



Contour[®] next *EZ*

Blood Glucose
Monitoring System



USER GUIDE

Intended Use

The CONTOUR®NEXT EZ blood glucose monitoring system from Bayer (meter, test strips and control solution) is intended for use by persons with diabetes for self-testing, and by health care professionals for use on a single patient. The CONTOUR NEXT EZ system is intended for the quantitative measurement of glucose (from 0.6 mmol/L to 33.3 mmol/L) in fresh capillary whole blood samples drawn from the fingertip only. Venous blood samples may also be used by health care professionals.

The CONTOUR NEXT EZ blood glucose monitoring system may also be used by health care professionals to monitor hypoglycemia in neonates. The system should not be used for diagnosis or screening. Diagnosis of neonatal hypoglycemia should be performed using a laboratory glucose method. For neonates exhibiting hypoglycemic symptoms, provide appropriate medical care to treat symptoms and monitor patient. If symptoms are inconsistent with meter results, obtain a laboratory blood glucose test. The CONTOUR NEXT EZ blood glucose monitoring system has not been evaluated specifically with pre-term neonates.

The CONTOUR NEXT EZ blood glucose monitoring system may be used as an aid to monitor the effectiveness of an individual's personal blood glucose control program. The CONTOUR NEXT EZ blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus.

The CONTOUR NEXT EZ blood glucose monitoring system is intended for *in vitro* diagnostic use only.

The CONTOUR NEXT EZ blood glucose monitoring system is intended for single-patient use only and should not be shared.

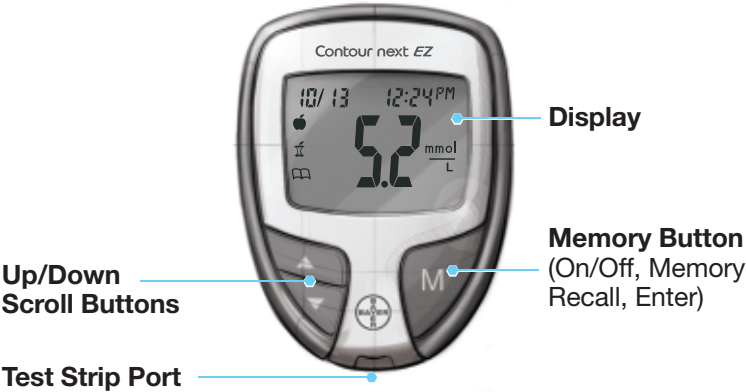
Information For Safety

-  Read your CONTOUR®NEXT EZ 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.

Potential Biohazard

- Always wash and dry your hands well with soap and water before and after testing, handling the meter, lancing device or test strips.
- The meter, lancing device and lancets provided by Bayer are for single-patient use. Do not share them with anyone including other family members. Do not use on multiple patients.
- All parts of this kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection. For instructions, please see Cleaning and Disinfection, page 16.
- The lancing device provided by Bayer 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 or as advised by your health care professional. All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.
- Keep out of reach of children. This kit contains small parts which could cause suffocation if accidentally swallowed.
- Keep batteries away from children. Lithium batteries are poisonous. If swallowed, immediately contact your poison control center.

Your CONTOUR®NEXT EZ Meter



Your CONTOUR®NEXT Test Strip

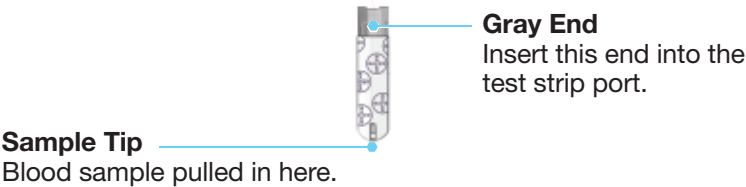


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GETTING
STARTED

TESTING

SETUP AND USE

TECHNICAL,
SERVICE & CARE

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** (page 41). 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.
888	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 mmol/L. The 7 appears when viewing 7 day HI-LO summary.
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: You no longer have to worry about coding your meter or marking a control test result. Your CONTOUR NEXT EZ meter is designed with No Coding technology, to automatically code itself every time you insert a 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, time and units of measure (mmol/L) where you purchased your meter.

IMPORTANT NOTE:

- Your meter has been preset and locked to display results in mmol/L (millimoles of glucose per liter). In some countries, the meters are preset to display units in mg/dL (milligrams of glucose per deciliter);

- Results in mmol/L will always have a decimal point;
- Results in mg/dL will never have a decimal point.

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

Check your display to ensure that results are being displayed in mmol/L. If they are not, contact Bayer Diabetes Care Helpline at 1-800-268-7200.

Customizable: The CONTOUR®NEXT EZ meter allows you to set personal choices for some features. For more information, please see pages 27 - 35.

Information For Safety

- 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.
- Wash and dry your hands well before testing.**
- 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 5°C and 45°C.
- **Check the expiry dates on your test strips and control solution.** It is important to not use the test strips or control solution if the expiry date printed on the bottle label and carton has passed. The control solution should not be used 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.

Information For Safety

- **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.
- 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 Bayer Diabetes Care Helpline at 1-800-268-7200 for replacement parts.
- **The lancing device provided by Bayer 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 following steps are shown in the proper order for performing a blood glucose test, pages 8-14.

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 end facing up.
4. Insert the gray 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 by Bayer is intended for self-testing by a single patient. It must not be used on more than one person due to the risk of infection.

WARNING

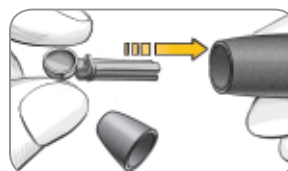
- Dispose of the used lancet as medical waste or as advised by your health care professional.
-  Do not reuse lancets. Use a new lancet each time you test.



1. Remove the endcap from the lancing device. Hold the endcap dial and gently snap off the endcap from top to bottom.



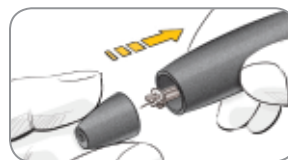
2. Loosen the round protective cap on a lancet by rotating it 1/4 turn, but do not remove it.



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



4. Twist off the round protective lancet cap. Save it 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.

Getting the Blood Drop and Testing



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

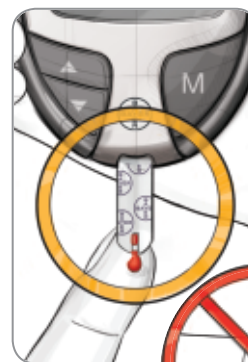


2. Stroke your hand and finger towards the puncture site to form a drop of blood. Do not squeeze around the puncture site.



Suggested drop size

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



Fingertip Testing

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.

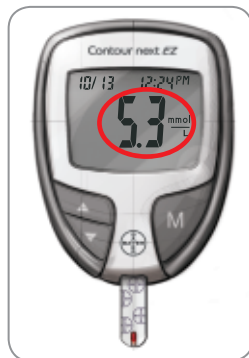


Do not press the tip against the skin or place the blood on top of the test strip or you could get inaccurate results or errors.

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

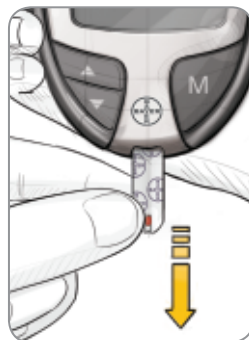
You have 20 seconds to apply more blood onto the same strip. If you are not able to provide enough blood within that time, an E2 error code will be displayed. Dispose of the used test strip as medical waste and start over with a new strip.

5. After a beep, you will see the meter count down 5 seconds. Your blood test result will be 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 **Advanced Mode settings (L-2)** on pages 27 - 29. 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.



Test Results

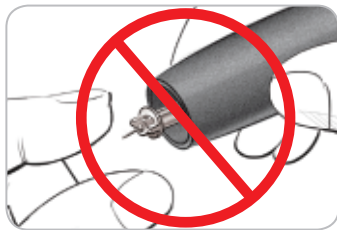
Expected Values

Blood glucose values will vary depending on food intake, medication dosages, health, stress, or exercise. Consult with your health care professional for the target value that is appropriate for you. According to the Canadian Diabetes Association, standard medical practice goals for a non-pregnant individual with diabetes¹:

- Before a meal: 4.0 to 7.0 mmol/L
- 2 hours after a meal: 5.0 to 10.0 mmol/L

- If your blood glucose reading is under 2.8 mmol/L, or you see **L** (less than 0.6 mmol/L) on the meter display, follow medical advice immediately.
- If your test result is above 13.9 mmol/L, or you see **H** (greater than 33.3 mmol/L) 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. Your Bayer device has an automatic lancet ejection feature.
2. Refer to the separate lancing device insert provided by Bayer 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.

Caring for Your Meter

CAUTION: Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt.

- Store your meter in the carrying case provided whenever possible.
- **Wash hands and dry well before handling to keep the meter and test strips free of water, oils and other contaminants.**
- Keep blood, control solution, and cleaning fluid from entering the test strip port.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.

Cleaning and Disinfection

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



WARNING

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

NOTE: If the meter is being operated by a second person who is providing testing assistance, the meter and lancing device should be disinfected prior to use by the second person. Health care professionals should follow their institution's policy on the frequency of disinfection.

The cleaning and disinfecting directions provided will not cause any damage or degradation to the external case, buttons or display. Your CONTOUR NEXT EZ meter and lancing device from Bayer have been tested for 260 cycles of cleaning and disinfection (one cycle

per week for 5 years). These devices have been demonstrated to withstand 5 years of cleaning and disinfection without damage. You should call Bayer Diabetes Care Customer Service for assistance if your device malfunctions for any cause or if you notice any changes in the meter case or display.

For more information see:

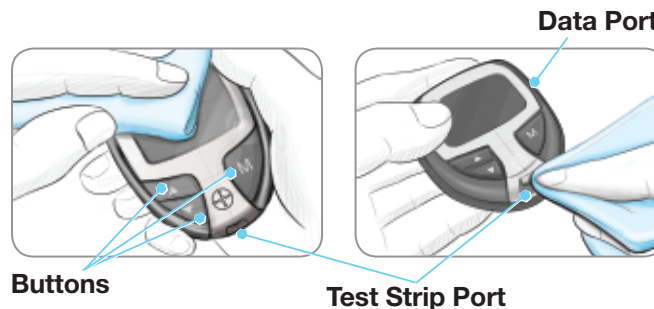
FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication (2010).

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

Cleaning Your Meter

Supplies Needed for Cleaning:

- Germicidal wipes containing 0.55% sodium hypochlorite (bleach)
 - Paper towels
1. Carefully clean the meter with 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.



Buttons

Test Strip Port

Disinfecting Your Meter

Supplies Needed for Disinfecting:

- Germicidal wipes containing 0.55% sodium hypochlorite (bleach)
 - Paper towels
 - Timing device
1. Before disinfecting, clean the meter as described in **Cleaning Your Meter**.

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

Using a new 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 Your Lancing Device provided by Bayer

Supplies Needed for Cleaning:

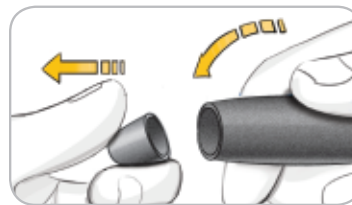
- Germicidal wipes containing 0.55% sodium hypochlorite (bleach)
 - Paper towels
1. Clean the lancing device with germicidal wipes until all soil is removed.
 2. Dry as necessary with a clean paper towel.

Disinfecting Your Lancing Device provided by Bayer

Supplies Needed for Disinfecting:

- Germicidal wipes containing 0.55% sodium hypochlorite (bleach)
 - Paper towels
- 18 • Timing device

1. Before disinfecting, clean the lancing device as described in **Cleaning Your Lancing Device**.



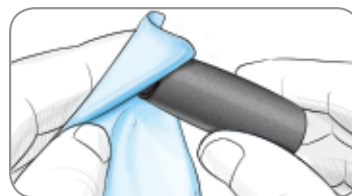
2. Remove the endcap and lancet, if present.

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



3. Using a new germicidal wipe, carefully wipe all external and internal surfaces of the endcap until wet.

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



4. Use the germicidal wipes to disinfect all exposed surfaces of your lancing device until wet.

5. Dry all lancing device surfaces and endcap with a clean paper towel if needed.

The lancing device graphics are for illustration purposes only. Refer to the lancing device insert provided by Bayer for detailed instructions.

Control Solution Testing

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,
- When you open a new bottle or package of test strips,
- If you think your meter may not be working properly,
- If you have repeated unexpected blood glucose results.

Normal, Low or High control solutions are available and sold separately. Always use CONTOUR NEXT control solutions from Bayer. Other brands could present incorrect results. If you need help locating CONTOUR NEXT control solutions, call Bayer Diabetes Care Helpline at 1-800-268-7200.

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

NOTE: Check the expiry date on the test strip bottle and the expiry and discard dates on the control solution bottle. Do not use expired materials.



3. Hold the test strip with the gray end facing up.
4. Insert the gray 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.

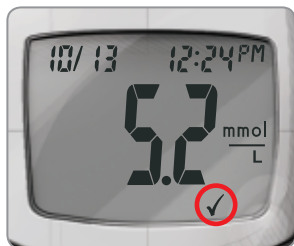


7. Squeeze a small drop of solution onto a clean, nonabsorbent surface.
Do not apply control solution to your fingertip or to the test strip directly from the bottle.

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.



You will see the meter count down 5 seconds until the test is complete and your control test result is displayed.



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.

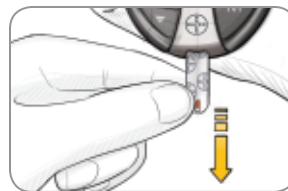
10. Compare your control test result with the Normal Control Range provided on the test strip bottle or carton.



NOTE: Low and High control range values can be found on the bottom of the test strip carton.

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 meter for blood glucose testing until you resolve the issue. See “What You Should Do” on page 44.



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



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.



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 4.0 mmol/L). 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 3.3 - 5.0 mmol/L).



Your HI blood glucose setting will now flash (default 10.0 mmol/L). To change, press ▲ or ▼ until you reach your desired HI setting. Press **M** to set. (The range of values for HI is 5.6 - 13.9 mmol/L).

Post-Meal Test Reminder Set-up

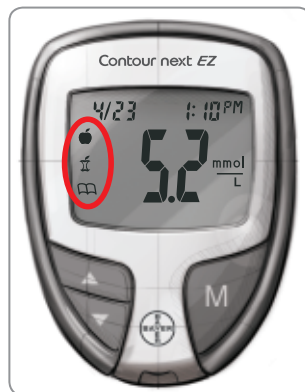


To change the reminder time for post-meal testing, press ▲ or ▼ to display the options available. Select 2.5, 2.0, 1.5, or 1.0 hour(s) to set your post-meal reminder (default is 2.0 hours). Press **M** to set.



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 pages 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.



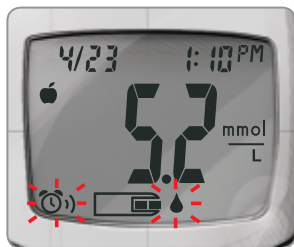
If you want to set the reminder, press **M**. The  will appear and stop flashing.

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 (page 8).



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.

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 diabetes management software from Bayer and a data cable. For a free download of the software go to www.bayerglucofacts.com. For more information, call Bayer Diabetes Care Helpline at 1-800-268-7200.

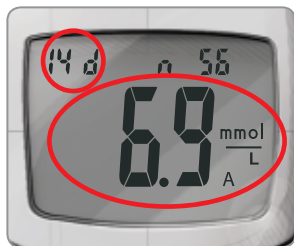
IMPORTANT: The CONTOUR NEXT EZ meter has not been tested by Bayer for use with any software other than diabetes management software from Bayer. Bayer is not responsible for any erroneous results from the use of other software.

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		 5.2 mmol/L	Result is marked as a pre-meal test. You can now set a reminder.
Reminder Press ▲ or ▼	 (Flashing)	Press M		 5.2 mmol/L	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		 6.9 mmol/L	Result is marked as a post-meal test.
Logbook Press ▲ or ▼	 (Flashing)	Press M		 6.9 mmol/L	Result is marked in memory as unique. You should note this in your logbook.

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. Any 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 10.0 mmol/L) and LO results (below 4.0 mmol/L) 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.



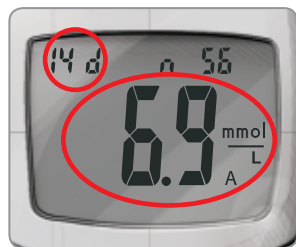
When **End** appears on the display, you have viewed all of the results in the memory.

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.
- **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.

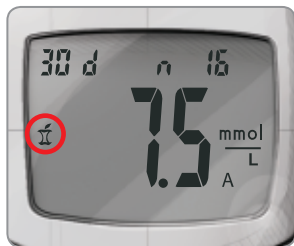


Press **▲** to view the **30 day average**.

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

If you do not resolve the problem, contact
Bayer Diabetes Care Helpline at 1-800-268-7200.

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: 5°C – 45°C. Let the meter adjust to this temperature for 20 minutes before performing a test.
E2 	The test strip has not filled enough for an accurate test. Insufficient blood drop.	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 you do not resolve the problem, contact
Bayer Diabetes Care Helpline at 1-800-268-7200.

What You See	What It Means	What You Should Do
E3 	- The meter is sensing a used test strip. - The wrong control solution was used.	- 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 	Test strip not inserted correctly.	Remove and reinsert the test strip properly (see page 8).
E5 E9 E6 E12 E8 E13	Potential software or hardware issue.	Remove the test strip and retest using a new test strip. If you continue to have problems, contact Bayer Diabetes Care Helpline at 1-800-268-7200.
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 from Bayer.
E10	Invalid date or time.	This error occurs only in Communication mode. See pages 24 - 25 to reset the date or time. If you continue to see this error, please contact Bayer Diabetes Care Helpline at 1-800-268-7200.

If you do not resolve the problem, contact
Bayer Diabetes Care Helpline at 1-800-268-7200.

What You See	What It Means	What You Should Do
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 from Bayer should be used.
	Test result is above 33.3 mmol/L.	- 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 immediately.
CAUTION: Glucose levels above 13.9 mmol/L may indicate a potentially serious medical condition.		
	Test result is below 0.6 mmol/L.	- Repeat the test using a new test strip. - If your result still flashes LO, contact your health care professional immediately.
CAUTION: Glucose levels below 2.8 mmol/L may indicate a potentially serious medical condition.		

If you do not resolve the problem, contact
Bayer Diabetes Care Helpline at 1-800-268-7200.

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 expiry date or is past the discard date.	Check all expiry 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, to ensure the control solution is mixed well.
	Incorrect control solution was used.	Make sure you are using CONTOUR®NEXT control solution from Bayer.
	Meter could be damaged.	If result is still out of range, contact Bayer Diabetes Care Helpline at 1-800-268-7200.

If you do not resolve the problem, contact
Bayer Diabetes Care Helpline at 1-800-268-7200.

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 on page 2. If the display is not correct, contact Bayer Diabetes Care Helpline at 1-800-268-7200.
Results are not displayed in expected units of measure (mmol/L).	This will affect the way you see your results.	Contact Bayer Diabetes Care Helpline at 1-800-268-7200.

Changing the Batteries

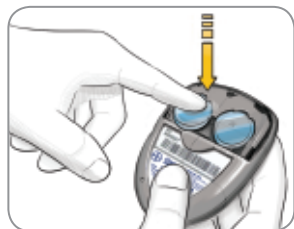


Batteries should be replaced when the meter continually displays  or the meter briefly shows  and then turns off (**See Error Codes and Symbols, page 41**).

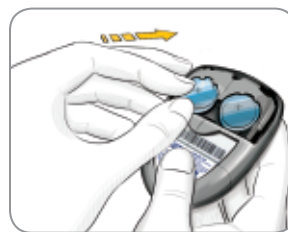


1. Turn off your meter before changing your batteries.
2. Press firmly on the battery cover and slide in the direction of the arrow.

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.

Information for Safety

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.



Contour
next **EZ**

Need Help? 1-800-268-7200
www.diabetes.bayer.ca

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.
- Your meter should be cleaned and disinfected once a week. For cleaning and disinfection instructions, see pages 16-19.

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 Canadian Diabetes Association, some of the most common symptoms are:²

Low blood glucose (Hypoglycemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- seizure
- irritability
- 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 2.8 mmol/L or above 13.9 mmol/L, contact your health care professional immediately.

For additional information and a complete list of symptoms, contact your health care professional or refer to the Canadian Diabetes Association website at www.diabetes.ca.

System Specifications

Test Sample: Venous or capillary whole blood

Test Result: Referenced to plasma/serum glucose

Sample Volume: 0.6 µL

Measuring Range: 0.6 - 33.3 mmol/L

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)

Operating Temperature Range: 5°C - 45°C

Humidity: 10 - 93% RH

Dimensions: 77 mm (H) x 57 mm (W) x 19 mm (T)

Weight: 47.5 grams (1.7 oz.)

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 requirements specified in ISO 15197:2013. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the CONTOUR NEXT EZ system.

The CONTOUR®NEXT EZ meter meets the requirements of IEC 61326-2-6 for immunity to electrostatic discharge. It is advisable to 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 cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters or other 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 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 a phenothiazine derivative as 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 venous and capillary whole blood. 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).³

Limitations

Preservatives: Blood may be collected by health care professionals into test tubes containing heparin. Do not use other anticoagulants or preservatives.

Altitude: Up to 6301 meters does not significantly affect results.

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

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

Contraindications: Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension, hyperosmolar hyperglycemia and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.⁴

Interference: Reducing substances occurring in the blood naturally or from therapeutic treatments will not significantly affect results. See reagent test strip insert for more information.

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

Technical Information

Accuracy

The CONTOUR®NEXT EZ blood glucose monitoring system was tested in 100 capillary blood samples using 600 CONTOUR®NEXT test strips. Two replicates were tested with each of 3 lots of CONTOUR NEXT test strips for a total of 600 readings. Results were compared to the YSI® glucose analyzer, which is traceable to the CDC hexokinase method. The tables below compare the performance of the 2 methods.

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

Difference range in values between YSI laboratory reference method and CONTOUR NEXT EZ meter	Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
Number (and percent) of samples within specified range	168 of 186 (90.3%)	186 of 186 (100%)	186 of 186 (100%)

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

Difference range in values between YSI laboratory reference method and CONTOUR NEXT EZ meter	Within ± 5%	Within ± 10%	Within ± 15%
Number (and percent) of samples within specified range	327 of 414 (79.0%)	412 of 414 (99.5%)	414 of 414 (100%)

Technical Information

Table 3 – System accuracy results for glucose concentrations between 1.0 mmol/L and 25.6 mmol/L

Within ± 0.83 mmol/L or $\pm 15\%$	600 of 600 (100%)
--	-------------------

Acceptance criteria in ISO 15197: 2013 are that 95% of all differences in glucose values (i.e., between reference method and meter) should be within ± 0.83 mmol/L for glucose values less than 5.55 mmol/L, and within $\pm 15\%$ for glucose values greater than or equal to 5.55 mmol/L.

User Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 115 lay persons showed the following results: 100% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and 98.8% within $\pm 15\%$ of the medical laboratory glucose concentrations at or above 5.55 mmol/L.

Precision

A repeatability study was conducted with the CONTOUR®NEXT EZ blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from 2.6 to 18.8 mmol/L. Multiple replicates (n=300) were tested using multiple CONTOUR NEXT EZ blood glucose meters and 3 lots of CONTOUR®NEXT blood glucose test strips. The following precision results were obtained.

Technical Information

Table 4 – System repeatability results for CONTOUR®NEXT EZ meter using CONTOUR®NEXT test strips

Mean, mmol/L	Pooled Standard Deviation	95% Confidence Interval of Standard Deviation, mmol/L	Coefficient of Variation, %
2.6	0.04	0.04 – 0.05	1.7
4.7	0.06	0.06 – 0.07	1.3
7.7	0.12	0.11 – 0.13	1.5
11.2	0.15	0.13 – 0.16	1.3
18.1	0.28	0.26 – 0.30	1.5

Intermediate precision (which includes variability across multiple days) was evaluated using 3 control solutions. With each of 3 lots of CONTOUR NEXT test strips, each control was tested once on each of 10 instruments on 10 separate days for a total of 300 readings.

Table 5 – System intermediate precision results for CONTOUR NEXT EZ meter using CONTOUR NEXT test strips

Control Level	Mean, mmol/L	Standard Deviation, mmol/L	95% Confidence Interval of Standard Deviation, mmol/L	Coefficient of Variation, %
Low	2.37	0.03	0.031 – 0.036	1.4
Normal	7.12	0.09	0.080 – 0.095	1.2
High	20.89	0.36	0.331 – 0.392	1.7

Service Information

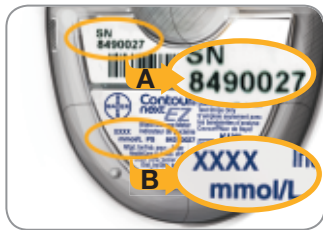
If you have a problem and none of the problem solving steps in this user guide help, contact Bayer Diabetes Care Helpline at 1-800-268-7200. We have trained specialists to help you.

Important

- Speak to a Bayer Diabetes Care 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 Bayer Diabetes Care Helpline:



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

2. Locate the CONTOUR NEXT test strips' expiry date on the bottle. _____
3. Check the battery icon on the display.
(See page 46, Changing the Batteries.)

Warranty

Important: Bayer Inc. ("Bayer") has no knowledge of the performance of the CONTOUR®NEXT EZ meter if used with any test strip other than CONTOUR®NEXT and therefore this warranty is invalid if the CONTOUR NEXT EZ meter is used with any test strip other than the CONTOUR®NEXT test strip or when the CONTOUR NEXT test strip is altered or modified in any manner.

Manufacturer's Warranty: Bayer Inc. warrants to the original purchaser that this meter will be free from defects in materials and workmanship for as long as you own your system. Bayer Inc. shall replace with a reconditioned meter or, at its option, repair at no charge a meter that is found to be defective.

This warranty is subject to the following exceptions and limitations:

1. The enclosed warranty card must be completed, signed and returned to validate your warranty.
2. This warranty is limited to replacement due to defects in parts or workmanship. Bayer Inc. shall not be required to replace any meters which are necessitated by abuse, accidents, alteration, misuse, neglect, maintenance by other than Bayer, or failure to operate the meter in accordance with instructions. Further, Bayer assumes no liability for malfunction or damage to Bayer meters caused by the use of reagents other than the appropriate Bayer reagents (e.g., CONTOUR NEXT test strips) manufactured or recommended by Bayer.

3. Bayer Inc. reserves the right to make changes in design of this instrument without obligation to incorporate such changes into previously manufactured meters.
4. This warranty is available only to registrants with a Canadian address.

THIS WARRANTY IS EXPRESSLY LIMITED TO THE METER AND MADE IN LIEU OF ANY AND ALL OTHER WARRANTIES EXPRESSED OR IMPLIED (EITHER IN FACT OR BY OPERATION OF LAW) INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE WHICH ARE EXPRESSLY EXCLUDED, UNLESS PROHIBITED BY LAW, AND IS THE ONLY WARRANTY GIVEN BY BAYER.

Limitations of Liability: IN NO EVENT SHALL BAYER BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF BAYER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

For warranty service: Purchaser must contact Bayer Diabetes Care Helpline at 1-800-268-7200 for assistance and/or instructions for the use of this instrument.



Supplies

When calling or writing for supplies be sure to include the number with the name of the replacement part or accessory item.

Replacement Parts

Part Number*	Item
40030030	Two 3-volt lithium batteries DL2032 or CR2032
84194050	CONTOUR®NEXT EZ user guide
84245772	CONTOUR®NEXT test strips, box of 50
84245799	CONTOUR®NEXT test strips, box of 100
84330028	CONTOUR®NEXT control solution, Normal
84329992	CONTOUR NEXT control solution, Low
84330001	CONTOUR NEXT control solution, High

*Part numbers are subject to change without notice.

References

- 1 Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Can J Diabetes. 2013;37(suppl 1): S33.
- 2 Canadian Diabetes Association, www.diabetes.ca
- 3 *Tietz Fundamentals of Clinical Chemistry, 5th Edition*, Edited by Burtis CA and Ashwood ER, W. B. Saunders Co., Philadelphia, PA, 2001, p. 444.
- 4 Atkin S, et al. Fingerstick Glucose Determination in Shock. *Ann Intern Med*. 1991; 114:1020-1024.



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9 a.m. to 9 p.m. EST, 7 days a week at:
1-800-268-7200
www.diabetes.bayer.ca**

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