

Ascensia[™] CONTOUR[™]

Blood Glucose Monitoring System

USER GUIDE



For Use With
Ascensia[™] CONTOUR[™]
Blood Glucose Meter
and Ascensia[™]
MICROFILL[™] Test Strips



Bayer HealthCare

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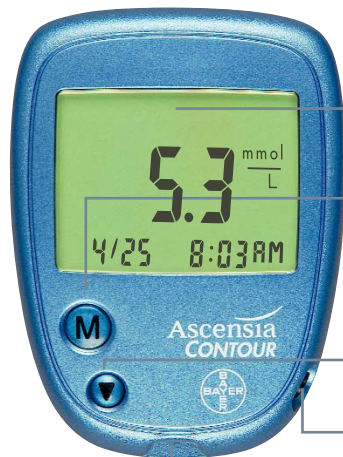
Thank you for choosing the Ascensia™ *CONTOUR*™ Blood Glucose Monitoring System! We are proud to be your partner in helping you manage your diabetes. Our goal is to make this the simplest, most straightforward Meter you'll ever use.

Additional Materials:

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

For short simple instructions, a quick reference guide is also provided for your convenience. It can be useful when traveling.

Your Ascensia™ CONTOUR™ Meter



Screen: This is where your blood glucose result will display.

Memory (M) Button: Use to view results stored in the memory and change Set-up features.

Scroll (▼) Button: Use to scroll through your blood glucose results in the memory and change Set-up features.

Data Port: Allows Meter to communicate with a personal computer via a cable.

Test Strip Slot: This is where you insert the Test Strip.



Gray Electrode End: Insert this end of Test Strip into Meter.

Ascensia MICROFILL Test Strips: Use for blood glucose or control solution testing. Come in a handy bottle with an easy-to-open flip-top lid.

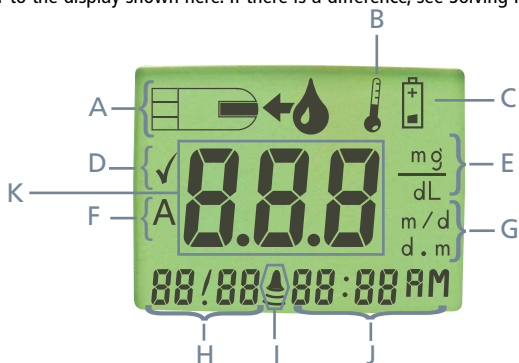
Sample End or Tip of Test Strip: Lightly touch this end of Test Strip to blood drop.

Note: Fold this page out for easy reference.

Caution: Before using any product to test your blood glucose (sugar), read all instructions carefully and practice the test.

Ascensia™ CONTOUR™ Meter Display Segments

A full display, as shown here, indicates that all characters in the display are working properly. You will briefly see this display each time the Meter turns on. Compare your Meter to the display shown here. If there is a difference, see Solving Problems, page 21.



- A. **Apply Sample:** When your Meter is ready for you to apply a sample of blood or control solution, it will show you this picture of a blood drop being “sipped” into the Test Strip.
- B. **Temperature Symbol:** If you see this on your screen, you will know that it is either too cold or too hot for your Meter to test accurately.
- C. **Low Battery Symbol:** This is the symbol you will see when the battery life is low. Replace batteries.
- D. **Control Marker:** This ✓ is the Meter’s way of telling you it has detected Control Solution. **Note:** The ✓ does not indicate the Control Test result is within the specified range.
- E. **Units-of-Measure:** Blood glucose results can be displayed either in millimole per liter (mmol/L) or milligram per deciliter (mg/dL) depending on the country where you live.
- F. **Average:** This “A” is used when displaying the 14-day average.
- G. **Date Format:** The date can be displayed either as month/day (m/d) or as day.month (d.m) depending on the country where you live.
- H. **Date:** The month and day are displayed here.
- I. **Beeper:** This picture will tell you if the beeper is on or off.
- J. **Time:** The hour, minutes and AM/PM are displayed here.
- K. **Results/Errors:** This is the area where your test results or any possible error codes will be displayed.

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The Ascensia™ *CONTOUR*™ Blood Glucose Monitoring System (Meter, Test Strips and Controls) is intended for self-testing by persons with diabetes, and by healthcare professionals, to monitor the level of glucose in whole blood. The Ascensia *CONTOUR* System is specific for glucose and has been referenced to plasma/serum glucose values.

Your Ascensia™ CONTOUR™ Meter...

- ❖ **Easy to Use**
- ❖ **No Coding Required**
- ❖ **Small Blood Sample**
- ❖ **15 Second Test Time**
- ❖ **Sleek Design**

Easy: The Ascensia CONTOUR Blood Glucose Monitoring System is all about simplicity. You'll notice its noncomplicated approach the first time you see it. Simple things—like the use of two simple buttons and a clear display—are sure to make this your favorite Meter right from the start.

Automatic: The designers of the Ascensia CONTOUR Meter have worked very hard to make your life a little easier. You no longer have to worry about coding the Meter (it's automatic) or marking a Control Test result (it's automatic, too). The Ascensia CONTOUR Meter will even automatically tell you if a Test Strip is underfilled.

Makes Sense: Your new Ascensia CONTOUR Meter just makes sense. You'll find features that customers *just like you* asked for. Practical features like a **15 second** test time, a very **small** blood sample size and a simple testing procedure make the Ascensia CONTOUR Meter *your* Meter.

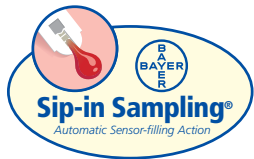
Convenient: The Meter's small size, sleek design, and ease of use means you'll take it everywhere with you. Your Ascensia CONTOUR Meter takes up about as much room in your pocket or bag as your key ring. You'll have it with you and will be more likely to test more often, which can mean better control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

Everyday Use

Before You Begin...

A few things you should know:

- A) Gather your testing supplies: your Meter, Test Strips, Ascensia™ MICROLET® Adjustable Lancing Device, and lancets.
- B) Wash your hands thoroughly with warm soapy water and dry them well.
- C) Avoid excessive “milking” of your finger when forming a drop of blood.
- D) Test immediately after forming a drop of blood on your finger.
- E) **DO NOT** press Test Strip firmly against the finger.
- F) **DO NOT drop blood directly on flat surface of the Test Strip.** Your Test Strip is designed to easily “sip” the blood into the Test Strip.



WARNING: Do not change your medication based on Ascensia CONTOUR results without the advice of your physician or healthcare professional.

Testing Your Blood Glucose Level...

Insert Test Strip



1. Hold the round end of the Test Strip with the gray electrode side up, and insert the Test Strip into the Meter until it stops.



The Meter will run a quick self-test and then prompt you to apply blood by showing you a picture of a blood drop being "sipped" into the Test Strip.

Obtain Blood Drop



2. Remove the Endcap from the Ascensia™ MICROLET® Device.
See package insert for Ascensia™ MICROLET® Adjustable Lancing Device for complete instructions for obtaining a blood drop.

3. Insert lancet firmly until it comes to a full stop. This will “cock” the device.



4. Twist off lancet cap.



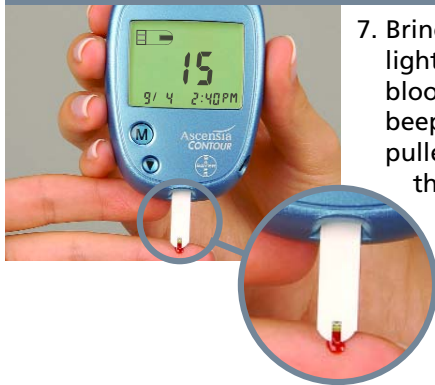
5. Replace the Endcap.



6. Press Ascensia™ MICROLET® Device firmly against puncture site and press button to release. Form a *small* drop of blood.



Test Blood Glucose



7. Bring **tip** of the Test Strip to lightly touch the drop of blood. Hold until the Meter beeps. Blood is automatically pulled into the Test Strip through the tip. The Meter will now begin counting down the 15 seconds until the test is complete.

8. Leave the Test Strip in the Meter until the test result appears on the display.




Caution: If you see "HI" or "LO" displayed, your blood glucose level may be above 33.3 mmol/L (600 mg/dL) or below 0.6 mmol/L (10 mg/dL). Repeat test. If you receive the same result, call your physician or health care professional *immediately*.

Turn Meter Off/Dispose of Used Test Strip

9. To turn your Meter off, simply remove the used Test Strip. Your test result will automatically be stored in memory.

Caution: Dispose of the used Test Strip and lancet carefully to prevent injury or contamination to others.

 **Helpful Hint:** You should always turn your Meter off by removing the Test Strip following a test. This will conserve your battery power.

However, if you forget to turn the Meter off, the meter will turn itself off after three minutes.



Multiple Site Testing

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:

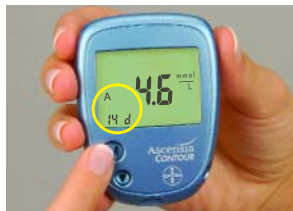
1. Use a fingertip sample for testing blood glucose whenever you will be participating in risky activities such as before driving a car or operating machinery.
2. If you have hypoglycemic unawareness (you do not recognize the symptoms of or cannot tell when you have low blood sugar) Multiple Site Testing 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 2 hours after a meal, more than two hours after taking medication, or more than two hours after exercise.



Viewing Your Stored Test Results...

Recall Test Results and Your 14-Day Average

Note: Your Ascensia™ CONTOUR™ Meter automatically calculates a 14-day average for you based on your blood glucose readings over the past 14 days.



1. Press the **M** Button. This will turn your Meter on and display your 14-day average.

Note: The “A” and “14d” icons on the screen indicate that the number displayed is your 14-day blood glucose average.

😊 **Helpful Hint:** The display will show three dashes if there are no blood glucose test results in the memory.



2. Press the ▼ Button to access memory and scroll through your blood glucose results one by one. You will see the most recent test result. You may also press and hold this button to continuously scroll through the test results. Your Meter can hold up to 240

test results. When you reach the end of the test results, “End” will be displayed. The Meter will also beep. You may press the ▼ Button to view the 14-day average and the blood glucose test results again.

3. Press the **M** Button to turn off your Meter.

Delete All Test Results

If you wish to delete all test results, follow these simple steps:

- 1) Press the **M** Button to turn your Meter on and display your 14-day average.
- 2) Press and hold the **▼** Button. (Your results will begin to scroll on the screen.) While holding the **▼** Button, press and hold the **M** Button until **"dEL"** appears on the screen (this will take about 3 seconds).
- 3) Release both buttons. **"dEL"** and **"ALL"** will now alternate on the screen 5 times and all test results will be deleted. The Meter will now show you 3 dashes along with the **"A"** and **"14d"** icons. Your results have been deleted.
- 4) Press the **M** Button to turn your Meter off.



😊 **Helpful Hint:** If you change your mind and decide that you do not wish to delete all of the test results while the **"dEL"** and **"ALL"** icons are alternating on the display, simply press any button and the test results will not be deleted.

Performing a Control Test...

There are times when you will want to do a quality Control Test so you know that your system is working properly. You may also want to do a Control Test to check the way you perform a test.

Before you begin, gather your testing supplies: your Meter, Test Strips and a bottle of Ascensia™ *MICROFILL*™ Control Solution.

Insert Test Strip

1. Hold the round end of the Test Strip with the gray electrode side up, and insert it in the Meter until it stops. The Meter will run a quick self-test and then you will see a flashing drop on the screen. This is your signal to apply Control Solution.

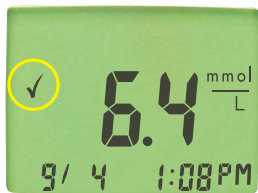



Prepare Control Drop

2. Squeeze a small drop of Control Solution on a clean nonabsorbent surface (such as a clean piece of wax paper). Do not apply Control Solution to the Test Strip directly from the bottle.

Perform Control Test

3. Bring the **tip** of the Test Strip to lightly touch the drop of Control Solution. Control Solution is automatically pulled into the strip through the tip. Hold until the Meter beeps. The Meter will now begin counting down the 15 seconds until the test is complete. Leave the Test Strip in the Meter until the Control Test result appears on the display. Compare your Normal Control Test result with the range printed on the Test Strip bottle label. This range also appears on the bottom of the test strip box along with the ranges for the Low and High Controls. (If the control test result falls outside of the control range, see Solving Problems, page 21.)



 **Helpful Hint:** The Ascensia *CONTOUR* Meter automatically recognizes and marks a Control Test result for you. You will notice that this has been done by the check mark (✓) displayed on the screen. This way, your Control Test results will not be included in your 14-day blood glucose average.

Note: The ✓ does not indicate the Control Test result is within the specified range.

Turn Meter Off/Dispose of Used Test Strip



4. To turn your Meter off, simply remove the Test Strip. The marked Control Result will automatically be stored in memory. Dispose of the used Test Strip.

Helpful Hints...

When using the Meter...

- ❖ Insert the Test Strip firmly until it comes to a full stop.
- ❖ Your Meter will turn off automatically after 3 minutes.
- ❖ Control Test results are automatically marked with a ✓ and will not be included in your 14-day average (see page 11).
Note: The ✓ does not indicate the Control Test result is within the specified range.
- ❖ You may mark any result you obtain by pressing the ▼ Button *before* you remove the Test Strip. Remember that marking a result means that it will not be included in your 14-day average.
- ❖ When your Meter has 240 results in memory and you perform another test, the Meter will keep the most recent result taken. This will replace the oldest result taken.

When using a Test Strip...

- ❖ Always check the expiration date on the Test Strip bottle or box. If the Test Strips have expired, replace with new Test Strips.
- ❖ Always use Test Strips within 6 months (180 days) after opening bottle. Don't forget to write the "first opening date" in the space provided on the bottle label.
- ❖ To be sure the Test Strip fills completely, *lightly* touch the Test Strip end to the blood drop or Control Solution drop **until** the Meter beeps.
- ❖ Capillary action will automatically "sip" the blood or Control Solution into the Test Strip.
- ❖ Test Strips can not be reused.
- ❖ The Ascensia *CONTOUR* Meter has been designed for use with Ascensia *MICROFILL* Test Strips **only**. Do not use any other Test Strips with the Ascensia *CONTOUR* Meter.

Beyond Everyday Use

Setting Time, Date and Other Features...



To start, **press and hold** the **M** Button until you see the time displayed. While you are holding the **M** Button, the Meter will run a quick self-test (full display shown) and then enter the Set-up mode (time display shown).

😊 **Helpful Hints:** ❖ You may turn the Meter off at any time during Set-up by pressing and holding the **M** Button until the Meter turns off. ❖ You will notice that during Set-up, one of the icons on the screen will flash. This is an easy way to tell what item you are currently changing. ❖ The Meter always scrolls in one direction when the ▼ Button is pressed. To scroll quickly, press and hold the ▼ Button.

Set the Time

To change the hour, press ▼.



To enter the hour and move on to change the minutes, press **M**.



To change the minutes, press ▼.

To enter the minutes and move on to choose between AM and PM, press M.

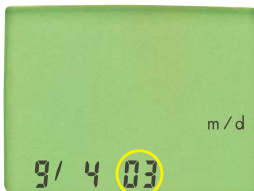
Note: the PM option is not available when using the 24-hour clock format.

To choose between AM and PM, press ▼.



To enter your choice and move on to select the year, press M.

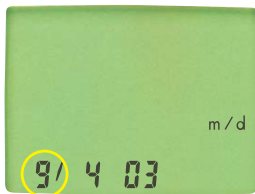
Set the Date



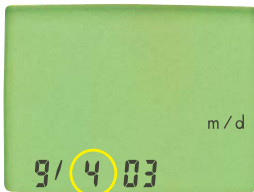
To change the year, press ▼.

To enter the year and move on to choose the month, press M.

To change the month, press ▼.



To enter the month and move on to choose the day, press M.





To choose the day, press ▼.

To enter the day and move on to turn the beeper "On" or "Off," press M.

Turn the Beeper "On" or "Off"

Your Ascensia™ *CONTOUR*™ Meter will also let you turn the beeper "On" or "Off." Be aware that if you turn the beeper off, you may miss important cues from your Meter—such as the two beeps that occur when you get an error.

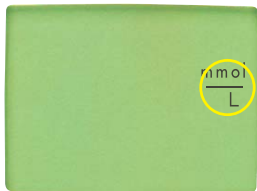


To turn the beeper "On"  or "Off" , press ▼.

To enter your beeper selection and move on to choose between the Units-of-Measure (mmol/L or mg/dL), press **M**.

Select "Units-of-Measure"

Note: Changing the Units-of-Measure changes the way you see your results. A mmol/L result looks like this $5.3 \frac{\text{mmol}}{\text{L}}$ (with a decimal point). A mg/dL result looks like this $95 \frac{\text{mg}}{\text{dL}}$ (no decimal point).



To choose the Units-of-Measure, press ▼.

mmol/L (millimoles per liter) $\frac{\text{mmol}}{\text{L}}$

or

mg/dL (milligrams per deciliter) $\frac{\text{mg}}{\text{dL}}$

To enter the Units-of-Measure and move on to choose between a 12-hour or 24-hour clock, press **M**.

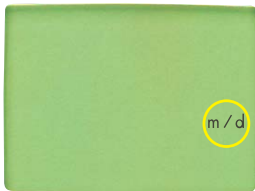
Select 12-hour or 24-hour Clock

To choose the 12- or 24-hour clock, press ▼.

To enter your choice, press the M Button.

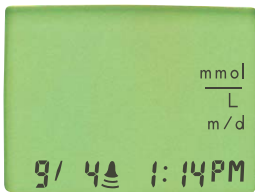


Select Date Format



To choose the way you see the date, (m/d or d.m) press ▼.

To enter your choice, press the M Button.

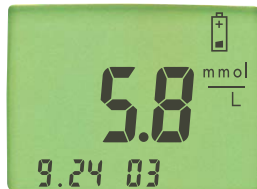


When you have reached the end of Set-up, your Meter will show you all of the current settings and turn off automatically.

Installing Batteries...

Two 3-volt lithium batteries (size 2032) come already installed in your Meter. Batteries should be replaced when the Meter continually displays the battery symbol.

Note: After replacing batteries, you will need to reset the time (see page 13).



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



2. Place new batteries under the blue prongs and into the battery compartment with the "+" side up.

Slide cover back into place, lining up with open slots, and close firmly. Test results stored in the memory are not erased when batteries are changed. The date, units of measure and other formatting choices do not need to be reset.

WARNING: 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.

Meter and Test Strip Care...

- ❖ 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.

Caution: Do not allow solution to run down or in around the buttons. Doing so may cause a malfunction.






- ❖ Store Meter in the carrying case provided or a replacement case of your choice whenever possible.

Warning Potential Biohazard:

Health care professionals or persons using this system on multiple patients should be aware of the following and 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 blood specimens in National Committee for Clinical Laboratory Standards, Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissues: Approved Guideline. NCCLS Document M29-A [ISBN 1-56238-339-6] NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA, 1997. This document has complete information on the topic of user protection and can be used as background material for instruction.

Solving Problems...

If you see the letter "E" followed by a number, or if your Meter beeps twice, an error has occurred. The following chart gives you a list of possible errors and describes what they mean.

What You See	What it Means	What You Should Do
	Low battery	Replace the batteries as soon as possible.
E 1 	Temperature out of range	Test only when the Meter temperature is between 50°F and 104°F (10°C and 40°C).
E 2 	Test Strip underfill	Remove the Test Strip and repeat the test with a new Test Strip.
E 3 	Used Test Strip	Replace Test Strip with a new, unused Test Strip. Wait until you see the flashing blood drop before you add blood sample.
E 4 	Test Strip not inserted correctly	Remove the Test Strip and insert it properly. (See pg. 4.)
E 5 and above	All other errors	When you see the letter E followed by a number that is not listed here, remove Test Strip and retest with a new Test Strip. If you continue to experience difficulty, call the Bayer Diabetes Helpline 1-800-268-7200.
The display goes blank when the meter is turned on.	<ul style="list-style-type: none"> Meter will turn off after 3 minutes of inactivity. This feature prolongs your battery life OR The battery may need to be replaced 	<ul style="list-style-type: none"> Insert new Test Strip to test, press the M Button. <p>OR</p> <ul style="list-style-type: none"> Replace the batteries if needed.
LO	Test result is below 0.6 mmol/L (10 mg/dL)	Repeat test. If LO appears again, contact your healthcare professional (HCP) immediately. CAUTION: Glucose levels below 2.8 mmol/L (50 mg/dL) may indicate a potentially serious medical condition.

What You See	What it Means	What You Should Do
HI	Test result is above 33.3 mmol/L (600 mg/dL)	Wash your hands and test site. Repeat the test. If the test result is still "HI," contact your physician or healthcare professional (HCP) immediately. CAUTION: Glucose levels above 13.9 mmol/L (250 mg/dL) may indicate a potentially serious medical condition.
Control Test result is out-of-range (too high or too low).	<ul style="list-style-type: none"> • Control Solution is past expiration date or is past the 3-month open use date. • Test Strip is past expiration date or is past the 6 month open use date. • Deteriorated Test Strip due to heat, cold or exposure to moisture. • Control Solution not at room temperature. 	Check all expiration dates. Do not use expired testing materials. Run another Control Test. If still out-of-range, retest with a new Test Strip and Control Solution. If still out of range, call the Bayer Diabetes Helpline 1-800-268-7200.
Some display segments do not appear during self-test.	Possible meter electronics or battery failure. Compare display with picture on inside of Front Cover.	Replace batteries. If display is still incorrect, call the Bayer Diabetes Helpline 1-800-268-7200. This may affect the way you see your results.

Specifications

Test Sample:	Whole blood
Test Result:	Referenced to plasma/serum glucose
Reaction Chamber	
Sample Volume:	0.6 μ L
Measuring Range:	0.6–33.3 mmol/L (10–600 mg/dL)
Measuring Time:	15 seconds
Memory Feature:	Stores most recent 240 test results
Battery Type:	Two 3-volt lithium batteries (DL or CR2032)
Battery Life:	Approximately 1000 Tests (1 year of average use)
Operating	
Temperature Range:	50°–104°F (10°–40°C)
Humidity:	10–93% RH
Dimensions:	74mm (H) x 53mm (W) x 17.3mm (T)
Weight:	2 oz. (52.3 grams)
Alarm:	“Beeps” whenever a Test Strip is inserted into 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.
CE Certification:	This device conforms to Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices.

Performance Evaluations

(for Healthcare Professionals)

Precision

- Laboratory Precision:** To assess the repeatability (within-run precision) of the Ascensia™ *CONTOUR*™ Blood Glucose Monitoring System, 100 blood glucose readings (10 readings on each of 10 instruments) were obtained with venous blood specimens at five glucose concentrations. The following table summarizes the mean and pooled within-Meter %CV at each level.

Mean	2.6 mmol/L	5.1 mmol/L	8.0 mmol/L	13.1 mmol/L	20.9 mmol/L
%CV	2.4%	2.5%	2.8%	3.1%	2.4%

- Control Testing Precision:** Precision results were obtained from duplicate assays of Control Solutions at two diabetes clinics with the Ascensia *CONTOUR* System. Testing was performed over 63 days. People with diabetes and healthcare professionals (HCP) at each clinic evaluated two reagent lots. One lot was evaluated at both clinics. The tables below show the combined results for the lay users and HCPs. The overall standard deviations (SD) and coefficients of variation (CV) include the within run and between run / day variations.

Low Control Solution

Reagent Lot	Operator	Duplicate Assays (n =)	Mean (mmol/L)	Overall SD (mmol/L)	Overall CV (%)
22B	HCP (n = 1)	35	2.34	0.074	3.2
	Lay User (n = 51)	76	2.35	0.102	4.3
22C	HCP (n = 4)	39	2.39	0.063	2.6
	Lay User (n = 53)	78	2.39	0.093	3.9
23B	HCP (n = 5)	74	2.36	0.063	2.7
	Lay User (n = 104)	154	2.32	0.112	4.8

Normal Control Solution

Reagent Lot	Operator	Duplicate Assays (n =)	Mean (mmol/L)	Overall SD (mmol/L)	Overall CV (%)
22B	HCP (n = 1)	35	6.64	0.254	3.8
	Lay User (n = 51)	76	6.69	0.216	3.2
22C	HCP (n = 4)	39	6.77	0.179	2.6
	Lay User (n = 53)	78	6.79	0.271	4.0
23B	HCP (n = 5)	74	6.71	0.169	2.5
	Lay User (n = 104)	154	6.67	0.204	3.1

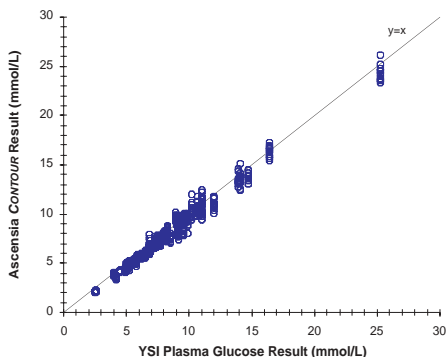
High Control Solution

Reagent Lot	Operator	Duplicate Assays (n =)	Mean (mmol/L)	Overall SD (mmol/L)	Overall CV (%)
22B	HCP (n = 1)	35	18.72	0.737	3.9
	Lay User (n = 51)	76	18.96	0.829	4.4
22C	HCP (n = 4)	39	19.53	0.498	2.6
	Lay User (n = 53)	78	19.49	0.619	3.2
23B	HCP (n = 5)	74	19.18	0.578	3.0
	Lay User (n = 104)	154	18.03	0.524	2.9

Accuracy

1. Bayer Accuracy Evaluation:

To assess the accuracy of the Ascensia™ *CONTOUR*™ System, 60 fresh fingerstick specimens from people with diabetes were tested with the Ascensia *CONTOUR* System (12 – 14 readings per fingerstick) and the YSI 2300 STAT Plus Glucose Analyzer. The glucose concentration of the samples ranged from 2.5 to 25.2 mmol/L with an average of 8.4 mmol/L. The range of hematocrits was 32% to 49% with an average of 40%.



Passing and Bablok Regression Statistics / Pearson correlation

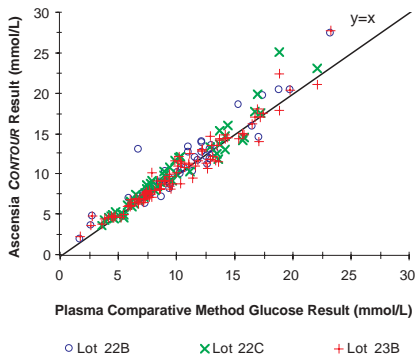
n	y =	95% Confidence Interval		r
		Slope	Intercept	
746	$1.01x - 0.49$	1.00 to 1.03	-0.58 to -0.39	0.992

2. Professional / Lay User Evaluation

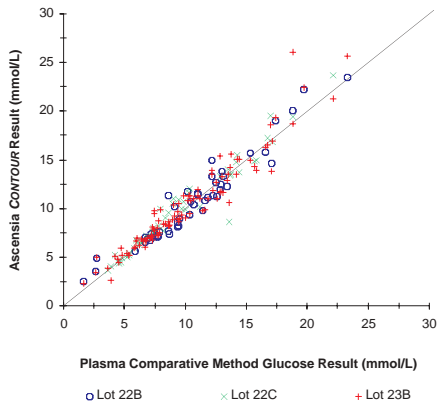
A Patient Use evaluation was conducted at two diabetes clinics. Lay users with diabetes were given product instructions with no training. After reviewing the instructions, the users performed fingersticks and glucose assays using the Ascensia™ CONTOUR™ System. Two reagent lots were evaluated at each clinic; one was common to both sites. After the user's self test, the attending HCP performed Ascensia CONTOUR System assays from the lay user's

fingerstick. Following the Ascensia™ *CONTOUR*™ System assays, a blood sample was collected for comparative laboratory glucose and hematocrit determinations. The glucose concentration of the samples from the two sites ranged from 1.7 to 23.3 mmol/L with an average of 10.1 mmol/L. The range of hematocrits was 28 to 55% with an average of 44%.

A. Lay User Results



B. Health Care Professional Results



Passing and Bablok Regression Statistics / Pearson correlation

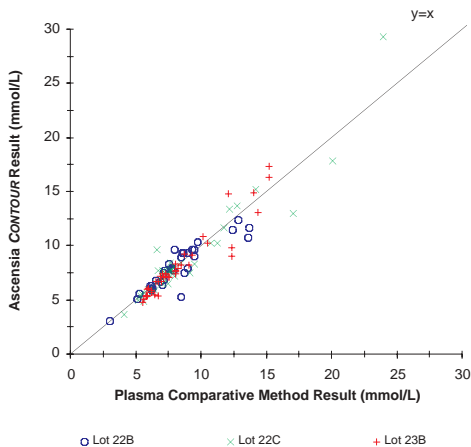
Reagent Lot	Opr.	n	y =	95% Confidence Interval		r
				Slope	Intercept	
22B	Lay	50	$1.03x - 0.00$	0.93 to 1.15	-1.17 to 0.85	0.947
	HCP	50	$1.01x - 0.28$	0.91 to 1.11	-1.22 to 0.61	0.967
22C	Lay	51	$1.07x - 0.14$	1.00 to 1.16	-0.79 to 0.45	0.969
	HCP	51	$1.04x - 0.08$	0.99 to 1.10	-0.47 to 0.39	0.972
23B	Lay	101	$1.00x + 0.14$	0.95 to 1.04	-0.23 to 0.54	0.973
	HCP	101	$0.98x + 0.20$	0.94 to 1.05	-0.27 to 0.62	0.960

Opr. = Operator; Lay = Lay User; HCP = Healthcare Professional

Arterial Blood Evaluation (Effect of pO₂: Performance with Arterial Specimens)

An arterial specimen study was performed at a hospital site. Ascensia™ CONTOUR™ results from arterial samples were compared to the site blood glucose method. The glucose concentration of the samples ranged from 3.1 to 24.0 mmol/L, with an average of 8.5 mmol/L. The sample hematocrit range was 22 to 58%, with an average of 39%. The pO₂ values ranged from 43 to 205 mm Hg, with an average of 104 mm Hg. The reference range for arterial pO₂ is 83 to 108 mm Hg (11.1 to 14.4 kPa)¹. Mean biases were -2.9% at pO₂ concentrations <83 mm Hg (n = 33, Mean pO₂ = 71 mm Hg), -2.5% at pO₂ concentrations between 83 to 108 mm Hg (n = 40, Mean pO₂ = 94 mm Hg), and -0.8% at pO₂ concentrations >108 mm Hg (n = 38, Mean pO₂ = 143 mm Hg). Two samples had glucose concentrations <4.2 mmol/L and the bias was calculated as an absolute difference rather than a percentage. These samples had biases of -0.06 mmol/L and -0.44 mmol/L; pO₂ values were 80 and 112 mm Hg, respectively.

¹ Carl Burtis and Edward Ashwood (eds.): Tietz Textbook of Clinical Chemistry. 3rd Ed., W.B. Saunders Co. Philadelphia, PA. 1999, p. 1827.



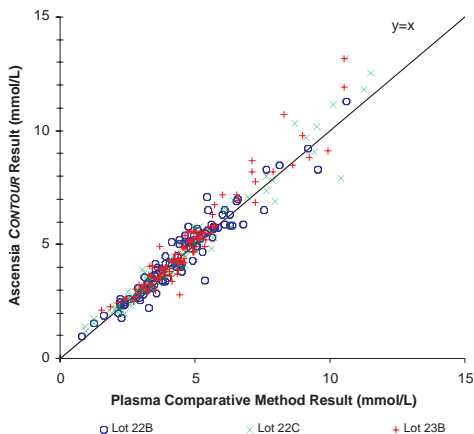
Passing and Bablok Regression Statistics / Pearson correlation

Reagent Lot	Opr.	n	y =	95% Confidence Interval		r
				Slope	Intercept	
22B	HCP	34	$1.00x - 0.01$	0.84 to 1.15	-1.08 to 1.04	0.909
22C	HCP	40	$1.06x - 0.62$	0.92 to 1.19	-1.48 to 0.42	0.952
23B	HCP	39	$1.12x - 1.22$	1.00 to 1.24	-1.96 to -0.31	0.948
Combined	HCP	113	$1.08x - 0.70$	1.00 to 1.15	-1.23 to -0.12	0.943

Opr. = Operator; HCP = Healthcare Professional

Neonatal Blood Evaluation (Performance with Neonatal / Hospitalized Infant Samples)

Neonatal samples (n = 306) were collected from routine, intermediate care, and intensive care nurseries at three sites. The infants ranged in age from less than one day to 5 months (11 wks. premature birth). The median age was two days. Nine venous, 176 capillary and 121 arterial samples were evaluated with the Ascensia™ *CONTOUR™* Blood Glucose Monitoring System using three reagent lots. The lots were rotated each day of sample collection over the duration of the evaluation. Meter results were compared to laboratory glucose assay methods used at each of the sites (Corning 860, Beckman LX20, Hitachi 917 analyzers). Sample glucose concentrations ranged from 0.8 to 11.5 mmol/L, with an average of 4.6 mmol/L. The hematocrit range was 21 to 70%, with an average of 48.3%. A pO₂ was obtained with 116 samples. The range was 33 to 499 mm Hg, with an average of 126.9 mm Hg. A bilirubin assay was performed with 283 samples. The range was 3.4 to 319.8 μmol/L, with an average of 95.8 μmol/L.



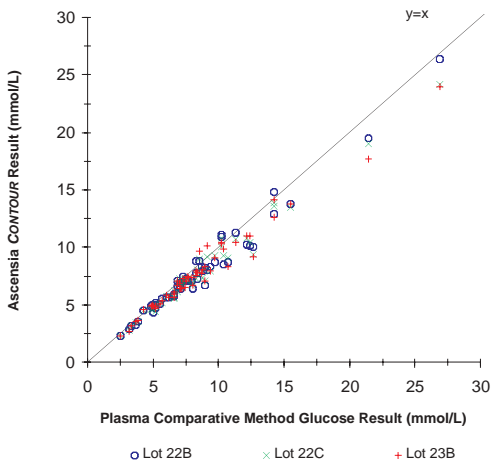
Passing and Bablok Regression Statistics / Pearson correlation

Reagent Lot	Opr.	n	y =	95% Confidence Interval		r
				Slope	Intercept	
22B	HCP	106	1.05x - 0.15	1.00 to 1.11	-0.43 to 0.04	0.958
22C	HCP	101	1.03x - 0.09	0.98 to 1.08	-0.33 to 0.11	0.975
23B	HCP	99	1.13x - 0.46	1.05 to 1.21	-0.80 to -0.11	0.964
Combined	HCP	306	1.07x - 0.21	1.03 to 1.10	-0.36 to -0.07	0.966

Opr. = Operator; HCP = Healthcare Professional

Altitude Evaluation

Performance was evaluated at an altitude of 3,048 meters. Fifty-six samples were obtained from 54 different subjects with diabetes. Three reagent lots were used with the Ascensia™ CONTOUR™ System to measure each subject's capillary blood glucose. After performing the Meter assays, additional capillary blood was collected for a comparative blood glucose (Yellow Springs Instruments Analyzer) and hematocrit determination. The glucose range of the samples was 2.5 to 26.9 mmol/L, with an average concentration of 8.4 mmol/L. The hematocrit range was 38 to 60%, with a mean of 48%.



Passing and Bablok Regression Statistics / Pearson correlation

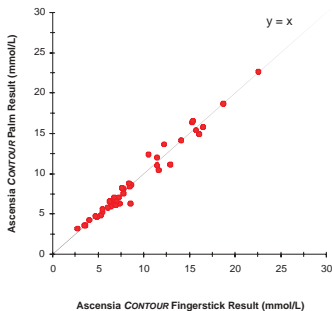
Reagent Lot	Opr.	n	y =	95% Confidence Interval		r
				Slope	Intercept	
22B	HCP	56	0.90x + 0.15	0.85 to 0.97	-0.25 to 0.33	0.984
22C	HCP	56	0.90x + 0.13	0.86 to 0.96	-0.19 to 0.41	0.988
23B	HCP	56	0.89x + 0.21	0.85 to 0.94	-0.09 to 0.48	0.983

Opr. = Operator; HCP = Healthcare Professional

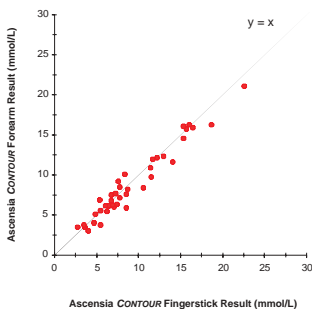
Multiple Site Testing Evaluation

Forty persons with diabetes, in steady state for glucose, performed self-capillary blood glucose assays using the Ascensia™ *CONTOUR*™ System and one reagent lot. A fingerstick was performed with the Ascensia™ *MICROLET*® Adjustable Lancing Device. Samples from the palm, forearm, thigh, and abdomen were then obtained, and those results were compared to the Ascensia *CONTOUR* results obtained from the finger. One subject was unable to obtain a sample from the abdomen. The blood glucose range from the fingerstick measurements was 2.7 to 22.6 mmol/L, with an average of 9.2 mmol/L. The hematocrit range was 36 to 52%, with an average of 42%.

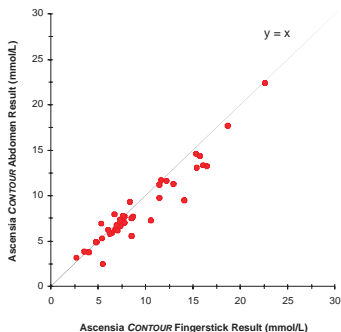
A. Results from the Palm



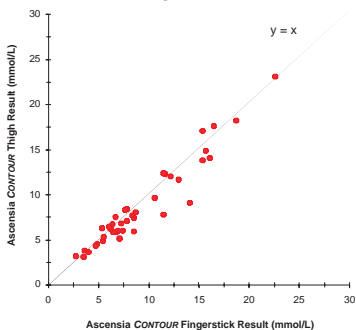
B. Results from the Forearm



C. Results from the Abdomen



D. Results from the Thigh



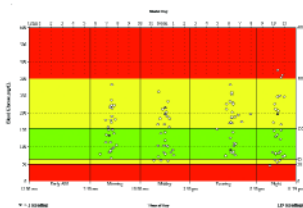
Passing and Bablok Regression Statistics / Pearson correlation

Alternate Site	Opr.	n	y =	95% Confidence Interval		r
				Slope	Intercept	
Palm	Lay	40	$1.00x - 0.06$	0.95 to 1.07	-0.63 to 0.24	0.986
Forearm	Lay	40	$0.96x - 0.04$	0.89 to 1.04	-0.73 to 0.72	0.973
Abdomen	Lay	39	$0.85x + 0.63$	0.76 to 0.95	-0.09 to 1.14	0.958
Thigh	Lay	40	$0.97x - 0.23$	0.88 to 1.07	-0.95 to 0.34	0.962

Opr. = Operator; Lay = Lay User

Transfer Test 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 Ascensia™ *WinGlucofacts®* (version 1.3 or higher) or Ascensia™ *WinGlucofacts® Professional* software (version 3.01 or higher), and an Ascensia™ Data Cable.

Caution: The Ascensia™ *CONTOUR™* Meter cannot be used with any other software except software supplied by Bayer. Use of any other software package can result in erroneous results.

For more information, contact the Bayer Diabetes Helpline: 1-800-268-7200 or visit our website at www.ascensia.ca.

Service

If attempts to correct a problem fail, please call our Bayer Diabetes Helpline. We have friendly, knowledgeable people who are there to help 12 hours a day, 7 days a week (9 a.m.–9 p.m. EST).

In Canada, call toll free: **1-800-268-7200**

Important:

- Speak to a Customer Service Representative before returning your Meter for any reason. He/she will give you the information needed to get your problem handled correctly and efficiently.
- Have your *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* Normal Control Solution nearby.
- Fill out the following check list before calling!

Check List

1. The Meter serial number (found on the back of the meter) is: _____
2. The date and time the problem occurred was: _____
3. I have read the user guide and followed the testing steps: _____
4. I am using Control Solution and Test Strips that have not expired or passed their open use life dates: _____
5. I do not need to replace the batteries: _____
6. Please include the Lot number and expiration date of the Test Strips and Controls being used. For the Test Strips, this information is printed on the carton as well as on the back of each bottle. For the Controls, this information is printed on the bottle. _____

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	3-volt Lithium Battery (DL or CR2032) — 2 (Available at most camera stores)
99971529	Ascensia™ <i>CONTOUR</i> ™ User Guide
50184257	Ascensia™ <i>CONTOUR</i> ™ Quick Reference Guide
3479	Ascensia Data Cable
3420C	Ascensia™ WinGlucofacts® Diabetes Management Software**

*Part numbers are subject to change without notice

**Cable included

You can obtain these parts in Canada from:

Bayer Inc.
Diagnostics Division
77 Belfield Road
Toronto, Ontario M9W 1G6

Replacement Products

Number	Product Name
7081	Ascensia™ <i>MICROFILL</i> ™ Test Strips (box of 50)
7091	Ascensia™ <i>MICROFILL</i> ™ Test Strips (box of 100)
7100	Ascensia™ <i>MICROFILL</i> ™ Normal Control Solution
7101	Ascensia™ <i>MICROFILL</i> ™ Low and High Control Solutions
6540B	Ascensia™ <i>MICROLET</i> ® Adjustable Lancing Device
6546A	Ascensia™ <i>MICROLET</i> ® Lancets (box of 100)
6550A	Ascensia™ <i>MICROLET</i> ® Lancets (box of 200)

Accessory items may be obtained from Diabetes Care Centers, retail drug stores or other home healthcare distributors.

Warranty

Manufacturer's Warranty: Bayer Inc. Diagnostics Division ("Bayer") 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 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 shall not be required to replace any units which malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by other than Bayer, or failure to operate the instrument in accordance with instructions. Further, Bayer assumes no liability for malfunction or damage to Bayer instruments caused by the use of reagents other than reagents (i.e., Ascensia™ *MICROFILL*™ Test Strips) manufactured or recommended by Bayer.
3. Bayer reserves the right to make changes in design of this instrument without obligation to incorporate such changes into previously manufactured instruments.

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

Limitations of Capability:

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 the Bayer Diabetes Helpline of Bayer Inc., by calling toll free 1-800-268-7200, for assistance and/or instructions for obtaining service of this instrument.

Manufactured for:



Bayer HealthCare

Bayer HealthCare LLC
Mishawaka, IN 46544 USA

Distributed by:
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