Dexcom one
USER GUIDE

Instructions For Use

Table of Contents

◯ Chapter 1
Welcome!

Congratulations on making the Dexcom ONE Continuous Glucose Monitoring (CGM) System (Dexcom ONE) part of your life!

1.1 Get started

To set up your Dexcom ONE, follow instructions in the **Start Here** guide or the Dexcom ONE video tutorials available at **dexcom.com**.
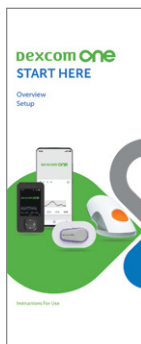
This booklet, the Dexcom ONE User Guide, introduces you to the home screen, shows you how to turn on alerts and customize your alert sounds, guides you through making treatment decisions, and shows you how to start a new sensor session.

Images in this guide are representational. Your materials may look different.

Optional receiver may not be available in all regions.

Critical safety notices

Dexcom ONE alerts

⚠️ No glucose alerts unless you turn them on.

• Turn on alerts during setup to get glucose and system alerts when sensor warmup is over.

⚠️ **Dexcom ONE alerts will NOT override your smartphone's settings.**

• You will **NOT** hear high or low glucose alerts if your phone is set to silent (sound is turned off)

• You will hear alerts ONLY when your smartphone's sound is turned on.

• Check your smartphone's settings or you may miss an alert.

⚠️ **Dexcom ONE alerts will NOT override your receiver settings.**

• If your receiver is set to vibrate, you will not hear high or low glucose alerts.

• Turn on receiver sound to hear alerts.

◯ **Chapter 2**
Dexcom ONE safety statements

Indications for use

The Dexcom ONE Continuous Glucose Monitoring System (Dexcom ONE) is a glucose monitoring system indicated for persons, including pregnant women, ages 2 years and older. Dexcom ONE is designed to replace fingerstick blood glucose (BG) testing for diabetes treatment decisions.

Interpretation of Dexcom ONE results should be based on the glucose trends and several sequential readings over time. Dexcom ONE also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

Dexcom ONE is intended for use by patients at home and in healthcare facilities.

Important user information

Please review the product instructions before using Dexcom ONE. Indications, contraindications, warnings, precautions, risks and benefits, and other important user information can be found in the product instructions that are included with Dexcom ONE. You and your healthcare professional must discuss how you should use the information displayed on Dexcom ONE to help manage your diabetes. Getting familiar with the system could take days, weeks, or even months. The product instructions contain important information on troubleshooting Dexcom ONE and on the performance characteristics of the system.

Contraindication

- **No MRI/CT/diathermy – MR unsafe** (MR)

  Do not wear any component of Dexcom ONE during magnetic resonance imaging (MRI), computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.

Dexcom ONE has not been tested in those situations. The magnetic fields and heat could damage the components of Dexcom ONE, which may cause it to display inaccurate CGM sensor glucose readings (Dexcom ONE readings) or may prevent alerts. Without Dexcom ONE readings or alert notifications, you might miss a severe low or high glucose event.

Warnings

- **Read user materials**

Before you use your Dexcom ONE, carefully read the materials included with it. If you do not, you might:

- Not use Dexcom ONE correctly
- Not understand Dexcom ONE information
- Affect how well it works

- **Do not ignore low/high symptoms**

Do not ignore how you feel. If your glucose alerts and Dexcom ONE readings do not match what you are feeling, use your blood glucose meter (BG meter) to make diabetes treatment decisions or, if needed, seek immediate medical attention.

When in doubt, get your BG meter out.

- **No number, no arrow, no CGM treatment decision**

If your Dexcom ONE does not show a number or arrow, or your Dexcom ONE readings do not match your symptoms, use your BG meter to make diabetes treatment decisions.

No number, no arrow, no treatment decision. When in doubt, get your BG meter out.

- **Do not use if…**

Do not use Dexcom ONE if you are on dialysis, or critically ill. It is not known how different conditions or medications common to these populations may affect performance of the system. Dexcom ONE readings may be inaccurate in these populations.

- **Take Healthcare Professional Advice**

Has your healthcare professional given you self-monitoring tasks? You should keep doing them. Having Followers does not replace medical advice.

Follow Dexcom ONE instructions. If you do not, you could have a severe low or high glucose event.

Precaution

- **Avoid sunscreen and insect repellent**

  Some skin care products, such as sunscreens and insect repellents, can make the plastic used in your Dexcom ONE crack. Before using your Dexcom ONE, make sure there are no cracks in your transmitter and transmitter holder. If you find a crack, please contact Technical Support at **dexcom.com**, or contact your local Dexcom representative. Do not allow these skin care products to contact your Dexcom ONE. After using skin care products, wash your hands before touching your Dexcom ONE. If any skin care products get on your Dexcom ONE, immediately wipe with a clean cloth.

- **Hydroxyurea precaution**

  If you are taking hydroxyurea, your Dexcom ONE readings may be falsely elevated and result in missed hypoglycemia alerts or errors in diabetes management decisions. The level of inaccuracy depends on the amount of hydroxyurea in your body. Use your BG meter.

- **Be accurate, be quick**

  If you calibrate your Dexcom ONE using your BG meter, enter the BG meter value on your meter within five minutes of measuring your BG.

- **Use fingertips**

  Use a BG sample from your fingertips when calibrating as blood glucose from other places may be less accurate and not as timely. Calibration is not required but you can do optional BG calibration to align with your meter.

- **Going through security check point**

  When wearing your Dexcom ONE, ask for 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) or putting any part of the Dexcom ONE system in the baggage x-ray machine.

You can wear Dexcom ONE for the walk-through metal detector. If you do, use your BG meter for treatment decisions until you leave the security area.

Because we have not tested every x-ray and scanner, we do not know if they damage Dexcom ONE.

Not sure what kind of machine it is? Be safe – request either hand-wanding or full-body pat-down.

Start up safety statements

Warnings

- **Use BG meter during startup**

  When you start a new sensor, you will not get any Dexcom ONE readings or alerts until you enter your sensor code. Use your BG meter to make treatment decisions during the 2-hour sensor warmup period.

Precautions

- **Use correct sensor code**

  When you start a new sensor, you must enter a code into your display device to use Dexcom ONE. Each sensor has its own code printed on the back of the adhesive patch. Do not use a code from a different sensor or make up a code. If you do not enter the correct code, your sensor will not work as well and could be inaccurate.

System/hardware/software safety statements

Warnings

- **Sensor wire breaks off or detaches**

  Do not ignore broken or detached sensor wires. A sensor wire could remain under your skin. If this happens, please contact Technical Support

at **dexcom.com**, or contact your local Dexcom representative.

If a sensor wire breaks off under your skin and you cannot see it, do not try to remove it. Contact your Healthcare Professional as soon as possible. Also seek professional medical help if you have symptoms of infection or inflammation – redness, swelling, or pain – at the insertion site.
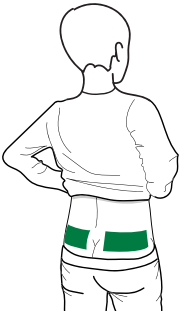
- **Where to insert: abdomen, back of arms, or buttocks?**

   All patients can use their abdomen or back of upper arms. Patients 2 to 17 years old can also choose their upper buttocks. Look for a place on your abdomen, back of upper arms, or upper buttocks where you have some padding.

   The sensor is not tested or approved for other sites. Talk to your Healthcare Professional about the best site for you.

   Ages 2-17 years: Insert in your abdomen, back of upper arms, or upper buttocks

   Ages 18 and older: Insert in your abdomen or back of upper arms.

Ages 2-17	**Anyone age 2 or older**
Can insert in upper buttocks	Can use abdomen or back of upper arm

- **Where to store**

  You can store your sensors at room temperature or in your refrigerator – as long as it is between 2°C and 30°C. Do not store sensors in the freezer.

Precautions

- **Do not start sensor past use by date**

  You can start a new sensor **on or before** its Use By date. This gives you full wear.

  Starting a sensor **past** its Use By date may cause incorrect results.

  The Use By date is in YYYY-MM-DD (Year-Month-Day) format on the sensor package label, next to the hourglass symbol.

- **Check package**

  Do not use sensor if its sterile package has been damaged or opened, because it might cause an infection.

- **Clean and dry skin**

  Clean and dry your hands and your insertion site before inserting your sensor.

  Wash your hands with soap and water, not gel cleaners, and then dry them before opening the sensor package. If your hands are dirty when you insert the sensor, you may get germs on the insertion site and get an infection.

  Clean your insertion site with alcohol wipes to prevent infections. Do not insert the sensor until your skin is dry. If your insertion site is not clean and completely dry, you run the risk of infection or the transmitter holder not sticking well.

  Make sure you do not have insect repellent, sunscreen, perfume, or lotion on your skin.

- **Where to insert: things to check**

  Keep the safety guard on until you put the Dexcom ONE applicator against your skin. If you remove the safety guard first, you may hurt yourself by accidentally pushing the button that inserts the sensor before you mean to.

  Change your insertion site with each sensor. 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 8 cm from insulin pump infusion set or injection site

- Away from waistband, scarring, tattoos, irritation, and bones

- Unlikely to be bumped, pushed, or laid on while sleeping

- **Use correct transmitter and sensor**

  Dexcom ONE components are not compatible with any previous Dexcom products. Do not mix transmitters, receivers, and sensors from different generations.

Transmitter safety statements

Warnings

- **Inspect**

  Do not use a damaged or cracked transmitter. A damaged transmitter could cause injuries from electrical shocks and may make Dexcom ONE not work correctly.

- **Use as directed**

  The transmitter is small and may pose a choking hazard. Do not put it in your mouth or let children hold it without adult supervision.

Precautions

- **Reuse transmitter – do not throw away**

  When ending a session, do not throw away the transmitter. The transmitter is reusable until Dexcom ONE notifies you that the transmitter battery is about to expire.

  For Healthcare Professionals: Please see cleaning and disinfection instructions in Professional Use Instructions.

- **Do not start transmitter past use by date**

  You can start a new transmitter **on or before** its Use By date to get full use.

  Starting a transmitter **past** its Use By date may cause incorrect results.

  The Use By date is in YYYY-MM-DD (Year-Month-Day) format on the transmitter package label, next to the hourglass symbol.

Display device safety statements

Warnings

- **Check settings**

  - **Optional alerts:** You will be prompted to turn on the optional alerts when setting up your Dexcom ONE system. You must turn them on to get glucose and system alerts. Follow the instructions and safety warnings in this user guide to make sure you receive alerts on your display device.

    No glucose alerts unless you turn them on. Turn alerts on during setup to get glucose and system alerts when sensor warmup is over. Dexcom ONE alerts will **NOT** override your display device settings. You will **NOT** hear high or low glucose alerts if your display device is set to silent (sound is off). Check your display device settings, or you may miss an alert.

      - Glucose Alerts:
        - Low Glucose
        - High Glucose
      - System Alerts include:
        - Sensor Expired
        - Sensor Failed (This issue may happen any time during a sensor session.)
        - Transmitter Failed
        - App Stopped: Phone Storage Full

- **Smartphone volume/sound:** Make sure your smartphone volume is turned up, not muted and speaker works. If your smartphone is on mute, "Total Silence," or "Do Not Disturb" modes, you will not receive any alerts related to Dexcom ONE.

- **Receiver volume/sound (optional display device):** Test your receiver speaker and vibrations regularly.

  To make sure the speaker and vibrations work, plug in the receiver to charge. The Speaker Test screen appears for a few seconds. Follow the directions on the screen to test the speaker and vibrations. If it doesn't beep and vibrate, Contact Technical Support at **dexcom.com** or your local Dexcom representative, and use your app or BG meter until the receiver is fixed.

- *Bluetooth®:* When using *Bluetooth* headphones, speakers, etc., your alerts may sound on your display device or on the smartphone accessory. Each accessory is different. Test yours so you know where you will hear your alerts.

- **Notifications (smartphone):** Make sure your smartphone settings allow Dexcom app notifications to show your lock screen. This will allow you to see notifications without unlocking your phone. During Dexcom ONE setup, enable Dexcom app notifications or you will not get alerts.

- **Battery:** Keep the battery of your display device charged to avoid missing Dexcom ONE data.

- **Compatibility (smartphone):** Before upgrading your smartphone or its operating system, check **dexcom.com/compatibility**. Automatic updates of the app or your phone operating system can change settings or shut down the app. Always update manually and verify correct device settings afterward.

  While connected to the internet, the app checks periodically and will display a message if it's not compatible (or no longer

compatible) with your phone or your phone's operating system (OS). The message may include a timeframe for updates.

- **Time (smartphone):** Let the date and time on your smartphone automatically update when you travel across time zones or switch between standard and daylight-saving times. Do not manually change your smartphone time, because it can make the time on the trend screen wrong and the app may stop displaying data.

- **Do not use receiver if damaged (receiver is an optional display device):** Do not use a receiver that is damaged or cracked. A damaged receiver could cause injuries from electrical shocks and may make the Dexcom ONE System not work correctly.

  Follow Dexcom ONE instructions. If you do not, you could have a severe low or high glucose event.

Tips

- Use Dexcom ONE receiver: If you use the Dexcom receiver, be sure to use the one that comes with your Dexcom ONE system. Receivers from previous generations won't work with the Dexcom ONE system.

Precautions

- **Secure internet:**

  Only use a cellular internet connection, a trusted Wi-Fi network (like your home or office), or use a secure internet connection such as a VPN service when using your Dexcom ONE system.

  Don't use unsecured public Wi-Fi such as guest networks in others' homes, restaurants, schools, libraries, hotels, airports, airplanes, etc. Those could expose your Dexcom ONE system to viruses or hacking.

- **Keep transmitter close to display device:**

  Keep your transmitter and display device within 6 meters with no obstacles (like walls or metal) between them. Otherwise, they might not be able to communicate. If water is between

your transmitter and the display device – for example, if you are showering or swimming – keep them closer to each other. The range is reduced because *Bluetooth* does not work as well through water.

- **Keep receiver clean and dry (receiver is an optional display device):**
- Do not submerge your receiver in water and do not get dirt or water in the USB port. That could damage it.

- **Get alerts on display device you use**

  You will be prompted to turn on the optional alerts when setting up your Dexcom ONE system. You must turn them on to get glucose and system alerts.

  No glucose alerts unless you turn them on. Turn alerts on during setup to get glucose and system alerts when sensor warmup is over. Dexcom ONE alerts will **NOT** override your phone's settings. You will **NOT** hear high or low glucose alerts if your phone is set to silent (sound is off). Check your phone's settings, or you may miss an alert.

- **Is it on?**

  If the display device is turned off (shut down), it will not show Dexcom ONE readings or alerts. Make sure your display device is turned on.

- **Check smartphone accessory devices**

  When using smartphone accessory devices (such as headphones or *Bluetooth* speakers), keep in mind you may get your alerts on only one device or accessory, not all. After connecting any smartphone accessory devices, make sure that your smartphone settings allow you to continue receiving alerts.

◯ Chapter 3
Display device screens

This chapter describes the Dexcom ONE glucose information and navigation features on your display device.
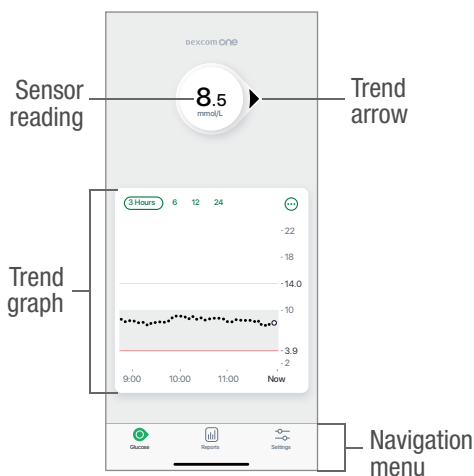
3.1 Home screen

You spend most of your time on the home screen. It shows your sensor readings (readings) and glucose trend information. In the app, the home screen is called the Glucose screen. Access it by tapping the **Glucose** icon ◉ in the navigation menu.

Overview

The home screens have 3 main sections:

1. Sensor reading (number) and trend arrow

2. Trend graph

3. Navigation menu or Menu

App home screen

Sensor reading

Trend arrow

Trend graph

Navigation menu

Receiver home screen
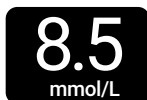

Sensor reading — Trend arrow

Trend graph — Menu

Navigation

Sensor readings

The number at the top of your home screen is your current sensor reading. It updates every 5 minutes.

App

8.5
mmol/L

Receiver

8.5
mmol/L

I**f alerts are OFF**, the app background and receiver text will always be **white**.

When you turn on your:

- **Low Alert:** Color changes to **red** when your glucose goes too low.
- **High Alert:** Color changes to **yellow** when your glucose goes too high.

Trend arrow

Trend arrows help you predict where your glucose will be in the next 30 minutes. Use them to be proactive in managing your diabetes.

App	Receiver	What it means
	→	**Steady** Changing up to: • 0.06 mmol/L each minute • 1.8 mmol/L in 30 minutes
	↗ ↘	**Slowly rising or falling** Changing: • Between 0.06–0.1 mmol/L each minute • Up to 3.4 mmol/L in 30 minutes
▲ ▼	↑ ↓	**Rising or falling** Changing: • Between 0.1–0.2 mmol/L each minute • Up to 5 mmol/L in 30 minutes
▲ ▼	↑↑ ↓↓	**Rapidly rising or falling** Changing more than: • 0.2 mmol/L each minute • 5 mmol/L in 30 minutes
		No arrow Cannot determine trend. Use BG meter to make treatment decisions.

Trend graph

The trend graph displays current and past readings and shows your alert levels when alerts are turned on.

App

Hours Shown

Alert settings

High Alert Level (when alert is on)

Current Sensor Reading

Low Alert Level (when alert is on)

Past sensor readings

Receiver

Past Sensor Readings

High Alert Level (when alert is on)

Current Sensor Reading

Low Alert Level (when alert is on)

Hours shown

Menu
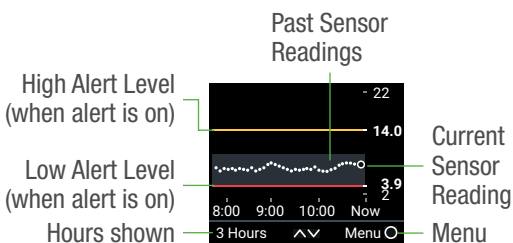
- **Current and past sensor readings:** The larger dot on the right is your current reading. The smaller dots to the left are your past readings.

- **High and Low Alert levels:** When alerts are on, they appear as lines on your trend graph. Low is red. High is yellow.

- **Target range:** The gray box shows the fixed target range of 3.9-10.0 mmol/L, the international consensus for the recommended target range.

App only

- **Hours shown:** To show readings over the past 3, 6, 12, or 24 hours, tap a number at the top.

- **Alert settings:** Turn on alerts or adjust an alert setting by tapping the More menu (3 dots).

Receiver only

- **Hours shown:** To show readings over the past 3, 6, 12, or 24 hours, use the up and down ∧∨ navigation buttons.

- **Menu:** Access the Menu by pressing the round Select button.

App navigation menu

You can access other features in the app using the icons in the navigation menu.

Icon	Description
◉	**Glucose:** Your home screen
ᵢₗₗ	**Reports:** Shows your glucose information for a specific period, including average glucose and average time in range.
⚬⚬	**Settings:** Edit alerts, change settings, customize sounds, calibrate your Dexcom ONE, and more.

Receiver navigation menu

From the home screen, press the **Select** button to access the Menu. This gets you to other features. Use the navigation buttons to move around the receiver. The receiver screens show you where to press.

Scroll up
Go back
Select
Scroll down

- **Reports:** Get your summary glucose information for a specific period.

- **Settings:** Edit alerts, change settings, customize sounds, and more. (More in **Chapter 4: Alerts**.)

- **Information:** Find out how much time you have left in your sensor. You can also test the speaker.

- **Calibration:** Use your BG meter for optional calibrations. (More in **Chapter 7: Calibration**.)

- **Replace sensor and stop sensor session:** Stop this sensor and start a new one. (More in **Chapter 6: Starting a new sensor**.)

- **Power off:** Turn off the receiver. No readings or alerts when powered off.

3.2 Reports

Using your navigation menu, access glucose reports that summarize your glucose data for a specific period. To access your reports in the:

- **App:** Tap the **Reports** icon in the navigation menu.

- **Receiver:** From the home screen, go to **Menu > Reports** to choose a report.
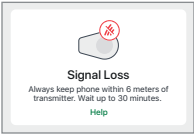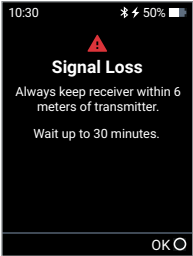
Available information:

- **Average Glucose:** The average of all the readings in the selected date range.

- **GMI:** Glucose Management Indicator (GMI) Is calculated using average sensor glucose data. GMI can be an indicator of how well glucose levels are managed. GMI will likely differ from A1C.

- **Time in Range:** Percentage of time that glucose levels are in Low, Target, and High ranges based on international consensus for target range.

3.3 Screen issues

Sometimes the number is missing, or you are not getting readings.

Display	What it means
App LOW ▶ *Receiver* LOW →	Sensor reading is below 2.2 mmol/L.
App HIGH ▶ *Receiver* HIGH →	Sensor reading is above 22.2 mmol/L.
App Signal Loss Always keep phone within 6 meters of transmitter. Wait up to 30 minutes. Help *Receiver* 10:30 ⚹⚡50% ⚠ **Signal Loss** Always keep receiver within 6 meters of transmitter. Wait up to 30 minutes. OK ○	System alerts show system issues not related to your glucose, but they tell you that you are NOT getting readings or alerts. (More in **Appendix A: Troubleshooting**.)

◯ Chapter 4
Alerts

Turning on alerts can help you stay in your target range. They are an important tool when making treatment decisions with Dexcom ONE. Talk to your healthcare professional about the best Low Alert and High Alert settings for you.

When alerts are turned on, you will hear them or feel them vibrate when your glucose is too high or too low, or when your readings are temporarily unavailable.

Critical safety notices

Dexcom ONE alerts

⚠️ No glucose alerts unless you turn them on.

• Turn on alerts during setup to get glucose and system alerts when sensor warmup is over.

⚠️ **Dexcom ONE alerts will NOT override your smartphone's settings.**

• You will **NOT** hear high or low glucose alerts if your smartphone is set to silent (sound is turned off).

• You will hear alerts ONLY when your smartphone sound is on.

• Check your smartphone's settings or you may miss an alert.

⚠️ **Dexcom ONE alerts will NOT override your receiver settings.**

• If your receiver is set to vibrate, you will not hear high or low glucose alerts.

• Turn on receiver sound to hear alerts.

4.1 Low and high alerts

What You See	What It Means
App ⚠ Low Glucose 3.8 mmol/L ▶ *Receiver* 10:30 ✳ ⚡ 50% ▬ ⚠ **Low Glucose Alert** 3.8 → mmol/L OK ○	**Low Glucose Alert (Low Alert)** Lets you know your Dexcom ONE sensor reading is below your Low Alert level. • Turn on your Low Alert during setup. • Change it in the app by going to **Settings > Alerts**. • Change it in receiver by going to **Menu > Settings > Alerts**. • You can choose your alert level and tone.
App ⚠ High Glucose 18.5 mmol/L ◣ *Receiver* 10:30 ✳ ⚡ 50% ▬ ⚠ **High Glucose Alert** 18.5 ↗ mmol/L OK ○	**High Glucose Alert (High Alert)** Lets you know when your Dexcom ONE sensor reading is above your High Alert level. • Turn on your High Alert during setup. • Change it in the app by going to **Settings > Alerts.** • Change it in receiver by going to **Menu > Settings > Alerts**. • You can choose your alert level and tone.

4.2 Turn on alerts

Dexcom ONE gives you the option of turning on alerts when you set up your system. You just follow the prompts on your screen. You can also turn on or change your alerts after setup.

App

1. Go to **Settings > Alerts**.

2. Tap the alert you want to set.

3. Follow the screen prompts**.**

‹ Settings	Alerts	
Low	Off	›
High	Off	›
Signal Loss	Off	›
Brief Sensor Issue	Off	›
Technical Alerts	On	›

Dexcom ONE alerts will not override your phone settings.

You will NOT hear or feel alerts if your phone is set to silent.

| ◎ Glucose | ▥ Reports | ⚏ Settings |
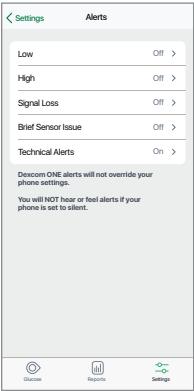
You can also turn on or adjust your Low Alert and High Alert by tapping the **More** icon in the top-right corner of your trend graph.

iOS	Android
⋯	● ● ●

App alert settings

- **Dexcom ONE alerts will NOT override your smartphone's settings.** You will **NOT** hear high or low glucose alerts if your smartphone is set to silent (sound is off). Check your smartphone's settings, or you may miss an alert.
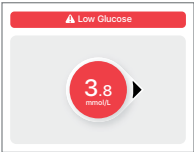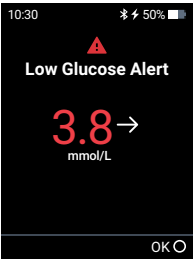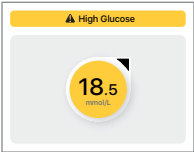
- Alert vibrations feel the same as notifications you get from other apps on your smartphone. The only way to know if it is from Dexcom ONE is to look at your smartphone.

Receiver

1. Go to **Menu > Settings > Alerts**.

2. Select the alert you want to set.

3. Follow the screen prompts.
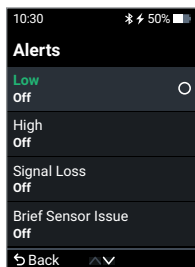
Receiver alert settings

- **Dexcom ONE alerts will NOT override your receiver settings.**

- If your receiver is set to vibrate, you will **NOT** hear high or low glucose alerts.

- Check your receiver sound settings: Go to **Menu > Settings > Alert Sounds.**

- Turn on receiver sound to hear alerts.

Customizing alert sounds

App

Tap **Tone** in an alert menu to choose a different sound for that alert.
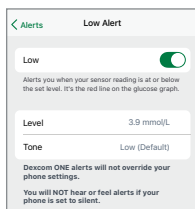
Receiver

To choose different alert sounds on your receiver:

1. Go to **Menu > Settings > Alert Sounds**.

2. Select a sound style, such as Soft Tones.
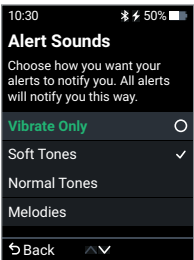
Use alerts to achieve goals

You should talk with your healthcare professional to customize your alerts to help you achieve your goals. For example, are you worried about insulin stacking—taking doses too close together?

To use your Dexcom ONE as a tool to avoid insulin stacking, your healthcare professional should advise you to turn on the Snooze feature in your High Alert setting. That way, you can choose how long you want to wait before getting another High Alert after you confirm the first one. The alert will repeat at the interval you choose until your Dexcom ONE readings are back in your target range. This reminds you to check your readings later to make sure your glucose values have come down.

The screens below show Snooze Alerts set at 2 hours. If your Dexcom ONE readings remain high for 2 hours after your first High Alert, you will get another alert. This lets you know you might want to take more insulin. If 2 hours pass and you are in your target range, your High Alert will not repeat.

App
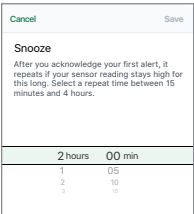
Receiver
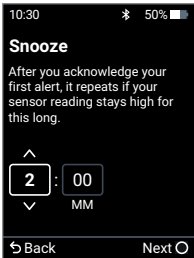
If your sensor readings tend to be high after meals, your healthcare professional may advise you to delay your first High Alert to give your insulin a chance to work. You can set the **Delay 1st Alert** and select the length of the delay in the **High Alert** setting.

Changes you make to alerts in your app are not reflected in your receiver and vice versa. If you want the alerts to be the same, you need to make changes to both devices.

◯ Chapter 5
Treatment decisions

With Dexcom ONE, you can make treatment decisions without using your blood glucose (BG) meter (BG meter). However, you should keep using your BG meter to make treatment decisions until you know how Dexcom ONE works for you.

Sometimes you must use your BG meter instead of Dexcom ONE. And other times it is best not to treat, just watch and wait.

Work with your healthcare professional to put together a plan for making treatment decisions. Always use your healthcare professional's instructions to treat.

You can keep using your BG meter until you are familiar with your CGM.

Both your BG meter and your CGM give you a number. They measure glucose from different sources (blood and interstitial fluid), so those numbers may be different. And, if you took a lab test at the same time, the lab result may give you a third number. The lab result is considered the most accurate number.

5.1 When to use your BG meter instead of your Dexcom ONE

We do not recommend continuous glucose monitoring for people who cannot or will not:
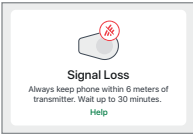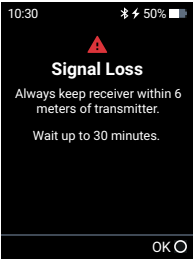
• Use their BG meter to test their blood glucose if their symptoms do not match their Dexcom ONE readings.

• Keep in touch with their healthcare professional about diabetes management.

Rely on your BG meter for treatment decisions when:

• Dexcom ONE is missing a number, an arrow, or both.

   Examples: Use your BG meter if you see any of these.

Display	What it means
App *Receiver*	No number
App *Receiver*	No arrow
App *Receiver*	No number or arrow

In other words, no number, no arrow, no CGM treatment decision.

- Your Dexcom ONE readings do not match your symptoms.

  Example: you do not feel right but your readings show your glucose is in target range. Wash your hands thoroughly and use your BG meter. If the BG meter value matches your symptoms, use the BG meter value to treat.

5.2 When to watch and wait

There are times when you should not treat at all, just watch and wait.

Stacking insulin: Do not stack insulin by taking doses too close together. Wait at least 2 hours between doses so you do not accidentally force your glucose down too low. Sometimes, it is best to watch and wait.

5.3 How to use the trend arrows

Talk to your healthcare provider about using the trend arrows to determine how much insulin to take.

Up arrow: Consider taking a little more insulin when your glucose is rising

Down arrow: Consider taking a little less insulin than usual when your glucose is falling

5.4 Treat with professional advice

Talk to your healthcare provider about:

- Using Dexcom ONE to manage your glucose

- Setting alert levels

- Comparing BG meter values and sensor readings

- Fingerstick best practices

5.5 Practice making treatment decisions

Use the examples below to practice making treatment decisions.
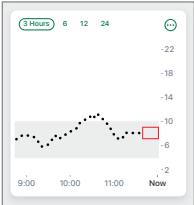
Discuss them with your healthcare professional and review:

- When you need to use your BG meter

- How you can use your Dexcom ONE

- When to watch and wait instead of treat

You can keep using your BG meter until you are familiar with your CGM.

Situation	Solution

Early morning:
Your Low Alert wakes you up.
You see:
 	
4.4 mmol/L
	Think about:
	- Number and Arrow: You have both.
	  - Number: Your glucose is low – 4.4 mmol/L.
	  - Slowly Falling Arrow: Glucose is falling up to 3.4 mmol/L in 30 minutes.
	What you should do:
	- Use your Dexcom ONE to treat as you normally would.

Situation	Solution
Breakfast time: Ninety minutes later you are sitting down for breakfast. **You see:** ▲ 7.3 mmol/L	**Think about:** • Number and Arrow: You have both. • Up Arrow: Glucose is rising up to 5 mmol/L in 30 minutes. **What you should do:** • Use your Dexcom ONE to treat. Take your normal dose and, because of the up arrow, a little more.
After breakfast: Thirty minutes after dosing to cover breakfast, you get a High Alert. **You see:** ▲ 12.4 mmol/L	**Think about:** • Insulin: You took insulin less than an hour ago. It takes time to work. **What you should do:** • Nothing. Watch and wait to avoid stacking insulin. Do not treat for at least another hour and a half.
An hour later: You watched and waited. **You see:** 9.1 mmol/L ▶	**Think about:** • Insulin: The insulin you took with breakfast has you back in your target range. **What you should do:** • Nothing. No treatment needed.

Situation	Solution
Mid-morning: You are about to have a mid-morning snack. **You see:** 	**Think about:** • **No number** and **No arrow**: You have neither. Notice the gap in Dexcom ONE readings. • Error Message: You are not getting Dexcom ONE readings. **What you should do:** • Use your BG meter for treatment decisions.
Lunch time: Three hours later, you are about to dose for lunch. **You see:** 	**Think about:** • Number and Arrow: You have both. • Down arrow: Your glucose is falling up to 5 mmol/L in 30 minutes. **What you should do:** • Use your Dexcom ONE to treat. Because of the down arrow, take a little less.
Mid-afternoon: It is 3 hours after lunch. **You see:** 	**Think about:** • Number and no arrow: You do not have an arrow. **What you should do:** • Use your BG meter for treatment decisions.

Situation	Solution
Early Evening:	**Think about:**
Just before dinner, you feel a little shaky and sweaty.	• Symptoms and Dexcom ONE reading: Your symptoms do not match your Dexcom ONE sensor readings.
You see:	**What you should do:**
6.8 mmol/L ▶	• Thoroughly wash your hands and take a fingerstick. If your BG meter value matches your symptoms, use it for treatment decisions.

5.6 Additional treatment help

Talk to your healthcare professional about:

• Using Dexcom ONE to manage your diabetes

• Setting High and Low alert levels

• Comparing BG meter values and sensor readings

• Fingersticking best practices

Online video tutorials

Access online video tutorials at **dexcom.com**.

You can view videos on the following topics:

• Sensor accuracy

• Getting started and setting up the app

• Inserting your sensor and attaching the transmitter

• How to replace your sensor

• Traveling with your Dexcom CGM

We also have training available online to support your continuous glucose monitoring (CGM) learning experience.

◇ **Chapter 6**
Starting a new sensor or transmitter

A sensor session lasts up to 10 days. A transmitter is reusable for about 3 months. This section explains how to start a new sensor or transmitter when the current one expires.

If you are inserting your first sensor, follow the instructions in the **Start Here** guide included with your system.

6.1 Starting a new sensor
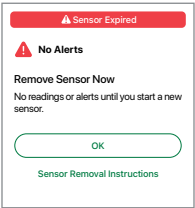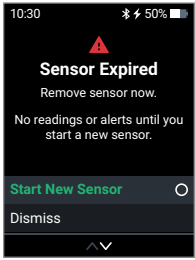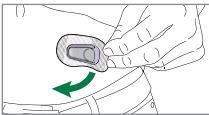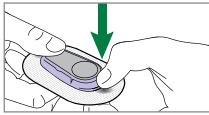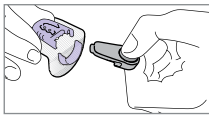
Your system alerts you when you have 24 hours left in your session, then 6 hours, 2 hours, and finally, 30 minutes. You can start a new sensor session:

- *Automatically:* Wait until your sensor expires
- *Manually:* End your session early, at your convenience
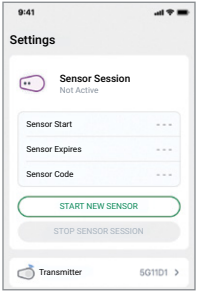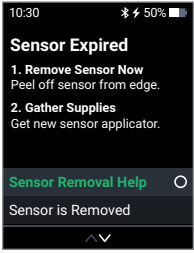
Automatically start a new sensor

Once your sensor expires, you will not get sensor readings until you start a new sensor session. Follow these steps to:

- Remove the sensor from your body
- Remove your transmitter from the holder
- Start a new sensor session
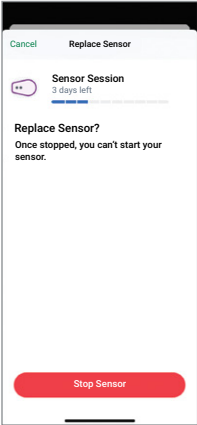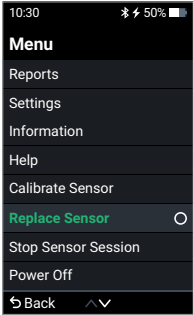
1	*App* ⚠ Sensor Expired ⚠ **No Alerts** **Remove Sensor Now** No readings or alerts until you start a new sensor. OK Sensor Removal Instructions *Receiver* 10:30 ✳⚡50% ⚠ **Sensor Expired** Remove sensor now. No readings or alerts until you start a new sensor. **Start New Sensor** ◯ Dismiss ∧∨	Dexcom ONE lets you know when to replace sensor. Remove sensor (see next step), then: • App: Tap **OK.** • Receiver: Tap **Start New Sensor.** Then follow the instructions below to remove your sensor.
2		Peel off patch from the edge.
3		Break purple transmitter holder at notches
4		1. Slide transmitter out of holder. 2. Keep transmitter to use with next sensor. 3. Throw out adhesive patch according to your local guidelines for disposal of blood-contacting components.

5	*App*
	
	9:41 .ıl 🔋
	
	Settings
	
	⬭ **Sensor Session**
	   Not Active
	
	Sensor Start - - -
	Sensor Expires - - -
	Sensor Code - - -
	
	(START NEW SENSOR)
	
	STOP SENSOR SESSION
	
	◠ Transmitter 5G11D1 >
	
	Receiver
	
	10:30 ✳ ⚡ 50% ▮
	
	Sensor Expired
	1. Remove Sensor Now
	Peel off sensor from edge.
	2. Gather Supplies
	Get new sensor applicator.
	
	Sensor Removal Help O
	Sensor is Removed
	⌄⌃
		1. App: Tap **Start New Sensor**
		
		   Receiver: Tap **Sensor is Removed**
		
		2. Follow onscreen instructions to:
		
		   • Enter the new sensor code
		
		   • Insert new sensor and re-attach your current transmitter (**Note:** Sensor insertion instructions are also available in the **Start Here** guide and at **dexcom.com**)
		
		   • Start the 2-hour sensor warmup	

Manually start new sensor

To stop a sensor session early, at your convenience:

App	App:
	1. Go to **Settings**
	2. Tap **Replace Sensor**
	Receiver:
	Go to **Menu > Replace Sensor**
Receiver	

Then, to:

• Remove the sensor from your body

• Start a new sensor

Follow the instructions in **Automatically Start a New Sensor**, beginning at step 2.

6.2 Starting a new transmitter

Remember, your transmitter is reusable for about 3 months. When it is time to pair a new transmitter, you must also start a new sensor session.

Your system will alert you when you have 3 weeks left and again when you have 2 weeks left. Once you've used the transmitter for its last sensor session, the system tells you to replace your sensor and transmitter.

You can start a new transmitter:

- *Automatically:* Wait until the current transmitter expires

- *Manually:* End it early, at your convenience

Automatically start new transmitter and sensor
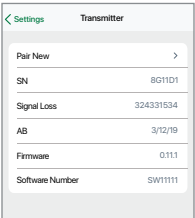
When your transmitter expires, you'll be prompted to pair a new transmitter. Follow these steps:

1	*App*
	
	⚠ Transmitter and Sensor Expired
	
	⚠ **No Alerts**
	
	Remove Sensor and Transmitter Now
	Pair a new transmitter with a new sensor. No readings or alerts until you start a new sensor.
	
	(OK)
	
	Sensor Removal Instructions
	
	―――
	
	Receiver
	
	10:30　　　 ✳ ⚡ 50% ▢
	⚠
	Transmitter and Sensor Expired
	No readings or alerts
	
	Remove sensor and transmitter now. Pair a new transmitter with a new sensor.
	
	Pair New Transmitter ○
	Dismiss
	∧∨
		App: Tap **OK.**
		
		Receiver: Tap **Pair New Transmitter**
		
		1. Follow onscreen instructions to remove the sensor and transmitter and:
		
		   • **App:** Enter the new transmitter SN and new sensor code
		
		   • **Receiver:** Enter the new sensor code and new transmitter SN
		
		2. Insert new sensor and attach new transmitter (instructions are available in the **Start Here** guide and at **dexcom.com**)
		
		3. Start the 2-hour sensor warmup
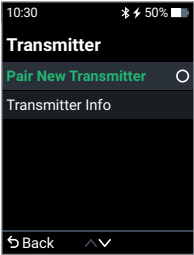
Manually start new transmitter and sensor

To stop a transmitter early, at your convenience, follow these steps:

App

1		Go to **Settings > Transmitter** and tap **Pair New** Follow onscreen instructions to: • Stop your sensor • Enter the new transmitter SN and new sensor code • Insert new sensor and attach new transmitter (instructions are available in the **Start Here** guide and at **dexcom.com**) • Start the 2-hour sensor warmup

Receiver

1	10:30 ✳ ⚡ 50% 🔋 **Transmitter** **Pair New Transmitter** ○ Transmitter Info ↺ Back ∧∨	Go to **Menu > Information > Transmitter > Pair New Transmitter** Follow onscreen instructions to: Remove your sensor • Enter the new transmitter SN and sensor code • Insert new sensor and attach new transmitter (Instructions are available in the **Start Here** guide and at **dexcom.com**) • Start the sensor and the 2-hour sensor warmup

◯ Chapter 7
Calibration
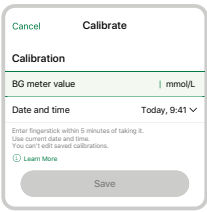
You may want to calibrate your Dexcom ONE using a BG meter value.

If you calibrate, enter your BG meter value into the app or the receiver, not both. The other device will update after about 5 minutes.
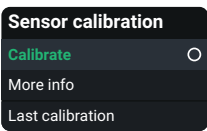
To get an accurate BG meter value, follow these steps:

1. Wash your hands with soap and water.

2. Dry your hands.

3. Take a fingerstick.

App

1	**Cancel** **Calibrate** Calibration BG meter value | mmol/L Date and time Today, 9:41 ⌄ Enter fingerstick within 5 minutes of taking it. Use current date and time. You can't edit saved calibrations. ⓘ Learn More **Save**	To calibrate your Dexcom ONE, go to **Settings > Calibrate.** Follow onscreen instructions.

Receiver

1	**Sensor calibration** **Calibrate** ◯ More info Last calibration	To calibrate your Dexcom ONE, go to **Menu > Calibrate** sensor.

If **Calibrate sensor** is not an option on your Dexcom ONE receiver menu, you can update your receiver at **dexcom.com/clarityapp.**

1. Go to **dexcom.com/clarityapp.**

2. Upload your glucose information.

When the upload is complete, Clarity will walk you through the update

BG meter values and sensor readings

Your sensor readings come from different fluids than your BG meter values, so they won't usually match. Neither number is as accurate as the lab test your healthcare provider does.

For information on accuracy and calibrating your Dexcom ONE, go to the Accuracy and calibration section in **Appendix A: Troubleshooting**.

APPENDIX

◯ Appendix A
Troubleshooting

This appendix has brief instructions for the most common questions. They are listed in alphabetical order, as shown below:

A.1 Accuracy and calibration

A.2 Accuracy – sensor readings do not match symptoms

A.3 Adhesive patch

A.4 App shuts off

A.5 Cannot hear alerts

A.6 Common alerts

- Brief sensor issue
- Pairing unsuccessful
- Signal loss alert
- Transmitter battery low and last session alerts
- Transmitter failed

A.7 End sensor session early

A.8 Gap in graph

A.9 Technical support

A.10 Recharge receiver

A.11 Water and Dexcom ONE

For full troubleshooting information, go to the frequently asked questions section on the Dexcom website **(dexcom.com)**.

A.1 Accuracy and calibration

Issue

Why aren't your BG meter value and sensor reading the exact same number?

Solution

Accuracy

One reason is they're measuring glucose in different fluids. The BG meter measures blood glucose while the sensor measures interstitial fluid. And if your healthcare provider did a lab test at the same time, the lab result may give a third number. The lab test is considered the most accurate number.

Other reasons there could be a difference between your BG meter and your Dexcom ONE are:

- **Hand cleanliness:** Wash your hands with soap and water (not hand sanitizer) and dry them. Then test. Many inaccurate BG meter values are from hands not being washed thoroughly before testing.
- **Sensor's first day:** With newly inserted sensors, the differences between your BG meter and the sensor reading may be greater. Generally, the numbers get closer over the first 24 hours.
- **Pressure on sensor:** Sometimes when something is pressing on your sensor, for example, if you're lying on it, it can affect your sensor readings. Relieve the pressure and the numbers should get closer.
- **Glucose changing quickly:** When your glucose is rapidly changing, it can be more difficult to compare your BG meter value and sensor reading because blood glucose changes a little before interstitial fluid glucose. The numbers should get closer when your glucose stabilizes.
- **Test strips:** Make sure your test strips are stored as directed and not expired. Also, make sure to use enough blood on the test strip.

  If your sensor readings are always much higher (or always much lower) than your BG meter values for several hours, consider calibrating your Dexcom ONE.

Calibration

Calibrating your Dexcom ONE is optional. It can make Dexcom ONE more accurate or less accurate compared to the lab result, but it should bring the sensor readings closer to your BG meter value.

Don't calibrate in these situations:
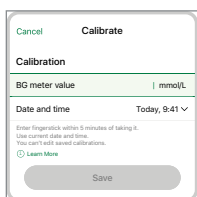
- **Sensor site pressure:** Don't calibrate if the sensor reading seems inaccurate because of pressure on the sensor. The sensor should recover on its own when the pressure is relieved.

- **Rapidly changing glucose:** Calibration works best when your glucose is stable. Consider waiting to calibrate if your glucose is changing rapidly.

When calibrating, make sure to:
- **Clean hands:** Wash your hands with soap and water and dry them.
- **Enter within 5 minutes:** Enter the calibration within 5 minutes of taking a fingerstick.
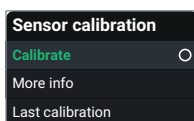
To calibrate your Dexcom ONE using your BG meter (optional):

App	*Receiver*

In the app, go to **Settings > Calibrate.**

In the receiver, go to **Menu > Calibrate Sensor.**

Follow onscreen instructions.

When you calibrate your Dexcom ONE using your BG meter, remember:

- **Calibrate in one display device:** Calibrate in one display device, even if you use both the app and receiver. The sensor sends calibration information between them.

- **Meter values:** Dexcom ONE reports readings from 2.2 - 22.2 mmol/L, but you can still calibrate your Dexcom ONE if your BG meter value is between 1.2 and 33.3 mmol/L.

- **Calibration Not Used alert:** If you get a Calibration Not Used alert, take another fingerstick and calibrate again.

A.2 Accuracy — sensor readings do not match symptoms

If your readings do not match your symptoms:

- Wash your hands with soap and water. Dry them. Then take a fingerstick with your BG meter. If your BG meter value matches your symptoms, use it to make treatment decisions.

A.3 Adhesive patch

Issue

Applicator will not come off
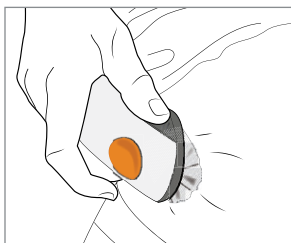
Solution

1. Gently peel off adhesive patch with applicator attached.

2. Check insertion site to make sure the sensor is not left in the skin.

3. Do not reuse applicator.

4. Contact Technical Support at **dexcom.com**, or contact your local Dexcom representative.

Issue

Adhesive patch peeling off body
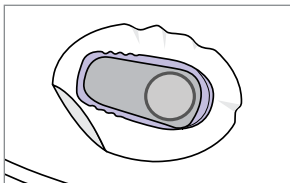
Solution

After your sensor is inserted, you can reduce peeling by:

• Putting Overpatch or medical tape (such as Blenderm) over the adhesive patch. Do not cover transmitter. Avoid open wounds.

• To order Overpatch, contact Technical Support at **dexcom.com**, or contact your local Dexcom representative.
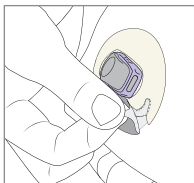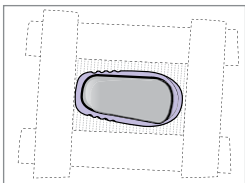
Overpatch   Medical Tape

For your next sensor session, you can prevent peeling before inserting your sensor by:

• Making sure your skin is clean and dry before inserting sensor.

• Using adhesive products (such as Mastisol®, SkinTac™) under patch. Avoid spot where needle inserts.

• Thoroughly rubbing patch onto skin.

Issue
Skin irritation around sensor site
Solution
Some people are sensitive to the sensor adhesive. If you have significant skin irritation, such as itching, burning and/or rashes at the site of the adhesive patch, contact your health care professional.

A.4 App shuts off

If your app shuts itself off, it may be because the smart device's memory or storage is full. To fix this, close open apps that are not in use and delete files you do not use.

A.5 Cannot hear alerts

1. No glucose alerts unless you turn them on. If you did not turn on alerts during setup, turn them on now.

   • App: Go to **Settings > Alerts**

   • Receiver: Go to **Menu > Settings > Alerts**

2. **Dexcom ONE alerts will NOT override your smart device's settings.**

   • *App:* You will NOT hear high or low glucose alerts if your phone is set to silent (sound is off) or vibrate.

   • *Receiver:* If your receiver is set to vibrate, you will not hear high or low glucose alerts. Turn on receiver sound to hear alerts: **Menu > Settings > Alert Sounds.**

3. If alerts are turned on, and your smartphone is set to sound, verify that the app, *Bluetooth*, volume, and notifications are on.

4. Go to **Chapter 2** for suggested smartphone settings. Go to your smartphone product instructions to test the speaker.

A.6 Common alerts

Issue

Brief sensor issue

App

> ⚠ **No Alerts**
>
> **Brief Sensor Issue**
> Don't remove sensor. Temporary issue.
> Wait up to 3 hours.
>
> OK

Receiver

> 10:30   ⁕ ⚡ 50% 🔋
>
> ⚠
> **Brief Sensor Issue**
> Don't remove sensor.
> Temporary issue.
>
> Wait up to 3 hours.
>
> OK ⭘
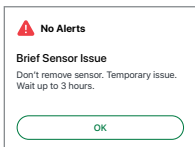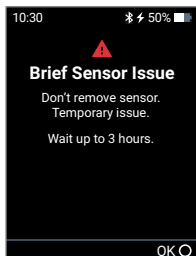
Sensor is temporarily unable to measure glucose.

Solution

1. Check transmitter; is it snapped into transmitter holder?

2. Wait up to 3 hours while the Dexcom ONE fixes itself.

3. If not corrected after 3 hours, contact Technical Support at **dexcom.com**, or contact your local Dexcom representative.

No alerts or sensor readings until fixed. Use your BG meter for treatment decisions.

No Readings alert may lead to Sensor Failed alert.

Tap or select **OK** to clear the alert, then to go **Help** on the home screen for more information.

Issue

Pairing unsuccessful

App

Pairing Unsuccessful   Done

Pairing Unsuccessful

Try Pairing Again

Receiver

10:30   ⚡ 50% 🔋

Pairing Unsuccessful

Check troubleshooting tips and
try pairing again.

Try Pairing Again   ○

Troubleshooting Tips

Edit Transmitter SN

⌃⌄
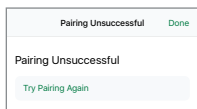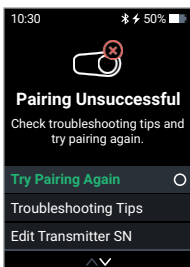
Dexcom ONE did not pair.

Solution

1. Make sure transmitter is snapped into transmitter holder.

2. Check the transmitter serial number (SN) and try again.

3. If you did not do the following when pairing, pair again, and do them:

   • Accept the *Bluetooth* Pairing Request.

   • Stay within 6 meters of the display device.

4. Do not use an expired transmitter.

5. Replace your sensor, attach the transmitter again, and pair. If you need a replacement, contact Technical Support at **dexcom.com**, or contact your local Dexcom representative.

No alerts or sensor readings until fixed. Use your BG meter for treatment decisions.

Issue

Signal loss

App	*Receiver*

No Alerts

Signal Loss
Always keep phone within 6 meters of transmitter. Wait up to 30 minutes.

OK

10:30   50%

Signal Loss
Always keep receiver within 6 meters of transmitter.

Wait up to 30 minutes.

OK
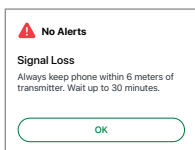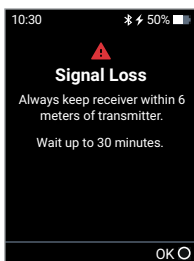
Display device and transmitter are not communicating.

Solution

Try each of these tips and wait 10 minutes to see if *Bluetooth* reconnects:

1. Be sure your transmitter and display device are within 6 meters of each other. If you are in water, keep device closer than 6 meters.

2. Turn *Bluetooth* off and on.

3. Restart display device. Reopen Dexcom ONE app if using your smartphone.

4. If these tips do not solve the problem, contact Technical Support at **dexcom.com**, or contact your local Dexcom representative.

No alerts or sensor readings until fixed. Use your BG meter for treatment decisions.

Issue

Transmitter battery low and last session alerts
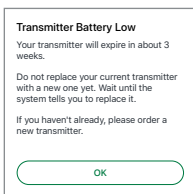
App   *Receiver*

Transmitter Battery Low

Your transmitter will expire in about 3 weeks.

Do not replace your current transmitter with a new one yet. Wait until the system tells you to replace it.

If you haven't already, please order a new transmitter.

OK

10:30   ✳ ⚡ 50% ▭

Transmitter Battery Low

Your transmitter will expire in about 3 weeks.

Do not replace your current transmitter with a new one yet. Wait until the system tells you to replace it.

If you haven't already, please order a new transmitter.

OK   ○

Transmitter battery expiring.

Solution

Order new transmitter.

When your transmitter battery is about to expire, Dexcom ONE tells you when it:

- Has 3 weeks left
- Has 2 weeks left
- Has 1 more session
- Is too low for another session
- Is critically low and must be replaced immediately

Issue	
Transmitter failed	
App	*Receiver*

10:30	⚡ 50%

⚠️ **Transmitter Failed**
No readings or alerts.

Remove sensor and transmitter now. Pair a new transmitter with a new sensor.

Pair New Transmitter ○

Dismiss

⌃⌄
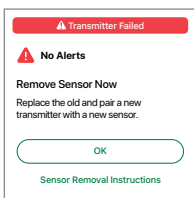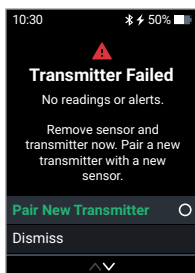
Transmitter not working. Sensor session automatically stops.

Solution
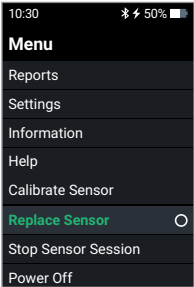
To report this issue and get a replacement, contact Technical Support at **dexcom.com**, or contact your local Dexcom representative. No alerts or sensor readings until replaced. Use your BG meter for treatment decisions.

A.7 End sensor session early

You might want to end your sensor session early. Once you stop your sensor session, you will not be able to restart it.

App

1	Tap **Settings**
	◎ Glucose ▥ Reports ⚙ Settings
2	Tap **Stop Sensor Session**
	Remove the sensor and transmitter. Go to **Chapter 6** for more information.
	REPLACE SENSOR
	STOP SENSOR SESSION

1	Go to **Menu**
2	Select **Stop Sensor Session**
	Remove the sensor and transmitter. Go to **Chapter 6** for more information.

A.8 Gap in graph

Your graph may show a gap if you are not getting readings. When readings resume, Dexcom ONE can fill in up to 3 hours of missed readings.
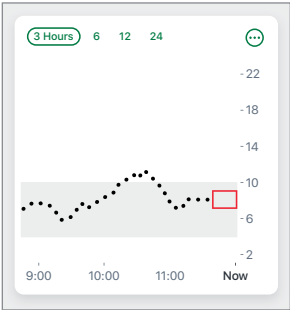
A.9 Technical support

For help with the Dexcom ONE CGM system, contact Technical Support at **dexcom.com**, or contact your local Dexcom representative.

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which you are established.

A.10 Recharge receiver

Issue
Your receiver needs to be charged when:
• **Battery icon shows low charge**
• **Receiver won't turn on. This can happen during normal use or after storage or shipping**
Solution
Use the Dexcom supplied charger. Full charge may take up to 3 hours.

A.11 Water and Dexcom ONE

Once snapped into place, the transmitter is water resistant. Swim, shower, take a bath: no need to worry about water and your Dexcom ONE – just leave your display device in a dry area.

If you are in water, your display device needs to be closer than 6 meters to get sensor readings.

◯ Appendix B
Dexcom Clarity

Dexcom Clarity is an important part of your CGM system, providing a holistic view of your diabetes management by highlighting glucose patterns, trends, and statistics. It can help you identify glucose patterns and, with your healthcare provider, determine the potential causes of those patterns.

Get reports on the web at **dexcom.com/clarityapp** and on the go using the Dexcom Clarity app. Just log in with your Dexcom information. When you also use the Dexcom CGM app, you automatically and continuously send your glucose data to your Dexcom Clarity account (internet connection required).

With a sharing code provided by your clinic, you can authorize your clinic to have continuous access to your data during visits or anytime you might need assistance.

If you only use the receiver, upload your data to Clarity at least once every six months.

To get started, either:

- Share using Dexcom Clarity app:

    1. Log into the Dexcom Clarity app with your Dexcom login

    2. Tap **Profile > Authorize** Sharing and follow the instructions on the screen

- Or share using the Dexcom Clarity website:

    1. Log into Dexcom Clarity online at **dexcom.com/clarityapp**

    2. Follow the instructions on the screen

◯ Appendix C
Taking care of your Dexcom ONE

C.1 Dexcom ONE storage and maintenance

Sensor
- Keep in its sterile packaging until you are ready to use it.
- Store at temperatures between 2°C and 30°C.

Transmitter
- Keep in box until ready for use. Check transmitter and do not use if damaged.
- Store at temperatures between 0°C and 45°C.
- Store between 10% and 95% relative humidity.

Receiver
- Keep physical control of your Dexcom receiver to prevent unauthorized access to your personal information.
- Keep battery charged. Only use Dexcom USB charging/download cable.
- When carrying the receiver in your purse or pocket consider using a screen protector that doesn't interfere with the information displayed. Protect it from metal items and pointed objects.
- Don't get sunscreen or insect repellent on it.
- Update the date/time on the receiver when needed.
- Clean when dirty or at least once a month. Disinfect when needed to avoid cross-contamination.

To clean

1. Use one of these cleaners:

    - Damp cloth with liquid hand soap and water
    - Bleach wipes
    - Ammonium wipes

2. Wipe

    - Using moderate pressure, wipe the receiver all over, 3 times up-and-down and 3 times side-to-side, to remove all dirt or soil

3. Let air dry

To disinfect

1. Repeat cleaning instructions using a new bleach or ammonium wipe.

2. Wipe receiver until completely wet. Use wipe to keep receiver wet for 2 minutes.

3. Let air dry.

Tips

- Don't get water or other fluids inside the receiver through openings like the USB port
- Don't use anything abrasive on the receiver
- If the receiver has a screen protector, remove it before cleaning and disinfecting
- Using alcohol wipes to clean the receiver hasn't been tested

Use correct transmitter and sensor

- Dexcom ONE components are not compatible with any previous Dexcom products. Do not mix transmitters, receivers, and sensors from different generations.

C.2 System disposal

Different regions have different requirements for disposing of electronics (transmitter) and parts that have come in contact with blood or other bodily fluids (sensor). Follow your area's local waste management requirements.

◇ **Appendix D**
Packaging symbols

Symbols are on the Dexcom ONE packaging. They show proper and safe use of the Dexcom ONE. For symbol descriptions, refer to the table below.

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:

Symbol	Meaning
~	Alternating Current
EC REP	Authorized Representative in the European Community
LOT	Batch/Lot Number
✳	*Bluetooth* is on; device pairing is enabled
REF	Catalog Number
⚠	Caution, Consult Instructions for Use
▢	Class II Equipment
📖	Consult Instructions for Use
⚠	Danger: Piercing object
ᴧ	Date of Manufacture
===	Direct Current
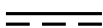
	Do Not Reuse
	Do Not Use if Package is Damaged
	Electronic piercing waste
	Electronic piercing waste disposal box
	For Indoor Use Only
	French Triman logo: Recycle and dispose separately
	Waste Electrical and Electronic Equipment (WEEE) – Follow local requirements for proper disposal
	Humidity Limitation
	Importer
	Input
IP28	Degrees of Ingress Protection Provided by Enclosure Objects > 12.5 mm diameter; immersion in water
	Keep Away from Heat
	Keep Dry
	Manufacturer
CE 2797	CE Marking of Conformity
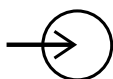
MD	Indicates the item is a Medical Device
(MR)	MR (Magnetic Resonance) Unsafe
PN	Part Number
⊞	Pharmacy
☒	Piercing object disposal box
SN	Serial Number
STERILE R	Sterilized Using Irradiation
⬭	Single sterile barrier system with protective packaging outside
⌡	Temperature Limit
⬙	Type BF Applied Part
UK CA 0086	UKCA Marking of Conformity
UK REP	UK Responsible Person
UDI	Unique device identifier
⧗	Use By Date

○ **Appendix E**
Risks and benefits

The intended purpose of the Dexcom ONE Continuous Glucose Monitoring System (Dexcom ONE) is to continuously measure the glucose in the interstitial fluid, calculate the blood glucose reading, and make this value available to the user and follower, if applicable.

When using any medical device, there are risks and benefits. In this appendix, you'll learn what they are.

E.1 Risks

The risks when using Dexcom ONE are:

- Not getting your alerts
- Using Dexcom ONE to make treatment decisions when you should not
- Sensor insertion issues
- Adhesive reactions
- Sensor wire remains under the skin

Not getting alerts

Check your display device if you aren't getting alerts:

- Battery charged
- App on
- Alerts on
- Volume up
- Speaker and vibrations work
- In range within 6 meters
- No System errors, such as Brief Sensor Issue or Signal Loss
- Warmup and after session ends: You will **NOT** get alerts or Dexcom ONE readings during the 2-hour Dexcom ONE warmup or after a sensor session ends.
- App *Bluetooth* on

Make sure your smartphone settings follow Dexcom's recommended settings.

Go to **Appendix A: Troubleshooting** and the recommended settings in **Chapter 2** for more information.

Using Dexcom ONE for treatment decisions

You can use your Dexcom ONE for treatment decisions in all but a few situations.

Situation: How you feel is inconsistent with your Dexcom ONE reading

Treatment Decision Tool: Take a fingerstick for a BG measurement and use the number to make a treatment decision

Situation: Your CGM display is missing Dexcom ONE reading (number) or arrow(s), or both

Treatment Decision Tool: Take a fingerstick for a BG measurement and use the number to make a treatment decision

Some users found accuracy between different sensors varied significantly. When you insert each sensor, pay attention to its accuracy before deciding to use it for treatment decisions.

For more information on how to make treatment decisions using your Dexcom ONE, go to **Chapter 5**.

Paracetamol/acetaminophen interfering substance risks

With the Dexcom ONE, you can take a standard or maximum paracetamol/acetaminophen dose of 1 gram (1,000mg) every 6 hours and still use the Dexcom ONE readings to make treatment decisions. Taking higher than the maximum dose of paracetamol/acetaminophen (e.g. > 1 gram every 6 hours in adults) may affect the Dexcom ONE readings and make them look higher than they really are.

Hydroxyurea interfering substance risks

Hydroxyurea, a medication used to treat some cancers or blood disorders, may falsely elevate your Dexcom ONE readings and result in missed

hypoglycemia alerts or errors in diabetes management decisions. The level of inaccuracy depends on the amount of hydroxyurea in your body. Use your BG meter.

Sensor insertion risks

Inserting the sensor can cause infection, bleeding, or pain. Some people are sensitive to the sensor adhesive. If you have significant skin irritation, such as itching, burning, and/or rashes at the site of the adhesive patch, contact your healthcare professional.

No sensor wires broke or detached in clinical studies; however, there is a remote chance a sensor wire could break or detach and remain under your skin. Sterile broken or detached sensor wires usually do not pose a significant medical risk. If a sensor wire breaks off or detaches, remains under your skin, and shows signs of infection or inflammation, contact your Healthcare Professional and Technical Support at **dexcom.com,** or contact your local Dexcom representative.

E.2 Benefits

Some benefits of using your Dexcom ONE are:

- Managing your diabetes

- Knowing where your glucose was and where it is going

- Getting immediate feedback on your lifestyle decisions

- Making treatment decisions using your Dexcom ONE

- Decreasing the pain and hassle from frequent blood glucose testing, sparing the fingertips

Knowing your trends

The Dexcom ONE not only sends you a glucose reading every 5 minutes but also provides overviews of your glucose trends and patterns. This lets you see the overall picture and how the foods you eat, medications you take, and exercise impact your glucose levels.

Making treatment decisions using Dexcom ONE

With Dexcom ONE, there is no need to take fingersticks to calibrate the system or for treatment decisions (as long as your symptoms match your Dexcom ONE readings). This can reduce the pain and burden of excessive fingersticks (Price and Walker, 2016) and potential errors due to inaccurate calibration (Wadwa, 2018).

Helping your diabetes management

The optional alerts features notify you when your glucose goes outside your target range. This lets you take action to prevent glucose from going too low or too high. Go to **Chapter 4** for more information.

References

Aleppo, G (2017). Replace-BG: a randomized trial comparing continuous glucose monitoring with and without routine blood glucose monitoring in well-controlled adults with type 1 diabetes. *Diabetes Care, 40*(4), 538-545. doi: 10.2337/dc16-2482.

Price D, Walker T. The Rationale for Continuous Glucose Monitoring-based Diabetes Treatment Decisions and Non-adjunctive Continuous Glucose Monitoring Use. *Eur Endocrinol.* 2016;12(1):24-30. doi:10.17925/EE.2016.12.01.24

Wadwa RP, Laffel LM, Shah VN, Garg SK. Accuracy of a factory-calibrated, real-time continuous glucose monitoring system during 10 days of use in youth and adults with diabetes. *Diabetes Technol Ther.* 2018;20(6):395-402.

○ Appendix F
Dexcom ONE warranty

Sometimes things happen. Dexcom has you covered!

This appendix covers our warranty information outlining what we cover and for how long.

F.1 Dexcom receiver limited warranty

What is covered and for how long?

Dexcom, Inc. or its local Dexcom affiliate ("Dexcom") provides a limited warranty to the individual end user ("you" or "User") that the Dexcom receiver (the "receiver") is free from defects in material and workmanship under normal use ("Limited Warranty") for the period commencing on the date of original purchase and expiring one (1) year thereafter, provided it is not modified, altered, or misused.

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

System modifications are not permitted and void all warranties

This Limited Warranty is based on User properly using the continuous glucose monitoring system in accordance with the documentation provided by Dexcom. You are not permitted to use the continuous glucose monitoring system otherwise. Misusing the continuous glucose monitoring system, improperly accessing it or the information it processes and transmits, "jailbreaking" or "rooting" your continuous glucose monitoring system or smartphone, and taking other unauthorized actions may put you at risk, cause the continuous glucose monitoring system to malfunction, are not permitted, and void your Limited Warranty.

What is not covered?

This Limited Warranty does not cover:

- 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.

- Equipment with the SN number removed or made illegible.

- All surfaces and other externally exposed parts that are scratched or damaged due to normal use.

- 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.

- Defects or damage from improper testing, operation, maintenance, installation, or adjustment.

- Installation, maintenance, and service of products or services other than the CGM system (which may be subject to a separate limited warranty), whether provided by Dexcom or any other party; this includes your smartphone or smart device and your connection to the Internet.

- A receiver that has been taken apart physically or has had any of its software accessed in any unauthorized manner.

- Water damage to the receiver. Although the receiver is designed to withstand splashing, you should avoid getting the receiver wet.

Dexcom's obligations under the limited warranty

During the Limited Warranty Period, Dexcom will replace, without charge to User, any defective receiver.

To obtain assistance regarding a defective receiver, contact Dexcom Technical Support at **dexcom.com** or contact your local Dexcom distributor.

Limits on Dexcom's limited warranty and liability obligations

The Limited Warranty described above is the exclusive limited 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, express or implied, including without limitation any warranty of merchantability, fitness for a particular purpose, or non-infringement, except to the extent prohibited by applicable law.

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

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 User and cannot be transferred to anyone else, and it states User'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 does not change or limit your rights under any warranty the User has from a seller or under mandatory applicable law.

F.2 Dexcom sensor limited warranty

What is covered and for how long?

To the extent allowed by law, the Dexcom ONE sensor is provided to you "as is." Dexcom hereby disclaims all warranties (express, implied, and statutory) with respect to the sensor, including, but not limited to, the implied warranties of merchantability and fitness

for a particular purpose. There are no warranties which extend beyond the description herein.

F.3 Dexcom transmitter limited warranty

What is covered and for how long?

Dexcom, Inc. or its local Dexcom affiliate ("Dexcom") provides a limited warranty to the individual end user ("you" or "User") that the Dexcom ONE transmitter (the "transmitter") is free from defects in material and workmanship under normal use ("Limited Warranty") for the period commencing on the date of the original purchase and expiring three (3) months thereafter.

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

What is not covered?

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

This Limited Warranty does not cover:

- 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.

- Equipment with the SN number removed or made illegible.

- All surfaces and other externally exposed parts that are scratched or damaged due to normal use.

- Malfunctions resulting from the use of the transmitter in conjunction with accessories, ancillary products, and peripheral equipment, whether hardware or software, not furnished or approved by Dexcom.

- Defects or damage from improper testing, operation, maintenance, installation, or adjustment.

- Installation, maintenance, and service of products or services other than the continuous glucose monitoring 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.

- A transmitter that has been taken apart physically or has had any of its software accessed in any unauthorized manner.

- Beyond specifications listed in the Dexcom ONE User Guide.

Dexcom's obligations under the limited warranty

During the Warranty Period, Dexcom will replace, without charge to User, any defective transmitter. To obtain assistance regarding a defective transmitter, contact Dexcom at **dexcom.com**, or contact your local Dexcom representative.

Limits on Dexcom's warranty and liability obligations

The Limited Warranty described above is the exclusive limited warranty for the transmitter, 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, express or implied, including without limitation any warranty of merchantability, fitness for a particular purpose, or non-infringement, except to the extent prohibited by applicable law.

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

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 User and cannot be transferred to anyone else, and it states User'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 does not change or limit your rights under any warranty the User has from a seller or under mandatory applicable law.

○ **Appendix G**
Technical information

G.1 Device performance characteristics summary

When LOWER is better

Adults	Performance metrics*	Pediatrics
9.8%	**Overall Accuracy** **Mean ARD% (MARD), 2.22–22.22 mmol/L** (% average absolute error versus reference across all glucose levels)	7.7%
Day 1: 8.6% Day 2: 8.7% Days 4–5: 10.7% Day 7: 10.6% Day 10: 10.6%	**Accuracy Over Time** **Mean ARD% (MARD), 2.22–22.22 mmol/L**	Day 1: 10.5% Day 2: 7.8% Days 4–5: 7.2% Day 7: 6.2% Day 10: 7.1%

When HIGHER is better

Adults	Performance metrics*	Pediatrics
92% [100%]	**Clinical Accuracy** **% of readings that were in the Clarke Error Grid (CEG) A Zone** [% CEG A+B Zone]	96% [99.8%]

*Reference is YSI (Yellow Springs Laboratory Instrument)

G.2 Product specifications

WARNING: Use of accessories 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.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the Dexcom ONE CGM system including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: Misuse of the USB cable can present a strangulation risk.

The device behaves normally while charging, however, do not hold the receiver while charging for over a minute as the device can get warm to the touch.

CAUTION: If you have difficulty reading your receiver in bright sunlight, you may need to seek a shady location.

Sensor product specifications

Glucose range	2.2–22.2 mmol/L
Sensor useful life	Up to 10 days
Storage and transport conditions	Temperature: 2°C–30°C Store sensors in a cool, dry place
Sterilization	Sterile by radiation

Transmitter and receiver product specifications

	Transmitter	Receiver
Memory storage	N/A	180 days of glucose data
Electrical safety class	Internally Powered	Internally/battery powered, re-chargeable; AC mains powered
Useful Life (typical)	3 months	3 years
Battery longevity (typical)	3 months	7 days
Battery charging time	Non-rechargeable	Approximately 3 hours
Operational conditions	Temperature: 10°C–42°C Humidity: 10%–95% RH	Temperature: 0°C–40°C Humidity: 10%–90% RH
Storage and transport conditions	Temperature: 0°C–45°C Humidity: 10%–95% RH	Temperature: 0°C–40°C Humidity: 10%–90% RH
Operating altitude	-396 meters to 4,206 meters	-382 meters to 5,000 meters

Transmitter and receiver product specifications

	Transmitter	**Receiver**
Ingress protection	IP28: Protection against insertion of large objects and immersion in water for up to 2.4 meters for 24 hours	IP54: Protected from ingress of dust; Protected from splashing water in any direction
Protection against electrical shock	Type BF applied part	No applied parts
Alarm audible output	N/A	50dBA at 1 meter
TX/RX frequencies	2.402–2.480 GHz	
Bandwidth	1.07 MHz	1.39 MHz
Maximum output power	1.0 mW EIRP	7.4 mW EIRP
Modulation	Gaussian Frequency-Shift Keying	
Data rate	1 Mbps	
Data communication range	6 meters	

The maximum surface temperature of
Applied part = 43°C.

Essential performance

The Dexcom ONE system measures patients'
glucose sensor readings with specified accuracy
under the stated operating conditions. The Essential
Performance of the Dexcom ONE CGM system also

includes reporting the corresponding measured glucose sensor readings and alerts on the display device.

Quality of service summary

Quality of Service for the Dexcom ONE System wireless communication using *Bluetooth* Low Energy is assured within the effective range of 6 meters, unobstructed, between the Dexcom ONE transmitter and paired display device at regular 5-minute intervals. If connection is lost between the transmitter and display device, upon re-connection any missed packets (up to 3 hours) will be transmitted from the transmitter to the display device. The Dexcom ONE CGM System is designed to only accept radio frequency (RF) communications from recognized and paired display devices.

Security measures

The Dexcom ONE System is designed to transmit data between the transmitter and designated display devices in accordance to the industry standard BLE protocols. It will not accept radio frequency (RF) communications using any other protocol, including *Bluetooth* classic communication protocols.

In addition to the security provided by the BLE connection, communication between the Dexcom ONE transmitter and the Dexcom ONE receiver and mobile application is protected by additional levels of security and safety mitigations using an encrypted and proprietary data format. This format embeds various methods to verify data integrity and to detect potential instances of data tampering. While the format is proprietary, industry standard encryption protocols (e.g., RSA and AES) are used in different parts of this proprietary data format.

Unless disabled, the Dexcom ONE mobile application regularly communicates with Dexcom Servers. Communication between the Dexcom ONE applications and Dexcom Servers is protected by a number of mechanisms, designed to safeguard against data corruption. This includes industry standard JWIT token based authentication and authorization. All such communication takes place exclusively over an encrypted data path using industry standard SSL format.

USB charging/download cable specifications

Input/output	5 V DC, 1A
Type	USB A to USB micro B
Length	0.91 meters

Power supply/charger specifications

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)

Electromagnetic immunity and emissions declaration and guidance

The transmitter and receiver are 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.

Immunity test	Transmitter compliance level	Receiver compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air	
Magnetic field (50Hz) IEC 61000-4-8	30 A/m	
Electrical fast transient/burst IEC 61000-4-4	N/A	± 2 kV for power supply lines
Surge IEC 61000-4-5	N/A	± 0.5 kV, ± 1 kV line(s) to line(s)

Immunity test	Transmitter compliance level	Receiver compliance level
Voltage dips and interruptions **IEC 61000-4-11** **IEC 60601-1-11**	N/A	0% 230V for 1 cycle 0% 230V for 0.5 cycle at 8 phase angles 70% 230V (30% dip in 230V) for 25 cycles 0% 230V for 250 cycles
Conducted fields disturbance **IEC 61000-4-6**	N/A	6 Vrms 150 kHz to 80 MHz
Radiated fields disturbance **IEC 61000-4-3**	10 V/m at 80 MHz to 2700 MHz (AM Modulation)	
Radiated and conducted fields **Aircraft use**	Meets RTCA/DO-160 edition G Section20, Category T	

Electromagnetic interference can still occur in the home health care environment as control over the EMC environment cannot be guaranteed. An interference event can be recognized by gaps in sensor readings or gross inaccuracies. The user is encouraged to try to mitigate these effects by one of the following measures:

- If the Dexcom ONE sensor reading does not match your symptoms or expectations take a fingerstick. Usually, the Dexcom ONE sensor reading is close to the BG meter value. Your Dexcom ONE is working normally if those two numbers are:

    - Within 20% (if Dexcom ONE reading is 3.9 or more)

    or

    - Within 1.1 mmol/L (if Dexcom ONE reading is less than 3.9)

For example, your Dexcom ONE is working normally in this situation:

- Dexcom ONE reading: 6.5
- Acceptable range (20%): 5.2 – 7.7 mmol/L
- BG meter value: 5.5

- Your Dexcom ONE may not be working normally when those two numbers are:

  - More than 30% apart (if Dexcom ONE reading is 3.9 or more)

  or

  - More than 1.7 mmol/L apart (if the Dexcom ONE reading is less than 3.9)

  In that case, use your BG meter value to make treatment decisions.

  For example, your Dexcom ONE may not be working normally in this situation:

- Dexcom ONE reading: 6.5
- Acceptable range (30%): 4.6 – 8.4 mmol/L
- BG meter value: 9

  Your Dexcom ONE may be working normally but is not aligned with your BG meter when those two number are:

- Between 21% and 30% apart (if Dexcom ONE reading is 3.9 or more)

  or

- Between 1.2 mmol/L and 1.7 mmol/L apart (if Dexcom ONE reading is less than 3.9)

  In that case, make treatment decisions on the number that matches your symptoms and expectations.

- If display device misses 20 minutes of sensor glucose data (4 readings), the Signal Loss error displays. To resolve, go to **Appendix A: Troubleshooting**.

- If display device shows the loading screen unexpectedly and does not display the trend screen within 3 minutes, contact Technical Support at **dexcom.com**, or contact your local Dexcom representative. For more information, go to **Appendix A: Troubleshooting**.

- If your receiver does not work for 6 minutes, contact Technical Support at **dexcom.com**, or contact your local Dexcom representative.

Electromagnetic emissions specifications

Immunity test	Compliance
Radio frequency emissions CISPR 11	Group 1, Class B
Radio frequency emissions Aircraft Use	Meets FAA RTCA /DO-160 edition G Section 21, Category M for in-cabin use.

G.3 Radio regulations compliance

Hereby, Dexcom, Inc. declares that the radio equipment type Dexcom ONE System is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: **dexcom.com/doc**.

◌ Appendix H
Professional use instructions

H.1 Introduction

Dexcom ONE supports multi-patient use. You just:

- Prepare Dexcom ONE for your patient
- Tell the patient what Dexcom ONE is and how it works
- Set up the system with the patient
- Follow up with the patient to share insights on their glucose trends, patterns, and statistics

This helps both of you manage their diabetes better. The following sections go through each step and give you resources to share with your patients as you guide them through a sensor session.

H.2 Prepare Dexcom ONE for patient

Decide whether the patient should be able to see their Dexcom ONE readings (unblinded). Will this motivate them to manage their diabetes better?

Whether the receiver is blinded or unblinded, all Dexcom ONE patients:

- Must carry their receiver to record data for later analysis
- Will get system alerts, such as Signal Loss and Brief Sensor Issue

The differences between blinded and unblinded are:

- **Unblinded:** Receiver shows patient's sensor reading, trend arrow, graph, Low and High glucose alerts.
- **Blinded:** Receiver does not show any unblinded information. In addition, it does not show the Warmup Complete message.

Go to **dexcom.com/clarityapp** for more information (may not be available in all regions).

Follow the instructions to clean and disinfect the receiver and transmitter between patients.

---

1. Prepare receiver

a. Charge and reset receiver:

- Resetting the receiver removes the previous patient's data. To ensure patient privacy, reset the receiver after each use.

b. Clean and disinfect

- See instructions in the Storage and Maintenance section in Appendix C.
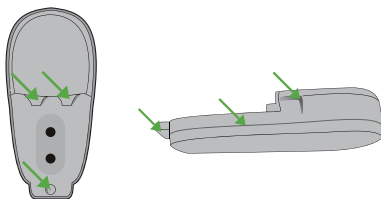
---

2. Clean transmitter

a. Prepare

- Protect: Wear clean gloves and goggles

- Prepare Soak: Put Clorox Healthcare® Bleach Germicidal Cleaner solution (Clorox) in a container deep enough to submerge the transmitter

b. Clean

- Rinse and Scrub: Rinse transmitter in cold tap water while brushing with a soft bristle brush until all visible soil is gone

- Soak and Scrub:

    - Put transmitter in prepared soak for 3 minutes

    - While immersed, scrub uneven areas (see green arrows) with a soft bristled brush or a pre-saturated bleach wipe

---

c. Rinse and dry

- Rinse: Remove from soak and rinse transmitter under flowing cold tap water for 10 seconds
- Dry: Wipe transmitter dry with cloth

d. Inspect

- Verify there is no visible soil. If there is, clean again.

3. Disinfect transmitter

a. Prepare

- Protect: Wear clean gloves and goggles
- Prepare Soak and syringe:
  - Put CaviCide® solution (Cavicide) in a container deep enough to submerge the transmitter
  - Fill syringe with about 30 mL of Cavicide

b. Disinfect

- Flush:
  - Focus on the uneven areas
  - Swirl in Cavicide for 10 seconds
  - Refill syringe
- Scrub:
  - Saturate clean cloth or wipe with Cavicide
  - Wipe entire transmitter for at least 3 minutes or until all soil is removed
  - Focus on the uneven areas
- Flush:
  - Focus on the uneven areas
  - Swirl in Cavicide for 10 seconds
- Soak:
  - Put transmitter in prepared soak
  - Swirl it for 30 seconds
  - Then let it soak for another 3 minutes

c. Rinse and dry

- Rinse: Remove from soak and rinse transmitter under flowing cold tap water for 10 seconds

- Dry: Wipe transmitter dry with cloth

H.3 Explain to patient what Dexcom ONE is and how it works

This table shows you what to explain to your patients and lets you know where you can find patient-centered information to help them understand.
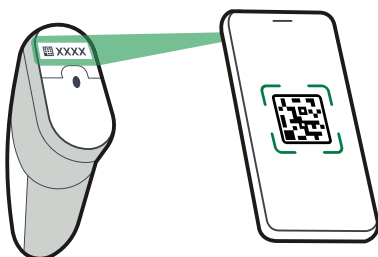
Explain	Show
What CGM is	Go to **Start Here** guide's How It Works section
Dexcom ONE Components	Go to **Start Here** guide's Overview section

H.4 Set up Dexcom ONE with patient

Set up system with patients

With your patient, follow the setup instructions in Start Here to set up the app or receiver.

Be sure to enter the Sensor Code found on the applicator adhesive backing.

The setup instructions include inserting the sensor and attaching the transmitter.

Additional set up with patients

Blinded

Explain why the patient is using blinded mode.

Unblinded

While setting up Dexcom ONE with your patient, create a personalized glucose target zone by setting low and high alerts appropriate for their A1C.

During the 2-hour sensor warmup, use the table below to explain how to interpret the information on Dexcom ONE.

Explain	Show
Introduce Home Screen	**Chapter 3: Display device screens** in this guide
What are Alerts	**Chapter 4: Alerts**
Managing Diabetes with Dexcom ONE	**Chapter 5: Treatment decisions**
Resource	Suggest your patient review the Dexcom website on their own to review the information you introduce
Dexcom Clarity App	Let your patients who use the app know about Clarity's trends, statistics, and patterns. Go to **dexcom.com/clarityapp** for more information.

H.5 Follow up with patient

You can see a patient's glucose data at any time during their sensor session at **dexcom.com/clarityapp.** Clarity identifies trends, patterns, and presents statistics. You can review this information with the patient to give them insights about how to better manage their diabetes.

At the end of the session, remove Dexcom ONE from the patient. Go to **Chapter 6: Starting a new sensor session or transmitter** for more information.

H.6 Next steps

Your patient may want to have their own Dexcom ONE. It is available for personal use. Direct them to **dexcom.com** for more information.

You are ready to use Dexcom ONE on another patient and introduce them to the benefits of Dexcom ONE.

◯ **Appendix I**
Glossary

A1C	Blood test used to diagnose type 1 or 2 diabetes and to gauge how well you are managing your diabetes. A1C reflects your average blood sugar level for the past 2 to 3 months.
Airplane Mode	A setting on a smart device where certain features are disabled to comply with airline regulations.
Alternative Site Testing	Using a blood sample from non-fingertip (alternate) sites such as the palm, forearm, or upper arm for meter values. Only use fingertip tests to calibrate Dexcom ONE.
Android	Operating system used for smart devices.
App or Application	Software installed on a smart or mobile device. The Dexcom ONE app is a display for continuous glucose monitoring.
App Store or Play Store	Internet store for downloading applications to a smart device.
Apple Watch	A smart watch for iPhone.
Blood Glucose (BG) Meter	A medical device used to measure how much glucose is in the blood.
Blood Glucose (BG) Value	Blood glucose value is the amount of glucose in the blood measured by a meter.
Bluetooth	A technology that allows devices to communicate wirelessly with each other.

Calibration	When you calibrate your Dexcom ONE using your BG meter, you take a fingerstick measurement from your BG meter then enter the value into your receiver or smart device. Calibrating your Dexcom ONE using your BG meter is optional. Calibration with your BG meter may align your sensor readings with your BG meter values.
Continuous Glucose Monitoring (CGM)	A sensor inserted under the skin checks glucose levels in interstitial fluid. A transmitter sends readings to a display device.
Contraindication	A situation where Dexcom ONE should not be used because it may be harmful to you. The risk of use outweighs the benefit.
Default	A manufacturer's preset option for a device setting.
GMI (Glucose Management Indicator)	Glucose Management Indicator (GMI) Is calculated using average sensor glucose data. GMI can be an indicator of how well glucose levels are managed. GMI will likely differ from A1C. Reference: Bergenstal, Richard M. et al. "Glucose Management Indicator (GMI): A New Term for Estimating A1C From Continuous Glucose Monitoring." Diabetes Care, ADA, November 2018.

Hyperglycemia	High BG. Same as "high" or high blood sugar. Hyperglycemia is characterized by an excess of glucose in the bloodstream. It is important to treat hyperglycemia. If left untreated, hyperglycemia can lead to serious complications. The default High Alert in Dexcom ONE is set to 11.1 mmol/L. Consult your healthcare professional to determine the appropriate hyperglycemia 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 is important to treat hypoglycemia. If left untreated, hypoglycemia can lead to serious complications. The default Low Alert in Dexcom ONE is set to 4.4 mmol/L. Consult your healthcare professional to determine the appropriate hypoglycemia setting for you.
Indications	How, for what purposes, and under what circumstances you should use Dexcom ONE.
iOS	Operating system used for Apple smart devices.

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 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 encounters.
	An IP22 rating lets you know your electronic device will not allow you to stick your fingers in it and will not get damaged or be unsafe during specific testing with water dripping down.
Jailbroken or Rooted	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 install Dexcom ONE app on a jailbroken or rooted smart device. It may not work correctly.
mg/dL	Milligrams per deciliter. The standard unit of measure for BG readings in the United States.
mmol/L	Millimoles per litre. A unit of measure for BG values.

Notification	An app message that appears on the screen of a smart device. Notification may also include a sound or vibration, depending on the smart device settings.
Precaution	Special care to be exercised by you or your healthcare professional for the safe and effective use of Dexcom ONE.
Safety Statement	A statement of the intended uses of Dexcom ONE and relevant warnings, precautions, and contraindications.
Sensor Reading	The glucose concentration measured in the interstitial fluid.
Sensor Session	The period after inserting a new sensor. During this period, your Dexcom ONE reading shows on your display device(s) every 5 minutes.
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 or Mobile Device	An electronic device that is cordless, mobile, and connected to the internet, such as a smartphone or tablet.
Stacking Insulin	Taking a dose of insulin soon after your most recent dose. This can result in low blood sugar. Does not apply to taking insulin doses to cover what you just ate.
Warning	Describes serious and life-threatening circumstances, the consequences, and how to avoid the hazard while using Dexcom ONE.

Index

Glossary

Page intentionally left blank

Dexcom

Dexcom

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

+1.858.200.0200
dexcom.com

Outside US: Contact your local
Dexcom representative

$C \epsilon$ **EC REP**

2797   MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

UK CA 0086   **UK REP**

MDSS-UK RP Ltd.
6 Wilmslow Road, Rusholme
Manchester M14 5TP
United Kingdom