# Contour® next ))

Blood Glucose Monitoring System

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

NO CODING®

Second-Chance® sampling

6:30 AM   7/22/18
✓ 93 mg/dL ₿

**Uses only CONTOUR® NEXT blood glucose test strips.**

## USER GUIDE

## INTENDED USE

The CONTOUR®NEXT 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 blood glucose monitoring system is intended to be used by a single person and should not be shared. The CONTOUR NEXT 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 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 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

**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. If the blood glucose reading is 250 mg/dL or greater, check your ketone levels.[1,9]

**Talk to Your Health Care Professional:**

- Before setting any **Target Ranges** in your meter or in the CONTOUR®DIABETES app.

- Before changing your treatment or medication based on test results.
- About whether Alternative Site Testing (AST) is appropriate for you.
- Before making any other decision of medical relevance.

**Potential Biohazard**

- Always wash your hands with antibacterial soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.
- All parts of the k t 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 *Cleaning and Disinfection* on page 53

- 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://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

  "Centers for Disease Control and Prevention. Infection Prevention during Blood Glucose Monitoring and Insulin Administration. US Department of Health and Human Services; update June 8, 2017."

  http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.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.[2,3]
- The lancing device usually provided with your k t 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 k t 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.
- **This device is not intended for use in health care or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by the US FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.**
- **Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.**

## LIMITATIONS

- **Serious Illness:** The system should not be used to test critically ill patients and should not be used by persons with reduced peripheral blood flow. Accurate measurement of glucose in peripheral blood flow can be adversely affected by clinical conditions such as shock, severe hypotension, and severe dehydration.[4-6]
- **Meter Operating Temperature Range:** 41°F–113°F
- **Control Testing Temperature Range:** 59°F–95°F
- **Test Strip Storage Conditions:** 41°F–86°F, 10%–80% Relative Humidity (RH)
- **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:** This system has not been tested at altitudes higher than 20,674 feet (6301 meters).
- **Alternative Site Testing:** See Alternative Site Testing instructions on page 23.
- **Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.**
- **Neonatal Use:** The CONTOUR NEXT meter is **not indicated** for neonatal use.

## PRECAUTIONS

- 📖 Read your CONTOUR NEXT user guide, the lancing device package insert, if provided, and all instructional materials provided in your meter k t 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 Customer Service. See the back cover for contact information.
- Your CONTOUR NEXT meter works ONLY with CONTOUR NEXT test strips and CONTOUR®NEXT control solution.
- 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.

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- 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 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 the 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 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 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**  or  **5.2**
    mg/dL      mmol/L

  - ❖ Check your display screen to be sure the results are shown correctly (mg/dL). If not, contact Customer Service. See the back cover for contact information.

- The CONTOUR NEXT blood glucose monitoring system has a measuring range of 20 mg/dL to 600 mg/dL.
  - ❖ For results under 20 mg/dL or over 600 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**. Also, check your ketone levels.[1,9]

## Your Meter Features

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

**Automatic:** The CONTOUR NEXT 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**

Second-Chance® sampling allows you to apply more blood 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 blood glucose monitoring system. We are proud to be your partner in helping you manage your diabetes.

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

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## Your CONTOUR NEXT meter

**Up/Down Scroll Buttons**
Press to scroll up ▲
Press and hold to keep scrolling
Press to scroll down ▼
Press and hold to keep scrolling

**OK Button**
Press and hold to turn the meter On or Off
Press to accept a selection

**Test Strip Port Light**

**Test Strip Port**

## Navigate with 3 Buttons

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

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

The ▲ and ▼ 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 **Averages** and return to the **Home** screen, press the **OK** button.

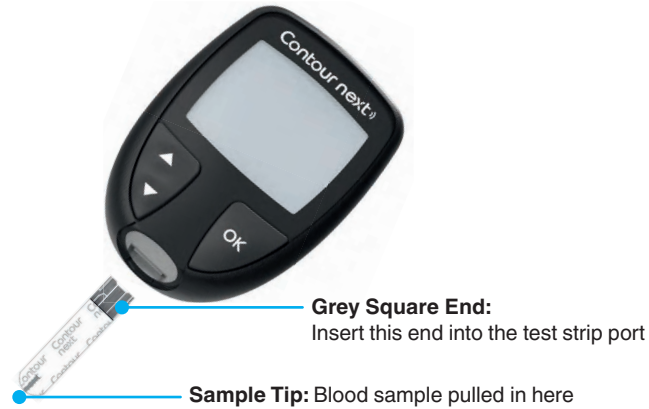**NOTE:** When a symbol is blink ng, you can select it.

## Your CONTOUR NEXT meter Screen

Time
Test Result in Target
Test Strip Port
Date
Meal Marker
Test Strip Port Light

| Symbol | What the Symbol Means |
|--------|----------------------|
| ⬆ | Blood sugar test result is **above** Target Range. |
| ✓ | Blood sugar test result is **in** Target Range. |
| ⬇ | Blood sugar test result is **below** Target Range. |
| HI | Blood sugar test result is above 600 mg/dL. |
| LO | Blood sugar test result is below 20 mg/dL. |
| 📖 | Your **Logbook**. |
| ⚙ | Meter **Settings**. |
| 🍎 | **Fasting** marker. |

| Symbol | What the Symbol Means |
|--------|----------------------|
| 🍎 | **Before Meal** marker. |
| 🍎 | **After Meal** marker. |
| ✕ | **No** marker selected. |
| ◎ | A **Target Range** or **Target Range** setting. |
| 💡 | **smartLIGHT** target range indicator setting. |
| | Meter is ready to test. |
| | Add more blood to **same** test strip. |
| | Control solution test result. |
| ✳ | **Bluetooth**® symbol: indicates the **Bluetooth** wireless setting is On; the meter can communicate with a mobile device. |
| 🔋 | Indicates low batteries. |
| 🔋 | Indicates dead batteries. |
| E | Indicates a meter error. |
| ⏰ | Reminder feature. |
| 🔊 | Sound feature. |
| 7d Avg | 7-, 14-, 30-, and 90-day averages. |
| n | Total number of blood sugar readings used to calculate averages. |

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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

## Check the Meter Display

Press and hold the **OK** button until the meter turns on, about 3 seconds.

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 Customer Service. This may affect the way you see your results.

**NOTE:** Your meter comes with a pre-set time, date, and target range. You can change these features in **Settings**. See *Settings* on page 36.

## Target Ranges

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 above, in, or below your Target Range.

⬆ Above Your Target Range.

✔ In Your Target Range.

⬇ Below Your Target Range.

You can change **Target Ranges** in **Settings** ⚙.
See *Settings* on page 36.

CONTOUR®NEXT blood glucose monitoring system

90002936_UG_LTN_b1310303_US_EN_0-12nCMS_V0.indd   6-7                                                  1/3/2019   2:22:44 PM

## 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 meter comes with **Meal Markers** turned Off. You can turn **Meal Markers** On and change **Target Ranges** in **Settings** ⚙. See *Settings* on page 36.

**Meal Marker choices if Meal Marker feature is On**

| Symbol | What the Symbol Means | Comparison/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). | If you mark your test result as **Fasting**, the meter compares your result against the **Before Meal Target Range**.<br>Pre-set **Before Meal Target Range**: 70 mg/dL‒ 30 mg/dL |
| | **Before Meal:** Use the **Before Meal** marker when testing blood sugar levels within 1 hour before a meal. | If you mark your test result as **Before Meal**, the meter compares your result against the **Before Meal Target Range**.<br>Pre-set **Before Meal Target Range**: 70 mg/dL‒ 30 mg/dL |

| Symbol | What the Symbol Means | Comparison/Target Range |
|---|---|---|
| | **After Meal:** Use the **After Meal** marker when testing blood sugar levels within 2 hours after the first bite of a meal. | If you mark your result as **After Meal**, the meter compares the result against the **After Meal Target Range**.<br>Pre-set **After Meal Target Range**: 70 mg/dL‒ 80 mg/dL |
| | **No Mark Selected:** Use the **No Mark** symbol when testing at times other than after fasting or before or after a meal. | If you do not mark the result, the meter compares your test result against the **Overall Target Range**.<br>Pre-set **Overall Target Range**: 70 mg/dL‒ 80 mg/dL |

## Get Ready to Test

ℹ Read your CONTOUR NEXT 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 Customer Service. See the back cover for contact information.

> **CAUTION:** Your CONTOUR NEXT 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 meter.
*   CONTOUR NEXT test strips.
*   Lancing device and lancets from your k t, if provided.

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

> **WARNING: Potential Biohazard**
> *   All parts of the k t are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection, see page 53.
> *   Always wash your hands with antibacterial 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 page 53.

## 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 k t 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.
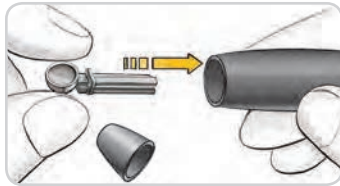
> **WARNING: Potential Biohazard**
> Always dispose of used test strips and lancets as medical waste or as advised by your health care professional.
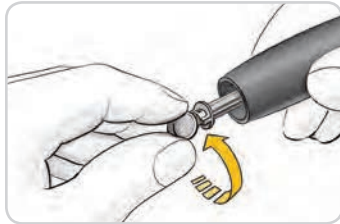
**1.** Remove the endcap from the lancing device.

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

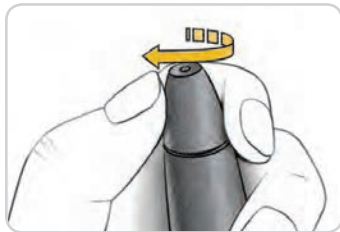CONTOUR®NEXT blood glucose monitoring system

**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.
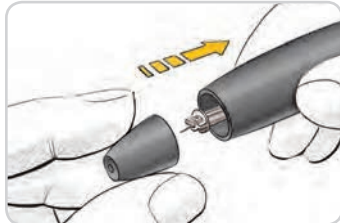
**5.** Replace the endcap.

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

The amount of pressure applied to the puncture site also affects puncture depth.
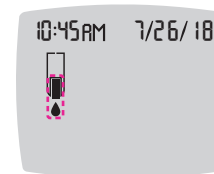
## Insert the Test Strip

**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.

10:45AM   7/26/18

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.

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## Get the Blood Drop: Fingertip Testing

**NOTE: For Alternative Site Testing instructions, see page 23.**

> **WARNING: Potential Biohazard**
>
> Always wash your hands with antibacterial soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.

**1.** Press the lancing device firmly against the puncture site and press the release button.
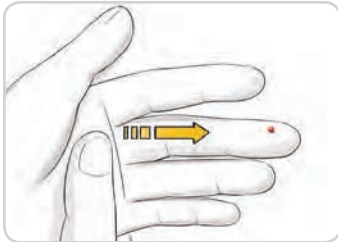
**2.** Stroke your hand and finger toward the puncture site to form a drop of blood.

Do not squeeze around the puncture site.
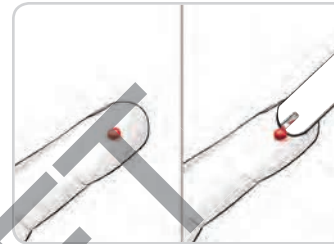
**3.** Test immediately after you have formed a small, round blood drop, as shown.

**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.

> **CAUTION:** Do not press the tip of the test strip against the sk n 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 the **Meal Marker** feature is On, do not remove the test strip until you select a **Meal Marker**.

## Second-Chance sampling—Apply More Blood
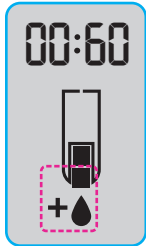


1. If the meter beeps twice and the screen displays a blink ng blood drop with a plus sign, the test strip does not have enough blood.
2. Apply more blood to the **same** test strip within 60 seconds.

**NOTE:** 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 **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: breakfast, lunch, dinner, or overnight. For more information about Meal Markers, see page 8.

Example:



**Do not press the OK button or remove the test strip yet.**

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

To turn **Meal Markers** On, see *Set Meal Markers* on page 42.



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

   *or*

2. To select a different **Meal Marker**, press the ▲ or ▼ button on the meter to scroll between markers.

Example: If you scroll up to **Before Meal**, the **Before Meal** 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.

**4.** If this is a **Before Meal** reading, you can set a **Reminder** to test your blood sugar later. See the next section, *Set a Reminder*.

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**.

## Set a Reminder

**1.** Make sure the **Reminder** ⏱ feature is On in **Settings**.
See *Set Reminder Feature* on page 43.

**2.** Mark a blood sugar reading as a **Before Meal** reading, then press the **OK** button.

**3.** To scroll from 2 hours to 0.5 hours by half-hour intervals, press the ▲ or ▼ button.

**4.** To set the **Reminder**, press the **OK** button.
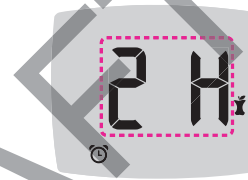
The screen returns to the **Before Meal** reading. The **Reminder** symbol ⏱ displays to confirm the Reminder is set.

**Blood sugar test is complete.**
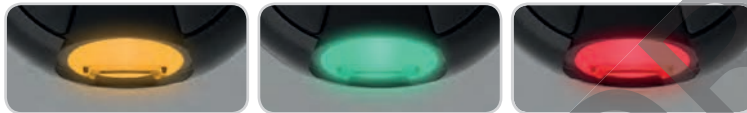
## smartLIGHT target range indicator

When your blood sugar test is complete, the meter displays your result with the units, time, date, meal marker (if selected), and target range symbol: Above Target 🔼, In Target ✔, or Below Target 🔽.

Example: Blood test result with **Meal Marker** selected and a **Reminder** set:



If the **smartLIGHT** target range indicator is On, the test strip port displays a color representing your result value compared to your **Before Meal**, **After Meal**, or **Overall Target Range**.

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



**Above Target Range** ↑      **In Target Range** ✔      **Below Target Range** ↓

If your blood sugar result is below target, the **smartLIGHT** target range indicator is red and the meter beeps twice.

**NOTE:** To change an Individual Target Range, see *Change Individual Target Ranges* on page 45. To change the Overall Target Range, see *Change Overall Target Range* on page 44.



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

*or*

To turn the meter off, remove the test strip.

## 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. If the blood glucose reading is 250 mg/dL or greater, check your ketone levels.[1,9] |

## 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 100 mg/dL in the fasting state and less than 140 mg/dL in the post-prandial state (after a meal).[7] You should consult with your health care professional for glucose values specific to your needs.

## LO or HI Results

10:45AM 11/26/18
LO
mg/dL

10:45AM 11/26/18
HI
mg/dL

- 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**. Also, check your ketone levels.[1,9]

## 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 antibacterial soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.

For Alternative Site Testing, use the clear endcap. Your CONTOUR NEXT 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 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 antibacterial soap and warm water.

   Rinse and dry well.

2. Attach the clear AST endcap to the lancing device, if provided with your k t.

   **Refer to the lancing device insert for detailed instructions.**
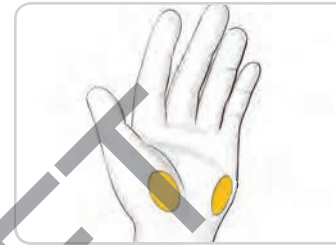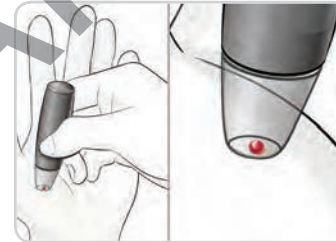
3. Select a puncture site from a fleshy area on the palm. Avoid veins, moles, bones, and tendons.

**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.

6. Lift the lancing device straight up and away from the sk n 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.

## Second-Chance sampling for ASTA — pply More Blood
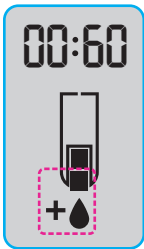


1. If the meter beeps twice and the screen displays a blinking blood drop with a plus sign, the test strip does not have enough blood.
2. Apply more blood to the **same** test strip within 60 seconds.

**NOTE:** 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**.



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

   *or*

4. To select another **Meal Marker**, press the ▲ or ▼ button to scroll between markers.

**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). | **Before Meal Target Range** |
| | **Before Meal:** Use the **Before Meal** marker when testing blood sugar levels within 1 hour before a meal. | |
| | **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** |

**5.** When the **Meal Marker** you want is blink ng, press the **OK** button. To set a Reminder to test your blood after a meal, see *Set a Reminder* on page 19.

For more information about **Meal Markers**, see *Select a Meal Marker* on page 16.

## 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 k t 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.[2,3]**
- **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 antibacterial soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.

CONTOUR®NEXT blood glucose monitoring system

## 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 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 work ng properly.
• You have repeated, unexp ected blood sugar results.

| WARNING |
| --- |
| • **Do not calibrate your continuous glucose monitoring device from the control result.**<br>• **Do not calculate a bolus based on a control result.** |

**CAUTION:** Do not use exp ired materials. Using exp ired material can cause inaccurate results. Always check the exp iration 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 should test your CONTOUR NEXT meter with control solution only 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 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.

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

CONTOUR®NEXT blood glucose monitoring system

`10:45AM   7/26/18`
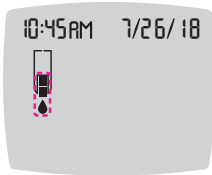
The meter turns on, displaying a test strip with a flashing blood drop.

**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.**

`10:45AM   7/26/18`
`130 mg/dL`

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** or in blood sugar Averages. Control test results are not evaluated against any Target Ranges.

**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 meter for blood sugar testing until you resolve the issue. Contact Customer Service. See the back cover for contact information.

## Logbook

The **Logbook** contains blood sugar test results and Meal 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**.
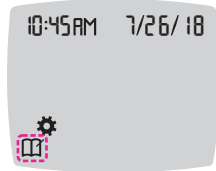
## Review the Logbook

**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 3 seconds.

The **Logbook** is blink ng.

**2.** To select the blink ng **Logbook** symbol, press the **OK** button.

**3.** To view your individual test results in the **Logbook**, 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 *LO or HI Results* on page 22 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.

## View Averages

**1.** To enter the **Logbook** from the Home screen, press the **OK** button while the **Logbook** is blink ng.

**2.** To view your Averages, press the ▲ button from the *first* **Logbook** screen.

7-day Average        Number of tests
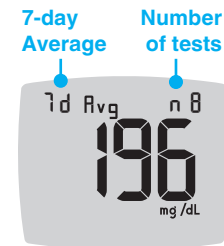
**3.** To scroll through your 7-, 14-, 30-, and 90-day Averages, press the ▲ button.

**4.** To return to your Logbook readings, press the ▼ button on the **7 d Avg** (7-day Average).

**5.** To ei t Averages and return to the **Home** screen at any time, press the **OK** button.

90002936_UG_LTN_b1310303_US_EN_0-12nCMS_V0.indd   34-35    1/3/2019   2:22:56 PM

## 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.
• Turn **Reminder** feature On or Off.
• View and change **Target Ranges**.
• Turn **smartLIGHT** feature On or Off.
• Turn **Bluetooth** wireless functionality On or Off.

You must accept or change each setting with the **OK** button.

### 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 blink ng, press the **OK** button to enter **Settings**.

**4.** Press the ▲ or ▼ button to navigate to the setting you want to change.

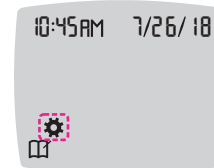**5.** Press the **OK** button when the setting you want to change is blink ng.

**6.** To ei t from the **Settings** menu and return to the **Home** screen, press the ▲ or ▼ button until the **Settings** symbol is blink ng.

**7.** Press the **OK** button.

**NOTE:** If you are in a setting such as Date and you need to ei t, press the **OK** button repeatedly until you get back to the **Home** screen.

### Change the Time

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

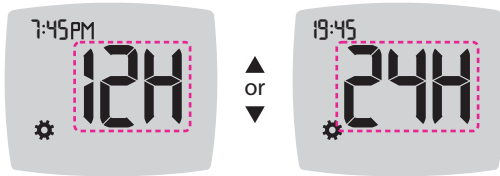The **Home** screen has 2 options: **Logbook** and **Settings** .

**2.** To highlight the **Settings** symbol , press the ▼ button.

**3.** When the **Settings** symbol is blink ng, press the **OK** button to enter **Settings**.
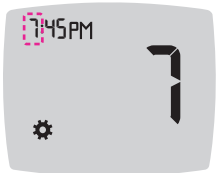
**4.** Press the **OK** button when the current time is blink ng on the **Settings** screen. The time format is blink ng.

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

7:45PM
**12H**
⚙

or
▲
▼

19:45
**24H**
⚙

Time Format

The hour is blinking.

7:45PM
**7**
⚙

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

The minutes are blinking.

7:45PM
**45**
⚙

**7.** To change minutes, press the ▲ or ▼ button, then press the **OK** button.

**8.** For a 12-hour time format, select **AM** or **PM**, as needed, then press the **OK** button.

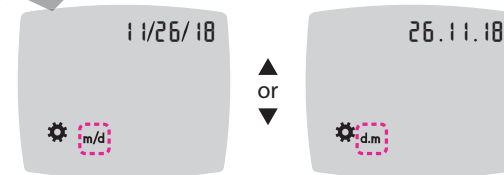The meter returns to the **Home** screen.

## Change the Date

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

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

10:45AM   7/26/18
⚙
📖

**2.** To highlight the **Settings** symbol ⚙, press the ▼ button.

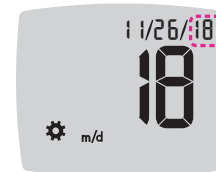**3.** When the **Settings** symbol is blinking, press the **OK** button to enter **Settings**.

**4.** Press the ▼ button until the current date is blinking on the **Settings** screen, then press the **OK** button.
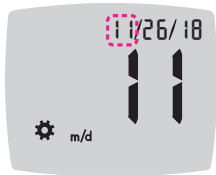
11/26/18
⚙ m/d

or
▲
▼

26.11.18
⚙ d.m

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.

11/26/18
**18**
⚙ m/d

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

90002936_UG_LTN_b1310303_US_EN_0-12nCMS_V0.indd   38-39                    1/3/2019   2:22:59 PM

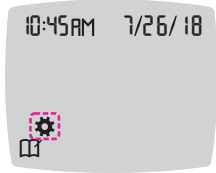**7.** To change the month (blink ng), press the ▲ or ▼ button, then press the **OK** button.

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

The meter returns to the **Home** screen.

## Set the Sound

**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 blink ng, press the **OK** button to enter **Settings**.

**4.** Press the ▼ button repeatedly until the **Sound** symbol 🔊 is blink ng on the **Settings** screen, then press the **OK** button.

▲ 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 **smartLIGHT** feature to Off.
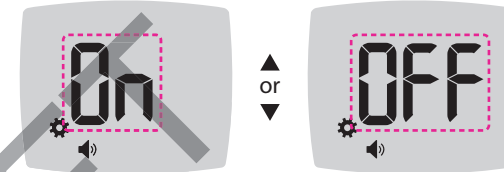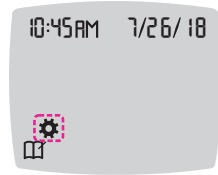
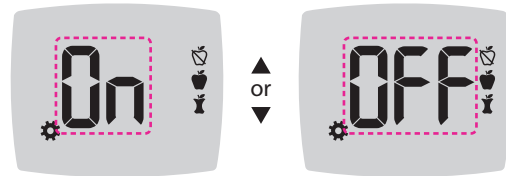The meter returns to the **Home** screen.

## Set Meal Markers

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

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

   `10:45AM   7/26/18`

   2. To highlight the **Settings** symbol ⚙, press the ▼ button.

   3. When the **Settings** symbol is blink ng, press the **OK** button to enter **Settings**.

4. Press the ▼ button repeatedly until the **Meal Marker** symbols 🍎 🍏 🍎 are blink ng, then press the **OK** button.

   `On` 🍎    or ▲▼    `OFF` 🍎

   Meal Marker Symbols: 🍎 🍏 🍎

Your meter comes with the **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. The meter returns to the **Home** screen.

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

## Set Reminder Feature

When **Meal Markers** are On, you can set a **Reminder** to test your blood sugar after you mark a reading as **Before Meal**. If **Meal Markers** are Off, see *Set Meal Markers* on page 42.

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

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

   `10:45AM   7/26/18`

   2. To highlight the **Settings** symbol ⚙, press the ▼ button.

   3. When the **Settings** symbol is blink ng, press the **OK** button to enter **Settings**.

4. Press the ▼ button repeatedly until the **Reminder** symbol ⏰ is blink ng, then press the **OK** button.

   Your meter comes with the **Reminder** feature turned Off.

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

   `On` ⏰    or ▲▼    `OFF` ⏰

   Reminder Symbol: ⏰

6. Press the **OK** button. The meter returns to the **Home** screen.

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## Change Overall Target Range

When the **Meal Marker** feature is Off, your meter provides a pre-set **Overall Target Range**. A Target Range has a low limit and a high limit, such as 70 mg/dL–180 mg/dL. You may want your blood sugar readings to stay within a target range. You can change the **Overall Target Range** in **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 blink ng, press the **OK** button to enter **Settings**.

4. Press the ▼ button repeatedly until the **Target** symbol 🎯 is blink ng, then press the **OK** button. The meter displays the **Overall Low Target** screen.

5. To change the blink ng **Low** end of the **Overall Target Range**, press the ▲ or ▼ button.

6. To set the **Low** end, press the **OK** button.

7. To change the blink ng **High** end of the **Overall Target Range**, press the ▲ or ▼ button.

8. To set the **High** end, press the **OK** button.

The meter returns to the **Home** screen.

## Change Individual Target Ranges

When the **Meal Marker** feature is On, you have 2 Target Ranges on your meter: a **Before Meal Target Range** 🍎 (which is the same as Fasting) and an **After Meal Target Range** 🍎. When the **Meal Marker** feature is Off, there is only 1 **Overall Target Range**.

You can change these ranges in **Settings** in your meter and in the CONTOUR DIABETES app.

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

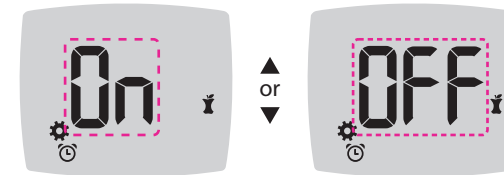The **Home** screen has 2 options: **Logbook** 📖 and **Settings** ⚙.
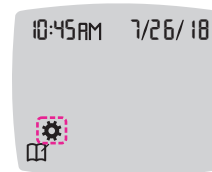
2. To highlight the **Settings** symbol ⚙, press the ▼ button.

3. When the **Settings** symbol is blink ng, press the **OK** button to enter **Settings**.

4. Press the ▼ button repeatedly until the **Target** symbol 🎯 is blink ng, then press the **OK** button. The meter displays the **Low Target** screen.

CONTOUR®NEXT blood glucose monitoring system

**NOTE:** There is only one Low target number for both the **Before Meal** 🍎 and **After Meal** ⏳ Target Ranges.

**Change Low for Both Target Ranges**
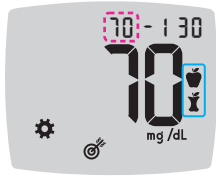
5. To change the blink ng **Low** for both **Target Ranges** (**Before Meal** 🍎, **After Meal** ⏳), press the ▲ or ▼ button.
6. To set the **Low** end of both **Target Ranges**, press the **OK** button.

   The meter displays the **Before Meal High Target** screen.

**Change Before Meal Target Range**

7. To change the blink ng **High** end of the **Before Meal Target Range**, press the ▲ or ▼ button.
8. To set the **High** end, press the **OK** button.

   The meter displays the **After Meal High Target** screen.

**NOTE:** The **Before Meal Target Range** is also the Target Range for a blood sugar reading marked as **Fasting**.

**Change After Meal Target Range**

9. To change the blink ng **High** end of the **After Meal Target Range**, press the ▲ or ▼ button.
10. To set the **High** end, press the **OK** button.

The meter returns to the **Home** screen.

## Set smartLIGHT target range indicator

Your meter comes with the **smartLIGHT** feature turned On.

When the **smartLIGHT** target range indicator is On, the test strip port displays a color that indicates if your reading is above, in, or below your personal Target Range.
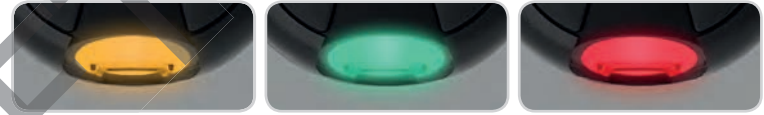
| **Above Target Range** ▲ | **In Target Range** ✓ | **Below Target Range** ▼ |
| --- | --- | --- |

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

   The **Home** screen has 2 options: **Logbook** 📖 and **Settings** ⚙.
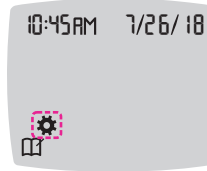
2. To highlight the **Settings** symbol ⚙, press the ▼ button.
3. When the **Settings** symbol is blink ng, press the **OK** button to enter **Settings**.

4. Press the ▼ button repeatedly until the **smartLIGHT** symbol 💡 is blink ng, then press the **OK** button.
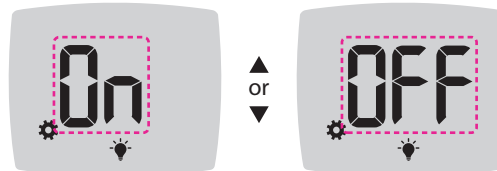
smartLIGHT Symbol: 💡

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

**6.** Press the **OK** button.

## Set Bluetooth Wireless Functionality

After pairing your meter with a mobile device, the **Bluetooth** setting can be turned On or Off. For pairing instructions, see page 50.

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

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

10:45AM  7/26/18
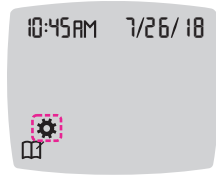
**2.** To highlight the **Settings** symbol ⚙, press the ▼ button.

**3.** When the **Settings** symbol is blink ng, press the **OK** button to enter **Settings**.

**4.** Press the ▼ button repeatedly until the **Bluetooth** symbol is blink ng, then press the **OK** button.
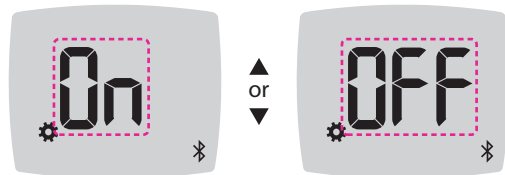
On     or ▲▼     OFF

**Bluetooth** Symbol: 

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

**6.** Press the **OK** button.

The meter returns to the **Home** screen.

## The CONTOUR DIABETES app for Your CONTOUR NEXT meter

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

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

• Add Notes after testing that help to explain your results:

 o List meals containing carbs.
 o Note changes in medication.
 o Add photos of your meal.
 o 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 **View All** 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 **My Readings**.

• Displays your trends and test results as they compare with your targets.

When your CONTOUR NEXT meter is paired with the CONTOUR DIABETES app:

• You can set or change a **Meal Marker** in the meter **Logbook** from the app.

• The app will always sync your most recent Target Range from the app or meter, across the system.

- The app date and time can sync to your meter.
- You can manage your meter settings from the app, like Sound or smartLIGHT target range indicator.

## Download the CONTOUR DIABETES app

1. On your compatible 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.diabetes.ascensia.com** to learn more.

## Pairing Mode

**CAUTION:** There is a remote possibility that a computer specialist could listen in on your wireless communications when you pair the blood glucose meter and would then be able to read your blood sugar readings from your meter. If you believe this is a risk, pair your blood glucose meter far away from other people. After you pair your device, you do not need to take this precaution.

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:

1. If your meter is off, press and HOLD the **OK** button until the meter turns on. The **Home** screen displays.

2. Press and HOLD the ▲ button for about 3 seconds, until you see the blinking **Bluetooth** symbol (as shown in Step 3). A blue light blinks when you are in pairing mode.

3. When the meter serial number displays, follow the instructions on the app to match the meter serial number.

**Meter serial number** — `12   34 56  7`

Example: Your meter in pairing mode.

**Pass code** — `CO dE   89 12 34`

When a connection is made, the meter displays the 6-digit pass code you need to enter on the smart device.

CONTOUR®NEXT blood glucose monitoring system

When you have successfully paired your meter with the CONTOUR DIABETES app, the meter's blue light and the **Bluetooth** symbol display.

The meter returns to the **Home** screen.

**NOTE:** You can update your Target Ranges from the meter or from the app. The most recently changed Target Ranges will update in the meter and the app when they are synced.

## 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 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, by a disinfectant that is effective against common microbial and viral pathogens. You should call 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 antibacterial 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 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 meter.

Clorox Germicidal Wipes are available for purchase online at http://www.officedepot.com or http://www.amazon.com. For more information, contact 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://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
Centers for Disease Control and Prevention. Infection Prevention during Blood Glucose Monitoring and Insulin Administration. US Department of Health and Human Services; update June 8, 2017. http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.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 USB port.

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.

> **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 USB port.

1. Before disinfecting, clean the meter as described in *Cleaning Your Meter*.
2. Using a new germicidal wipe, carefully wipe all outer surfaces of your meter until wet.

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



| Buttons | Test Strip Port |
|---------|-----------------|

3. Use a clean paper towel to dry the meter surfaces and the test strip port.

## Cleaning and Disinfecting Your Lancing Device

**Refer to the instructions provided with your lancing device for cleaning and disinfection.**

## Transfer Results to the CONTOUR DIABETES app

> **CAUTION:** The CONTOUR NEXT 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 meter wirelessly to your compatible smartphone or tablet. See *Download the CONTOUR DIABETES app* on page 50 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 meter is connected to a computer.

You can transfer test results from the CONTOUR NEXT meter to a computer where they can be summarized in a report with graphs and tables. To make use of this feature, you need 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.

**USB Port**

Ensure your meter's USB port door is completely closed when not in use.

> **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 at a frequency of 3 tests per day before the batteries are dead.

10:45AM   7/26/18
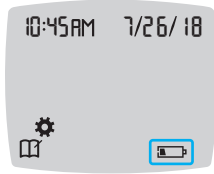
The meter operates normally, displaying the **Low Batteries** symbol until you replace the batteries.
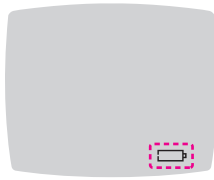
When you are no longer able to perform a test due to low batteries, the meter displays the **Dead Batteries** screen. Replace the batteries immediately.

## Replace the Batteries



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

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 up on the new batteries.
5. Press each battery into a compartment.

6. Slide the battery cover back into place.
7. 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 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. |

| Error Code | What It Means | What to Do |
|---|---|---|
| **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. |
| 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⎯99 | 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 Customer Service. See the back cover for contact information.

## Customer Service Checklist

When speaking with the Customer Service representative:

1. Have your CONTOUR NEXT 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 Customer Service. See the back cover for contact information.

• Two 3-volt CR2032 or DL2032 coin cell batteries.
• CONTOUR NEXT user guide.
• CONTOUR NEXT 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.

## Technical Information: User Accuracy

The CONTOUR NEXT ONE blood glucose monitoring system was tested by XXX 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 < XX mg/dL**

| Difference range in values between YSI laboratory reference method and CONTOUR NEXT ONE meter | Within ± X mg/dL | Within ± XX mg/dL | Within ± XX mg/dL |
|---|---|---|---|
| Number (and percent) of samples within specified range | XX of XX (XX.X%) | XX of XX (XX.X%) | XX of XX (XXX%) |

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

| Difference range in values between YSI laboratory reference method and CONTOUR NEXT ONE meter | Within ± X% | Within ± XX% | Within ± XX% |
|---|---|---|---|
| Number (and percent) of samples within specified range | XXX of XXX (XX.X%) | XXX of XXX (XX.X%) | XXX of XXX (XX.X%) |

**Table 3: System accuracy results for glucose concentrations between XX.X mg/dL and XXX mg/dL**

| Within ± XX mg/dL or ± XX% |
|---|
| XXX of XXX (XX.X%) |

## Technical Information: Precision

A measurement repeatability study was conducted with the CONTOUR NEXT ONE blood glucose monitoring system using X venous whole blood specimens with glucose levels from XX mg/dL to XXX mg/dL. With each blood specimen, each of X lots of CONTOUR NEXT test strips was tested 10 times on each of XX instruments for a total of XXX 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 | XX% CI of SD, mg/dL | Coefficient of Variation, % |
|---|---|---|---|
| XX.X | X.X | X.XXX-.XX | X.X |
| XX.X | X.X | X.XXX-.XX | X.X |
| XXX.X | X.X | X.XXX .XX | X.X |
| XXX.X | X.X | X.XXX-.XX | X.X |
| XXX.X | X.X | X.XXX-.XX | X.X |

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

**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, % |
|---|---|---|---|---|
| X | XX.X | X.X | X.XXX .XX | X.X |
| X | XXX.X | X.X | X.XXX .XX | X.X |
| X | XXX.X | X.X | X.XXX .XX | X.X |

## 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):

- shak ness
- sweating
- fast heartbeat
- blurred vision
- confusion

- passing out
- seizure
- irritability
- ex reme 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

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**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.** If the blood glucose reading is 250 mg/dL or greater, check your ketone levels.[1,9]

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

## 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.

If you have questions, contact 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

**Test Strip Storage Conditions:** 41°F–86°F, 10%–80% Relative Humidity (RH)

**Dimensions:** 78.5 mm (L) x 56 mm (W) x 18 mm (H)

**Weight:** 53 grams

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

**Radio Frequency Technology: Bluetooth** Low Energy

**Radio Frequency Band:** 2.4 GHz–2.483 GHz

**Maximum Radio Transmitter Power:** 1 mW

**Modulation:** Gaussian Frequency Shift Keying (GFSK)

**Electromagnetic Compatibility (EMC):** The CONTOUR NEXT 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 meter.

## Product Labeling Symbols

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

| Symbol | What It Means |
|---|---|
| Discard Date: | Control Discard Date |
| 15x | Shake 15 times |

## ISO Symbols

The following symbols from the International Organization for Standardization (ISO) are used throughout the product labeling for the CONTOUR NEXT blood glucose monitoring system (meter packaging and labeling, and test strip and control solution packaging and labeling).

| Symbol Graphic | Symbol Title | Explanatory Text | Standard Title | Standard Reference |
|---|---|---|---|---|
| REF | Catalog or model number | Indicates the manufacturer's catalognumber so that the medical device can be identified. | Medical devices—symbols to be used with medical device labels, labeling and information to be supplied. | ISO 15223-1, Clause 5.1.6 |
| ⧗ | Use by | Indicates the date after which the medical device is not to be used. | | ISO 15223-1, Clause 5.1.4 |
| LOT | Batch Code | Indicates the manufacturer's batch code so that the medical device can be identified. | | ISO 15223-1, Clause 5.1.5 |
| IVD | In Vitro Diagnostic Medical Device | Indicates a medical device that is intended to be used as an in vitro diagnostic medical device. | | ISO 15223-1, Clause 5.5.1 |
| | Manufacturer | Indicates the medical device manufacturer. | | ISO 15223-1, Clause 5.1.1 |
| 45°C 5°C | Temperature range | Indicates the temperature limits to which the medical device can be safely exposed. | | ISO 15223-1, Clause 5.3.7 |
| CONTROL | Control | Indicates a control material that is intended to verify the performance characteristics of another medical device. | | ISO 15223-1, Clause 5.5.2 |
| 📖 | Consult instructions for use | Indicates the need for the user to consult the instructions for use. | Medical devices—symbols to be used with medical device labels, labeling and information to be supplied. | ISO 15223-1, Clause 5.4.3 |
| | | | Medical electrical equipment — Part 1: General requirements for basic safety and essential performance. | IEC 60601-1, Table D.1, Symbol 11 |
| ⚠ | Caution: Read all warnings and precautions in instructions for use | Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. | Medical devices—symbols to be used with medical device labels, labeling and information to be supplied. | ISO 15223-1, Clause 5.4.4 |
| | | | Medical electrical equipment — Part 1: General requirements for basic safety and essential performance. | IEC 60601-1, Table D.1, Symbol 10 |

**Principles of the Procedure:** The CONTOUR NEXT 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 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).[8]

## References

1. American Diabetes Association. DKA (Ketoacidosis) & Ketones. Last edited: March 18, 2015. http://www.diabetes.org/living-with-diabetes/complications/ketoacidosis-dka.html

2. 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://wayback archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

3. Centers for Disease Control and Prevention. Infection Prevention during Blood Glucose Monitoring and Insulin Administration. US Department of Health and Human Services; update June 8, 2017. http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

4. Wickham NWR, et al. Unreliability of capillary blood glucose in peripheral vascular disease. *Practical Diabetes.* 1986;3(2):100.

5. Atkin SH, et al. Fingerstick glucose determination in shock *Annals of Internal Medicine.* 1991;114(12):1020-1024.

6. 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.

7. American Diabetes Association. Standards of medical care in diabetes—2016. *Diabetes Care.* 2016;39(supplement 1):S15.

8. Burtis CA, Ashwood ER, editors. *Tietz Fundamentals of Clinical Chemistry*. 5th edition. Philadelphia, PA: WB Saunders Co; 2001;444.

9. Joslin Diabetes Center. Ketone Testing: What You Need to Know. Accessed September 25, 2018. https://www.joslin.org/info/ketone_testing_what_you_need_to_know.html

## 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 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 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 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 meter or test results when used with any software other than the CONTOUR DIABETES app (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.

# Index

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Customer Service is available Monday through Sunday, 8:00 am through 12:00 Midnight, Eastern Time.

For information on patents and related licenses, see **www.patents.ascensia.com**.

Purchase of this product does not alone confer a license to use under these patents. Such a license only arises, and extends only to, when the CONTOUR NEXT meters and CONTOUR NEXT test strips are used together. No test strip supplier other than the supplier of this product is authorized to grant such a license.

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ASCENSIA
Diabetes Care

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