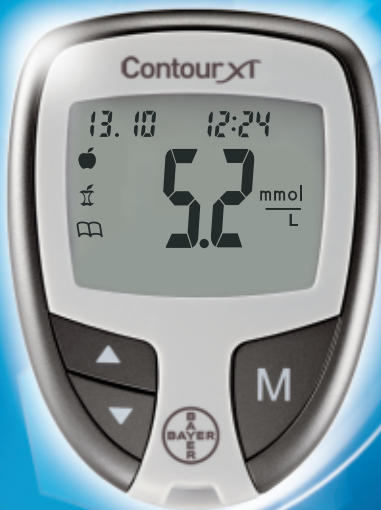




Contour[®]

Blood Glucose
Monitoring System

XT




User Guide



INTENDED USE: The CONTOUR[®]XT blood glucose monitoring system (Meter, tests strips and control solutions) is intended for self-testing by people with diabetes and by healthcare professionals to monitor glucose concentrations in venous whole blood and in fresh capillary whole blood drawn by 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 XT 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

-  Read your CONTOUR XT 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

Healthcare 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 healthcare settings as recommended for potentially infectious human specimens prior to repair service or investigation.¹

For complete cleaning instructions, see page 13.

- The MICROLET 2 lancing device is not suitable for use by healthcare professionals. It must not be used on more than one person due to the risk of infection.

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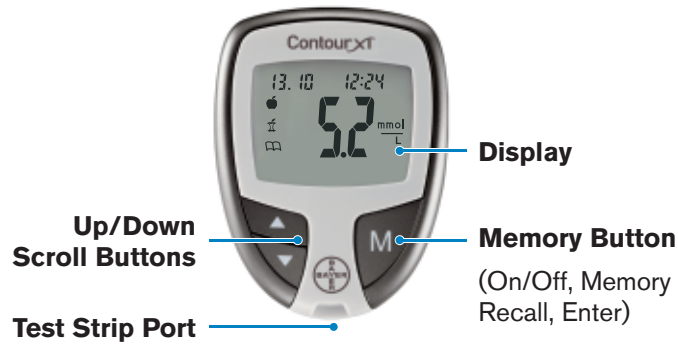
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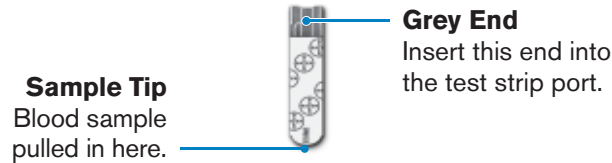
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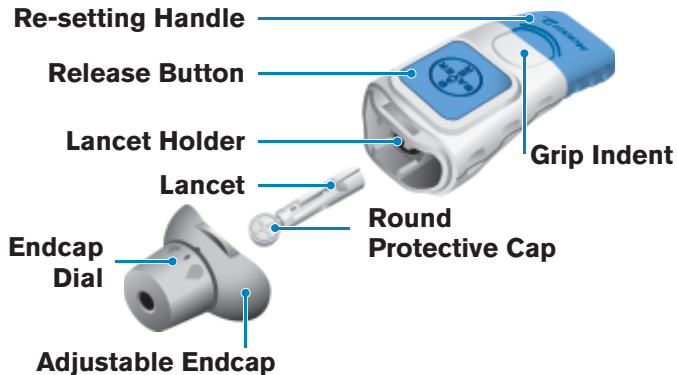
Your CONTOUR[®]XT Meter



Your CONTOUR[®]NEXT Test Strip



Your MICROLET[®]2 Lancing Device



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 (pages 32 – 34). This may affect the way you see your results.

8.8.8
Top area on the display presenting date and time.



Indicates sound is turned on.

AM or **PM** will appear if the meter is in 12 hour setup.

Apple icon
Pre-meal result marker.



The batteries are low and need to be changed, and will remain on display until batteries are changed.

Apple icon
Post-meal result marker.

8.8.8 Center area on the display that shows either your test result or any error codes.

d.m/d
Day/month format.

Open book icon
Identifies a Diary entry.

Battery icon **Water drop icon**
The meter is ready to test.

Alarm clock icon
Indicates a reminder has been set.

Checkmark icon
Control solution result marker.

mmgl
7dL
Results are displayed as mmol/L or mg/dL. The 7 appears when viewing 7 day HI-LO summary.

A
Indicates Average.

Thank you for choosing the CONTOUR[®] XT blood glucose monitoring system! We are proud to be your partner in helping you manage your diabetes.

Your Meter Features

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

Automatic: Your CONTOUR XT 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 XT meter has been preset at the factory with the standard date and time for your convenience.

- Your meter has been preset and locked to display results in 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 Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland).



Customizable: The CONTOUR XT meter allows you to set personal choices for some features. For more information, please see pages 21 – 27.

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. For the control solution do not use if it has been six months since you first opened the bottle. It will help to write the six month discard date on the control solution label.



Information For Safety

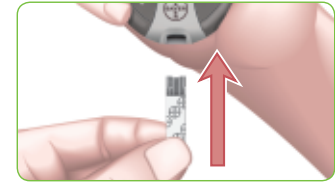
- **Have all the materials you will need ready before you begin testing.** This includes your CONTOUR[®]XT meter, the CONTOUR[®]NEXT test strips, the MICROLET[®]2 lancing device and MICROLET[®] lancets. You will also need CONTOUR NEXT control solution to run a quality control check. CONTOUR NEXT control solutions are available separately. Call Bayer Diabetes Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland)
- 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 Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland) 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 XT 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.


CONTOUR[®]XT meter CONTOUR[®]NEXT test strips

The following steps are shown in the proper order for performing a blood glucose test, pages 7 – 12.

Preparing the Test Strip

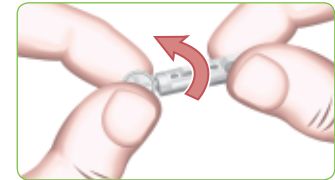
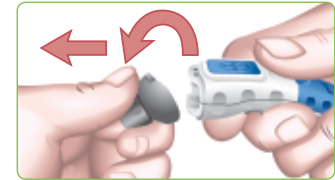
1. Wash and dry your hands well before testing.
2. Remove a CONTOUR[®]NEXT test strip from the bottle. Use only Bayer's CONTOUR NEXT test strips.
3. Hold the test strip with the grey end facing up.
4. Insert the grey end into the test strip port on the meter.



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.

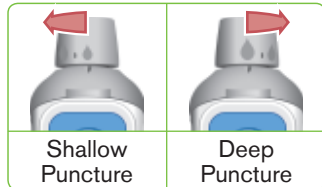
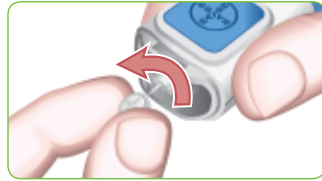
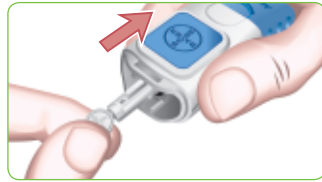
Preparing the Lancing Device

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 ¼ turn, but do not remove it. Always use MICROLET[®] lancets for best operation.



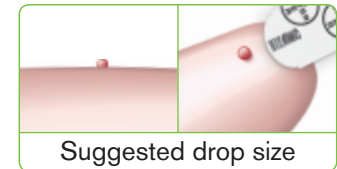
Need Help? 0845 600 6030 (UK) / 1 890 920 111 (Ireland)
www.bayerdiabetes.co.uk

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 grey endcap prior to getting your blood drop.
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.



Getting the Blood Drop and Testing


1. Press the endcap firmly against the puncture site and press the blue release button with your thumb.
2. Stroke your hand and finger towards the puncture site to form a drop of blood. Do not squeeze around the puncture site.
3. Test immediately after a good blood drop has formed.



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.

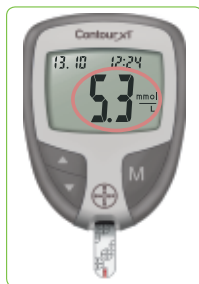
Hold the tip of the test strip in the blood drop until the meter beeps.

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

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

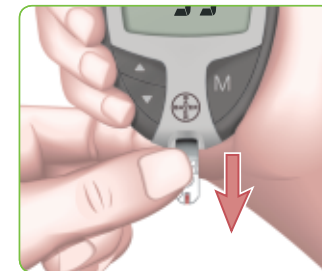


NOTE: You can set your meter to use meal marker options. See Advanced Mode settings (L-2) on pages 21 – 22. If you want to mark your result you will need to do it before removing the test strip.



Fingertip Testing

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 activity. Non diabetic plasma glucose concentrations are normally maintained within a relatively narrow range, roughly 3.9 - 6.1 mmol/L in a fasting state.² **You should consult with your healthcare professional for expected values specific to your needs.**

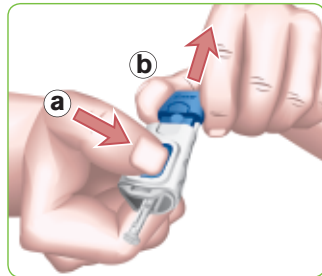
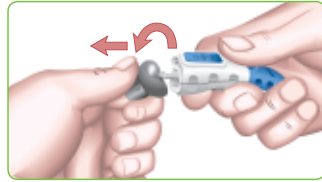


- **If your blood glucose reading is under 2.8 mmol/L, or you see $\text{L} \text{O}$ (less than 0.6 mmol/L) on the meter display, follow medical advice immediately.**
- **If your test result is above 13.9 mmol/L, or you see $\text{H} \text{!}$ (greater than 33.3 mmol/L) on the meter display, call your healthcare professional as soon as possible.**
- **Always consult your healthcare professional before changing your medication based on CONTOUR[®]XT test results.**

Need Help? 0845 600 6030 (UK) / 1 890 920 111 (Ireland)
www.bayerdiabetes.co.uk

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 grey endcap dial as shown, and gently snap off the endcap.
2. Place the round protective lancet cap on a flat surface with the Bayer 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®XT 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.



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

Control Solution Testing

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

Using anything other than CONTOUR NEXT control solution could present incorrect results.

You should perform a control test:

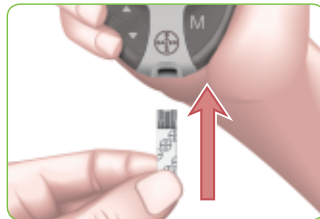
- When using your meter for the first time
- When you open a new bottle or package of test strips
- If you think your meter may not be working properly
- If you have repeated unexpected blood glucose results

Normal, Low or High control solutions are available separately. Call Bayer Diabetes Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland). Always use Bayer's CONTOUR NEXT control solutions. Other brands could present incorrect results.

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 grey end facing up.
4. Insert the grey end into the test strip port on the meter.



CONTOUR[®]XT meter CONTOUR[®]NEXT test strips

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.**



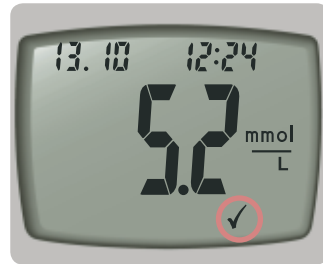
7. Immediately touch the **tip** of the test strip to the drop of control solution. The solution is pulled into the test strip through the tip.
8. Hold it in the drop until the meter beeps.

Need Help? 0845 600 6030 (UK) / 1 890 920 111 (Ireland)
www.bayerdiabetes.co.uk

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.

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

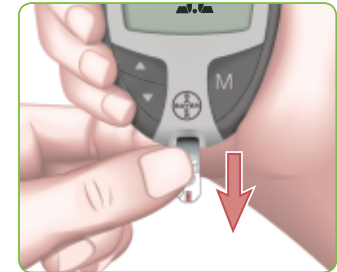


CONTOUR[®]XT meter CONTOUR[®]NEXT test strips

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 34.

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[®]XT meter allows you to set the date, time, and sound as you like them.

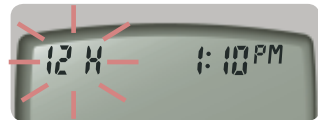
- You can view 12 or 24 hour time;
- month/day or day.month, and;
- choose to have your meter beep or not.

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

Press **M** to set.



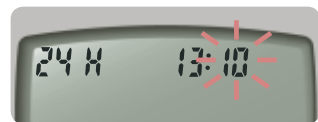
The number in the **hour** position will now flash. Press **▲** or **▼** until you reach the current hour.

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.

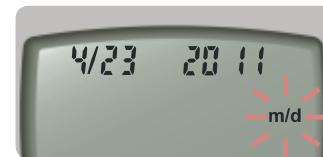
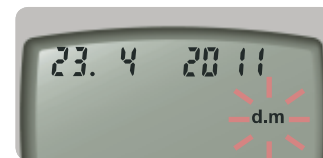
Press **M** to set.



Setting the Month and Day Format

d.m 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).

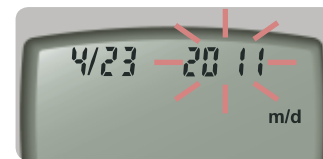
Press **M** to set.



Setting the Date

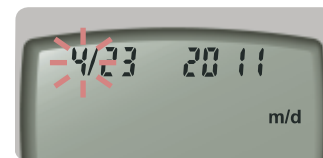
The **year** will be flashing. Press **▲** or **▼** to select the current year.

Press **M** to set.



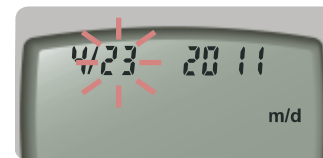
The **month** will now flash. Press **▲** or **▼** to select the month.

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.

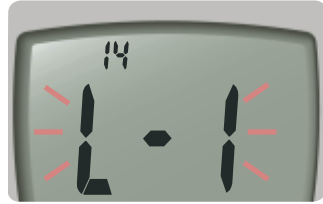


To turn the beep sound off during testing, press **▲** or **▼** to display **OFF**.

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.

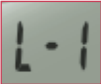
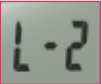


If you are using Basic Mode (**L-1** will appear on your display), you have completed your meter set-up.



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

Your new CONTOUR[®]XT 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)	ADVANCED MODE (L-2)
<ul style="list-style-type: none"> 7 day HI and LO summary 14 day average 480 test result memory 	<ul style="list-style-type: none"> 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
 <p>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:</p> <ol style="list-style-type: none"> Press M to turn your meter on. Wait to see the flashing test strip. Press and hold ▲ or ▼ for 3 seconds. L-2 will flash. Press ▲ or ▼ to change to L-1. Press M to set. 	 <p>To set your meter to Advanced Mode, and take advantage of meal markers and other functions available to you:</p> <ol style="list-style-type: none"> Press M to turn your meter on. Wait to see the flashing test strip. Press and hold ▲ or ▼ for 3 seconds. L-1 will flash. Press ▲ or ▼ to change to L-2. Press M to set.

Personalising LO, HI and Reminder Settings

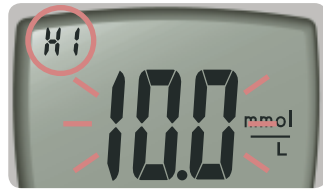
If you selected Advanced Mode (L-2 on your display) you can change your meter's personal low and high blood glucose settings. By personalizing these settings, your CONTOUR[®]XT meter will help you track these HI and LO results.



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[®]XT meter set-up for Advanced Mode!



Using the Markers

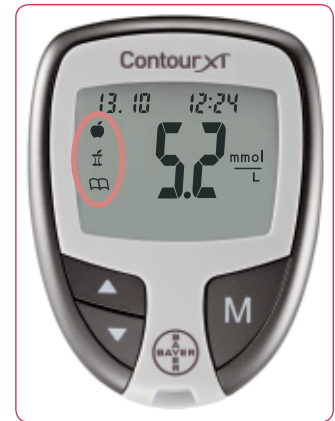
If you have set-up your meter in Advanced Mode, your meter will display three markers after you test your blood.

-  **Pre-meal** = Marks a test result that was taken before a meal.
-  **Post-meal** = Marks a test result that was taken after a meal.
-  **Diary** = The diary 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 diary. 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.

Need Help? 0845 600 6030 (UK) / 1 890 920 111 (Ireland)
www.bayerdiabetes.co.uk



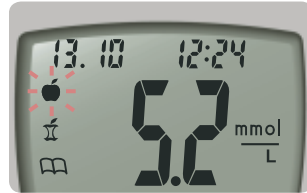
If you do not want to mark the test result

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 diary, press ▲ or ▼ until the 📅 flashes. Press **M** to set.

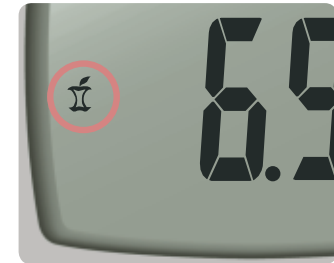
Using the Reminder Feature

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 7).


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[®]XT 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.bayerdiabetes.co.uk or call Bayer Diabetes Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland).

IMPORTANT: The CONTOUR XT 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.

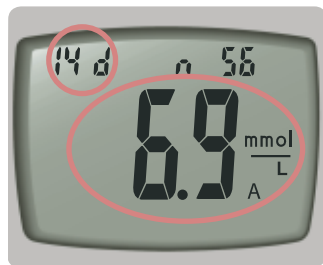
After performing a test

TO MARK RESULTS	YOU WILL SEE	TO SET	YOU WILL SEE	WHAT IT MEANS
<p>Pre-Meal Press ▲ or ▼</p>	 (Flashing)	Press M		Result is marked as a pre-meal test. You can now set a reminder.
<p>Reminder Press ▲ or ▼</p>	 (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.
<p>Post-Meal Press ▲ or ▼</p>	 (Flashing)	Press M		Result is marked as a post-meal test.
<p>Diary Press ▲ or ▼</p>	 (Flashing)	Press M		Result is marked in memory as unique. You should note this in your diary.

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.



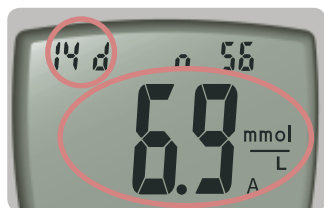
NOTES

- 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.



CONTOUR[®]XT meter CONTOUR[®]NEXT test strips

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

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.
E3 	<ul style="list-style-type: none"> The meter is sensing a used test strip. The wrong control solution was used. 	<ul style="list-style-type: none"> Remove the test strip and retest using a new test strip. Wait until you see the flashing blood drop on the display before testing. If control testing, make sure to use CONTOUR®NEXT control solution.
E4 	Test strip not inserted correctly.	Remove and reinsert the test strip properly (see page 7).



Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland).

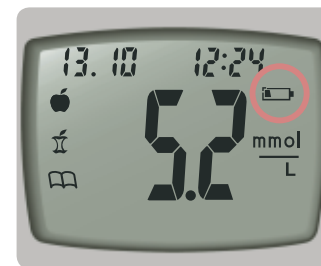
WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
E5 E9 E6 E12 E8 E13	Potential software or hardware issue.	Remove the test strip and retest using a new test strip. If you continue to have problems, contact Bayer Diabetes Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland).
E7 	Incorrect test strip.	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 18 – 19 to reset the date or time. If you continue to see this error, please contact Bayer Diabetes Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland).
E11	Abnormal result.	Remove the test strip and retest using a new test strip. Ensure 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.	<ul style="list-style-type: none"> Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes "HI", contact your healthcare professional as soon as possible.
 Glucose levels above 13.9 mmol/L may indicate a potentially serious medical condition.		
LO 	Test result is below 0.6 mmol/L.	<ul style="list-style-type: none"> Repeat the test using a new test strip. If your result still flashes "LO", follow medical advice immediately.
 Glucose levels below 2.8 mmol/L may indicate a potentially serious medical condition.		

If you do not resolve the problem, contact Bayer Diabetes Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland).

WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
Control test result is out of range (too high or too low).	<ul style="list-style-type: none"> Test strip or control solution is past the expiry date or is past the discard date. Test strip is deteriorated due to heat or exposure to moisture. Control solution is not at room temperature or may not be mixed well. Incorrect control solution was used. Meter could be damaged. 	<ul style="list-style-type: none"> Check all expiry dates and discard dates. Do not use expired testing materials. Run another control test with a new test strip and control solution. Gently rock the control bottle to ensure the control solution is mixed well. Make sure you are using Bayer's CONTOUR[®]NEXT control solution. If result is still out of range, contact Bayer Diabetes Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland).
Some display segments do not appear when the meter initially turns on.	Possible meter electronics failure.	Compare meter display with the illustration on page 3. If the display is not correct, contact Bayer Diabetes Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland).
Results are not displayed in expected units of measure (mmol/L).	This may affect the way you see your results.	Contact Bayer Diabetes Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland).

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 32**).



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.



- 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

- 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 13.

Symptoms of High or Low Blood Glucose

You can better understand your test results by being aware of the symptoms of high or low blood glucose.

According to the American Diabetes Association, some of the most common symptoms are:³

Low blood glucose (Hypoglycaemia):

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

High blood glucose (Hyperglycaemia):

- 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 healthcare professional immediately.

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

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:

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[®]XT 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 XT. 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 XT 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 XT 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 the glucose with the reagents on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and the mediator. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation is required.

Comparison Options: The CONTOUR[®]XT 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

Limitations

Preservatives: Blood may be collected by healthcare 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.

Lipaemic 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, paracetamol) will not significantly affect results. The limiting concentrations of these compounds are listed on your test strip insert.

Symbols Used

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

	Use by date (last day of month)		Do not reuse
	Batch code		Sterilized using irradiation
	Temperature limitations		Recycle Packaging
	Consult instructions for use		Batteries must be disposed of in accordance with laws in your country. Contact your competent local authority for information on the relevant laws regarding disposal and recycling in your area.
	<i>In Vitro</i> Diagnostic Medical Device		
	Manufacturer		
	Caution		The meter should be treated as contaminated and disposed of according to local safety rules. It should not be disposed of with waste electronic equipment.
	Catalogue number		Contact your healthcare professional or local waste disposal authority for medical waste disposal guidelines.
	Control Range Normal		
	Control Range Low		
	Control Range High		

Technical Information

The CONTOUR[®]XT 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 XT 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 (88.9%)	54 of 54 (100.0%)	54 of 54 (100.0%)

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

Difference range in values between YSI laboratory reference method and CONTOUR XT meter	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%*
Number (and percent) of samples within specified range	439 of 546 (80.4%)	544 of 546 (99.6%)	546 of 546 (100.0%)	546 of 546 (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[®]XT blood glucose monitoring system using five venous whole blood specimens with glucose levels from 2.2 to 17.0 mmol/L. Multiple replicates (n=100) were tested using multiple CONTOUR XT blood glucose meters and one lot of CONTOUR[®]NEXT blood glucose test strips. The following precision results were obtained.

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

Mean, mmol/L	Pooled Standard Deviation mmol/L	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 Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland). 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[®]XT 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 Support:

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 35, Changing the Batteries.)



Warranty

Manufacturer's Warranty: Bayer HealthCare warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for life. Bayer HealthCare shall, at no charge, replace a unit found to be defective with an equivalent or current version of the owner's model.

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

1. Consumable parts and/or accessories are warranted for 90 days only.
2. This warranty is limited to replacement due to defects in parts or workmanship. Bayer HealthCare shall not be required to replace any units which malfunction or are damaged due to abuse, accidents, alteration, modification, misuse, neglect, maintenance by someone other than Bayer HealthCare, or failure to operate the instrument in accordance with instructions. Further, Bayer HealthCare assumes no liability for malfunction or damage to Bayer HealthCare instruments caused by the use of reagents other than the appropriate Bayer reagents (e.g., CONTOUR[®]NEXT test strips) manufactured or recommended by Bayer HealthCare.
3. Bayer HealthCare reserves the right to make changes in design of this instrument without obligation to incorporate such changes into previously manufactured instruments.
4. Bayer HealthCare has no knowledge of the performance of the CONTOUR[®]XT blood glucose meter when used with any test strips other than CONTOUR NEXT test strips, and therefore makes no warranty of the performance of the CONTOUR XT meter when used with any test strips other than CONTOUR NEXT test strips or when the CONTOUR NEXT test strip is altered or modified in any manner.

5. Bayer HealthCare makes no warranty of the performance of the CONTOUR®XT meter or test results when used with any control solution other than CONTOUR®NEXT control solution.

BAYER HEALTHCARE MAKES NO OTHER EXPRESS WARRANTY FOR THIS PRODUCT. THE OPTION OF REPLACEMENT, DESCRIBED ABOVE, IS BAYER HEALTHCARE'S ONLY OBLIGATION UNDER THIS WARRANTY.

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

For warranty service: Contact Bayer Diabetes Support at 0845 600 6030 (UK) / 1 890 920 111 (Ireland) 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
81534497	CONTOUR®XT user guide
83412055	CONTOUR®NEXT control solution, Normal

*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 Longo DL, et al.: *Harrison's Principles of Internal Medicine, 18th edition*. 2011:3003
- ³ American Diabetes Association, www.diabetes.org
- 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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