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 overthe-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

- **I** 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.



* 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.



Table of Contents

Intended Use, Important Safety Information	i
Your CONTOUR®NEXT Meter	2
Initial Setup	5

Getting Ready to Test	10
Getting the Blood Drop - Fingertip Testing	14
Test Results	17
Alternative Site Testing (AST) - Palm	20
Expected Test Result Values	25
Control Solution Testing	25
Test Reminders	

Logbook	32
Notes	33
Trends (Averages and Summaries)	34
Setup	
AutoLog	44

Caring for Your Meter	53
Cleaning and Disinfection	54
Transferring Results to a Computer	
Batteries	58
Error Detection Displays	60

System Support Information	62
Technical Information	
Symptoms of High or Low Blood Glucose	66
Specifications	67
Warranty	70
Index	72

Your CONTOUR®NEXT Metel

Your CONTOUR®NEXT Meter



OK Button

Press and hold to

turn the meter On

Press to accept a

highlighted selection

or Off

Using the Meter Buttons

Up/Down

Press to scroll up

Press and hold

Press to

scroll down

Press and hold

to keep scrolling

to keep scrolling

- 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 \blacktriangle or \blacktriangledown 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:

 ✓ Language: English ✓ OK X No 		
Symbol	What it Means	
2	When you select More Information.	
	On confirmation screens and when blood sugar test result is in Target range.	
8	On error screens and when blood sugar test result is either below 20 mg/dL or above 600 mg/dL.	
Ð	When blood sugar test result is above Target.	
Ð	When blood sugar test result is below Target.	

GETTING STARTED

Contour

lext



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.

LANGUAGE	
🗸 English 🗌	
Español	
Italiano	
Deutsch	
Français	

- 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 selections. The language order may differ depending on your country.
- 3. When your language is highlighted, press the **OK** button.

🔽 Language:

English

- A screen confirms your language.
- 4. Press the **OK** button to confirm.
- 🗸 0K × No

SETUP

- Time: 1:03 PM Accept Change
- 5. The time will appear and you can Accept or Change.

GETTING STARTED

To Change Time

To Change Time



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

2. Use the \blacktriangle or \checkmark buttons to make

any changes to your hour. When the

desired choice is highlighted, press

the **OK** button to move to minutes.



Continue

TIME



- 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 #M 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



- If you want to change the date, use the ▼ button to select Change and press the OK button.
- Use the ▲ or ▼ buttons to change the year. Press the OK button to move to month.
- DATE

Continue

DATE

Change Year:

8/23/12



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



- Use the ▲ or ▼ buttons to change the day. Press the OK button.
- Date set: 9/23/12
- A screen confirms your date setting. Press the OK button to continue to view the Target Range settings.

Done

Change

6

GETTING STARTED

Target Ranges

9 0

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.

TARGETS

Target ranges are your blood sugar goals.

Continue More Inf<u>ormation</u>

- TARGETS
- Target ranges can be changed later in the Setup menu.

View pre-set Targets

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.

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

ARGETS O Fasting: 70 - 130 mg/dL

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

Continue

TARGETS

Before Meal: 70 - 130 mg/dL Continue



- **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.
- 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

i 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

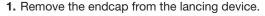
The lancing device graphics are for illustration purposes only. Your lancing device may look different. Refer to your lancing device insert for detailed instructions on preparing the lancing device.

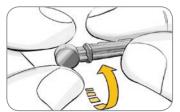
WARNING: Potential Biohazard

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.

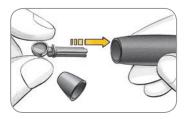
WARNING

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





2. Loosen the round protective cap on a lancet by rotating the cap 1/4 turn, but do not remove the cap.

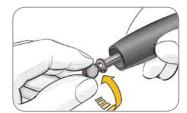


3. Insert the lancet firmly into the lancing device until the lancet comes to a complete stop.

TESTING

Getting Ready to Test





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

5. Replace the endcap.

- - 6. 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**
- 1. Remove a CONTOUR®NEXT test strip from the bottle. Tightly close the bottle lid immediately after you have removed the test strip.



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

Contour



3. 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.

Apply More Blooc

• 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

• All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

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.

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

Apply More Blood

patients!^{4,5}



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.

(E01) A Too Little Blood Remove used strip. Repeat test with new 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.

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

puncture site.

formed.

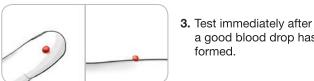
and finger toward the

puncture site to form a

a good blood drop has

drop of blood. Do not

squeeze around the



Suggested drop size



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.

AutoLog

TESTING

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.

C 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.

fifter 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.

RUTOLOG	
Testing	
No Mark	
O Fasting	
📫 Before Meal	
🋱 After Meal	
	_

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).

AUTOLOG
Select Mark
No Mark
O Fasting
🙃 Before Meal
🛱 After Meal

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.

Test Results with AutoLog Off



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

OPTIONS Main Menu Add Note Add Reminder

TESTING

Test Results with AutoLog On

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.



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.



OPTIONS

Main Menu Add Note Add Reminder 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







The lancing device graphics are for illustration purposes only.

1. Wash your hands and the puncture site with soap and warm water.

Rinse and dry well.

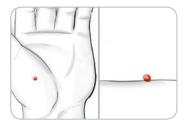
- 2. Attach the clear AST endcap to the lancing device. Refer to the lancing device insert for detailed instructions.
- **3.** Select a puncture site from a fleshy area on the palm. Avoid veins, moles, bones and tendons.
- 4. Press the lancing device firmly against the puncture site and then press the release button.

TESTING

Site Testing

Getting a Blood Drop for Alternative Site Testing

TESTING



- **5.** Maintain steady pressure until a small, round blood drop forms.
- Non-
- 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:

- Smeared 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.

(EO1) Too Little Blood Remove used strip. Repeat test with new 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.

TESTING

Expected

TESTING

Quality Control



TESTING

Control Solution Testing

- 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.



0-348-

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



OPTIONS

Main Menu

Add Reminder

Add Note

- **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.
- REMINDER Countdown: 2 hrs Start Change

Go Back

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

TESTING

Turning Off a Reminder After Testing

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

🕒 REMINDER	о т.
Reminder in: 30 mins	2. Τα Ρι
	A sc
Stop	The
Change	cloc
Go Back	the s

o stop the Countdown, select Stop. ress the **OK** button.

creen confirms your choice.

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

Changing the Reminder Time



TESTING

Turning Off a Reminder After Testing

1. Press the \blacktriangle or \checkmark button to select the correct hours. Press the **OK** button to continue.



- **2.** Press the \blacktriangle or \checkmark button to select the minutes (in 15 minute increments).
- 3. Press the OK button to continue.



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

OPTIONS Main Menu Add Note Change Reminder

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:

Logbook	
Trends	
Setup	

- 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.



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

FEATURES

LOGBOOK End of Logbook Back to Beginning Previous Screen

Main Menu

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.

Main Menu Add Note Add Reminder

OPTIONS

- Press the ▼ button to select fidd Note. If you have marked your test result using AutoLog, that entry will have a check in front of it.
- notes After Meal Time After Meal Don't Feel Right Sick Stress
- 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 Irends. 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 <u>test result</u> Above Target, 10 <u>test results</u> In Range and 2 <u>test results</u> 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.









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 mo/dL for the 14 days.

4. Continue to press the **▼** button to see

your 14-day Before Meal Average.

 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.

14-day After Meal Summary. This

Above Target, 19 test results In Range

7. Press the ▼ button to see your

example shows 3 test results

and 1 test result Below Target. In

this example the Target Range is

70 - 180 mg/dL for the 14 days.

Viewing Trends with AutoLog Or

FEATURES



 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

TRENDS	
	Ot
End of Trends	thr
	Yo
	aft
Que Mare Trende	thr
See More Trends	
Main Menu	on

TRENDS 7-Day Trends 14-Day Trends 30-Day Trends 90-Day Trends Main Menu

- Other trend time periods are available hrough the See More Trends menu. You will see the See More Trends menu after the Overall Average screen. Scroll hrough your Trends using the ▼ button on your meter.
- 1. Select See More Trends and press the OK button.
- 2. 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.

- **1.** Turn on the meter by pressing and holding the **OK** button.
- 2. Press the ▼ button to select Irends 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.
- 4. Press the OK button to See More Trends or select Main Menu.
- See More Trends Main Menu

End of Trends

RENDS

FEATURES

Changing the Trends Time Period

37

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:



FEATURES

Setup

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

12:35 AM	
	The Main Menu
Logbook	Irends and Setu
Trends	2. Press the ▼ k
Setup	3. Press the OK
	0. 1 1033 the O N

has 3 choices: Logbook,

p.

button to highlight Setup.

C button.

Setting a Reminder

SETUP Reminder: Off Date Time Sound AutoLoa



- 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

C	REMINDER
	Reminder in: 1 hr 45 mins
	Stop
	Change
l	Go Back

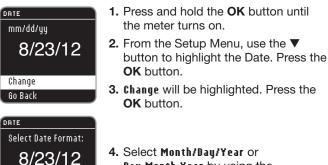
- 1. Go to the Main Menu. Select Setup and press the OK button.
- 2. With Reminder: On selected, press the OK button.
- 3. Select \$top and press the OK button.
- 4. The Countdown is now stopped.

A screen confirms your choice.

V Reminder is stopped.

Contour

Date



Month/Day/Year Day.Month.Year

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.

Continue

FEATURES

Date



6. Change month (highlighted) by using the \blacktriangle or \blacktriangledown button. Press the OK button.

DATE Change Day: 9/23/12 Continue

7. Change day by using the \blacktriangle or \blacktriangledown button. Press the **OK** button.

🗸 Date set:

9/23/12

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

Time

Done

Change



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

TIME

12-hour clock: 1:03 PM

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

Change Go Back



TIME Select Time Format: **1:03** PM 12-hour clock 24-hour clock

TIME

Change hour:

Continue

FEATURES

Time

2:03 PM

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

 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.

✓ Time set: 2:05 MM

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

Sound

Change

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.

SETUP
Date
Time
Sound: On
Autolog
Targets

- 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.

sound is On. Sound is On. Turn Off 60 Back

To turn off the Sound, select **Iurn 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

SETUP	
	1. Press and hold the
Time	the meter turns on.
Sound	2. From the Setup me
AutoLog: On	AutoLog and press t
Targets	OK button.
Language	

AUTOLOG	З
AutoLog is On.	
Accept	4
Turn Off More Information	

CONFIRM TARGET
III Overall: 70 – 180 mg/dL
Accept
Change

FEATURES

AutoLog

- **OK** button until
 - enu. choose the
- B. Make one of the following selections: Accept, Turn Off (Turn On), or More information.
- I. 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

- ARGETS Target ranges are your blood sugar goals.
- Set Targets More Information
- 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

target by pressing the **OK** button.

(70 - 130 mg/dL). You can Accept the

TARGETS

O Fasting: 70 - 130 mg/dL Accept

Change

TARGETS

Accept

Change

O Fasting: 70 - 130 mg/dL





6. Use the \blacktriangle or \checkmark 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 \blacktriangle or \blacktriangledown button and press the **OK** button when you are finished.

✓ Target set: O Fasting: 70 - 130 mg/dL

Done Change

FEATURES

Setting Targets When AutoLog is ON

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

8. Press the OK button to move to the

Before Meal target.

ARGETS

🗰 Before Meal: 70 - 130 mg/dL Accept Change

TARGETS 🗰 Before Meal: 70 – 130 Continue

TARGETS Before Meal:

- 70 130 Continue
 - 12. To change the Target, use the ▲ or ▼ button and press the **OK** button when you are finished.

10. To change the Target, press the ▼

button to highlight Change and

11. Use the \blacktriangle or \blacktriangledown 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

press the **OK** button.

next Target value.

🔽 Target set:

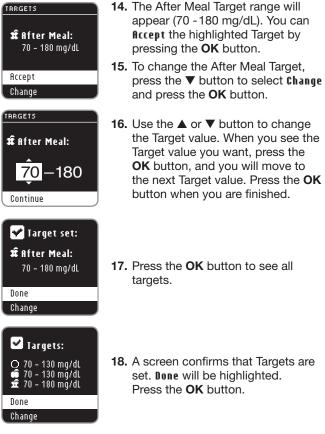
🗰 Before Meal:

Done

Change

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

70 - 130 mg/dL



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

SETUP Sound AutoLog Targets Language Display

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

ARGETS

Target ranges are your blood sugar goals.

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

TARGETS

Overall: 70 - 180 mg/dL Accept Change

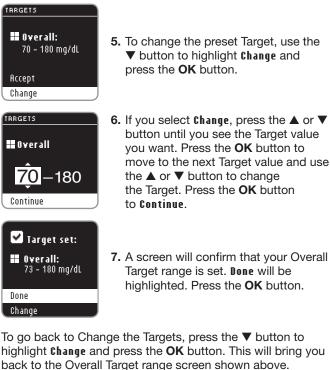
FEATURES

Set Targets More Information

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

48 next

FEATURES



- 5. To change the preset Target, use the ▼ button to highlight Change and press the **OK** button.
- 6. If you select Change, press the \blacktriangle or \blacktriangledown button until you see the Target value you want. Press the OK button to move to the next Target value and use the \blacktriangle or \checkmark button to change the Target. Press the **OK** button

Language





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





3. Press the \blacktriangle or \blacktriangledown 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.

- 🔽 Language: English 🗸 0K 🗶 No
- 4. Press the OK button to confirm your choice.

The Setup Menu will appear in the language you selected.

FEATURES

Setting Targets When AutoLog is OFF

Language

Display Background

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

the meter turns on.

SETUP Targets Language Display Customer Service Main Menu

DISPLAV

Display is white text on a black background.

Change Go Back



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

vour choice.

1. Press and hold the **OK** button until

2. From the Setup menu, scroll down to

Display and press the OK button.

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

HELP

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.

and **Disinfection**

Cleaning

HELP

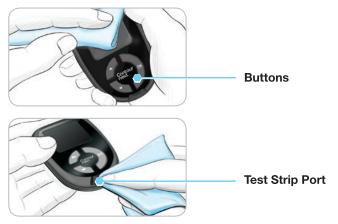
Disinfecting Your Meter

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.*



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.

Cleaning and Disinfection

HELP

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 GLUCOFACTS®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 GLUCOFACTS 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

A40 Low Batteries Replace batteries soon. 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.

A42 Dead Batteries Replace batteries now.

Contour

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.

59

Changing the

Batteries

HELP

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 ${\bf OK}$ 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

(E	23)
Result Under 20 mg/dL Follow Medical Adv Immediately.	vice

Continue

Error Detection Displays

HELP

(E22) Result Over 600 mg/dL Wash hands or test site. Repeat test with new strip. Continue 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 your blood sugar reading is under

your health care professional.

20 mg/dL, the "Follow Medical Advice

Immediately" screen will display and the meter will beep twice. Contact

 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
Σ	Use by date (last day of month)	IVD	In Vitro Diagnostic Medical Device
l	Consult instructions for use	LOT	Batch code

Parts

Information

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 $\geq 75 \mbox{ mg/dL}$

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

Contour

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

65

- Accuracy

Technical Information

TECHNICAL NFORMATION

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

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.

High blood glucose (Hyperglycemia):

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

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.

66

References

- Wickham NWR, et al. Unreliability of capillary blood glucose in peripheral vascular disease. *Practical Diabetes*. 1986;3(2):100.
- 2. Atkin SH, et al. Fingerstick glucose determination in shock. *Annals of Internal Medicine*. 1991;114(12):1020-1024.
- **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

- 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
- 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.

References

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 GLUCOFACTS[®]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. Warranty

TECHNICAL INFORMATION

Index

After Meal Marker (AutoLog)1	6
Alternative Site Testing (AST)	0
AutoLog (Meal Markers) 1	6
Averages (Trends)	4
Batteries	8
Low Batteries	8
Replacement	9
Before Meal Marker (AutoLog)1	6
Care and Maintenance	3
Cleaning and Disinfection5	4
Control Solution Testing	5
Display Background	2
Errors	0
Fasting Marker1	6
GLUCOFACTS®DELUXE diabetes management system	8
Lancing1	1
Logbook	2
Meal Markers (AutoLog)1	6
Meter Settings	8
Notes	3
Reminders (Test Reminders)2	9
Setup3	8
AutoLog On or Off44	4
Date4	0
Target Settings72	2
Time	1
Sound	3

Specifications	67
Summaries (Trends)	
Symptoms of High or Low Blood Glucose	
System Support Information	62
Target Ranges (Fasting, Before Meal, After Meal)	45
Target Settings	45
Technical Information	64
Test Reminders	29
Getting a Reminder	31
Setting a Reminder	
Setting a Reminder After Testing	29
Turning Off a Reminder	
Testing Your Blood Sugar	10
After Meal	16
Before Meal	16
Fasting	16
Getting Ready to Test	10
Test Results	25
Transferring Results to a Computer	58
Trends (Averages & Summaries)	
Warranty	70

Distributed by: Ascensia Diabetes Care US, Inc. 5 Wood Hollow Road Parsippany, NJ 07054

www.diabetes.ascensia.com

Customer Service: 800-348-8100 Available Monday through Sunday, from 8:00 am through 12:00 Midnight, Eastern Time.



For more information on patents, and related licenses, see: www.patents.ascensia.com

Ascensia, the Ascensia Diabetes Care logo, Clinilog, Contour, Glucofacts and the No Coding logo are trademarks and/or registered trademarks of Ascensia Diabetes Care Holdings AG. All other trademarks are the property of their respective owners.

