THE NEW FACE of Glucometer®

Ascensia DEX2

Diabetes Care System

(DEX

USER GUIDE

Ascensia™ *DEX®* and Ascensia™ *AUTODISC™* Unique 10-Test Disc

If you have any questions, comments or need help with reimbursement for your testing supplies, call 1-800-348-8100.



CAUTION: Before using any product to test your blood glucose (sugar), read all instructions and practice the test. If you want to perform a control test, please call Bayer Customer Service at 1-800-348-8100 to receive your first bottle of control solution at no charge. Do all quality control checks as directed and consult with a diabetes health professional. These recommendations apply to all blood glucose monitoring systems and are supported by the American Association of Diabetes Educators,* the American Diabetes Association, the Food and Drug Administration and Health Industry Manufacturers Association.

*You may call the American Association of Diabetes Educators for the location of a Certified Diabetes Educator (CDE) near you. 1-800-338-DMED.



USER GUIDE



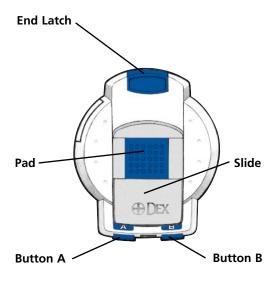
Bayer Corporation Mishawaka, IN 46544 USA Thank you for choosing the Ascensia™ *DEX*® 2 Diabetes Care System. We understand that convenience is important to people who monitor their blood glucose levels.

Convenient features of the Ascensia *DEX* 2 System include:

- Ten test strip disc directly dispensed from the meter.
- Fast results readings in thirty seconds.
- Stored test results meter memory provides you and your healthcare provider with time-specific averages.
- Computer accessibility with additional equipment, your test results are directly transferable, giving you access to more information about your blood glucose management.

These features are quickly accessed and easy to use. This User Guide is provided for your reference and guides you through the details of your Ascensia *DEX* 2 Diabetes Care System. If you need additional assistance with this product, contact Bayer Customer Service (within the U.S.A.) at: 1-800-348-8100.

Ascensia[™] *DEX*® and Microlet® are trademarks of Bayer Corporation.





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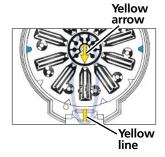
1. Remove the test strip disc from the paper pack.



2. Open the meter by releasing the end latch.

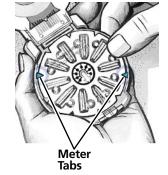


Line up the yellow arrow on the disc with the yellow line on the meter.



4. Important:

You must press the test strip disc under the two blue tabs on the meter.



If you cannot find the two blue tabs, remove the disc from the meter. Two large blue arrows point to the two blue tabs.



 Close the meter and snap the end latch closed. Your meter is now ready to run ten tests.

To remove the used disc, open the meter and lift the disc from under the two blue tabs.

1. Move the slide forward to turn the meter on.



2. Press button A.

The time appears and the minutes flash.

If a test result or the average appears instead of the time, press and hold button A.



3. Press button B to make a change.



Give a quick press to button A. Do not hold it in.

The hour flashes.

Press button B to make a change.



- Repeat step 4 to change the AM/PM.
- Continue repeating step 4 to change the month and day and then the year.
- Move the slide backward to turn the meter off.

 In a single motion, move the pad all the way to the left and then move the slide forward. Be sure slide is moved all the way to the end. This will push out a test strip.

Important:

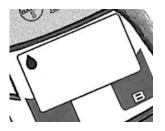
You must move the slide all the way forward.



A flashing blood drop appears on the display.

The meter is ready for the blood.

It will stay ready for 15 minutes, then turn itself off.

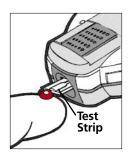


 Stick your finger with the Microlet device and form a small, round drop of blood. (For more information about the Microlet device, see page 26.) (For Multiple Site Testing information, see page 7.)



 Move the entire front edge of test strip to touch the edge of blood drop.

Blood is drawn into and fills the test strip.



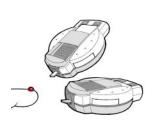
Important:

Hold the test strip in place until the meter beeps, then move it away.

The test strip must be filled by the time the meter beeps. If you are having difficulty, see page 29.



Blood drop may be applied to test strip from the positions shown below.



Do not apply blood to test strip with the meter below the blood drop.

Note: Multiple Site Testing

Consult with your healthcare professional prior to testing from a site other than your fingertips.

Blood glucose testing results from sites other than your fingertip could be significantly different. These differences may vary from individual to individual, and are physiological differences caused by factors such as food intake, health state and medication being used.

If you perform testing other than from a fingertip:

- A. Select a soft, fleshy area of skin that is free from hair and visible veins.
- B. Wash the puncture site with soap and warm water. Rinse and dry thoroughly. This ensures cleanliness and increases blood flow to the puncture site.
- C. After you have determined the proper depth of your selected site, set the lancing device for that depth of puncture.





Firmly press the lancing device against the skin at the selected lancing site, then press the button to lance the skin. When a drop of blood forms on the surface of your skin, bring the meter and test strip up to touch the drop. 5. The test result appears after 30 seconds.



If you want to delete your test result, press button B now, before you discard the test strip.

An X appears on the display.

The test result will be stored in memory, but it will be marked with the X. All results marked with an X are deleted from any averages that are calculated.



6. Important:

To discard the test strip, you must first turn the meter upside-down over a waste container.

 With meter turned upside-down, pull back the slide all the way until you hear it click into position.



The result is stored when the slide is closed.



Important:

If your glucose level is below 50 mg/dL (2.8 mmol/L) or above 250 mg/dL (13.9 mmol/L), test again.

If your glucose level is still below 50 mg/dL (2.8 mmol/L) or above 250 mg/dL (13.9 mmol/L), it may indicate a potentially serious medical condition. We recommend you consult your physician or healthcare professional immediately.

Number of test strips Two most recent results Two-week average Time-specific averages Individual test results

Begin with Step 1. Each item is accessed in sequence.

 Move the slide forward to turn the meter on.

> The number of test strips remaining in the meter appears with the present date and time.

Next, the two most recent test results appear with the date and time the tests were taken.



2. Press button A.

The two-week average appears with an A above it.

If it does not appear, you have not taken at least three tests within the last two weeks. Skip to step 6.



3. Press button B.

The A1 average appears with its time setting.

(For more information about all averages, see page 12.)



Continue to press button B to see the A2, A3, and A4 averages.

> If one of the averages does not appear, it is because you have not taken at least three tests within the last two weeks during the time setting for that average.

Press button B repeatedly to see individual test results.

To move quickly through all test results, press and hold button B. The meter beeps after the last result is reached.

6. Move the slide backward to turn the meter off.

NOTE: Three dashes — display if no average is available for a specific time. There must be at least 3 stored blood glucose test results in the last two weeks to display an average for a specific time.

The meter calculates four time-specific averages. The four times have already been set to:

A1 6:00 AM

A2 12:00 Noon

A3 6:00 PM

A4 9:00 PM

Your blood test must occur within one hour before or after each time setting to be included in the average calculations.

The following steps tell you how to change the times that have already been set.

- 1. Move the slide forward to turn the meter on.
- 2. Press button A.

The time appears and the minutes flash.

If the time does not appear, press and hold button A.

3. Press and hold button A until A1 appears.

Release button A and the minutes flash.



4. Press button B to make a change.



Give a quick press to button A.Do not hold it in.

The hour flashes.

Press button B to make a change.

6. Repeat step 5 to change the AM/PM.

- Repeat step 5 to access and change the time settings for A2, A3 and A4.
- 8. Move the slide backward to turn the meter off.

The meter has four basic features, each with two settings.

Beeper	on	off
Blood glucose units	mg/dL	mmol/L
Time format	12 hour	24 hour
Temperature unit	°F	°C

The following steps tell you how to change these features to a different setting.

 Move the slide forward to turn the meter on.



2. Press button A.

The time appears and the minutes flash.

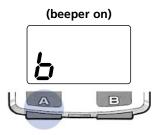
If the time does not appear, press and hold button A.

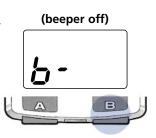


- Press and hold button A. A1 appears.
- 4. Press and hold button A.b (for beeper) appearsb is onb- is off

Press button B to make a change.

If you turn the beeper off, it is important that during a blood test when the meter displays 28, to begin the countdown, you move the test strip away from the blood drop.





- To move on to next feature, give a quick press to button A.
 Do not hold it in.
 - Press button B to make a change.
- Repeat step 5 to change the time format and temperature units.
- 7. Move the slide backward to turn the meter off.

The following steps tell you how to check that your system is working correctly. You will need a bottle of control solution and the test strip disc carton. If you would like to perform a control test, please call Bayer Customer Service at 1-800-348-8100 to get your first bottle of control solution at no charge.

 In a single motion, move the pad all the way to the left and then move the slide forward. Be sure slide is moved all the way to the end. This will push out a test strip.

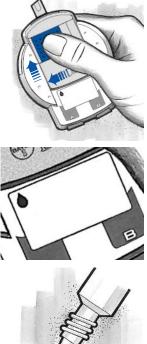
Important:

You must move the slide all the way forward.

2. A flashing blood drop appears on the display.

The meter is ready for the control solution. It will stay ready for 15 minutes, then turn itself off.

 Squeeze a small drop of control solution on a clean surface.



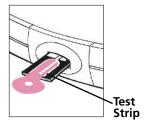
 Move the entire front edge of test strip to touch edge of control solution.



Control solution is drawn into and fills the test strip.

Important:

Hold the test strip in place until the meter beeps.



Do not apply control solution to test strip from the control bottle.



5. The test result appears after 30 seconds.



Important: Press button B twice.

A check mark ($\sqrt{}$) appears on the display.

The result will be stored in memory but it will be marked with the $\sqrt{.}$ All results marked with a $\sqrt{.}$ are not included in any averages that are calculated.

 The test result should fall within the range printed on the test strip disc carton.





8. Important:

To discard the test strip, you must first turn the meter upsidedown over a waste container. With the meter turned upside-down, pull back the slide all the way until you hear it click into position.

The test strip falls out.



You can transfer test results from the meter to a computer where they can be summarized in a report, graph or chart.

To make use of this feature, you need software and a special cable.

For more information, call Bayer Customer Service at 1-800-348-8100 in the U.S.A. only, or visit us on the web at www.ascensia.com, or www.bayercarediabetes.com.

- 1. Move the slide forward to turn the meter on.
- 2. Press button A.



Press and hold the A and B buttons for 5 seconds.

000 appears.

If you change your mind, press either button before closing the slide.



4. Move the slide backward to turn the meter off.

<u>/!</u>\

! 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.

Exterior of the meter

- Mix a solution of mild detergent and water.
 Or mix one part bleach and nine parts water.
- 2. Moisten a lint-free tissue with the solution.

Important: Do not use a very wet tissue. Excess moisture could affect the electronics.

- 3. Clean the meter exterior.
- 4. Wipe dry with a lint-free tissue.

Interior parts of the meter

- Open the meter by releasing the end latch.
- Mix a solution of mild detergent and water.



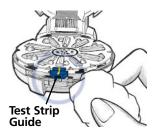
3. Moisten a lint-free tissue with the solution.

Important:

Do not use a very wet tissue. Excess moisture could affect the electronics.

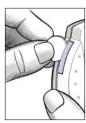
- Wipe the inside of the end latch.
- Wipe the test strip guide and nearby areas. Be sure to dry all areas with a lint-free tissue, especially the test strip guide, shown in blue.



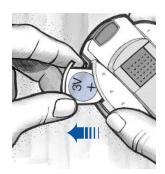


 Insert a coin into the battery capsule groove.

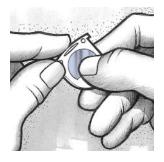




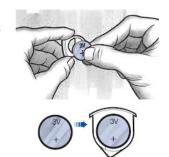
2. Pry the capsule loose and remove it from the meter.



3. Push your finger through the semicircular hole to release the batteries.



- 4. Insert two new lithium batteries (CR 2016) into the battery capsule with the + side facing up.
- Push down and snap them into position.
- 6. Replace the capsule into the meter.
- 7. Set the current time and date. Instructions are on page 3.





✓ ! WARNINGS:

Keep lithium batteries away from children.

Lithium batteries are poisonous.

If batteries are swallowed, immediately contact a physician or your local poison control authority.

Discard batteries according to your local environmental regulations.

 Pull the endcap from the Microlet Adjustable Lancing Device.

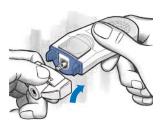


Push Microlet lancet all the way in. Twist off lancet cap.



3. Snap the endcap back on.

See Microlet package insert for more details on how to use the Microlet device.



 Wash your hands with warm, soapy water. Rinse and dry thoroughly.



27 Notes

Please refer to the possible solutions listed. If you need further assistance, contact: Bayer Customer Service at:

1-800-348-8100 24 hours a day

Display is blank

The meter will turn itself off and the display will go blank if you leave it on without doing anything for 15 minutes (3 minutes if it is not during a test). If this is the reason, simply move the slide back and then forward. The display should appear.

If this is not the reason, then make sure the battery capsule is snapped tightly into position.

If this is still not the reason, then replace the batteries. Instructions are on page 24.

An X appears automatically with a test result

The meter will automatically mark a test result with 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 50°F and 104°F (10°C and 40°C).

The test strip does not fill by the time meter beeps

Review the procedures in *Perform a blood glucose test*, pages 5–9, then retest. Be sure to touch the entire edge of the test strip to the edge of the blood drop.

If error continues, call Bayer Customer Service:

1-800-348-8100

24 hours a day

Countdown does not start after blood is applied Review the procedures in *Perform a blood glucose* test, pages 5–9, then retest.

Countdown starts before blood is applied Clean and dry the interior parts of the meter. Instructions are on page 23, then retest.

Control test result is not within range

Make sure the test strip disc and the control solution have not passed the expiration date. The dates are printed on each test strip disc and control bottle.

Make sure the control solution is at room temperature. Retest.

If you still experience this error, your test strips may have been exposed to excessive heat and they may have deteriorated. Replace the test strip disc. Instructions are on pages 1–2.



The battery life has ended. Replace the batteries. Instructions are on page 24.



Meter temperature is too hot or too cold. Test only when the meter temperature is between 50°F and 104°F (10°C and 40°C).



Meter cannot read the program number. You will have to enter it. Find the program number on the test strip disc or its carton and press button B until you reach the correct program number. Press button A to enter the number.



You may have moved the test strip or the slide during the test. Retest.



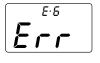
You may have turned the meter on when the end latch was open.

Move the slide all the way back and fasten the end latch.

Bayer Customer Service:

1-800-348-8100

24 hours a day



The meter does not contain a test strip disc. Insert one. If there is one in the meter, it is not compatible with your meter. Remove and replace it with a new one. Instructions are on pages 1–2.



Make sure you do not apply blood or control solution to the test strip before the blood drop appears on the display. Retest.

The inside of the meter may be wet. Clean and dry the test strip quide. Instructions are on page 23.



When the test strip was held in the blood drop, the test strip was not filled sufficiently. Retest. Also, the test strip may have been damaged due to intense heat exposure. Replace the test strip disc and retest.



The blood was drawn into the test strip too slowly.



Turn the meter off then on. If the error appears again, call Customer Service. If the meter is working, retest.

If after retesting the error appears again, call Customer Service. If you suspect your blood glucose is high, contact your physician immediately. Your blood glucose may be above 1,000 mg/dL (55.6 mmol/L).



Test result is below 10 mg/dL (0.6 mmol/L). Repeat the test. If still low, contact your Doctor or Diabetes Nurse regarding a possible hypoglycemic condition (low blood sugar).



Test result is above 600 mg/dL (33.3 mmol/L). Retest. If the result is still high, contact your physician or diabetes educator about a possible hyperglycemic condition (high blood sugar).

LO°F

Meter temperature is too cold. Test only when the meter temperature is between 50°F and 104°F (10°C and 40°C).



Meter temperature is too hot. Test only when the meter temperature is between 50°F and 104°F (10°C and 40°C).



The batteries are low. Replace the batteries within one week or the next 20 tests. Instructions are on page 24.

Customer Service

If attempts to correct a problem fail, please call our Customer Service Department. We have trained specialists to assist you. In the U.S.A. call toll free at:

1-800-348-8100 24 hours a day

Important

Check List

1. The meter serial number

- Speak to a Customer Service Representative before returning your meter for any reason. Information will be provided to resolve your problem correctly and efficiently.
- Have your Ascensia[™] DEX® 2 Meter ready for testing when you phone. It would also be helpful to have a bottle of Ascensia[™] AUTODISC[™] Normal Control solution available.
- · Fill out the following check list before calling:

2.	2. The date and time the problem occurred							
	·							
3.	I have tested with the Normal Control Yes No							
The Normal Control result was:								
	Lot number Expiration date							
4.	Please include 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								
4. Please include the Lot number and Expiration date test strip disc currently being used. This information is printed on the test strip disc and the test strip disc carton.								
	Lot number Expiration date							

Replacement Items

When calling or writing for supplies, be sure to include the number with the name of the replacement part or product.

Replacement Parts

Part number* Item

40030032 3-volt Lithium Battery (DL or CR 2016)

Two required (available at most stores)

Ascensia™ DEX® 2 User Guide 99G39529

Ascensia™ DEX® 2 Ouick Reference Guide 50184202

These parts are available in the United States from:

Bayer Corporation

Customer Service Department Order Entry P.O. Box 2004 Mishawaka, Indiana 46546

Replacement Products

Number	Product Name

3610A Ascensia™ AUTODISC™ Test Strip Disc

— 50s

AscensiaTM AUTODISCTM Normal Control 3642A 3643A

Ascensia™ AUTODISC™ Low and

High Control

Microlet Vaculance® Lancing Device 3416 6540B Microlet® Adjustable Lancing Device

Microlet® Lancets (100s) 6546B

6554 Microlet® Endcaps — Regular (10s) 6558 Microlet® Endcaps — Super (10s)

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

^{*}Part numbers subject to change without notice.

Specifications

Test: Capillary blood glucose

Referenced to plasma/serum

glucose

Calibration: Meter automatically reads pro-

gram number assigned to disc.

Capillary Volume: Approximately 2.5-3.5 µL

Test Range: 10-600 mg/dL (0.6-33.3 mmol/L)

Test Time: 30 seconds

System Features: 100 Test memory

Underfill detection Two week average

Four time-specific averages

Temperature: 50°F to 104°F (10°C to 40°C)

Humidity: 10-80% RH

Power Source: Two 3-volt lithium batteries

(CR 2016)

Battery Life: Approximately 1000 tests or

one year

U.S. Patent: U.S. 5,575,403 - 5,738,244 -

5,620,579 - 5,653,863 - 5,630,986 -

5,723,284 - Des. 369,216 Other patents pending

Ascensia DEX 2 System (Plasma/Serum Referenced)

1. Accuracy:

A patient-use clinical study was performed at diabetes care centers in three different locations. Glucose levels were measured with the Ascensia *DEX* 2 System on over 300 fresh capillary blood specimens by 61 persons with diabetes, and six healthcare professionals. The results were compared with the results of three laboratory automated chemistry analyzers, all of which used a hexokinase chemistry system. The comparative plasma glucose methods used were Hitachi 704 and 747 Analyzer (Boehringer Mannheim Corporation, Indianapolis, Indiana), and ACA® Discrete Chemistry Analyzer (E.I. Dupont De Nemours and Company, Wilmington, Delaware).

Figure 1 shows the comparison of the lay diabetic Ascensia *DEX* 2 System results with the plasma glucose results. The comparison of the healthcare professional results with the plasma glucose results is shown in Figure 2.

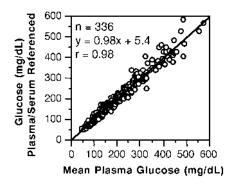


Figure 1 Ascensia *DEX* 2 System Results Obtained By 61 Lay Diabetics.

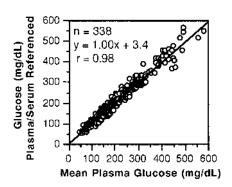


Figure 2 Ascensia *DEX* 2 System Results Obtained By 6 Healthcare Professionals.

2. Precision:

Precision Results for Whole Blood Specimens: Heparin anticoagulated glycolyzed whole blood pools were supplemented with glucose to obtain five glucose levels. Multiple replicates of the whole blood were tested on one day by multiple operators using multiple Ascensia *DEX* 2 meters and one lot of test strips. The plasma glucose levels of the blood specimens were also tested using the YSI 2300 Stat Plus Glucose Analyzer, a glucose oxidase method. The accuracy of the YSI was verified using control sera assayed using a modification of the CDC hexokinase reference procedure [HEW] publication no.(CDC)77-83301.

YSI	Ascensia DEX 2 Results							
Mean Plasma Glucose (mg/dL)	No. of Tests	Mean (mg/dL)	Bias (mg/dL)	Bias (%)	S D (mg/dL)	C V (%)		
25	78	21	-4.1	-16.3	2.9	13.8		
56	78	54	- 1.8	-3.3	3.6	6.7		
115	80	116	0.9	0.7	4.1	3.6		
216	79	216	-0.2	-0.1	7.2	3.3		
429	80	430	1.4	0.3	11.5	2.7		

Precision Results for Controls:

The Ascensia AUTODISC Control solutions were tested on multiple days by one operator using one meter and one lot of test strips. The following precision results were obtained:

	Ascensia DEX 2 Results									
				Within-run		Total				
Control		No. of Tests	Mean (mg/dL)	S D (mg/dL)	C V (%)	S D (mg/dL)	C V (%)			
Low Normal High	20 20 20	60 60 60	69 127 372	2.7 4.7 5.7	3.9 3.7 1.5	3.5 5.7 7.1	5.1 4.5 1.9			

5-Year Limited Warranty

Manufacturer's Warranty: Bayer Corporation ("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:

- 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 Disc) manufactured or recommended by Bayer.
- 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 DEX 2 Blood Glucose Meter when used with any Test Strips other than Ascensia AUTODISC Test Strips, and therefore makes no warranty of the performance of the Ascensia DEX 2 meter when used with any Test Strips 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.

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 the Customer Service Department of Bayer Corporation, by calling toll free 1-800-348-8100, for assistance and/or instructions for obtaining service of this instrument.



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