

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.

Contour next GEN

5.2

mmol/L

NO CODING

SmartGlucose sampling

USER GUIDE

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.

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 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*.

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
	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)
	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)
	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)
	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)

CONTACT INFORMATION

Manufactured for:
Ascensia Diabetes Care Holdings AG
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4052 Basel, Switzerland

www.diabetes.ascensia.com
Customer Service: 1-800-268-7200
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 test strips are used together. No test strip supplier other than the supplier of this product is authorized to grant such a license.

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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.

5

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

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

19

13

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: Set a Test Reminder*. 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 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**.

Enter 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.

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

26

27

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
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

- 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 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**.

7

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.

14

15

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**.

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*.

4 SETTINGS

In **Settings** you can personalize:

- Time format and time.
- Date format and date.
- Sound.
- Meal Markers.

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

Access Settings

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

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

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

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

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

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**.

28

29

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.

1 GETTING STARTED

Your CONTOUR NEXT GEN meter and CONTOUR NEXT test strip

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: test result is above Target Range.
	Green Light: test result is in Target Range.
	Red Light: test result is below Target Range.
	Blood glucose test result is above Target Range.
	Blood glucose test result is in Target Range.
	Blood glucose test result is below Target Range.
	Test result is above 33.3 mmol/L.
	Test result is below 0.6 mmol/L.

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

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.

16

17

Expected Test Result Values

Blood glucose values will vary depending on food intake, medication dosages, health, stress, or activity. Nondabetic 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.

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.

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 Time Format

24 Hour Time Format

3. To change minutes (blinking), 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.

30

31

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.

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: test result is above Target Range.
	Green Light: test result is in Target Range.
	Red Light: test result is below Target Range.
	Blood glucose test result is above Target Range.
	Blood glucose test result is in Target Range.
	Blood glucose test result is below Target Range.
	Test result is above 33.3 mmol/L.
	Test result is below 0.6 mmol/L.

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

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**.

17

18

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. Use 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.

23

24

4

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

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.

5

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.

6

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.

7

Warnings

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

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

8

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.

25

26

9

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.

10

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: test result is above Target Range.
	Green Light: test result is in Target Range.
	Red Light: test result is below Target Range.
	Blood glucose test result is above Target Range.

3.740 [96]	3.780 [96]	3.780 [96]	3.780 [96]	3.780 [96]	3.819 [97]	3.819 [97]																																																																																																																	
<div> <div> </div> <div> Set the Sound </div> </div> <p>1. From the Home screen, select the Settings symbol and press OK to enter Settings.</p> <p>2. When you are on the Settings screen, press the button repeatedly until the Sound symbol is blinking, then press OK.</p> <div> </div> <p>Sound Symbol: </p> <p>3. To turn the Sound On or Off, press the or button.</p> <p>4. Press OK.</p> <p>Your meter comes with the Sound turned On. Certain error messages override any Sound setting.</p> <p>When Sound is On:</p> <ul style="list-style-type: none"> One long beep indicates a confirmation. Two beeps indicate an error or something that needs your attention. <p>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.</p>	<div> <div> </div> <div> Set Meal Marker Feature </div> </div> <p>1. From the Home screen, select the Settings symbol and press OK to enter Settings.</p> <p>2. When you are on the Settings screen, press the button repeatedly until the Meal Marker symbol is blinking, then press OK.</p> <div> </div> <p>Meal Marker Symbols: </p> <p>Your meter comes with the Meal Marker feature turned Off.</p> <p>3. To turn Meal Markers On or Off, press the or button.</p> <p>4. Press OK.</p> <p>NOTE: When the Meal Marker feature is On, you can select a Meal Marker during a blood glucose test.</p>	<div> <div> </div> <div> Set Reminder Feature </div> </div> <p>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.</p> <p>1. From the Home screen, select the Settings symbol and press OK to enter Settings.</p> <p>2. When you are on the Settings screen, press the button repeatedly until the Reminder symbol is blinking, then press OK.</p> <p>Your meter comes with the Reminder feature turned Off.</p> <p>3. To turn the Reminder feature On or Off, press the or button.</p> <div> </div> <p>Reminder Symbol: </p> <p>4. Press OK.</p>	<div> <div> </div> <div> Change Overall Target Range </div> </div> <p>WARNING</p> <p>Discuss your Target Range settings with your health care professional.</p> <p>Your meter provides a pre-set Overall Target Range in Settings. You can change the Overall Target Range in Settings.</p> <p>1. From the Home screen, select the Settings symbol and press OK to enter Settings.</p> <p>2. When you are on the Settings screen, press the button repeatedly until the Target symbol is blinking, then press OK.</p> <div> </div> <p>3. To change the blinking Low end of the Overall Target Range, press the or button.</p> <p>4. Press OK.</p> <p>5. To change the blinking High end of the Overall Target Range, press the or button.</p> <p>6. Press OK.</p>	<div> <div> </div> <div> Change Before/After Meal Target Ranges </div> </div> <p>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.</p> <p>1. From the Home screen, select the Settings symbol and press OK to enter Settings.</p> <p>2. When you are on the Settings screen, press the button repeatedly until the Target symbol is blinking, then press OK.</p> <p>Before Meal/After Meal Low Target</p> <div> </div> <p>The Before Meal / After Meal Low Target number is blinking.</p> <p>NOTE: There is only 1 Low number for both the Before Meal and After Meal Target Ranges.</p> <p>3. To change the blinking Low for both Target Ranges, press the or button.</p> <p>4. Press OK.</p> <p>Before Meal High Target</p> <div> </div> <p>5. To change the blinking High end of the Before Meal Target Range, press the or button.</p> <p>6. Press OK.</p>	<p>NOTE: The Before Meal Target Range is also the Target Range for a blood glucose reading marked as Fasting.</p> <p>After Meal High Target</p> <div> </div> <p>7. To change the blinking High end of the After Meal Target Range, press the or button.</p> <p>8. Press OK.</p>	<div> <div> </div> <div> Set Bluetooth Wireless Functionality </div> </div> <p>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.</p> <p>1. From the Home screen, select the Settings symbol and press OK to enter Settings.</p> <p>2. When you are on the Settings screen, press the button repeatedly until the Bluetooth symbol is blinking, then press OK.</p> <div> </div> <p>Bluetooth Symbol: </p> <p>3. To turn Bluetooth wireless functionality On or Off, press the or button.</p> <p>4. Press OK.</p>																																																																																																																	
<div> <div> </div> <div> CONTOUR DIABETES app </div> </div> <p>The CONTOUR DIABETES app for Your CONTOUR NEXT GEN meter</p> <p>Your CONTOUR NEXT GEN meter is designed to work with the CONTOUR DIABETES app and your compatible smartphone or tablet.</p> <p>You can do the following with your CONTOUR DIABETES app:</p> <ul style="list-style-type: none"> 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. <p>The CONTOUR DIABETES app:</p> <ul style="list-style-type: none"> 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. 	<p>Download the CONTOUR DIABETES app</p> <p>1. On your compatible smartphone or tablet, go to the App Store[®] or the Google Play[™] store.</p> <p>2. Search for the CONTOUR DIABETES app.</p> <p>3. Install the CONTOUR DIABETES app.</p> <p>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.</p>	<p>3. When the meter displays the serial number, follow the instructions on the app to match the meter serial number.</p> <p>Enter serial number</p> <div> </div> <p>Example: Your meter in pairing mode.</p> <p>Pass code</p> <div> </div> <p>When a connection is made, the meter displays the 6-digit pass code.</p> <p>4. Enter the pass code on the smart device.</p> <p>When you have successfully paired your meter with the CONTOUR DIABETES app, the meter displays a blue light and the Bluetooth symbol.</p> <p>The meter returns to the Home screen.</p> <p>Bluetooth</p> <p>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.</p>	<div> <div> </div> <div> 5 HELP </div> </div> <p>Meter Care</p> <p>Caring for your meter:</p> <ul style="list-style-type: none"> 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. <p>The cleaning and disinfecting directions provided should not cause any damage or degradation to the external case, buttons, or display.</p> <p>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 <i>Contact Information</i>.</p>	<div> <div> </div> <div> Cleaning and Disinfection </div> </div> <p>WARNING</p> <ul style="list-style-type: none"> 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. <p>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 <i>Contact Information</i>.</p> <ul style="list-style-type: none"> 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. <p>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.</p>	<p>For more information</p> <p>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.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2009/13372a-eng.php</p>	<div> <div> </div> <div> Cleaning Your Meter </div> </div> <p>Clean and disinfect your meter once a week.</p> <p>Supplies needed for cleaning:</p> <ul style="list-style-type: none"> Clorox Healthcare Bleach Germicidal Wipes containing 0.55% sodium hypochlorite (bleach). Paper towels. <p>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.</p> <p>1. Carefully clean the meter with germicidal wipes until all soil is removed.</p> <p>2. Dry as necessary with a clean paper towel.</p>																																																																																																																	
<div> <div> </div> <div> Transfer Results to a Personal Computer </div> </div> <p>CAUTION: Do not attempt to perform a blood glucose test when the CONTOUR NEXT GEN meter is connected to a computer.</p> <p>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.</p> <div> </div> <p>Ensure your meter's USB port door is completely closed when not in use.</p> <p>CAUTION: Use only approved equipment (for example, USB cable) from the manufacturer or certified body such as UL, CSA, TUV, or CE.</p>	<div> <div> </div> <div> Batteries </div> </div> <p>When the batteries are low, the meter operates normally, displaying the Low Batteries symbol until you replace the batteries.</p> <p>When you are no longer able to perform a test, the meter displays the Dead Batteries screen. Replace the batteries immediately.</p>	<p>3. Remove both of the old batteries and replace them with two 3-volt CR2032 or DL2032 coin cell batteries.</p> <p>NOTE: Always check the date and time after you replace the batteries.</p> <div> </div> <p>4. Make sure the "+" sign is facing up on the new batteries.</p> <p>5. Press each battery into a compartment.</p> <p>6. Slide the battery cover back into place.</p> <p>7. Discard old batteries according to your local environmental regulations.</p> <p>WARNING</p> <p>Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately contact your poison control center.</p>	<div> <div> </div> <div> Control Solution </div> </div> <p>WARNING</p> <p>Shake the control solution well before testing.</p> <div> </div> <p>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.</p> <p>You should perform a control test when:</p> <ul style="list-style-type: none"> 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. <p>WARNING</p> <ul style="list-style-type: none"> Do not calibrate your continuous glucose monitoring device from the control result. Do not calculate an insulin dose based on a control result. 	<div> <div> </div> <div> Control Solution Testing </div> </div> <p>NOTE: Tightly close the bottle lid immediately after you remove the test strip.</p> <p>1. Remove a CONTOUR NEXT test strip from the bottle.</p> <div> </div> <p>2. Insert the gray square end of the test strip into the test strip port until the meter beeps.</p> <p>The meter turns on, displaying a test strip with a flashing blood drop.</p> <p>CAUTION: Do not use control solution that is more than 6 months past the date you first opened the bottle.</p> <p>NOTE: If this is the first time you are opening the control solution, write the date on the bottle.</p> <p>3. Shake the control solution bottle well, about 15 times before every use. Unmixed control solution may cause inaccurate results.</p>	<p>4. Remove the bottle cap and use a tissue to wipe away any solution around the bottle tip before dispensing a drop.</p> <p>5. Squeeze a small drop of solution onto a clean, nonabsorbent surface.</p> <p>CAUTION: Do not apply control solution to your fingertip or to the test strip directly from the bottle.</p> <p>6. Immediately touch the tip of the test strip to the drop of control solution.</p> <p>7. Hold the tip in the drop until the meter beeps.</p> <p>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.</p> <p>8. Compare your control test result with the range printed on the test strip bottle or on the bottom of the test strip box.</p> <p>9. Remove the test strip and dispose as medical waste or as advised by your health care professional.</p> <p>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 <i>Contact Information</i>.</p>																																																																																																																		
<div> <div> </div> <div> 6 TECHNICAL INFORMATION </div> </div> <p>Error Detection Displays</p> <p>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.</p> <p>If you experience continued errors, contact Customer Service. See <i>Contact Information</i>.</p> <table> <tr> <th>Error Code</th><th>What It Means</th><th>What to Do</th></tr> <tr> <td>Strip Errors</td><td></td><td></td></tr> <tr> <td>E 1</td><td>Too Little Blood</td><td>Remove the strip. Repeat the test with a new strip.</td></tr> <tr> <td>E 2</td><td>Used Test Strip</td><td>Remove the strip. Repeat the test with a new strip.</td></tr> <tr> <td>E 3</td><td>Strip Upside Down</td><td>Remove the strip and insert it correctly.</td></tr> <tr> <td>E 4</td><td>Wrong Strip Inserted</td><td>Remove the strip. Repeat the test with a CONTOUR NEXT test strip.</td></tr> <tr> <td>E 6</td><td>Moisture Damaged Strip</td><td>Remove the strip. Repeat the test with a new strip.</td></tr> <tr> <td>E 8</td><td>Strip or Test Errors</td><td>Repeat the test with a new strip. If the error persists, contact Customer Service.</td></tr> </table>	Error Code	What It Means	What to Do	Strip Errors			E 1	Too Little Blood	Remove the strip. Repeat the test with a new strip.	E 2	Used Test Strip	Remove the strip. Repeat the test with a new strip.	E 3	Strip Upside Down	Remove the strip and insert it correctly.	E 4	Wrong Strip Inserted	Remove the strip. Repeat the test with a CONTOUR NEXT test strip.	E 6	Moisture Damaged Strip	Remove the strip. Repeat the test with a new strip.	E 8	Strip or Test Errors	Repeat the test with a new strip. 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Test in 20 minutes.</td></tr> <tr> <td>System Errors</td><td></td><td></td></tr> <tr> <td>E30-E39</td><td>Meter software or hardware malfunctioned</td><td>Turn the meter off. Turn the meter back on. If the error persists, contact Customer Service.</td></tr> </table> <p>Speak to a Customer Service representative before returning your meter for any reason. Contact Customer Service. See <i>Contact Information</i>.</p>	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-E39	Meter software or hardware malfunctioned	Turn the meter off. Turn the meter back on. If the error persists, contact Customer Service.	<p>When speaking with the Customer Service representative:</p> <div> </div> <p>1. Have your CONTOUR NEXT GEN blood glucose meter, CONTOUR NEXT test strips, and CONTOUR NEXT control solution available when you call.</p> <p>2. Locate the model number (A) and serial number (B) on the back of the meter.</p> <p>3. Locate the test strips' expiration date on the bottle.</p> <p>4. Check the battery status.</p>	<p>Technical Information: Accuracy</p> <p>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.</p> <p>Table 1: System accuracy results for glucose concentration < 5.55 mmol/L</p> <table> <tr> <th>Difference range in values between YSI laboratory reference method and CONTOUR NEXT GEN meter</th><th>Within ± 0.28 mmol/L</th><th>Within ± 0.55 mmol/L</th><th>Within ± 0.83 mmol/L</th></tr> <tr> <td>Number (and percent) of samples within specified range</td><td>160 of 192 (83.3%)</td><td>190 of 192 (99.0%)</td><td>192 of 192 (100%)</td></tr> </table> <p>Table 2: System accuracy results for glucose concentration ≥ 5.55 mmol/L</p> <table> <tr> <th>Difference range in values between YSI laboratory reference method and CONTOUR NEXT GEN meter</th><th>Within ± 5%</th><th>Within ± 10%</th><th>Within ± 15%</th></tr> <tr> <td>Number (and percent) of samples within specified range</td><td>262 of 408 (64.2%)</td><td>397 of 408 (97.3%)</td><td>408 of 408 (100%)</td></tr> </table>	Difference range in values between YSI laboratory reference method and CONTOUR NEXT GEN meter	Within ± 0.28 mmol/L	Within ± 0.55 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%)	Difference range in values between YSI laboratory reference method and CONTOUR NEXT GEN meter	Within ± 5%	Within ± 10%	Within ± 15%	Number (and percent) of samples within specified range	262 of 408 (64.2%)	397 of 408 (97.3%)	408 of 408 (100%)	<p>Table 3: System accuracy results for glucose concentrations from 1.9 mmol/L to 29.1 mmol/L</p> <table> <tr> <th>Within ± 0.83 mmol/L or ± 15%</th></tr> <tr> <td>600 of 600 (100%)</td></tr> </table> <p>Acceptance criterion in ISO 15197:2013 is that 95% of the measured glucose values shall fall within either a 0.83 mmol/L of the average measured values of the reference measurement procedure at glucose concentrations < 5.55 mmol/L or within ± 15% of glucose concentrations ≥ 5.55 mmol/L.</p> <p>User Accuracy</p> <p>A study evaluating glucose values from fingertip capillary blood samples obtained by 324 lay persons showed the following results:</p> <p>100% within a 0.83 mmol/L of the medical laboratory values at glucose concentrations < 5.55 mmol/L, and 98.60% within ± 15% of the medical laboratory glucose concentrations ≥ 5.55 mmol/L.</p> <p>Technical Information: Precision</p> <p>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.</p>	Within ± 0.83 mmol/L or ± 15%	600 of 600 (100%)	<p>Table 1: System repeatability results for CONTOUR NEXT GEN meter using CONTOUR NEXT test strips</p> <table> <tr> <th>Mean, mmol/L</th><th>Pooled Standard Deviation, mmol/L</th><th>95% CI of SD, mmol/L</th><th>Coefficient of Variation, %</th></tr> <tr> <td>2.23</td><td>0.06</td><td>0.059-0.068</td><td>2.8</td></tr> <tr> <td>4.36</td><td>0.07</td><td>0.067-0.079</td><td>1.7</td></tr> <tr> <td>7.63</td><td>0.11</td><td>0.102-0.121</td><td>1.5</td></tr> <tr> <td>11.80</td><td>0.18</td><td>0.170-0.202</td><td>1.6</td></tr> <tr> <td>18.94</td><td>0.24</td><td>0.223-0.264</td><td>1.3</td></tr> </table> <p>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.</p> <p>Table 2: System intermediate precision results for CONTOUR NEXT GEN meter using CONTOUR NEXT test strips</p> <table> <tr> <th>Control Level</th><th>Mean, mmol/L</th><th>Pooled Standard Deviation, mmol/L</th><th>95% CI of SD, mmol/L</th><th>Coefficient of Variation, %</th></tr> <tr> <td>Low</td><td>2.34</td><td>0.03</td><td>0.032-0.038</td><td>1.5</td></tr> <tr> <td>Normal</td><td>6.99</td><td>0.10</td><td>0.096-0.113</td><td>1.5</td></tr> <tr> <td>High</td><td>20.53</td><td>0.38</td><td>0.352-0.417</td><td>1.9</td></tr> </table>	Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %	2.23	0.06	0.059-0.068	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	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	<p>Industry Canada Statement</p> <p>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.</p> <p>Specifications</p> <p>Test Sample: Capillary and venous whole blood</p> <p>Test Result: Referenced to plasma/serum glucose</p> <p>Sample Volume: 0.6 µL</p> <p>Measuring Range: 0.6 mmol/L–33.3 mmol/L of glucose in blood</p> <p>Countdown Time: 5 seconds</p> <p>Memory: Stores most recent 800 test results</p> <p>Battery Type: Two 3-volt CR2032 or DL2032 coin cell batteries, 225 mAh capacity</p> <p>Battery Life: Approximately 1000 tests (1 yr. average use, 3 tests per day)</p> <p>Meter Storage Temperature Range: -20°C–65°C</p> <p>Meter Operating Temperature Range: 5°C–45°C</p> <p>Control Testing Temperature Range: 15°C–35°C</p> <p>Meter Operating Humidity Range: 10% RH–93% RH</p>
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Difference range in values between YSI laboratory reference method and CONTOUR NEXT GEN meter	Within ± 0.28 mmol/L	Within ± 0.55 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%)																																																																																																																				
Difference range in values between YSI laboratory reference method and CONTOUR NEXT GEN meter	Within ± 5%	Within ± 10%	Within ± 15%																																																																																																																				
Number (and percent) of samples within specified range	262 of 408 (64.2%)	397 of 408 (97.3%)	408 of 408 (100%)																																																																																																																				
Within ± 0.83 mmol/L or ± 15%																																																																																																																							
600 of 600 (100%)																																																																																																																							
Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %																																																																																																																				
2.23	0.06	0.059-0.068	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																																																																																																																				
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																																																																																																																			
<p>Test Strip Storage Conditions: 0°C–30°C, 10%–80% Relative Humidity (RH)</p> <p>Dimensions: 78.5 mm (L) x 56 mm (W) x 18 mm (H)</p> <p>Weight: 53 grams</p> <p>Meter Life: 5 years with normal use in accordance with instructions</p> <p>Sound Output: 45 dB(A)–85 dB(A) at a distance of 10 cm</p> <p>Radio Frequency Technology: Bluetooth Low Energy</p> <p>Radio Frequency Band: 2.4 GHz–2.483 GHz</p> <p>Maximum Radio Transmitter Power: 1 mW</p> <p>Modulation: Gaussian Frequency Shift Keying (GFSK)</p> <p>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.</p>	<p>Product Labeling Symbols</p> <p>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).</p> <table> <tr> <th>Symbol</th><th>What It Means</th></tr> <tr> <td></td><td>Use by date (last day of the month)</td></tr> <tr> <td></td><td>Do not reuse</td></tr> <tr> <td></td><td>Sterilized using irradiation</td></tr> <tr> <td></td><td>Indicates a medical device that has been subjected to a sterilization process.</td></tr> <tr> <td></td><td>Batch Code</td></tr> <tr> <td></td><td>Catalogue number</td></tr> <tr> <td></td><td>Control Discard Date</td></tr> <tr> <td></td><td>Temperature limitations</td></tr> <tr> <td></td><td>Consult instructions for use</td></tr> <tr> <td></td><td>In Vitro Diagnostic Medical Device</td></tr> <tr> <td></td><td>Control Range Low</td></tr> <tr> <td></td><td>Control Range Normal</td></tr> <tr> <td></td><td>Control Range High</td></tr> </table>	Symbol	What It Means		Use by date (last day of the month)		Do not reuse		Sterilized using irradiation		Indicates a medical device that has been subjected to a sterilization process.		Batch Code		Catalogue number		Control Discard Date		Temperature limitations		Consult instructions for use		In Vitro Diagnostic Medical Device		Control Range Low		Control Range Normal		Control Range High	<p>Symbol What It Means</p> <p> Shake 15 times</p> <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> <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.</p> <p>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.</p> <p>NOTE: Glucose concentrations drop rapidly due to glycolysis (approximately 5%–7% per hour).⁶</p>	<p>References</p> <ol style="list-style-type: none"> Wickham NWR, et al. Unreliability of capillary blood glucose in peripheral vascular disease. <i>Practical Diabetes</i>. 1986;3(2):100. Atkin SH, et al. Fingertick glucose determination in shock. <i>Annals of Internal Medicine</i>. 1991;114(12):1020-1024. Desatchy A, et al. Accuracy of bedside glucometry in critically ill patients: influence of clinical characteristics and perfusion index. <i>Mayo Clinic Proceedings</i>. 2008;83(4):400-405. Cryer PE, Davis SN. Hypoglycemia. In: Kasper D, et al, editors. <i>Harrison's Principles of Internal Medicine</i>. 19th edition. New York, NY: McGraw Hill; 2015. http://accessmedicine.mhmedical.com/content.aspx?bookid=1130&sectionid=79753191 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.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2009/13372a-eng.php Burtis CA, Ashwood ER, editors. <i>Tietz Fundamentals of Clinical Chemistry</i>. 5th edition. Philadelphia, PA: WB Saunders Co; 2001:444. 	<p>3. To turn the smartLIGHT feature On or Off, press the or button to display the option you want.</p> <p>4. Press OK.</p>																																																																																							
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<div> <div> </div> <div> CONTOUR DIABETES app </div> </div> <p>The CONTOUR DIABETES app for Your CONTOUR NEXT GEN meter</p> <p>Your CONTOUR NEXT GEN meter is designed to work with the CONTOUR DIABETES app and your compatible smartphone or tablet.</p> <p>You can do the following with your CONTOUR DIABETES app:</p> <ul style="list-style-type: none"> 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. <p>The CONTOUR DIABETES app:</p> <ul style="list-style-type: none"> 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. 	<p>Download the CONTOUR DIABETES app</p> <p>1. On your compatible smartphone or tablet, go to the App Store[®] or the Google Play[™] store.</p> <p>2. Search for the CONTOUR DIABETES app.</p> <p>3. Install the CONTOUR DIABETES app.</p> <p>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.</p>	<p>3. When the meter displays the serial number, follow the instructions on the app to match the meter serial number.</p> <p>Enter serial number</p> <div> </div> <p>Example: Your meter in pairing mode.</p> <p>Pass code</p> <div> </div> <p>When a connection is made, the meter displays the 6-digit pass code.</p> <p>4. Enter the pass code on the smart device.</p> <p>When you have successfully paired your meter with the CONTOUR DIABETES app, the meter displays a blue light and the Bluetooth symbol.</p> <p>The meter returns to the Home screen.</p> <p>Bluetooth</p> <p>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.</p>	<div> <div> </div> <div> 5 HELP </div> </div> <p>Meter Care</p> <p>Caring for your meter:</p> <ul style="list-style-type: none"> 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. <p>The cleaning and disinfecting directions provided should not cause any damage or degradation to the external case, buttons, or display.</p> <p>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 <i>Contact Information</i>.</p>	<div> <div> </div> <div> Cleaning and Disinfection </div> </div> <p>WARNING</p> <ul style="list-style-type: none"> 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. <p>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 <i>Contact Information</i>.</p> <ul style="list-style-type: none"> 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. <p>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.</p>	<p>For more information</p> <p>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.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2009/13372a-eng.php</p>	<div> <div> </div> <div> Cleaning Your Meter </div> </div> <p>Clean and disinfect your meter once a week.</p> <p>Supplies needed for cleaning:</p> <ul style="list-style-type: none"> Clorox Healthcare Bleach Germicidal Wipes containing 0.55% sodium hypochlorite (bleach). Paper towels. <p>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.</p> <p>1. Carefully clean the meter with germic</p>																																																																																																																	