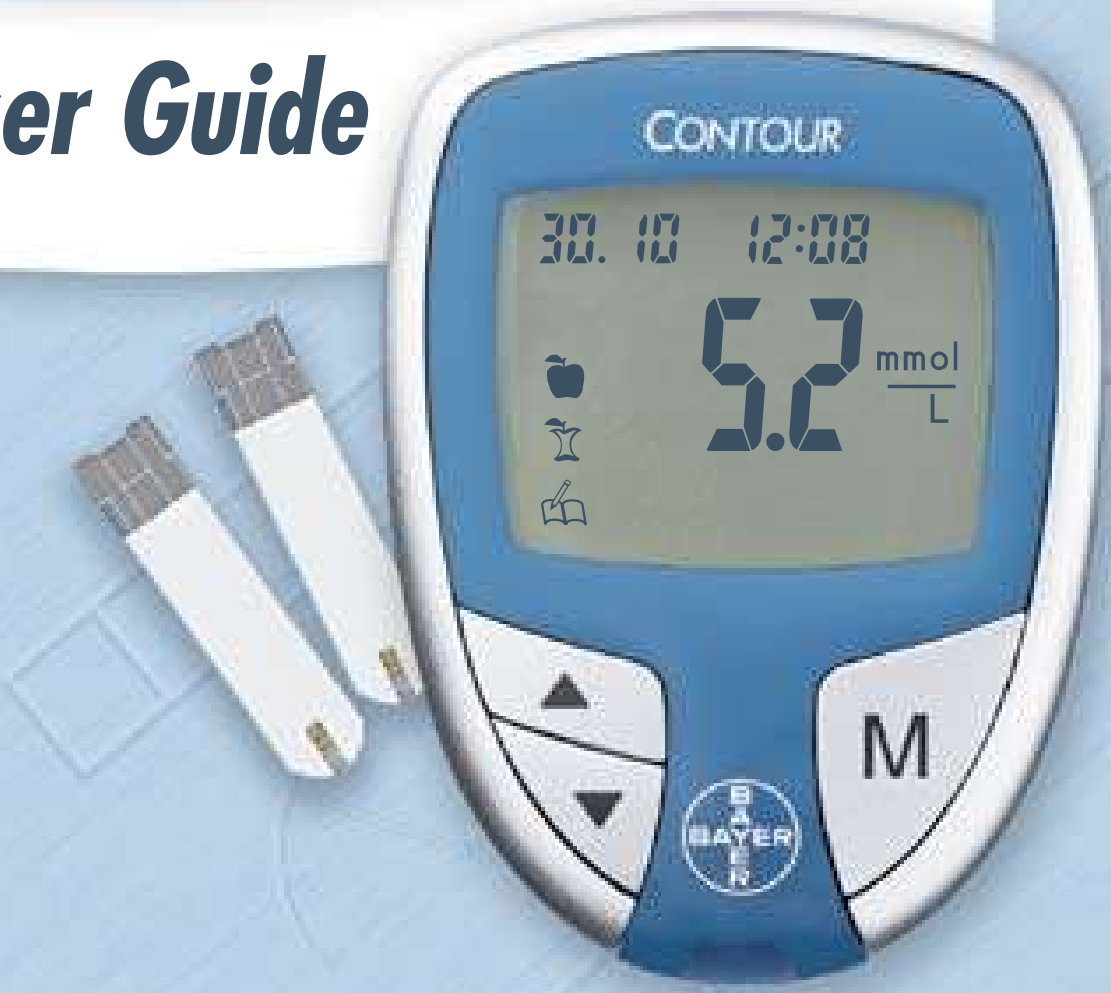


ASCENSIA®
CONTOUR®
Blood Glucose Monitoring System

User Guide



For Use With
Ascensia® *CONTOUR*®
Blood Glucose Meter and
Ascensia® *MICROFILL*®
Test Strips



Thank you for choosing the Ascensia® *CONTOUR*® Blood Glucose Monitoring System! We are proud to be your partner in helping you manage your diabetes. Our goal is to make this the simplest, most straightforward meter you will ever use.

The Ascensia *CONTOUR* Blood Glucose Monitoring System is intended for self-testing by people with diabetes and by healthcare professionals to monitor glucose concentrations in whole blood.

Additional Materials

- **Ascensia® *MICROFILL*® Test Strips**—Use for blood glucose or control solution testing. Supplied in a handy bottle with an easy-to-open flip-top lid.
- **Ascensia® *MICROLET*® Adjustable Lancing Device**—Use for fingertip puncture with an Ascensia *MICROLET* Lancet.
- **BATTERIES**—Use two 3-volt (DL2032 or CR2032) lithium batteries. Replace when necessary.

For short simple instructions, a quick reference guide is also provided. It can be more convenient when travelling.

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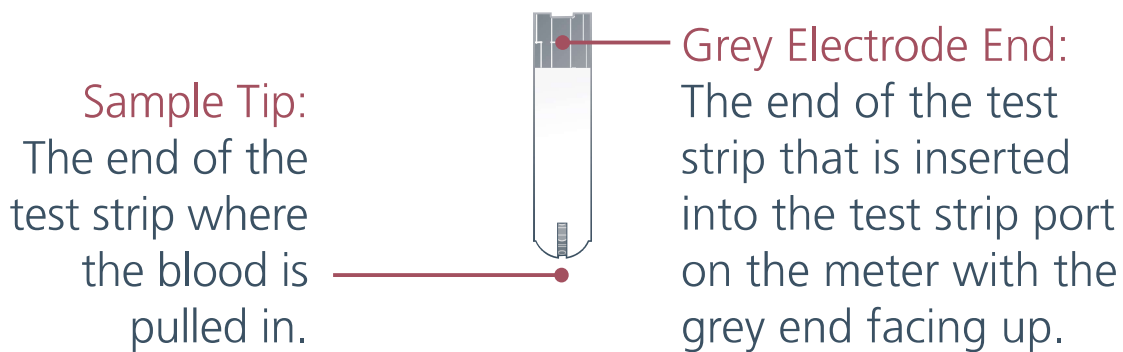
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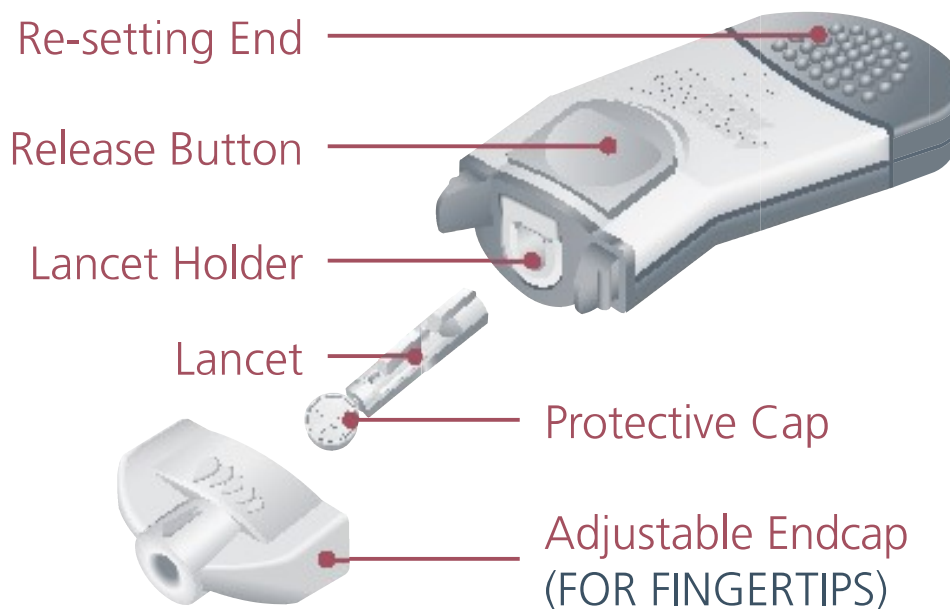
Your Ascensia® *CONTOUR*® Meter:



Your Ascensia® *MICROFILL*® Test Strip:




Your Ascensia® *MICROLET*® Lancing Device:



Your Meter Display

The picture below shows all the symbols that will appear on your meter display. When the meter is off, press and continue holding the ▲ or ▼ button. All segments will be displayed and remain on while holding the button down for 10 seconds. Repeat as needed to compare your meter to the display shown below.

While all characters are displayed, it is most important to verify that 8.8.8 is fully displayed. If there is a difference, see Error Codes and Symbols (page 17). This may affect the way you see your results.

 Top area on the display presenting date and time.	 Indicates beeper is turned on.	AM or PM will appear if the meter is in 12 hour setup.
 Indicates an alarm has been set.		d.m/d Displays the date format.
 Pre-meal result marker.		mmgl <u>7dL</u> Results are displayed along with the preset units of measure. The 7 appears when viewing number of results over past 7 days.
 Post-meal result marker.	 Control result marker.	A Average.
 Identifies a test result as unique or different.	 Indicates the meter is ready to test.	 Indicates the batteries are low. Will remain on until batteries are changed.
	 Indicates it is too cold or too hot for your meter to test accurately.	

Your Meter Features

Programmed: Your Ascensia *CONTOUR* Meter has been preset at the factory with the standard date, time, and meter features used where you live. To change these settings or use advanced meter features, such as meal markers, read through the Options section of your user guide.

Easy: The Ascensia *CONTOUR* Blood Glucose Monitoring System is all about simplicity. You will notice its uncomplicated approach the first time you see it. Simple things like the use of three large buttons and a clear display are sure to make this your favorite meter right from the start.

Automatic: You no longer have to worry about coding the meter or marking a control test result. The Ascensia *CONTOUR* Meter does it automatically. It will even tell you when a test strip is under-filled.

Makes Sense: You will find features that customers *just* like you asked for. Practical features like a **speedy** test time, a very **small** blood sample size, and a simple testing procedure (*no coding required!*) make the Ascensia *CONTOUR* Meter *your* meter.

Convenient: Your Ascensia *CONTOUR* Meter takes up about as much room in your pocket or bag as your key ring. The meter's small size, sleek design, and ease of use allows you to take it everywhere. You will be likely to test more often, which can mean better control of your diabetes.

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; this will also help you decide what to do if your results seem unusual.

Some of the most common symptoms are:¹

High blood glucose (Hyperglycemia):

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

Low blood glucose (Hypoglycemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- strange behavior
- confusion
- passing out
- seizure

Ketones (Ketoacidosis) from untreated Hyperglycemia:

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

If you are experiencing any symptoms, test your blood glucose. If your test result is below 2.8 mmol/L or above 13.9 mmol/L, contact your doctor immediately.


For additional information and advice, contact your healthcare professional.

Important Things to Know

Your Ascensia CONTOUR Blood Glucose Meter is specific for glucose and has been referenced to plasma/serum values. Methods calibrated to plasma/serum can be 9 to 15% higher than the results of whole blood glucose assay methods.

- ▶ ***Always keep the test strips in the original bottle. Tightly close the bottle immediately after removing a test strip.*** The bottle is especially designed to provide a dry environment for the test strips. Extended exposure to room humidity from leaving the bottle open or not storing the test strips in the original bottle will damage your test strips.
- ▶ Avoid excessive “milking” of your finger when forming a drop of blood and test immediately after forming the blood drop.
- ▶ ***DO NOT drop blood directly on the flat surface of the test strip.*** Your test strip is designed to easily “sip” the blood into the sample tip.
- ▶ ***DO NOT press the test strip against your finger.*** This may block the sample tip.
- ▶ ***DO NOT use a test strip that appears damaged or has been used.*** Test strips are for single use only.

IMPORTANT NOTE: Your meter has been preset and locked to display results in mmol/L (millimoles of glucose per liter). Results in mmol/L will **always** have a decimal point (e.g., $5.3 \frac{\text{mmol}}{\text{L}}$); results in mg/dL (milligrams of glucose per deciliter) will **never** have a decimal point (e.g., $96 \frac{\text{mg}}{\text{dL}}$). Check your display to ensure that results are being displayed in the expected units; if they are not, contact Bayer Customer Service at the number below.

1. Have all the materials you will need ready before you begin testing. This includes your Ascensia *CONTOUR* Meter, the Ascensia *MICROFILL* Test Strips, and the Ascensia *MICROLET* Lancing Device with Ascensia *MICROLET* Lancets. You may also need Ascensia® *MICROFILL*® Control Solution to run a quality control check.
2.  Read your user guide and all instructional materials provided in your meter kit before testing.
3. Let the meter and test strips adjust to the temperature of the location where you are testing. Whenever the meter is moved from one location to another, allow 20 minutes for the meter to adjust to the temperature of that new location before performing a blood glucose test. The products have been designed to give accurate results at temperatures between 5°C and 45°C.
4. It is important not to use the test strips or control solution if the expiry date printed on the bottle label and carton has passed or it has been six months (180 days) since you first opened the bottle. It will help to write the six month **discard date** on the label in the area provided when you first open the test strips or control solution.
5. Wash your hands thoroughly with warm soapy water and dry them well.

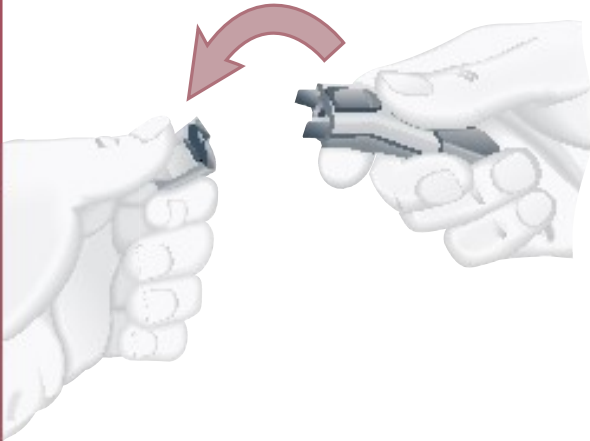


Potential Biohazard: Healthcare professionals or persons using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral diseases.²

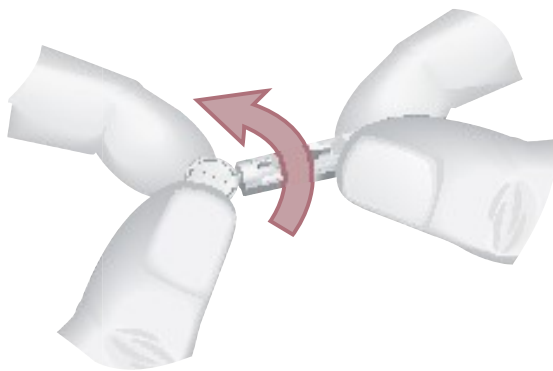
Getting Ready to Test:



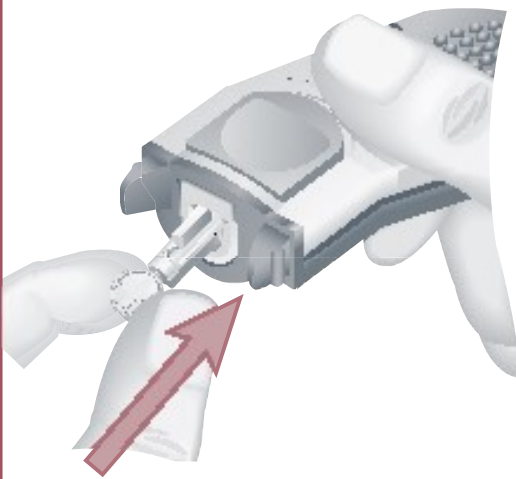
Read the Ascensia *MICROLET* Lancing Device insert for complete instructions.



Remove the endcap from the Ascensia *MICROLET* Lancing Device.

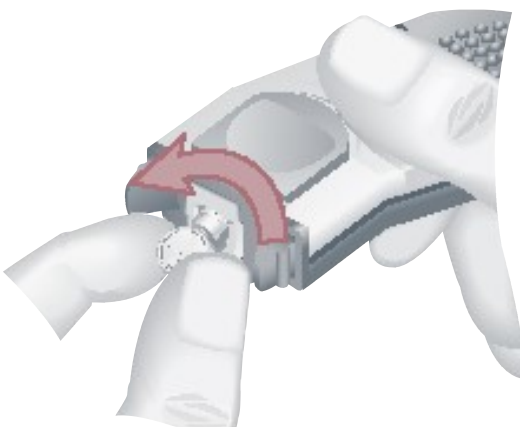


Rotate (do not remove) the protective cap on a lancet $\frac{1}{4}$ turn.



Insert the lancet firmly until it comes to a full stop. This will "re-set" the device.

NOTE: You can also pull and release the Re-setting End.



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

Replace the device endcap.

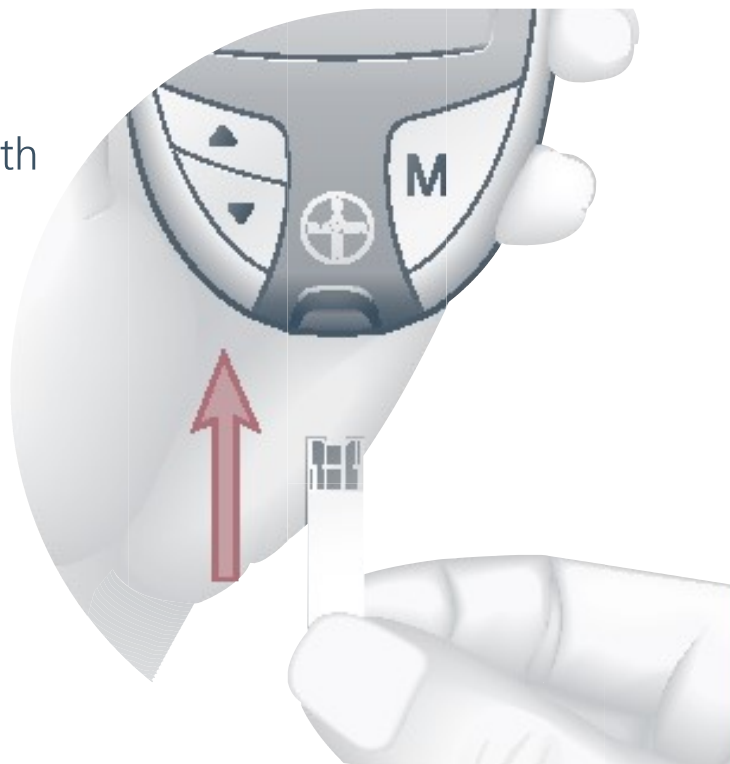


Remove a test strip from the bottle. **Tightly close the bottle lid immediately after you have removed the test strip.**

NOTE: Check the expiry and discard dates. Make sure the test strip does not appear torn or damaged.

Hold the test strip with the grey end facing up.

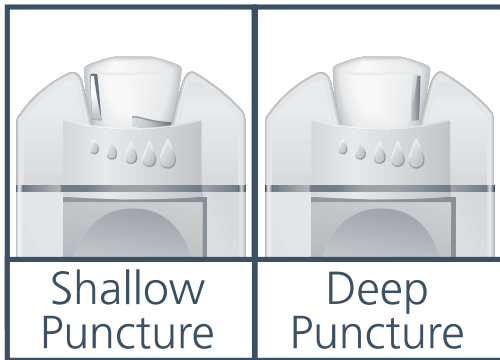
Insert the grey end into the test strip port on the meter. *No coding needed!*



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



Getting the Blood Drop:

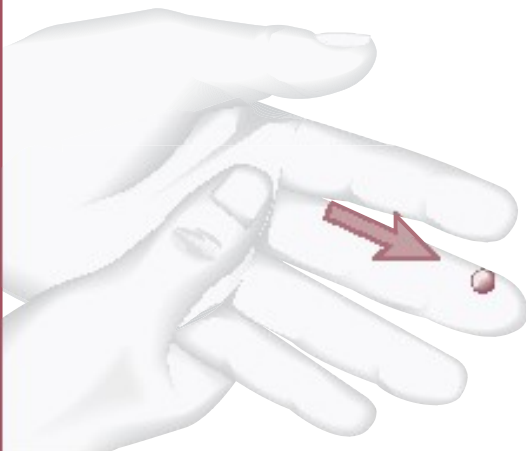


Fingertip Testing—

The depth of the puncture depends upon the adjustable endcap setting you choose and the amount of pressure applied to the puncture site. You should determine which combination works best.



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



Wait a few seconds. Stroke your hand and finger towards the puncture site to form a drop of blood. Do not squeeze around the puncture site (“milking”).

Test immediately after you have formed a blood drop (see page 12).

Multiple Site Testing—



Read the lancing device insert for complete instructions.

Blood samples for glucose testing may be taken from sites other than your fingertips. Multiple Site Testing using blood from the forearm, palm, abdomen or thigh may give glucose results that significantly differ from fingertip blood.

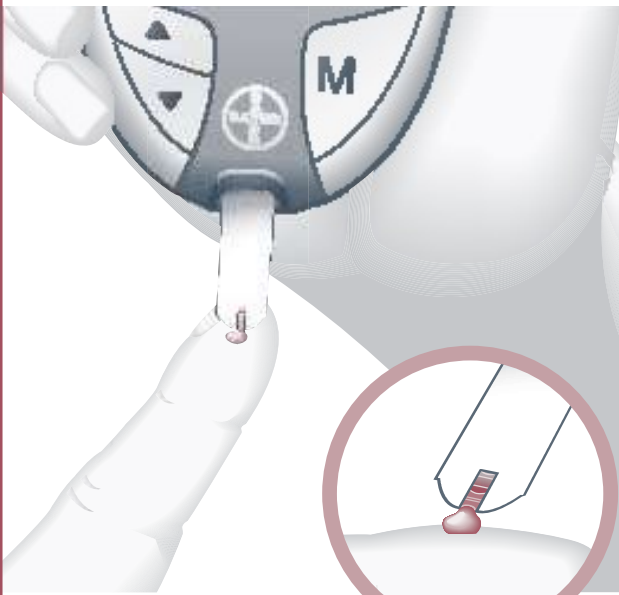


Differences occur when blood glucose levels are changing rapidly, such as after a meal, after insulin and with exercise.

We recommend the following:

- 1.** Use a fingertip sample for testing blood glucose whenever you will be participating in risky activities such as before driving a car or operating machinery.
- 2.** If you have hypoglycemic unawareness (you do not recognise the symptoms of or cannot tell when you have low blood glucose) Multiple Site Testing is not recommended. Please consult with your healthcare professional if you have low blood glucose levels.
- 3.** Select a soft, fleshy area of skin that is free from hair and visible veins for Multiple Site Sampling.
- 4.** Consult your healthcare professional to determine if Multiple Site Testing is right for you.
- 5.** Use multiple sampling sites for blood glucose tests only when it is more than two hours after a meal, more than two hours after taking medication, or more than two hours after exercise.

Testing Your Blood:



Immediately touch the **tip** of the test strip to the drop of blood. The blood is pulled into the test strip through the tip. **Do not press the tip against the skin or place the blood on top of the test strip.**

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



After the beep, you will see the meter countdown the five seconds until the test is complete and your result is displayed.



Your test result will automatically be stored in the meter memory.

You can set your meter to use special marker options (see pages 21–24).

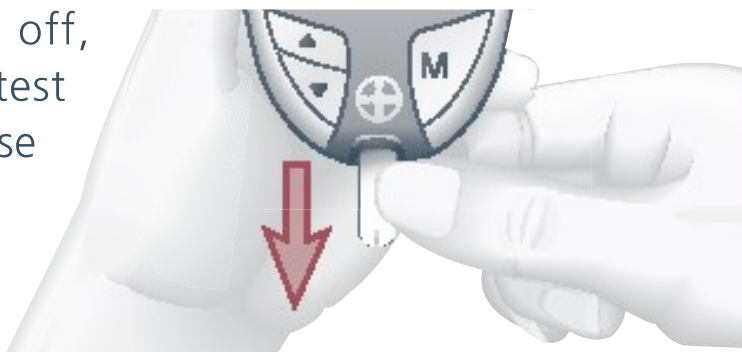
Expected Values: Blood glucose values will vary depending on food intake, medication dosages, health, stress or exercise. Consult your healthcare professional for the target value that is appropriate for you. Standard medical practice goals for a typical non-pregnant individual with diabetes are:³

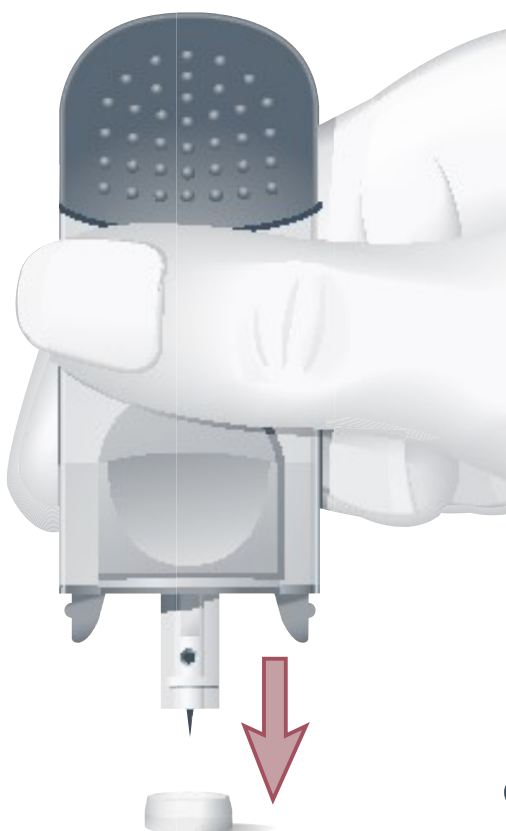
- Before a meal glucose: 5.0 to 7.2 mmol/L
- 2 hours after a meal: less than 10.0 mmol/L



- If your test result is below 2.8 mmol/L, above 13.9 mmol/L, or you see “LO” or “HI” on the meter display, call your physician or healthcare professional immediately.
- Do not change your medication based on *Ascensia CONTOUR* blood glucose results without the advice of your physician or healthcare professional.

To turn your meter off, simply remove the test strip. Carefully dispose of the used test strip.

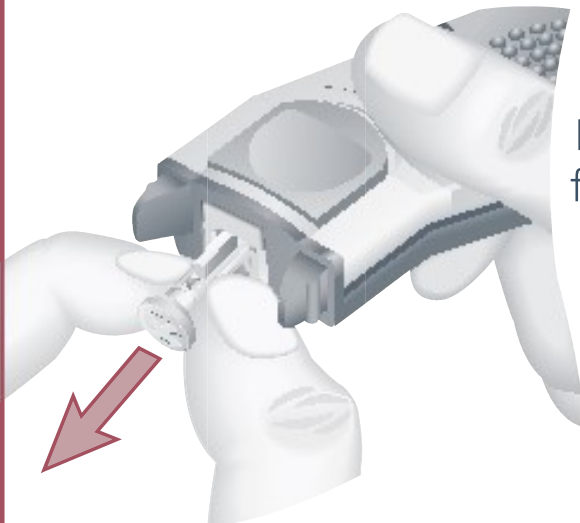




To remove the used lancet: Place the protective cap on a flat surface with the Bayer logo facing down. Remove the endcap. (Do not use the same endcap on another person.)

With the used lancet still in the lancing device, push the lancet needle completely into the middle of the exposed side of the cap. This will “re-set” the device.







Push the blue release button to expose the lancet.






Grasp the lancet body and pull it straight out of the device. Do not reuse lancets, they are for single use only. Dispose of the used lancet carefully to prevent injury or contamination to others.

Error Codes and Symbols:

If you do not resolve the problem, contact Bayer Customer Service at 0845 600 6030 in the UK or 1 890 920 111 in Ireland.

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 then the meter will turn off)	Dead batteries	Replace the batteries.
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 twenty minutes before testing.
E2 	The test strip has not filled enough for an accurate test.	Remove the test strip and retest using a new test strip.
E3 	The meter is sensing a used test strip.	Remove the test strip and retest using a new test strip. Wait until you see the flashing blood drop on the display before adding the blood sample.
E4 	Test strip not inserted correctly.	Remove and reinsert the test strip properly (see page 8).
E5 E12 E6 E13 E8 E14 E9	Potential software or hardware issue	Remove the test strip and retest using a new test strip. If you continue to have problems, contact Bayer Customer Service.

If you do not resolve the problem, contact Bayer Customer

WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
E7 	Wrong test strip	Remove the test strip and retest using Ascensia <i>MICROFILL</i> Test Strip. If you continue to have problems, contact Bayer Customer Service.
E10	Invalid date or time	See set-up instructions (page 21) to set the date and time on your meter. If you continue to have problems, contact Bayer Customer Service.
E11	Abnormal result	Remove the test strip and retest using a new test strip. Carefully follow testing instructions in your user guide. If you continue to have problems, contact Bayer Customer Service.
HI	Test result is above 33.3 mmol/L	<ul style="list-style-type: none"> • Wash your hands and the test site. Repeat the test using a new test strip. • If your result is still "HI", contact your physician or healthcare professional immediately.
 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 is still "LO", contact your physician or healthcare professional immediately.
 Glucose levels below 2.8 mmol/L may indicate a potentially serious medical condition.		

WHAT YOU SEE	WHAT IT MEANS	WHAT YOU SHOULD DO
<p>Control test result is out-of-range (too high or too low).</p>	<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. 	<ul style="list-style-type: none"> • Make sure you are using Ascensia <i>MICROFILL</i> Control Solution. • Gently rock the control bottle to ensure the control solution is mixed well. • Run another control test. • If result is still out-of-range, retest with a new test strip and control solution. • If result is still out of range, call Bayer Customer Service. • Check all expiry dates and discard dates. Do not use expired testing materials.
<p>Some display segments do not appear when the meter initially turns on.</p>	<p>Possible meter electronics failure.</p>	<p>Compare meter display with the illustration on page 3. If the display is not correct, contact Bayer Customer Service.</p>
<p>Results are not displayed in expected units of measure (mmol/L or mg/dL).</p>	<p>This may affect the way you see your results.</p>	<p>Contact Bayer Customer Service.</p>

Control Solution Testing:

Use Ascensia *MICROFILL* Control Solutions to practice on the system or to run a check to make sure the meter and the test strips are working properly. Using another control solution could present incorrect results.

Remove a test strip from the bottle. Tightly close the bottle lid immediately after you have removed the test strip.

NOTE: Check the expiry and discard date. Make sure the test strip does not appear torn or damaged.



Hold the test strip with the grey end facing up.

Insert the grey end into the test strip port on the meter.

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



Gently rock the control bottle before opening to ensure it is mixed well. Squeeze a small drop of control solution on a clean nonabsorbent surface (such as a piece of wax paper). **Do not apply control solution to the test strip directly from the bottle.**

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.



Hold it in the drop until the meter beeps.

After the beep, you will see the meter countdown five 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.

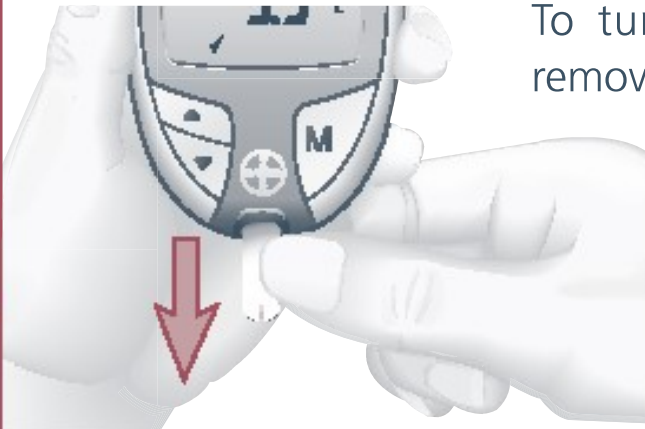




Compare your control test result with the Normal Control Range printed on the test strip bottle label or on the bottom of the test strip box.

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

If your control test result is out-of-range, see the “What You Should Do” recommendations on page 17.



To turn your meter off, simply remove the test strip. The result will automatically be marked ✓ and stored in the meter memory. Control results will not be included in your 14 day blood glucose average or in the 7 day total.

Carefully dispose of the used test strip.

Setting the Date, Time, and Sound:

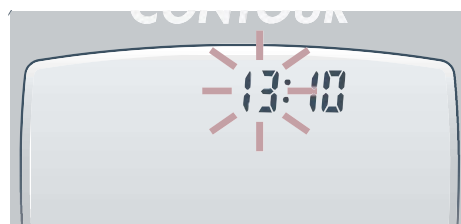
You can set your meter to display different options.

To get into set-up mode, press and hold **M** for three seconds. A complete display will briefly appear, then go to a display with the time.



Setting the Time:

The number in the **hour** position will be flashing.



Press ▲ or ▼ until you reach the correct time.

Press **M** to set.

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



Press **M** to set.



Setting the Date:

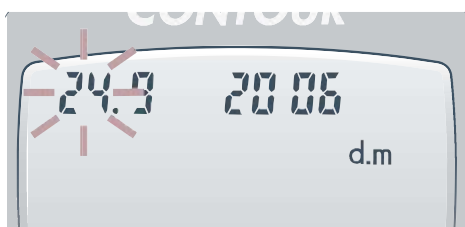
The date will now appear on the display. The **year** will be flashing. Press ▲ or ▼ to reach the current year.

Press **M** to set.



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

Press **M** to set.



The **day** will now flash. Press ▲ or ▼ to set 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 "beeps" during testing.



Press ▲ or ▼ to choose whether to turn the buzzer on or off. (You will hear a beep when you switch to the **On** screen.)

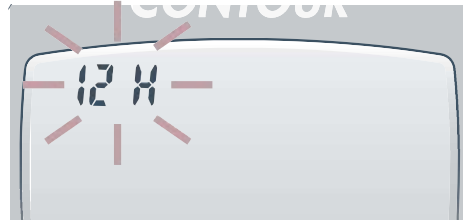
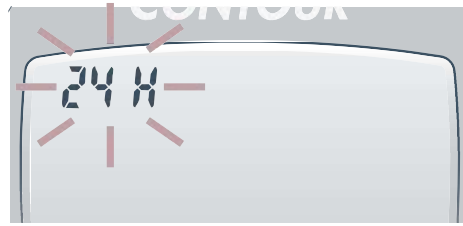
Press **M** to set.

Setting the 12 or 24 Hour Clock:

24H will now flash on the display. Press ▲ or ▼ to choose the 12H or 24H setting.

This option lets you set the meter to display time as a 12 hour setting with AM and PM or as a 24 hour display (military time).

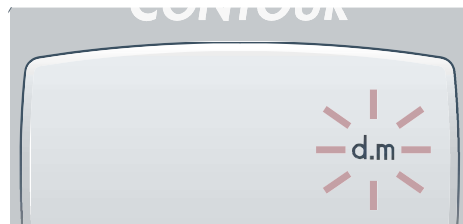
Press **M** to set.

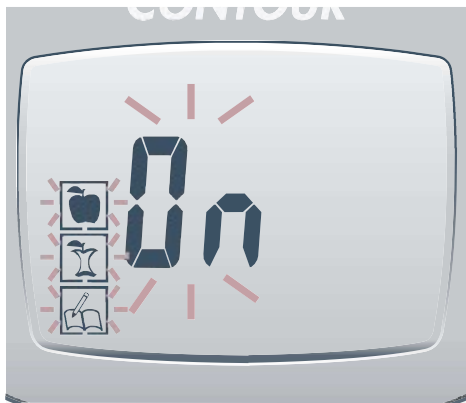


Setting the Month and Day format:

d.m will now flash on the display. Press ▲ or ▼ to choose how you want the date to appear (month/day or day.month).

Press **M** to set.





Setting the Markers and Alarm:

Markers and Alarm:

You will now see three markers displayed on your meter along with the word "On".

Your Ascensia *CONTOUR* Meter can give you the option of marking your test results.

(See pages 26–29 to learn how to use these options!)

Press ▲ or ▼ to turn the marker option on or off.

Press **M** to set.



You have now completed the set-up of your meter!

The final display will remain on for 3 seconds showing all the options you have chosen.


If you ever want to change the options you have chosen, simply go back to page 21 and follow the set-up instructions.


Using the Markers and Alarm:

If you have set your meter with the marker option on (see pages 21–24), your meter will display three markers next to your blood glucose test result.



 **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** = Marks any result as being unique or different in some way and for which you may want to make notes in your Glucolog® record 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.

If you do not want to mark the test result:

Press **M** or remove the used test strip to automatically save the test result in the meter memory.

OR

Press **▲** or **▼** until all three markers disappear from the display. Press **M** and remove the used test strip.



Dispose of the used test strip and lancet properly to prevent injury or contamination to others.

If you want to mark the test result:

Press **▲** or **▼** to move to the marker you want to set. You will know when you have chosen a marker when you see the box around it flashing on the display.

Press **M** to set.




If you mark a result with the , the  will appear with a box flashing around it.

This allows you to set an alarm that will go off in 2½ hours, to remind you to run a post-meal test.

If you want to set the alarm, press **M**.



If you do not want to set the alarm, press **▲** or **▼**. The  will disappear showing an empty flashing box.


Press **M** to set.

The Alarm:

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





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, you may want to mark this test with the  to identify this test result as your post-meal result.




If you do not want to run another test immediately after the alarm sounds, press any button to turn your meter off.


The meter will only set one alarm. It will remember the last alarm set. Any previous alarm setting will be lost.


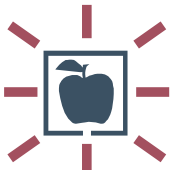






For example: An alarm has been set. You decide to retest before that alarm goes off. If you mark the new test result with a pre-meal marker  and set a new alarm , the old alarm setting will be ignored and only the new setting will sound in 2½ hours.


To Cancel an Alarm:







Press **M** to enter the meter memory. The 14 day average will appear along with the .

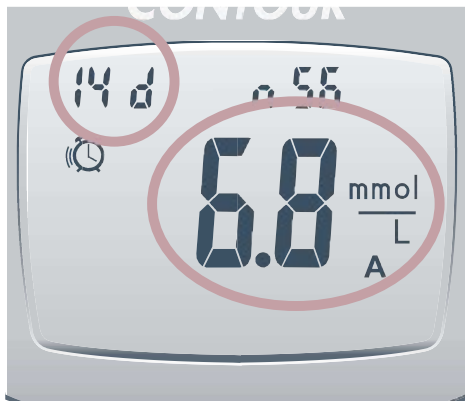
Press **M** again and a box will appear and flash around the .

TO MARK RESULTS	YOU WILL SEE	TO SET
 Pre-Meal Press ▲ or ▼	 ON	Press M
 Alarm Press ▲ or ▼	 ON	Press M
 Post-Meal Press ▲ or ▼	 ON	Press M
 Logbook Press ▲ or ▼	 ON	Press M

Press ▲ or ▼. The  will now indicate the alarm has been turned off.


Press **M** to set.

YOU WILL SEE	WHAT IT MEANS
	Result is marked as a pre-meal test. You can now set an alarm.
	Alarm is set to go off in 2½ hours to remind you to run a post-meal test.
	Result is marked as a post-meal test.
	Result is marked in memory as unique. You should note this in your Glucolog record diary.



Using the Memory:

With the meter off, press the **M** button on the meter to view stored test results.

The **14 day average** will appear on the display with the average for test results taken over the last 14 days. If you have set an alarm that has not sounded yet, you will also see a  symbol.

Number of results: The number of results included in the average is shown at the top of the display. Your control results are not included in this 14 day average.

Press ▲ to view the 7 day total.

7 day total: Your meter will display the total number of results taken during the last seven days.

High and low results: At the top of the display you will see the number of high results (above 10.0 mmol/L) and low results (below 4.0 mmol/L) during that seven day period.

Press ▼ to review previous results.

Previous results: Results will be shown starting with the most recent. Each result will show the date and time the test was taken as well as any symbols you chose to mark the test result.

You can press ▲ or ▼ to scroll forward or backward through the results. You can press and release the button to view stored results one at a time or you can hold it to move through results continuously.

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



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.

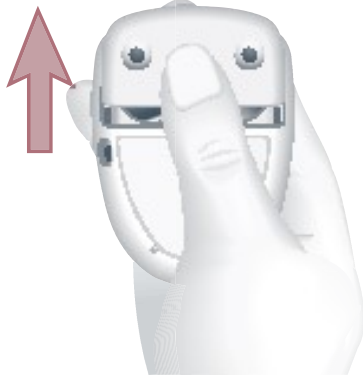
Press **M** to turn the meter off, or it will automatically turn off after three minutes.



Changing the Batteries:

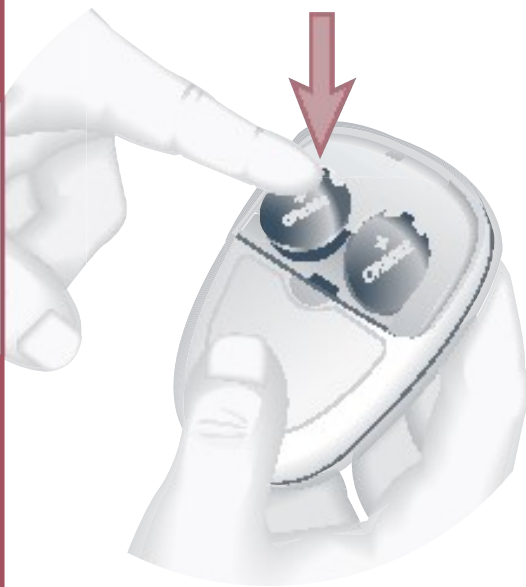


Batteries should be replaced when the meter continually displays  or the meter briefly shows  and then turns off (**See *Error Codes and Symbols*, page 15**).



Press firmly on the battery cover and slide in the direction of the arrow.

NOTE: *If you do not put the new batteries in the meter within five minutes of taking the old ones out, you may need to reset the date and time. Your other meter settings and stored results will be saved.*

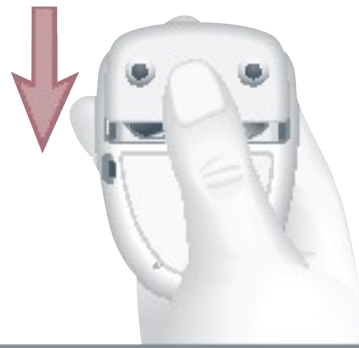


Remove the old batteries by pressing the top of the battery which will raise the bottom of the battery up.



Place new batteries under the prongs and into the battery compartment with the “+” side up.

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



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

Caring for the System

- Store meter in the carrying case provided whenever possible.
- Wash hands and dry thoroughly before handling to keep the meter and test strips free of oils and other contaminants.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- Avoid exposing meter and test strip to excessive humidity, heat, cold, dust, or dirt.
- The exterior of the 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 solution to run down into the test strip port or around the buttons. Doing so may cause a malfunction.

Transferring Results to a Computer:



You can transfer test results from the Ascensia *CONTOUR* 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 diabetes management software and a Bayer data cable.

IMPORTANT: The Ascensia *CONTOUR* Meter has not been tested or certified by Bayer for use with any software other than the Bayer diabetes management software. Bayer is not responsible for any erroneous results from the use of other software.

For more information, call our Customer Service Department (0845 600 6030 in the UK or 1 890 920 111 in Ireland), or visit our website at www.ascensia.co.uk.

Technical Information:

Accuracy

The accuracy of the Ascensia *CONTOUR* Blood Glucose Monitoring System has been assessed in a correlation study conducted by healthcare professionals. In this study, 108 fresh capillary blood specimens were tested with the Ascensia *CONTOUR* Blood Glucose Monitoring System by 108 untrained people with diabetes using three test strip lots. The reference measurement was done on the YSI Glucose Analyzer. Ascensia *CONTOUR* data compare well with the results from the YSI method.

Regression Statistics (Plasma/Serum Reference):

plasma reference glucose range: 4.2 to 22.0 mmol/L

Lot	y =	Correlation Coefficient (r)
1	1.02x – 0.01 mmol/L	0.972
2	1.03x – 0.24 mmol/L	0.963
3	0.95x – 0.02 mmol/L	0.974

Precision

A study was conducted with the Ascensia *CONTOUR* Blood Glucose Monitoring System with five heparinized whole blood specimens with glucose levels from 2.2 to 18.0 mmol/L. Multiple replicates (n=100) were tested using multiple Ascensia *CONTOUR* Blood Glucose Meters and one lot of Ascensia *MICROFILL* Blood Glucose Test Strips. The following precision results were obtained:

Plasma/Serum:

Mean	SD	Coefficient of variation
2.1 mmol/L	0.10 mmol/L	4.8%
5.6 mmol/L	0.28 mmol/L	5.1%
6.5 mmol/L	0.24 mmol/L	3.7%
11.4 mmol/L	0.38 mmol/L	3.3%
18.1 mmol/L	0.65 mmol/L	3.6%

Specifications:**Test Sample:** Whole blood**Test Result:** Referenced to plasma/serum glucose**Sample Volume:** 0.6 μ L**Measuring Range:** 0.6–33.3 mmol/L**Measuring Time:** 5 seconds**Memory Feature:** Stores most recent 480 test results**Battery Type:** Two 3-volt lithium batteries
(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:** 52.3 grams**Alarm:** “Beeps” whenever a test strip is inserted into or removed from the meter, when the test strip is filled with blood or control solution, and when a test result appears in the display. Two beeps will sound for an error. Twenty beeps will sound when a programmed alarm goes off.

Symbols Used:

The following symbols are used throughout the product labeling for the Ascensia® *CONTOUR*® Blood Glucose Monitoring System (meter packaging and labeling, test strip packaging and labeling and control solution packaging and labeling).



Expiry date (use by last day of month)



Batch code



Temperature limitations



Consult instructions for use



In vitro diagnostic device



Manufactured by



Authorized representative



Caution, consult accompanying documents



Product code number



Control Range Low



Control Range Normal



Control Range High

Manufacturer's Warranty: Bayer HealthCare warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for 5 years from the date of original purchase (except as noted below). During the stated 5-year period, 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. A 90-day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to replacement due to defects in parts or workmanship. Bayer HealthCare shall not be required to replace any units which malfunction or are damaged due to abuse, accidents, alteration, 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 reagents (i.e., Ascensia® *MICROFILL*® 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 Ascensia® *CONTOUR*® Blood Glucose Meter when used with any test strips other than Ascensia *MICROFILL* Test Strips, and therefore makes no warranty of the performance of the Ascensia *CONTOUR* Meter when used with any test strips other than Ascensia *MICROFILL* Test Strips or when the Ascensia *MICROFILL* Test Strip is altered or modified in any manner.

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.

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you. This warranty gives you specific legal rights and you may also have other rights which vary from state to state.

For Warranty Service: Purchaser must contact their Bayer HealthCare Representative for assistance and/or instructions for obtaining service of this instrument.

Service Information:

If you have a problem and none of the problem solving steps in the user guide help, call your Bayer Customer Service Representative. We have trained specialists to help you.

Important:

- ▶ Speak to a Bayer HealthCare 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 Ascensia *CONTOUR* Blood Glucose Meter and Ascensia *MICROFILL* Test Strips available when you phone. It would also be helpful to have a bottle of Ascensia *MICROFILL* Control Solution nearby.

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)
N1146C	Ascensia® <i>CONTOUR</i> ® User Guide
40453276	Bayer Data Cable

* Part numbers are subject to change without notice

REFERENCES

¹ American Diabetes Association, www.diabetes.org

² *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.

³ American Diabetes Association: Standards of Medical Care in Diabetes (Position Statement). *Diabetes Care* 29 (Suppl. 1):S10, 2006.



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