Contour next GEN
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, 8:00 am through 12:00 Midnight, Eastern Time. If this is a medical emergency, please 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 GEN 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

90013664 Rev. 11/24

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INTENDED USE

The CONTOUR NEXT GEN blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips. The CONTOUR NEXT GEN blood glucose monitoring system is intended to be used by a single person and should not be shared. The CONTOUR NEXT GEN 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 GEN blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes or for neonatal use. The CONTOUR NEXT blood glucose test strips are for use with the CONTOUR®NEXT GEN blood glucose meter to quantitatively measure glucose in fresh capillary whole blood drawn from the fingertips.

The system is intended for in vitro diagnostic use only.

WARNING

The CONTOUR NEXT GEN blood glucose meter is not intended for use with Alternative Site Testing (AST).

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 Ascensia Diabetes Care 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.
- 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.
- 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, 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, those dehydrated 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
- **Meter Storage Temperature Range:** -4°F–149°F
- **Meter Operating Humidity Range:** 10% RH–93% RH
- **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%
- **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 (6,301 meters).
- **Hematocrit:** CONTOUR NEXT blood glucose test strip results are not significantly affected by hematocrit levels in the range of 20% to 55%.
- **Xylose:** Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.
- **Neonatal Use:** The CONTOUR NEXT GEN meter is **not indicated** for neonatal use.

PRECAUTIONS

- Read your CONTOUR NEXT GEN 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 test strips.

  For replacement parts, contact Customer Service. See *Contact Information*.
- Your CONTOUR NEXT GEN 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.

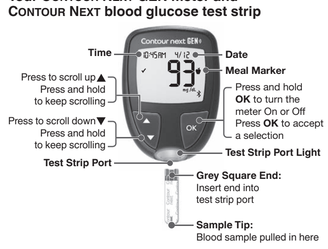
  NOTE: If this is the first time you are opening the control solution, write the date on the bottle.
- Do not use control solution that is more than 6 months past the date you first opened the bottle.
- If your control solution test result is out of range, contact Customer Service. See *Contact Information*. 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 GEN 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 GEN 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 have a decimal point.

  Example: 93 mg/dL or 5.2 mmol/L
  - ❖ Check your display screen to be sure the results are shown correctly (mg/dL). If not, contact Customer Service. See *Contact Information*.
- The CONTOUR NEXT GEN 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:
    - ○ If your meter does not display a value and displays the **LO** screen, **contact your health care professional immediately**.
    - ○ 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

The CONTOUR NEXT GEN blood glucose monitoring system consists of the CONTOUR NEXT GEN meter, CONTOUR NEXT blood glucose test strips and the CONTOUR DIABETES app.

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



- To exit from the **Logbook** or **Averages** and return to the **Home** screen, press **OK**.
- When a symbol is blinking, you can select it.

Check the Meter Display

Press and hold **OK** 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. Verify that the meter screen fully displays **8.8.8** 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. See *Contact Information*. 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 Section *4 Settings*.

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.
	Test result is **above** Target Range.
✓	Test result is **in** Target Range.
	Test result is **below** Target Range.
Hi	Test result is above 600 mg/dL.
Lo	Test result is below 20 mg/dL.

Symbol	What the Symbol Means
	Your **Logbook**.
	Meter **Settings**.
	Fasting marker.
	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: means the **Bluetooth** wireless setting is On; the meter can communicate with a mobile device.
	Low batteries.
	Dead batteries.
E	Meter error.
	Reminder feature.
	Sound feature.
7d Avg	7-, 14-, 30-, and 90-day averages.
n	Total number of blood glucose readings used to calculate averages.

The Home Screen

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

- To highlight the **Logbook** or **Settings**, press the ▼ button.
- To enter the **Logbook**, press **OK** while the **Logbook** symbol is blinking.
- To enter **Settings**, press **OK** while the **Settings** symbol is blinking.

Your Meter Features

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.

2 TESTING

Get Ready to Test

Read your CONTOUR NEXT GEN 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 GEN 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 GEN 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 antibacterial 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, see Section *5 Help: Cleaning and Disinfection*.

High / Low Blood Glucose

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 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.
- 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 test strips are stored in a bottle, tightly close the bottle lid immediately after removing a test strip.

1. Remove a CONTOUR NEXT blood glucose 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: 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.
- 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.
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**.

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

Second-Chance sampling—Apply 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.

About Meal Markers

You can attach a **Meal Marker** to your blood glucose result when the **Meal Marker** feature is turned On.

Your CONTOUR NEXT GEN meter comes with **Meal Markers** turned Off. You can turn **Meal Markers** On and change **Target Ranges** in **Settings**. See Section *4 Settings*.

Symbol	What It Means	Target Range
Fasting	Use when testing after fasting (no food or drink for 8 hours, except water or non-caloric beverages).	The meter compares your result against the **Before Meal Target Range**. (Pre-set to 70 mg/dL–130 mg/dL)
Before Meal	Use when testing within 1 hour before a meal.	The meter compares your result against the **Before Meal Target Range**. (Pre-set to 70 mg/dL–130 mg/dL)
After Meal	Use when testing within 2 hours after the first bite of a meal.	The meter compares your result against the **After Meal Target Range**. (Pre-set to 70 mg/dL–180 mg/dL)
No Mark	Use when testing at times other than after fasting or before or after a meal.	The meter compares your result against the **Overall Target Range**. (Pre-set to 70 mg/dL–180 mg/dL)

Add a Meal Marker to a Reading

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.**

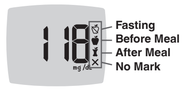
For more information, see Section *2 Testing: About Meal Markers*.

Example:

Do not press OK or remove the test strip yet.

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

To turn **Meal Markers** On, see Section *4 Settings: Set Meal Marker Feature*.



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 on the meter to scroll between markers.
3. When the **Meal Marker** you want is blinking, press **OK**.
4. If this is a **Before Meal** reading, you can set a **Reminder** to test your blood glucose later. See Section *2 Testing: Set a Test Reminder*.

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**.

Set a Test Reminder

1. Make sure the **Reminder** feature is On in **Settings**.

   See Section *4 Settings: Set Reminder Feature*.
2. Mark a blood glucose reading as a **Before Meal** reading, then press **OK**.

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

The screen returns to the **Before Meal** reading. The meter displays the **Reminder** symbol to confirm the Reminder is set.

smartLIGHT target range indicator

When your blood glucose 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:

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

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

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

If your blood glucose result is below target, the **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**.

NOTE: To change an individual target range, see Section *4 Settings: Change Before/After Meal Target Ranges*. To change the Overall Target Range, see Section *4 Settings: Change Overall Target Range*.

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

To turn the meter off, remove the test strip.

Blood glucose test is complete.

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 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.

Expected Test Result Values

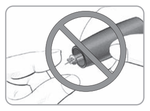
Blood glucose values will vary depending on food intake, medication dosages, health, stress, or activity. Nondiabetic plasma glucose concentrations should be less than 100 mg/dL in the fasting state and less than 140 mg/dL in the postprandial state (after a meal).[5] You should consult with your health 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**.

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 antibacterial 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**.

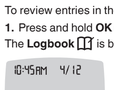
Review the Logbook

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 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.

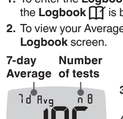
If you scroll past the oldest entry, the meter displays the **End** screen.

If you see a **LO** or **HI** test result, go to 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.

View Averages

1. To enter the **Logbook** from the Home screen, press **OK** while the **Logbook** is blinking.
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 exit Averages and return to the **Home** screen at any time, press **OK**.

4 SETTINGS

In **Settings** you can personalize:

- **Time** format and time.
- **Date** format and date.
- **Sound.**
- **Meal Markers.**
- **Reminder** feature.
- **Target Ranges.**
- **smartLIGHT** feature.
- **Bluetooth** wireless functionality.

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**.

4. To scroll through **Settings** options as shown in the image, press the ▲ or ▼ button until the symbol you want is blinking.
5. Press **OK**.

6. To exit from the **Settings** menu and return to the **Home** screen, press the ▲ or ▼ button until the **Settings** symbol is blinking.
7. Press **OK**.

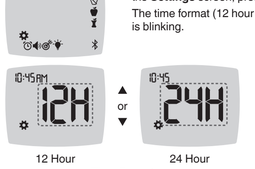
NOTE: If you are in a setting such as Date and you need to exit, press **OK** repeatedly until you get back to the **Home** screen.

Change the Time

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

2. When the current time is blinking on the **Settings** screen, press **OK**.

   The time format (12 hour or 24 hour) is blinking.



12 Hour 24 Hour

Time Format

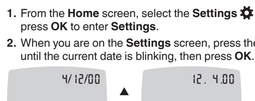
3. To change the time format, if needed, press the ▲ or ▼ button, then press **OK**.

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

5. To change minutes (blinking), press the ▲ or ▼ button, then press **OK**.
6. For a 12-hour time format, select **AM** or **PM**, as needed, then press **OK**.

Change the Date

1. From the **Home** screen, select the **Settings** symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button until the current date is blinking, then press **OK**.



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**.

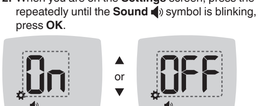
4. To change the year (blinking), press the ▲ or ▼ button, then press **OK**.

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**.

Set the Sound

1. From the **Home** screen, select the **Settings** symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Sound** symbol is blinking, then press **OK**.



Sound Symbol:

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

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.

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

TURN OVER TO SEE BACK

90013664_CntrNxtGEN_BW_UG_EN_F1B1_v1.indd
November 28, 2024 4:47 PM

ARTWORK ROUTING FOR APPROVAL

SGK
18211 NE 68th Street, E120
Redmond, WA 98052
T: 425-881-5454
SGK is a Matthews International Corporation

Art Production

DATE:	November 28, 2024
CLIENT:	Ascensia Diabetes Care
DESCRIPTION:	Contour Next GEN Meter BW UG Pamphlet
MARKET(S):	United States
SGK JOB#:	403929668
SKU# / P. BAN#:	MULTI / MULTI
DIMENSIONS:	673 mm (W) x 764 mm (H)
PRINTER SPEC:	101005614 REV D
BARCODE:	90013664 (2D Matrix)
COLORS:	Black Fold

NEW BAN#: 90013664 Rev. 11/24
PREVIOUS BAN#: 90010655
Alt#1 - 11/28/24 Unmasking & Copy Changes

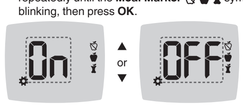
Master Template No: CTS-176_Rev02

NOTE: THIS COLOR PROOF INDICATES COLOR BREAK ONLY AND MAY NOT ACCURATELY REFLECT ACTUAL PRODUCTION COLOR.

V-1 LANGUAGE(S): ENGLISH

Set Meal Marker Feature

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Meal Marker** symbols are blinking, then press **OK**.



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**.

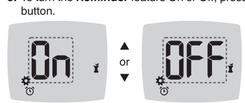
NOTE: When the **Meal Marker** feature is On, you can select a **Meal Marker** during a blood glucose test.

Set Reminder Feature

When **Meal Markers** are On, you can set a **Reminder** to test your blood glucose after you mark a reading as **Before Meal**. If **Meal Markers** are Off, see Section *4 Settings: Set Meal Marker Feature*.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Reminder** symbol is blinking, then press **OK**.

   Your meter comes with the **Reminder** feature turned Off.
3. To turn the **Reminder** feature On or Off, press the ▲ or ▼ button.



Reminder Symbol:

4. Press **OK**.

Change Overall Target Range

WARNING

Discuss your Target Range settings with your health care professional.

Your meter provides a pre-set **Overall Target Range**. You can change the **Overall Target Range** in **Settings**.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Target** symbol is blinking, then press **OK**.

3. To change the blinking **Low** end of the **Overall Target Range**, press the ▲ or ▼ button.
4. Press **OK**.

5. To change the blinking **High** end of the **Overall Target Range**, press the ▲ or ▼ button.
6. Press **OK**.

Change Before/After Meal Target Ranges

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

You can change these ranges in **Settings** in your meter and in the Contour Diabetes app.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Target** symbol is blinking, then press **OK**.

Before Meal/After Meal Low Target

The **Before Meal** / **After Meal** **Low** Target number is blinking.

NOTE: There is only 1 **Low** number for both the **Before Meal** and **After Meal** Target Ranges.

3. To change the blinking **Low** for both Target Ranges, press the ▲ or ▼ button.
4. Press **OK**.

Before Meal High Target

5. To change the blinking **High** end of the **Before Meal Target Range**, press the ▲ or ▼ button.
6. Press **OK**.

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

After Meal High Target

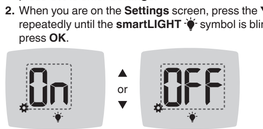
7. To change the blinking **High** end of the **After Meal Target Range**, press the ▲ or ▼ button.
8. Press **OK**.

Set smartLIGHT target range indicator

Your meter comes with the **smartLIGHT** target range indicator turned On. When this feature is On, the test strip port light displays a color that corresponds to your test result.

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

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **smartLIGHT** symbol is blinking, then press **OK**.



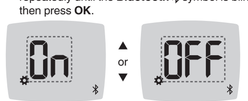
smartLIGHT Symbol:

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

Set Bluetooth Wireless Functionality

After pairing your meter with a mobile device, you can turn the **Bluetooth** setting On or Off. For pairing instructions, see Section *4 Settings: Pairing Mode*.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Bluetooth** symbol is blinking, then press **OK**.



Bluetooth Symbol:

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

Contour Diabetes app

The Contour Diabetes app for Your Contour Next GEN meter

Your Contour Next GEN meter is designed to work with the Contour Diabetes app and your compatible smartphone or tablet. Visit **compatibility.contourone.com** for a list of compatible operating systems that work with the Contour Diabetes app. Check this list before upgrading your operating system.

You can do the following with your Contour Diabetes app:

- 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.
- 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.
- Syncs your most recent Target Range from the app or meter, across the system.
- Syncs the app date and time to your meter.

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.

CAUTION: The Contour Next GEN 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.

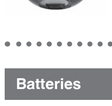
Pairing Mode

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:

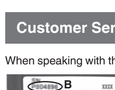
1. If your meter is off, press and HOLD **OK** until the meter turns on. The meter displays the **Home** screen.



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

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

Meter serial number



Example: Your meter in pairing mode.

Pass code

When a connection is made, the meter displays the 6-digit pass code.

4. Enter the pass code on the smart device.

When you have successfully paired your meter with the Contour Diabetes app, the meter displays a blue light and the **Bluetooth** symbol.

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

Bluetooth

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.

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

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.

Clean and disinfect your Contour Next GEN meter once a week. Use only Clorox Healthcare Bleach Germicidal Wipes (EPA #67619-12) containing 0.55% sodium hypochlorite (bleach). The wipes are proven safe to use with the Contour Next GEN meter.

Clorox Healthcare Bleach Germicidal Wipes (EPA #67619-12) 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 Healthcare Bleach 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

Clean and disinfect your meter once a week.

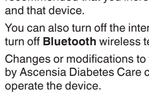
Supplies needed for disinfecting:

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

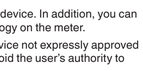
CAUTION: Do not allow cleaning solution to run into the meter through open areas, such as around the buttons or the meter's test strip or USB port.

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. After keeping the meter wet 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 a Personal Computer

CAUTION: Do not attempt to perform a blood glucose test when the Contour Next GEN meter is connected to a computer.

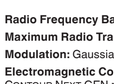
You can transfer test results from the Contour Next GEN meter to a computer where they can be summarized in a report with graphs and tables. To make use of this feature, you need diabetes management software and a 1-meter (or 3-foot) long USB-A to Micro USB-B cable. This type of cable is available in electronics retail stores.

USB Port

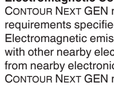
Ensure your meter's USB port door is completely closed when not in use.

CAUTION: Use only approved equipment (for example, USB cable) from the manufacturer or certified body such as UL, CSA, TUV, or CE.

Batteries

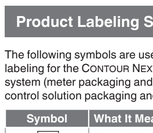


When the batteries are low, the meter operates normally, displaying the **Low Batteries** symbol until you replace the batteries.



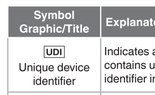
When you are no longer able to perform a test, the meter displays the **Dead Batteries** screen. Replace the batteries immediately.

Replace the Batteries



1. 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: Always check the date and time after you replace the batteries.



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 old batteries according to your local environmental regulations.

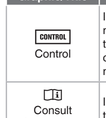
WARNING

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.



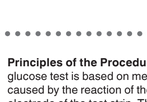
CAUTION: Use only Contour Next control solution (Level 1 and Level 2) with your Contour Next GEN blood glucose monitoring system. Using anything other than Contour Next control solution can cause inaccurate results.

You should perform a control test when:

- You think your test strip may be damaged.
- 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 an insulin dose based on a control result.**



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

Refer to your control solution insert.

Level 1 and Level 2 control solutions are available and sold separately. You should test your Contour Next GEN meter with control solution only when the temperature is 59°F–95°F. Store control solutions between 48°F and 86°F.

Contact Customer Service for more information on how to purchase control solution. See *Contact Information.*

Control Solution Testing

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

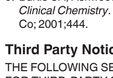
1. Remove a Contour Next blood glucose test strip from the bottle or foil packet.

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 GEN 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 blood glucose 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 GEN blood glucose meter and Contour Next blood glucose test strips 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 following table 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		
	9732	7922	7383
Contour Next GEN blood glucose meter (with two 3-volt CR2032 or DL2032 coin cell batteries)	•	•	•
Contour Next GEN user guide	•	•	•
Contour Next GEN 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 GEN meter results may vary slightly from your actual blood glucose value due to slight differences in testing technique and the natural variation in test technology. The table below shows the results where typical users enrolled in a clinical study used the Contour Next GEN meter to measure their blood glucose levels. For example, in this study, the Contour Next GEN meter displayed results within 15% of their actual blood glucose level in 366 out of 371 measurements as compared to an approved lab instrument.

Table 1: System accuracy results for glucose concentrations across the entire tested range

Difference range between the actual blood glucose level and the Contour Next GEN meter result	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Percent (and number) of samples within specified range	64.96% (241/371)	93.53% (347/371)	98.65% (366/371)	99.19% (368/371)

Technical Information: Precision

A measurement repeatability study was conducted with the Contour Next GEN blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from 39 mg/dL to 348 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 GEN 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, %
40.1	1.1	1.04–1.23	2.8
78.6	1.3	1.21–1.43	1.7
137.5	2.0	1.84–2.18	1.5
212.6	3.3	3.07–3.64	1.6
341.2	4.4	4.02–4.76	1.3

Intermediate measurement precision (which includes variability across multiple days) was evaluated using control solutions at 5 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 GEN 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	43.1	0.6	0.56–0.66	1.4
2	83.9	1.1	0.98–1.17	1.3
3	126.3	1.5	1.41–1.67	1.2
4	219.9	2.9	2.64–3.12	1.3
5	370.6	6.5	6.04–7.15	1.8

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 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 *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

Meter Life: 5 years with normal use in accordance with instructions

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 GEN 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 GEN meter.

Product Labeling Symbols

The following symbols are used throughout the product labeling for the Contour Next GEN 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
10x	Shake 10 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 GEN blood glucose monitoring system (meter packaging and labeling, and test strip and control solution packaging and labeling).

Symbol Graphic/Title	Explanatory Text	Standard Reference[6-8]
UDI Unique device identifier	Indicates a carrier that contains unique device identifier information.	ISO 15223-1, Clause 5.7.10
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
Use-by date	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 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
Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1, Clause 5.3.7

Symbol Graphic/Title	Explanatory Text	Standard Reference[6-8]
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.	ISO 15223-1, Clause 5.4.3
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.	ISO 15223-1, Clause 5.4.4 IEC 61010-1, Table 1, Symbol 14
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
STERILE R Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1, Clause 5.2.4

Principles of the Procedure: The Contour Next GEN 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 GEN 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).[9]

References

1. US Food and Drug Administration. Use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010. http://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
2. 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
3. Wickham NWR, et al. Unreliability of capillary blood glucose in peripheral vascular disease. *Practical Diabetes*. 1986;3(2):100.
4. Atkin SH, et al. Fingerstick glucose determination in shock. *Annals of Internal Medicine*. 1991;114(12):1020-1024.
5. American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of medical care in diabetes—2020. *Diabetes Care*. 2020;43(supplement 1):S14–S31.
6. International Organization for Standardization / Technical Committee 210. *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied—Part 1: General requirements*. ISO 15223-1:2016.
7. IEC 61010-2-101 Edition 3.0—Safety requirements for electrical equipment for measurement, control and laboratory use—Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.
8. IEC 61010-1 Edition 3.1—Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 1: General requirements.
9. Burtis CA, Ashwood ER, editors. *Tietz Fundamentals of Clinical Chemistry*. 5th edition. Philadelphia, PA: WB Saunders Co; 2001;444.

Third Party Notices

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