Contour® next ONE

Blood Glucose Monitoring System

Works with free CONTOUR®DIABETES app.

Warranty information and online meter registration available at **www.diabetes.ascensia.com/warranty** or call our Customer Service.

NO CODING®

Second-Chance® sampling

Uses only CONTOUR®NEXT blood glucose test strips.

USER GUIDE

CONTACT INFORMATION

Customer Service is available Monday through Sunday, from 8:00 am through 12:00 Midnight, Eastern Time. If this is a medical emergency, contact your health care professional or dial 911. To leave a message for Customer Service, remain on the line. One of our representatives will return your call as soon as possible.

Distributed by:

Ascensia Diabetes Care US Inc.

5 Wood Hollow Road

Parsippany, NJ 07054

www.diabetes.ascensia.com

Customer Service: 1-800-348-8100

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 any patents. Such a license only arises, and extends only to, when the CONTOUR NEXT ONE meters and CONTOUR NEXT blood glucose test strips are used together. No test strip supplier other than the supplier of this product is authorized to grant such a license.

ASCENSIA Diabetes Care

90013719 Rev. 12/24

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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 blood glucose 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.

NOTE: This document uses the term 'blood glucose' to mean 'blood sugar.'

IMPORTANT SAFETY INFORMATION

WARNING

If your blood glucose reading is under the critical level you have established with your health care professional, follow their advice immediately.

If your blood glucose reading is over the recommended limit set by your health care professional:

1. Wash and dry your hands well.
2. Retest with a new strip.

If you get a similar result, follow your health care professional's advice immediately.

Talk to Your Health Care Professional:

- Before setting any **Target Ranges** in your meter or in compatible software.
- Before changing your treatment or medication based on test results.
- If you obtain test results that are not consistent with the way you feel.
- 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 soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.
- 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.
- 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 Section *5 HELP: Cleaning and Disinfection*.
- 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.[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.
- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by 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. Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hypoxia state, or a hyperglycemic-hyperosmolar state, with or without ketosis.[3,4]
- **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).
- **Second-Chance sampling conditions:** Temperature Range 59°F–95°F, Hematocrit 20%–55%.
- **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 Section *2 TESTING: Alternative Site Testing (AST): Palm*.
- **Hematocrit:** CONTOUR NEXT blood glucose test strip results are not significantly affected by hematocrit levels in the range of 20% to 60%.
- **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 packaging is open or damaged, do not use those strips.

  For replacement parts, contact Customer Service. See *Contact Information* or the carton.
- Your CONTOUR NEXT ONE meter works ONLY with CONTOUR NEXT blood glucose test strips and CONTOUR®NEXT control solution.
- Always keep the CONTOUR NEXT blood glucose test strips in their original bottle or foil packet. 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 or foil packet 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 Customer Service. See *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 ONE meter is connected to a computer.
- Use only approved equipment (for example, USB cable) from the manufacturer or certified body such as UL, CSA, TUV, or CE.

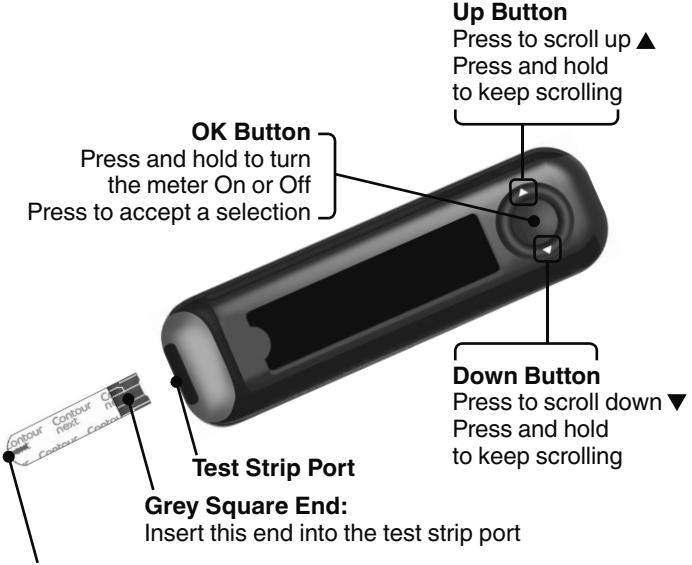
- Your CONTOUR NEXT ONE meter has been preset and locked to display results in mg/dL (milligrams of glucose per deciliter of blood).
  - ❖ Results in mg/dL do not have a decimal point.
  - ❖ Results in mmol/L do have a decimal point.

    Example: 

  - ❖ Check your display screen to be sure the results are shown correctly. If not, contact Customer Service. See *Contact Information*.
- The CONTOUR NEXT ONE 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 meter does not display a value and displays the **LO** screen, **contact your health care professional immediately**.
    - o If your meter does not display a value and displays the **HI** screen, wash your hands or the test site and repeat the test with a new strip. If the meter again displays the **HI** screen, **follow medical advice immediately**.

1 GETTING STARTED

Your CONTOUR NEXT ONE meter and CONTOUR NEXT blood glucose test strip



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

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

Your CONTOUR NEXT ONE meter Screen

Your Meter Symbols

Symbol	What the Symbol Means
	Yellow Light: test result is **above** Target Range.
	Green Light: test result is **in** Target Range.
	Red Light: test result is **below** Target Range.
✓	Blood glucose test result is in **Target Range**.
HI	Blood glucose test result is above 600 mg/dL.
LO	Blood glucose test result is below 20 mg/dL.
▲	Blood glucose test result is above **Target Range**.
▼	Blood glucose 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.

Your Meter Features

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.

The CONTOUR DIABETES app for Your ONE meter

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

You can do the following with your CONTOUR DIABETES app:

- Perform your initial meter setup.
- Add Notes after testing that help to explain your results.
- Set testing reminders.
- Access easy-to-read graphs of test results over a day or over a period of time.
- Share reports.
- Review your **Fasting**, **Before Meal**, **After Meal**, and **Overall** results on a daily graph.
- Change meter settings, as necessary.

The CONTOUR DIABETES app:

- Automatically stores your results.
- Saves your Notes in **My Readings**.
- 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.

CAUTION: The CONTOUR NEXT ONE meter has not been tested for use with any software other than compatible Ascensia Diabetes Care software. The manufacturer is not responsible for any erroneous results from the use of other software.

Initial Setup from the CONTOUR DIABETES app

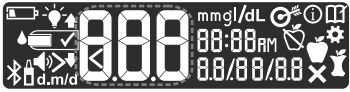
The easiest way to set up your new meter is to download the CONTOUR DIABETES app to your smartphone or tablet and follow the instructions in the app.

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.

Initial Setup from the Meter

Press and hold **OK** for 3 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 Customer Service. This may affect the way you see your results. See *Contact Information*.

1 View Overall Target Range

Initial setup begins with a view of the **Overall Target Range**.

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 **OK**.

Continue to *Set the Time*.

2 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 **OK**.

3. To change the minutes, press the ▲ or ▼ button on the outer ring, then press **OK**.

For a 12-hour format, select **AM** or **PM**, press the ▲ or ▼ button, then press **OK**.

Continue to *Set the Date*.

3 Set the Date

The year is blinking.

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

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

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

4 Setup Is Complete

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

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

2 TESTING

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.

Examine the product for missing, damaged, or broken parts. If the test strip packaging is open or damaged, do not use those test strips. For replacement parts, contact Customer Service. See *Contact Information*.

CAUTION: Your CONTOUR NEXT ONE meter works only with CONTOUR NEXT blood glucose 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 blood glucose test strips.
- Lancing device and lancets from your kit, if provided.

To perform a quality control check, see Section *5 HELP: Control Solution Testing*.

Some supplies are sold separately. See Section *6 TECHNICAL INFORMATION: Customer Service Checklist*.

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 Section *5 HELP: Cleaning and Disinfection*.
- 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.
- 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.
- For complete instructions on cleaning and disinfecting your meter and lancing device, see Section *5 HELP: Cleaning and Disinfection*.

High / Low Blood Glucose (Sugar)

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 glucose. If your test result is under the critical level you have established with your health care professional or over the recommended limit, follow your health care professional's advice immediately.

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

Prepare the Lancing Device

Refer to your lancing device insert for detailed instructions on preparing the lancing device and fingertip or palm testing.

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.
- 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.

WARNING: Potential Biohazard

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

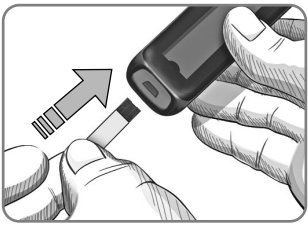
Insert the Test Strip

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

NOTE: If strips are stored in a bottle, tightly close the bottle lid immediately after you remove the test strip.

Some supplies are not available in every region.

1. Remove a CONTOUR NEXT test strip.



2. 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.

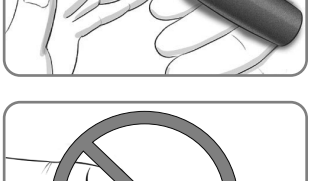
Get the Blood Drop: Fingertip Testing

WARNING

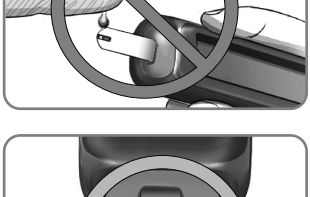
- Always wash your hands with soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.
- If your meter is being operated by a second person who is providing testing assistance to you, the meter and lancing device should be disinfected prior to use by the second person.

1. Press the lancing device firmly against the puncture site and press the release button.
2. 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 skin or place the blood on top of the test strip. These actions could lead to inaccurate results or errors.



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

About Meal Markers

During a blood glucose test, you can attach a **Meal Marker** to your result when the **Meal Marker** feature in the meter is turned **On**.

Symbol	What the Symbol Means	Related Target Range
Fasting	Use when testing blood glucose levels after fasting (no food or drink for 8 hours, except water or non-caloric beverages).	**Fasting Target Range** (Preset to 70 mg/dL–130 mg/dL)
Before Meal	Use when testing blood glucose levels within 1 hour before a meal.	**Before Meal Target Range** (Preset to 70 mg/dL–130 mg/dL)

Symbol	What the Symbol Means	Related Target Range
After Meal	Use when testing blood glucose levels within 2 hours after the first bite of a meal.	**After Meal Target Range** (Preset to 70 mg/dL–180 mg/dL)
No Mark	Use when testing at times other than after fasting or before or after a meal.	**Overall Target Range** (Preset to 70 mg/dL–180 mg/dL)

Your CONTOUR NEXT ONE meter comes with **Meal Markers** turned **Off**. You can turn **Meal Markers On** in **Settings**. See Section *4 SETTINGS: Set Meal Marker Feature*.

Add a Meal Marker to a Reading

NOTE: During a blood glucose 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.**

For more information, see *About Meal Markers*.

Example:

OK Button

Do not press OK or remove the test strip 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 **OK**

   or

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

OK Button

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

If you do not select a **Meal Marker** 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 glucose reading is stored in the **Logbook** without a **Meal Marker**.

Blood Glucose Test Is Complete

When your blood glucose 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.

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

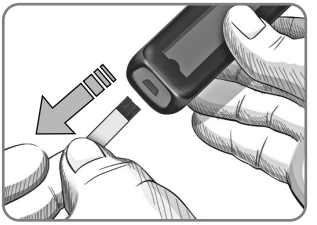
Green means **In Target** ✓
Red means **Below Target** ↓
Yellow means **Above Target** ↑

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

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

1. To move to the **Home** screen, press **OK**

or



2. 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 or if your test results are not consistent with the way you feel.**
- **If your blood glucose reading is under the critical level you have established with your health care professional, follow medical advice immediately.**
- **If your blood glucose reading is over the recommended limit set by your health care professional:**
  1. Wash and dry your hands well.
  2. Retest with a new strip.

If you get a similar result, follow your health care professional's advice immediately.

Expected Test Result Values

Blood glucose 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 postprandial state (after a meal).[5] You should consult with your health care professional for glucose values specific to your needs.

LO or HI Results

- If your meter does not display a value and displays the **LO** screen, your blood glucose reading is under 20 mg/dL. **Contact your health care professional immediately.**

- If your meter does not display a value and displays the **HI** screen, your blood glucose reading is over 600 mg/dL. Wash your hands or the test site and repeat the test with a new strip. If the meter again displays the **HI** screen, **follow medical advice immediately**.

Alternative Site Testing (AST): Palm

See the lancing device insert for detailed instructions on Alternative Site Testing.

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.**

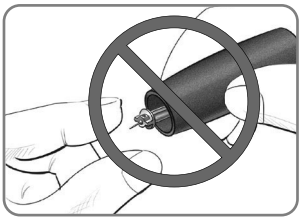
Alternative Site Testing is recommended only when it is more than 2 hours after a meal, diabetes medication, or exercise.

For Alternative Site Testing, you must 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. To obtain a clear endcap, contact Customer Service. See *Contact Information*.

Do not use AST under the following conditions:

- If you think your blood glucose is low.
- When blood glucose is changing rapidly.
- If you are unable to feel symptoms of low blood glucose.
- If you get AST 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.

Eject and Dispose of the Used Lancet



1. Do not use your fingers to remove the lancet from the lancing device.
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.

3 LOGBOOK

The **Logbook** contains blood glucose test results and their **Meal Markers**. When the **Logbook** reaches the maximum 800 results, the oldest test result is 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 **OK**.

To review entries in the **Logbook**:

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

The **Logbook** 🕮 is blinking on the **Home** screen.

2. To select the blinking **Logbook** 🕮 symbol, press **OK**.

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 Section *2 TESTING: LO or HI Results* for more information.

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

4 SETTINGS

In **Settings** you can:

- Change the time format and time.
- Change the date format and 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.

NOTE: Press **OK** to accept the current or changed setting before moving to the next setting.

Access Settings

1. Press and hold **OK** 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 **OK** to enter **Settings**. The time format is blinking.

To exit **Settings** at any time, press and hold **OK**. The meter turns off.

Change the Time

If you are not on the **Time Format** screen:

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
   The time format (12 hour or 24 hour) is blinking.

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

or

Time Format

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

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

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

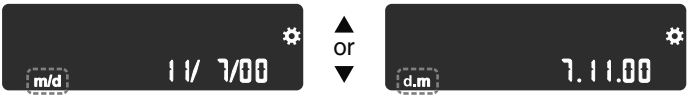
The meter displays the **Date Format** screen.

Change the Date

If you are not on the **Date Format** screen:

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.

2. Continue to press **OK** until you see the **Date Format** screen.



Date Format

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

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

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

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

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

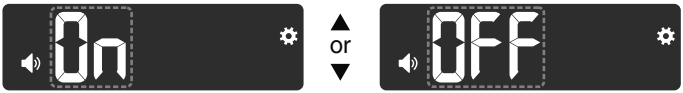
The meter displays the **Sound** screen.

Set the Sound

If you are not on the **Sound** screen:

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.

2. Continue to press **OK** until you see the **Sound** screen.



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.

3. To turn the **Sound On** or **Off**, press the ▲ or ▼ button.
4. Press **OK**.

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

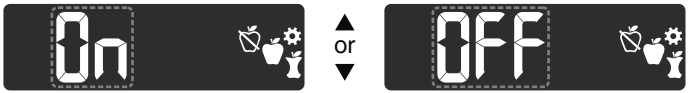
The meter displays the **Meal Marker** screen.

Set Meal Marker Feature

If you are not on the **Meal Marker** screen:

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.

2. Continue to press **OK** until you see the **Meal Marker** screen.



Meal Marker Symbols:

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

3. To turn **Meal Markers On** or **Off**, press the ▲ or ▼ button.
4. Press **OK**.

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

The meter displays the **Fasting Target Range** screen.

View Target Ranges

WARNING

Discuss your Target Range settings with your health care professional.

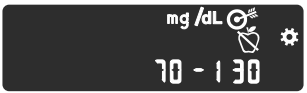
When the **Meal Marker** feature is **On**, your meter displays a **Fasting**, **Before Meal**, **After Meal**, and **Overall Target Range** in **Settings**.

NOTE: You can only change the **Target Ranges** in the CONTOUR DIABETES app.

If you are not on the **Fasting Target Range** screen:

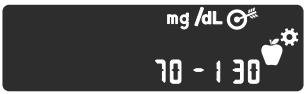
1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.

2. Continue to press **OK** until you see the **Fasting** 🍏 **Target Range** screen below.



3. Press **OK**.

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



4. Press **OK**.

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

5. Press **OK**.

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

6. Press **OK**.

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

Set Target Lights (smartLIGHT target range indicator)

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

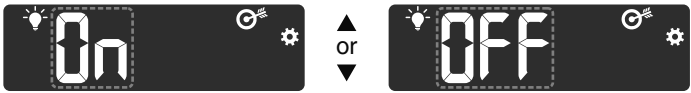
When this feature is **On**, the test strip port on your meter displays a **Target Light** in a color that corresponds to your test result.

Green means **In Target** ✓
Red means **Below Target** ▼
Yellow means **Above Target** ▲

If you are not on the **Target Lights** screen:

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.

2. Continue to press **OK** until you see the **Target Lights** screen.



Target Light Symbol:

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

The meter displays the **Bluetooth** screen.

Set Bluetooth Wireless Functionality

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

If you are not on the **Bluetooth** screen:

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.

2. Continue to press **OK** until you see the **Bluetooth** screen.

▲ or ▼

Bluetooth Symbol: ᛒ

3. To turn **Bluetooth On** or **Off**, press the ▲ or ▼ button.

4. Press **OK**.

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

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

Example: Your meter in pairing mode:

Follow the instructions on the app to match the meter serial number.

5 HELP

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, 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. See *Contact Information*.

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. The meter and lancing device are intended for single-patient use only.

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.

Clorox Germicidal Wipes are available for purchase online at http://www.officedepot.com or http://www.amazon.com. For technical assistance or questions on cleaning and disinfection, call Customer Service: 1-800-348-8100.

- **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

Clean and disinfect your meter once a week.

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

Clean and disinfect your meter once a week.

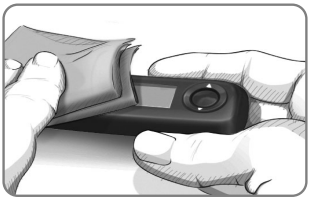
Supplies needed for disinfecting:

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

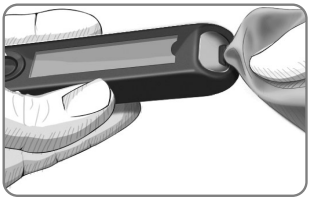
1. Before disinfecting, clean the meter as described in *Cleaning Your Meter*.

NOTE: 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

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 for use with any software other than compatible Ascensia Diabetes Care software. 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 Section *1 GETTING STARTED: Download the CONTOUR DIABETES app* 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 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.

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.

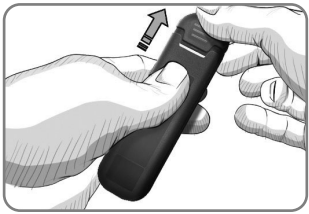
Batteries

When the batteries are low, the meter operates normally, displaying the **Low Batteries** symbol until you replace the batteries.

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

Replace the Batteries

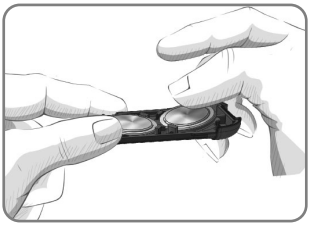
When you replace the batteries, the number of tests can vary depending on the battery manufacturer.



1. Turn off your meter.
2. Turn the meter over and slide the back 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 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 prongs on the left side of one compartment and press down on the right side of the battery.
7. Press the second battery into the other compartment the same way.
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.

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.

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 glucose results.

WARNING

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

Some supplies are not available in every region.

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

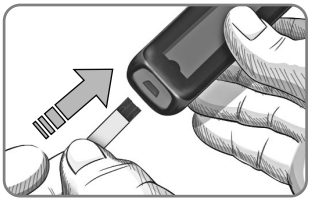
Level 1 and Level 2 control solutions are available and sold separately if not included in the meter kit. You can test your CONTOUR NEXT ONE meter with control solution when the temperature is 59°F–95°F.

Store control solutions between 48°F and 86°F. Contact Customer Service to obtain control solution. See *Contact Information*.

Control Solution Testing

NOTE: Tightly close the bottle lid immediately after you remove the test strip.

1. Remove a CONTOUR NEXT test strip from the bottle or foil packet.



2. 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.

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

4. Remove the bottle cap and use a tissue to wipe away any solution around the bottle tip before dispensing a drop.
5. 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.

6. Immediately touch the tip of the test strip to the drop of control solution.
7. **Hold the tip in the drop until the meter beeps.**

   The meter counts down for 5 seconds before the meter displays the control test result. The meter automatically marks the result as a control test. Control test results are not included in your meter **Logbook**, in blood glucose averages, or in targets in the CONTOUR DIABETES app.
8. Compare your control test result with the range printed on the test strip bottle, foil packet, or bottom of the test strip box.
9. Remove the test strip and dispose as medical waste or as advised by your health care professional.

If your control test result is out of range, do not use your CONTOUR NEXT ONE meter for blood glucose testing until you resolve the issue. Contact Customer Service. See *Contact Information*.

6 TECHNICAL INFORMATION

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 **OK** to turn off the meter.

If you experience continued errors, contact Customer Service. See *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–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 Customer Service. See *Contact Information*.

Customer Service Checklist

When speaking with the Customer Service representative:

1. Have your CONTOUR NEXT ONE blood glucose meter, CONTOUR NEXT blood glucose 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 or foil packet.
4. Check the battery status.

Meter Kit Contents

The table below lists all parts included in this meter kit. Required parts that may not be included in your kit are indicated by an asterisk (*). Locate the model number (**A**) on the back of the meter (see above).

To order parts required for use but not included in your kit, contact Customer Service at 1-800-348-8100, Monday through Sunday, 8:00 am through 12:00 Midnight, Eastern Time.

	Model Number	
	9550	7825
CONTOUR NEXT ONE blood glucose meter (with two 3-volt CR2032 or DL2032 coin cell batteries)	•	•
CONTOUR NEXT ONE user guide	•	•
CONTOUR NEXT ONE quick reference guide	•	•
CONTOUR NEXT blood glucose test strips*	•	
CONTOUR NEXT control solution*	•	
MICROLET®NEXT lancing device	•	•
MICROLET® lancets	•	•
Carrying case	•	•

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 blood glucose 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%)	17 of 17 (100%)

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%	Within ± 20%
Number (and percent) of samples within specified range	288 of 355 (81.1%)	342 of 355 (96.3%)	354 of 355 (99.7%)	355 of 355 (100%)

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

Within ± 15 mg/dL or ± 15%
371 of 372 (99.7%)

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 blood glucose 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 blood glucose 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 blood glucose 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.

Table 2: System intermediate precision results for CONTOUR NEXT ONE meter using CONTOUR NEXT blood glucose 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

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 Customer Service. See *Contact Information*.

Specifications

Test Sample: Capillary whole blood only

Test Result: Referenced to plasma/serum glucose

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)

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 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 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.

Product Labeling Symbols

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

Symbol	What It Means
	Control Discard Date
	Shake 15 times

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

Symbol Graphic/Title	Explanatory Text	Standard Reference[6,7]
REF Catalog or model number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1, Clause 5.1.6
LOT Batch Code	Indicates the manufacturer's batch code so that the medical device can be identified.	ISO 15223-1, Clause 5.1.5 IEC 61010-2-101, Table 1, Symbol 102
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
UDI Unique device identifier	Indicates a carrier that contains unique device identifier information.	ISO 15223-1, Clause 5.7.10

Symbol Graphic/Title	Explanatory Text	Standard Reference[6,7]
 Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1, Clause 5.4.3
 Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1, Clause 5.3.7
 Control	Indicates a control material that is intended to verify the performance characteristics of another medical device.	ISO 15223-1, Clause 5.5.2
 Do not re-use	Indicates a medical device that is for single use or for use on a single patient during a single procedure.	ISO 15223-1, Clause 5.4.2

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).[8]

References

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