

Contour[®] next

Blood Glucose Monitoring System



Uses only CONTOUR[®]NEXT blood glucose test strips

USER GUIDE

INDICATIONS FOR USE

The CONTOUR®NEXT blood glucose monitoring system is an over-the-counter (OTC) device utilized by persons with diabetes in home settings for the quantitative measurement of glucose in whole blood, and is for single-patient use only, and should not be shared. The system is intended for self-testing outside the body (in vitro diagnostic use) and is to be used as an aid to monitor the effectiveness of diabetes control. The CONTOUR NEXT blood glucose monitoring system is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. Alternative site testing should be done only during steady state times (when glucose is not changing rapidly). The system consists of a CONTOUR NEXT blood glucose meter, CONTOUR®NEXT test strips and CONTOUR®NEXT control solutions.

CONTOUR NEXT test strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples.

The CONTOUR NEXT control solutions are aqueous glucose solutions intended for use in self-testing by people with diabetes as a quality control check to verify that the CONTOUR NEXT system is working properly.

The CONTOUR NEXT blood glucose monitoring system is not intended for the diagnosis or screening for diabetes mellitus and is not intended for use on neonates.

IMPORTANT SAFETY INFORMATION

WARNINGS

Serious Illness

- Capillary (fingerstick or Alternative Site) blood glucose testing may not be clinically appropriate when peripheral flow is decreased. Shock, severe hypotension, hyperosmolar hyperglycemia, diabetic ketoacidosis, and occurrence of severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.¹⁻³

- Do not calibrate a continuous glucose monitoring device from an Alternative Site test result.
- Do not calculate an insulin dose based on an Alternative Site test result.

Talk to Your Health Care Professional

- Before setting any Target ranges on your meter,
- Before changing your medication based on test results,
- If your blood sugar reading is under 50 mg/dL follow medical advice immediately,
- If your blood sugar reading is over 250 mg/dL, wash and dry your hands well and repeat the test with a new strip. If you get a similar result, call your health care professional as soon as possible,
- About whether Alternative Site Testing (AST) is appropriate for you.


Potential Biohazard

- Always wash your hands well with soap and water and dry them well before and after testing, handling the meter, lancing device, or test strips.
- The meter, lancing device and lancets are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!^{4,5}
- All parts of this kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection. For complete instructions on cleaning and disinfecting your meter and lancing device, please see pages 54 to 57. For more information about cleaning and disinfecting your meter or lancing device see: US Food and Drug Administration. Use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm> and Centers for Disease Control and Prevention. CDC clinical reminder: use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens.

US Department of Health and Human Services; 8/23/2010.
<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

- The lancing device should not be used for assisted blood draws by health care professionals or at health care provision sites.
- Use a new lancet each time you test because it is no longer sterile after use.
- Always dispose of test strips and lancets as medical waste. 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 which could cause suffocation if accidentally swallowed.
- Keep batteries away from children. Lithium batteries are poisonous. If swallowed, immediately contact your poison control center.

PRECAUTIONS

-  Read your CONTOUR[®]NEXT meter user guide, the lancing device package insert and all instructional materials provided in your meter kit before testing. Please follow all instructions for use and care exactly as described to help avoid inaccurate results.
- Examine product for missing, damaged, or broken parts. If the test strip bottle is open inside a new box of strips, do not use those strips. Contact Customer Service for replacement parts. See the back cover for contact information.
- The CONTOUR NEXT meter only works 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. 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.

- Check the expiration dates on your test strips and control solution. Do not use the test strips or control solution if the expiration date printed on the bottle label and carton has passed. This can cause inaccurate results. For the control solution, do not use if it has been six months since you first opened the bottle. It will help to write the six month discard date on the control solution label.
 - If your control solution test result is out of range, contact Customer Service. See the back cover for contact information. Do not use the meter for blood glucose testing until you resolve this issue.
 - The meter has been designed to give accurate results at temperatures between 41°F and 113°F. If you are outside this range, you should not test. 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 perform a blood glucose test when the CONTOUR[®]NEXT meter is connected to a computer.
 - Use only approved equipment from the manufacturer or certified body such as UL or TUV.
 - It is advisable to avoid use of electronic devices in very dry environments, especially if synthetic materials are present.
 - Your CONTOUR NEXT meter has been preset and locked to display results in mg/dL (milligrams of glucose per deciliter of blood).
 - ✦ Results in mg/dL will **never** have a decimal point;
 - ✦ Results in mmol/L will **always** have a decimal point.
- Example: 93 mg/dL or 5.2 mmol/L**
- ✦ Check your display screen to be sure the results are shown the right way. If not, contact Customer Service. See the back cover for contact information.

- The CONTOUR[®]NEXT blood glucose monitoring system has a measuring range of 20 mg/dL to 600 mg/dL.
 - ✦ For results over 600 mg/dL or under 20 mg/dL:
 - If your blood sugar reading is under 20 mg/dL, the “**Result Under 20 mg/dL**” screen will instruct you to “**Follow Medical Advice Immediately.**” Contact your health care professional.
 - If your blood sugar reading is over 600 mg/dL the “**Result Over 600 mg/dL**” screen will instruct you to “**Wash hands or test site. Repeat test with new strip.**” If results are still over 600 mg/dL, “**Follow Medical Advice Immediately**” is displayed.

Your Meter Features

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

Automatic: The CONTOUR[®]NEXT meter is designed with No Coding[™] technology, to automatically code itself every time you insert a test strip. It will also automatically mark a control solution test.



Enough Blood: The CONTOUR NEXT meter alerts you when a test strip is under-filled and allows you to add more blood. Your test strip is designed to easily “sip” the blood into the sample tip. Do not drop blood directly on the flat surface of the test strip.

Thank you for choosing the CONTOUR NEXT blood glucose monitoring system. We are proud to be your partner in helping you manage your diabetes.

CAUTION: Your CONTOUR[®]NEXT meter **ONLY** works with CONTOUR[®]NEXT test strips and CONTOUR[®]NEXT control solution.

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Your CONTOUR®NEXT Meter



Using the Meter Buttons

- Press and hold the **OK** button **until the meter turns on**.
- Press and hold the **OK** button **until the meter turns off**.
- The ▲ or ▼ scroll buttons on the meter allow you to scroll through the menus. You can hold the ▲ or ▼ button to scroll continuously through a list.
- Press the **OK** button to select the highlighted option.
- To exit from the Logbook or Trends and return to the Main Menu, press the **OK** button.
- To exit from Setup and return to the Main Menu, scroll down to **Main Menu** and press the **OK** button.



Listed below are symbols that appear on the CONTOUR®NEXT meter screen. These symbols will appear in the left side of the screen, as shown here:



Example of Language confirmation screen

Symbol	What it Means
	When you select More Information .
	On confirmation screens and when blood sugar test result is in Target range.
	On error screens and when blood sugar test result is either below 20 mg/dL or above 600 mg/dL.
	When blood sugar test result is above Target.
	When blood sugar test result is below Target.

Your CONTOUR[®]NEXT Test Strip

Gray Square End
Insert this end into the test strip port

Sample Tip
Blood sample pulled in here



Initial Setup

1. Press and hold the **OK** button until the meter turns on. After a welcome screen, you will see the Select Language screen.



2. Press the ▼ button if needed to select your desired language. Press the ▼ button to scroll down to see more language choices.

This screen example shows the language order may differ depending on your country.

3. When your language is highlighted, press the **OK** button.



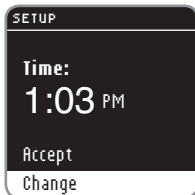
A screen confirms your language.

4. Press the **OK** button to confirm.



5. The time will appear and you can **Accept** or **Change**.

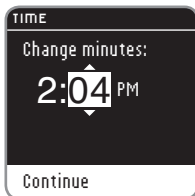
To Change Time



1. If you want to change the time, use the ▼ button to select **Change** and press the **OK** button.

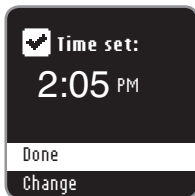


2. Use the ▲ or ▼ buttons to make any changes to your hour. When the desired choice is highlighted, press the **OK** button to move to minutes.



3. Use ▲ or ▼ buttons to make any changes to your minutes. Continue this process until the minutes are set the way you want. Press the **OK** button when done.

4. Use the ▲ or ▼ buttons to select **AM** or **PM**. Press the **OK** button.



5. A screen confirms your time setting. Press the **OK** button to move on to set date.

To Change Date



1. If you want to change the date, use the ▼ button to select **Change** and press the **OK** button.



2. Use the ▲ or ▼ buttons to change the year. Press the **OK** button to move to month.



3. Use the ▲ or ▼ buttons to change the month. Press the **OK** button to move to day.



4. Use the ▲ or ▼ buttons to change the day. Press the **OK** button.



5. A screen confirms your date setting. Press the **OK** button to continue to view the Target Range settings.

Target Ranges

The next screens display the preset blood sugar Target ranges for Fasting, Before Meal and After Meal blood sugar.

WARNING

Discuss your Target ranges with your health care professional.



1. Press the **OK** button to continue.



2. After you have completed initial setup, you can change the Target ranges using the Setup menu. Next you will see each preset Target (Fasting, Before Meal and After Meal). Press the **OK** button to continue.



3. The preset Fasting Target range will appear (70 - 130 mg/dL). Press the **OK** button to continue to the Before Meal Target range.



4. The preset Before Meal Target range will appear (70 - 130 mg/dL). Press the **OK** button to continue to the After Meal Target range.




5. The preset After Meal Target range will appear (70 - 180 mg/dL). Press the **OK** button.

Initial setup is complete. You can now test your blood sugar.

You can also change Target settings by going to the Main Menu and selecting Setup. See page 38.

Getting Ready to Test

 Read your CONTOUR[®]NEXT meter user guide, the lancing device insert and all instructional materials provided in your meter kit before testing. Please follow all instructions for use and care exactly as described.

Examine product for missing, damaged, or broken parts. If the test strip bottle is open inside a new box of strips, do not use those strips. Contact Customer Service for replacement parts. See the back cover for contact information.

CAUTION: Your CONTOUR[®]NEXT meter only works with CONTOUR[®]NEXT test strips and CONTOUR[®]NEXT control solutions.

Have all the materials you will need ready before you begin testing. This includes your CONTOUR NEXT meter, CONTOUR NEXT test strips, and the lancing device and lancets. You may also need CONTOUR NEXT control solution to perform a quality control check. CONTOUR NEXT control solutions are sold separately if not included in the meter kit.

WARNING

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


Preparing the Lancing Device

The lancing device graphics are for illustration purposes only. Your lancing device may look different. Refer to your lancing device insert for detailed instructions on preparing the lancing device.

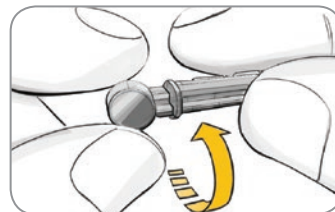
WARNING: Potential Biohazard

The lancing device provided with your kit is intended for self-testing by a single patient. It must not be used on more than one person due to the risk of infection.

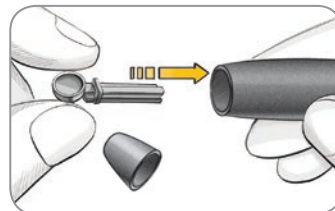
WARNING

- Dispose of the used lancet as medical waste or as advised by your health care professional.
-  Do not reuse lancets. Use a new lancet each time you test.

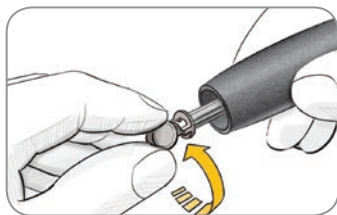
1. Remove the endcap from the lancing device.



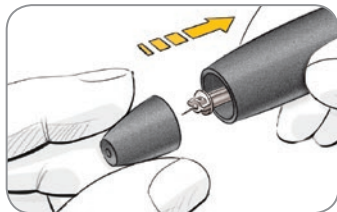
2. Loosen the round protective cap on a lancet by rotating the cap $\frac{1}{4}$ turn, but do not remove the cap.



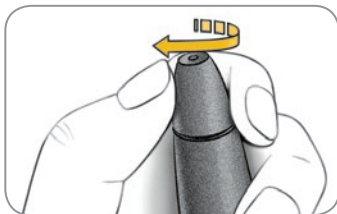
3. Insert the lancet firmly into the lancing device until the lancet comes to a complete stop.



- Twist off the round protective lancet cap. Save the cap for disposing of the used lancet.



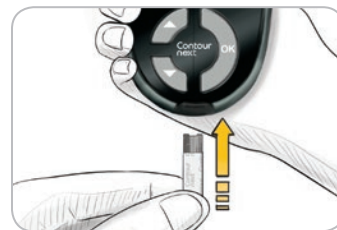
- Replace the endcap.



- Rotate the endcap dial to adjust the puncture depth.
The amount of pressure applied to the puncture site also affects puncture depth.

Inserting the Test Strip

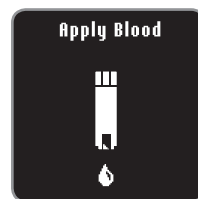
- Remove a CONTOUR®NEXT test strip from the bottle. **Tightly close the bottle lid immediately after you have removed the test strip.**



- Hold the test strip with the gray square end facing toward the meter.



- Insert the gray square end firmly into the test strip port until the meter beeps.



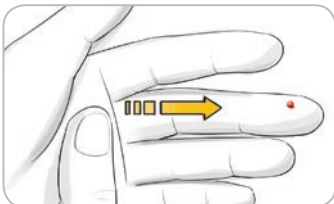
You will see the Apply Blood screen. The meter is now ready to test a blood drop.

HINT: After the test strip is inserted, if you do not apply blood to the test strip within 3 minutes, the meter will turn off. Remove the test strip and reinsert it to begin a test.

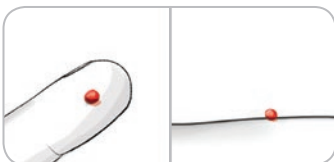
Getting the Blood Drop – Fingertip Testing



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



2. Stroke your hand and finger toward the puncture site to form a drop of blood. Do not squeeze around the puncture site.



Suggested drop size



3. Test immediately after a good blood drop has formed.

4. Immediately touch the tip of the test strip to the drop of blood. The blood is pulled into the test strip through the tip.

Hold the tip of the test strip in the blood drop until the meter beeps.

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

WARNING

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!^{4,5}
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Always wash your hands well with soap and water and dry them well before and after testing, handling the meter, lancing device, or test strips.

For complete instructions on cleaning and disinfecting your meter and lancing device, please see pages 54 - 57.

Apply More Blood



If the first blood drop is not enough, the meter will beep twice and display “Apply More Blood to continue testing.” You have about 30 seconds to apply more blood onto the same strip.





If you do not re-apply enough blood within about 30 seconds, you will see a screen telling you to remove the strip and start with a new strip.

AutoLog

Your meter comes with an AutoLog feature that lets you mark your test result as **No Mark**, **Fasting**, **Before Meal** and **After Meal**.

No Mark – No Mark can be selected if you are testing at other times than before or after a meal or fasting.

 **Fasting** – Use the Fasting marker when testing blood sugar levels after fasting (no food or drink for 8 hours, except water or non-caloric beverages).

 **Before Meal** – The Before Meal marker is used when testing blood sugar levels within 1 hour before a meal.

 **After Meal** – The After Meal marker is used when testing blood sugar levels within 2 hours after the first bite of a meal.

Your meter comes with AutoLog turned on. You will get the most information from each result if you keep this feature turned on.



Test Results

Test Results with AutoLog On

- **Your CONTOUR®NEXT meter comes with AutoLog on.** You can turn AutoLog off using the Setup menu (see page 44).



After you place blood on the test strip, your test result will not display until you make an AutoLog selection. Use the **▲** or **▼** button to select **No Mark**, **Fasting**, **Before Meal**, or **After Meal**, and then press the **OK** button.

If your result is outside your Target range setting, you will see your result without pushing a button.



To get the most from your AutoLog feature, mark your test result right away. If you make your AutoLog selection very quickly, you may see the remainder of the testing countdown.

If you have not made your AutoLog selection within 1 minute, the screen will dim. Press any button to turn the screen back on and make your choice. If you have not made your choice within 3 minutes, the meter turns off. Your blood sugar result will not be lost — it will be stored in Logbook as No Mark.

CAUTION: If your result is above or below your set Target ranges, you will always see your result without pushing a button.



After making your selection, your test result appears. Press the **OK** button to move to **See Options**.



Leave the test strip in the meter to add a note related to this result or set a reminder. Press the **OK** button and you can select **Main Menu**, **Add Reminder** (see page 29) or **Add Note** (see page 33).

To turn the meter off if you do not want to set a reminder or add a note, remove the test strip.

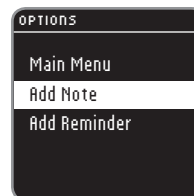
Test Results with AutoLog Off



After applying blood to the test strip when AutoLog is Off, your result will appear. You may see the 5 second countdown screen.



Your test result appears. Press the **OK** button to move to **See Options**.



Leave the test strip in the meter to add a note related to this result or set a reminder. Press the **OK** button and you can select **Main Menu**, **Add Reminder** (see page 29) or **Add Note** (see page 33).

To turn the meter off if you do not want to set a reminder or add a note, remove the test strip.

Alternative Site Testing (AST) - Palm

WARNING

- Ask your health care professional if Alternative Site Testing (AST) is right for you.
- Do not calibrate a continuous glucose monitoring device from an AST result.
- Do not calculate an insulin dose based on an AST result.

IMPORTANT: For Alternative Site Testing, use the clear endcap. Your CONTOUR®NEXT meter can be used for fingertip or palm testing. See the lancing device insert for complete instructions in Alternative Site Testing.

IMPORTANT: Do not use AST under the following conditions:

- If you think your blood sugar is low
- When blood sugar is changing rapidly (after a meal, insulin dose or exercise)
- If you are unable to feel symptoms of low blood sugar (hypoglycemic unawareness)
- If you get alternative site blood sugar results that do not agree with how you feel
- During illness or times of stress
- If you will be driving a car or operating machinery

Alternative Site results may be different from fingertip results when glucose levels are changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise). Additionally, glucose levels may not rise as high or fall as low as levels in the fingertip. As such, fingertip results may identify hypoglycemic levels sooner than alternate site results.

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

If you do not have a clear endcap to perform AST, contact Customer Service. See the back cover for contact information.

Getting a Blood Drop for Alternative Site Testing



1. Wash your hands and the puncture site with soap and warm water. Rinse and dry well.
2. Attach the clear AST endcap to the lancing device. **Refer to the lancing device insert for detailed instructions.**

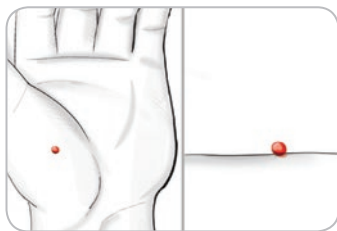


3. Select a puncture site from a fleshy area on the palm. Avoid veins, moles, bones and tendons.

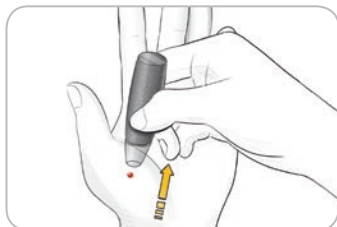


4. Press the lancing device firmly against the puncture site and then press the release button.

The lancing device graphics are for illustration purposes only.



5. Maintain steady pressure until a small, round blood drop forms.



6. Lift the device straight up and away from the skin without smearing the blood.



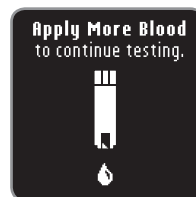
7. Test immediately after you have formed a small, round blood drop.

Immediately touch the tip of the test strip to the drop of blood. The blood is pulled into the test strip through the tip.

Do not test the blood sample from palm if you get:

- Smearred blood
- Clotted blood
- Runny blood
- Clear fluid mixed with the blood

8. Hold the tip of the test strip in the blood drop until the meter beeps. Do not press the tip against the skin or place the blood on top of the test strip or you could get inaccurate results or errors.



If the first blood drop is not enough, the meter will beep twice and display “**Apply More Blood to continue testing.**” You have about 30 seconds to apply more blood to the same strip.



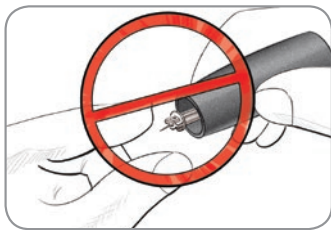
If you do not re-apply enough blood within about 30 seconds, you will see a screen telling you to remove the strip and start with a new strip.

9. If you have the AutoLog feature turned on, the AutoLog screen appears. Your test result will not display until you make a selection. Select **Fasting**, **Before Meal**, **After Meal**, or **No Mark** by pressing the **OK** button when the selection is highlighted.

CAUTION: If your result is above or below your set Target ranges, you will always see your result without pushing a button.

Please see Test Results with AutoLog On, page 17, or Test Results with AutoLog Off, page 19.

Ejecting and Disposing of the Used Lancet



1. Do not use your fingers to remove the lancet from the lancing device. The lancing device provided with your kit has an automatic lancet ejection feature.

2. Refer to the separate lancing device insert, if provided with your kit, for instructions on automatic ejection of the lancet.

WARNING

- Dispose of the used lancet as medical waste.
- Do not reuse lancets. Use a new lancet each time you test.

WARNING: Potential Biohazard

- Items in this kit are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients! ^{4,5}
- Always dispose of the used test strip and lancet as medical waste. All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.

Expected Test Result Values

Blood sugar values will vary depending on food intake, medication dosages, health, stress, or activity. Non-diabetic plasma glucose concentrations should be < 100 mg/dL in the fasting state and < 140 mg/dL in the post-prandial state.⁶ **You should consult with your health care professional for glucose values specific to your needs.**

WARNING

You should consult with your health care professional for glucose values specific to your needs.

- If your blood sugar reading is under 50 mg/dL, follow medical advice immediately.
- If your blood sugar reading is over 250 mg/dL, wash and dry your hands well and repeat the test with a new strip. If you get a similar result, call your health care professional as soon as possible.
- Always consult your health care professional before changing your medication based on test results.

Control Solution Testing

WARNING

Shake the control solution well before testing.



CAUTION: Use only CONTOUR[®]NEXT control solutions (Level 1 or Level 2) with your CONTOUR[®]NEXT blood glucose monitoring system. Using any other control solution or any other combination of control solution and strips can cause inaccurate results.

Quality Control



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

You should perform a control test when:

- Using your meter for the first time.
- You open a new bottle or package of test strips.
- You think your meter may not be working properly.
- You have repeated, unexpected blood glucose results.

WARNING

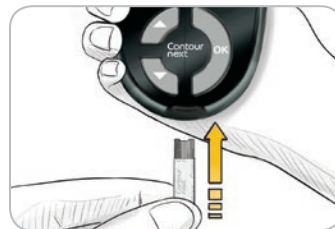
- Do not calibrate your continuous glucose monitoring device from a control result.
- Do not calculate a bolus based on a control result.



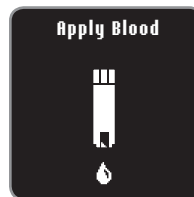
CAUTION: Check the expiration date on the test strip bottle and the expiration date and discard date on the control solution bottle. **DO NOT** use expired materials.

Level 1 and Level 2 control solutions are available and sold separately if not included in the meter kit. You can test your CONTOUR[®]NEXT meter with control solution when the temperature is 59°F–95°F. Always use CONTOUR[®]NEXT control solutions. Other brands could present incorrect results. If you need help locating CONTOUR NEXT control solutions, contact Customer Service. See the back cover for contact information.

1. Remove the test strip from the bottle and firmly snap the lid closed.
2. Hold the test strip with the gray square end facing up.



3. Insert the gray square end of the test strip into the test strip port until the meter beeps.



4. The meter will turn on and show a test strip with a flashing blood drop.

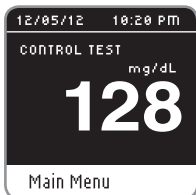


5. Shake the control solution bottle well, about 15 times before every use.

6. Remove the bottle cap and use a tissue to wipe away any solution around the bottle tip before dispensing a drop.
7. Squeeze a small drop of control solution onto a clean non-absorbent surface. **Do not apply control solution to your finger or to the test strip directly from the bottle.**
8. Immediately touch the **tip** of the test strip to the drop of control solution.



9. Hold the tip in the drop until the meter beeps.



10. The meter will count down for 5 seconds and the control test result will display on the meter. It will be automatically marked as a control test and stored in the Logbook. Control test results will not be included in your blood sugar averages.



11. Compare your control test result with the range printed on the test strip bottle or the bottom of the test strip box.
12. Remove the test strip and dispose as medical waste.

CAUTION: If the result you get does not fall within the range listed on the test strip bottle label or carton, there may be a problem with the test strips, the meter or your testing technique.

If your control test result is out of range, do not use your CONTOUR[®]NEXT meter for blood glucose testing until you resolve the issue. Contact Customer Service. See the back cover for contact information.

Test Reminders

A reminder for your next test can be set after testing or from the Setup menu. See page 39 for Setting a Reminder from the Setup Menu.

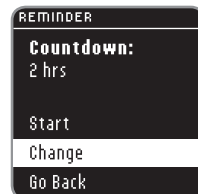
Setting a Reminder After Testing



1. With the test strip still in the meter, press the **OK** button when **See Options** is highlighted.



2. Press the **▼** button to select **Add Reminder**.
3. Press the **OK** button to start the countdown. The default time is either 2 hours or the last reminder time that was set.



You can change the Reminder Countdown time to the time you wish by selecting **Change**. Then press the **OK** button.

Turning Off a Reminder After Testing

1. Press the **OK** button and if the Countdown is currently on, the screen will show **Reminder in**.



2. To stop the Countdown, select **Stop**. Press the **OK** button.

A screen confirms your choice.

The Countdown is now stopped and the clock symbol will no longer appear on the screen.

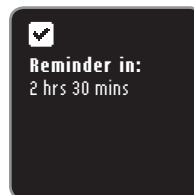
Changing the Reminder Time



1. Press the ▲ or ▼ button to select the correct hours. Press the **OK** button to continue.



2. Press the ▲ or ▼ button to select the minutes (in 15 minute increments).
3. Press the **OK** button to continue.



A screen confirms the **Reminder** Countdown time.



When the **Reminder** feature is on, the clock symbol is in the header area of many of the menu screens.

Remove the test strip from the meter. The meter retains the Reminder time that you set until you change it.

Getting a Reminder



When the Reminder time is reached, 20 beeps will sound. The meter will turn on and a Reminder screen will appear. You can stop the beeps by pressing the **OK** button or inserting a test strip.

HINT: If you are testing within 15 minutes of the Reminder, the Reminder will be cancelled.

Logbook

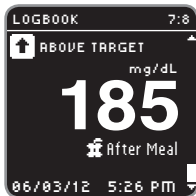
Reviewing the Logbook

The Logbook contains blood sugar test results and notes that you have made to those test results. The Logbook will hold up to 800 results. When the maximum is reached, the oldest test result will be removed as a new test is completed and saved to the Logbook.

To review these entries in the Logbook:



1. Press and hold the **OK** button until the meter turns on.
2. Press the **OK** button again to select **Logbook** from the Main Menu.



3. Press the **▲** or **▼** button to view your individual test results. Press the **▲** or **▼** button to scroll through your test results.



When you reach the oldest entry you will see the End of Logbook screen.

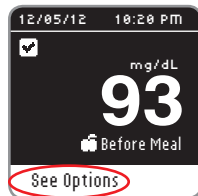
4. Press the **OK** button to go back to the beginning to review entries. Use the **▼** button to select **Previous screen** or **Main Menu** and then press the **OK** button.

HINT: From any screen while viewing the Logbook, press the **OK** button on your meter to return to the Main Menu.

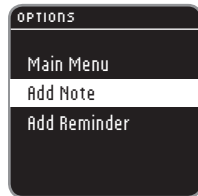
Notes

Adding a Note

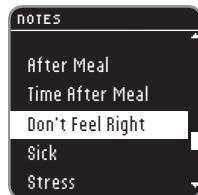
You may add Notes to your test result that may help explain results. Your Notes will be saved in the Logbook.



1. From the test result screen, press the **OK** button when **See Options** is highlighted.



2. Press the **▼** button to select **Add Note**. If you have marked your test result using AutoLog, that entry will have a check in front of it.



3. Press the **▲** or **▼** button to scroll through the choices. Some may not be visible until you scroll up or down. Press the **OK** button when your choice is highlighted. A screen confirms your choice. All options may not be available based on the meal marker you choose.

HINT: You can remove a Note that you just added. Highlight the Note and press the **OK** button. Once you return to the Main Menu, you cannot remove a Note or change a Note.

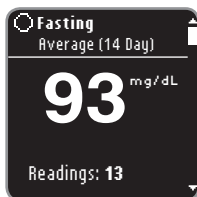
Trends (Averages and Summaries)

The Trends feature displays your average and a summary of your test results as they compare to your targets, over a period of time that you select. The options available are 7, 14, 30 and 90-day averages. Your meter has been preset to 14-day averages. You can review your 14-day Fasting, Before Meal, and After Meal Summaries and Averages.

Your 90-day average is not intended to be reflective of your HbA1c result.

Viewing Trends with AutoLog On

1. Press and hold the **OK** button to turn the meter on.
2. Use the ▼ button to highlight **Trends**. Press the **OK** button.



You will see your 14-day **Fasting Average** first. This example shows that your average of 13 readings is 93 mg/dL.



3. Press the ▼ button to see your 14-day **Fasting Summary**. This example shows 1 test result **Above Target**, 10 test results **In Range** and 2 test results **Below Target**. In this example the **Target Range** is 70 - 130 mg/dL for the 14 days.

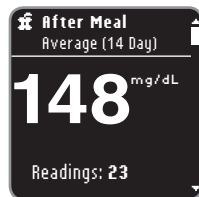
HINT: From any screen while viewing the Logbook, press the **OK** button on your meter to return to the Main Menu.



4. Continue to press the ▼ button to see your 14-day **Before Meal Average**.



5. Press the ▼ button to see your 14-day **Before Meal Summary**. This example shows 3 test results **Above Target**, 20 test results **In Range** and 2 test results **Below Target**. In this example the **Target Range** is 70 - 130 mg/dL for the 14 days.



6. Continue to press the ▼ button to see your 14-day **After Meal Average**. This example shows your average of 23 readings is 148 mg/dL.



7. Press the ▼ button to see your 14-day **After Meal Summary**. This example shows 3 test results **Above Target**, 19 test results **In Range** and 1 test result **Below Target**. In this example the **Target Range** is 70 - 180 mg/dL for the 14 days.



- Continue to press the ▼ button to see your **Overall 14-day Average**. This example includes **ALL** your results for 14 days and shows an overall average for 58 readings of 119 mg/dL.



If it happens that your **AVERAGE** is above or below your target ranges, you will see an added message as shown.

Changing the Trends Time Period



Other trend time periods are available through the **See More Trends** menu. You will see the **See More Trends** menu after the Overall Average screen. Scroll through your Trends using the ▼ button on your meter.

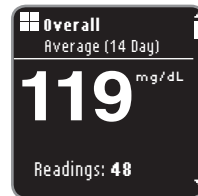


- Select **See More Trends** and press the **OK** button.
- You can select the time period by highlighting your choice and pressing the **OK** button.

Viewing Trends with AutoLog Off

If you have AutoLog turned off, you will only see trends for your overall Target.

- Turn on the meter by pressing and holding the **OK** button.
- Press the ▼ button to select **Trends** and then press the **OK** button.



You will see your 14-day Overall Average first.



- Press the ▼ button to view your **Overall Summary**. You will see your 14-day **Overall Summary**. This example shows 3 test results Above Target, 40 test results In Range and 5 test results Below Target. In this example the **Target Range** is 75 - 130 mg/dL for the 14 days.



- Press the **OK** button to **See More Trends** or select **Main Menu**.

Setup

In Setup you can:

Turn a Reminder on or off or Set a Reminder, Change the date, Change the time, Set Sound on or off, Turn AutoLog on or off, view or set Target ranges, Change the Language, Change the Display Background or Enter the Customer Service Mode.

To get to the Setup Menu:



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



- The Main Menu has 3 choices: **Logbook**, **Trends** and **Setup**.
2. Press the ▼ button to highlight **Setup**.
 3. Press the **OK** button.

Setting a Reminder



1. Press and hold the **OK** button until the meter turns on.
2. On the Setup Menu, you will see a list of options with the Reminder option highlighted.



3. To change a Reminder, press the **OK** button and follow steps on page 30 "Changing the Reminder Time." To leave the Reminder option as it is set, press the ▼ button to go back to **Main Menu**.

Turning Off a Reminder



1. Go to the Main Menu. Select **Setup** and press the **OK** button.
2. With **Reminder: On** selected, press the **OK** button.
3. Select **Stop** and press the **OK** button.
4. The Countdown is now stopped.



A screen confirms your choice.

Date



1. Press and hold the **OK** button until the meter turns on.
2. From the Setup Menu, use the ▼ button to highlight the Date. Press the **OK** button.
3. **change** will be highlighted. Press the **OK** button.



4. Select **Month/Day/Year** or **Day.Month.Year** by using the ▲ or ▼ button. Press the **OK** button.



5. Change year (highlighted) by using the ▲ or ▼ button. Press the **OK** button.



6. Change month (highlighted) by using the ▲ or ▼ button. Press the **OK** button.

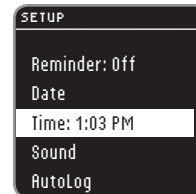


7. Change day by using the ▲ or ▼ button. Press the **OK** button.

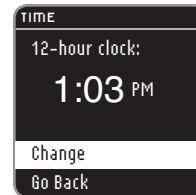


8. A screen confirms your date setting. **Done** will be highlighted. Press the **OK** button.

Time



1. Press and hold the **OK** button until the meter turns on.
2. From the Setup Menu, use the ▼ button to highlight the Time. Press the **OK** button.



3. **Change** will be highlighted. Press the **OK** button.



4. Change the time format if needed. Press the **OK** button.



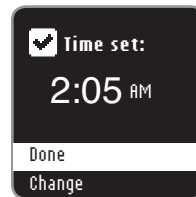
5. Change the hour (highlighted) by using the **▲** or **▼** button. Press the **OK** button to continue.



6. Change minutes (highlighted) by using the **▲** or **▼** button. Press the **OK** button to continue.



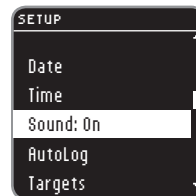
7. When in 12-hour clock mode, select **AM** or **PM** and press the **OK** button.



8. **Done** will be highlighted. Press the **OK** button.

Sound

Your meter comes with the Sound turned on. Certain error messages and the Reminder bell override any Sound setting. One long beep indicates a confirmation when Sound is On. Two beeps indicates an error or something that needs your attention when Sound is On.



1. Press and hold the **OK** button until the meter turns on.
2. From the Setup Menu, select **Sound** and press the **OK** button to turn sound on or off. Press the **OK** button again to change the setting. A screen will confirm your choice.

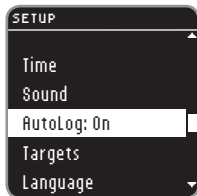


To turn off the Sound, select **Turn Off**. To keep the Sound on, select **Go Back**. The Setup menu appears upon completion. Some sounds stay on, even with the Sound turned off.

AutoLog

Your meter comes with AutoLog turned On.

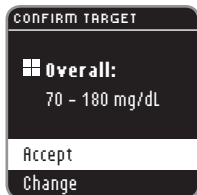
AutoLog Settings



1. Press and hold the **OK** button until the meter turns on.
2. From the Setup menu, choose **AutoLog** and press the **OK** button.



3. Make one of the following selections: **Accept**, **Turn Off (Turn On)**, or **More information**.
4. If you select **Accept** or **Turn (On/Off)**, a screen is shown confirming that AutoLog is on or AutoLog is off.



5. A screen then shows the current Target settings. Press the **OK** button to **Accept** these Target ranges. To change the Target range, highlight **Change** and press the **OK** button. **Set Target** will be highlighted. To set targets, see the Target setup section on the following page.

Blood Sugar Target Ranges

Your CONTOUR[®]NEXT meter comes preset with blood sugar Target ranges for Fasting, Before Meal, and After Meal results. The preset range is 70 - 130 mg/dL for Fasting and Before Meal, and 70 - 180 mg/dL for After Meal. These Target ranges are only available when AutoLog is ON. If AutoLog is OFF, you will have an Overall Target range only, which is preset to 70 - 180 mg/dL.

WARNING

Discuss your Target range settings with your health care professional.

Setting Targets When AutoLog is ON



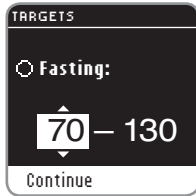
1. Press and hold the **OK** button until the meter turns on.
2. From the setup menu, select **Targets**. Press the **OK** button.
3. **Set Targets** will be highlighted. Press the **OK** button.



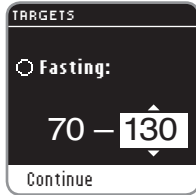
4. The Fasting Target range will appear (70 - 130 mg/dL). You can **Accept** the target by pressing the **OK** button.



5. To change the Target, press the **▼** button to highlight **Change** and press the **OK** button.



6. Use the ▲ or ▼ button to change the highlighted value. When you see the value you want, press the **OK** button, and you will move to the next Fasting Target value (130 mg/dL).



7. To change this Fasting Target value, use the ▲ or ▼ button and press the **OK** button when you are finished.



8. Press the **OK** button to move to the Before Meal target.



9. The Before Meal Target range will appear (70 - 130 mg/dL). You can **Accept** the Targets by pressing the **OK** button.



10. To change the Target, press the ▼ button to highlight **Change** and press the **OK** button.



11. Use the ▲ or ▼ button to change the highlighted Before Meal Target value. When you see the Target value you want, press the **OK** button, and you will move to the next Target value.



12. To change the Target, use the ▲ or ▼ button and press the **OK** button when you are finished.



13. Press the **OK** button to move to the After Meal target.



14. The After Meal Target range will appear (70 - 180 mg/dL). You can **Accept** the highlighted Target by pressing the **OK** button.

15. To change the After Meal Target, press the ▼ button to select **Change** and press the **OK** button.



16. Use the ▲ or ▼ button to change the Target value. When you see the Target value you want, press the **OK** button, and you will move to the next Target value. Press the **OK** button when you are finished.



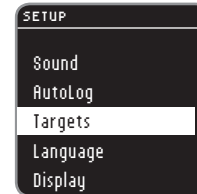
17. Press the **OK** button to see all targets.



18. A screen confirms that Targets are set. **Done** will be highlighted. Press the **OK** button.

To go back to Change the Targets, press the ▼ button to highlight **Change** and then press the **OK** button. This will bring you back to the Fasting screen.

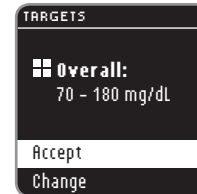
Setting Targets When AutoLog is OFF



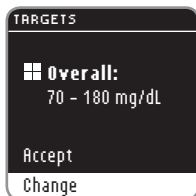
1. Press and hold the **OK** button until the meter turns on.
2. From the Setup Menu, select **Targets**. Press the **OK** button.



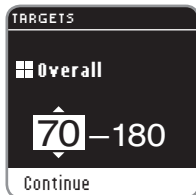
3. **Set Targets** will be highlighted. Press the **OK** button.



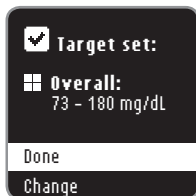
4. The Overall Target screen will appear. You can **Accept** the preset Target range by pressing the **OK** button.



- To change the preset Target, use the ▼ button to highlight **Change** and press the **OK** button.



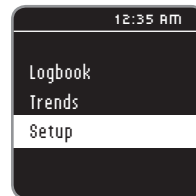
- If you select **Change**, press the ▲ or ▼ button until you see the Target value you want. Press the **OK** button to move to the next Target value and use the ▲ or ▼ button to change the Target. Press the **OK** button to **Continue**.



- A screen will confirm that your Overall Target range is set. **Done** will be highlighted. Press the **OK** button.

To go back to Change the Targets, press the ▼ button to highlight **Change** and press the **OK** button. This will bring you back to the Overall Target range screen shown above.

Language



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



- From the Setup Menu, scroll down to Language and press the **OK** button.



- Press the ▲ or ▼ button to highlight your choice. Press the ▼ button to see more choices. Press the **OK** button.

This screen example shows the language selections. The language order may differ depending on your country.



- Press the **OK** button to confirm your choice.

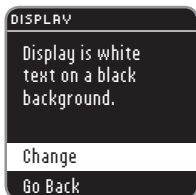
The Setup Menu will appear in the language you selected.

Display Background

You can change the Display to show black background with white text, or white background with black text.



1. Press and hold the **OK** button until the meter turns on.
2. From the Setup menu, scroll down to **Display** and press the **OK** button.



3. To change the display, select **Change** and press the **OK** button. To keep the current setting, select **Go Back** and press the **OK** button.



Your new display background will show. A screen will confirm your choice. The Setup menu will appear with your choice.

Customer Service (on the Setup Menu)

This option is needed only if you are speaking to a Customer Service representative. It is not for use at any other time. The Customer Service representative will give you a code to use to verify certain settings.

Caring for Your Meter

- Store 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 meter and test strips to excessive humidity, heat, cold, dust or dirt.
- Clean your meter as recommended in the next section.

Cleaning and Disinfection

Your CONTOUR®NEXT meter should be cleaned and disinfected once a week. Use **only** Clorox® Germicidal Wipes containing 0.55% sodium hypochlorite (bleach), which has been proven to be safe to use with the CONTOUR NEXT meter.

Refer to the lancing device insert provided with your kit for detailed instructions for cleaning and disinfecting the lancing device.

Cleaning is the removal of visible dirt and debris, but does not reduce the risk for transmission of infectious diseases. Your CONTOUR NEXT system should be cleaned of dirt and debris once a week.

Disinfecting (if performed properly) reduces the risk of transmitting infectious diseases. Your meter and lancing device should be disinfected once a week.

WARNING

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

NOTE: 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.

Signs of Deterioration

The cleaning and disinfecting directions provided should not cause any damage or degradation to the external case, buttons or display.

Your CONTOUR NEXT meter has been tested for 260 cycles of cleaning and disinfection (one cycle per week for 5 years). This device has been demonstrated to withstand 5 years of

cleaning and disinfection without damage. You should contact Customer Service for assistance if your device malfunctions for any cause or if you notice any changes in the meter case or display.

Clorox® Germicidal Wipes are available for purchase online at <http://www.officedepot.com> or <http://www.amazon.com> or for more information contact Customer Service at 1-800-348-8100 (available Monday through Sunday, 8:00 am to 12 Midnight, Eastern Time).

For more information see:

US Food and Drug Administration. Use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

Centers for Disease Control and Prevention. CDC clinical reminder: use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens. US Department of Health and Human Services; 8/23/2010. <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

Cleaning Your Meter

Supplies Needed for Cleaning:

- Clorox® Germicidal Wipes containing 0.55% sodium hypochlorite (bleach)
- Paper towels

1. Carefully clean the meter with Clorox Germicidal Wipes until all soil is removed.

Do not allow cleaning solution to run into the meter through areas such as around the buttons or the meter's test strip or data ports.

2. Dry as necessary with a clean paper towel.

Disinfecting Your Meter

Supplies Needed for Disinfecting:

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

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

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

Using a new Clorox® Germicidal Wipe, carefully wipe all outer surfaces of your meter until wet. *Do not allow cleaning solution to run into the meter through areas such as around the buttons or the meter's test strip or data ports.*



Buttons



Test Strip Port

2. Dry all meter surfaces and test strip port using a clean paper towel if needed.

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.

Transferring Results to a Computer

You can transfer test results from the CONTOUR[®]NEXT meter to a computer, where they can be summarized in a report with graphs and tables. To make use of this feature, you need GLUCOFACETS[®]DELUXE diabetes management software and a USB-to-Micro USB cable. This type of cable is available in the electronics department of most retail stores. For a free download of the software go to www.glucofacts.ascensia.com or contact Customer Service. See the back cover for contact information.

IMPORTANT:

- The CONTOUR NEXT meter has not been tested or certified for use with any software other than GLUCOFACETS DELUXE diabetes management software. Ascensia Diabetes Care is not responsible for any erroneous results from the use of other software.
- You cannot perform a blood sugar test when the CONTOUR NEXT meter is connected to a computer.

Batteries



When the batteries are low, the **Low Batteries** screen displays. Press the **OK** button to acknowledge the warning. The system continues to operate normally, but the low batteries icon appears on the Main menu until the batteries are replaced. Change the batteries right away. You may only test about 10 more times over the next three days before the batteries run out.



When you are no longer able to perform a test due to low batteries, the **Dead Batteries** screen will show. Change the batteries immediately.

Changing the Batteries



Turn off your meter before changing your batteries. Press firmly on the battery cover and slide in the direction of the arrow.

HINT: If you put the new batteries in the meter within 5 minutes of taking the old ones out, all your settings and results will be saved. If you take more than 5 minutes to change the batteries, check the date and time to ensure they are still correct. Other settings and results will be saved.

Remove both of the old batteries. Replace with two 3-volt lithium batteries (DL2032 or CR2032).



Place new batteries into the battery compartment with the "+" side up. Slide the battery cover back into place.

Discard batteries according to your local environmental regulations.

WARNING

Keep batteries away from children. Lithium batteries are poisonous. If swallowed, immediately contact your physician or poison control center.

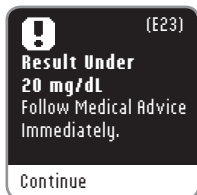
Error Detection Displays

The meter display screen provides information for test result, strip, or system errors.

If there is an error the meter will beep 2 times. Follow the on-screen instructions. Press the **OK** button if needed.

If you experience continued errors, contact Customer Service. See the back cover for contact information.

For Result Above 600 mg/dL or Below 20 mg/dL



- If your blood sugar reading is under 20 mg/dL, the **“Follow Medical Advice Immediately”** screen will display and the meter will beep twice. Contact your health care professional.



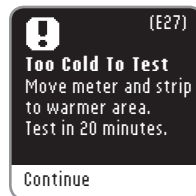
- If your blood sugar reading is over 600 mg/dL, the next screen will tell you to retest. The meter will beep twice. Wash and dry your hands well and retest with a new strip.
- If results are still over 600 mg/dL, **“Follow Medical Advice Immediately”** is displayed.

Strip Errors



A strip error displays if a used strip is inserted, the strip is inserted upside down, or the wrong strip is inserted.

Testing Condition Errors



A testing condition error displays when the meter is too cold or too hot to test.

System Errors



A system error displays when either the meter software or hardware malfunctions.

System Support Information

Speak to a Customer Service representative before returning your meter for any reason. See the back cover for contact information.

Checklist:

When speaking with Customer Service:



Have your CONTOUR[®]NEXT blood glucose meter, CONTOUR[®]NEXT test strips, and CONTOUR[®]NEXT control solution available when you phone.

Locate the model number (A) and serial number (B) on the back of the meter.

Locate the test strips' expiration date on the bottle. Check the battery status.





Parts Information

To replace missing parts or reorder supplies, call Customer Service. See the back cover for contact information.

Two 3-volt Lithium Batteries DL2032 or CR2032
CONTOUR[®]NEXT User Guide
CONTOUR[®]NEXT Test Strips
CONTOUR[®]NEXT Control Solution Level 1
CONTOUR[®]NEXT Control Solution Level 2

Symbols Used

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

Symbol	What it Means	Symbol	What it Means
	Use by date (last day of month)		In Vitro Diagnostic Medical Device
	Consult instructions for use		Batch code

Technical Information

Accuracy

The CONTOUR[®]NEXT blood glucose monitoring system was tested using 100 capillary blood samples and three lots of CONTOUR[®]NEXT test strips. The results were compared to the YSI[®] Glucose Analyzer laboratory reference method, traceable to the CDC hexokinase method. The tables below show how well the two methods compared.

Table 1 - System accuracy results for glucose concentration < 75 mg/dL

Difference range in values between YSI laboratory reference method and CONTOUR NEXT meter	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Number (and percent) of samples within specified range	74 of 78 (94.9%)	77 of 78 (98.7%)	78 of 78 (100%)

Table 2 - System accuracy results for glucose concentration ≥ 75 mg/dL

Difference range in values between YSI laboratory reference method and CONTOUR NEXT meter	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Number (and percent) of samples within specified range	390 of 522 (74.7%)	513 of 522 (98.3%)	521 of 522 (99.8%)	522 of 522 (100%)

Acceptance criteria in ISO 15197: 2003 are that 95% of all differences in glucose values (i.e., between reference method and meter) should be within 15 mg/dL for glucose values less than 75 mg/dL, and within 20% for glucose values greater than or equal to 75 mg/dL.

Technical Information

Precision

To assess precision under repeatability conditions, venous human blood samples were pooled and adjusted to a hematocrit of 42%. Blood was collected in tubes using sodium heparin as the anticoagulant. The glucose levels of the test solutions were prepared either by allowing samples to age to a final concentration or by using the aqueous 20% glucose solution to adjust the final test concentration. Five glucose levels were evaluated.

For each of 3 lots of sensors, ten CONTOUR[®]NEXT instruments were tested with ten replicates. In total three hundred replicates were used for each blood glucose level. The mean blood glucose levels, pooled standard deviations and %CVs were calculated and are presented here.

Repeatability

Glucose Level (mg/dL)	40	87	122	206	327
Pooled SD	0.8	1.2	1.6	2.7	4.6
%CV	2.1	1.4	1.3	1.3	1.4

To assess intermediate measurement precision, the performance of ten CONTOUR[®]NEXT meters was evaluated with three lots of sensors. The evaluation was performed by three operators who utilized three liquid control glucose levels under normal conditions of use over the course of 10 days. In total, three hundred sensors were used for each glucose level. The Grand Mean, pooled standard deviation and pooled %CV for each glucose level were calculated and are presented here.

Intermediate Precision

Glucose Level (mg/dL)	Glucose Level (mg/dL)	Pooled SD	Pooled CV (%)
Low (30 - 50)	43.4	0.7	1.6
Normal (96 - 144)	129.0	1.8	1.4
High (280 - 420)	383.8	6.3	1.6

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, 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

Ketones (Ketoacidosis):

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

High blood glucose (Hyperglycemia):

- frequent urination
- excessive thirst
- blurred vision
- increased fatigue
- hunger

WARNING

If you are experiencing any of these symptoms, test your blood glucose. If your test result is under 50 mg/dL or above 250 mg/dL, contact your health care professional immediately.

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

Specifications

Test Sample: Capillary whole blood

Test Result: Glucose measurements are reported as plasma equivalents.

Sample Volume: 0.6 µL

Measuring Range: 20 - 600 mg/dL

Countdown Time: 5 seconds

Memory: Stores most recent 800 test results

Battery Type: Two 3-volt lithium batteries (DL2032 or CR2032)

Battery Life: Approximately 1000 tests (1 yr. average use)

Control Solution Operating Temperature Range: 59°F–95°F

Meter Operating Temperature Range: 41°F–113°F

Humidity: 10 - 93% RH

Dimensions: 3.15" (H) x 2.09" (W) x 0.50" (T)

Weight: 1.6 oz. (45 grams)

Meter Life: 5 years

Sound Output: 55 to 80 dBA at a distance of 10 cm

Electromagnetic Compatibility (EMC): The CONTOUR[®]NEXT meter complies with the electromagnetic requirement 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 meter. The CONTOUR NEXT 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 meter meets the requirements of IEC 61326-1 for radio frequency interference. To avoid radio frequency interference, do not use the CONTOUR NEXT meter near electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

References

1. Wickham NWR, et al. Unreliability of capillary blood glucose in peripheral vascular disease. *Practical Diabetes*. 1986;3(2):100.
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3. Desachy A, et al. Accuracy of bedside glucometry in critically ill patients: influence of clinical characteristics and perfusion index. *Mayo Clinic Proceedings*. 2008;83(4):400-405.
4. US Food and Drug Administration. Use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
5. Centers for Disease Control and Prevention. CDC clinical reminder: use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens. US Department of Health and Human Services; 8/23/2010. <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>
6. American Diabetes Association. Standards of medical care in diabetes—2015. *Diabetes Care*. 2015;38(supplement 1):S10.
7. *Tietz Fundamentals of Clinical Chemistry*, 5th Edition, Edited by Burtis CA and Ashwood ER, W. B. Saunders Co., Philadelphia, PA 2001, p. 444.

Principles of the Procedure: The CONTOUR®NEXT blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the 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 is required.

Comparison Options: The CONTOUR®NEXT system is designed for use with capillary whole blood. Capillary samples should be applied directly to the CONTOUR NEXT test strip. Comparison to 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)⁷ with CONTOUR®NEXT test strips.

Limitations

Lipemic Specimen: Cholesterol concentrations >1,168 mg/dL or triglyceride concentrations >4,709 mg/dL may produce inaccurate results.

Peritoneal Dialysis Solutions: Icodextrin does not interfere with CONTOUR NEXT test strips.

Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.

Hematocrit: CONTOUR NEXT test strip results are not significantly affected by hematocrit levels in the range of 15% to 65%.

Interference: Certain substances occurring in the blood naturally (uric acid, bilirubin) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect results. The limiting concentrations of these compounds are listed on your test strip insert.

Warranty

Manufacturer's Warranty: Ascensia Diabetes Care warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for 5 years from the date of original purchase (except as noted below). During the stated 5-year period, Ascensia Diabetes Care shall, at no charge, replace a unit found to be defective with an equivalent or current version of the owner's model.

Limitations of Warranty: This warranty is subject to the following exceptions and limitations:

1. A 90-day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to replacement due to defects in parts or workmanship. Ascensia Diabetes Care shall not be required to replace any units that malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by someone other than Ascensia Diabetes Care, or failure to operate the instrument in accordance with instructions. Further, Ascensia Diabetes Care assumes no liability for malfunction of or damage to Ascensia Diabetes Care instruments caused by the use of test strips or control solution other than the appropriate products recommended by Ascensia Diabetes Care (i.e., CONTOUR[®]NEXT test strips and CONTOUR[®]NEXT control solutions).
3. Ascensia Diabetes Care reserves the right to make changes in the design of this instrument without obligation to incorporate such changes into previously manufactured instruments.
4. Ascensia Diabetes Care has not validated the performance of the CONTOUR[®]NEXT blood glucose meter when used with any test strips other than CONTOUR NEXT test strips, and therefore does not warrant the

performance of the CONTOUR[®]NEXT meter when used with any test strips other than CONTOUR[®]NEXT test strips or when the CONTOUR NEXT test strip is altered or modified in any manner.

5. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR NEXT meter or test results when used with any control solution other than CONTOUR[®]NEXT control solution.
6. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR NEXT meter or test results when used with any software other than the CONTOUR[™]DIABETES APP (where supported) or the GLUCOFAC[®]DELUXE diabetes management software (where supported) from Ascensia Diabetes Care.

ASCENSIA DIABETES CARE MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY FOR THIS PRODUCT. THE OPTION OF REPLACEMENT, DESCRIBED ABOVE, IS THE ONLY OBLIGATION OF ASCENSIA DIABETES CARE UNDER THIS WARRANTY.

IN NO EVENT SHALL ASCENSIA DIABETES CARE BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF ASCENSIA DIABETES CARE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. Some States do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you. This warranty gives you specific legal rights and you may also have other rights which vary from State to State.

For warranty service: Purchaser must contact Ascensia Diabetes Care Customer Service for assistance and/or instructions for obtaining service of this instrument. See the back cover for contact information.

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Eastern Time.



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