

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.



Uses only CONTOUR[®]NEXT blood glucose test strips.

USER GUIDE

CONTACT INFORMATION

Manufactured for:
Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basel, Switzerland

www.diabetes.ascensia.com

Customer Service: 1-800-268-7200

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Table of Contents

1 GETTING STARTED

Your meter display
Meter symbols and the Home screen

2 TESTING

Symptoms of High / Low blood glucose
Fingertip testing
Add a Meal Marker to a blood glucose result
The smartLIGHT target range indicator
Understand test results

3 LOGBOOK

View test results and blood glucose averages

4 SETTINGS

Change the Time and Date
Turn Off Sound
Turn On/Off Meal Marker Feature
Turn On/Off Reminder Feature
Change Target Ranges
Turn Off smartLIGHT target range indicator
Turn On/Off Bluetooth Feature
Download the CONTOUR DIABETES app
Put your meter in pairing mode

5 HELP

Clean and disinfect your meter
Replace meter batteries
Test with control solution

6 TECHNICAL INFORMATION

Error messages
Order meter kit supplies
Accuracy and Precision
Meter specifications

INTENDED USE

The CONTOUR NEXT GEN blood glucose monitoring system is intended to be used for the measurement of blood glucose in both insulin and non-insulin treated patients with diabetes as an aid for patients and their health care professionals in monitoring the effectiveness of the patient's diabetes control. The CONTOUR NEXT GEN blood glucose monitoring system is intended for self-testing by persons with diabetes and health care professionals for use on a single patient in venous blood and fresh capillary whole blood drawn from the fingertip or palm. The CONTOUR NEXT GEN blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use).

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

The meter is for the quantitative measurement of glucose in whole blood from 0.6 mmol/L–33.3 mmol/L.

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

The system is intended for in vitro diagnostic use only.

INTENDED USE: CONTOUR DIABETES app

The CONTOUR[®]DIABETES app is intended for use by individuals with insulin and non-insulin treated diabetes, and/or their caregivers, to store, view, trend, and share blood glucose meter readings, either manually entered in the app or wirelessly transmitted from the CONTOUR family of meters. Other related health indicators which can be captured and shown in a printable report and graphical format on a mobile device for insulin and non-insulin treated patients with diabetes are available to support diabetes management. The app is available for use on supported Apple iOS and Android devices and is designed to be used with a wirelessly enabled CONTOUR branded meter.

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.

Serious Illness

The system should not be used to test critically ill patients. Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.¹⁻³

Talk to Your Health Care Professional:

- Before setting any **Target Ranges** in your meter or in the CONTOUR DIABETES app.
- Before changing your treatment or medication based on test results.
- About whether Alternative Site Testing (AST) is appropriate for you.
- Before making any other decision of medical relevance.

Potential Biohazard

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

- The lancing device provided with your kit should not be used for assisted blood draws by health care professionals or at health care provision sites.
- Always dispose of used test strips and lancets as medical waste or as advised by your health care professional.
- All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.
- Keep out of reach of children. This kit contains small parts that could cause suffocation if accidentally swallowed.
- Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately contact your poison control center.

Limitations

- **Altitude:** This system has not been tested at altitudes higher than 6301 meters.
- **Hematocrit:** CONTOUR NEXT test strip results are not significantly affected by hematocrit levels in the range of 0% to 70%.
- **Xylose:** Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.

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 bottle is open inside a new box of strips, do not use those test strips.
For replacement parts, contact Customer Service. See *Contact Information* or the carton.
- Your CONTOUR NEXT GEN meter works ONLY with CONTOUR NEXT test strips and CONTOUR®NEXT control solution.
- Always keep the CONTOUR NEXT test strips in their original bottle. Tightly close the bottle immediately after removing a test strip. The bottle is designed to keep the test strips dry. Do not place or store other items or medications in the test strip bottle. Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt.

Exposure to room humidity by leaving the bottle open or not storing the strips in their original bottle can damage your test strips. This could lead to inaccurate results.

Do not use a test strip that appears damaged or has been used.

- 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 5°C and 45°C. 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.

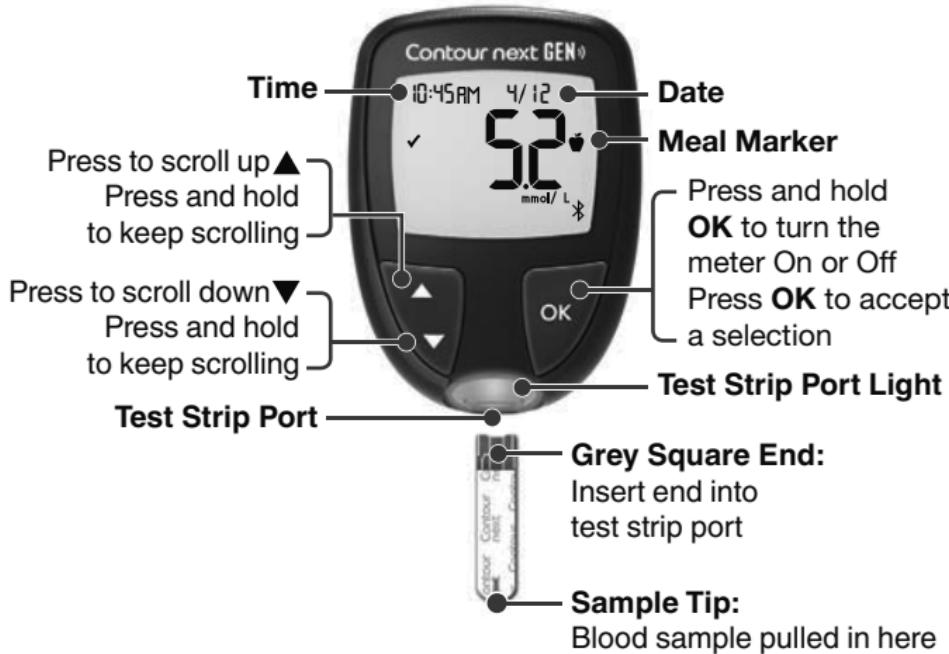
- Avoid use of electronic devices in very dry environments, especially if synthetic materials are present.
- Your CONTOUR NEXT GEN meter has been preset and locked to display results in mmol/L (millimoles of glucose per liter of blood).
 - ❖ Results in mmol/L have a decimal point.
 - ❖ Results in mg/dL do not have a decimal point.

Example:

 or 

- ❖ Check your display screen to be sure the results are shown correctly. If not, contact Customer Service. See *Contact Information*.
- The CONTOUR NEXT GEN blood glucose monitoring system has a measuring range of 0.6 mmol/L to 33.3 mmol/L.
 - ❖ For results under 0.6 mmol/L or over 33.3 mmol/L:
 - 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**.

Your CONTOUR NEXT GEN meter and CONTOUR NEXT 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**.



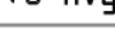
All symbols on the screen and the white strip port briefly light up. Verify that the meter screen fully displays **8.8.8** and that the white light from the test strip port is visible.

If there are missing characters or if the strip port light is a colour 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	Yellow Light: test result is above Target Range.
Green Light	Green Light: test result is in Target Range.
Red Light	Red Light: test result is below Target Range.
↑	Blood glucose test result is above Target Range.
✓	Blood glucose test result is in Target Range.
↓	Blood glucose test result is below Target Range.
H	Test result is above 33.3 mmol/L.
L	Test result is below 0.6 mmol/L.

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.
	Meter error.
	Reminder feature.
	Sound feature.
	7-, 14-, 30-, and 90-day averages.
	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** 

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.

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 bottle is open inside a new box of strips, 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 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 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.
- 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
- increased fatigue
- excessive thirst
- hunger
- blurred vision

Ketones (Ketoacidosis):

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

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

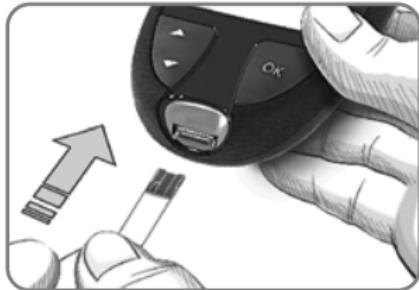
Insert the Test Strip

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

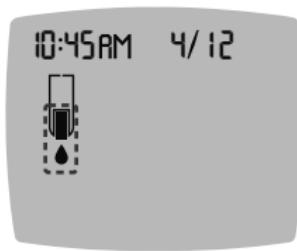
NOTE: Tightly close the bottle lid immediately after removing the test strip.



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

NOTE: For information on Alternative Site Testing, see Section 2 *Testing: Alternative Site Testing (AST): Palm.*

WARNING: Potential Biohazard

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



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



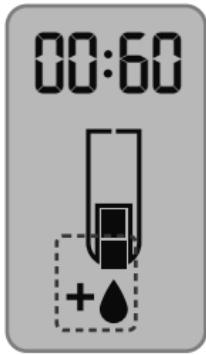
2. Immediately touch the tip of the test strip to the drop of blood.
The blood is drawn into the test strip through the tip.
3. Hold the tip of the test strip in the blood drop until the meter beeps.

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 3.9 mmol/L–7.2 mmol/L)
 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 3.9 mmol/L–7.2 mmol/L)
 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 3.9 mmol/L–10.0 mmol/L)
 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 3.9 mmol/L–10.0 mmol/L)

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 \uparrow , In Target \checkmark , or Below Target \downarrow .

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 colour representing your result value compared to your **Before Meal**, **After Meal**, or **Overall Target Range**.



Yellow means **Above Target** \uparrow

Green means **In Target** \checkmark

Red means **Below Target** \downarrow

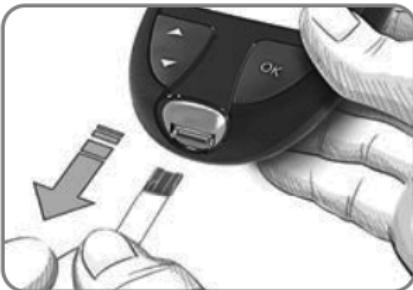
If your blood glucose result is below target, the **smartLIGHT** is red and the meter beeps twice.

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.**
- **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.

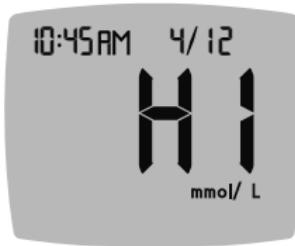
Expected Test Result Values

Blood glucose values will vary depending on food intake, medication dosages, health, stress, or activity. Nondiabetic plasma glucose concentrations are normally maintained within a relatively narrow range, approximately 3.9 mmol/L–6.1 mmol/L in a fasting state.⁴ You should consult with your health care professional for glucose values specific to your needs.

LO or HI Results



- If the meter beeps twice and displays the **LO** screen, your blood glucose reading is under 0.6 mmol/L. **Follow medical advice immediately.** Contact your health care professional.



- If the meter beeps once and displays the **HI** screen, your blood glucose reading is over 33.3 mmol/L.

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

If results are still over 33.3 mmol/L, **follow medical advice immediately.**

To turn the meter Off, remove the test strip.

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.⁵
- 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.

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 GEN 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.

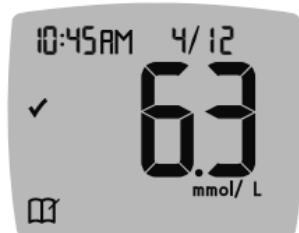
The **Logbook** contains blood glucose test results and their Meal Markers. When the **Logbook** reaches the maximum 800 results, the oldest test result is removed as a new test is completed and saved to the **Logbook**.

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 **Number**
Average **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**.

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** gear 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** gear 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

▲
or
▼



24 Hour

Time Format

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



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

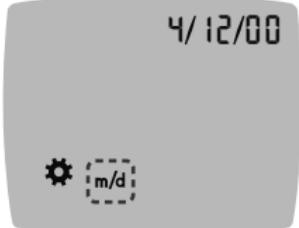


- To change minutes (blinking), press the **▲** or **▼** button, then press **OK**.

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

Change the Date

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



▲
or
▼



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**.

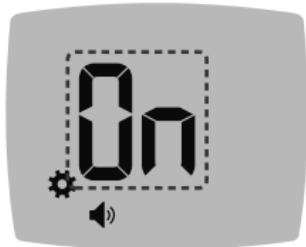


6. To change the day (blinking), press the **▲** or **▼** button, then press **OK**.



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**.



▲
or
▼



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:

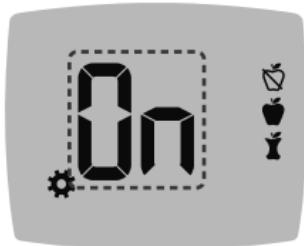
- One long beep indicates a confirmation.
- Two beeps indicate an error or something that needs your attention.

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.



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**.



▲
or
▼



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**.

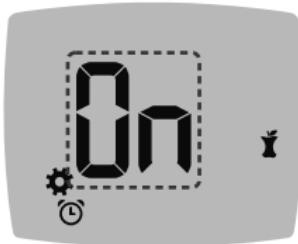
NOTE: When the **Meal Marker** feature is On, you can select a **Meal Marker** during a blood glucose test.



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**.



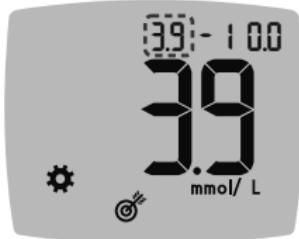
Change Overall Target Range

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

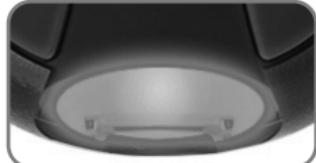


7. To change the blinking **High** end of the **After Meal Target Range**, press the **▲** or **▼** button.
8. Press **OK**.



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 colour 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**.



▲
or
▼



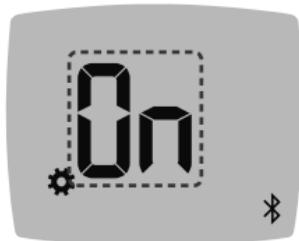
smartLIGHT Symbol: 

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**.



▲
or
▼



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.

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.
- Offers quick and valuable tips to help you manage your diabetes.
- 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 StoreSM or the Google PlayTM 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 the CONTOUR DIABETES app. 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:

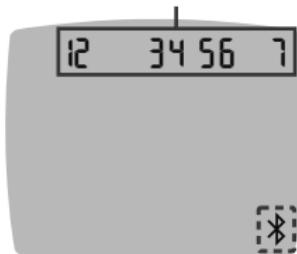
1. If your meter is off, press and HOLD **OK** until the meter turns on. The meter displays the **Home** screen.



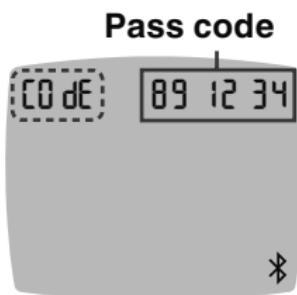
2. Press and HOLD the **▲** button for about 3 seconds, until you see the blinking **Bluetooth** symbol (as shown in the next step). A blue light blinks when you are in pairing mode.

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

Meter serial number

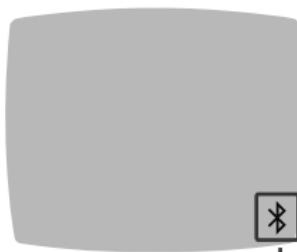


Example: Your meter in pairing mode.



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.

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.

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

Clorox Healthcare Bleach Germicidal Wipes are available for purchase online. For more information, contact Customer Service. See *Contact Information*.

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

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

For more information

Health Canada advisory. Blood lancing devices for personal use may transmit blood-borne viruses if used on more than one person. Government of Canada; 3/25/09. <http://www.healthcanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2009/13372a-eng.php>

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.

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

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



Buttons



Test Strip Port

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

Cleaning and Disinfecting Your Lancing Device

Refer to the 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

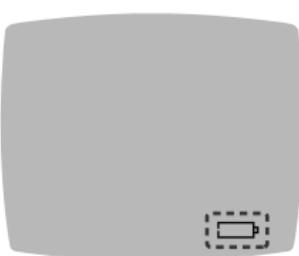
Ensure your meter's USB port door is completely closed when not in use.

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

Batteries

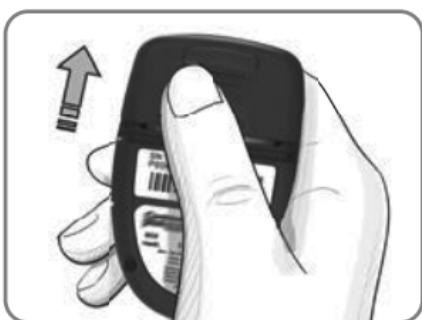


When the batteries are low, the meter operates normally, displaying the **Low Batteries** symbol until you replace the batteries.



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 (Normal, Low, and High) 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:

- Using your meter for the first time.
- You open a new 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 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.

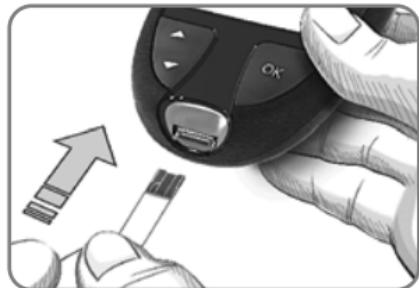
Normal, Low, or High control solutions are available and sold separately if not included in the meter kit. You should test your CONTOUR NEXT GEN meter with control solution only when the temperature is 15°C–35°C. Store control solutions between 9°C and 30°C.

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.



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 or on the 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*.

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*.

Strip Errors		
Error Code	What It Means	What to Do
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 GEN blood glucose meter, CONTOUR NEXT test strips, and CONTOUR NEXT control solution available when you call.
2. Locate the model number (**A**) and serial number (**B**) on the back of the meter.
3. Locate the test strips' expiration date on the bottle.
4. Check the battery status.

Parts Information

To replace missing parts or reorder supplies, contact Customer Service. See *Contact Information*.

- Two 3-volt CR2032 or DL2032 coin cell batteries.
- CONTOUR NEXT GEN user guide.
- CONTOUR NEXT GEN quick reference guide.
- CONTOUR NEXT test strips.
- CONTOUR NEXT normal control solution.
- CONTOUR NEXT low control solution.
- CONTOUR NEXT high control solution.
- Lancing device, as in your kit, if provided.
- Lancets, as in your kit, if provided.

Some supplies are sold separately and are not available through Customer Service.

Technical Information: Accuracy

The CONTOUR NEXT GEN blood glucose monitoring system was tested with capillary blood samples from 100 subjects. Two replicates were tested with each of 3 lots of CONTOUR NEXT test strips for a total of 600 readings. Results were compared to the YSI glucose analyzer, which is traceable to the CDC hexokinase method. The following accuracy results were obtained.

Table 1: System accuracy results for glucose concentration < 5.55 mmol/L

Difference range in values between YSI laboratory reference method and CONTOUR NEXT GEN meter	Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
Number (and percent) of samples within specified range	160 of 192 (83.3%)	190 of 192 (99.0%)	192 of 192 (100%)

Table 2: System accuracy results for glucose concentration ≥ 5.55 mmol/L

Difference range in values between YSI laboratory reference method and CONTOUR NEXT GEN meter	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
Number (and percent) of samples within specified range	262 of 408 (64.2%)	397 of 408 (97.3%)	408 of 408 (100%)

Table 3: System accuracy results for glucose concentrations from 1.9 mmol/L to 29.1 mmol/L

Within \pm 0.83 mmol/L or \pm 15%

600 of 600 (100%)

Acceptance criterion in ISO 15197:2013 is that 95% of the measured glucose values shall fall within either \pm 0.83 mmol/L of the average measured values of the reference measurement procedure at glucose concentrations < 5.55 mmol/L or within \pm 15% at glucose concentrations ≥ 5.55 mmol/L.

User Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 324 lay persons showed the following results:

100% within \pm 0.83 mmol/L of the medical laboratory values at glucose concentrations < 5.55 mmol/L and 98.60% within \pm 15% of the medical laboratory glucose concentrations ≥ 5.55 mmol/L.

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 2.2 mmol/L to 19.3 mmol/L. With each blood specimen, each of 3 lots of CONTOUR NEXT test strips was tested 10 times on each of 10 instruments for a total of 300 readings. The following precision results were obtained.

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

Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %
2.23	0.06	0.058–0.068	2.8
4.36	0.07	0.067–0.079	1.7
7.63	0.11	0.102–0.121	1.5
11.80	0.18	0.170–0.202	1.6
18.94	0.24	0.223–0.264	1.3

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

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

Control Level	Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %
Low	2.34	0.03	0.032–0.038	1.5
Normal	6.99	0.10	0.096–0.113	1.5
High	20.53	0.38	0.352–0.417	1.9

Industry Canada Statement

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device. The Class B digital apparatus complies with Canadian ICES-003.

This equipment complies with radiation exposure limits set forth for an uncontrolled environment.

Specifications

Test Sample: Capillary and venous whole blood

Test Result: Referenced to plasma/serum glucose

Sample Volume: 0.6 μ L

Measuring Range: 0.6 mmol/L–33.3 mmol/L 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 Storage Temperature Range: -20°C–65°C

Meter Operating Temperature Range: 5°C–45°C

Control Testing Temperature Range: 15°C–35°C

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

Test Strip Storage Conditions: 0°C–30°C, 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 ISO 15197:2013. 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. The CONTOUR NEXT GEN meter meets the requirements of IEC 61000-4-2 for immunity to electrostatic discharge. Avoid use of electronic devices in very dry environments, especially if synthetic materials are present. The CONTOUR NEXT GEN meter meets the requirements of IEC 61326-1 for radio frequency interference. To avoid radio frequency interference, do not use the CONTOUR NEXT GEN meter near electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the 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
	Use by date (last day of the month)
	Do not reuse
STERILE R	Sterilized using irradiation
STERILE	Indicates a medical device that has been subjected to a sterilization process.
LOT	Batch Code
REF	Catalogue number
Discard Date:	Control Discard Date
	Temperature limitations
	Consult instructions for use
IVD	In Vitro Diagnostic Medical Device
CONTROL L	Control Range Low
CONTROL N	Control Range Normal
CONTROL H	Control Range High

Symbol	What It Means
	Shake 15 times
	<p>Batteries must be disposed of in accordance with laws in your country. Contact your competent local authority for information on the relevant laws regarding disposal and recycling in your area.</p> <p>The meter should be treated as contaminated and disposed of according to local safety rules. It should not be disposed of with waste electronic equipment.</p> <p>Contact your health care professional or local waste disposal authority for medical waste disposal guidelines.</p>

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 and venous 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).⁶

References

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