





USER GUIDE

Intended Use

The CONTOUR®NEXT EZ blood glucose monitoring system is intended for self-testing by people with diabetes and by health care professionals to monitor glucose concentrations in capillary or venous whole blood. Capillary samples may be drawn from the fingertip only. It is intended for *in vitro* diagnostic use only. The test provides a quantitative measurement of glucose in blood from 0.6 mmol/L to 33.3 mmol/L. The CONTOUR NEXT EZ blood glucose monitoring system is not intended for diagnosis of, or screening for diabetes mellitus, and is not for use in neonatal care.

Information For Safety

- II Read your CONTOUR®NEXT EZ user guide, the MICROLET®2 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.
- Wash and dry your hands well before testing.
- Used test strips and lancets are possible biohazards and must be disposed of as medical waste.

WARNING: Potential Biohazard

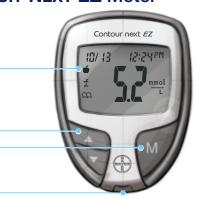
Health care professionals or persons using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral diseases. The user should follow the recommendations for prevention of blood-borne transmissible diseases in health care settings as recommended for potentially infectious human specimens prior to repair service or investigation.¹

For complete cleaning instructions, see page 15.

 The MICROLET®2 device is not suitable for use by health care professionals. It must not be used on more than one person due to risk of infection.



Your CONTOUR®NEXT EZ Meter



Your CONTOUR® NEXT Test Strip

Gray End

Display

Up/Down Scroll Buttons -Memory Button (On/Off, Memory

Recall, Enter) **Test Strip Port**

Insert this end into the test strip port.

Sample Tip

Blood sample pulled in here.

Your MICROLET®2 Lancing Device

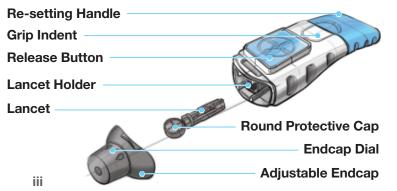


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Your Meter Overviewiii

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 3.8.8 is fully displayed. If there are missing segments, see Error Codes and Symbols (page 37). This may affect the way you see your results.

Icon	What it Means
88/88	Top area on the display presenting date and time.
Ó	Pre-meal result marker.
Í	Post-meal result marker.
m	Identifies a Logbook entry.
(O)	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 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 vour 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:

53 mmol or 55 mg

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 23 - 31.

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.



- 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.



GETTING STARTED

Information For Safety

TESTING

- 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 MICROLET®2 lancing device and MICROLET® 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 MICROLET®2 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 MICROLET® 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

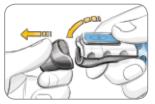
- 1. Wash and dry your hands well before testing.
- 2. Remove a CONTOUR®NEXT test strip from the bottle.



- 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.

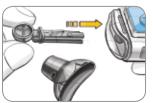
Preparing the Lancing Device



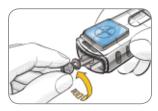
1. Remove the endcap from the MICROLET®2 lancing device with your thumb on the grip indent as shown.



2. Loosen the round protective cap on a lancet by rotating it 1/4 turn, but do not remove it. Always use MICROLET® lancets for best operation.



3. Insert the lancet firmly into the lancing device until it comes to a full stop. This will re-set the device. You can also pull and release the re-setting handle.



4. Twist off the round protective lancet cap. Be sure to save it for disposing of the used lancet.



5. Replace the gray endcap prior to getting your blood drop.



Shallow **Puncture**



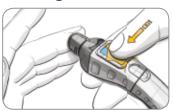
Deep **Puncture**

6. The puncture depth depends on the endcap setting and the amount of pressure applied to the puncture site. You will determine which combination works best for you.

TESTING

Getting Ready to

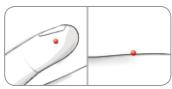
Getting the Blood Drop and Testing



 Press the endcap firmly against the puncture site and press the blue release button with your thumb.



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

Test immediately after a good blood drop has formed. 4. Immediately touch the tip of the test strip to the drop of blood. The blood is pulled into the test strip through the tip.

Hold the tip of the test strip

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 _____.

Fingertip

Testina

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.



TESTING

Testing

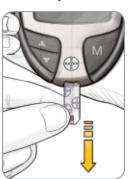
Your Blood

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 23 - 25. 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 diabetes²:

- 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 (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 # (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.



TESTING

Testing

Your Blood

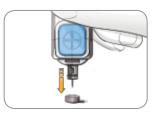
Testing Your Blood

TESTING

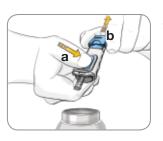
Removing the Used Lancet



1. In one hand, hold the lancing device with your thumb on the grip indent. With your other hand, hold the gray endcap dial as shown and gently snap off the endcap.



- 2. Place the round protective lancet cap on a flat surface with the Baver logo facing down.
- 3. With the used lancet still in the lancing device, push the lancet needle completely into the middle of the exposed side of the cap.



- 4. While pressing the release button (a), pull the re-setting handle (b), and the lancet will drop into the container you have selected.
- 5. Dispose of the used lancet as medical waste.

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

Cleaning Your Meter

The exterior of the CONTOUR®NEXT EZ meter can be cleaned using a moist (not wet) lint free tissue with a mild detergent or disinfectant solution, such as 1 part bleach mixed with 9 parts water. Wipe dry with lint free tissue after cleaning.

CAUTION: Do not allow cleaning solution to run in or around the button, battery cover or test strip port. Doing so may cause a malfunction.

www.baverdiabetes.ca



Control Solution Testing

Use only Bayer's CONTOUR®NEXT control solutions (Normal, Low or High) with your CONTOUR®NEXT EZ blood glucose monitoring system.

Using anything other than CONTOUR NEXT control solution could present incorrect 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 Bayer's CONTOUR NEXT control solutions. 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 control solution. 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. Gently rock the control bottle before opening to ensure it is mixed well.



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



TESTING

Control Solution Testing

Control Solution Testing

- 7. Immediately touch the tip of the test strip to the drop of control solution. The solution is pulled into the test strip through the tip.
- **8.** Hold the test strip in the drop until the meter beeps.



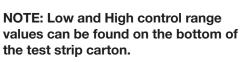
You will see the meter count down 5 seconds until the test is complete and your control test result is displayed.



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.

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

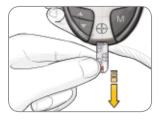




TESTING

Control Solution Testing

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 40.



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

23.



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

Press M to set.



The **month** will now flash. Press \blacktriangle or \blacktriangledown 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

and Sound

Setting the Sound



The flashing bell symbol will now appear on the display along with the word \mathbf{n} .

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



To turn the beep sound off during testing, press \blacktriangle or \blacktriangledown to display $\P F$.

Press M to set.



After setting the sound, <code>↓ · |</code> 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 <code>↓ · ¿</code>, 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

t-up for Basic

SETUP AND USE

- 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.



23

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!



Personalizing LO, HI and

SETUP AND USE

Using Marker and Reminder Features

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 premeal marker, press **M** when the **f** flashes.



The (3) 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 (⑤₁) will appear and stop flashing. If you do not want to set the reminder, press ▲ or ▼ and the (⑥₁) will disappear. Press

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

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 premeal 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, $\tilde{\chi}$ 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 (3).

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 Bayer's diabetes management software —GLUCOFACTS® Deluxe— and a data cable from Bayer. For a free download of the software go to www.bayerglucofacts.com or 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 Bayer's diabetes management software. Bayer is not responsible for any erroneous results from the use of other software.



Fransferring Results

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.



Viewing Basic Mode Results

Press \mathbf{M} to turn your meter on. Press \mathbf{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.
- 🞵 represents the number of test results.



Basic

Mode

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.



Viewing Results: Advanced Mode



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 [nd.

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		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.	



SERVICE & CAR

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
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 20 - 21 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 Bayer's CONTOUR®NEXT test strip should be used.	
-}HI(-	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.		
-,10/-	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
	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.
Control test result	Test strip is deteriorated due to heat or exposure to moisture.	Run another control test with a new test strip and control solution.
is out of range (too high or too low).	Control solution is not at room temperature or may not be mixed well.	Gently rock the control bottle to ensure the control solution is mixed well.
	Incorrect control solution was used.	Make sure you are using Bayer's CONTOUR®NEXT control solution.
	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.



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Changing

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 37).



- **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.]



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.



Caring for Your Meter

Caring for Your Meter

- Store meter in the carrying case provided whenever possible.
- Wash and dry hands well before handling to keep the meter and test strips free of water, oils and other contaminants.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt.
- Clean your meter as recommended on page 15.

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:³

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: 2003. 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.

Immunity to electrostatic discharge meets the requirements of IEC 61000-4-2: 2008. It is advisable to avoid use of electronic devices in very dry environments especially if synthetic materials are present. The CONTOUR®NEXT EZ meter has been tested for radio frequency interference at the frequency range and test levels specified by ISO 15197: 2003. 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 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 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 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).⁴



TECHNICAL, SERVICE & CAF

Technical Information

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 Testina.

Lipemic Specimen: Cholesterol concentrations >30.2 mmol/L or triglyceride concentrations >53.2 mmol/L 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.

Contraindications: Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension, hyperosmolar hyperglycaemia and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.5

Interference: Reducing 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.

Technical Information

The CONTOUR®NEXT EZ blood glucose monitoring system was tested using 100 capillary blood samples (duplicate replicates from three CONTOUR®NEXT 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 < 4.2 mmol/L

Difference range in values between YSI laboratory reference method and CONTOUR NEXT EZ meter Within ± 0.3 mmol/L		Within ± 0.6 mmol/L	Within ± 0.8 mmol/L*	
Number (and percent) of samples within specified range	48 of 54	54 of 54	54 of 54	
	(88.9%)	(100.0%)	(100.0%)	



Technical Information

Table 2 - System accuracy results for glucose concentration ≥ 4.2 mmol/L

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	439 of	544 of	546 of	546 of
	546	546	546	546
	(80.4%)	(99.6%)	(100.0%)	(100.0%)

^{*}Acceptance criteria in ISO 15197: 2003 are that 95% of all differences in glucose values (i.e., between reference method and meter) should be within 0.8 mmol/L for glucose values less than 4.2 mmol/L, and within 20% for glucose values greater than or equal to 4.2 mmol/L.

Technical Information

A repeatability study was conducted with the CONTOUR®NEXT EZ blood glucose monitoring system using five venous whole blood specimens with glucose levels from 2.2 mmol/L to 17.0 mmol/L. Multiple replicates (n=100) were tested using multiple CONTOUR NEXT EZ blood glucose meters and one lot of CONTOUR®NEXT blood glucose test strips. The following precision results were obtained.

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

Mean, mmol/L	Pooled Standard Deviation	Coefficient of Variation, %
2.28	0.04	1.8
4.15	0.08	1.9
6.50	0.08	1.3
10.59	0.12	1.2
17.05	0.29	1.7



Service Information

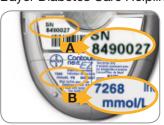
If you have a problem and none of the problem solving steps in this user guide help, contact Bayer Diabetes Care Helpline at 1-800-268-7200. We have trained specialists to help you.

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 42, 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 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.

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Supplies

- 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
84310760	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 Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Third Edition. Clinical and Laboratory Standards Institute (CLSI), document M29-A3, (ISBN 1-56238-567-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2005.
- ² Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2008 Clinical Practical Guidelines for the Prevention and Management of Diabetes in Canada. Can J Diabetes. 2008;32(suppl 1): S30.
- ³ Canadian Diabetes Association, www.diabetes.ca
- ⁴ Tietz Fundamentals of Clinical Chemistry, 5th Edition, Edited by Burtis CA and Ashwood ER, W. B. Saunders Co., Philadelphia, PA, 2001, p. 444.
- ⁵ Atkin, S. et al.: Fingerstick glucose determination in shock. Ann. Int. Med. 114:1020-24; 1991.





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