



**Contents of the Prodigy Voice® Meter**

The Prodigy Voice® meter is available as a meter kit only. Please review the contents of your purchase to confirm that all the components are included as listed below:

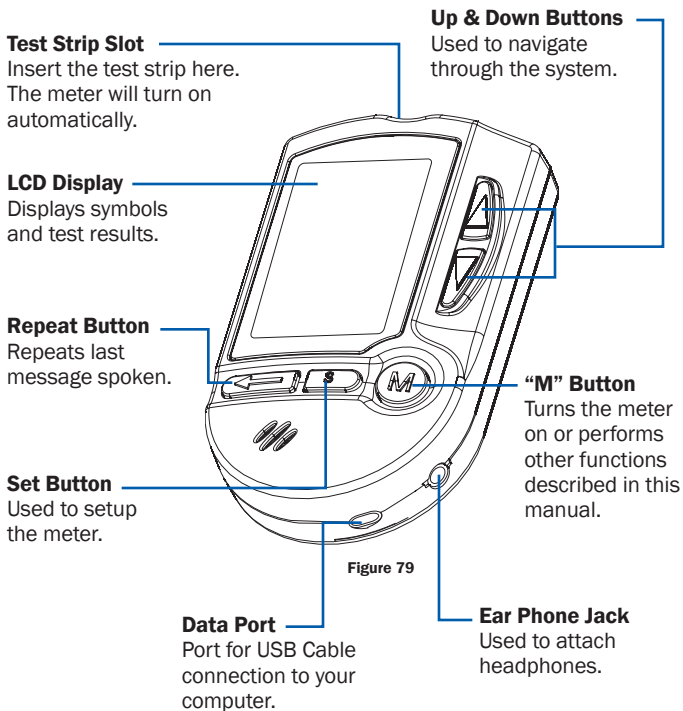
**Meter Kit Includes**

- Prodigy Voice® Talking Meter
- Two (2) AAA Alkaline Batteries
- Prodigy® Control Solution (4 mL)
- Prodigy® Test Strips (10 ct)
- Sterile Lancets (10 ct)
- Lancing Device
- Carrying Case
- Complete Instructions:
  1. Manual
  2. Logbook
  3. Quick Reference
  4. Warranty Card

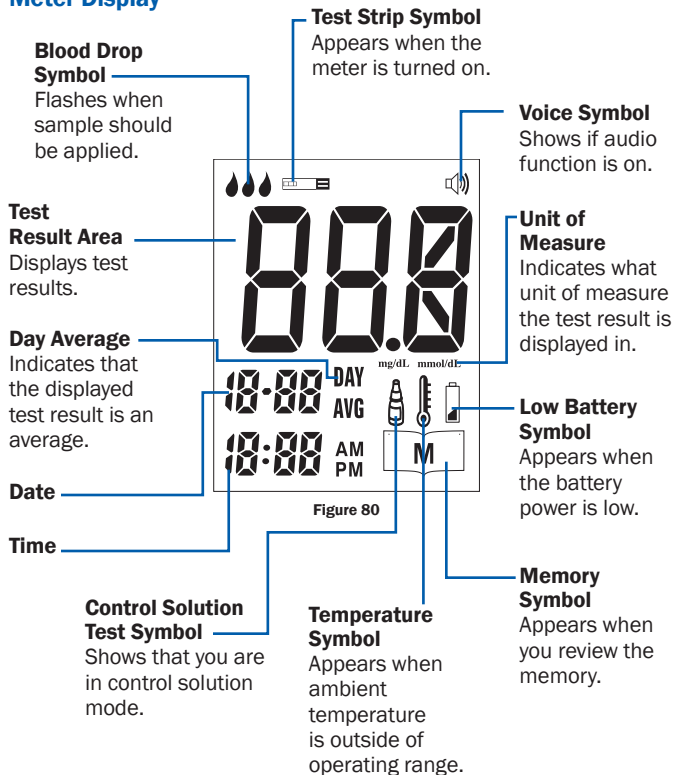
**Important:** Please review the contents of your purchase. If any items are missing, please return your meter to the place of purchase.

Setting Up the Prodigy Voice® Meter

Key Functions of the Meter



Meter Display



**Speaking Function**

The Prodigy Voice® meter talks you through each step of your setup, testing procedure and memory recall.

When does the meter speak?	What does the meter say?
When the meter is turned on.	Thank you for using Prodigy Voice®. Today's date November 18, 2009. The time 10:08 PM.
When room temperature is outside operating range; which is 50°F – 104°F (10°C – 40°C).	Room temperature is out of range.
When the meter is ready to test (⦿ appears on display).	Please apply blood to the test strip.
When the test is completed. (The result appears on display)	Your blood glucose (number) milligrams per deciliter/ millimoles per liter.
When you turn off the meter.	Goodbye.
When a used test strip is inserted.	Test strip has been used. Replace with a new one.

**Setup Steps**

The Prodigy Voice® meter has the volume, time, date and unit of measure presets. However, if you replace the batteries, you should check the time and date.

**STEP 1: Insert the Batteries**

Open the battery cover located on the backside of the meter. Insert two (2) AAA Alkaline batteries and align them properly. See Figure 81.

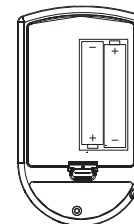


Figure 81

**STEP 2: Enter Setup Mode**

Start with the meter off. Then press and hold the “SET” button located on the front of the meter until the meter speaks. The meter is now in setup mode. See Figure 82.

Voice speaks: **“Your Prodigy® meter is on. You are now in setting mode.”**

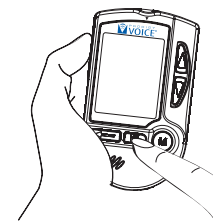



Figure 82

**STEP 3: Setting Volume Level**

The meter displays “VOL” Press the “Up” or “Down” button to select the speaking volume. See Figure 83.

- Number 0 indicates that the speaking function is turned off.
- Numbers 1 to 7 indicate speaking volume from low to high, where “” is displayed on the LCD during testing.

Voice speaks: “Volume Level 4.”

Then press the “SET” button and the year segment will appear and start flashing.

**STEP 4: Set the Year**

Press the “Up” or “Down” button to advance the year. With the correct year on the display, press the “SET” button and the date will appear on the display with the month segment flashing. See Figure 84.

Voice speaks: “The Year 2009.”

**STEP 5: Set the Month**

Press the “Up” or “Down” button to advance the month. With the correct month on the display, press the “SET” button and the date segment will start flashing. See Figure 85.

Voice speaks: “The Month November.”



Figure 83



Figure 84

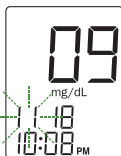


Figure 85

**STEP 6: Set the Date**

Press the “Up” or “Down” button to advance the date. With the correct date on the display, press the “SET” button and the time will appear on the display with the hour segment flashing. See Figure 86.

Voice speaks: “The Date 18.”

**STEP 7: Set the Hour**

Press the “Up” or “Down” button to advance the hour. With the correct hour on the display, press the “SET” button and the minutes segment will start flashing. See Figure 87.

Voice speaks: “The Hour 10 PM.”

**STEP 8: Set the Minutes**

Press the “Up” or “Down” button to advance the minutes. With the correct minutes on the display, press the “SET” button and the current unit of measurement will start flashing. See Figure 88.

Voice speaks: “The Minutes 08.”

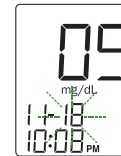


Figure 86

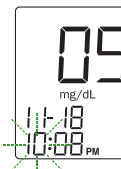


Figure 87

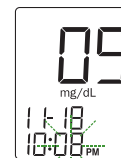


Figure 88

**STEP 9: Select Unit of Measurement**

Press and hold the “Up” or “Down” button until the unit of measurement you are choosing appears on the display. Press the “SET” button and the memory segment will start flashing. Your meter can display test results in milligrams per deciliter (mg/dL) or millimoles per liter (mmol/L). See Figure 89.

- The mg/dL unit is standard in the United States.
- The mmol/L unit is standard in Canada and Europe.

Voice speaks: “Blood glucose unit is mg/dL.”

**Important:** Day averages are calculated from results obtained during the 7, 14, 21, 30, 60 and 90 days preceding the current date and time settings.

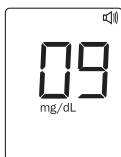


Figure 89

**STEP 10: Delete Memory**

When the “dEL” symbol and the “M” symbol appear on the display, you can choose to clear the memory. See Figure 90.

Voice speaks: “Deleting record function: To skip, press ‘Set’ button. If you press the ‘M’ key for five (5) seconds, all records will be deleted.”



Figure 90

If you do not want to clear the memory, press the “SET” button to skip this step. If you want to clear ALL memory, press and hold the “M” button for five (5) seconds. “- - -” will appear to indicate all memory has been deleted. See Figure 91.

Voice speaks: “All records have been deleted.”

Setup is now completed. “OFF” is displayed before shut down and the meter will audibly summarize your settings. See Figure 92.

Voice speaks: “Volume level 4; The date November 18, 2009; The time 10:08 PM; mg/dL; Goodbye.”

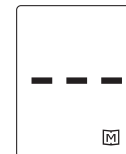


Figure 91



Figure 92

## Performing a Blood Glucose Test

### Tips for Applying Blood to Test Strips without Sight

Using the following five (5) tips may help you place a blood sample into the test strip successfully if you have little or no vision. The examples describe two (2) ways to bring the sample and the test strip together. Other techniques may work just as well. Keep experimenting until you have a technique that consistently works for you.

#### Tip One—*Smaller has its Advantages*

Because the Prodigy Voice™ meter is so easy to move around, you can experiment with many different approaches to determine which works best for you. Get comfortable holding the meter in one hand while testing. The meter can be moved towards your finger as easily as your finger can be moved to the test strip.

#### Tip Two—*Aim for the Tip*

The tip of the test strip contains an opening to the absorbent channel in the center where the blood should be applied. The absorbent channel draws the blood into the test strip, much like a straw, when the tip touches the blood sample. Blood should be applied only on the very tip. Blood applied to the bottom or sides of the test strip may cause inaccurate readings. It is important that the test strip does not bend at all when applying the sample.

#### Tip Three—*Using a Sideways Approach*

When testing, it may be helpful to rest or hold the meter on one side rather than flat or face up. In this position, the test strip sticks out of one end and the side with the buttons faces towards you.

The idea here is that the finger can be brought to the test strip from below until it touches the tip of the test strip. Then, the meter can be

repositioned so the sample touches the absorbent opening at the end of the test strip. Notice how the meter can be positioned so that the test strip can be sticking out to the left or to the right. This allows for either hand to be used for testing.

#### Tip Four—*Example 1*

- Step 1—Place the meter on one side in front of you on a table with the test strip pointing to the left.
- Step 2—Gently squeeze a finger on the left hand and obtain a sample.
- Step 3—Bring your finger toward the tip of the test strip from the bottom. Place the puncture site on your finger to the tip of the test strip.
- Step 4—If you do not make contact with the blood and the meter does not begin the test, while keeping the finger in contact with the test strip, lift the rounded end of the meter from the table so the round end of the test strip is flush with the sample.
- Step 5—Move the test strip slightly, if necessary, until you hear the meter beep then say “now testing.” Hold the meter in place until you hear the test result. This procedure can be used with either hand by starting with the meter resting on the other side.

#### Tip Four—*Example 2*

- Step 1—Gently squeeze the finger to bring blood to the finger.
- Step 2—Puncture the finger.
- Step 3—Hold the meter in your hand. Place your index finger under the test strip to help you guide the meter to where you have poked.

- Step 4—Using overlapping dragging motions in an upward direction, repeat the motion around the puncture sight until you hear the meter beep then say, “now testing.”
- Step 5—Hold the test strip in place until you hear the meter say your test results.

**Tip Five—Practice, Practice, Practice**

As with all new skills, practicing is the key to feeling comfortable performing this new skill with confidence and ease. Don't give up; remember to practice, practice, practice. We suggest using Prodigy® control solution when practicing.

Practice until, with relative ease, you can get a test result that falls within the target range for the Prodigy® control solution three (3) tests in a row. It can be helpful to have someone with sight to watch you practice in order to provide feedback or to answer any questions you may have.


**Performing a Blood Glucose Test**

**STEP 1: Insert the Test Strip**

Insert a test strip with the contact bars end entering into the test strip slot first. Push the test strip as far as it will go without bending it. The meter turns on automatically. See Figure 93.

Voice speaks: “Thank you for using Prodigy Voice®. Today's date November 18, 2009. The time 10:08 am. Please apply blood to the test strip.”

**STEP 2: Apply Blood Sample**

When the meter shows the “” symbol, apply blood to the opening of the absorbent channel of the test strip where it meets the narrow channel. Blood will be drawn into the test strip. See Figure 94.

**Important:** If you do not apply a blood sample within two (2) minutes, the meter will automatically turn off. You must remove the test strip and re-insert it again to turn on the meter and restart the test procedure.

The test strip confirmation window should be completely filled before the meter begins to count down. The meter will beep when the confirmation window is full.

Voice speaks: “Now testing.”



Figure 93

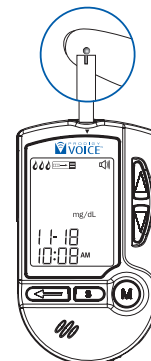


Figure 94

**Caution: DO NOT:**

- Smear or scrape the blood onto the test strip.
- Apply blood to the test strip when the test strip is not in the meter.
- Put blood or foreign objects into the test strip slot.

If you have trouble filling the test strip, please contact Customer Care at **1.800.243.2636** for assistance.

**STEP 3: View and Hear Your Result**

After the meter counts down from 6 to 1, your blood glucose test result appears along with the unit of measurement.

Voice speaks: **"Your blood glucose 106 mg/dL."**

The blood glucose test result is automatically stored in the meter memory. Turn the meter off by removing the test strip. Discard the used test strip carefully to avoid contamination. See *Figure 95*.

**Note:** If at any time you need to hear the last message spoken, press the "Repeat" button and the last message will be repeated.



Figure 95

**STEP 4: Remove the Lancet**

Always use caution when removing the lancet. Take the lancet out carefully. Place the protective cap back on the lancet's exposed tip. If using a twist lancet, place the cap on a hard surface and push the exposed tip into the protective cap and discard properly.

**Caution:** If you cannot test due to a problem with your testing supplies, contact Customer Care at **1.800.243.2636**. Failure to test could delay treatment and/or lead to serious medical conditions.



Using the Meter Memory

The Prodigy Voice™ meter stores the 450 most recent blood glucose test results with date and time in its memory. It also provides you with 7, 14, 21, 30, 60 and 90-day averages of your blood glucose test results. You can review the individual or average test results.

**OPTION 1: Recalling Individual Test Results**

While the meter is turned off, press the “M” button to turn the meter on. After the prompts, press the “M” button again to enter memory mode and recall individual test results. Press the “Up” or “Down” buttons to advance to the next or previous test results. See *Figure 96*.

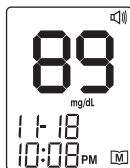


Figure 96

Voice speaks: “Memory record for November 18, 2009, 10:08 PM. Your blood glucose 89 mg/dL.”

Once you scroll through all the individual test results in the meter memory, “End” will display and the meter will turn off. See *Figure 97*.



Figure 97

**Note:** Once you are in the individual test recall mode, you cannot advance to the averaging simply by pressing the “M” button.

**OPTION 2: Recalling Average Test Results**

While the meter is off, press the “M” button and the meter will turn on.

Voice speaks: “Your Prodigy® meter is on. Today’s date November 18, 2009; The time 10:08 PM. Please insert the test strip.”



Figure 98

After the audible prompts, press the “M” button for two (2) seconds and the meter will recall the 7-day average. See *Figure 98*.

Voice speaks: “7-day average 106 mg/dL.”

Press the “Up” button to advance to the next average test result.

**Note:** The meter reports 7, 14, 21, 30, 60 and 90-day averages.

**Exit the Memory Mode**

To exit the memory mode during either option, press and hold the “M” button for approximately five (5) seconds and the meter will turn off.

**Important:** If you do not press any buttons for two (2) minutes, the meter will display “OFF” and turn off automatically.

## Specifications

**Dimensions:** 3.94 in. (L) x 2.25 in. (W) x 0.75 in. (H)  
100 mm (L) x 57 mm (W) x 19 mm (H)

**Weight:** 1.2 oz with battery  
36 g

**Power Source:** Two (2) 1.5 Volt AAA Alkaline Batteries

**Battery Life:** Over 1,000 tests

**Display:** LCD

**Memory:** 450 test results with date and time

**External Output:** USB Data Port

Auto electrode inserting detection

Auto sample loading detection

Auto reaction time count-down

Auto turn-off after two (2) minutes without action

Temperature warning

**Operating Condition:** 50°F – 104°F (10°C – 40°C),  
below 85% R.H. (non-condensing)

**Storage/Transportation Condition:** 39.2°F – 115°F (4°C – 46°C),  
below 85% R.H.

**Measurement Units:** mg/dL or mmol/L

**Measurement Range:** 20–600 mg/dL (1.1–33.3 mmol/L)

*The specifications may be changed without prior notice.*

## Viewing Results on a Personal Computer

Test results in memory can be transmitted to your personal computer. Prodigy® Diabetes Management Software and a cable are needed before installation.

### STEP 1: Install Software

Install Prodigy® Diabetes Management Software on your computer.

### STEP 2: Connect to a Personal Computer

Connect the cable to your computer. Then, connect the cable to the data port of the meter. **“Lnk”** (Pcl appears on the Prodigy Voice®) will appear if the cable is correctly connected to the meter and PC.

**Important:** The Prodigy AutoCode®, Prodigy Pocket® and Prodigy Voice® meters use a USB cable to connect to a computer.

For the Prodigy AutoCode®, Prodigy Pocket® and Prodigy Voice® meters, **“Usb”** will appear on the display, indicating that the meter is successfully communicating to your computer. You can begin to download the data from the meter.

### STEP 3: Transmit Data

Follow the instructions provided in the software to transmit data. Results transmitted will include date and time. Remove the cable and the meter will automatically turn off.

**Caution:** While the meter is connected to the PC, it is unable to perform a blood glucose test.

## Caring for your Prodigy® Meter

### Cleaning your System

Your Prodigy® meter should be cleaned whenever it is visibly dirty by wiping the outside of the meter using a cloth dampened with either mild detergent mixed with water or 70% isopropyl (rubbing) alcohol. Do not use bleach or other harsh abrasives to clean your meter.

Do not get any liquids, dirt, dust, blood or control solution inside the meter through the test strip port or the data port. Never spray cleaning solution on the meter or immerse it in any liquid.

### Lancing Device

Wipe your Prodigy® Lancing Device with a soft cloth dampened with water and mild detergent or 70% isopropyl (rubbing) alcohol. Do not immerse the lancing device in any liquid. Do not use bleach.

### Disinfecting your System

If your Prodigy® meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person.

### Lancing Device

Disinfect your Prodigy® Lancing Device about once a week. After cleaning the device, unscrew the cap and place it in 70% isopropyl (rubbing) alcohol for several minutes. Make sure the cap is completely dry before reattaching it to the device.

Please contact **Customer Care** if you have any questions at **1.800.243.2636**.

### Storing Your System

The Prodigy® meters do not require special maintenance.

- Store the meter, test strips and control solution in the carrying case after each use in a cool, dry place.
- Do not refrigerate.
- Do not store in the kitchen or bathroom.

*\*Your meter is a precision instrument. Please handle it with care.*



### Battery

The Prodigy Voice® and Prodigy AutoCode® meters come with two (2) 1.5 V AAA alkaline batteries. The Prodigy Pocket™ meter comes with one (1) CR2032 battery. Batteries are manufactured in a charged state and not designed for recharging. Recharging the batteries can cause battery leakage, or in some cases, high pressure rupture. **Replace all batteries at the same time.**

**Warning:** Batteries can explode or leak and cause burns if installed backwards, disassembled, charged or exposed to water, fire or high temperatures.

### Low Battery

The meter will alert you when the power is getting low by displaying two (2) different messages:

1. When the “” symbol appears alone on the display, the meter is functional and the result remains accurate, but you should change the battery as soon as possible.
2. When the “” symbol appears together with the “E-b” symbol on the display, the battery does not have enough power for a test. You must change the battery before using the meter.

### Battery Replacement

To replace the battery, make sure the meter is turned off.

**STEP 1:** With the meter off, press the buckle on the battery cover and lift up to open the cover.

**STEP 2:** Remove the old battery(s) and replace with new one(s). Be sure to align the battery(s) properly.

**STEP 3:** Close the battery cover. If the meter does not power on after you have replaced the battery(s), check that the battery(s) is correctly installed.

**STEP 4:** Turn the meter on by pressing the “M” button to check the time and date. Replacing the battery(s) does not affect the meter’s memory (previous test results stored in the memory). However, the date, time and units settings may need to be updated.



**Caution:** As with all small objects, the battery should be kept away from small children. If the battery is swallowed, seek medical assistance immediately.

### System Troubleshooting





#### Special Messages

Special messages and Error messages help to identify certain problems but do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing an error message.

In the event of a problem, refer to the information under “Action” in the “Error Messages” section. If you have a problem, please refer to the “Troubleshooting Guide” section. If you follow the actions recommended but the problem is not resolved, please contact Customer Care at **1.800.243.2636** for assistance.

Message	What it means
	“Lo” appears when your result is below the measurement limit, which is less than 20 mg/dL (1.1 mmol/L). “Lo” indicates hypoglycemia (low blood glucose). You should immediately consult your healthcare professional.
	“Hi” appears when your result is above the measurement limit, which is higher than 600 mg/dL (33.3 mmol/L). You should immediately consult your healthcare professional.

Error Messages


Message	Description
	<p><b>What it means:</b> Appears when the battery cannot provide enough power for a test.</p> <p><b>Action:</b> Replace the battery immediately.</p>
	<p><b>What it means:</b> Appears when inserting a used test strip.</p> <p><b>Action:</b> Test with a new test strip. If the problem persists, please contact Customer Care at <b>1.800.243.2636</b>.</p>
	<p><b>What it means:</b> Appears when the environmental temperature is out of the system operating range (50° F – 104° or 10° C – 40° C).</p> <p><b>Action:</b> Repeat the test after the meter and test strip are within the operating temperature range.</p>
	<p><b>What it means:</b> Low blood alert</p> <p><b>Action:</b> Apply more blood to the test strip within five (5) seconds of the error message. If time runs out, simply insert a new test strip.</p>

Troubleshooting Guide

❖ The meter does not display a message after inserting a test strip.

Probable Cause	Action
Battery exhausted.	Replace the battery.
Battery incorrectly installed or absent.	Check that the battery is correctly installed.
Test strip inserted upside down or incompletely.	Insert the test strip correctly with the bar end entering into the test strip first.
Defective meter.	Please contact Customer Care at <b>1.800.243.2636</b> for assistance.

❖ The test does not start after applying the sample.

Probable Cause	Action
Insufficient blood sample.	Repeat the test using a new test strip with a larger blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic shut-off. (Two (2) minutes after last user action).	Repeat the test with a new test strip. Apply sample only when the “  ” symbol appears on the display.
Defective meter.	Please contact Customer Care at <b>1.800.243.2636</b> for assistance.

❖ **The control solution test is out of range.**

Probable Cause	Action
Error in performing the test.	Read the instructions thoroughly and repeat the test again.
Control solution bottle not shaken well.	Shake the control solution bottle vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiration date or the discard date of the control solution.
Control solution that is too warm or too cold.	Control Solution, meter, and test strips should come to room temperature (68 – 77 ° F/20 – 25 ° C) before testing.
Test strip deterioration.	Please repeat the test with a new test strip.
Meter malfunction.	Please contact Customer Care at <b>1.800.243.2636</b> for assistance.

**Information About your Prodigy® Meter**

**Comparing Meter and Laboratory Results**

The test results you obtain from your meter may differ somewhat from your laboratory results due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way (*see test strip package insert for typical accuracy and precision data as well as important information on limitations*). To make an accurate comparison between meter and laboratory results, follow the guidelines below.

**Before you go to the laboratory:**

- Perform a control solution test to make sure that the meter is working properly.
- It is strongly recommended to fast for at least eight (8) hours before doing comparison tests.
- Take your meter with you to the laboratory.

**While at the laboratory:**

- Make sure that the samples for both tests (the meter test and the laboratory test) are taken and tested within 15 minutes of each other.
- Wash your hands before obtaining a blood sample.
- Never use your meter with blood that has been collected in a gray top test tube.
- Use fresh capillary blood only.

You may still have a variation from the result because blood glucose levels can change significantly over short periods, especially if you have recently eaten, exercised, taken medication or experienced stress.<sup>1</sup> In addition, if you have eaten recently, the blood glucose level from a finger stick can be up to 70 mg/dL (3.9 mmol/L)

higher than blood drawn from a vein (venous sample) used for a lab test.<sup>2</sup>

Therefore, it is best to fast for eight (8) hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of bodily fluids (severe dehydration) may also cause a meter result to be different from a laboratory result.

References: 1) Surwit, R.S., and Feinglos, M.N.: *Diabetes Forecast* (1988), April, 49-51. 2) Sacks, D.B.: "Carbohydrates." Burtis, C.A, and Ashwood, E.R. (ed.), *Tietz Textbook of Clinical Chemistry*. Philadelphia: W.B. Saunders Company (1994), 959.

### Performance Characteristics

- **Accuracy:** ±15 mg/dL when glucose <75 mg/dL  
±20% when glucose >75 mg/dL

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- **Precision:** This study shows the CV (correlation variation) is less than 5%.

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- **The device has been certified to meet the following standards**  
98/79/EC, IEC 60601-1, IEC 61010-1, IEC 60601-1-2, IEC61326, and ISO 15197

### Expected Test Results

Time of day	Plasma glucose range for people without diabetes	Your target range
Before meal	70-130 mg/dL (3.8 - 7.2 mmol/L)	_____ (mg/dL)/(mmol/L)
After meals	Less than 180 mg/dL (10 mmol/L)	_____ (mg/dL)/(mmol/L)
Bedtime	Not specified	_____ (mg/dL)/(mmol/L)
Between 2 AM and 4 AM	Not specified	_____ (mg/dL)/(mmol/L)

Source: ADA Clinical Practice Recommendations 2012  
Please work with your doctor to determine a target range that works best for you.

Your Prodigy® meter is designed to help you and your healthcare professional manage your diabetes. You must always rely on your healthcare professional to interpret your test results and to decide how to treat your diabetes.

### Unexpected Test Results

Unexpected test results can occur. When this happens, please refer to these cautions.

#### Low Blood Glucose Test Results

False low results may occur if you are severely dehydrated. If you think you are severely dehydrated, contact your healthcare professional immediately.

If your test result is lower than 70 mg/dL or “Lo” appears on your meter screen, this could be a result of hypoglycemia. Although this result could be due to a testing error, it is best to treat first and retest later. Contact your healthcare professional immediately. See *Figure 99*.



Figure 99

### High Blood Glucose Test Results

If your test result is higher than 180 mg/dL, this could be a result of hyperglycemia. If you are uncertain about this test result, retest. If the result continues to be higher than 180 mg/dL, contact your healthcare professional immediately.

If “Hi” appears on your meter screen, this could be a result of severe hyperglycemia (results higher than 600 mg/dL). Retest your blood glucose. If “Hi” appears again, contact your healthcare professional immediately. See *Figure 100*.



Figure 100

### Repeated Unexpected Test Results

If you continue to get unexpected test results, check your blood glucose monitoring system by performing a control solution test. Refer to “*Performing a Control Solution Test*” section in this manual.

### Unusual Red Blood Cell Count

A hematocrit range (percentage of red blood cells in the blood) that is extremely high (above 55%) or low (below 30%) can also cause false readings.

### Accuracy of Meter Measurements

**FAQ:** Can two (2) blood glucose meters produce different readings that are from the same blood sample? Does this make one reading more accurate than the other?

**Answer:** Yes, different meters can produce different readings using the same blood sample.  
No, this does not necessarily mean that one result is more accurate than the other.

The reasons for this are as follows:

1. The FDA recognized standard for glucose meter accuracy is ISO 15197: In Vitro Diagnostic Test Systems—Requirements for Blood Glucose Monitoring Systems for Self Testing in Managing Diabetes Mellitus. This standard sets accuracy requirements that manufacturers must meet before being approved by the FDA to market their glucose meters.
2. The accuracy requirements for the blood glucose monitoring system—meters and test strips—as stated in ISO 15197 is this:

Ninety-five percent (95%) of the individual glucose results shall fall within  $\pm 15$  mg/dL (0.83 mmol/L) of the results of the manufacturer’s measurement procedure at glucose concentrations  $< 75$  mg/dL ( $< 4.2$  mmol/L) and within  $\pm 20\%$  at glucose concentrations  $\geq 75$  mg/dL ( $\geq 4.2$  mmol/L).

### How does this answer the FAQ?

The accuracy of the system is determined by a clinical study using 100 blood samples at interval glucose concentrations ranging from



< 50 mg/dL to over 400 mg/dL measured using both the manufacturer's meter and a clinical blood glucose analyzer for comparison (reference measurement).








**Example 1**

If the manufacturer's reference measurement is 70 mg/dL this means that the meter measurements are considered accurate if they fall within ± 15 mg/dL of 70 mg/dL (from of 55 mg/dL to 85 mg/dL).

If meter A produces a measurement of 60 mg/dL and meter B measures 80 mg/dL, then both are in the acceptable range and meet the accuracy requirement.

Each manufacturer has met the System Accuracy requirement as part of its testing to be cleared for marketing. In the System Accuracy, testing a distribution of blood glucose readings will result at the various glucose concentration levels for one manufacturer's system. This is the same for other manufacturer's systems. Because of the range of acceptable readings for the accuracy requirement, identical readings from two different meters on the same blood sample may not happen.

**Symbols Information**

Symbol	Referent
	Do not re-use. Single use only.
	Consult Operating Instructions.
	Keep away from sunlight.
	Keep dry.
	Temperature limitation.
	Use by.
	Date of manufacture.
<b>LOT</b>	Batch code.
<b>REF</b>	Catalog number.
<b>SN</b>	Serial number.
<b>CONTROL</b>	Control.

## Warranty Information

### Limited Lifetime Warranty

Prodigy Diabetes Care, LLC extends a limited lifetime warranty to consumers who purchase a new Prodigy® brand meter. Under this limited lifetime warranty, your new meter is covered from the original date of purchase, as long as it has not been modified, altered, or misused. Under this limited lifetime warranty, Prodigy® will replace, free of charge, the meter if it is defective in material or workmanship.

NO OTHER WARRANTIES, EXPRESS OR IMPLIED, ARE MADE. PDC WILL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING DIRECTLY OR INDIRECTLY FROM THE FAILURE OF THE PRODUCT TO PERFORM IN ACCORDANCE WITH SPECIFICATIONS.

Some states do not allow the exclusion or limitation of other express or implied warranties or incidental or consequential damages, so the above limitations or exclusions may not apply to you.

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**PRODIGY®**

**Prodigy Diabetes Care, LLC 1.800.366.5901**

9300 Harris Corners Parkway, Suite 450  
Charlotte, NC 28269



AR REP Advena Ltd; 33 Bridge Street,  
Hereford HR4 9DQ, UK

For **Customer Care**  
call: **1.800.243.2636**

**[www.prodigymeter.com](http://www.prodigymeter.com)**

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