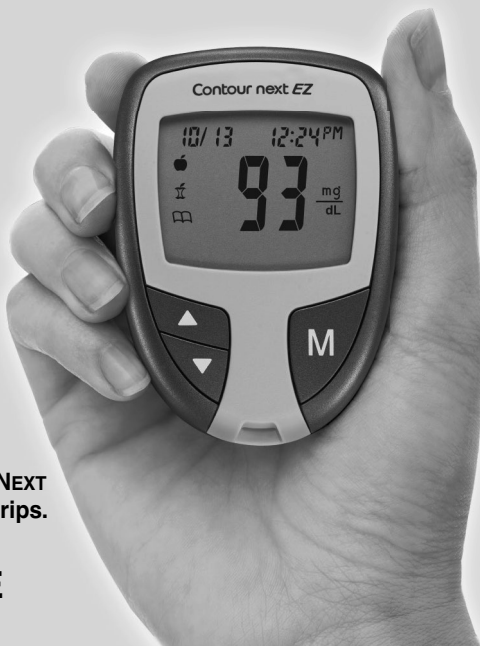


Contour® next EZ

Blood Glucose Monitoring System

Online meter registration available at
www.diabetes.ascensia.com or call our
Customer Service.



Uses only CONTOUR®NEXT
blood glucose test strips.

USER GUIDE

CONTACT INFORMATION

Customer Service is available Monday through Sunday, 8:00 am through 12:00 Midnight, Eastern Time. If this is a medical emergency, please contact your health care professional or dial 911. To leave a message for Customer Service, remain on the line. One of our representatives will return your call as soon as possible.

1-800-348-8100

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

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

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INTENDED USE


The CONTOUR[®]NEXT EZ blood glucose monitoring system is an over the counter (OTC) device utilized for **self-testing** by persons with diabetes at home for **the quantitative** measurement of glucose in whole blood, 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 EZ blood glucose monitoring system is indicated for use with fresh fingertip capillary whole blood samples. The clinical utility of this device is to aid in monitoring the effectiveness of your diabetes control program.

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

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 EZ system is working properly.

IMPORTANT SAFETY INFORMATION

-  Read your CONTOUR NEXT EZ 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 to help avoid inaccurate results.
- Used test strips and lancets are possible biohazards and must be disposed of as medical waste.

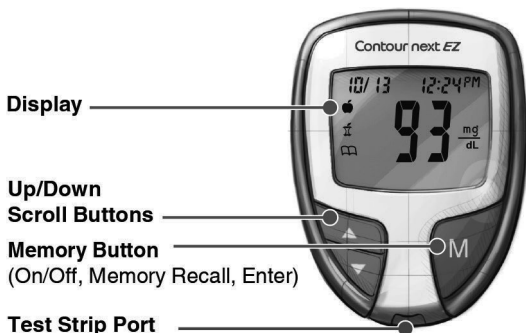
WARNING

- 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!^{1,2}
 - 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, see *Cleaning and Disinfection* in section 2, *Testing*.
 - This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.
 - Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.
-
- Examine product for missing, damaged, or broken parts. If the test strip bottle is open inside the new box of strips, do not use those strips. Contact Customer Service for replacement parts. See *Contact Information*.

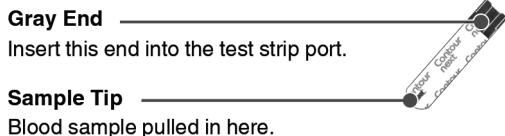
1

GETTING STARTED

Your CONTOUR[®]NEXT EZ meter



Your CONTOUR NEXT test strip





Your Meter Display

The picture below shows all the symbols that appear on your meter display. To view, with the meter off, press and hold ▲ or ▼. All display segments will appear for 10 seconds. If you need more than 10 seconds to check the display, press and hold ▲ or ▼ again.



While all characters are displayed, it is very important to verify that **8.8.8** is fully displayed. If there are missing segments, see *Error Codes and Symbols* in section 4, *Technical, Service & Care*. This may affect the way you see your results.

Icon	What It Means
88/88	Top area on the display presenting date and time.
🍏	Pre-meal result marker.
🍴	Post-meal result marker.
📖	Identifies a Logbook entry.
🕒	Indicates a reminder has been set.
8.8.8	Center area on the display that shows either your test result or any error codes.
🔋💧	The meter is ready to test.
✓	Control solution result marker.
🌡️	Indicates it is too cold or too hot for your meter to test accurately.
A	Indicates Average.
mmgl 7dL	Results are displayed as mg/dL or mmol/L. The 7 appears when viewing 7 day HI-LO summary.

Icon	What It Means
d.m/d	Day/month format.
	The batteries are low and need to be changed, and will remain on display until batteries are changed.
AM PM	Appear if the meter is in 12 hour setup.
	Indicates sound is turned on.

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

Your Meter Features

Easy: The CONTOUR NEXT EZ blood glucose monitoring system is about simplicity. You will notice its simple approach the first time you see it.

Automatic: Your CONTOUR NEXT EZ meter is designed with No Coding technology, to automatically code itself every time you insert a CONTOUR NEXT test strip. It will even tell you when a test strip is underfilled.



Programmed: Your CONTOUR NEXT EZ meter has been preset at the factory with the standard date and time for your convenience.

- Your meter has been preset and locked to display results in mg/dL (milligrams of glucose per deciliter). In some countries, the meters are preset to display units in mmol/L (millimoles of glucose per liter);
- Results in mg/dL will never have a decimal point;
- Results in mmol/L will always have a decimal point.

Example: $96 \frac{\text{mg}}{\text{dL}}$ or $5.3 \frac{\text{mmol}}{\text{L}}$

Check your display to ensure that results are being displayed in mg/dL. If they are not, contact Customer Service. See Contact Information.

Customizable: The CONTOUR NEXT EZ meter allows you to set personal choices for some features. For more information, see section 3, *Setup and Use*.

Important Safety Information

- ***Always keep the test strips in the original bottle. Tightly close the bottle immediately after removing a test strip.*** The bottle is designed to keep the test strips dry. Exposure to room humidity from leaving the bottle open or not storing them in the original bottle can damage your test strips. This could lead to inaccurate test results.
- ***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.***
- ***Test strips are for single use only. Do not use a test strip that appears damaged or has been used.***
- ***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.
- ***Do not press the test strip against your finger when testing.*** This may block the sample tip.
- ***Let the meter and test strips adjust to the temperature where you are testing.*** Whenever the meter is moved from one location to another, allow approximately 20 minutes for the meter to adjust to the temperature of a new location before performing a blood glucose test. The meter has been designed to give accurate results at temperatures between 41°F and 113°F.



- **Check the expiration dates on your test strips and control solution.** It is important to not use the test strips or control solution if the expiration date printed on the bottle label and carton has passed. 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.
- For more information about cleaning and disinfecting your meter or lancing device see:
“FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010)
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.html>
“CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010) <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

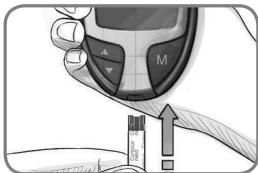
Important Safety Information

- **Have all the materials you will need ready before you begin testing.** This includes your CONTOUR NEXT EZ meter, the CONTOUR NEXT test strips, the lancing device and lancets. You will also need CONTOUR NEXT control solution to run a quality control check. CONTOUR NEXT control solutions are sold separately if not included in the meter kit.
- **The lancing device 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.**
- **Use a new lancet each time you test because it is no longer sterile after use.**
- Do not perform a blood glucose test when the CONTOUR NEXT EZ meter is connected to an external device, e.g., computer.
- Use only approved equipment from the manufacturer or certified body such as UL or TUV.
- The CONTOUR NEXT EZ blood glucose monitoring system has not been evaluated using capillary blood samples obtained from sites other than the fingertip.
- **Use only CONTOUR NEXT test strips with your CONTOUR NEXT EZ system.**
- **Use only CONTOUR NEXT control solution with your CONTOUR NEXT EZ system.**


The following steps are shown in the proper order for performing a blood glucose test.

Preparing the Test Strip

1. Wash and dry your hands well before testing.
2. Remove a CONTOUR NEXT test strip from the bottle.



3. Hold the test strip with the gray square end facing up.
4. Insert the gray square end into the test strip port on the meter.

The meter will turn on. An image of a test strip with a flashing blood drop  will appear letting you know the meter is ready to test.


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

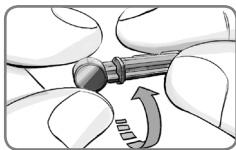
The lancing device provided with your kit is intended for self-testing by a single patient. It must not be used on more than one person due to the risk of infection.

WARNING

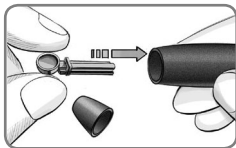
- Dispose of the used lancet as medical waste or as advised by your health care professional.
-  Do not reuse lancets. Use a new lancet each time you test.

Getting Ready to Test

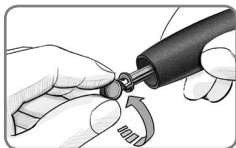
1. Remove the endcap from the lancing device.



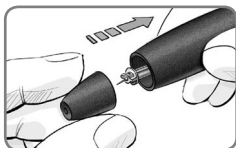
2. Loosen the round protective cap on a lancet by rotating the cap $\frac{1}{4}$ turn, but do not remove the cap.



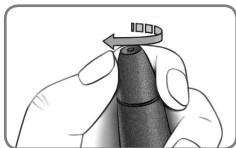
3. Insert the lancet firmly into the lancing device until the lancet comes to a complete stop.



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



5. Replace the endcap.

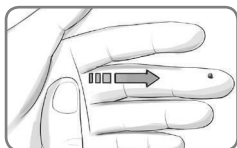


6. Rotate the endcap dial to adjust the puncture depth. The amount of pressure applied to the puncture site also affects the puncture depth.

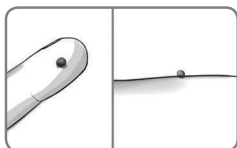
Getting the Blood Drop and Testing



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



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



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

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.

Fingertip Testing




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

WARNING

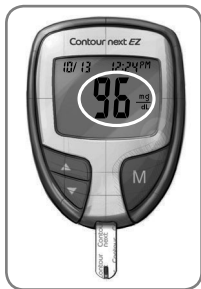
- **The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!^{1,2}**
- **All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning 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, see *Cleaning and Disinfection* in section 2, *Testing*.

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.

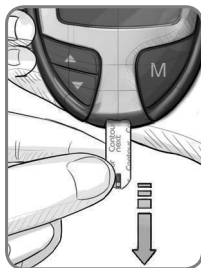
If the first blood drop is not enough, the meter may beep twice and display a strip underfill screen image  .

You have 20 seconds to apply more blood to the same strip. If you are not able to apply enough blood within that time, an E2 error code will be displayed. Dispose of the used test strip as medical waste and start over with a new strip.



5. After a beep, you will see the meter count down 5 seconds and your blood test result is displayed and automatically stored in the meter memory. Please do not touch the test strip during the countdown as this may result in an error.

NOTE: You can set your meter to use meal marker options. See *Set-up for Basic (L-1) and Advanced (L-2) Modes* in section 3, *Setup and Use*. If you want to mark your result you will need to do it before removing the test strip.



6. Remove the test strip to turn your meter off. Dispose of the used test strip as medical waste.
7. Always wash your hands well with soap and water before and after testing, handling the meter, lancing device, or test strips.

Test Results

Expected Values

Blood glucose 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.³ **You should consult with your health care professional for glucose values specific to your needs.**

CAUTION:

- If your blood glucose reading is under 50 mg/dL, or you see **L0** (less than 10 mg/dL) on the meter display, follow medical advice immediately.
- If your test result is above 250 mg/dL, or you see **H1** (greater than 600 mg/dL) on the meter display, call your health care professional as soon as possible.
- Always consult your health care professional before changing your medication based on CONTOUR NEXT EZ test results.

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 or as advised by your health care professional.
- Do not reuse lancets. Use a new lancet each time you test.

WARNING: Potential Biohazard

- Always dispose of test strip and lancet as medical waste or as advised by your health care professional.
- All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.
- Please refer to your lancing device package insert for instructions on how to properly remove and dispose of the lancet.

Do not reuse lancets. Use a new lancet each time you test.

Cleaning and Disinfection

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

NOTE: If the 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 EZ 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 (Monday through Sunday, from 8:00 am through 12:00 Midnight, Eastern Time).

For more information see:

“FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010)

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.html>

“CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010) <http://www.cdc.gov/injectionsafety/Fingertick-DevicesBGM.html>

Cleaning Your Meter

Supplies Needed for Cleaning:

- Clorox Germicidal Wipes containing 0.55% sodium hypochlorite (bleach)
 - Paper towels
1. 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

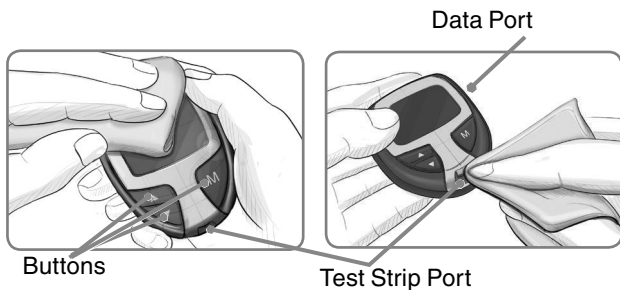
Supplies Needed for Disinfecting:

- 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.



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.

Control Solution Testing

WARNING

Shake the control solution well before testing.



CAUTION: Use only CONTOUR NEXT control solution with your CONTOUR NEXT test strips. Using any other control solution may 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

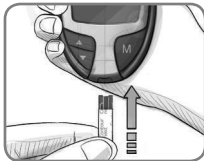
- **Do not calibrate your continuous glucose monitoring device from the control result.**
- **Do not calculate a bolus based on a control result.**



CAUTION: Check the expiration date on the test strip bottle and the expiration and discard dates 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 EZ 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 *Contact Information*.

1. Wash and dry your hands well before and after testing.
2. Remove a test strip from the bottle and firmly snap the lid closed.



3. Hold the test strip with the gray square end facing up.
4. Insert the gray square end into the test strip port on the meter.



The meter will turn on. An image of a test strip with a flashing blood drop will appear letting you know the meter is ready to test.



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 nonabsorbent surface. **Do not apply control solution to your fingertip 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.



The meter will automatically recognize and ✓ mark the control result for you.

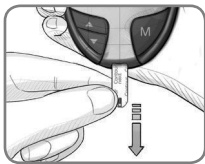
NOTE: The ✓ does not indicate the control test result is within the specified range. It only marks it as a control solution test. It will not be included in your averages.



11. Compare your control test result to the ranges provided on the test strip bottle or carton.

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 EZ meter for blood glucose testing until you resolve the issue. Contact Customer Service. See *Contact Information*.



To turn your meter off, simply remove the test strip. Dispose of the used test strip as medical waste.

The result will be automatically ✓ marked and stored in the meter memory. Control results will not be included in your blood glucose averages or in the 7 day HI-LO summary.

IMPORTANT: To ensure accuracy of your blood glucose test results and accuracy of your control test results, use only CONTOUR NEXT control solutions.

Setting the Time, Date and Sound

Your CONTOUR NEXT EZ meter allows you to set the date, time, and sound as you like them.

- You can view 12 or 24 hour time;
- month/day or day.month; and
- choose to have your meter beep or not.

To get into set-up mode when the meter is off, press and hold **M** for 3 seconds. A complete display will briefly appear, then numbers will flash in the top left corner of the display.

Setting the Time



With the **12H** flashing on the display, press **▲** or **▼** to select the 12H (with AM and PM) or 24H setting.



Press **M** to set.



The number in the **hour** position will now flash. Press **▲** or **▼** until you reach the current hour.

Press **M** to set.



The **minute** will now flash. Press **▲** or **▼** to select the current minute.

Press **M** to set.



If you selected a 12 hour time setting, the **AM** or **PM** will now flash. Press ▲ or ▼ to select AM or PM.

Press **M** to set.

Setting the Month and Day Format



m/d will now flash on the display. Press ▲ or ▼ to select the format you wish (m/d for month/day format or d.m for day.month format).

Press **M** to set.



Setting the Date



The **year** will be flashing. Press ▲ or ▼ to select the current year.

Press **M** to set.



The **month** will now flash. Press ▲ or ▼ to select the month.

Press **M** to set.



The **day** will now flash. Press ▲ or ▼ to select the day.

Press **M** to set.

Setting the Sound



The flashing bell symbol will now appear on the display along with the word **On**.

This option controls whether you want to hear the beep sound during testing.



To turn the beep sound off during testing, press **▲** or **▼** to display **OFF**.

Press **M** to set.



After setting the sound, **L-1** will flash.

To keep your meter in Basic Mode, press **M** to set. To change your meter to Advanced Mode, press **▲** or **▼** to change to **L-2**, and press **M** to set.



If you are using Basic Mode (**L-1** will appear on your display), you have completed your meter set-up.

Set-up for Basic (L-1) and Advanced (L-2) Modes

Your new CONTOUR NEXT EZ meter is pre-set for the Basic Mode and offers the same easy test procedure in either the Basic or Advanced Mode.

BASIC MODE (L-1)

- 7 day HI and LO summary
- 14 day average
- 480 test result memory

ADVANCED MODE (L-2)

- 7 day HI and LO summary
- 7, 14, and 30 day averages
- 480 test result memory
- Pre- and post-meal markers
- 30 day pre- and post-meal averages
- Selectable post-meal reminders (2.5, 2.0, 1.5, 1.0 hours)
- Personal HI and LO test settings

BASIC MODE (L-1)



Your meter is pre-set to Basic Mode. If you have set your meter to the Advanced Mode, and want to return to Basic Mode:

1. Press **M** to turn your meter on. Wait to see the flashing test strip.
2. Press and hold ▲ or ▼ for 3 seconds.
3. L-2 will flash.
4. Press ▲ or ▼ to change to L-1.
5. Press **M** to set.

ADVANCED MODE (L-2)



To set your meter to Advanced Mode, and take advantage of meal markers and other functions available to you:

1. Press **M** to turn your meter on. Wait to see the flashing test strip.
2. Press and hold ▲ or ▼ for 3 seconds.
3. L-1 will flash.
4. Press ▲ or ▼ to change to L-2.
5. Press **M** to set.

Personalizing LO, HI and Reminder Settings



If you selected Advanced Mode (L-2 on your display) you can change your meter's personal low and high blood glucose settings. By personalizing these settings, your CONTOUR NEXT EZ meter will help you track these HI and LO results.



The LO setting will flash (default 72 mg/dL). To change this setting, press **▲** or **▼** until you reach your desired LO setting, and then press **M** to set. (The range of values for LO is 60 mg/dL – 90 mg/dL.)



Your HI blood glucose setting will now flash (default 180 mg/dL). To change, press **▲** or **▼** until you reach your desired HI setting. Press **M** to set. (The range of values for HI is 100 mg/dL – 250 mg/dL.)

Post-Meal Test Reminder Set-up



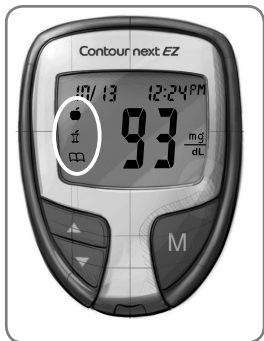
To change the reminder time for post-meal testing, press ▲ or ▼ to display the options available. Select 2.5, 2.0, 1.5, or 1.0 hour(s) to set your post-meal reminder (default is 2.0 hours).

Press **M** to set.





You have now completed your CONTOUR NEXT EZ meter set-up for Advanced Mode!


Using the Markers



If you have set up your meter in Advanced Mode, your meter will display three markers after you test your blood.

 **Pre-meal** = Marks a test result that was taken before a meal.

 **Post-meal** = Marks a test result that was taken after a meal.

 **Logbook** = The logbook marker can be used to mark any result as being unique or different in some way, and for which you may want to make notes in your logbook. Seeing a result with this symbol next to it in the memory will help remind you that there is more information recorded about this test result.

Please see the following panels to use these options.

If you do not want to mark the test result

Remove the used test strip to automatically save the test result in the meter memory with no markers. This will also turn the meter off.

If you want to mark the test result

Before you remove your test strip, press ▲ or ▼ to select the marker you want to set. The marker will flash.



To mark a result with the pre-meal marker, press **M** when the ☀ flashes.



The ⌚ will then flash. This feature allows you to set a reminder to remind you to run a post-meal test.

The reminder is available only after setting a pre-meal marker.



If you want to set the reminder, press **M**. The ⌚ will appear and stop flashing.

If you do not want to set the reminder, press ▲ or ▼ and the ⌚ will disappear. Press **M** to set.

To mark a result with the post-meal marker, press ▲ or ▼ until the 🍴 flashes. Press **M** to set.

To mark a result with the logbook, press ▲ or ▼ until the 📖 flashes. Press **M** to set.


Using the Reminder Feature



When the reminder sounds, the meter will automatically turn on. The reminder will beep 20 times, and the display will show the pre-meal test result you marked when you set the reminder. Pressing any button will silence the reminder.

You can now run another test by placing a test strip in the test strip port and following the testing instructions (see section 2, *Testing*).



When you have completed this test and the result is shown on the display,  will flash. To mark this test as a post-meal result, press **M**.


If you do not want to mark this test, remove the test strip to turn the meter off. Dispose of the used test strip as medical waste.

If you decide not to test after the reminder sounds, press any button to turn your meter off.

The meter will only set one reminder at a time. It will remember the last reminder set.

To Cancel a Reminder











When the meter is off, press **M** to turn on the meter. The date and time will appear along with the .

Press **▲** or **▼** twice and the reminder icon will disappear.

Press **M** to cancel the reminder.

After performing a test

To Mark Results	You Will See	To Set	You Will See	What It Means
Pre-Meal Press ▲ or ▼	 (Flashing)	Press M		Result is marked as a pre-meal test. You can now set a reminder.
Reminder Press ▲ or ▼	 (Flashing)	Press M		Reminder is set to go off in the amount of time you have set (1.0 – 2.5 hours) to remind you to run a post-meal test.
Post-Meal Press ▲ or ▼	 (Flashing)	Press M		Result is marked as a post-meal test.*
Logbook Press ▲ or ▼	 (Flashing)	Press M		Result is marked in memory as unique. You should note this in your logbook.

*Post-meal glucose measurements should be made 1–2 hours after the beginning of the meal.⁴

Transferring Results to a Computer

You can transfer test results from the CONTOUR NEXT EZ 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 software and a data cable.

For a free download of the software go to

www.glucofacts.ascensia.com or contact Customer Service.

See *Contact Information*. May not be available in all countries.

IMPORTANT: The CONTOUR NEXT EZ meter has not been tested for use with any software other than GLUCOFACTS DELUXE software. Ascensia Diabetes Care is not responsible for any erroneous results from the use of other software.

Viewing Basic Mode Results

Press **M** to turn your meter on. Press **M** again to view the memory.



The **14 day average** will appear in the center of the display with the number of results shown at the top of the display. Control results are not included in this 14 day average.



Press ▲ to view the 7 day high and low summary.

At the top of the display you will see the number of HI results (above 180 mg/dL) and LO results (below 72 mg/dL) during the preceding 7 day period and the total number of results during that period.



Press ▼ twice to review previous results.

Results will be shown starting with the most recent. Each result will show the date and time the test was taken.

You can press ▲ or ▼ to scroll forward or backward through the results.



When **End** appears on the display, you have viewed all of the results in the memory.

NOTES:

- Averages include the specified time period plus the current day.
- The meter will hold 480 results in the memory. When the maximum is reached, the oldest test result will be removed as a new test is completed and saved to the memory.
- Press M to turn the meter off, or it will automatically turn off after 3 minutes.
- \bar{n} represents the number of test results.

Viewing Advanced Mode Results

In Advanced Mode (L-2), you have all of the options described in Basic Mode plus additional items available.



Press **M** to turn your meter on. Briefly press **M** again to view the **14 day average** including the number of results used to obtain the average.



Press **▼** to review previous results.

Results will be shown starting with the most recent. Each result will show the date and time the test was taken.

You can press **▲** or **▼** to scroll forward or backward through the results.

When **End** appears on the display, you have viewed all of the results in the memory.

Viewing Advanced Mode Averages

Press **M** to turn your meter on. Press **M** again to view the **14 day average** including the number of results used to obtain the average.



Press ▲ to view the 7 day high and low summary.

At the top of the display you will see the number of HI and LO results. In the center of the display is the total number of results.



Press ▲ to view the 7 day average.

You will see the average in the center of the display and the number of results along the top.



Press ▲ to view the 30 day average.

This will display the average in the center and the number of readings along the top.



Press ▲ again to view the 30 day average of results marked with a **pre-meal marker**.











Press ▲ again to view the 30 day average of results marked with a **post-meal marker**.





Press ▲ again and you will see **End**.
Press **M** to turn the meter off, or it will automatically turn off after 3 minutes.

Error Codes and Symbols


What You See	What It Means	What You Should Do
 (will remain on the display)	Low batteries.	Replace the batteries as soon as possible.
 (will flash for 10 seconds and then the meter will turn off)	Dead batteries.	Replace the batteries.
	The meter is ready to test.	Proceed with the testing of your blood.
	Not enough blood sample.	Add more blood within 20 seconds.
E1 	Temperature out of range.	Move to an area that is within the operating range for the meter: 41° – 113°F. Let the meter adjust to this temperature for 20 minutes before performing a test.

What You See	What It Means	What You Should Do
E2 	<p>The test strip has not filled enough for an accurate test. Insufficient blood drop.</p>	<p>Remove the test strip and retest using a new test strip. Wait until you see the flashing blood drop on the display before testing.</p>
E3 	<ul style="list-style-type: none"> • The meter is sensing a used test strip. • The wrong control solution was used. 	<ul style="list-style-type: none"> • Remove the test strip and retest using a new test strip. Wait until you see the flashing blood drop on the display before testing. • If control testing, make sure to use CONTOUR NEXT control solution.
E4 	<p>Test strip not inserted correctly.</p>	<p>Remove and reinsert the test strip properly (see <i>Preparing the Test Strip</i> in section 2, <i>Testing</i>).</p>
E5 E9 E6 E12 E8 E13	<p>Potential software or hardware issue.</p>	<p>Remove the test strip and retest using a new test strip. If you continue to have problems, contact Customer Service. See <i>Contact Information</i>.</p>

What You See	What It Means	What You Should Do
E7 	Incorrect test strip.	Remove the test strip and retest using a new test strip. Make certain that you are using a CONTOUR NEXT test strip.
E10	Invalid date or time.	This error occurs only in Communication mode. See <i>Setting the Time, Date and Sound</i> (in section 3, <i>Setup and Use</i>) to reset the date or time. If you continue to see this error, please contact Customer Service. See <i>Contact Information</i> .
E11	Abnormal result.	Remove the test strip and retest using a new test strip. Be sure you wash and dry your hands well and carefully follow instructions in this user guide. Only CONTOUR NEXT test strips should be used.

What You See	What It Means	What You Should Do
	Test result is above 600 mg/dL.	<ul style="list-style-type: none"> • Wash and dry your hands well and the test site. Repeat the test using a new test strip. • If your result still flashes HI, contact your health care professional as soon as possible.

CAUTION: Glucose levels above 250 mg/dL may indicate a potentially serious medical condition.

	Test result is below 10 mg/dL.	<ul style="list-style-type: none"> • Repeat the test using a new test strip. • If your result still flashes LO, follow medical advice immediately.
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CAUTION: Glucose levels below 50 mg/dL may indicate a potentially serious medical condition.



What You See	What It Means	What You Should Do
Control test result is out of range (too high or too low).	Test strip or control solution is past the expiration date or is past the discard date.	Check all expiration dates and discard dates. Do not use expired testing materials.
	Test strip is deteriorated due to heat or exposure to moisture.	Run another control test with a new test strip and control solution.
	Control solution is not at room temperature or may not be mixed well.	Shake the control solution bottle well, about 15 times before every use.
	Incorrect control solution was used.	Make sure you are using CONTOUR NEXT control solution.
	Meter could be damaged.	If result is still out of range, contact Customer Service. See <i>Contact Information</i> .

What You See	What It Means	What You Should Do
Some display segments do not appear when the meter initially turns on.	Possible meter electronics failure.	Compare meter display with the illustration in <i>Your Meter Display</i> (in section 1, <i>Getting Started</i>). If the display is not correct, contact Customer Service. See <i>Contact Information</i> .
Results are not displayed in expected units of measure (mg/dL).	This may affect the way you see your results.	Contact Customer Service. See <i>Contact Information</i> .

If you do not resolve the problem, contact Customer Service. See *Contact Information*.

Changing the Batteries

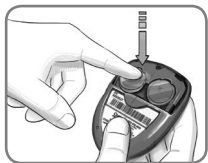


Batteries should be replaced when the meter continually displays  or the meter briefly shows  and then turns off (**see *Error Codes and Symbols* in section 4, *Technical, Service & Care*.**



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

NOTE: 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, you will need to reset the date and time although your other settings and results will be saved.



3. Remove the old batteries by pressing the top of the battery which will raise the bottom of the battery up.



4. Place new batteries under the prongs and into the battery compartment with the “+” side up. [Use two 3-volt (DL2032 or CR2032) lithium batteries.]



5. Slide the battery cover back into place, lining up with the open slots, and close firmly.

WARNING

Keep batteries away from children. Lithium batteries are poisonous. If swallowed, immediately contact your doctor or poison control center. Discard batteries according to your local environmental regulations.

Ascensia Diabetes Care offers the Free Batteries for Life Program. When your batteries are low, please contact Customer Service. See *Contact Information*.

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 and disinfect your meter as recommended in *Cleaning and Disinfection* (in section 2, *Testing*).

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:⁵

Low blood glucose (Hypoglycemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- irritability
- seizure
- extreme hunger
- dizziness

High blood glucose (Hyperglycemia):

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

Ketones (Ketoacidosis):

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

Information For Safety

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 or refer to the website of the American Diabetes Association: www.diabetes.org.

System Specifications

Test Sample: Capillary whole blood

Test Result: Glucose measurements are reported as plasma equivalents.

Sample Volume: 0.6 μ L

Measuring Range: 20 mg/dL–600 mg/dL

Results: 5-second countdown

Memory Feature: Stores most recent 480 test results

Battery Type: Two 3-volt lithium batteries, 225 mAh capacity (DL2032 or CR2032)

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

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

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

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

Dimensions: 3.03" (H) x 2.24" (W) x 0.74" (T)
77 mm (H) x 57 mm (W) x 19 mm (T)

Weight: 1.7 oz. (47.5 grams)

Sound: A beep sounds when the meter is turned on, a test strip is inserted, when a test strip is filled with blood, or when a test result appears on the display. Two beeps sound when the meter turns off or to indicate an error. You will hear twenty beeps when a programmed reminder sounds.

Electromagnetic Compatibility (EMC): The

CONTOUR NEXT EZ 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 EZ meter. The CONTOUR NEXT EZ 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 EZ meter meets the requirements of IEC 61326-1 for radio frequency interference. To avoid radio frequency interference, do not use the CONTOUR NEXT EZ meter near electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

Principles of the Procedure: The CONTOUR NEXT EZ 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 EZ 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).⁶

Limitations

Altitude: Up to 20,674 feet (6,301 meters) does not significantly affect results.

Alternative Site Testing: Not for use with Alternative Site Testing.

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%.

Contraindications: The system should not be used to test critically ill patients. Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.⁷

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.

Symbols Used

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

Symbol	What It Means
	Batch code
	Use by Date (last day of month)
	Consult instructions for use
	<i>In Vitro</i> Diagnostic Medical Device
	Shake 15 times

Technical Information

The CONTOUR NEXT EZ blood glucose monitoring system was tested by 115 lay users using capillary blood samples and three CONTOUR NEXT test strip lots. 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 EZ meter	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL*
Number (and percent) of samples within specified range	6 of 7 (85.7%)	7 of 7 (100.0%)	7 of 7 (100.0%)

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

Difference range in values between YSI laboratory reference method and CONTOUR NEXT EZ meter	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%*
Number (and percent) of samples within specified range	83 of 108 (76.9%)	104 of 108 (96.3%)	107 of 108 (99.1%)	108 of 108 (100.0%)

*Acceptance criterion is that 95% of the measured glucose values shall fall within either ± 15 mg/dL of the average measured values of the reference measurement procedure at glucose concentrations < 75 mg/dL or within ± 20% at glucose concentrations ≥ 75 mg/dL.

A repeatability study was conducted with the CONTOUR NEXT EZ blood glucose monitoring system using five venous whole blood specimens with glucose levels from 47 to 326 mg/dL. Multiple replicates (n=100 per lot) were tested using multiple CONTOUR NEXT EZ blood glucose meters and three lots of CONTOUR NEXT blood glucose test strips. The following precision results were obtained.

System repeatability results for CONTOUR NEXT EZ meter using CONTOUR NEXT test strips

Mean, mg/dL	Pooled Standard Deviation	Coefficient of Variation, %
47	0.8	1.7
84	1.1	1.3
139	2.1	1.5
202	2.6	1.3
326	5.0	1.5

Service Information

If you have a problem and none of the problem solving steps in this user guide help, contact Customer Service. See *Contact Information*. We have trained specialists to help you.

Important

- **Speak to a Customer Service Representative before returning your meter for any reason. He/she will give you the information needed to get your problem handled correctly and efficiently.**
- **Have your CONTOUR NEXT EZ blood glucose meter and CONTOUR NEXT test strips available when you phone. It would also be helpful to have a bottle of CONTOUR NEXT control solution nearby.**

Check List

This check list may be helpful when speaking with Customer Service:



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

2. Locate the CONTOUR NEXT test strips' expiration date on the bottle.

3. Check the battery icon on the display. (See *Changing the Batteries* in section 4, *Technical, Service & Care*.)

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 EZ 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 EZ 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 EZ 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 EZ meter or test results when used with any software other than the CONTOUR[®]DIABETES app (where supported) or the GLUCOFACTS DELUXE 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 *Contact Information*.

References

1. US Food and Drug Administration. Use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
2. 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>
3. American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of medical care in diabetes—2020. *Diabetes Care*. 2020;43(supplement 1):S14–S31.
4. American Diabetes Association: Clinical Practice Recommendations. *Diabetes Care*. 2011;34(1):S1–S96.
5. American Diabetes Association, www.diabetes.org
6. Burtis CA, Ashwood ER, editors. *Tietz Fundamentals of Clinical Chemistry*. 5th edition. Philadelphia, PA: WB Saunders Co; 2001;444.
7. Atkin SH, et al. Fingerstick glucose determination in shock. *Annals of Internal Medicine*. 1991;114(12):1020-1024.

Supplies

Replacement Parts

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

Item

Two 3-volt lithium batteries DL2032 or CR2032

CONTOUR NEXT EZ user guide

CONTOUR NEXT test strips

CONTOUR NEXT control solution, Level 1

CONTOUR NEXT control solution, Level 2