PRODIGY®

AutoCode®
Blood Glucose Monitoring System

Pocket®
Blood Glucose Monitoring System

VOICE®
Blood Glucose Monitoring System

Owner's Manual

PCM262 Rev.4 01/12

Dear Prodigy® Meter Owner:

Thank you for choosing the Prodigy® meter as your blood glucose monitoring system. Please read this manual carefully as it contains important information about your new Prodigy® system. A warranty registration card is included with your system. Please return the completed card to us or complete warranty online at www.prodigymeter.com.

Prodigy® meters are designed to help you and your healthcare professionals monitor your blood glucose levels. This owner's manual will help you learn how to use your Prodigy® meter effectively. Customer Care is available 24 hours, 7 days a week by calling toll free **1.800.243.2636**. All questions concerning test results should be directed to your healthcare professional.

Prodigy® meters have the latest technology for blood glucose monitoring and are made with quality components. All Prodigy® meters are easy to use, give you fast, accurate test results with a minimal sample of blood, have large, easy-to-read display screens, lightweight and portable for your convenience.

Prodigy® meters:

- Require No Coding, allowing you to save time and avoid human error due to improper coding.
- Allow you to perform Alternate Site Testing (AST).
- Have memory and data management capabilities. Prodigy® meter's free software gives you and your healthcare professionals powerful graphic tools to manage your diabetes.

Table of Contents

Important Safety Instructions

Read this before using your Prodigy® meter. The following basic safety precautions should always be taken.

- Your Prodigy® meter, test strips, lancets and lancing device are for single patient use only. Do not share them with anyone, including other family members. Do not use on multiple patients.
- Close supervision is necessary when the device is used by, on, or near children, handicapped persons or invalids.
- Use the device only for the intended use described in this manual.
- Do not use test strips and control solutions with your Prodigy® meter that are not supplied by Prodigy®.
- Do not use the device if it is not working properly, or if it has suffered any damage.
- Before using any product to test your blood glucose, read all instructions thoroughly and practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional.
- Keep the test strip vial away from children; the vial cap and the test strips can be a potential choking hazard.
- Never chew or swallow a test strip. If this occurs, please seek medical assistance immediately.
- All parts of this kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- These devices are intended to be used for patient self-monitoring

and should not be used to collect blood from more than one person as this poses a risk of transmitting blood-borne pathogens such as Hepatitis B or HIV.

For further information, please refer to:

"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood-borne Pathogens: Initial Communication" (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood-borne Pathogens" (2010) http://cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

DO NOT CHANGE YOUR TREATMENT BASED ON A SINGLE RESULT THAT DOES NOT MATCH HOW YOU FEEL OR IF YOU BELIEVE THAT YOUR TEST RESULT COULD BE INCORRECT.

Important Health-Related Information

Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration consult a healthcare professional immediately.

Under normal blood concentrations and conditions, the following should not significantly affect results:

- Elevated blood triglycerides
- Reducing substances such as uric acid and ascorbic acid
- Acetaminophen
- Dopa
- Methyldopa
- L-dopa
- Tolbutamide

If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all instructions described in this owner's manual, call your healthcare professional.

Test results below 60 mg/dL (3.3 mmol/L) indicate low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L) indicate high blood glucose (hyperglycemia). If your results are below 60 mg/dL or above 240 mg/dL, repeat the test, and if the results are still below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), consult your healthcare professional immediately.

Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate results may occur for individuals experiencing a hyperglycemic-hyperosmolar state. Please refer to the test strip package insert for additional important information.

Alternate Site Testing (AST)

There are important limitations to Alternate Site Testing (AST). Please consult your healthcare professional before performing AST.

What is AST?

Alternate Site Testing (AST) means you can use parts of the body other than your fingertips to check your blood glucose levels. Prodigy® meters allow you to test on your palm, forearm, upper arm, calf or thigh. *See Figure 1.*

What is the Advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, nerve endings are not so numerous and you will not feel as much pain as you will experience at the fingertip.

When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at the fingertip reflects these changes faster than capillary blood at other sites. Therefore, if you are testing your blood glucose level during or immediately after a meal, physical exercise or stressful event, take the blood sample from your fingertip only.

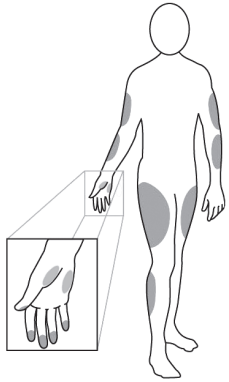


Figure 1

Use AST only:

- ❖ Two hours or more after your last meal.
- ❖ Two hours or more after taking insulin.
- ❖ Two hours or more after exercise.
- ❖ During a relaxed and calm state.

Do not use AST if:

- ❖ You have reason to believe you have hypoglycemia or hyperglycemia.
- ❖ Your routine glucose results are often fluctuating.
- ❖ You are pregnant.

**To increase accuracy when using AST, rub the puncture site before extracting blood.*

About Prodigy® Test Strips

Key Functions of the Test Strip

All Prodigy® meters measure the amount of sugar in the blood, commonly referred to as blood glucose. Blood is applied to the opening of the absorbent channel of the test strip and is automatically drawn into the test strip.

The test strip consists of the following parts:

Absorbent Channel
Apply a drop of blood and it will be drawn in automatically.

Confirmation Window
Shows whether enough blood has been drawn into the test strip's absorbent channel.

Test Strip Handle
Hold this part to insert the test strip into the test strip port on the meter.

Contact Bars
Insert this end of the test strip into the meter. Push it in firmly until it will not go any further.

Figure 2

Please refer to the *"Performing a Blood Glucose Test"* section for your meter for complete instructions.

Important Test Strip Information

- Store test strip packages in a cool, dry place between 39.2°F–104°F (4°C–40°C). Keep away from direct sunlight and heat. Do not refrigerate.
- Store your test strips in their original vial only. Do not transfer them to a new vial or any other container.
- With clean, dry hands you may touch the test strip anywhere on its surface when removing it from the vial or inserting it into the meter.
- Do not clean the testing site with alcohol.
- Immediately use a test strip after removing it from the vial, replace the vial cap and close it tightly.
- Only apply a blood sample or a control solution sample to the test strip's absorbent channel. Applying other substances to the test strip's absorbent channel will cause inaccurate results.
- Record the discard date on the vial label when you first open it. Discard remaining test strips 90 days after the first opening date.
- Do not use test strips beyond the expiration date printed on the package.

Warning: Keep the test strip vial away from children; the vial cap and the test strips can be a potential choking hazard. Never chew or swallow a test strip. If this occurs, please seek medical assistance immediately.

Control Solution Testing

About Prodigy® Control Solution

Prodigy® control solution is a red liquid containing glucose that will react with test strips and produce a test result. Prodigy® meters can use high or low control solution.

- ❖ First, check your contents to see if you have a high or low control solution kit.
- ❖ Then, after completing a control solution test, compare test results with the correct range (high or low) located on the back of the test strip vial.

Why Perform a Control Solution Test?

- To ensure that your meter and test strips are working properly together.
- To allow you to practice testing without using your own blood.

It is recommended to do a control solution test:

- Once a week (to ensure that you continue to have accurate test results).
- When you begin using a new vial of test strips.
- When test strips are exposed to extreme environmental conditions.
- If you drop the meter.
- When you change the battery.

Important Control Solution Test Information

- Use only Prodigy® control solutions with Prodigy® meters.
- Check the expiration date on the control solution bottle. Do not use if expired.
- Control solution, meter and test strips should be at room temperature (68 – 77 °F/20 – 25 °C) before testing.
- Use within a period of 90 days from the date that you first open the control solution. Record the discard date on the control solution bottle and discard after 90 days.
- Store the control solution tightly closed at temperatures below 86 °F (30 °C). Do not refrigerate.

Important: The control solution ranges are located on the back of the Prodigy® test strip vial. They are not recommended target ranges for your blood glucose level.

Performing a Control Solution Test

Start with the meter off.

STEP 1: Wash your Hands

Wash your hands with mild soap and water before performing any test. Be sure to dry them thoroughly.

STEP 2: Insert Test Strip

Insert a test strip with the contact bar 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 and beeps.

STEP 3: Mark as a Control Solution Test

After the "💧" symbol appears on display, press the **"M"** button and a "🧴" symbol appears on the display. With the "🧴" symbol on the display, the meter will not store your test result in the memory. If you decide not to perform a control solution test, press the **"M"** button again and the "🧴" symbol will disappear.

Important: Be sure that you are in control solution mode so that the test result will not be stored in the meter memory.

STEP 4: Apply Control Solution

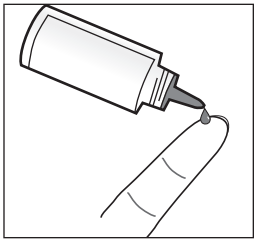


Figure 3

- Shake the control solution bottle well, then remove the cap.
- Squeeze the bottle to discard the first drop and wipe off the dispenser tip with clean tissue paper or cotton.
- Squeeze the bottle again to get a second drop onto a clean, non-absorbent surface or on your fingertip. *See Figure 3.*
- Apply the drop to the opening of the absorbent channel of the test strip (where it meets the narrow channel) until the confirmation window is filled. *See Figures 4 and 5.*
- The meter will beep and begin to count down.

Caution: To avoid contaminating the control solution with the content of the test strip, **DO NOT DIRECTLY APPLY CONTROL SOLUTION ONTO THE TEST STRIP.**

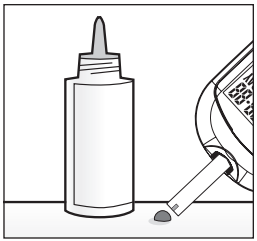


Figure 4

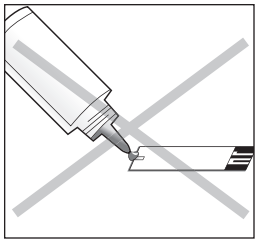


Figure 5

STEP 5 : Check if the Test Result is in Range.
After Seven (7) seconds, the control solution test result appears on the display. Compare the test result with the range printed on the test strip vial. Each vial of Prodigy® No Coding Test Strips may have a different control solution range. The result should fall within the printed range on the test strip vial. *See Figure 6.*

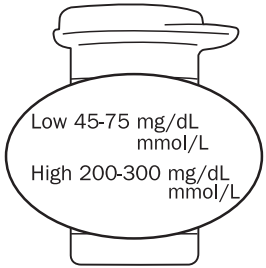


Figure 6

Out of Range Results
If the result is not within the printed range, the meter and/or test strips may not be working properly. Repeat the control solution test.

Out of range results may occur due to:
- damaged or expired test strips
- contaminated or expired control solution
- a meter malfunction
- not following the directions

If test results continue to fall outside the range printed on the test strip vial, check *"Troubleshooting Guide"* located in the *"System Troubleshooting"* section.

Expiration or Damage
Prodigy® No Coding Test Strips and Control Solutions have expiration dates printed on their labels. When one of these is first opened, you must record the discard date (date opened plus three (3) months) in the space provided.

Caution: Do not use test strips or control solution that have exceeded the discard date, are expired or have been damaged. Your results may be inaccurate.

Contact Customer Care
If your test strips have been damaged or if you continue to get out-of-range results, it means that the system or the control solution may not be working properly. DO NOT use the system to test your blood glucose level. If you are unable to resolve the problem, contact Customer Care at **1.800.243.2636.**

Preparing the Lancing Device

STEP 1: Remove the cap of the lancing device by twisting it off. *See Figure 7.*

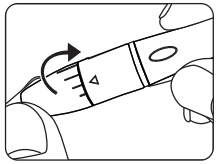


Figure 7

STEP 2: Insert a sterile lancet into the lancet holder of the lancing device and push down firmly until it is fully seated. Do not twist the lancet. *See Figure 8.*

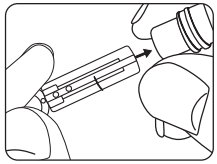


Figure 8

STEP 3: Remove the protective cap from the lancet by twisting it and then ***save*** it for later use. *See Figure 9.*

STEP 4: Replace the cap onto the lancing device. Screw the cap until it is snug but not too tight.

STEP 5: Set the Lancing Level.
The adjustable tip offers five (5) levels of skin penetration. To select the desired depth, twist the adjustable tip in either direction until the number lines up with the arrow. To select the best depth: 1–2 for soft or thin skin, 3 for average skin, 4–5 for thick or callused skin. *See Figure 10.*

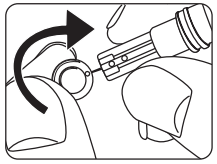


Figure 9

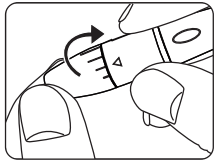


Figure 10

Warning: To reduce the risk of infection:
- Never share a lancet or lancing device.
- Always use a new, sterile lancet.
- Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt or debris in or on the lancets and the lancing device.
- These devices are intended to be used for patient self-monitoring and should not be used to collect blood from more than one person as this poses a risk of transmitting blood-borne pathogens such as Hepatitis B or HIV.

STEP 6: Cock the Lancing Device. Slide the ejection/cocking control back until it clicks. If it does not click, the Lancing Device may have been cocked when the lancet was inserted. *See Figure 11.*

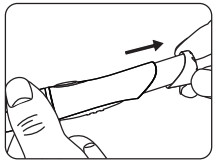


Figure 11

**The Lancing Device is prepared and ready to lance your finger for a blood sample.*

Getting a Blood Sample

STEP 1: Wash Your Hands and Puncture Site
Use warm, soapy water. Rinse and dry your hands thoroughly.

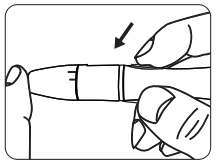


Figure 12

STEP 2: Select and Lance a Puncture Site
- **Fingertip**
  Hold the Lancing Device firmly against the side of your finger. Press the release button. You will hear a click, indicating that the puncture is complete. *See Figure 12.*

- **Sites other Than Your Fingertip**
  Please refer to the *"About Alternate Site Testing (AST)"* Section. Please consult your healthcare professional before obtaining blood from sites other than your fingertip.

Figure 13

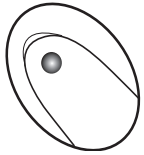


Figure 14

STEP 3: Obtain a Blood Sample
Do not smear the blood sample. *See Figure 13.* To obtain the most accurate results, wipe off the first drop of blood and gently squeeze another drop of blood. *See Figure 14.*

STEP 4: Remove the Lancet
Remove the cap of the lancing device by twisting it off. Place the protective cap back on the exposed tip of the lancet by pushing the lancet into it. *See Figure 15.*

**Always use caution when removing the lancet. Discard the lancet according to your local safety regulations.*

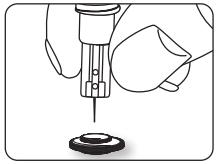


Figure 15

Warning: The first drop of blood usually contains tissue fluid and serum, which may affect the test result. It should be discarded.

Introduction to Prodigy® Meters

Intended Use

Prodigy® blood glucose monitoring systems are intended for use outside the body (in vitro diagnostic use only) and should only be used for blood glucose (blood sugar) testing with fresh capillary whole blood samples.

These systems are intended for use in the home and in clinical settings and should not be used for the diagnosis of diabetes or for the testing of newborns.

Test Principle

Blood glucose is measured by an electric current that is produced when a blood sample mixes with the reagent (special chemicals) of the test strip. The electrical current changes with the amount of glucose in the blood sample. Prodigy® meters measure the strength of the electrical current, calculates your blood glucose level and then displays your result in either mg/dL or mmol/L.

Prodigy® meters, test strips and control solutions have been designed, tested and proven to work together as a system to produce accurate blood glucose test results.

Important: Use only Prodigy® control solutions and test strips with your Prodigy® meter. Using other test strips and control solutions with this meter can produce inaccurate results.

PRODIGY AutoCode®
Blood Glucose Monitoring System

Contents of the Prodigy AutoCode® Meter

The Prodigy AutoCode® meter is available as a meter only or as a meter kit. Please check the "REF" number marked on the outside of the box to see if you have purchased a "Meter" or a "Meter Kit." Please review the contents of your purchase to confirm that all the components are included as listed below:

Meter Includes	Meter Kit Includes
• Prodigy AutoCode® Meter • Two (2) AAA Batteries • Carrying Case • Complete Instructions: 1. Manual 2. Logbook 3. Quick Reference 4. Warranty Card *(Additional supplies can be purchased from your provider.)*	• Prodigy AutoCode® Meter • Two (2) AAA 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 AutoCode® Meter

Key Functions of the Meter

Test Strip Slot
Insert the test strip here.
The meter will turn on automatically.

LCD Display
Guides you through the test using symbols and simple messages.

Talking Symbol
Confirms audio function.

Main Button
Turns the meter on or performs other functions described in this manual.

Data Port
Port for USB Cable connection to your computer.

Set Button
Located on the back of the meter, inside the battery compartment; used to setup the meter.

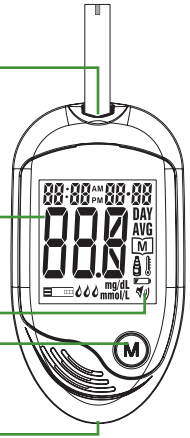


Figure 16

Meter Display

Day Average
Indicates that the displayed test result is an average.

Memory Symbol
Appears when you review the memory.

Test Result Area
Displays test results.

Time

Date

Temperature Symbol
Appears when ambient temperature is outside of operating range.

Test Strip Symbol
Appears when the meter is turned on.

Low Battery Symbol
Appears when the battery power is low.

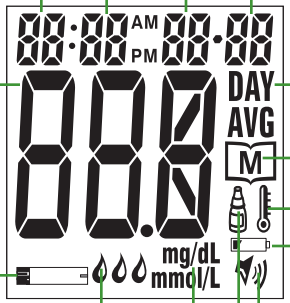


Figure 17

Blood Drop Symbol
Flashes when sample should be applied.

Voice Symbol
Shows if audio function is on.

Unit of Measure
Indicates what unit of measure the test result is displayed in.

Control Solution Test Symbol
Shows that you are in control solution mode.

Speaking Function

The Prodigy AutoCode® meter talks you through each step of your testing procedure.

When does the meter speak?	What does the meter say?
When the meter is turned on.	Your Prodigy® meter is on. Please wait. Please insert the test strip.
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 into the test strip.
When the test is completed (the result appears on the display).	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.

Setup Steps

The Prodigy AutoCode® meter has the language, 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.

STEP 2: Enter Setup Mode

Press and hold the **"SET"** button located in the battery compartment. The meter is now in the setup mode.

Voice Speaks: **"Your Prodigy® meter is on. Please wait. Setting mode. English."**

STEP 3: Select Language

The language option appears first with **"L-1"** on the LCD. By default, **"L-1"** indicates the default language (English); **"L-2"** indicates the second language (Spanish); **"L-3"** indicates the third language (French); and **"L-4"** indicates the fourth language (Arabic). *See Figure 18.*

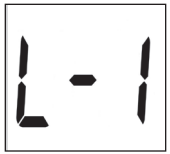


Figure 18

Press the **"M"** button to select a language. With the correct language selected, press the **"SET"** button and a number will appear.

STEP 4: Setting Volume Level
The meter displays a number.

- Numbers 1 to 3 indicate speaking volume from low to high, where "🔊" is displayed on the LCD during testing. *See Figure 19.*
- Number 0 indicates that the speaking function is turned off. *See Figure 20.*

Figure 19

Press the **"M"** button to select the speaking volume. Then press the **"SET"** button and the year segment will appear and start flashing.

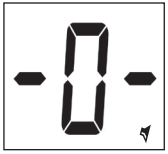


Figure 20

STEP 5: Set the Year
Press and release the **"M"** 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 21.*

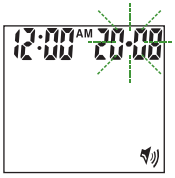


Figure 21

STEP 6: Set the Month
Press and release the **"M"** 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 22.*

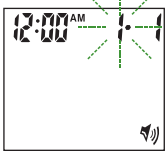


Figure 22

STEP 7: Set the Date
Press and release the **"M"** 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 23.*

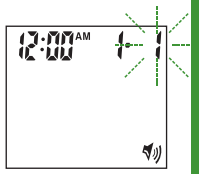


Figure 23

STEP 8: Set the Hour
Press and release the **"M"** 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 24.*

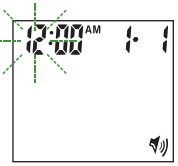


Figure 24

STEP 9: Set the Minutes
Press and release the **"M"** 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 25.*

Important: Day averages are calculated from results obtained during the 7, 14 and 28 days preceding the current date and time settings.

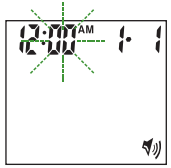


Figure 25

STEP 10: Select Unit of Measurement
Press and release the **"M"** button until the unit of measurement you are choosing appears on the display. Press the **"SET"** button and the memory segment will start flashing. *See Figures 26 and 27.*

Figure 26

Your meter can display test results in milligrams per deciliter (mg/dL) or millimoles per liter (mmoL/L).

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

Figure 27

STEP 11: Delete Memory
When the **"dEL"** symbol and the flashing **"M"** symbol appear on the display, you can choose to clear the memory. If you do not want to clear the memory, press the **"SET"** button again to skip this step.

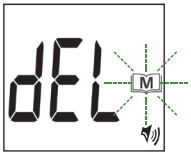


Figure 28

If you want to clear ALL memory, press the **"M"** button for (4) four seconds and both **"dEL"** and **"M"** will flash. Press the **"M"** button again to delete ALL memory. The "- - -" will appear to indicate all memory has been deleted and the meter will turn off. *See Figure 28.*

Setup is now complete. Press the **"SET"** button. **"OFF"** is displayed and the meter turns off. *See Figure 29.*

Figure 29

Performing a Blood Glucose Test

STEP 1: Insert the Test Strip
Insert a test strip with the contact bar 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 30.*


Figure 30

Voice Speaks: **"Your Prodigy® meter is on. Please wait. Please apply blood into the test strip."**

STEP 2: Apply Blood Sample
When the meter shows the **"💧"**, 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 31.*

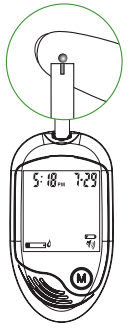


Figure 31

If the test strip confirmation window is full (*See Figure 32*), you will hear a beep.

Voice Speaks: **"Now testing."**

If the confirmation window is not full, **"L-b"** is displayed and a new test strip will need to be used.

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


Figure 32

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.

STEP 3: Read Your Result

After the meter counts down from 6 to 1, your blood glucose test result appears along with the unit of measure, date and time. *See Figure 33.*

Voice Speaks: **"Blood glucose 108 mg/dL."**

This blood glucose 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.

Figure 33

Important: If you do not apply a blood sample within (4) four 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.

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 AutoCode® meter stores a maximum of the 450 most recent blood glucose test results with date and time in its memory. It also provides you with 7, 14 and 28–day averages of your blood glucose test results. You can review the individual or average test results by entering the memory mode.

STEP 1: Enter the Memory Mode

While the meter is turned off, press the **"M"** button twice. The 7–day average will appear, indicating that you are in the memory mode.

If you continue to press the **"M"** button, the 14 and 28–day averages will appear in order. You can then review the last 450 individual test results in memory.

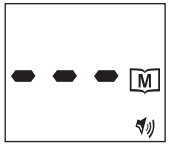


Figure 34

When using the meter for the first time or when the memory has been deleted, "---" appears, indicating there are no test results in the meter memory. *See Figure 34.*

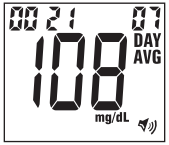


Figure 35

STEP 2: Recalling Average Test Results

The 7–day average is calculated from the blood glucose results obtained during the last 7 days. It also indicates how many blood glucose tests have been performed within this period, e.g., 21 (21 tests in the last 7 days). *See Figure 35.*

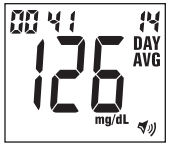


Figure 36

The 14–day average is calculated from the blood glucose test results obtained during the last 14 days. *See Figure 36.*

It, too, indicates how many blood glucose tests have been performed, e.g., 41 (41 tests in the last 14 days). The 28–day average shows the same information.

STEP 3: Recalling Individual Test Results
After the 28–day average, the most recent test result with date and time will be shown. Press the **"M"** button once and the next most recent test result will appear. *See Figure 37.*

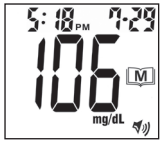


Figure 37

Each time you press and release the **"M"** button, the meter will recall up to your last 450 test results in order. When the memory is full, the oldest test result is dropped as the newest is added. After reaching the last individual result, it will return back to the 7–day average.

STEP 4: Exit the Memory Mode
Press and hold the **"M"** button for two (2) seconds to turn off the meter.

Important: If you do not press any buttons for one (1) minute, the meter will display **"OFF"** and turn off automatically.

Specifications

Dimensions:	3.63 in. (L) x 2.05 in. (W) x 0.75 in. (H) 92 mm (L) x 52 mm (W) x 19 mm (H)
Weight:	2.76 oz with battery 55 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.

PRODIGY Pocket
Blood Glucose Monitoring System

Contents of the Prodigy Pocket® Meter

The Prodigy Pocket® meter is available as a meter only or as a meter kit. Please check the "REF" number marked on the outside of the box to see if you have purchased a "Meter" or a "Meter Kit." Please review the contents of your purchase to confirm that all the components are included as listed below:

Meter Includes

- Prodigy Pocket® Meter*
- One (1) 3V CR2032 Battery
- Carrying Case
- Complete Instructions:
  1. Manual
  2. Logbook
  3. Quick Reference
  4. Warranty Card

(Additional supplies can be purchased from your provider.)

Meter Kit Includes

- Prodigy Pocket® Meter*
- One (1) 3V CR2032 Battery
- 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

**Available in five colors (Blue, Green, Black, Pink and Camouflage).*

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 Pocket® Meter

Key Functions of the Meter

Test Strip Slot
Insert the test strip here.
The meter will turn on automatically.

LCD Display
Guides you through the test using symbols and simple messages.

Main Button
Turns the meter on or performs other functions described in this manual.

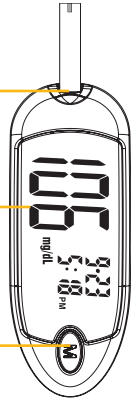


Figure 38

Set Button
Located in the battery compartment; used to set up the meter.

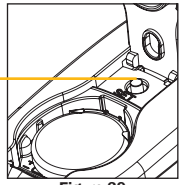


Figure 39

Data Port
USB Port for USB cable connection to your computer.

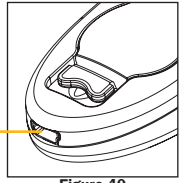


Figure 40

Meter Display

Control Solution Test Symbol
Shows that you are in control solution mode. Your test result will not be stored in meter memory.

Temperature Symbol
Appears when ambient temperature is outside of operating range.

Low Battery Symbol
Appears when the battery power is low.

Time **Date**

Test Result Area
Displays test results.

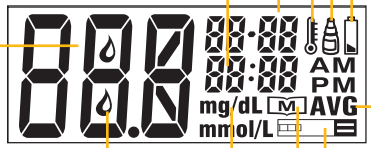


Figure 41

Day Average
Indicates that the displayed test result is an average.

Blood Drop Symbol
Flashes when sample should be applied.

Test Strip Symbol
Appears when the meter is turned on.

Unit of Measure
Appears with the test result to indicate what unit of measure the test result is displayed in.

Memory Symbol
Appears when you review the memory.

Setup Steps

The Prodigy Pocket® meter has the date, time and unit of measurement presets. However, if you replace the battery, you should check and update the time and date.

STEP 1: Insert the Battery

Open the battery cover located on the backside of the meter. Insert one (1) 3 Volt CR2032 lithium battery. The meter should beep and turn on.

STEP 2: Enter Setup Mode

Start with the meter off. Then press the **"SET"** button located in the battery compartment. The meter is now in the setup mode.

STEP 3: Set the Year

The year appears with the number flashing. Press and release the **"M"** 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 42.

STEP 4: Set the Month

Press and release the **"M"** 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 43.

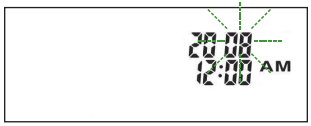


Figure 42

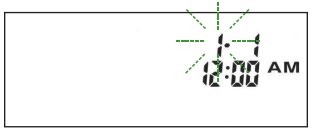


Figure 43

STEP 5: Set the Date

Press and release the **"M"** 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 44.

Figure 44

STEP 6: Set the Hour

Press and release the **"M"** 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 45.

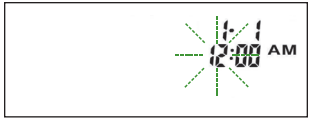


Figure 45

STEP 7: Set the Minutes

Press and release the **"M"** button to advance the minutes. With the correct minute on the display, press the **"SET"** button and the current unit of measurement will start flashing. *See Figure 46.*

Figure 46

Important: Day averages are calculated from results obtained during the 7, 14 and 28 days preceding the current date and time settings. When the date and time are changed, the 7, 14 and 28–day averages may change.

STEP 8: Unit of Measure
Press and release the **"M"** button until the unit of measurement you are choosing appears on the display. *See Figures 47 and 48.*

Figure 47

Your meter can display test results in milligrams per deciliter (mg/dL) or millimoles per liter (mmol/L).

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

Figure 48

STEP 9: Delete Memory
Press the **"SET"** button and **"dEL"** will appear with the flashing "M" symbol. When the **"dEL"** symbol and the flashing "M" symbol appear on the display, you can choose to clear the memory. If you do not want to clear the memory, press the **"SET"** button again to skip this step. If you want to clear ALL memory, press and hold the **"M"** button for four (4) seconds. The "- - -" image will appear on the LCD screen to indicate that all memory has been deleted.

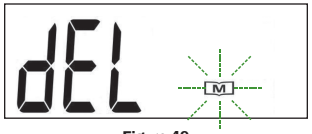


Figure 49

Setup is now completed. Press the **"SET"** button to turn off the meter. **"OFF"** is displayed before shut down. *See Figures 49 and 50.*

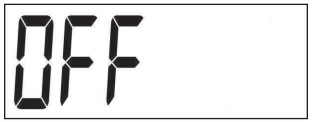


Figure 50

Performing a Blood Glucose Test

STEP 1: Insert the Test Strip
Insert a test strip with the contact bar end entering into the test slot first. Push the test strip as far as it will go without bending it. The meter turns on automatically. *See Figure 51.*

Figure 51

STEP 2: Apply Blood Sample
When the meter shows the "🩸", 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 52.*

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. *See Figure 53.*

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

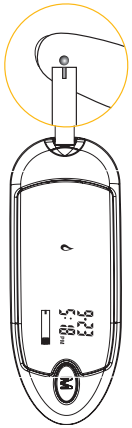


Figure 52

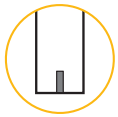


Figure 53

Caution:
DO NOT:
- Smear or scrape the blood onto the test strip.
- Apply blood to the test strip when the test strip is out of the meter.
- Put blood or foreign objects into the test strip port.

STEP 3: Read Your Result
After the meter counts down from 6 to 1, your blood glucose test result appears along with the unit of measure, date and time. This blood glucose 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 54.*

Figure 54

Important: If you do not apply a blood sample within five (5) 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.

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 Pocket® stores the 120 most recent blood glucose test results with date and time in its memory. It also provides you with 7, 14 and 28–day averages of your blood glucose test results. You can review the individual or average test results by entering the memory mode.

STEP 1: Enter the Memory Mode
While the meter is turned off, press the **"M"** button twice. The 7-day average will appear, indicating that you are in the memory mode. If you continue to press the **"M"** button, the 14 and 28–day averages will appear in order.
You can then review the last 120 individual test results in the memory. When using the meter for the first time, **"- - -"** appears, showing that there are no test results in the memory. *See Figure 55.*

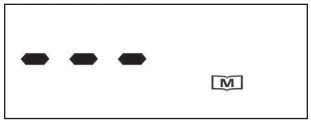


Figure 55

STEP 2: Recalling Average Test Results
The 7–day average is calculated from the blood glucose results obtained during the last 7 days. It also indicates how many blood glucose tests have been performed within this period, e.g., 21 (21 tests in the last 7 days). *See Figure 56.*

Figure 56

The 14–day average is calculated from the blood glucose results obtained during the last 14 days. *See Figure 57.*

Figure 57

It, too, indicates how many blood glucose tests have been performed, e.g., 41 (41 tests in the last 14 days). The 28–day average shows the same information.

STEP 3: Recalling Individual Test Results
After the 28–day average, the most recent test result with date and time will be shown. Press the **"M"** button once and the next most recent test result will appear.
Each time you press and release the **"M"** button, the meter will recall up to your last 120 test results in order.

Figure 58

When the memory is full, the oldest result is dropped as the newest is added. After reaching the last set of results, the meter will display the 7–day average again. *See Figures 57 and 59.*

Figure 59

STEP 4: Exit the Memory Mode
Press and hold the **"M"** button for three (3) seconds to turn off the meter.

Important: If you do not press any button for one (1) minute, the meter will show **"OFF"** and turn off automatically.

Specifications

Dimensions: 3.54 in. (L) x 1.38 in. (W) x 0.69 in. (H)
90 mm (L) x 35 mm (W) x 17.5 mm (H)

Weight: 1.2 oz with battery
36 g

Power Source: One (1) 3 Volt CR2032 Battery

Battery Life: Over 1,000 tests

Display: LCD

Memory: 120 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.

PRODIGY VOICE
Blood Glucose Monitoring System

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

Test Strip Slot
Insert the test strip here. The meter will turn on automatically.

Up & Down Buttons
Used to navigate through the system.

LCD Display
Displays symbols and test results.

Repeat Button
Repeats last message spoken.

"M" Button
Turns the meter on or performs other functions described in this manual.

Set Button
Used to setup the meter.

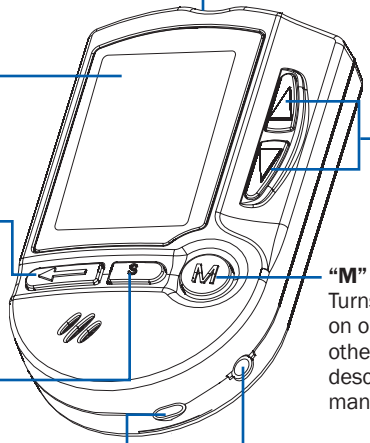


Figure 79

Data Port
Port for USB Cable connection to your computer.

Ear Phone Jack
Used to attach headphones.

Meter Display

Blood Drop Symbol
Flashes when sample should be applied.

Test Strip Symbol
Appears when the meter is turned on.

Voice Symbol
Shows if audio function is on.

Test Result Area
Displays test results.

Unit of Measure
Indicates what unit of measure the test result is displayed in.

Day Average
Indicates that the displayed test result is an average.

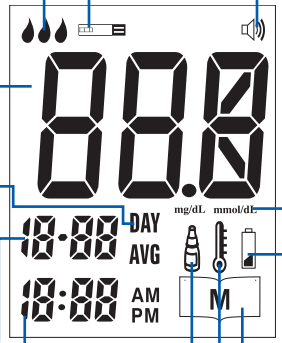


Figure 80

Low Battery Symbol
Appears when the battery power is low.

Date

Time

Memory Symbol
Appears when you review the memory.

Control Solution Test Symbol
Shows that you are in control solution mode.

Temperature Symbol
Appears when ambient temperature is outside of operating range.

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.*

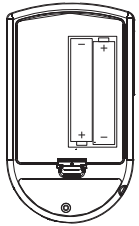


Figure 81

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."**

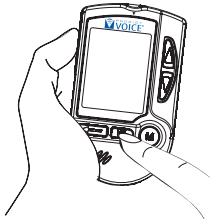


Figure 82

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.

Figure 83

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.*

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.*

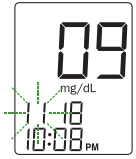


Figure 85

Voice speaks: **"The Month November."**

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.*

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.*

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.*

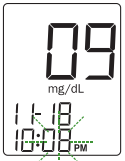


Figure 88

Voice speaks: **"The Minutes 08."**

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.

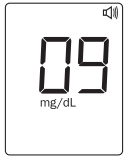


Figure 89

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.

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."**

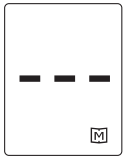


Figure 91

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 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."**

Figure 93

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 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.*

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.

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.*

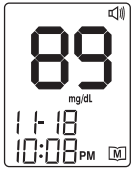


Figure 96

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.

Figure 98

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

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

Disnifect 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

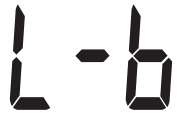
Special Messages

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
	**What it means:** Appears when the battery cannot provide enough power for a test. **Action:** Replace the battery immediately.
	**What it means:** Appears when inserting a used test strip. **Action:** Test with a new test strip. If the problem persists, please contact Customer Care at **1.800.243.2636**.
	**What it means:** Appears when the environmental temperature is out of the system operating range (50°F–104° or 10°C–40°C). **Action:** Repeat the test after the meter and test strip are within the operating temperature range.
	**What it means:** Low blood alert **Action:** 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.

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 **1.800.243.2636** 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 **1.800.243.2636** 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 **1.800.243.2636** 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.[1] 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.[2]

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
- **Precision:** This study shows the CV (correlation variation) is less than 5%.
- **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
Fasting and before meal	Less than 110 mg/dL (6.1 mmol/L)	_____ (mg/dL)/(mmol/L)
2 hours after meals	Less than 140 mg/dL (7.8 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 2008
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.

Unxpected 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 manaul.

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 ±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 ± 20% at glucose concentrations ≥ 75 mg/dL (≥ 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.
LOT	Batch code.
REF	Catalog number.
SN	Serial number.
CONTROL	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. DDI 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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