

Ascensia[®] BREEZE[™]

Diabetes Care System

USER GUIDE



Ascensia[®] BREEZE[™] and
Ascensia[®] AUTODISC[™]
Unique 10-Test Disc



Bayer HealthCare

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Introduction:

Thank you for choosing the Ascensia® *BREEZE*™ Diabetes Care System! We are proud to be your partner in helping you to manage your diabetes. We understand that people who regularly check their blood glucose levels want a meter that is simple, straightforward and easy to use. As you use your Ascensia® *BREEZE*™ System, you will appreciate the:

- Ease of running a test, and discarding a used test strip.
- Use of a 10-Test Disc—which means no individual test strips to fumble with.
- User-friendly design—buttons make recalling your results or setting the time as easy as making a telephone call.
- Ease of recalling a 14-Day Average.

This ease of use comes with the added bonus of the reliability that you count on from Bayer.

This user guide shows you how to use your Ascensia® *BREEZE*™ Diabetes Care System. It will answer any questions you might have and guide you through the testing process. *It is here to help you!*

This User Guide is divided into two sections. Part 1 — **Everyday Use** will guide you through the basic use of the meter. Part 2 — **Beyond Everyday Use** will guide you through special features—such as how to change the time and the date, or where to find more help with this product.

A look at your Ascensia BREEZE Meter...

Release Button:

Press to release and discard used test strip.

Battery Holder:

(side of meter)
Holds one CR2025 lithium battery.

On/Off Button:

Use this button to manually turn the meter On or Off.

Meter Handle:

Use this handle to push out a test strip and automatically turn on the meter.

Screen: This is where your test results will be displayed.

Data Port: (side of meter)
Insert cable here to allow communication between meter and a personal computer.

Button Door:
Open to expose meter buttons.

Fold this page out for easy reference when using your user guide.



On/Off Button:
Use this button to manually turn the meter On or Off.

Memory Button:
Use this button to view your blood glucose results stored in memory and to view your 14-day average.

Set-Up Button:
Use this button to enter the Set-Up mode and easily change the time, date or other features.



Up/Down Buttons:
Use these buttons with the Memory button to see your results or use with the Set-Up button to change the time, date, etc.

Accept (OK) Button:
Use this button to accept changes made in the Set-Up mode.

(Button door open)

Simply place the easy reference sticker on the Button Door as shown. See sheet of stickers provided in your meter package and select the language of your choice.



Testing Materials:



10-Test AUTODISC™
(Contains ten test strips.)



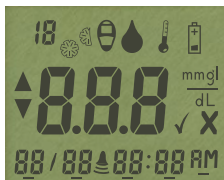
Normal Control Solution



MICROLET® Adjustable
Lancing Device and Lancet

Important Information:

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



A full display, as shown here, indicates that all characters in the display are working properly. To view the full display, pull the meter handle all the way out. Compare your meter to the display shown here. If there is a difference, please see Troubleshooting page 44.

Table of Contents:

Everyday Use

Inserting a 10-Test <i>AUTODISC</i>	2
Running a Blood Glucose Test	5
Running a Control Test	12

Beyond Everyday Use

Recalling Test Results	17
Setting Time, Date and Other Features	19
Transferring Test Results to a Computer	26
Cleaning Your Meter	27
Replacing the Battery	28

Technical Information

Specifications	31
Performance Evaluations	32
Multiple Site Testing Evaluation	37

Solving Problems

Solving Problems	39
Troubleshooting and Error Codes	40
Customer Service	45
Replacement Items	46
5-Year Limited Warranty	47

The Ascensia® *BREEZE*™ Diabetes Care 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® *BREEZE*™ System is specific for glucose and has been referenced to plasma/serum glucose.

Everyday Use

INSERTING A 10-TEST AUTODISC™:

WARNING: Never open the meter with the meter handle pulled out.

Open Meter

1. Hold the meter with the display screen down. Open the meter by pressing down on the back edge of the **open latch** and then pulling the front cover up.



2. Open the new 10-test disc package. Check the expiration date on the disc.



Insert Disc

3. Insert a new 10-test disc—yellow arrow (bumpy side) up. The arrow may point in any direction.



Close Meter

4. Close the meter and snap it shut. **Keep the meter flat.**



😊 **Helpful Hint:** The meter must be kept flat when closing. If the meter is not kept flat, the disc may move and become damaged and you may waste test strips.

Counting Number of Strips Left

Your Ascensia® BREEZE™ Meter will automatically count down the number of test strips you have left.

To see this count when the meter is off, press the ⓘ button.

Note: This count is reset to 10 every time you open the meter. To keep an accurate count, open the meter only when all 10 of the test strips have been used in the 10-test disc.

Your meter will also tell you when you need to insert a new 10-test disc. It will do this by showing you a picture of a disc being inserted into the meter.

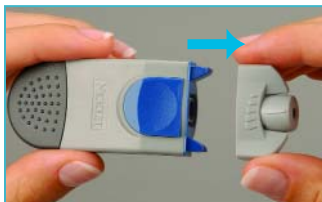


RUNNING A BLOOD GLUCOSE TEST:

1. Wash your hands well with soap and warm water. Rinse and dry thoroughly.



2. Remove the endcap from the MICROLET® Adjustable Lancing Device. (See MICROLET® Device package insert for complete instructions.)



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



4. Twist off lancet cap and replace the endcap.



Push out Test Strip

Caution: Your meter is designed to push out one test strip at a time. Do not attempt to push out a new test strip with one already showing.

5. Your Ascensia® *BREEZE*™ Meter was designed with a special, easy-to-use “Pull and Push” design. Here’s how it works:

Hold the meter comfortably in one hand. Firmly grasp the **Meter Handle** with the other hand (shown here). Now, just “Pull and Push”—“Pull” the handle out until it stops and “Push” it back in until it stops again.



Note: This will automatically turn your meter on if it is not already on. For regular, everyday use you don't have to worry about turning it on—just "Pull and Push."

Note: The **release button** is UP, a test strip is pushed out and a flashing blood drop appears on the screen. The meter is now ready to run a blood glucose test.

6. Stick your finger with the MICROLET® Device and form a small round drop of blood.



Test

7. Your test strip is like a straw; it sips in a sample of blood. Move the entire front edge of the test strip to touch the edge of the blood drop. The blood is automatically pulled into the test strip and fills the test strip.

Hold the test strip in place **until** the meter beeps, and three dashes appear on the screen, then move it away. By doing this, you will make sure the test strip is completely filled.



8. While the meter calculates your blood glucose level, you will see a sequence of dashes on the screen.



After 30 seconds, your test result will appear on the screen.



9. To **release** the used test strip, hold the meter with the test strip pointing down over a waste container. Press the **release button**. Make sure the heel of your hand is not against the meter handle.

Note: If you block the meter handle with your hand, the test strip may not release properly.



10. Press the **Ⓚ** button to turn the meter off.

If you forget to turn your meter off, the meter will turn off automatically after three minutes. This will save battery power.

Caution: If your glucose result is below 2.8 mmol/L (50 mg/dL), above 13.9 mmol/L (250 mg/dL) or if the meter shows "HI" or "LO," test again. If your glucose level is still below 2.8 mmol/L (50 mg/dL), above 13.9 mmol/L (250 mg/dL), or if the meter again shows "HI" or "LO," it may indicate a potentially serious medical condition.

If this is the case: *We recommend you consult your physician or healthcare professional immediately.*

Caution: Any changes in medication based on Ascensia® **BREEZE™** blood glucose results without the advice of a physician or healthcare professional is not recommended.

For best results:

- Blood is pulled **IN** the test strip *not* dropped **ON**.
- Do not allow blood to run down into the meter.
- Do not add more blood after the meter beeps.



RUNNING 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 do your test. Simply follow these steps:

Note: Look on the bottom flap of the box of test strips to find the control range.



Push out Test Strip

1. Hold the meter comfortably in one hand. Firmly grasp the **Meter Handle** with the other hand (shown here). Now, just **"Pull and Push"**—"Pull" the handle out until it stops and "Push" it back in until it stops again.



Note: The **release button** is UP, a test strip is pushed out and a flashing blood drop appears on the screen. The meter is now ready to run a control test.

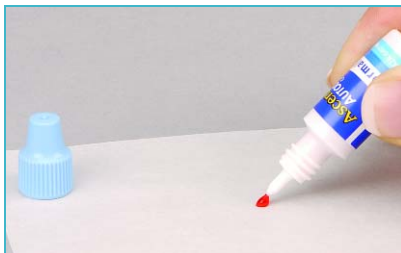
2. Squeeze a small drop of control solution onto a nonabsorbent surface (such as a clean piece of wax paper). Do not apply control solution to the test strip *directly* from the bottle.

Note: The control solution contains a red dye and may stain.

Test

3. Move the entire front edge of the test strip to touch the edge of the drop of control solution. The control solution is automatically pulled into the test strip.

Important: Hold the test strip in place **until** the meter beeps, and three dashes appear on the screen, then move it away. By doing so, you will make sure the test strip is completely filled.



4. While the meter calculates your control test result, you will see a sequence of dashes on the screen. After 30 seconds, your control test result will appear on the screen. Compare this control test result with the range printed on the bottom flap of the test strip carton.



Note: You will want to “mark” your control test **now** so that it will not be included in your 14-day average. (See next page.)



Marking a Control Test

Marking a test result as a control test excludes it from the 14-day average.

You must mark the result **immediately** after the test is performed—while the result is still displayed on the screen. To do this, follow these steps:

5. Open the Button Door.


Press the  button to mark as a control.

The “Control” marker looks like this: ✓

Press  to accept.

6. To **release** the used test strip, hold the meter with the test strip pointing down over a waste container. Press the **release button**. Make sure the heel of your hand is not against the meter handle.

Note: If you block the meter handle with your hand, the test strip may not release properly.



7. Press the  to turn your meter off.



Marking a Deleted Blood Test

Marking a test result as a deleted blood test excludes it from the 14-day average.

You must mark the result **immediately** after the test is performed—while the result is still displayed on the screen. To do this, follow these steps:

1. Open the Button Door.
2. Press the  button to mark as deleted.
3. The “Delete” marker looks like this: 
4. Press  to accept.
5. Press the  to turn your meter off.



Beyond Everyday Use

RECALLING TEST RESULTS:


Your Ascensia® *BREEZE*™ Meter can store up to 100 test results in its memory. This makes it easy to see your earlier blood glucose test results. To view those results:

1. Open the Button Door.
2. Press the **M** button.

The meter will now show you the most recent test result.

3. Press the  button to see all of your stored results.



 **Helpful Hint:** Your meter can store up to 100 test results. If there are no stored test results in memory, the meter will tell you this by showing three dashes. When the memory is full, the meter will remember the newest result and discard the oldest.

Viewing Your 14-Day Average

Your Ascensia® BREEZE™ Meter also keeps a 14-day average of your blood glucose results for you (14 d A). To see this average, simply follow these steps.

1. Open the Button Door and press the (M) button. The meter will show you your last result.
2. Press the (M) button again to see your blood glucose average for the last 14 days.

You may press the (M) button again to review your stored test results.

Note: If there are no results in memory, the meter will show you three dashes.



Clearing Stored Test Results

To clear the results from the meter, follow these few steps:

1. Open the Button Door.
2. Press the (M) button.
3. Press again and hold the (M) button.
4. While holding the (M) button, press and hold the (C) button.
5. Hold both buttons together until all three dashes are continuously lit (for about 3 seconds).

If you change your mind and do not want to clear results, simply let go of the buttons before all three dashes have been lit.



SETTING TIME, DATE AND OTHER FEATURES:


😊 **Helpful Hint:** You may press the **⏸** button at any time during set-up to turn the meter off. Just remember to press the **OK** button first to store your changes!

Setting the Time

1. Open the Button Door.
2. Press **⏸**.
3. Press **⬆** or **⬇** to change the hour.
Press **OK** to accept and move on.
4. Press **⬆** or **⬇** to change the minutes.
Press **OK** to accept and move on.



5. Press  or  to select AM or PM.

Press  to accept and move on.




Setting the Date


Note: If you have just set the time, skip ahead to step 4.

1. Open the Button Door.



2. Press .


3. Press  until you see the "day" icon flashing.

4. Press  or  to change the day.



Press  to accept and move on.




5. Press  or  to change the month.

Press  to accept and move on.



6. Press  or  to change the year.

Press  to accept and move on.



Setting Buzzer Level


Your Ascensia® *BREEZE*™ Meter has an easy-to-use volume control for the buzzer. Here are the three different buzzer levels:




Note: If you have just set the date, skip ahead to step 4.

1. Open the Button Door.

2. Press .

3. Press  until you see the "buzzer" icon.

4. Press  or  to change the buzzer level.

Press  to accept and move on.



Setting Units-of-Measure

Important: Test results are shown in either mmol/L or mg/dL. The mmol/L results will **always** include a decimal point. The mg/dL results **do not** include a decimal point.

Example:





$$5.3 \frac{\text{mmol}}{\text{L}}$$


or

$$95 \frac{\text{mg}}{\text{dL}}$$

Your Ascensia® BREEZE™ Meter comes with the units-of-measure preset. However, you may change the units-of-measure if you wish.

Note: If you have just set the buzzer level, skip ahead to step 4.

1. Open the Button Door.
2. Press .
3. Press  until you see a "unit-of-measure" icon.
4. Press  or  to choose units-of-measure.

Press  to accept and move on.




Setting Time Format (12- or 24-hour Clock)

Your Ascensia® *BREEZE*™ Meter will let you choose either a 12-hour (12 H) or a 24-hour time setup (24 H).


Note: If you have just set the units-of-measure, skip ahead to step 4.

1. Open the Button Door.

2. Press .

3. Press  until you see the "time format" icon.

4. Press  or  to set 12- or 24-hour clock.

Press  to accept and move on.




Setting Date Format

Your Ascensia® BREEZE™ Meter will let you set the day and month option on your meter. You can choose to set it as "month/day" (MM/d) or as "day/month" (d/MM).

Note: If you just set the time format, skip ahead to step 4.

1. Open the Button Door.

2. Press .

3. Press  until you see the "date format" icon.

4. Press  or  to set the date format.

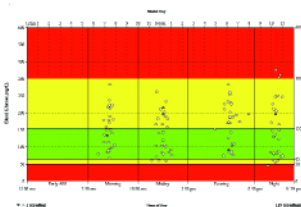
Press  to accept.



TRANSFERRING TEST RESULTS TO A COMPUTER:

You can transfer test results from the Ascensia® *BREEZE*™ Meter to a computer, where they can be summarized in a report with graphs and tables.

To make use of this feature, you will need the Ascensia™ *WinGlucofacts*® or Ascensia™ *WinGlucofacts*® *Professional* software, and Ascensia™ Data Cable.



CLEANING YOUR METER:

Your Ascensia® *BREEZE*™ Meter can be cleaned using a moist (**not wet**) lint-free tissue with a mild detergent or disinfecting solution (1 part bleach mixed with 9 parts water). Wipe both the outside and inside of the meter, taking care to keep detergent or disinfecting solution from running down into the test strip slot. Wipe dry with a lint-free tissue after cleaning.

If you do get moisture in the test strip slot, wick it away with a corner of a tissue as shown.



WARNING: Potential Biohazard!

Healthcare 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 into 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.

REPLACING THE BATTERY:

Your Ascensia® *BREEZE*™ Meter uses one 3-volt lithium battery (CR2025). A battery will already be installed in the meter when you buy it.

When it is time to put a new battery in the meter, the meter will tell you by displaying a flashing battery on the screen. You will not erase test results in the meter's memory when you change the battery. You will, however, need to reset the clock (see *pg. 19*).

Caution: If you have a low battery in your meter, you should replace the battery within approximately 20 readings or within one week.



Note: When battery life is very low, the display will show only a battery icon. When this occurs, the meter will not allow you to run a test until the battery is changed. This is so you always receive the most accurate results possible. When battery life has completely ended, nothing will show on the display and the meter will not respond.

Things To Remember

WARNING: Keep battery away from children! Lithium batteries are poisonous!

If swallowed, immediately contact your physician or poison control center. Dispose of old batteries properly.

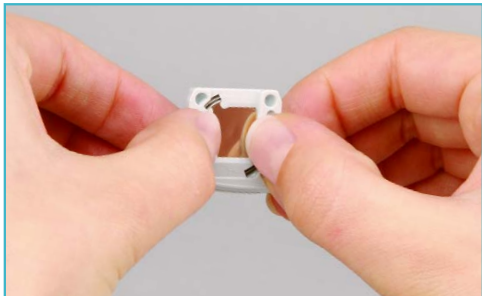
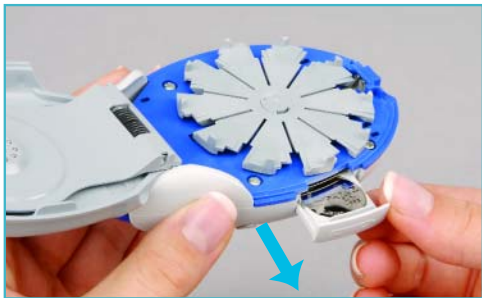
To replace the battery, follow these steps:

Note: A replacement battery (CR2025) can be found at most pharmacies.

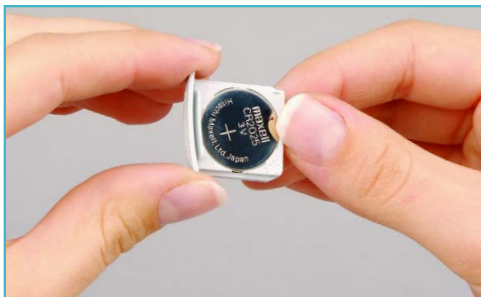
1. Hold the meter with the display screen down. Open the meter by pressing on the **open latch** and pulling up.
2. Slide out the battery holder.

Note: You must open the meter first in order to remove the battery holder. **DO NOT PRY** the battery holder out!

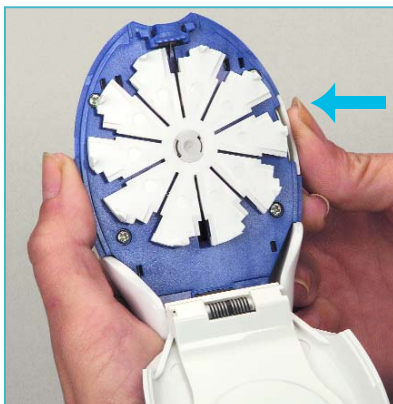
3. Remove the old battery. The battery should be removed from the holder with your finger.



4. Snap 1 new battery (CR2025) *firmly* in the holder with the + side up.



5. Gently slide the battery holder back into the battery compartment. **Make sure battery holder is pushed all the way in.**



6. Close the meter.
7. Reset the meter's time (see pg. 19).

You are now ready to resume testing!

Technical Information

SPECIFICATIONS:

Test:	Capillary blood glucose referenced to plasma/serum glucose values
Calibration:	Meter is automatically calibrated each time a new test strip disc is used.
Sample Size:	Approximately 2.5–3.5 μL
Test Range:	0.6–33.3 mmol/L (10–600 mg/dL)
Test Time:	30 seconds
Memory Feature:	Meter stores 100 test results.
Normal Operating Temperature:	10° to 40°C (50° to 104°F)
Humidity:	10 to 80% RH
Power Source:	One 3-volt lithium battery (CR2025)

PERFORMANCE EVALUATIONS:

Precision

1. **Laboratory Precision:** To assess the repeatability (within-run precision) of Ascensia® BREEZE™, 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	2.9 mmol/L	7.4 mmol/L	9.1 mmol/L	14.7 mmol/L	23.7 mmol/L
%CV	8.9%	4.1%	4.4%	3.8%	2.9%

2. **Control Testing Precision:** An imprecision study of the Ascensia® BREEZE™ System was conducted at two diabetes clinics. In each location, 50 lay persons with diabetes tested the low, normal and high control solutions in duplicate using the meter system. A different lot of test strips was used in each of the two locations. The table below shows the total standard deviations (SD) and coefficients of variation (CV), which include the within run and between run / day variations.

Low Control Solution

Strip Lot	Operator	No. of Assays	Mean (mmol/L)	Total SD (mmol/L)	Total CV (%)
A	Lay User (n=50)	100	4.272	0.267	6.2
B	Lay User (n=50)	100	4.100	0.244	6.0

Normal Control Solution

Strip Lot	Operator	No. of Assays	Mean (mmol/L)	Total SD (mmol/L)	Total CV (%)
A	Lay User (n=50)	100	8.394	0.400	4.8
B	Lay User (n=50)	100	8.317	0.356	4.3

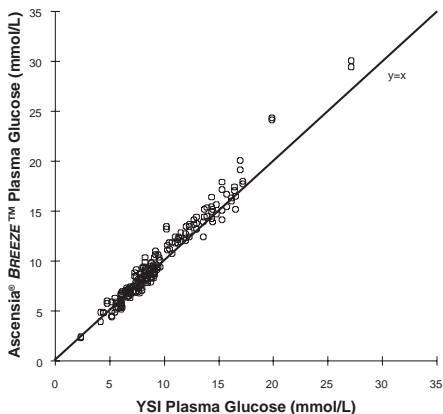
High Control Solution

Strip Lot	Operator	No. of Assays	Mean (mmol/L)	Total SD (mmol/L)	Total CV (%)
A	Lay User (n=50)	100	18.706	0.961	5.1
B	Lay User (n=50)	100	18.867	0.800	4.2

Accuracy

1. Bayer Accuracy Evaluation:

To assess the accuracy of the Ascensia® *BREEZE*™ System, 102 fresh fingerstick specimens from people with diabetes were tested with the Ascensia® *BREEZE*™ (2 readings per fingerstick) and the YSI 2300 STAT Plus Glucose Analyzer. The glucose concentration of the samples ranged from 2.3 to 30.1 mmol/L with an average of 9.9 mmol/L. The range of hematocrits was 29% to 55% with an average of 40%.



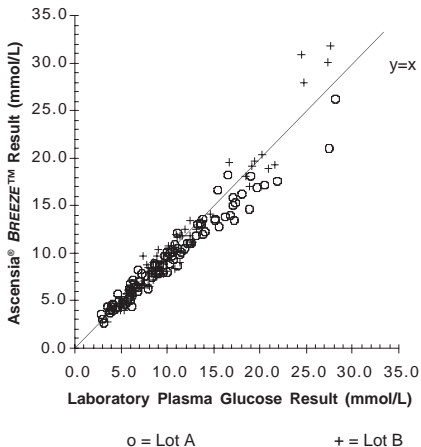
Weighted Deming Agreement Statistics / Pearson correlation

N	Y=	95% Confidence Interval		R
		Slope	Intercept	
204	1.07x - 0.21	1.03 to 1.10	-0.48 to 0.06	0.983

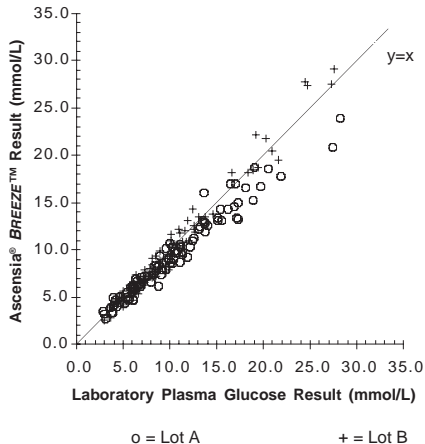
2. Professional / Lay User Evaluation: A patient use evaluation was conducted at two diabetes clinics. Lay users with diabetes learned to use the meter system by reviewing the meter user guide. After reviewing the instructions, the users performed fingersticks and glucose assays using the Ascensia® BREEZE™ System. Two test strip lots were evaluated, one at each of the two clinics. After the user's self test, the attending healthcare professional performed an Ascensia® BREEZE™ System assay from the lay user's fingerstick. A capillary blood sample was then collected for

comparative laboratory glucose and hematocrit determinations. The glucose concentrations of the 196 samples ranged from 2.9 to 28.2 mmol/L with an average of 8.9 mmol/L. The range of hematocrits was 32 to 55%, with an average of 45%.

A. Lay User Results



B. Healthcare Professional Results



Comparison of Meter to Laboratory Results[†]

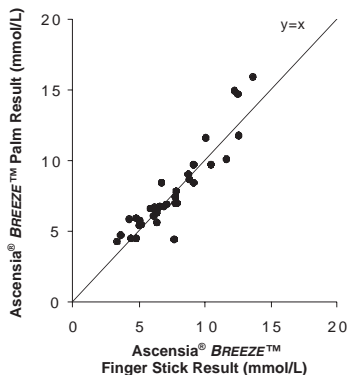
Lot	Opr.	N	Y=	95% Confidence Intervals		R
				Slope	Intercept	
A	Lay	100	$0.85x + 0.72$	0.81 to 0.89	0.38 to 1.06	0.98
	HCP	100	$0.84x + 0.65$	0.80 to 0.88	0.33 to 0.96	0.98
B	Lay	96	$1.02x - 0.58$	0.96 to 1.08	-1.04 to -0.13	0.97
	HCP	96	$1.03x - 0.61$	0.99 to 1.08	-0.94 to -0.29	0.98
A&B	All	392	$0.91x + 0.21$	0.89 to 0.94	0.01 to 0.40	0.97

[†] Weighted Deming regression, weighted linear correlation coefficient
 Opr. = Operator; Lay = Lay User; HCP = Healthcare Professional

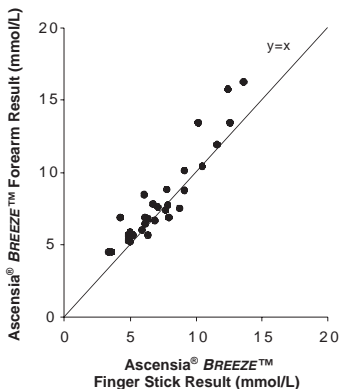
MULTIPLE SITE TESTING EVALUATION:

Forty-one persons with diabetes, in steady state for glucose, performed self-capillary blood glucose assays using the Ascensia® BREEZE™ System and one test strip lot (Lot A). A fingerstick was performed with the MICROLET® Adjustable Lancing Device. Samples from the palm, forearm, thigh and abdomen were obtained using the MICROLET® VACULANCE Lancing Device. Ascensia® BREEZE™ results from the multiple sites were compared to those obtained from the finger. The blood glucose range for the fingerstick measurements was 3.3 to 13.6 mmol/L, with an average of 7.5 mmol/L. The hematocrit range was 38 to 53%, with an average of 45%.

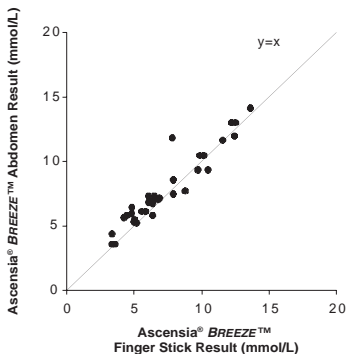
A. Results from Palm (n=36)



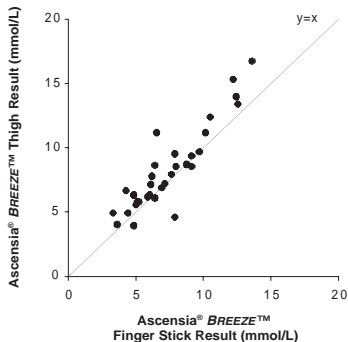
B. Results from Forearm (n=30)



C. Results from Abdomen (n=32)



D. Results from Thigh (n=32)



Comparison of Multiple Site to Fingertip Results†

Site	Opr.	N	Y=	95% Confidence Intervals		R
				Slope	Intercept	
Palm	Lay	36	$0.95x + 0.51$	0.77 to 1.13	-0.70 to 1.71	0.92
Forearm	Lay	30	$1.01x + 0.57$	0.82 to 1.19	-0.59 to 1.73	0.93
Abdomen	Lay	31‡	$0.92x + 0.98$	0.79 to 1.05	0.05 to 1.91	0.97
Thigh	Lay	32	$1.14x - 0.21$	0.92 to 1.37	-1.81 to 1.40	0.91

† Weighted Deming regression, weighted linear correlation coefficient

‡ One outlier excluded from statistics, but included in data plot

Opr. = Operator; Lay = Lay User;

Solving Problems

PROBLEM SOLVING:

You can solve many of the problems you might have by working through this section.

1. Do you have a 10-test disc in the meter? Yes____ No____

No? (see pg. 2)

2. Does it contain new test strips? Yes____ No____

No? (see pg. 2)

3. Is the 10-test disc within its expiration date?

Yes____ No____

No? (see pg. 2)

4. When you "Pull and Push" the **meter handle**, are you making sure you "Pull" **all the way out** and "Push" **all the way in**?

Yes____ No____

No? (see pg. 6)

5. Do you need to replace the battery? Yes____ No____






Yes? (see pg. 28)







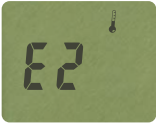


6. Is the battery holder pushed all the way into the battery compartment? Yes____ No____

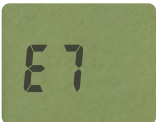
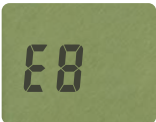
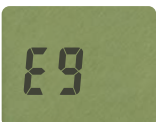


No? (see pg. 30)

TROUBLESHOOTING AND ERROR CODES:


When you have a problem or a question concerning what you see on your screen, the following may be helpful.

What You See	What It Means	What You Do
 The screen displays 'LO' in large digits, with 'mmol/L' to the right. Below the digits, it shows '1/07' and '2:04 AM'.	Test result is below 0.6 mmol/L (10 mg/dL).	Repeat test and make sure test strip is completely filled. If LO appears again, contact your physician or healthcare professional (HCP).
 The screen displays 'HI' in large digits, with 'mmol/L' to the right. Below the digits, it shows '1/07' and '2:04 AM'.	Test result is above 33.3 mmol/L (600 mg/dL).	Wash your hands and test site. Repeat the test. If HI appears again, contact your physician or HCP.
 The screen displays '8.88' in large digits, with 'mg/dL' to the right. Above the digits are icons for a battery, a water drop, and a thermometer. Below the digits, it shows '88/88' and '88:88 AM'. A checkmark and an 'X' are also visible.	You have not pushed the meter handle all the way in.	Push the meter handle in until it clicks. You must push the handle all the way in and see the flashing blood drop before you touch the strip to the blood drop.
 The screen displays a circular icon with a lightning bolt and a test strip, indicating a 10-test disc error.	The 10-test disc is out of test strips.	Insert a new 10-test disc.
 The screen displays '5.3' in large digits, with 'mmol/L' to the right. Below the digits, it shows '1/07' and '2:04 AM'. A thermometer icon and an 'X' are also visible.	The meter will mark a test result with a thermometer and an X if the meter is too cold or too hot when the test is performed. The result will not be included in any averages calculated.	Test only when the meter temperature is between 10°C and 40°C (50°F and 104°F).

What You See	What It Means	What You Do
	Low Battery icon flashes if battery power is low.	Replace battery within 20 readings or within one week.
	Battery life has ended.	Replace the battery.
	Meter cannot perform automatic calibration, and you must enter the Program Number manually.	Check test strip disc or carton for Program Number (P#). Use the  or  to select the correct number and press  to accept.
	Temperature is either too hot or too cold.	Allow the meter to reach room temperature.
	Test strip removed during the test, or release button pressed during the test.	Take care to not press release button or remove test strip during test. Release used test strip and repeat test (see pg. 8).
	The meter is open when the meter handle is pulled.	Close meter and push handle in.

What You See	What It Means	What You Do
	<p>Meter has detected an error; accurate test result not possible.</p>	<ul style="list-style-type: none"> • You may have applied blood too early to the test strip. Repeat test and wait until you see the flashing blood drop to apply blood. • There might also be moisture on the test strip guide. Clean meter if needed and dry thoroughly (see pg. 27). Repeat test.
	<p>Meter has detected an error; accurate test result not possible.</p>	<ul style="list-style-type: none"> • Test strip is not completely filled. Release used test strip and repeat test. (see pg. 8) or • 10-test disc may have been damaged due to intense heat or moisture exposure. Replace 10-test disc, using a new box if necessary.
	<p>There was a problem filling the test strip completely full.</p>	<p>Review pg. 8, and repeat test.</p>
	<p>Your Blood Glucose Level is very high or meter error.</p>	<p>Turn meter off, then on using . Retest. If error appears again, call your physician or healthcare professional (HCP). Your blood glucose may be above 55.5 mmol/L (1500 mg/dL). If the problem is with the meter and cannot be corrected, contact the Bayer Diabetes Helpline (see pg. 45).</p>

What You See	What It Means	What You Do
E11 or higher	Meter Malfunction	Turn meter off, then on using ①. Retest. If error remains, contact the Bayer Diabetes Helpline (see pg. 45).
The display goes blank when the meter is turned on.	<ol style="list-style-type: none"> 1. You may have accidentally pressed the ① button. 2. Meter will turn off after 3 minutes without use or 15 minutes of no use while waiting for you to apply blood or control solution. This is a normal expected action that saves battery life. 	<ol style="list-style-type: none"> 1. Press the ① button. 2. Press the ① button.
Meter will not turn on.	<ol style="list-style-type: none"> 1. Battery life has ended. 2. Battery holder is loose or battery is installed + side down. 	<ol style="list-style-type: none"> 1. Replace Battery (see pg. 28). 2. Check the battery and the battery holder to be sure they are tightly in place and correctly installed (see pg. 28). If display is still blank, replace battery (CR2025).
Meter fails to start countdown after blood is applied.	<ol style="list-style-type: none"> 1. Not enough blood. 2. The inside of your meter may be dirty, or foil from the 10-test disc may be lodged in the front of the meter. 	<ol style="list-style-type: none"> 1. Discard used test strip. Retest using a round drop of blood. 2. Clean inside of meter (see pg. 27). Retest.

What You See	What It Means	What You Do
<p>Control Test result is out of range (too high or too low).</p>	<ul style="list-style-type: none"> • Control solution is past expiration date or is past the 6-month open use-life date. • 10-test disc is past expiration date. • Deteriorated test strip due to heat or exposure to moisture. • Control solution not at room temperature. • Not enough control solution drawn into test strip. 	<p>Run another control test. If still out of range, retest with a new 10-test disc and control solution with an acceptable expiration date and open use-life date. If still out of range, contact the Bayer Diabetes Helpline (see <i>pg. 45</i>).</p>
<p>Meter shows dashes before blood is applied.</p>	<p>Your meter may be dirty.</p>	<p>Clean meter (see <i>pg. 27</i>). If you continue to experience difficulty, contact the Bayer Diabetes Helpline (see <i>pg. 45</i>).</p>
<p>Some display segments do not appear to be working when the meter handle is all the way out.</p>	<p>This may affect the way you see your results.</p>	<p>If there is a difference in your meter's display and the one shown on page v, contact the Bayer Diabetes Helpline (see <i>pg. 45</i>).</p>
	<p>Invalid test result.</p>	<p>Discard strip and retest.</p>

CUSTOMER SERVICE:

If a problem arises, work through the Solving Problems section (see *pg. 39*). You may easily find your solution there. If you are still having trouble, please call our Bayer Diabetes Helpline. We have friendly, knowledgeable people who are there to help 12 hours a day, 7 days a week (9–9 EST).

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

Important:

- Always speak with a customer service representative before returning your meter for any reason. They will be able to provide information that can help solve your problem quickly.
- Have your Ascensia® *BREEZE*™ Meter ready for testing when you phone. It would also be helpful to have a bottle of Ascensia® *AUTODISC*™ Normal Control Solution with you.
- Fill out the following check list before you call:

Check List:

1. The meter serial number _____
2. Date and time the problem occurred _____
3. I have tested with Normal Control Yes _____ No _____
The Normal Control result was: _____
Lot Number _____ Expiration Date _____
4. Please also give the Lot Number and Expiration Date of the test strip disc currently being used. This information is printed on the test strip disc and the test strip disc box.
Lot Number _____ Expiration Date _____

REPLACEMENT ITEMS:

If you call or write for supplies, please include the number with the name of the replacement part or product.

Replacement Parts

Part Number*	Item
40030035	1 lithium battery (CR2025) (available at most stores) Duracell Inc. DL2025 Panasonic Industrial Company CR2025 Renata CR2025
99A61189	Ascensia® BREEZE™ User Guide
50184270	Ascensia® BREEZE™ Quick Reference Guide

You can obtain these parts in Canada from:

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

Replacement Products

Number	Product Name
3611A	Ascensia® AUTODISC™ Test Strip Discs (box of 50)
3628A	Ascensia® AUTODISC™ Test Strip Discs (box of 100)
3642A	Ascensia® AUTODISC™ Normal Control Solution
3643A	Ascensia® AUTODISC™ Low and High Control Solutions
6540B	MICROLET® Adjustable Lancing Device
6546A	MICROLET® Lancets (box of 100)
6550A	MICROLET® Lancets (box of 200)

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

*Part numbers are subject to change without notice.

5-YEAR LIMITED WARRANTY:

Manufacturer's Warranty: Bayer Inc. Healthcare 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 the 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® AUTODISC™ Test Strip Discs) 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® *BREEZE*™ Meter when used with any Test Strip Discs other than Ascensia® *AUTODISC*™ Test Strip Discs, and therefore makes no warranty of the performance of the Ascensia® *BREEZE*™ Meter when used with any Test Strips or Test Strip Discs other than Ascensia® *AUTODISC*™ Test Strips or when the Ascensia® *AUTODISC*™ 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.

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.

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Subsidiary of Bayer Corporation
Mishawaka, IN 46544 U.S.A.

Distributed by:
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Toronto, Ontario M9W 1G6 Canada

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Rev. 4/04

99A61189

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