairs	> 340	> 320	> 280	> 240	≤ 240	
"HIGH"	Original	n	38	51	68	69	1	70
		Cumulative Percent	54%	73%	97%	99%	1%	
	Software 505	n	14	19	22	23	1	24
		Cumulative Percent	58%	79%	92%	96%	4%	

[1] *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. Because the system does not display glucose values below 40 mg/dL or above 400

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

CGM (mg/dL)	YSI (mg/dL) Row Percentage of Matched Pairs in Each CGM Glucose Range											
	< 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

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

CGM (mg/dL)	YSI (mg/dL) Row Percentage of Matched Pairs in Each CGM Glucose Range											
	< 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 and YSI Values (Original Pediatric Study)

CGM (mg/dL)	YSI (mg/dL) Row Percentage of Matched Pairs in Each CGM Glucose Range											
	< 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)

CGM (mg/dL)	YSI (mg/dL) Row Percentage of Matched Pairs in Each CGM Glucose Range											
	< 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 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.

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

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

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

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

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

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

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

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

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

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

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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 in Reference to YSI 15 Minutes Before and After (Adult)

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

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

[1] *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 in Reference to SMBG 30 Minutes Before and After (Pediatric, Ages 2-5 Years)

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

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

Low and High Glucose Alerts

The ability of the system to detect high and low glucose levels is assessed by comparing system results to YSI results at low and high 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

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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 in Reference to YSI 15 Minutes Before and After (Adult)

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

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

[1] *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 in Reference to SMBG 30 Minutes Before and After (Pediatric, Ages 2-5 Years)

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

[1] *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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Table 7-A. Percentage of System Readings[1] Within YSI Values With Data Stratified in 2-Hour Increments After Calibration (Adult)

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

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

[2] *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[1] Within YSI Values With Data Stratified in 2-Hour Increments After Calibration (Pediatric)

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

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

[2] *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[1]) - (Adult)

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

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

[2] *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 Stability Relative to YSI (Accuracy Over Time[1]) - (Pediatric, Ages 6-17 Years)

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

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

[2] *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[1]) - (Pediatric, Ages 2-17 Years)

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

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

[2] *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

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

[2] *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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Table 10-B. System Readings Within Wear Days (Pediatric)

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

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

[2] *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.

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

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

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

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

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

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of Paired CGM-SMBG	Percent Within 15/15% SMBG	Percent Within 20/20% SMBG	Percent Within 30/30% SMBG	Percent Greater than 40/40% SMBG
Overall	Original	16,318	64%	76%	89%	5%
	Software 505	4264	73%	84%	94%	2%
40-60	Original	487	44%	55%	68%	19%
	Software 505	240	54%	71%	86%	7%
61-80	Original	1340	59%	70%	85%	7%
	Software 505	399	64%	76%	92%	2%
81-180	Original	7084	62%	74%	90%	5%
	Software 505	1650	72%	84%	95%	2%
181-300	Original	5627	69%	80%	90%	5%
	Software 505	1526	79%	89%	97%	2%
301-350	Original	1176	65%	77%	90%	4%
	Software 505	319	72%	83%	94%	2%
351-400	Original	604	58%	72%	86%	6%
	Software 505	130	69%	79%	86%	8%

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

[2] *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 (Adult)

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

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

[2] *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 Glucose Ranges (Pediatric)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of Paired CGM-SMBG	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	16,318	2.2%	0.9%	15.3%	11.1%
	Software 505	4264	-0.7%	-1.1%	12.5%	9.5%
*40-60	Original	487	-22.1	-17.0	23.9	18.0
	Software 505	240	-15.9	-14.0	16.9	14.0
*61-80	Original	1340	-11.8	-8.0	17.0	11.0
	Software 505	399	-7.8	-6.0	13.7	10.0
81-180	Original	7084	1.1%	-1.0%	15.4%	11.4%
	Software 505	1650	-1.2%	-2.6%	12.1%	9.5%
181-300	Original	5627	5.7%	3.4%	13.5%	9.5%
	Software 505	1526	1.7%	0.9%	10.1%	7.7%
301-350	Original	1176	9.6%	7.2%	14.2%	10.4%
	Software 505	319	6.7%	5.9%	11.8%	8.9%
351-400	Original	604	12.7%	10.2%	16.1%	11.9%
	Software 505	130	12.0%	8.9%	15.7%	10.6%

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

[2] *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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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 real-time 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.

17.2 Product Specifications

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User is the single use operator in the home environment.

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

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

Sensor Product Specifications

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

Transmitter Product Specifications

Part Number	9438-06
Dimensions (Including Sensor Pod)	Length: 1.5 inches Width: 0.9 inches Thickness: 0.5 inches
Weight (Including Sensor Pod)	0.4 ounces
Power Supply	Silver oxide batteries (not replaceable)

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Part Number	9438-06
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 and 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	IP28: Protection against insertion of large objects and immersion in water for up to 8 feet for 24 hours 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 G5 Mobile 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 9438-06) is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

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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	MT22949
Reading Frequency	Every 5 minutes
Dimensions	Length: 4.0 inches Width: 2.5 inches Thickness: 0.55 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	4.0 ounces
Receiver Input	5V DC, 1A
Power Supply	MT23681
Communication Range	20 feet
Memory Storage	30 days of glucose data 7 days of tech support data
Re-Chargeable Battery Use	2 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 and Transport/Operating Conditions	Temperature: 32° F-104° F Humidity: 15%-95% RH, (Storage/Transport 10%-95% RH)
Operating Altitude	-1,200 feet to 13,500 feet
Medium Priority Alarm Audible Output	50 dB_{SPL} at 1 meter
Moisture Protection	IP22: Vertically falling drops Protection against insertion of large objects and dripping water
Limited Warranty	1 year
Safety 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.

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Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The receiver (MT22949) is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the receiver should ensure that it is used in such an environment.

Receiver Electromagnetic Immunity Specifications

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

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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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.

System Electromagnetic Immunity Specifications

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

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

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

a. Field strengths from fixed transmitters, such as base stations for radio

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(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.

Electromagnetic Emissions Specifications

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.

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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 and the Dexcom Transmitter/Receiver

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\ P^{½}$	80 MHz to 800 MHz $d = 1.2\ P^{½}$	800 MHz to 2.5 GHz $d = 2.3\ P^{½}$
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

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 propagation is affected by absorption and reflection from structures, objects and people.*

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USB Charging/Download Cable* Specifications

Part Number	MT20655
OEM Number	P-HJX-00110
Input/Output	5V DC, 1A
Type	USB A to USB micro B
Length	3 feet

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

Power Supply/Charger Specifications

Part Number	MT23681
Class	II
Input	AC Input 100-240 Vac, 50/60Hz, 0.2A, 0.2A rms at 100 Vac
DC Output	5V DC, 1A (5.0 Watts)

17.3 FCC Requirements

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

- G5 Mobile transmitter: PH29715
- G5 Mobile receiver: PH29949

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 G5:

Troubleshooting

18.1 Introduction

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

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

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 inaccurate sensor glucose readings.

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

Precaution

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

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

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

Precaution

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

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

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

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

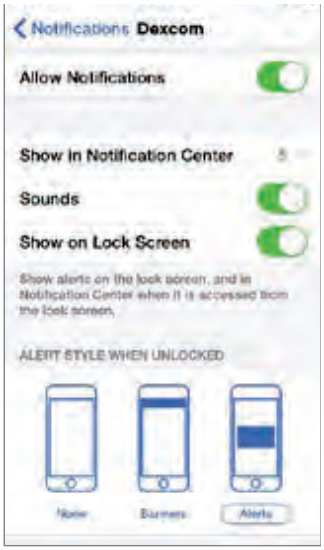
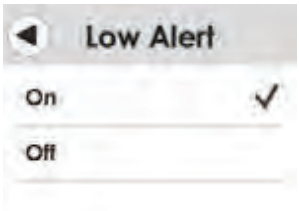
Water (for example, swimming, surfing, bathing, etc.) can severely limit communication range.

Consequences: Missing severe low or high Alarm or Alerts.

18.3 Troubleshooting

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No Alarm/Alerts or Glucose Readings

Device	What you see	Problem	What you do
Smart Device: In App		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 Disturb (if applicable).
Receiver			

Sensor Glucose Readings

Device	What you see	Problem	What you do

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

Device	What you see	Problem	What you do

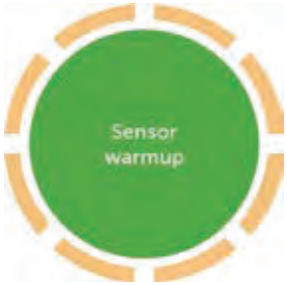
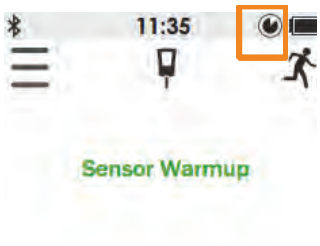
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Device	What you see	Problem	What you do
Smart Device: In App		Not getting sensor glucose readings.	See Chapter 9. *Don't* calibrate. **Wait** for more prompts. System may correct problem itself and continue to provide sensor glucose readings. 3 hours since last sensor reading: **Contact** Technical Support (see Chapter 16).
Receiver			
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 the sensor pod? Make sure you haven't taken acetaminophen. Don't calibrate. Use BG meter for BG reading. If this continues for more than 3 hours, contact Technical Support (see Chapter 16).
Receiver			

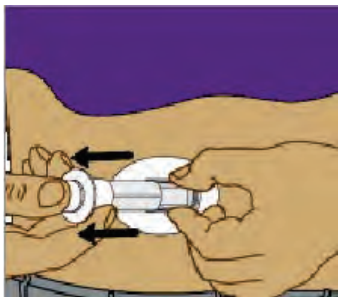
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Device	What you see	Problem	What you do
Smart Device: In App		System display device and transmitter not connecting. No sensor readings, Alarm/Alerts or notifications display until error is fixed.	See Chapter 9. *Don't* calibrate. **Verify** display device and transmitter are within 20 feet of each other without obstruction. **Wait** up to 30 minutes. Don't calibrate. Use BG meter for BG reading. More than 30 minutes? **App (if not fixed):** 1. **Go** to *Settings.* 2. **Tap** *Bluetooth*. 3. **Turn** *Bluetooth* Off and On. **App/Receiver:** If this continues for more than 3 hours, contact Technical Support (see Chapter 16).
Receiver			

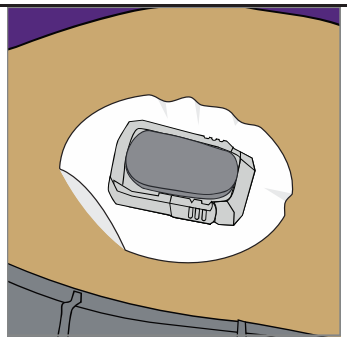
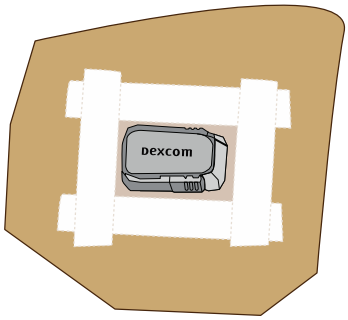
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Device	What you see	Problem	What you do
Smart Device: In App		No sensor glucose readings.	See Chapter 7. **Wait** up to 2 hours. System is counting down to when you do your initial calibration.
Receiver			

Applicator

Picture	Problem	What you do
	Safety lock stuck.	See Chapter 6. • **Pull** *safety lock* straight out:Away from your body • Follow direction of safety lock *up arrow*
	Collar won't pull up.	See Chapter 6. **Use** force when pulling the collar up. **Check** *white plunger* is completely down–flush to the applicator barrel.

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Picture	Problem	What you do
	Can't remove transmitter latch.	See Chapter 6. Don't pull it straight off. **Hold** *sensor pod* with one hand. **Twist** *transmitter latch* with other hand to break transmitter latch off.
 	Sensor pod won't stick.	**Put** medical tape over sensor pod's white adhesive patch (for example, Blenderm). **Don't** place tape over the transmitter.

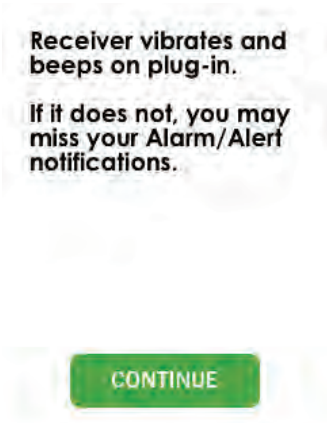
Hardware Error

Device	What you see	Problem	What you do

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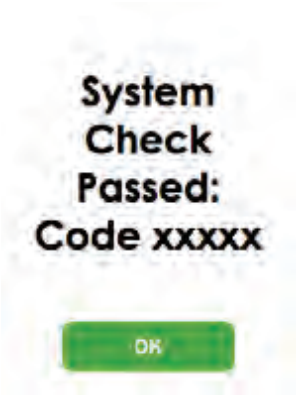
Device	What you see	Problem	What you do
Receiver		Won't turn on: Battery dead.	See Chapter 4. **Charge** *receiver* using electrical outlet, not computer/laptop. Full charge may take up to three hours.
Receiver		After full charge session: Won't turn on.	See Chapter 4. **Reset** *receiver*: 1. **Press and hold** *power button* for 10 seconds 2. **Release** *power button* 3. **Press and hold** for 2 seconds to turn back on **Connect** *receiver* to *charger*. Receiver will turn on. Processing screen appears.

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Device	What you see	Problem	What you do
Receiver		Power on or plug in receiver but don't get beep or vibration. Don't hear or feel Alarm/Alerts or prompts.	**Retry.** If it doesn't beep and/or vibrate again, contact Technical Support (See Chapter 16.1). You may not hear or feel Alarm/Alerts or prompts. Use app until issue is fixed.
Receiver		Receiver low battery prompt and icon.	See Chapter 4. **Charge** *receiver*.
Receiver		Loading screen displays unexpectedly.	**Wait** a few seconds for *System Check Passed* or Contact Technical Support Error screen (see next rows).

Device	What you see	Problem	What you do

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Device	What you see	Problem	What you do
Receiver		System check results (xxxxx displays as a code).	See Chapter 16. Do nothing. Receiver is able to continue to work and recover from an error. **Tap** *OK* to clear Alert. If the same code displays repeatedly, write down the error code and contact Technical Support. (see Chapter 16.1) Use BG meter for BG reading until resolved.
Receiver		Repeated hardware error.	See Chapter 16. **This locks your screen. Write down** error code. Contact Dexcom Technical Support (see Chapter 16.1).. **Check** BG value using BG meter.

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Device	What you see	Problem	What you do
Smart Device: In App		No *Bluetooth.* No sensor readings, Alarm/Alerts or notifications display until error is resolved.	See Chapter 5. **Go** to smart device's *Settings*. **Make sure** *Bluetooth* is On. If problem persists, please contact device's manufacturer.

Calibration Error

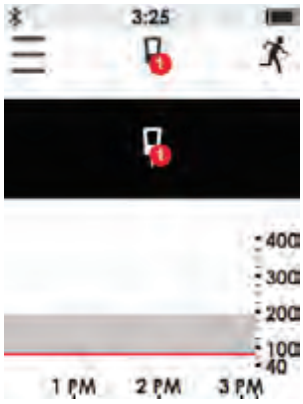
Device	What you see	Problem	What you do
BG Meter		System will not accept calibration if outside of the 40-400 mg/dL range.	See Chapter 7. **Wait** until your glucose is between 40-400 mg/dL. **Calibrate** only when your BG meter values are between 40-400 mg/dL.
Smart Device: In App		System didn't accept recent calibration (see Sensor Glucose Readings troubleshooting	See Chapter 7. **App**: **Tap** *question mark* to get more information. **Receiver**: **Wait** 15 minutes.

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Device	What you see	Problem	What you do
Receiver		for a possible reason). No sensor readings, Alarm/Alerts or notifications display until error is fixed.	**Enter** 1 calibration. If error screen still appears enter 1 more BG meter value. **Wait** 15 minutes. If no sensor glucose readings appear on the display, the sensor needs to be replaced. Contact Technical Support to report error (see Chapter 16.1).

Device	What you see	Problem	What you do
Smart Device: In App		System didn't accept recent calibration. No sensor readings, Alarm/Alerts or notifications display until error is fixed.	See Chapter 7. **Wait** 15 minutes. **Enter** 1 BG meter value. **Wait** 15 more minutes. If error screen still appears enter 1 more BG meter value. **Wait** 15 minutes. If no sensor glucose readings appear on the

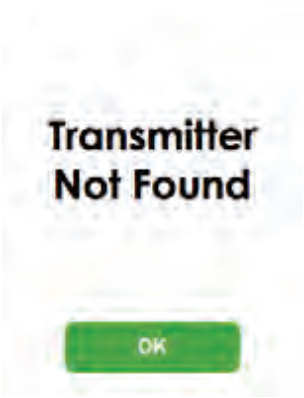
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Device	What you see	Problem	What you do
Receiver			display, the sensor needs to be replaced. **Contact** Technical Support (see Chapter 16.1) to report error.

Transmitter Error

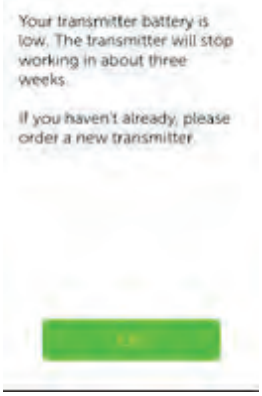
Device	What you see	Problem	What you do
Smart Device: In App		Transmitter not working. Sensor session automatically stopped. No sensor readings, Alarm/Alerts or notifications display until error is fixed.	Contact Technical Support (See Chapter 16). Use BG meter for BG reading. You won't get additional alerts after clearing.
Receiver			

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Device	What you see	Problem	What you do
Smart Device: In App		Pairing failed. No sensor readings, Alarm/Alerts or notifications display until error is fixed.	See Chapter 6. Sensor may not be inserted correctly. Insert a new sensor. For a replacement, contact Technical Support (see Chapter 16.1).
Receiver			

Device	What you see	Problem	What you do

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Device	What you see	Problem	What you do
Smart Device: In App		Transmitter low battery prompt.	Order a new transmitter.
Receiver			

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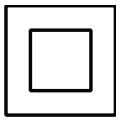
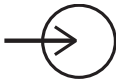
Chapter 19

Everything Else G5:

Symbols on Package Labels

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

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

	Alternating Current		Authorized Representative in the European Community
	Batch/Lot Number		*Bluetooth*
	Caution		Class II Equipment
	Date of Manufacture		Direct Current
	Do Not Reuse		Do Not Use If Package Is Damaged
	Electrical Equipment Designed Primarily for Indoor Use		European Union WEEE Directive 2012/19/EU
	Humidity Limitation		Input

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IP22	IP22: Protection Against Insertion of Large Objects and Dripping Water	IP28	IP28: Protection Against Insertion of Large Objects and Immersion in Water
	Keep Dry		Manufacturer
CE XXXX	Marking Certifies Device Meets European Council Directive 93/42/EEC		MR Unsafe
	Non-Ionizing Radiation	Rx Only	Prescription Required
	Refer to Instruction Manual/Booklet	SN	Serial Number
SB	Ship By Date	STERILE R	Sterile by Radiation
	Temperature Limitation		Type BF Applied Part
	Use By Date		

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5

SHARING IS CARING

- Dexcom *Share*

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Chapter 20

Sharing Is Caring:

Dexcom *Share*®

20.1 Learning About Dexcom *Share*

Glossary

Airplane Mode	A setting on a smart device where wireless features are disabled in order to comply with airline regulations.
Application or App	A software program, such as the 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.
BG 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 *Share* Cloud	A secure online storage server where Dexcom *Share* feature information is stored and then shared with Followers.
Dexcom Follow App	A software program that gets the Sharer's glucose information and prompt data from the Dexcom *Share* Cloud.
Dexcom *Share*	A secondary notification system using the following parts: • Dexcom G5 Mobile System • *Bluetooth* wireless technology • Sharer's smart device • G5 Mobile app • Internet • Follower's smart device • Dexcom Follow app
Do Not Disturb	A setting on a smart device where all incoming calls, Alerts, and notifications are silenced. Do Not Disturb can be set to specific times and can be set to allow exceptions (people who can disturb you).
Follower	A person that gets the Sharer's shared information in the Dexcom Follow app.
Follow Dashboard	On the Dexcom Follow app, the Follow Dashboard shows the glucose information of up to five Sharers.
Follower's Smart Device	Runs the Dexcom Follow app.

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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 *Share* Cloud using an Internet connection.
Hyperglycemia	High BG. Same as “high.” The Default High Glucose Alert in the G5 Mobile is set to 200 mg/dL. Consult your healthcare professional to determine the appropriate hyperglycemia setting for you.

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Hypoglycemia	Low BG. Same as “low.” The Default Low Glucose Alert in the G5 Mobile is set to 80 mg/dL. Consult your healthcare professional to determine the appropriate hypoglycemia 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 *Share*.
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™, used by a smart device to access the Internet.
No More Data Prompt	Prompts the Follower when the Sharer is unable to share glucose information.
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.

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Profile	Located in Follow Dashboard and displays the Sharer's glucose information, trend arrow, and profile picture.
Prompt	A visual message that appears on the screen of the Follower's smart device. Prompt may also include a sound, depending on the smart device's settings.
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 G5 Mobile app and the Dexcom Follow app.
Repeat	Amount of time the Follower chooses before he/she wishes to receive a repeated notification.
Sensor Glucose Reading	A glucose measurement taken by the G5 Mobile.
Sharer	The person who uses the G5 Mobile.
Sharing	The act of electronically transmitting glucose information from the Sharer's smart device to the Follower's smart device.

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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 receiver.
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.

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20.2 Dexcom *Share* Overview

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

Dexcom *Share* includes:

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

You cannot use the *Share* feature with the receiver.

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

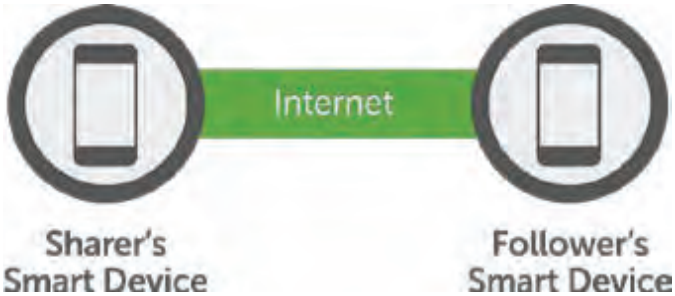


Figure 8. Sharing

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

Dexcom *Share* Parts

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	Sharer's smart device*[1]
	Follower's smart device*[1]
	G5 Mobile app
	Dexcom Follow app
	G5 Mobile transmitter*
	G5 Mobile/G4 PLATINUM Sensor*
	Internet/Wi-Fi or mobile data service/3G/4G/LTE*
	Bluetooth

**Must be purchased separately.*
[1] *A list of compatible devices can be found at dexcom.com/compatibility.*

Conditions Affecting Use

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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
- Sharer's smart device has Internet connection
- Notifications turned on. If turned off, Follower won't receive any notifications
- Follower's smart device has an Internet connection

Dexcom recommends charging the smart device while sharing.

20.3 Risks and Benefits

Risks

Dexcom *Share* is a feature of the G5 Mobile . The main risks involved with using the Dexcom *Share* feature are based on misunderstanding its purpose.

Remember that the Dexcom *Share* feature in the G5 Mobile 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.
2. **G5 Mobile:** Use the G5 Mobile to complement, but not replace, information obtained from the BG meter. It detects glucose trends and tracks glucose patterns.
3. **Dexcom *Share***: This is an optional add-on to the G5 Mobile 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 the patients 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 alert them.

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

The Dexcom *Share* feature may provide improved quality of life and greater peace of mind to patients, their caregivers and their support team by allowing the G5 Mobile Alarm, Alerts, 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 (Dexcom G5 Mobile System) 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 G5 Mobile user guide. Dexcom *Share* is a feature of the G5 Mobile.

If you do not have the Dexcom G5 Mobile System User Guide, you can view it on dexcom.com or call 1.888.738.3646 to request a copy. Availability hours: Monday-Friday, 6am-6pm PST. Please contact your healthcare professional during hours the line is unavailable.

Contraindications

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

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

Warnings

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

This device is not intended to replace self-monitoring practices advised by a physician. Dexcom *Share* does not work alone. Dexcom *Share* does not

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replace the Dexcom G5 Mobile System and requires *Share* to be turned “On” to communicate glucose information to the Follower.

You cannot use Dexcom *Share* to make treatment decisions, such as how much insulin to take. Dexcom *Share* does not replace a 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 G5 Mobile receiver as the main device to track sensor glucose information, notifications and Alarm.

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 alert the patient of low or high glucose events or other important information. At times, the Follower may not receive data, and the patient will not be notified of this fact.

When using Dexcom *Share*, make sure *Share* is turned “On.” If not, the patient will be unable to share data, and the Follower might miss helping the patient in the event of low or high 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 G5 Mobile app is reopened after the smart device is turned back on in order to resume sharing. If the G5 Mobile app is not reopened, the patient will be unable to share data, and the Follower might miss helping the patient in the event of low or high 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 G5 Mobile app may not be able to share glucose readings and the Dexcom Follow app may not be able to receive notifications or glucose readings during phone calls.

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Dexcom *Share* will resume sharing after the phone call has ended, and the Follower will receive any waiting notifications after the phone call has ended.

20.5 Setting Up Dexcom *Share*

Dexcom *Share* Description

What Dexcom *Share* does:

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

What Dexcom *Share* does not do:

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

Tips

- Read the rest of the G5 Mobile 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 G5 Mobile App

Step	What you see	What you do

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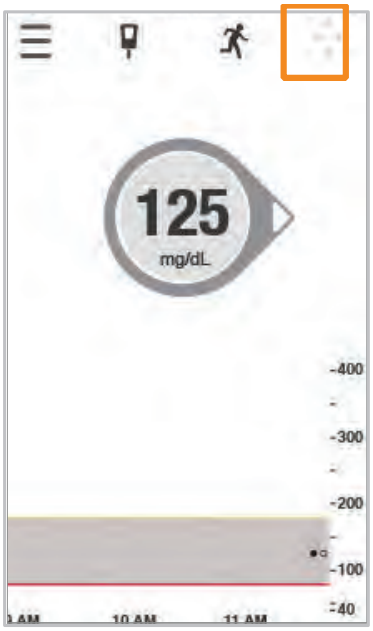
Step	What you see	What you do
1		Download the G5 Mobile app from your app store. See your smart device's user manual for instructions. Download the G5 Mobile app to use Dexcom *Share*.
2		Launch the G5 Mobile app. Set up your smart device (see Chapter 5) before sharing. Once your app has been set up, activate Dexcom *Share*.

A series of screens walk you through the Dexcom *Share* features, highlighting important information.

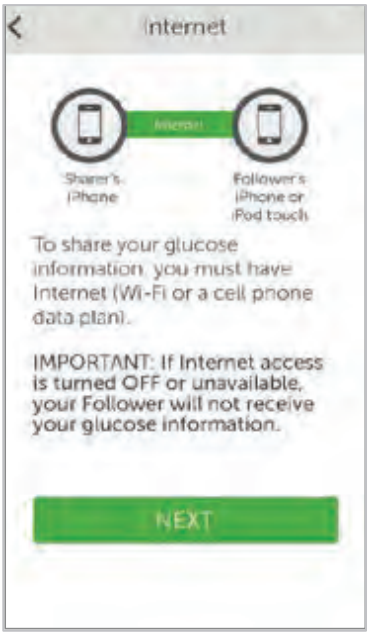
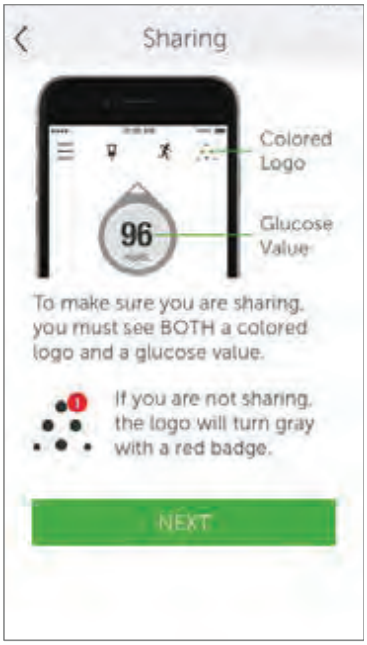
Activating Your *Share* Feature

Step	What you see	What it means	What you do

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Step	What you see	What it means	What you do
1		Activates Dexcom *Share*. If Dexcom *Share* icon is gray, your *Share* feature has not been turned on.	**Tap** *Dexcom Share icon* in the upper right corner of your smart device's home screen.
2		Dexcom *Share* Welcome Screen.	**Read** screen. **Tap** *Next* when done.

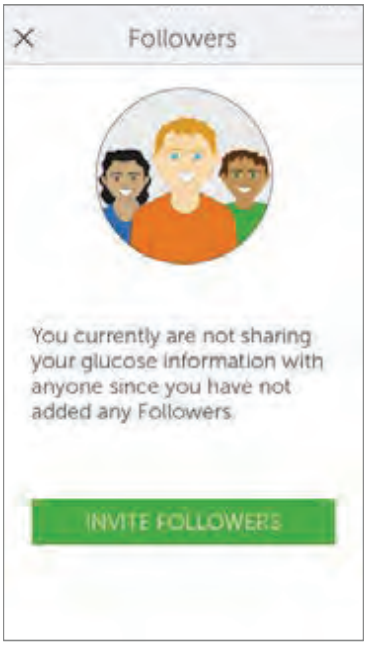
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Step	What you see	What it means	What you do
3		Message about Internet access.	**Tap** *Next*.
4		How to know you are sharing your data.	**Tap** *Next*.

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Step	What you see	What it means	What you do
5		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		**Tap** *Invite Followers* to set up your Followers.

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Step	What you see	What you do
2	 	**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 smart device. **Tap** *Next*.

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Step	What you see	What you do
3		**Tap** *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		**Choose** if your Follower gets your Urgent Low, Low, and High sensor glucose Alarm/Alerts. **Choose** if you want your Follower to get prompts if not receiving your sensor glucose readings. **Select** what Alarm/Alerts your Follower gets and how long you are low/high or not sharing data (for example, if you want your Follower to know when your glucose is above 200 mg/dL for more than 2 hours, you can set up in the Follower's Settings menu). **Tap** *Save* for each Follower Setting "Save." **Tap** *Next* when done.

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

20.6 Using Dexcom *Share*

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Dexcom *Share* Status

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

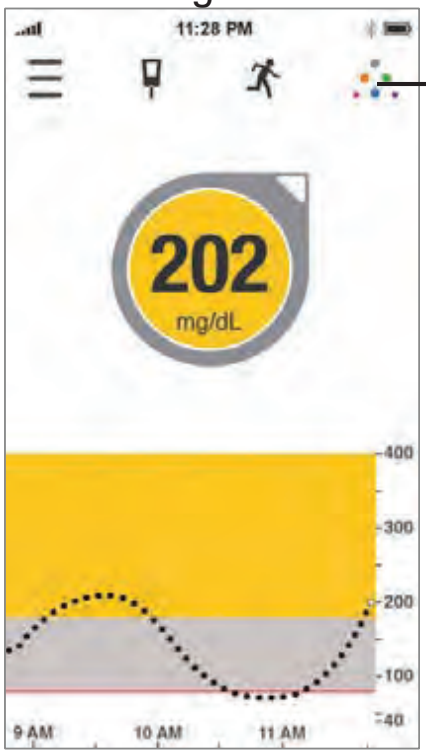


Figure 9. *Share* Status

Dexcom *Share* Status Icons

Status Tab	What it is
	The *Share* icon is in color when Dexcom *Share* is sending sensor glucose readings and information.

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Status Tab	What it is
	The *Share* icon is dark gray with a red circle when Dexcom *Share* is not working. The Sharer should tap on the grayed out *Share* icon when it is not working to get further information about the error.
	The *Share* icon is light gray when Dexcom *Share* has not been activated. The Sharer should tap the light gray icon to get started using Dexcom *Share*.

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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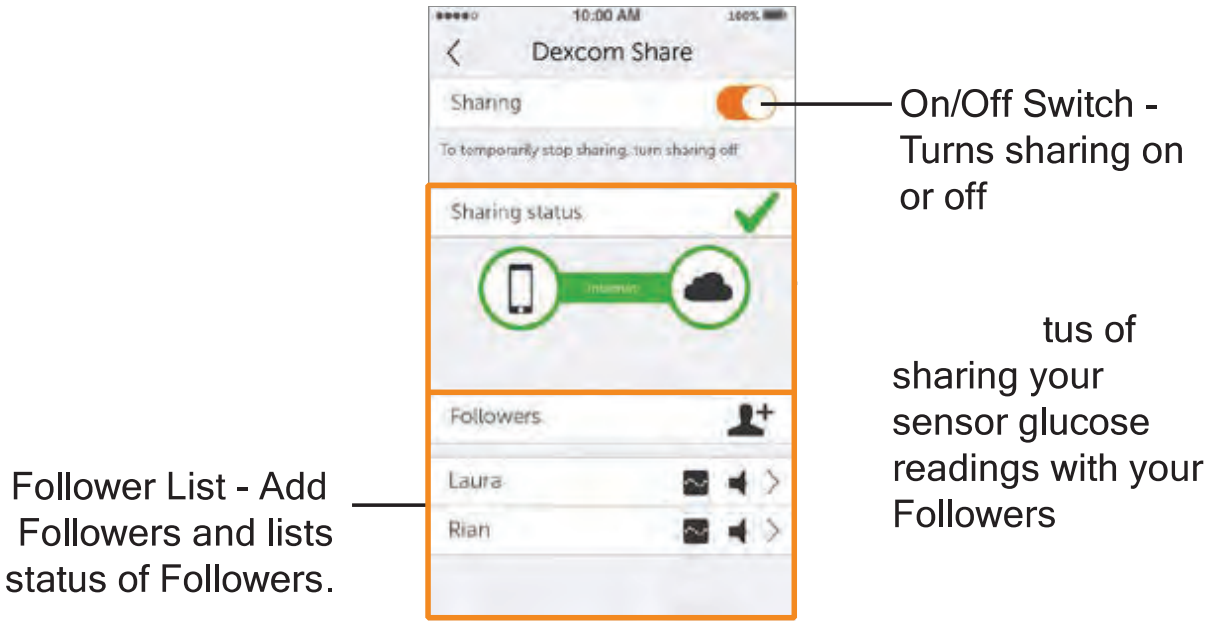


Figure 10. Dexcom *Share* Screen

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

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

Share Status Troubleshooting Tips

What you see	What it means	What you do
	Green Check: All connections are working	N/A.

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What you see	What it means	What you do
	Issue with: • Sharer's CGM data • Your smart device	The Sharer should make sure: • There is a glucose value on the smart device • Transmitter is in range of the smart device • To **tap** on blue *"?"* to learn more about how to troubleshoot this issue • To allow up to 10 minutes for status to turn green and a green check mark to appear If the Sharer continues to see this, the Sharer should turn off *Share* and then turn it back on.

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What you see	What it means	What you do
	Issue with: • Sharer's Internet connection • Dexcom *Share* Cloud	The Sharer should make sure: • Their Wi-Fi or cellular connection is On • They are in an area that has cellular reception • They are not on a voice call • They can access the web via a browser • To check later or follow up with their Internet connectivity provider • To **tap** on blue *"?"* to learn more about how to troubleshoot this issue

Followers List

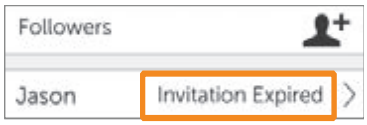
The Followers list allows the Sharer to manage Followers.

In the Followers list the Sharer can:

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

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Icon/Status

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

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

Stop Sharing

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

For reasons of safety and intended use, the Follower will get a message saying the Sharer's data has been 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. Followers only need to download and install the Dexcom Follow app.

What the Dexcom Follow app does:

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

What the Follow 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 app on smart device.

Glucose Alarm and Alerts

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

Types of prompts Followers get:

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

The Follower can change some of the initial settings to fit his/her needs. The Follower cannot change the Sharer’s permission settings to see the trend graph.

Sharer Status Changes That Notify the Follower

Some Sharer status changes will prompt the Followers.

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

The Follower Dashboard

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If the Sharer doesn't allow the Follower to see the trend graph, he/she will only see the glucose reading and trend arrow.

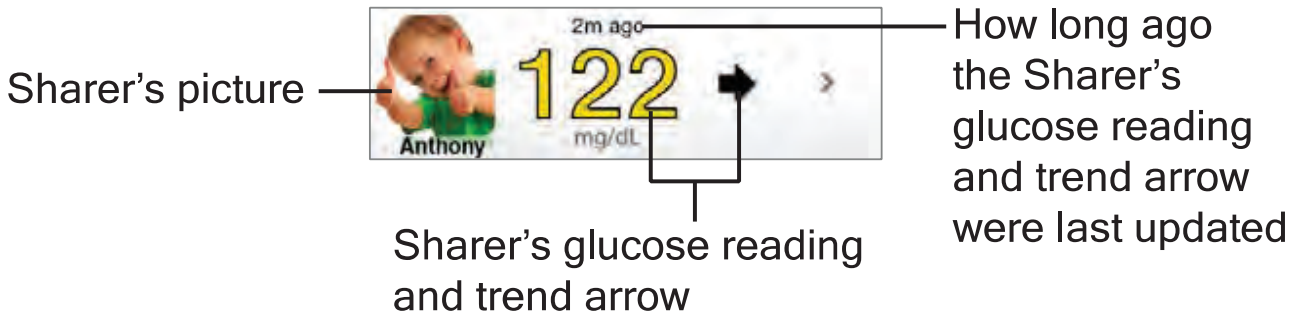
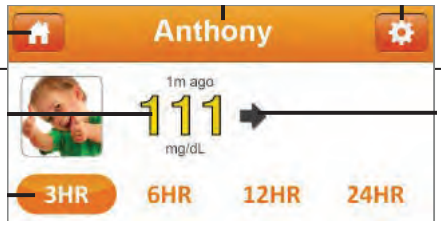


Figure 12. Follower Information

If the Sharer chooses to have the Follower see the trend graph, he/she will see:



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20.8 Troubleshooting

Dexcom *Share* Troubleshooting

Troubleshooting Status - See the “Troubleshooting Status Issues” portion of Chapter 20.6.

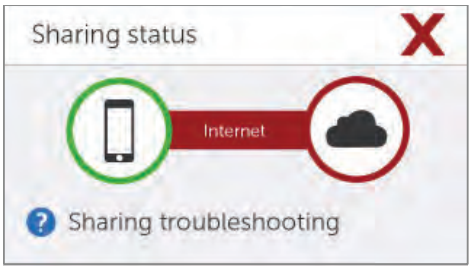


Figure 14. Sharing Status Troubleshooting

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 G5 Mobile 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 prompts
- Smart device is sufficiently charged or charging
- Smart device is within 20 feet of the transmitter

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- Smart device has 35 MB of available memory

Refer to the smart device user manual for further instructions

Tips

- Read the G5 Mobile user guide before using the Dexcom *Share* feature
- Always confirm information with a BG meter before you make treatment decisions

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Dexcom, Inc.
6340 Sequence Drive
San Diego, CA 92121 USA
Phone: 1.858.200.0200
Technical Support: 1.888.738.3646
Web: dexcom.com

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