Contour® next ONE

Blood Glucose Monitoring System

Works with the CONTOUR™ DIABETES app available for download on the App Store® or on Google Play™.

NO CODING®

Second-Chance® Sampling

Uses only CONTOUR® NEXT blood glucose test strips.

USER GUIDE

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	DESCRIPTION: Onyx Contour NEXT ONE Meter User Guide		
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	UNIT of MEASURE: mg/dL	MASTER REF: DCAM-69-1823 version 5.0	VERSION: V7

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3 5 25 50 75 98 100 3 5 25 50 75 98 100 3 5 25 50 75 98 100 3 5 25 50 75 98 100

INTENDED USE

The CONTOUR®NEXT ONE blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips or palm. The CONTOUR NEXT ONE blood glucose monitoring system is intended to be used by a single person and should not be shared. The CONTOUR NEXT ONE blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program.

The CONTOUR NEXT ONE blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing (palm) should be done only during steady state times (when glucose is not changing rapidly). The CONTOUR®NEXT test strips are for use with the CONTOUR®NEXT ONE blood glucose meter to quantitatively measure glucose in fresh capillary whole blood drawn from the fingertips or palm.

The system is intended for in vitro diagnostic use only.

IMPORTANT SAFETY INFORMATION

WARNING

Talk to Your Health Care Professional:

- Before setting any **Target Ranges** in the CONTOUR™DIABETES app.
- Before changing your medication based on test results.
- If your blood sugar reading is under 50 mg/dL follow medical advice immediately.
- If your blood sugar reading is over 250 mg/dL, or the critical level you have established with your health care professional:
  1. Wash and dry your hands well.
  2. Retest with a new strip.

  If you get a similar result, call your health care professional as soon as possible.
- About whether Alternative Site Testing (AST) is appropriate for you.

Potential Biohazard

- Always wash your hands with soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For complete instructions on cleaning and disinfecting your meter and lancing device, see pages 47 to 50.

- For more information about cleaning and disinfecting your meter or lancing device see: “US Food and Drug Administration. Use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010.” http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

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"Centers for Disease Control and Prevention. CDC clinical reminder: use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens. US Department of Health and Human Services; 8/23/2010." http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients.[1,2]
- The lancing device usually provided with your kit should not be used for assisted blood draws by health care professionals or at health care provision sites.
- Always dispose of used test strips and lancets as medical waste or as advised by your health care professional.
- All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.
- Keep out of reach of children. This kit contains small parts that could cause suffocation if accidentally swallowed.
- Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately contact your poison control center.

LIMITATIONS

- **Serious Illness:** The system should not be used to test critically ill patients. Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.[3-5]
- **Meter Operating Temperature Range:** 41°F–113°F
- **Control Testing Temperature Range:** 59°F–95°F

- **Test Strip Storage Temperature Range:** 41°F–86°F
- **Meter Operating Humidity Range:** 10% RH–93% RH
- **Sample Volume:** 0.6 µL
- **Measuring Range:** 20 mg/dL –600 mg/dL of glucose in blood
- **Altitude:** Up to 20,674 feet (6301 meters) does not significantly affect results.
- **Alternative Site Testing:** See Alternative Site Testing instructions on page 25.
- **Lipemic Specimen:** Cholesterol concentrations >1168 mg/dL or triglyceride concentrations >4709 mg/dL may produce inaccurate results.
- **Peritoneal Dialysis Solutions:** Icodextrin does not interfere with CONTOUR NEXT test strips.
- **Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.**
- **Neonatal Use:** The CONTOUR NEXT ONE meter is **not indicated** for neonatal use.

PRECAUTIONS

- Read your CONTOUR NEXT ONE user guide, the lancing device package insert, if provided, and all instructional materials provided in your meter kit before testing. Follow all instructions for use and care exactly as described to help avoid inaccurate results.
- Examine the product for missing, damaged, or broken parts. If the test strip bottle is open inside a new box of strips, do not use those strips.

For replacement parts, contact Diabetes Care Customer Service. See the back cover for contact information.

- Your CONTOUR NEXT ONE meter works ONLY with CONTOUR NEXT test strips and CONTOUR®NEXT control solution.

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- Always keep the CONTOUR NEXT test strips in their original bottle. Tightly close the bottle immediately after removing a test strip. The bottle is designed to keep the test strips dry. Do not place or store other items or medications in the test strip bottle. Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt. Exposure to room humidity by leaving the bottle open or not storing the strips in their original bottle can damage your test strips. This could lead to inaccurate results. Do not use a test strip that appears damaged or has been used.
- Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiration dates on your test materials.

NOTE: If this is the first time you are opening the control solution, write the date on the bottle.

- Do not use control solution that is more than 6 months past the date you first opened the bottle.
- If your control solution test result is out of range, contact Diabetes Care Customer Service. See the back cover for contact information. Do not use the meter for blood glucose testing until you resolve this issue.
- The meter is designed to give accurate blood testing results at temperatures between 41°F and 113°F. If meter or test strip is outside this range, you should not test until the meter and test strip are within this range. Whenever the meter is moved from one location to another, allow approximately 20 minutes for the meter to adjust to the temperature of the new location before performing a blood glucose test.
- Do not attempt to perform a blood glucose test when the CONTOUR NEXT ONE meter is connected to a computer.
- Use only approved equipment from the manufacturer or certified body such as UL, CSA, TUV, or CE.

- Your CONTOUR NEXT ONE meter has been preset and locked to display results in mg/dL (milligrams of glucose per deciliter of blood).
  - ❖ Results in mg/dL will **never** have a decimal point.
  - ❖ Results in mmol/L will **always** have a decimal point.

    Example: 93 mg/dL or 5.2 mmol/L
  - ❖ Check your display screen to be sure the results are shown correctly. If not, contact Diabetes Care Customer Service. See the back cover for contact information.
- The CONTOUR NEXT ONE blood glucose monitoring system has a measuring range of 20 mg/dL to 600 mg/dL.
  - ❖ For results over 600 mg/dL or under 20 mg/dL:
    - o If your blood sugar reading is under 20 mg/dL, the meter displays the **LO** screen. **Contact your health care professional immediately**.
    - o If your blood sugar reading is over 600 mg/dL, the meter displays the **HI** screen. Wash your hands or the test site. Repeat the test with a new strip. If results are still over 600 mg/dL, **follow medical advice immediately**.

Your Meter Features

Easy: The CONTOUR NEXT ONE blood glucose monitoring system is about simplicity. You will notice this the first time you use it.

Automatic: The CONTOUR NEXT ONE meter is designed with No Coding technology, to automatically code itself every time you insert a test strip. It will also automatically mark a control solution test.

NO CODING®

Second-Chance® Sampling

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Second-Chance® sampling allows blood sample re-application to the same test strip if the first blood sample is not enough. Your test strip is designed to easily 'sip' the blood into the sample tip. Do not drop blood directly on the flat surface of the test strip.

Thank you for choosing the CONTOUR NEXT ONE blood glucose monitoring system. We are proud to be your partner in helping you manage your diabetes.

CAUTION: Your CONTOUR NEXT ONE meter works ONLY with CONTOUR NEXT test strips and CONTOUR NEXT control solution.

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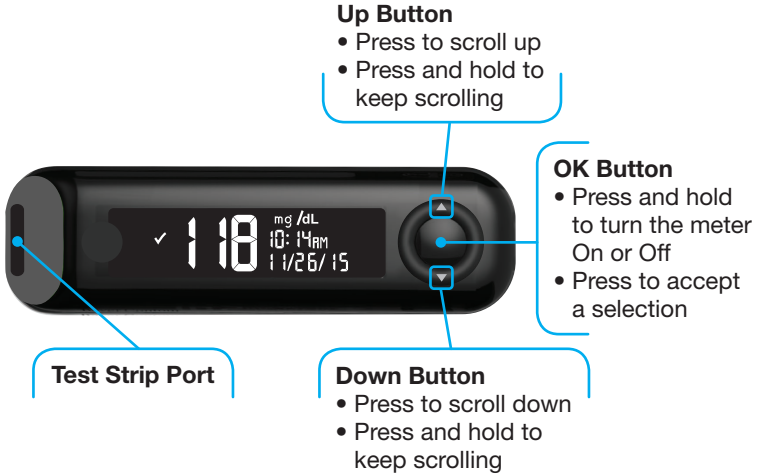
Your CONTOUR NEXT ONE meter



Up/Down Scroll Buttons

Using the Meter Buttons

Press and hold the **OK button** until the meter turns On.

Press and hold the **OK button** until the meter turns Off.

The ▲ or ▼ **buttons** on the meter allow you to scroll through the options. You can hold the ▲ or ▼ **button** to scroll continuously through a list.

Press the **OK button** to accept a selection.

To exit from the **Logbook** or the last **Settings** screen and return to **Home**, press the **OK button**.

NOTE: The meter screen dims after 30 seconds of inactivity. Press any button to bring up the screen.

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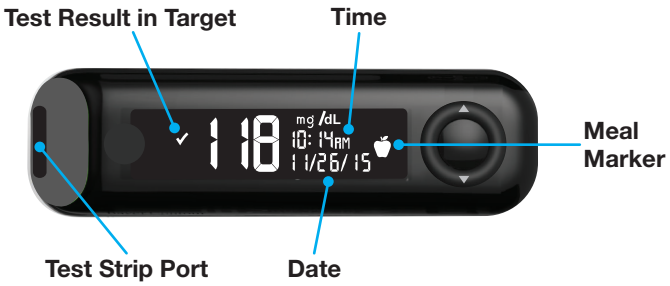
Your CONTOUR NEXT ONE meter Screen



Symbol	What the Symbol Means
✓	Blood sugar test result is in **Target Range**.
HI	Blood sugar test result is above 600 mg/dL.
LO	Blood sugar test result is below 20 mg/dL.
↑	Blood sugar test result is above **Target Range**.
↓	Blood sugar test result is below **Target Range**.
	Logbook entry.
	Meter **Settings**.
	Fasting marker.
	Before Meal marker.
	After Meal marker.

Symbol	What the Symbol Means
	No marker selected.
	A **Target Range** or **Target** setting.
	Target Light (**smartLIGHT**) setting.
	Meter is ready to test.
	Add more blood to strip.
	Control solution result.
	Bluetooth® symbol: indicates the **Bluetooth** setting is On; the meter can communicate with a mobile device.
	Indicates low batteries.
	Indicates dead batteries.
E	Indicates a meter error.

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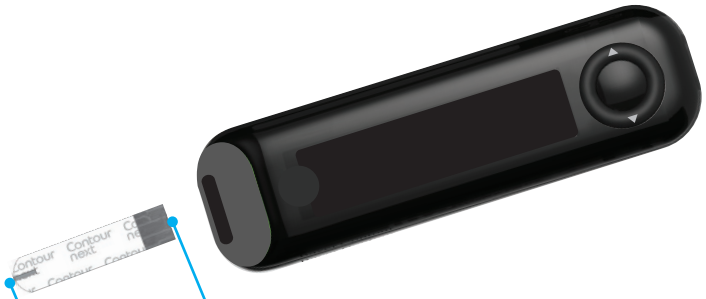
Your CONTOUR NEXT test strip



Grey Square End:
Insert this end into the test strip port

Sample Tip:
Blood sample pulled in here

The CONTOUR™DIABETES app for Your ONE meter

Your CONTOUR NEXT ONE meter was designed to work with the CONTOUR DIABETES app and your smartphone or tablet.

You can do the following things with your CONTOUR DIABETES app:

- Perform your initial meter setup.
- Add Notes after testing that help to explain your results.
  - List meals containing carbs.
  - Note changes in medication.
  - Add photos of your meal.
  - Log an increase or decrease in activity.
- Set testing reminders.
- Access easy-to-read graphs of test results over a day or over a period of time.
- Share reports.
- Discreetly view information.
- Review your **Fasting**, **Before Meal**, **After Meal**, and **Overall** results on a daily graph.
- Change meter settings, as necessary.

The CONTOUR DIABETES app does these things for you:

- Automatically displays your results.
- Saves your Notes in the **Logbook**.
- Displays your Trends and test results as they compare with your targets.

Download the CONTOUR DIABETES app

1. On your smartphone or tablet, go to the App Store® or the Google Play™ store.
2. Search for the CONTOUR DIABETES app.
3. Install the CONTOUR DIABETES app.

OR

Scan with QR Code app or visit www.contourone.com to learn more.

Initial Setup from the CONTOUR DIABETES app

The easiest way to set up your new meter is to download the CONTOUR DIABETES app to your smartphone or tablet and follow the instructions in the app.

If you do not pair your meter with the CONTOUR DIABETES app, follow the instructions in *Initial Setup from the Meter* the first time you turn on your meter.

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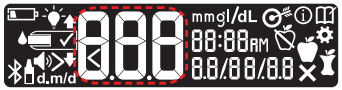
Initial Setup from the Meter

Press and hold the **OK button** for 2 seconds until the meter turns on.

The screen displays the **Power On Self Test**.



All symbols on the screen and the white strip port briefly light up. It is very important to verify that **8.8.8** displays fully and that the white light from the test strip port is visible.

If there are missing characters or if the strip port light is a color other than white, contact Diabetes Care Customer Service. This may affect the way you see your results.

Initial Setup begins with **View Pre-Set Target**.

View Pre-Set Target

The meter displays a pre-set **Overall Target Range**. You can change this pre-set Target Range from the CONTOUR DIABETES app after initial setup.

To move to the next screen, press the **OK button**. Continue to **Set the Time**.

Set the Time

The hour is blinking.

1. To change the hour, press the ▲ or ▼ **button** on the outer ring.

2. To set the hour and move to minutes, press the **OK button**.

3. To change the minutes, press the ▲ or ▼ **button** on the outer ring, then press the **OK button**. For a 12-hour format, select **AM** or **PM**, press the ▲ or ▼ **button**, then press the **OK button**. Continue to **Set the Date**.

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Set the Date

The year is blinking.

1. To change the year, press the ▲ or ▼ **button**, then press the **OK button**.

2. To change the month, press the ▲ or ▼ **button**, then press the **OK button**.
3. To change the day, press the ▲ or ▼ **button**, then press the **OK button**.

The meter briefly displays your saved settings, then beeps and turns OFF.

Setup is complete. You are ready to test your blood.

Target Ranges and Meal Markers

The meter compares your blood sugar results with a **Target Range** (for example, 70 mg/dL–130 mg/dL) to let you know if your test result is:

- within ☑ your **Target Range**.
- above ⬆ your **Target Range**.
- below ⬇ your **Target Range**.

☑ Within Your Target Range.

⬆ Above Your Target Range.

⬇ Below Your Target Range.

You can attach a **Meal Marker** to your blood sugar result using the **Meal Marker** feature in the meter. This feature lets you track your blood sugar levels over time with separate target ranges for Fasting, Before Meal, and After Meal markers.

- If you mark your test result as **Fasting**, the meter compares your result against the **Fasting Target Range**.
- If you mark your test result as **Before Meal**, the meter compares your result against the **Before Meal Target Range**.
- If you mark your result as **After Meal**, the meter compares the result against the **After Meal Target Range**.
- If you do not mark the result, the meter compares your test result against the **Overall Target Range**.

Symbol	Target Range
	Pre-set **Fasting Target Range**: 70 mg/dL – 130 mg/dL
	Pre-set **Before Meal Target Range**: 70 mg/dL – 130 mg/dL
	Pre-set **After Meal Target Range**: 70 mg/dL – 180 mg/dL
	Pre-set **Overall Target Range**: 70 mg/dL – 180 mg/dL

Your CONTOUR NEXT ONE meter comes with **Meal Markers** turned **Off**.

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You can change the time format, time, date format, date, **Sound** setting, **Meal Marker** setting, and the **Target Light** (**smartLIGHT**) setting by going to the **Home** screen and selecting **Settings** ⚙. See page 37.

Get Ready to Test

Read your CONTOUR NEXT ONE user guide, the lancing device package insert, if provided, and all instructional materials provided in your meter kit before testing. Follow all instructions for use and care exactly as described to help avoid inaccurate results.

Examine the product for missing, damaged, or broken parts. If the test strip bottle is open inside a new box of strips, do not use those strips. For replacement parts, contact Diabetes Care Customer Service. See the back cover for contact information.

CAUTION: Your CONTOUR NEXT ONE meter works only with CONTOUR NEXT test strips and CONTOUR NEXT control solution.

Fingertip Testing

Ensure that you have the materials you need before you begin testing:

- CONTOUR NEXT ONE meter.
- CONTOUR NEXT test strips.
- Lancing device and lancets from your kit, if provided.

To perform a quality control check, you also need CONTOUR NEXT control solution. Some supplies are sold separately. Contact Diabetes Care Customer Service. See the back cover for contact information.

WARNING: Potential Biohazard

- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection, see pages 47–50.
- Always wash your hands with soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.
- For complete instructions on cleaning and disinfecting your meter and lancing device, see pages 47–50.

Prepare the Lancing Device

The lancing device graphics are for illustration purposes only. Your lancing device may look different. Refer to your lancing device insert for detailed instructions on preparing the lancing device.

WARNING: Potential Biohazard

- The lancing device usually provided with your kit is intended for single-patient use only. It should not be used for assisted blood draws by health care providers or at health care provision sites, and should never be shared with anyone else, even a family member, due to risk of infection.
- Do not reuse lancets. Used lancets are not sterile. Use a new lancet each time you test.

WARNING: Potential Biohazard

Always dispose of used test strips and lancets as medical waste or as advised by your health care professional.

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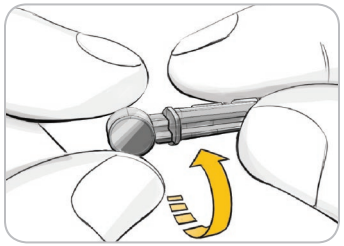
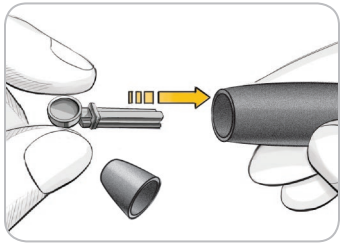
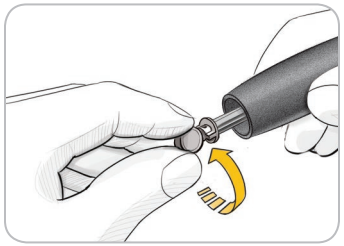
1. Remove the endcap from the lancing device.



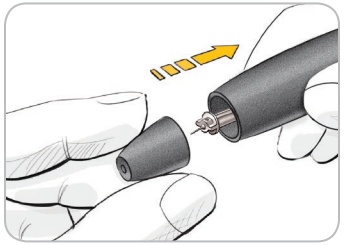
2. Loosen the round protective cap on a lancet by rotating the cap ¼ turn, but do not remove the cap.



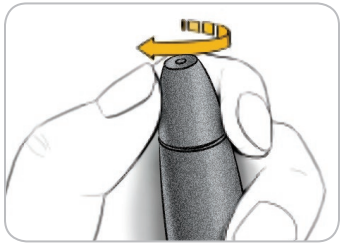
3. Insert the lancet firmly into the lancing device until the lancet comes to a complete stop.



4. Twist off the round protective lancet cap. Save the cap for disposing of the used lancet.



5. Replace the endcap.



6. Rotate the endcap dial to adjust the puncture depth.

   The amount of pressure applied to the puncture site also affects puncture depth.

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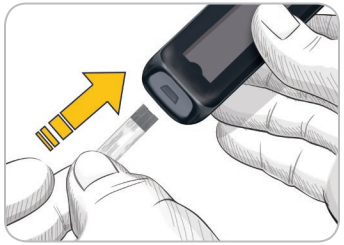
Insert the Test Strip

CAUTION: Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiration dates on your test materials.

1. Remove a CONTOUR NEXT test strip from the bottle.
2. **Tightly close the bottle lid immediately after you have removed the test strip.**



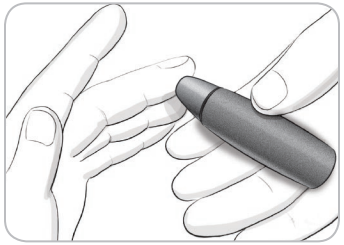
3. Hold the test strip with the grey square end facing toward the meter.
4. Insert the grey square end firmly into the test strip port until the meter beeps.

The screen displays the blinking blood drop indicating it is ready to test a blood drop.

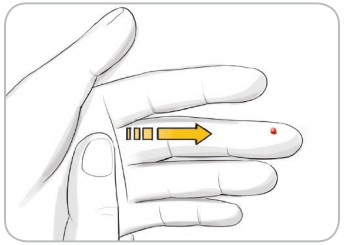
NOTE: After you insert the test strip, apply blood to the test strip within 3 minutes or the meter turns off. Remove the test strip and reinsert it to begin a test.

Get the Blood Drop: Fingertip Testing

NOTE: For Alternative Site Testing instructions, see page 25.

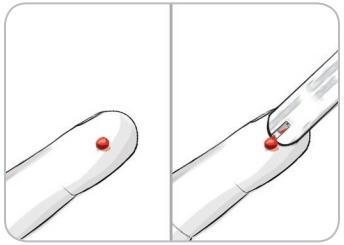


1. Press the lancing device firmly against the puncture site and press the release button.



2. Stroke your hand and finger toward the puncture site to form a drop of blood.

   Do not squeeze around the puncture site.



3. Test immediately after you have formed a small, round blood drop, as shown.
4. Immediately touch the tip of the test strip to the drop of blood.

   The blood is drawn into the test strip through the tip.

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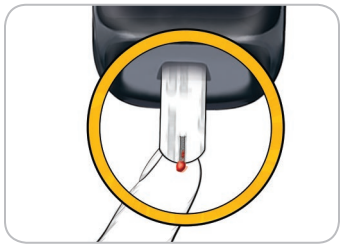
CAUTION: Do not press the tip of the test strip against the skin or place the blood on top of the test strip. These actions could lead to inaccurate results or errors.



5. **Hold the tip of the test strip in the blood drop until the meter beeps.**

NOTE: If Meal Marker feature is On, do not remove the test strip until you select a Meal Marker.

Apply More Blood

1. If the meter beeps twice and the screen displays a blinking blood drop, the test strip does not have enough blood.
2. Apply more blood to the test strip within 60 seconds.
3. If the screen displays an **E 1** error message, remove the strip and start with a new strip.

The meter displays your blood sugar result. If the **Meal Markers** are **On**, the **Meal Marker** symbol is blinking.

Select a Meal Marker

NOTE: During a blood sugar test, if **Meal Markers** are **On**, you can select a **Meal Marker** when the meter displays your result. **You cannot select a Meal Marker in the Settings screen.**

If the **Meal Marker** feature is **On**, a **Fasting**, **Before Meal**, **After Meal**, or **No Mark** marker is blinking on the blood sugar result screen. The meter suggests this **Meal Marker** based on the time of day and the meal period: fasting/breakfast, lunch, dinner, or overnight. Example:

Do not press the OK button yet.

You can select the blinking marker or choose a different **Meal Marker**.

1. If the blinking **Meal Marker** is the one you want, press the **OK button**

or

2. To select another **Meal Marker**, press the ▲ or ▼ **button** on the outer ring to scroll between markers.

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Meal Marker choices if Meal Marker feature is On

Symbol	What the Symbol Means	Related Target Range
	Fasting: Use the **Fasting** marker when testing blood sugar levels after fasting (no food or drink for 8 hours, except water or non-caloric beverages).	**Fasting Target Range**
	Before Meal: Use the **Before Meal** marker when testing blood sugar levels within 1 hour before a meal.	**Before Meal Target Range**
	After Meal: Use the **After Meal** marker when testing blood sugar levels within 2 hours after the first bite of a meal.	**After Meal Target Range**
	No Mark Selected: Use the **No Mark** symbol when testing at times other than after fasting or before or after a meal.	**Overall Target Range**

Example: If you scroll up to **Fasting**, the **Fasting** marker blinks.

Example: If you scroll down to **After Meal**, the **After Meal** marker blinks:

3. When the **Meal Marker** you want is blinking, press the **OK button**.

If you do not make a **Meal Marker** selection within 30 seconds, the screen dims. Press any button to turn the screen back on and make your selection.

If you do not make a **Meal Marker** selection within 3 minutes, the meter turns off. Your blood sugar reading is stored in the **Logbook** without a **Meal Marker**.

Blood Sugar Test is Complete

When your blood sugar test is complete, the meter displays your result with the units, time, date, meal marker (if selected), and target indicator: In Target ✓, Below Target ↓, or Above Target ↑.

Example: Blood test result with **Meal Marker** selected:

NOTE: To change a Meal Marker you selected, you must use the CONTOUR DIABETES app.

Example: Blood test result with **Meal Markers Off** or marker not selected:

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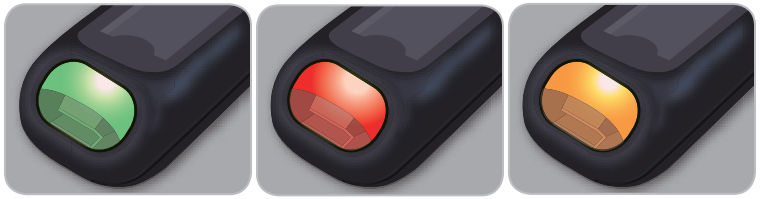
If the **Target Light** (**smartLIGHT**) setting is **On**, the test strip port displays a color representing your result value compared to the **Before Meal**, **After Meal**, or **Overall Target Range**.

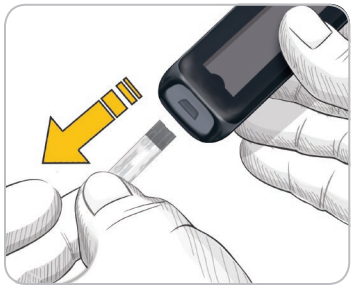


In Target ✓ **Below Target** ⬇ **Above Target** ⬆

If your blood sugar result is below target, the **Target Light** (**smartLIGHT**) is red and meter beeps twice.

If you do not select a **Meal Marker**, your blood sugar test result is compared to an **Overall Target Range**.

4. To move to the **Home** screen, press the **OK button**.



or

5. To turn the meter off, remove the test strip.

About Meal Markers

During a blood sugar test, you can attach a **Meal Marker** to your blood sugar result when the **Meal Marker** feature in the meter is turned **On**. This feature lets you track your blood sugar levels over time with separate **Target Ranges** for **Fasting**, **Before Meal**, and **After Meal** markers.

Your CONTOUR NEXT ONE meter comes with **Meal Markers** turned **Off**. You can turn **Meal Markers On** in **Settings**.

Turn Meal Markers On

To turn **Meal Markers On** see *Settings: Set Meal Markers* on page 41.

NOTE: You can select a Meal Marker only when the blood sugar test result displays on the screen.

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Test Results

WARNING

- **Always consult your health care professional before changing your medication based on test results.**
- **If your blood sugar reading is under 50 mg/dL, follow medical advice immediately.**
- **If your blood sugar reading is over 250 mg/dL:**
  1. Wash and dry your hands well.
  2. Retest with a new strip.

If you get a similar result, call your health care professional as soon as possible.

Expected Test Result Values

Blood sugar values will vary depending on food intake, medication dosages, health, stress, or activity. Nondiabetic plasma glucose concentrations should be less than 110 mg/dL in the fasting state and less than 140 mg/dL in the post-prandial state (after a meal).[6] You should consult with your health care professional for glucose values specific to your needs.

LO or HI Results

- If the meter beeps twice and displays the **LO** screen, your blood sugar reading is under 20 mg/dL. **Follow medical advice immediately.** Contact your health care professional.

- If the meter beeps once and displays the **HI** screen, your blood sugar reading is over 600 mg/dL:
  1. Wash and dry your hands well.
  2. Retest with a new strip.

  If results are still over 600 mg/dL, **follow medical advice immediately.**

Alternative Site Testing (AST): Palm

WARNING

- **Ask your health care professional if Alternative Site Testing (AST) is right for you.**
- **Do not calibrate a continuous glucose monitoring device from an AST result.**
- **Do not calculate an insulin dose based on an AST result.**

Always wash your hands with soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.

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For Alternative Site Testing, use the clear endcap. Your CONTOUR NEXT ONE meter can be used for fingertip or palm testing. See the lancing device insert for detailed instructions on Alternative Site Testing.

Do not use AST under the following conditions:

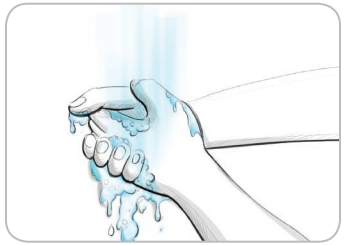
- If you think your blood sugar is low.
- When blood sugar is changing rapidly, such as after a meal, after an insulin dose, or during or after exercise.
- If you are unable to feel symptoms of low blood sugar (hypoglycemic unawareness).
- If you get alternative site blood sugar results that do not agree with how you feel.
- During illness or times of stress.
- If you will be driving a car or operating machinery.

Alternative site results may be different from fingertip results when glucose levels are changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise). Additionally, glucose levels may not rise as high or fall as low as levels in the fingertip. As such, fingertip results may identify hypoglycemic levels sooner than alternative site results.

Alternative Site Testing is recommended only when it is more than 2 hours after a meal, diabetes medication, or exercise.

If you do not have a clear lancing device endcap to perform AST, contact Diabetes Care Customer Service. See the back cover for contact information.

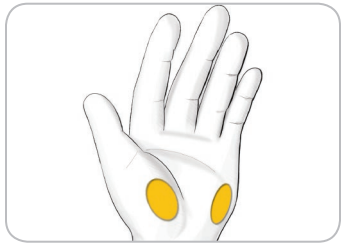
Get a Blood Drop: Alternative Site Testing



1. Wash your hands and the puncture site with soap and warm water.

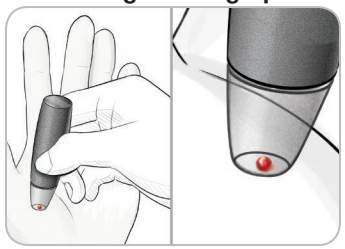
   Rinse and dry well.
2. Attach the clear AST endcap to the lancing device, if provided with your kit.

   Refer to the lancing device insert for detailed instructions.



3. Select a puncture site from a fleshy area on the palm. Avoid veins, moles, bones, and tendons.

The lancing device graphics are for illustration purposes only.



4. Press the lancing device firmly against puncture site, then press the release button.
5. Maintain steady pressure until a small, round blood drop forms.

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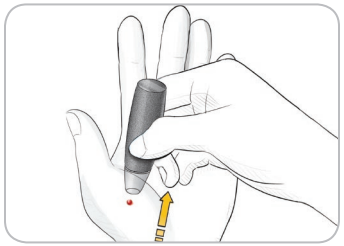

6. Lift the lancing device straight up and away from the skin without smearing the blood.

7. Test immediately after you have formed a small, round blood drop, as shown.

   Immediately touch the tip of the test strip to the drop of blood. The blood is drawn into the test strip through the tip.

Do not test the blood sample from palm if you get:

- Smeared blood.
- Clotted blood.
- Runny blood.
- Clear fluid mixed with the blood.

8. Hold the tip of the test strip in the blood drop until the meter beeps.

CAUTION: Do not press the test strip tip against the skin or place the blood on top of the test strip. These actions could lead to inaccurate results or errors.

Apply More Blood for Alternative Site Testing

1. If the meter beeps twice and the screen displays a blinking blood drop, the test strip does not have enough blood.

2. Apply more blood to the test strip within 60 seconds.
3. If the screen displays an **E 1** error message, remove the strip and start with a new strip.

If the **Meal Marker** feature is **On**, the meter suggests a **Fasting**, **Before Meal**, **After Meal**, or **No Mark** marker for your blood sugar result. This is based on the time of day and the meal period: fasting/breakfast, lunch, dinner or overnight. The **Meal Marker** is blinking.

Do not press the OK button yet.

You can select the blinking marker or choose a different **Meal Marker**.

4. If the blinking **Meal Marker** is the one you want, press the **OK button**

or

5. To select another **Meal Marker**, press the ▲ or ▼ **button** on the outer ring to scroll between markers.

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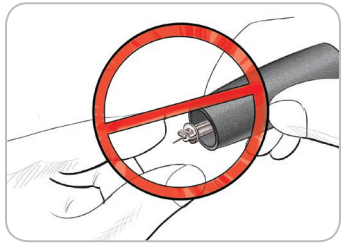
Meal Marker choices if Meal Marker feature is On

Symbol	What the Symbol Means	Related Target Range
	Fasting: Use the **Fasting** marker when testing blood sugar levels after fasting (no food or drink for 8 hours, except water or non-caloric beverages).	**Fasting Target Range**
	Before Meal: Use the **Before Meal** marker when testing blood sugar levels within 1 hour before a meal.	**Before Meal Target Range**
	After Meal: Use the **After Meal** marker when testing blood sugar levels within 2 hours after the first bite of a meal.	**After Meal Target Range**
	No Mark Selected: Use the **No Mark** symbol when testing at times other than after fasting or before or after a meal.	**Overall Target Range**

6. When the **Meal Marker** you want is blinking, press the **OK button**. For more information about **Meal Markers**, see *Select a Meal Marker* on page 19.

Eject and Dispose of the Used Lancet



1. Do not use your fingers to remove the lancet from the lancing device. The lancing device usually provided with your kit has an automatic lancet ejection feature.
2. **Refer to the separate lancing device insert, if provided with your kit, for instructions on automatic ejection of the lancet.**

WARNING: Potential Biohazard

- **The lancing device, lancets, and test strips are for single-patient use. Do not share them with anyone including other family members. Do not use on multiple patients.[1,2]**
- **All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.**
- Always dispose of used test strips and lancets as medical waste or as advised by your health care professional.
- **Do not reuse lancets. Used lancets are not sterile. Use a new lancet each time you test.**
- Always wash your hands with soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.

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Control Solution

WARNING

Shake the control solution well before testing.

CAUTION: Use only CONTOUR NEXT control solution (Level 1 and Level 2) with your CONTOUR NEXT ONE blood glucose monitoring system. Using anything other than CONTOUR NEXT control solution can cause inaccurate results.

Quality Control

- Shake the control solution bottle well, about 15 times before every use.
- Unmixed control solution may cause inaccurate results.

You should perform a control test when:

- Using your meter for the first time.
- You open a new bottle or package of test strips.
- You think your meter may not be working properly.
- You have repeated, unexpected blood sugar results.

WARNING

- **Do not calibrate your continuous glucose monitoring device from the control result.**
- **Do not calculate a bolus based on a control result.**

CAUTION: Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiration dates on your test materials.

Level 1 and Level 2 control solutions are available and sold separately if not included in the meter kit. You can test your CONTOUR NEXT ONE meter with control solution when the temperature is 59°F–95°F.

Always use CONTOUR NEXT control solutions. Other brands could yield incorrect results. If you need help locating CONTOUR NEXT control solutions, contact Diabetes Care Customer Service. See the back cover for contact information.

Control Solution Testing

1. Remove a CONTOUR NEXT test strip from the bottle.
2. Tightly close the bottle lid immediately after you remove the test strip.
3. Hold the test strip with the grey square end facing up.

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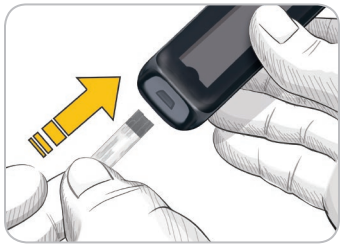

4. Insert the grey square end of the test strip into the test strip port until the meter beeps.

The meter turns on, displaying a test strip with a flashing blood drop.

CAUTION: Do not use control solution that is more than 6 months past the date you first opened the bottle.

NOTE: If this is the first time you are opening the control solution, write the date on the bottle.

5. Shake the control solution bottle well, about 15 times before every use.

6. Remove the bottle cap and use a tissue to wipe away any solution around the bottle tip before dispensing a drop.
7. Squeeze a small drop of solution onto a clean, nonabsorbent surface.

CAUTION: Do not apply control solution to your fingertip or to the test strip directly from the bottle.

8. Immediately touch the tip of the test strip to the drop of control solution.

9. **Hold the tip in the drop until the meter beeps.**

The meter counts down for 5 seconds before the control test result displays on the meter. The meter automatically marks the result as a control test. Control test results are not included in your meter **Logbook**, in blood sugar averages, or in targets in the CONTOUR DIABETES app.

10. Compare your control test result with the range printed on the test strip bottle or on the bottom of the test strip box.
11. Remove the test strip and dispose as medical waste or as advised by your health care professional.

If your result does not fall within the range listed on the test strip bottle label or carton, there may be a problem with the test strips, the meter, or your testing technique.

If your control test result is out of range, do not use your CONTOUR NEXT ONE meter for blood sugar testing until you resolve the issue. Contact Diabetes Care Customer Service. See the back cover for contact information.

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Logbook

The **Logbook** contains blood sugar test results and markers that you have made to those test results. The **Logbook** holds up to 800 results. When the **Logbook** reaches the maximum, the oldest test result will be removed as a new test is completed and saved to the **Logbook**.

Review the Logbook

NOTE: To return to the **Home** screen while viewing the **Logbook**, press the **OK button**.

To review entries in the **Logbook**:

1. Press and hold the **OK button** until the meter turns on, about 2 seconds.

The **Logbook** is blinking.

2. To select the blinking **Logbook** symbol, press the **OK button**.
3. To view your individual test results, press the ▼ **button**.

4. To scroll through your test results, press the ▲ or ▼ **button**.

To scroll faster, press and hold the ▲ or ▼ **button**.

If you scroll past the oldest entry, the meter displays the **End** screen.

If you see a **LO** or **HI** test result, go to page 25 for more information.

5. To go back to the beginning to review entries, press the **OK button** to go to the **Home** screen, then select the **Logbook** symbol.

Settings

In Settings you can:

- Change the time format.
- Change the time.
- Change the date format.
- Change the date.
- Turn **Sound** On or Off.
- Turn **Meal Markers** On or Off.
- View **Target Ranges**.
- Turn **Target Lights** (**smartLIGHT**) On or Off.
- Turn **Bluetooth** On or Off.

You must accept or change each setting with the **OK button** before moving to the next one.

Access Settings

1. Press and hold the **OK button** until the meter turns on.

The **Home** screen has 2 options: **Logbook** and **Settings**.

2. To highlight the **Settings** symbol, press the ▼ **button**.
3. When the **Settings** symbol is blinking, press the **OK button** to enter **Settings**.

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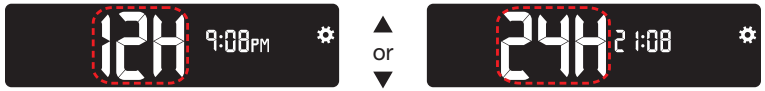
Change the Time

The time format is blinking.

1. To change the time format, if needed, press the ▲ or ▼ **button**, then press the **OK button**.



Time Format

The hour is blinking.

2. To change the hour, press the ▲ or ▼ **button**, then press the **OK button**.

The minutes are blinking.

3. To change minutes, press the ▲ or ▼ **button**, then press the **OK button**.
4. For a 12-hour time format, select **AM** or **PM**, as needed, then press the **OK button**.

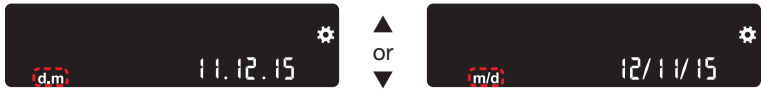
Change the Date

If your meter is not ON:

1. Press and hold the **OK button** until the meter turns on.

The **Home** screen has 2 options: **Logbook** and **Settings**.

2. To highlight the **Settings** symbol, press the ▼ **button**.
3. When the **Settings** symbol is blinking, press the **OK button** to enter **Settings**.
4. Continue to press the **OK button** until you see the **Date Format** screen.



Date Format

The date format (**m/d** or **d.m**) is blinking.

5. To select **Month/Day/Year (m/d)** or **Day.Month.Year (d.m)**, press the ▲ or ▼ **button**, then press the **OK button**.

6. To change the year (blinking), press the ▲ or ▼ **button**, then press the **OK button**.

7. To change the month (blinking), press the ▲ or ▼ **button**, then press the **OK button**.

8. To change the day (blinking), press the ▲ or ▼ **button**, then press the **OK button**.

The meter displays the **Sound** screen.

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Set the Sound

If your meter is not ON:

1. Press and hold the **OK button** until the meter turns on.

The **Home** screen has 2 options: **Logbook** and **Settings**.

2. To highlight the **Settings** symbol, press the ▼ **button**.
3. When the **Settings** symbol is blinking, press the **OK button** to enter **Settings**.
4. Continue to press the **OK button** until you see the **Sound** screen.

▲ or ▼

Sound Symbol:

Your meter comes with the **Sound** turned **On**. Certain error messages override any **Sound** setting.

When **Sound** is **On**:

- One long beep indicates a confirmation.
- Two beeps indicate an error or something that needs your attention.

5. To turn the **Sound On** or **Off**, press the ▲ or ▼ **button** to display the option you want.
6. Press the **OK button**.

NOTE: Some sounds remain **On** even when you turn the **Sound** feature **Off**. To turn sounds **Off** for a below-target blood sugar reading, turn the **Target Light** setting to **Off**.

The meter displays the **Meal Marker** screen.

Set Meal Markers

If your meter is not ON:

1. Press and hold the **OK button** until the meter turns on.

The **Home** screen has 2 options: **Logbook** and **Settings**.

2. To highlight the **Settings** symbol, press the ▼ **button**.
3. When the **Settings** symbol is blinking, press the **OK button** to enter **Settings**.
4. Continue to press the **OK button** until you see the **Meal Marker** screen.

▲ or ▼

Meal Marker Symbols:

Your meter comes with **Meal Marker** feature turned **OFF**.

5. To turn **Meal Markers On** or **Off**, press the ▲ or ▼ **button** to display the option you want.
6. Press the **OK button**.

NOTE: When the **Meal Marker** feature is **On**, you can select a **Meal Marker** during a blood sugar test.

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View Target Ranges

WARNING

Discuss your Target Range settings with your health care professional.

When the **Meal Marker** feature is **On**, your meter displays a **Fasting, Before Meal, After Meal**, and **Overall Target Range**. You can change these ranges only in the CONTOUR DIABETES app.

If your meter is not ON:

1. Press and hold the **OK button** until the meter turns on.

The **Home** screen has 2 options: **Logbook** and **Settings**.

2. To highlight the **Settings** symbol, press the ▼ **button**.
3. When the **Settings** symbol is blinking, press the **OK button** to enter **Settings**.
4. Continue to press the **OK button** until you see the **Fasting Target Range** screen below.

5. To move to the next **Target Range**, press the **OK button**.

The meter displays the **Before Meal Target Range**.

6. To move to the next **Target Range**, press the **OK button**.

The meter displays the **After Meal Target Range**.

7. To move to the next **Target Range**, press the **OK button**.

The meter displays the **Overall Target Range**.

8. To move to the next screen, press the **OK button**.

When the **Meal Marker** feature is **Off**, your meter displays the **Overall Target Range**.

You can change this range only in the CONTOUR DIABETES app.

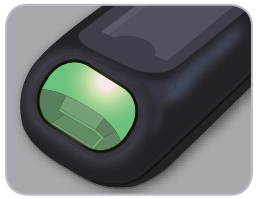
9. To move to the next screen, press the **OK button**.

The meter displays the **Target Lights** screen.

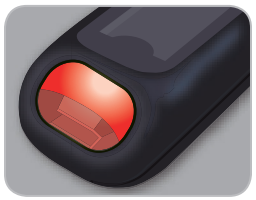
Set Target Lights (smartLIGHT)

Your meter comes with the **Target Light** setting turned **ON**.

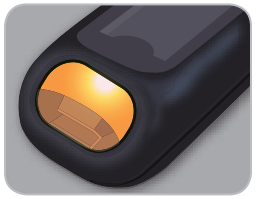
When this feature is **On**, the test strip port on your meter displays a **Target Light** in a color that corresponds to your test result.



In Target



Below Target



Above Target

85025015_CntrNxtONE_UG_EN.indd 42-43 8/18/16 10:06 AM

If your meter is not ON:

1. Press and hold the **OK button** until the meter turns on.

The **Home** screen has 2 options: **Logbook** and **Settings**.

2. To highlight the **Settings** symbol, press the ▼ **button**.
3. When the **Settings** symbol is blinking, press the **OK button** to enter **Settings**.
4. Continue to press the **OK button** until you see the **Target Lights** screen.

▲ or ▼

Target Light Symbol:

5. To turn **Target Lights On** or **Off**, press the ▲ or ▼ **button** to display the option you want.
6. Press the **OK button**.

Set Bluetooth

Bluetooth is not available until you pair your meter with a mobile device. After pairing, the **Bluetooth** setting is turned **ON**.

If your meter is not ON:

1. Press and hold the **OK button** until the meter turns on.

The **Home** screen has 2 options: **Logbook** and **Settings**.

2. To highlight the **Settings** symbol, press the ▼ **button**.
3. When the **Settings** symbol is blinking, press the **OK button** to enter **Settings**.
4. Continue to press the **OK button** until you see the **Bluetooth** screen.

▲ or ▼

Bluetooth Symbol:

5. To turn **Bluetooth On** or **Off**, press the ▲ or ▼ **button** to display the option you want.

6. Press the **OK button**. The meter briefly displays your saved settings, then beeps and returns to the **Home** screen.

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Pairing Mode

To pair your meter with the CONTOUR DIABETES app, download the app and follow the instructions to *Pair a Meter*.

To put your meter in pairing mode:

- Turn your meter off.
- Press and do not release the **OK button**.
- Continue to hold the **OK button** while all symbols on the screen and the white strip port briefly light up.
- Release the **OK button** when you see a flashing blue light from the test strip port. The **Bluetooth** icon is blinking and the meter serial number displays.

Example: Your meter in pairing mode:

Meter Care

Caring for your meter:

- Store the meter in the carrying case provided, whenever possible.
- Wash and dry hands well before handling to keep the meter and test strips free of water, oils, and other contaminants.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- Avoid exposing your meter and test strips to excessive humidity, heat, cold, dust, or dirt.
- Clean and disinfect your meter as recommended in the next section.

The cleaning and disinfecting directions provided should not cause any damage or degradation to the external case, buttons, or display.

Your CONTOUR NEXT ONE meter has been tested for 260 cycles of cleaning and disinfection (equivalent to one cycle per week for 5 years). This device has been demonstrated to withstand 5 years of cleaning and disinfection without damage. You should call Diabetes Care Customer Service for assistance if your device malfunctions for any reason or if you notice any changes in the external meter case or display.

Cleaning and Disinfection

WARNING

Always wash your hands with soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.

WARNING: Potential Biohazard

All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

WARNING

If your meter is being operated by a second person who is providing testing assistance to you, the meter and lancing device should be disinfected prior to use by the second person.

Clean and disinfect your CONTOUR NEXT ONE meter once a week. Use only Clorox Germicidal Wipes containing 0.55% sodium hypochlorite (bleach). The wipes are proven safe to use with the CONTOUR NEXT ONE meter.

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Clorox Germicidal Wipes are available for purchase online at http://www.officedepot.com or http://www.amazon.com. For more information, contact Diabetes Care Customer Service. See the back cover for contact information.

- **Cleaning** involves the removal of visible dirt and debris, but does not reduce the risk for transmission of infectious diseases.
- **Disinfecting** (if performed properly) reduces the risk of transmitting infectious diseases.

Evaluate your device after performing cleaning and disinfection to ensure that the procedure does not cloud the face/display of the meter and does not corrode or erode the plastic housing or buttons.

For more information

US Food and Drug Administration. Use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010.
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

Centers for Disease Control and Prevention. CDC clinical reminder: use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens. US Department of Health and Human Services; 8/23/2010.
http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Cleaning Your Meter

Supplies needed for cleaning:

- Clorox Germicidal Wipes containing 0.55% sodium hypochlorite (bleach).
- Paper towels.

CAUTION: Do not allow cleaning solution to run into the meter through open areas, such as around the buttons or the meter's test strip or data ports.

1. Carefully clean the meter with germicidal wipes until all soil is removed.
2. Dry as necessary with a clean paper towel.

Disinfecting Your Meter

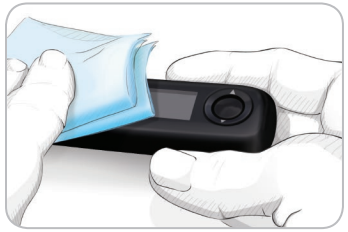
Supplies needed for disinfecting:

- Clorox Germicidal Wipes containing 0.55% sodium hypochlorite (bleach).
- Paper towels.
- Timing device.

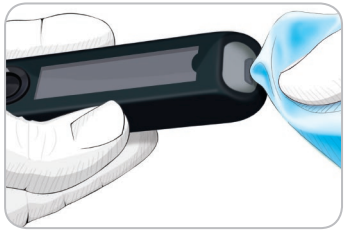
1. Before disinfecting, clean the meter as described in *Cleaning Your Meter*.

For proper disinfection, you must keep all meter surfaces wet for 60 seconds.

2. Using a new germicidal wipe, carefully wipe all outer surfaces of your meter until wet.



Buttons



Test Strip Port

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3. After wiping for 60 seconds, use a clean paper towel to dry the meter surfaces and the test strip port.

Cleaning and Disinfecting Your Lancing Device

Refer to the lancing device insert provided with your kit for detailed instructions for cleaning and disinfecting the lancing device.

Transfer Results to the CONTOUR DIABETES app

CAUTION: The CONTOUR NEXT ONE meter has not been tested or certified for use with any software other than the CONTOUR DIABETES app. The manufacturer is not responsible for any erroneous results from the use of other software.

You can automatically transfer results from your CONTOUR NEXT ONE meter wirelessly to your smartphone or tablet. See *Download the CONTOUR DIABETES app* on page 7 and follow the app instructions to pair your meter and get started.

Transfer Results to a Personal Computer

CAUTION: Do not attempt to perform a blood glucose test when the CONTOUR NEXT ONE meter is connected to a computer.

You can transfer test results from the CONTOUR NEXT ONE meter to a computer where they can be summarized in a report with graphs and tables. To make use of this feature, you need GLUCOFACTS®DELUXE diabetes management software and a 1-meter (or 3-foot) long USB-A to Micro USB-B cable. This type of cable is available in electronics retail stores. For a free download of the software, go to www.glucofacts.ascensia.com

CAUTION: Use only approved equipment from the manufacturer or certified body such as UL, CSA, TUV, or CE.

Batteries

When the batteries are low, the **Low Batteries** symbol displays on every screen.

Replace the batteries immediately. When you see this symbol, you can only test about 10 more times over the next 3 days before the batteries are dead.

The meter operates normally, displaying the **Low Batteries** symbol until you replace the batteries.

When you are no longer able to perform a test due to low batteries, the meter displays the **Dead Batteries** screen. Replace the batteries immediately.

Replace the Batteries

1. Before replacing your batteries, turn off your meter.
2. Turn the meter over and slide the back cover in the direction of the arrow.

   The battery holder comes out.

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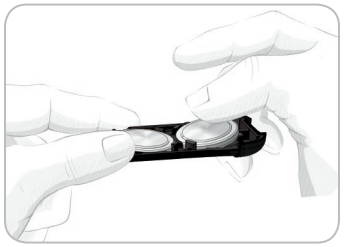
3. Remove both of the old batteries and replace them with two 3-volt CR2032 or DL2032 coin cell batteries.

NOTE: If you put the new batteries in the meter within 5 minutes of taking the old batteries out, the meter saves all your settings and results. Always check the date and time after you replace the batteries. If they are correct, other settings and results are also saved.



4. Make sure the '+' sign is facing down on the new batteries.
5. Hold the battery holder so that the round end is on the right.
6. Insert the edge of one battery into the left side of the compartment and press down on the right side.
7. Press the other battery into the left compartment.
8. Slide the battery holder back into place.
9. Discard batteries according to your local environmental regulations.

WARNING

Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately contact your poison control center.

Error Detection Displays

The meter screen displays error codes (**E** plus a number) for test result errors, strip errors, or system errors. When an error occurs, the meter beeps 2 times and displays an error code. Press the **OK button** to turn off the meter.

If you experience continued errors, contact Diabetes Care Customer Service. See the back cover for contact information.

Error Code	What it Means	What to Do
Strip Errors		
E 1	Too Little Blood	Remove the strip. Repeat the test with a new strip.
E 2	Used Test Strip	Remove the strip. Repeat the test with a new strip.
E 3	Strip Upside Down	Remove the strip and insert it correctly.
E 4	Wrong Strip Inserted	Remove the strip. Repeat the test with a CONTOUR NEXT test strip.
E 6	Moisture Damaged Strip	Remove the strip. Repeat the test with a new strip.
E 8	Strip or Test Errors	Repeat the test with a new strip. If the error persists, contact Customer Service.
Testing Errors		
E20	Testing Error	Repeat the test with a new strip. If the error persists, contact Customer Service.
E24	Too Cold to Test Control Solution	Move the meter, strip, and control solution to a warmer area. Test in 20 minutes.

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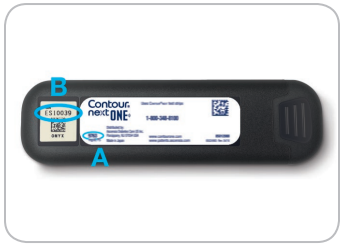
Error Code	What it Means	What to Do
E25	Too Hot to Test Control Solution	Move the meter, strip, and control solution to a cooler area. Test in 20 minutes.
E27	Too Cold to Test	Move the meter and strip to a warmer area. Test in 20 minutes.
E28	Too Hot to Test	Move the meter and strip to a cooler area. Test in 20 minutes.
System Errors		
E30–E99	Meter software or hardware malfunctioned	Turn the meter off. Turn the meter back on. If the error persists, contact Customer Service.

Speak to a Customer Service representative before returning your meter for any reason. Contact Diabetes Care Customer Service. See the back cover for contact information.

Customer Service Checklist

When speaking with the Diabetes Care Customer Service representative:



1. Have your CONTOUR NEXT ONE blood glucose meter, CONTOUR NEXT test strips, and CONTOUR NEXT control solution available when you call.
2. Locate the model number **(A)** and serial number **(B)** on the back of the meter.
3. Locate the test strips' expiration date on the bottle.
4. Check the battery status.

Parts Information

To replace missing parts or reorder supplies, contact Diabetes Care Customer Service. See the back cover for contact information.

- Two 3-volt CR2032 or DL2032 Coin Cell Batteries.
- CONTOUR NEXT ONE user guide.
- CONTOUR NEXT ONE quick reference guide.
- CONTOUR NEXT test strips.
- CONTOUR NEXT control solution level 1.
- CONTOUR NEXT control solution level 2.
- Lancing device, as in your kit, if provided.
- Lancets, as in your kit, if provided.

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Technical Information: User Accuracy

The CONTOUR NEXT ONE blood glucose monitoring system was tested by 372 lay users using capillary blood samples and three CONTOUR NEXT test strip lots. The results were compared to the YSI Glucose Analyzer laboratory reference method, traceable to the CDC hexokinase method. The following accuracy results were obtained.

Table 1: System accuracy results for glucose concentration < 75 mg/dL

Difference range in values between YSI laboratory reference method and CONTOUR NEXT ONE meter	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Number (and percent) of samples within specified range	14 of 17 (82.4%)	16 of 17 (94.1%)	16 of 17 (94.1%)

Table 2: System accuracy results for glucose concentration ≥ 75 mg/dL

Difference range in values between YSI laboratory reference method and CONTOUR NEXT ONE meter	Within ± 5%	Within ± 10%	Within ± 15%
Number (and percent) of samples within specified range	288 of 355 (81.1%)	342 of 355 (96.3%)	354 of 355 (99.7%)

Table 3: System accuracy results for glucose concentrations between 32.2 mg/dL and 458 mg/dL

Within ± 15 mg/dL or ± 15%
370 of 372 (99.5%)

Technical Information: Precision

A measurement repeatability study was conducted with the CONTOUR NEXT ONE blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from 43 mg/dL to 333 mg/dL. With each blood specimen, each of 3 lots of CONTOUR NEXT test strips was tested 10 times on each of 10 instruments for a total of 300 readings. The following precision results were obtained.

Table 1: System repeatability results for CONTOUR NEXT ONE meter using CONTOUR NEXT test strips

Mean, mg/dL	Pooled Standard Deviation, mg/dL	95% CI of SD, mg/dL	Coefficient of Variation, %
43.7	0.9	0.83–0.98	2.1
77.6	1.2	1.14–1.35	1.6
129.3	1.8	1.62–1.92	1.4
205.3	2.9	2.65–3.13	1.4
331.7	3.9	3.63–4.29	1.2

Intermediate measurement precision (which includes variability across multiple days) was evaluated using control solutions at 3 glucose levels. With each control solution, each of 3 lots of CONTOUR NEXT test strips was tested once on each of 10 instruments on 10 separate days for a total of 300 readings. The following precision results were obtained.

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Table 2: System intermediate precision results for CONTOUR NEXT ONE meter using CONTOUR NEXT test strips

Control Level	Mean, mg/dL	Pooled Standard Deviation, mg/dL	95% CI of SD, mg/dL	Coefficient of Variation, %
1	42.0	0.6	0.55–0.65	1.4
2	123.6	1.5	1.38–1.63	1.2
3	363.1	5.4	4.97–5.89	1.5

Symptoms of High or Low Blood Glucose

You can better understand your test results by being aware of the symptoms of high or low blood glucose. According to the American Diabetes Association (www.diabetes.org), some of the most common symptoms are:

Low blood glucose (Hypoglycemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- seizure
- irritability
- extreme hunger
- dizziness

High blood glucose (Hyperglycemia):

- frequent urination
- excessive thirst
- blurred vision
- increased fatigue
- hunger

Ketones (Ketoacidosis):

- shortness of breath
- nausea or vomiting
- very dry mouth

WARNING

If you are experiencing any of these symptoms, test your blood sugar. If your test result is under 50 mg/dL or above 250 mg/dL, contact your health care professional immediately.

For additional information and a complete list of symptoms, contact your health care professional.

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Federal Communications Commission (FCC) Certified Device

This equipment has been tested and found to meet the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

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

This device complies with part 15 of the FCC Rules. Operation is subject to the following 2 conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Compliance with these guidelines means that under normal, daily circumstances, the device should not affect the operation of other devices. In addition, the device should operate normally in the presence of other devices.

In the event there is interference from another device, it is recommended that you increase the distance between the meter and that device. You can also turn off the interfering device. In addition, you can turn off **Bluetooth** wireless technology on the meter. Changes or modifications to the device not expressly approved by Ascensia Diabetes Care could void the user's authority to operate the device. The device has been tested and found to comply with the limits for a Class B digital device. The device generates, uses, and can radiate radio frequency energy.

If you have questions, contact Diabetes Care Customer Service. See back cover for contact information.

Specifications

Test Sample: Capillary whole blood only

Test Result: Referenced to plasma/serum glucose

Sample Volume: 0.6 µL

Measuring Range: 20 mg/dL–600 mg/dL of glucose in blood

Countdown Time: 5 seconds

Memory: Stores most recent 800 test results

Battery Type: Two 3-volt CR2032 or DL2032 coin cell batteries, 225 mAh capacity

Battery Life: Approximately 1000 tests (1 yr. average use, 3 tests per day)

Meter Operating Temperature Range: 41°F–113°F

Control Testing Temperature Range: 59°F–95°F

Meter Operating Humidity Range: 10% RH–93% RH

Dimensions: 97 mm (L) x 28 mm (W) x 14.9 mm (H)

Weight: 36 grams

Meter Life: 5 years

Sound Output: 45 dB(A)–85 dB(A) at a distance of 10 cm

Radio Frequency Technology: Bluetooth Smart

Radio Frequency Band: 2.4 GHz–2.483 GHz

Maximum Radio Transmitter Power: 1 mW

Modulation: Gaussian Frequency Shift Keying (GFSK)

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Electromagnetic Compatibility (EMC): The CONTOUR NEXT ONE meter complies with the electromagnetic requirements specified in IEC 60601-1-2 Edition 4.0. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the CONTOUR NEXT ONE meter. The CONTOUR NEXT ONE meter meets the requirements of IEC 61000-4-2 for immunity to electrostatic discharge. The CONTOUR NEXT ONE meter meets the requirements of IEC 61000-4-3 for radio frequency interference. To avoid radio frequency interference, do not use the CONTOUR NEXT ONE meter near electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

Symbols Used

The following symbols are used throughout the product labeling for the CONTOUR NEXT ONE blood glucose monitoring system (meter packaging and labeling, and reagent and control solution packaging and labeling).

Symbol	What it Means
LOT	Batch Code
Discard Date:	Control Discard Date
	Consult instructions for use
IVD	In Vitro Diagnostic Medical Device
CONTROL	Control Solution – Level 1, Level 2
15x	Shake 15 times

Principles of the Procedure: The CONTOUR NEXT ONE blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and the mediator. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation by the user is required.

Comparison Options: The CONTOUR NEXT ONE system is designed for use with capillary whole blood. Comparison with a laboratory method must be done simultaneously with aliquots of the same sample.

NOTE: Glucose concentrations drop rapidly due to glycolysis (approximately 5%–7% per hour).[7]

References

1. US Food and Drug Administration. Use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
2. Centers for Disease Control and Prevention. CDC clinical reminder: use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens. US Department of Health and Human Services; 8/23/2010. http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html
3. Wickham NWR, et al. Unreliability of capillary blood glucose in peripheral vascular disease. *Practical Diabetes*. 1986;3(2):100.
4. Atkin SH, et al. Fingerstick glucose determination in shock. *Annals of Internal Medicine*. 1991;114(12):1020-1024.
5. Desachy A, et al. Accuracy of bedside glucometry in critically ill patients: influence of clinical characteristics and perfusion index. *Mayo Clinic Proceedings*. 2008;83(4):400-405.

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6. American Diabetes Association. Standards of medical care in diabetes—2016. *Diabetes Care*. 2016;39(supplement 1):S15.
7. Burtis CA, Ashwood ER, editors. *Tietz Fundamentals of Clinical Chemistry*. 5th edition. Philadelphia, PA: WB Saunders Co; 2001;444.

Warranty

Manufacturer's Warranty: Ascensia Diabetes Care warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for 5 years from the date of original purchase (except as noted below). During the stated 5-year period, Ascensia Diabetes Care shall, at no charge, replace a unit found to be defective with an equivalent or current version of the owner's model.

Limitations of Warranty: This warranty is subject to the following exceptions and limitations:

1. A 90-day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to replacement due to defects in parts or workmanship. Ascensia Diabetes Care shall not be required to replace any units that malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by someone other than Ascensia Diabetes Care, or failure to operate the instrument in accordance with instructions. Further, Ascensia Diabetes Care assumes no liability for malfunction of or damage to Ascensia Diabetes Care instruments caused by the use of test strips or control solution other than the appropriate products recommended by Ascensia Diabetes Care (i.e., CONTOUR NEXT test strips and CONTOUR NEXT control solutions.)
3. Ascensia Diabetes Care reserves the right to make changes in the design of this instrument without obligation to incorporate such changes into previously manufactured instruments.
4. Ascensia Diabetes Care has no knowledge of the performance of the CONTOUR NEXT ONE blood glucose meter when used with any test strips other than CONTOUR NEXT test strips, and therefore does not warrant the performance of the CONTOUR NEXT ONE meter when used with any test strips other than CONTOUR NEXT test strips or when the CONTOUR NEXT test strip is altered or modified in any manner.
5. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR NEXT ONE meter or test results when used with any control solution other than CONTOUR NEXT control solution.
6. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR NEXT ONE meter or test results when used with any software other than the CONTOUR DIABETES app (where supported) or the GLUCOFACTS DELUXE diabetes management software (where supported) from Ascensia Diabetes Care.

ASCENSIA DIABETES CARE MAKES NO OTHER EXPRESS WARRANTY FOR THIS PRODUCT. THE OPTION OF REPLACEMENT, DESCRIBED ABOVE, IS THE ONLY OBLIGATION OF ASCENSIA DIABETES CARE UNDER THIS WARRANTY.

IN NO EVENT SHALL ASCENSIA DIABETES CARE BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF ASCENSIA DIABETES CARE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

Some States do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you. This warranty gives you specific legal rights and you may also have other rights which vary from State to State.

For warranty service: Purchaser must contact Ascensia Diabetes Care Customer Service for assistance and/or instructions for obtaining service of this instrument. See the back cover for contact information.

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www.contourone.com

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