

Dear PRODIGY Voice System Owner:

This manual contains important information you must know about the system. Please read it thoroughly and carefully.

The greatest feature of the Voice system is its speaking function which is an acoustic aid for users especially with visual disability. Please note that this function is optional.

Another unique feature is its autocode function which means no need to calibrate your meter, therefore making it easier for you to monitor your blood glucose at home.

**IMPORTANT SAFETY INSTRUCTIONS
READ THIS BEFORE USING**

The following basic safety precautions should always be taken.

1. Close supervision is necessary when the device is used by, on, or near children, handicapped persons or invalids.
2. Use the device only for the intended use described in this manual.
3. Do not use strips and control solutions which are not supplied by the manufacturer.
4. Do not use the device if it is not working properly, or if it has suffered any damage.
5. 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 THESE INSTRUCTIONS

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IMPORTANT INFORMATION

- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- Test results below 60 mg/dL (3.3mmol/L)*¹ mean low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3mmol/L)*² mean high blood glucose (hyperglycemia). If you get results below 60 mg/dL or above 240 mg/dL, and do not have symptoms, first repeat the test. If you have symptoms or continue to get results that fall below 60 mg/dL or above 240 mg/dL, follow the treatment advice of your healthcare professional.
- Apply only capillary whole blood sample to test your blood glucose. Applying other substances will cause wrong results.
- 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, consult your healthcare professional.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- Please refer to your test strip package insert for additional important information.

*1: Kahn, R., and Weir, G.: Joslin's Diabetes Mellitus, 13th ed. Philadelphia: Lea and Febiger (1994), 489.

*2: Krall, L.P., and Beaser, R.S.: Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989), 261-263.

ABOUT ALTERNATIVE SITE TESTING (AST)

Important: There are limitations for doing AST.
Please consult your healthcare professional before you do AST.

What is AST?

Alternative site testing (AST) means that people use parts of the body other than fingertips to check their blood glucose levels. This system allows you to test on the palm, the forearm, the upper arm, the calf, or the thigh with the equivalent results to fingertip testing.

What is the advantage?

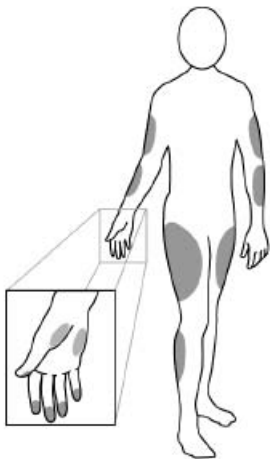
Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, since nerve endings were not so condensed, you will not feel as much pain as at the fingertip.

When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at fingertip reflects these changes faster than capillary blood at other sites. Therefore when testing blood glucose during or immediately after meal, physical exercise, or any other event, take blood sample from your finger only.

We strongly recommend you do AST **ONLY** in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.



Do **NOT** use AST if:

- You think your blood glucose is low.
- You are unaware of hypoglycemia.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.
- You are pregnant.

How to increase the accuracy?

Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained.

Blood from the site without rubbing exhibits a measurably different glucose concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

Please follow suggestions below before getting a drop of blood:

- Rub the puncture site about 20 seconds before puncturing your skin to get enough blood from the puncture site.
- Use a clear cap (included in the kit) instead of the lancing device cap.

INTRODUCTION OF THE SYSTEM

• Intended Use

The system is intended for use outside the body (in vitro diagnostic use only). It should be used only for testing glucose (sugar) and only with fresh capillary whole blood samples (from the finger, the palm, the forearm, the upper arm, the calf and the thigh). The system is intended for use in the home and in clinical settings. It should not be used for the diagnosis of diabetes or for the testing of newborns.

AST in this system can be used only during steady-state blood glucose conditions described in the “About AST” section.

• Principle of Measurement

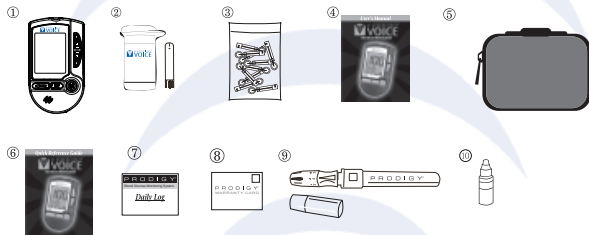
The test is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

• Contents of the System

The Prodigy® Voice system consists of three main products: Prodigy® Voice blood glucose meter, Prodigy® Voice test strips, and a Prodigy® control solution. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. **Use only Prodigy® Voice test strips and Prodigy® control solution with Prodigy® Voice meter.**

Your system includes:

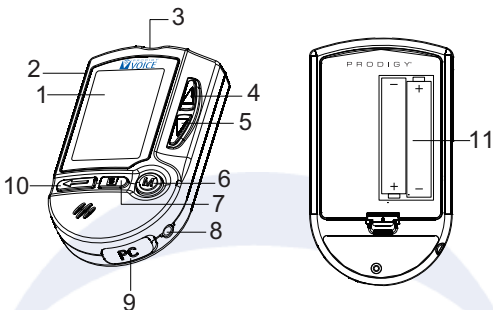
- | | |
|-------------------------------|---|
| 1) Prodigy® Voice Meter | 7) Daily log book |
| 2) Prodigy® Voice Test strips | 8) Lancing device with clear cap for Alternative Site Testing |
| 3) Sterile lancets | 9) Warranty card |
| 4) User's manual | 10) (1) Prodigy® Control Solution |
| 5) Carrying case | 11) Prodigy® Voice Manual CD (not shown) |
| 6) Quick Reference Guide | 12) (2) 1.5v AAA alkaline batteries (not shown) |



PLEASE NOTE

1. Check your box to be sure that it is was unopened prior to use, and that it contains all items listed above. If either of these conditions occurred, please return your system to the place of purchase.
2. There are 2 levels for PRODIGY® control solutions: low and high. *Please note that only one control solution is included in the standard kit, the other is optional. Please ask your local Customer Service for availability.*

• Appearance and Key Function of the Meter



1. **LCD DISPLAY**- Guides you through the test using symbols and simple messages.
2. **STRIP-EJECT BUTTON**- The used strip will be ejected after you push up the button.
3. **TEST SLOT**- Insert the test strip into the slot and the meter will automatically turn on.
4. **UP BUTTON**- Is used to increase the value of the current setting and the speaking volume.
5. **DOWN BUTTON**- Is used to decrease the value of the current setting and the speaking volume.
6. **M BUTTON**- "M" is also referred to as the main button. Press it to turn on the meter and enter the memory or perform other functions described in the manual.
7. **SET BUTTON**- Is used to set up the meter.
8. **EARPHONE JACK**- Used to hear results with an earphone (headset).
9. **DATA PORT**- Is for cable connection to your personal computer (cable required - sold separately).
10. **REPEAT BUTTON**- Is used to replay the previous recording that you want to hear again while operating the meter.
11. **BATTERY COMPARTMENT**- Where batteries are located.

• Meter Display Segments

TEST STRIP SYMBOL

Appears when the meter is turned on.

TEST RESULT AREA

Displays glucose results. A decimal point appears when the measurement unit is mmol/L.

TIME

DATE

DAY AVERAGE

Indicates that the displayed result is an average.

BLOOD DROP SYMBOL

Flashes when it is ready to apply the sample.

VOICE SYMBOL

Indicates if audio function is on or off.

MEASUREMENT UNIT

Appears with the test result either in mg/dL or in mmol/L.

CTL SYMBOL

Appears when doing a control solution test. The result will not be stored in the memory.

KETONE WARNING

Appears when the test result is equal or higher than 240mg/dL (13.3mmol/L).

MEMORY SYMBOL

Appears when you review the memory.

LOW BATTERY SYMBOL

Appears when the battery power is low.



• Appearance of the Test Strip

Your system measures the amount of sugar (glucose) in whole blood. Blood is applied to the absorbent channel of the test strip and is automatically drawn into the reaction cell where a chemical reaction takes place.

The test strip consists of the following parts:

Absorbent Channel

Apply a drop of blood here,
The blood will be drawn up automatically.

Confirmation Window

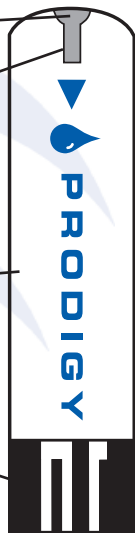
This is where you confirm if enough blood
has been drawn into the absorbent channel of the strip.

Test Strip Handle

Hold this part to insert the test strip into the meter slot.

Contact Bars

Insert this end of the test strip into the meter.
Push it in firmly until it will go no further.




See pages 24~29, "TESTING YOUR BLOOD", section for complete instructions.

PREPARATION BEFORE USE


• Battery Replacement

Your meter comes with two (2) 1.5V AAA size alkaline batteries. The meter will alert you when the power is getting low by displaying two different messages:

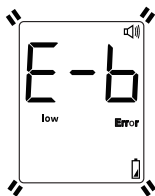
1. The  symbol appears together with other display messages: the meter is functional and the result remains accurate, but it is time to change the batteries.

Voice SPEAKS: *"Battery is low, please replace."*



2. The  symbol appears with the "E-b" symbol, "Error" and "low": the batteries can not provide enough power to do a test. You must change the batteries immediately. (Whole screen is blinking).

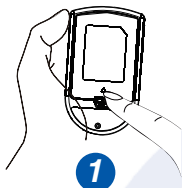
Voice SPEAKS: *"Battery is dead, please replace."*



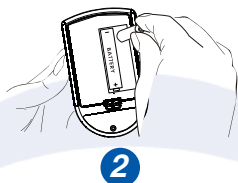
PLEASE NOTE

- Replacing the batteries does not affect the test results stored in memory. However, the time, date and unit settings may need to be re-set.
- Batteries might leak chemicals if not used for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).
- Please discard dead batteries properly.

To replace the batteries, make sure that the meter is turned off.



1
Press the edge of the battery cover and lift it up to remove.



2
Remove the old batteries and replace with two (2) new 1.5V AAA size alkaline batteries.



3
Close the battery cover. If the batteries are inserted correctly, you will hear a “beep” sound.

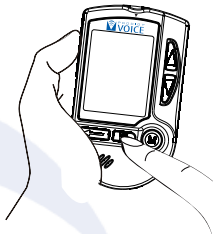
WARNING

As with all small objects, the batteries should be kept away from small children as a safety precaution. If the batteries are swallowed, seek medical assistance immediately.

• Setting the Meter and Deleting the Memory

Your meter comes with the time, date, unit of measurement, unit of temperature preset, speaking function and memory deletion. If you need to set these parameters, please follow steps below.

Start with the meter off. Then press and hold the set button. The meter is now in the setting mode. You can start setting up the meter.



STEP 1 Set the Year

Press the “Up” or “Down” button until the desired year appears.
Press the S button and then the month segment flashes.

Voice SPEAKS: “You are now in setting mode. The year is 2007.”



STEP 2 Set the Month

Press the “Up” or “Down” button until the desired month appears.
Press the S button and then the day segment flashes.

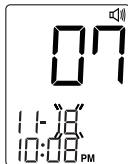
Voice SPEAKS: “The month is November”



STEP 3 Set the Day

Press the “Up” or “Down” button until the desired day appears.
Press the S button and then the hour segment flashes.

Voice SPEAKS: “The day is the 18th.”

**STEP 4 Set the Hour**

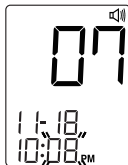
Press the “Up” or “Down” button until the desired hour appears.
Press the S button and then the minute segment flashes.

Voice SPEAKS: “The hour is 10 PM.”

**STEP 5 Set the Minutes.**

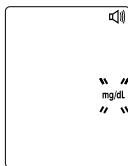
Press the “Up” or “Down” button until the desired minute appears.
Press the S button and then the current unit of measurement flashes.

Voice SPEAKS: “The minute is 08.”



STEP 6 Select mg/dL or mmol/L


Press the “Up” or “Down” button to select the unit of measurement you want to use. Press the S button and then the current unit of temperature flashes.



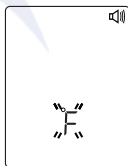
WARNING

The milligram per deciliter (mg/dL) is the standard unit in the United States. The millimole per liter (mmol/L) is the standard unit in Canada. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.




STEP 7 Select “°F” for Fahrenheit or “°C” for Celsius

Press the “Up” or “Down” button to select the unit of temperature you want to use. Press the S button and the meter will display “VOL”, “” and a flashing number.

Voice SPEAKS: “Temperature unit is degrees Fahrenheit.”



STEP 8 Select Speaking Function & Volume

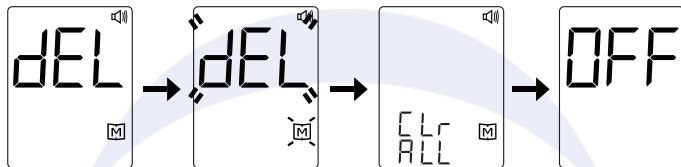
Press the “Up” and “Down” buttons until you hear the desired speaking volume. Number 0 indicates that the speaking function is turned off, where “” does not display on LCD during testing. Number 1 to 7 indicates speaking volume from low to high, where “” displays on LCD during testing. Press the S button and the meter will display “dEL” with flashing “” symbol.



Voice SPEAKS: “Voice volume is 7.”

STEP 9 Delete the Memory

When “dEL” and blinking “M” symbol is displayed, if you do not want to delete memory, press the S button again to skip this step and turn off the meter. If you would like to delete ALL memory, press the “Up” button twice. “CLL” and “ALL” and “M” are displayed on the meter, which means that all data stored are deleted. The memory of this meter is empty now. The meter will automatically turn off.



Voice SPEAKS: “Delete memory record function. Press “up” button to clear all records. Are you sure you want to delete ALL records? Press “up” button again to clear all records.”

PLEASE NOTE

- The time, date, unit of measurement and unit of temperature can **ONLY be changed** in the setting mode. Therefore, when you perform a glucose testing, it is not possible to change those parameters.
- Your meter displays 7, 14, 21, 28, 60 and 90 day averages which you can access from the meter memory. These averages are calculated from results obtained during the 7, 14, 21, 28, 60 and 90 days preceding the current date and time settings. When the date and time are changed, the 7, 14, 21, 28, 60 and 90 day averages may change.
- While the meter is in the setting mode, if no button is pressed for 3 minutes, the meter will turn off automatically.

BEFORE TESTING

• About Prodigy® Control Solutions

PRODIGY® control solutions contain a known amount of glucose that reacts with Prodigy® test strips. By testing your control solution and comparing the test results with the expected range printed on the test strip vial label, you can make sure that the meter and the test strips are working properly together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get accurate results.

How often should the control solution test be performed?

- When you use this system to test your blood for the first time, practice the procedure using control solution. When you can do three tests in a row that are within the expected range, you are ready to test your blood.
- For routinely check the meter and test strips, perform a single test for each level of control solution at least once a week.

When should the control solution test be performed?

- When you first get your Prodigy® Voice meter.
- When you begin using a new vial of test strips.
- Whenever you suspect that the meter or test strips are not working properly.
- When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate.
- When your test strips are exposed to extreme environmental conditions (See “Storage” section of this manual).
- When you want to practice performing the test.
- If you drop the meter.
- After changing the batteries.



• Important Control Solution Information

- Use only Prodigy® Control Solutions.
- Check the expiration date on the control solution bottle. Do not use if expired.
- Control solution, meter, and test strips should come to room temperature (68-77° F/20-25° C) before testing.
- Shake the bottle before use, discard the first drop of control solution after squeezing, wipe off the dispenser tip to avoid contamination. These steps ensure you will get a good sample and an accurate result.
- Use within a period of 90 days from the date opened. Record the discard date (date opened plus 90 days) on the control solution bottle. Discard after 90 days.
- Store the control solution tightly closed at temperatures below 86°F (30°C). Do not refrigerate.

PLEASE NOTE

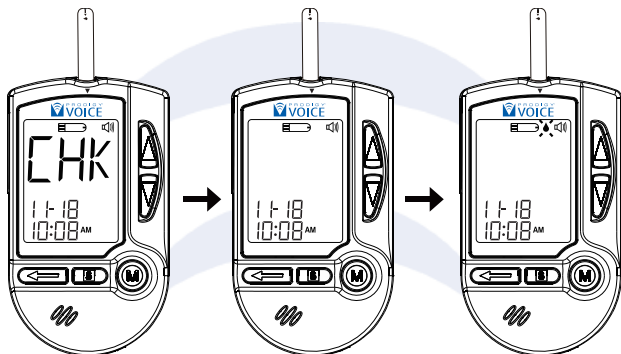
The control solution range printed on the test strip vial is for Prodigy® control solutions only. It is used to test meter and test strip performance. It is not recommended range for your blood glucose level.

• How to Perform a Control Solution Test

STEP 1 Insert the Test Strip

Insert a test strip with contact bars end first and facing up, into the test slot. The meter turns on automatically and displays the followings in sequence:

“CHK” and  →   → and flashing 



Voice SPEAKS: “Thank you for using Prodigy Voice.”

Test Strip inserted.

Today's date is (Today's date; Example: November 18th, 2007).

The time is (The time it is at time of test, Example: 10:08AM).

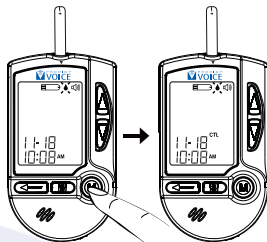
Prodigy Voice works only with the Prodigy Voice test strips.

Please apply blood to the test strip.”

STEP 2 Press the **M** button

While the “**▲**” symbol appears on the display, press the “**M**” button and then “**CTL**” will appear on the display. With the “**CTL**” symbol on the display, the meter will not store your test result in memory.

Voice SPEAKS: “You are now in control solution mode.”



If you decide not to perform a control solution test, press the “**M**” button again, and the “**CTL**” symbol will disappear, you are now in the testing mode.

Voice SPEAKS: “You are now in testing mode.”

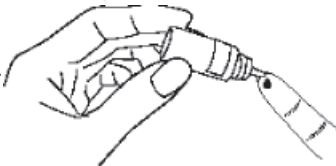
At this point you may test your blood glucose or turn the meter off by removing the test strip.

WARNING

- Contact bars must be inserted all the way into the meter or you may get an inaccurate test result.
- Every time you perform a control solution test, you must enter into the “**CTL**” test mode so that the test result will not be stored in the meter memory. Failure to do so will confuse the blood glucose test result with the control solution test result in memory.

STEP 3 Apply Control Solution

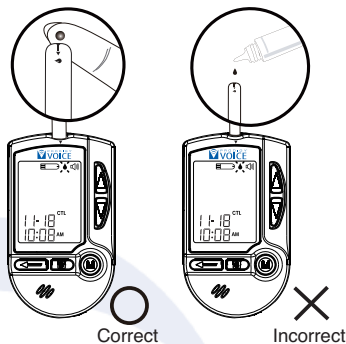
Shake the control solution bottle well. Remove the cap. Squeeze the bottle, discard the first drop and wipe off the dispenser tip with a clean tissue paper or cotton swab. Squeeze a drop on a clean non-absorbent surface or on your finger tip first. Then, apply the drop to the test strip absorbent channel,



(where it meets the narrow channel) until the drop is drawn into the test strip and the confirmation window is filled. The meter begins to count down.

Voice SPEAKS: "Now testing."

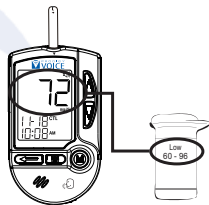
CAUTION: To avoid contaminating the control solution with the content of the test strip, you have to place a drop of control solution on a clean surface or on your clean finger tip first, then touch the strip to the drop.
DO NOT APPLY THE CONTROL SOLUTION DIRECTLY TO THE TEST STRIP!



STEP 4 Read and Compare the Result

After counting from 6 to 0, the test result of control solution is shown on the screen. Compare this result with the range printed on the test strip vial. It should fall within this range.

Voice SPEAKS: "Your blood glucose is seventy two milligrams per deciliter."



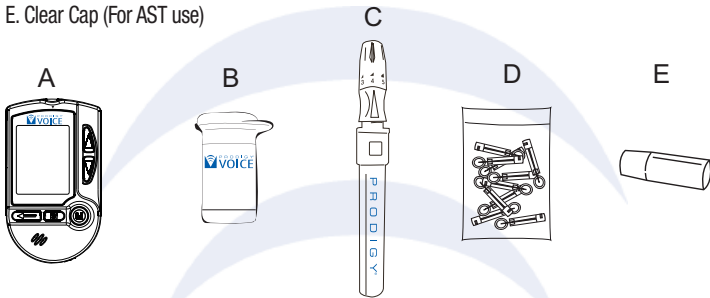
Out-of-range results

If test results fall outside the range printed on the test strip vial, check the section of "Problem in Operation" section in troubleshooting guide and repeat the test. If you continue to get out-of-range results, it means that the system may not be working properly. Do NOT test your blood glucose. *If you are unable to resolve the problem, contact the Technical Support line at 800-243-2636.*

TESTING YOUR BLOOD

Be sure to read this section and the test strip package insert found in the test strip box carefully before testing. Make sure you have all items needed to test:

- A. Blood Glucose Meter
- B. Test Strip
- C. Lancing Device
- D. Sterile Lancet
- E. Clear Cap (For AST use)

**WARNING**

To reduce the chance of infection:

- Never share a lancet or the lancet device with anyone.
- 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.

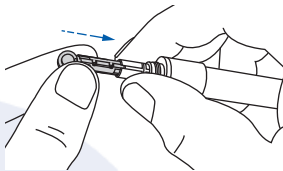
• Testing Procedure

Wash and dry your hands first, before start testing.

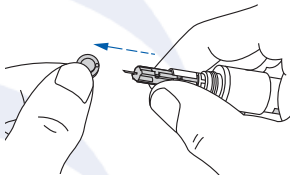
STEP 1 Set the Lancing Device

Insert a lancet in the adjustable lancing device.

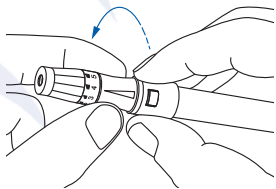
Screw off the cap of lancing device. Insert a lancet into the lancet holder and push down firmly until it is fully seated.



Twist and pull the protective cap until it separates from the lancet.



Replace the lancet device cap. Turn the cap until it is snug but not too tight.



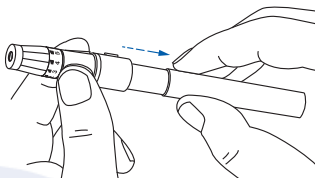
The adjustable tip offers 5 levels of skin penetration. Twist the adjustable tip in either direction until the number lines up with the Arrow. Select the best depth:

- 1-2 for soft or thin skin,
- 3 for average skin,
- 4-5 for thick or calloused skin.



Cock the lancing device

Slide the ejection/cocking control back until it clicks. If it does not click the device may have been cocked when the lancet was inserted.

**AST - Alternative Site Testing***** Blood from sites other than the fingertip**



A clear cap, included in the kit, makes it easier to get a drop of blood for AST. When you want to obtain blood from sites other than the finger, replace the lancet device cap with the clear cap. Turn the clear cap until it is snug but not too tight, and then slide the ejection/cocking control back until it clicks.



The lancing device is now ready for use. Set it aside for later use.

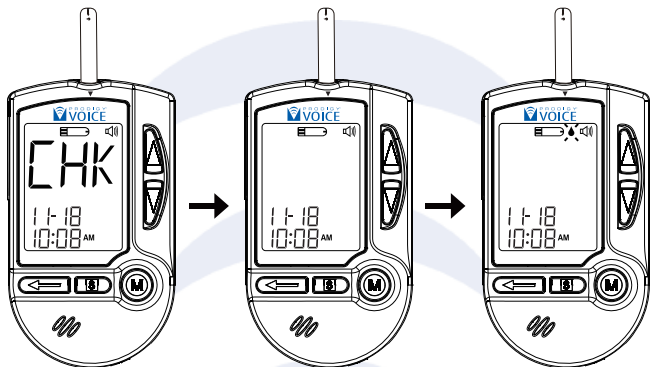


STEP 2 Insert Test Strip

Insert a test strip with contact bars end first and facing up, into the test slot. The meter turns on automatically and displays the followings in sequence:

“CHK” and “” → “”

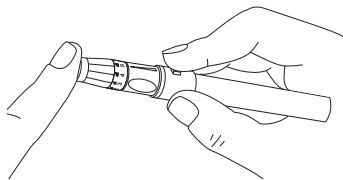
→ “”, and flashing “”



Voice SPEAKS: *“Thank you for using Prodigy Voice.
 Test Strip Inserted.
 Today’s date is (today’s date). The time is (the time).
 Prodigy Voice works only with the Prodigy Voice test strips.
 Please apply blood into the test strip.”*

STEP 3 Get a Drop of Blood

Select the puncture site either in fingertip or in other parts (AST). Wash your hands and the puncture site. Use warm, soapy water. Rinse and dry thoroughly.

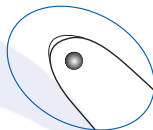


- **Fingertip**

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.

- **Gently Massage the Area**

Do not smear the blood sample. To obtain best accurate results, the first drop of blood should be discarded with a clean tissue paper or cotton. Use the second drop of blood for testing. The required blood sample is 0.6 microliter in volume.



○
Correct



✗
Incorrect

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


- **Sites other than fingertip**

Please refer to the of “About AST” section for available testing sites. Please consult your health care professional before obtaining blood from sites other than your fingertips.

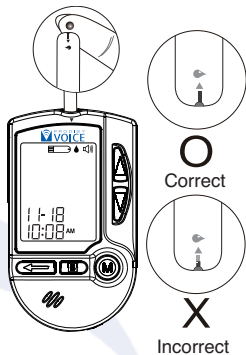
WARNING: The system requires a very small blood drop to perform a test. You can obtain it from a fingertip. Choose a different spot each time you test. Repeated punctures in the same spot may cause soreness and calluses.

Before you decide to do palm testing, please consult your health care professional.

STEP 4 Apply Blood into the Test Strip

When “” is flashing on the screen, apply your blood to the absorbent channel of the test strip until the confirmation window is fully covered with blood. The meter then begins to count down automatically.

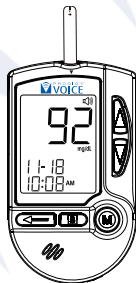
Voice SPEAKS: “Now Testing.”



STEP 5 Obtain an Accurate Result in 6 Seconds

The result of your blood glucose test is shown after the meter counts from 6 to 0. This reading is automatically stored in the meter.

Voice SPEAKS: “Your blood glucose is ninety-two milligrams per deciliter.”



PLEASE NOTE

- Do not push your finger (with blood on it) against the test strip or try to apply a smeared sample on the test strip.
- If you do not apply a blood sample to the test strip within 3 minutes, the meter will automatically turn off. You must remove and reinsert the test strip to restart the test procedure.
- Anytime you can press the “M” button to skip the current voice message and go to the next step.
- If you want to hear the previous voice message, you can press the “Repeat” button to replay it.
- The blood should be completely fill the confirmation window before the meter begins to count down. If you find that the confirmation window is not filled with blood when the meter is counting, NEVER try to add more blood to the test strip. Discard the test strip and retest with a new one.
- If you have trouble filling the test strip, please contact the Technical Support for help.

STEP 6 Eject the Used Test Strip

After finishing the measurement, you can either take out the used strip by simply pushing up the Strip-Eject button or remove the test strip directly with your hand. “OFF” is shown after the used strip is ejected and the meter will shut off automatically afterward.

Voice SPEAKS: *“Have a nice day.”*

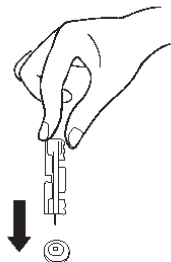
PLEASE NOTE

Please make sure the eject button is pointed into a disposal container.



STEP 7 Remove the Lancet

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

**WARNING**

The used lancet and the used test strip may be a potentially biohazard. Please discard it carefully according to your local regulations.



• Expected Test Results

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that keeping blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%^{*3}. The results you get with the PRODIGY Voice system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Plasma glucose range (mg/dL) for people without diabetes	Your target range (mg/dL)
Fasting and before meal	Less than 110	
2 hours after meals	Less than 140	
Bedtime	Not specified	
Between 2 AM and 4AM	Not specified	

Source: ADA Clinical Practice Recommendations 2003

Please work with your doctor to determine a target range that works best for you.

*3: American Diabetes Association position statement on the Diabetes Control and Complications Trial (1993).



COMPARING METER AND LABORATORY RESULTS

The result you obtain from your meter may differ somewhat from your laboratory result 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, and for important information on limitations). To make an accurate comparison between meter and laboratory results, follow the guidelines below.

Before you go to the lab:

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

While at the lab:

Make sure that the samples for both tests (the meter test and the lab 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 of time, especially if you have recently eaten, exercised, taken medication, or experienced stress^{*4}. 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^{*5}. Therefore, it is best to fast for eight 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 body fluid (severe dehydration) may also cause a meter result to be different from a laboratory result.

References

*4: Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (1988), April, 49-51.

*5: Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood, E.R. (ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.



USING THE METER MEMORY

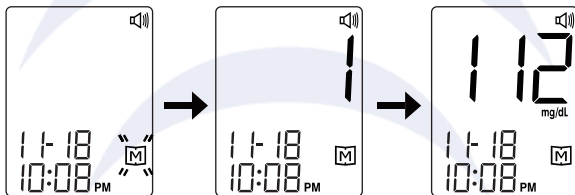
• View Results on the Meter

The Prodigy® Voice stores the 450 most recent blood glucose test results with date and time in its memory. It also provides you with 7, 14, 21, 28, 60 and 90 day averages of your blood glucose test results. You can review the test results in memory with these easy steps.

1. Recall the Stored Test Results

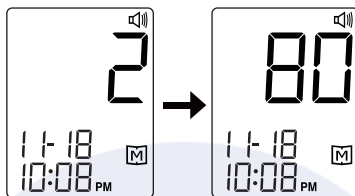
STEP 1. When the meter is off, press and release the M button.

The screen shows “M”. Press the M button again, “1” appears first and then the latest glucose result along with date and time will be shown on the screen.



Voice SPEAKS: *“Thank you for using Prodigy Voice.
Today’s date is (today’s date). The time is (the time).
Press “M” key for memory recall mode.”*

STEP 2. Press the “Up” and “Down” button to recall the test results stored in the meter.



Voice SPEAKS: “Memory Record for August 23rd, 2007. 8:36 AM. Your blood glucose was 80 milligrams per deciliter.”

STEP 3. Exit the memory mode, press and hold down the “M” button and the meter will be turned off.

Voice SPEAKS: “Have a nice day.”

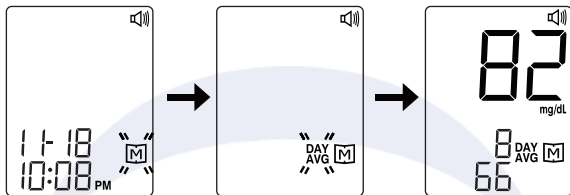


NOTE

If you leave the meter alone without any action for 3 minutes, the meter will turn off automatically.

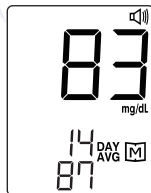
2. Read the Average of Blood Glucose Results

STEP 1. When the meter is off, press and release the M button. The screen shows “M”. Keep pressing the “M” button for 2-3 seconds, until blinking “DAY” appears. Release the “M” button and then the 7-day average result will appear on the screen.



Voice SPEAKS: “Thank you for using Prodigy Voice.
 Today’s date is (today’s date). The time is (the time).
 Press “M” key for memory recall mode.”

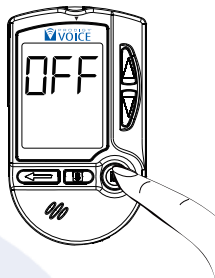
STEP 2. Press the “Up” and “Down” buttons to review the 14, 21, 28, 60 and 90 day average. Like the 7-day average, the 14- day average and the times of performing test in the past 14 days will be shown on the screen.



Voice SPEAKS: “The fourteen day average is eighty-three milligrams per deciliter for eighty-seven records.”

STEP 3. Exit the memory mode, press and hold down the “M” button, and the meter will turn off.

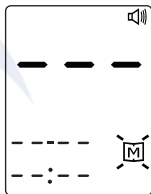
Voice SPEAKS: “Have a nice day.”



NOTE

- The control solution results are **NOT** stored in the memory (please turn to page 22-23 for **WARNING** information). The list of past results and the result average are for blood glucose results only.
- When using the meter for the first time, “—” is displayed when you recall the test results or review the average result. It means that there is no test result in memory.

Voice SPEAKS: “No memory record available.”



- Any time you want to exit the memory mode, keep pressing the M button for 5 seconds or leave it without any action for 3 minutes. The meter will turn off automatically.

• Viewing Results on a Personal Computer

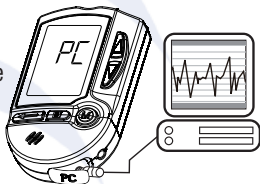
Results in memory can be transmitted to a personal computer. Prodigy Diabetes Management Software and an Interface Cable are required before installation. The software can be downloaded from www.prodigymeter.com. The interface cable is an optional accessory. To learn more about Prodigy Diabetes Management Software or to obtain an Interface Cable sold separately, please contact your local retailer or distributor.

STEP 1 Install Software

Install Prodigy Diabetes Management Software on your Computer by following the instructions provided on Prodigy's website: www.prodigymeter.com

STEP 2 Connect to Personal Computer

Connect the Interface Cable to your computer. With the meter turned off, connect the Interface Cable to the Data Port of the meter. Which is hidden by a plastic cover on the bottom right side panel of the meter. "PC" will appear on the display, indicating that the meter is ready to transmit data.



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.

PLEASE NOTE

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



CARING FOR YOUR METER AND TEST STRIPS

To avoid the meter and test strips getting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

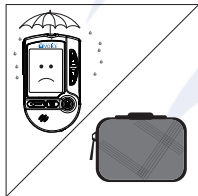
• Cleaning

Your meter does not require special maintenance. As long as no blood or control solution comes in direct contact with the meter, there is no special cleaning required.

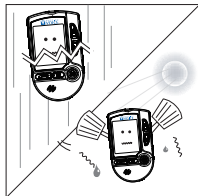
1. To clean the meter exterior, wipe with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft and dry cloth. Do not flush with water.
2. Do not use organic solvents to clean the meter.
 - *Your meter is a precision instrument. Please handle it with care.*

• Storage

1. Meter Storage



- Storage condition: -4°F~140°F (-20°C~60°C), below 95% relative humidity.
- Always store or transport the meter in its original storage case.



- Avoid dropping and strong impact.
- Avoid direct sunlight and humidity.

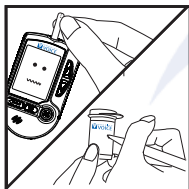
2. Strip Storage



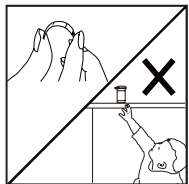
- Storage condition: 39.2°F~104°F (4°C~40°C), below 85% relative humidity. Do not refrigerate.
- Store your test strips in their original vial only. Do not transfer to other container.



- Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately replace the vial cap and close it tightly.
- Touch the test strip with clean and dry hands.

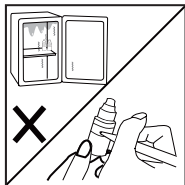


- You may touch the test strip anywhere with clean, dry hands when removing it from the vial or inserting it into the meter.
- Use each test strip immediately after removing it from the vial.
- Write the discard date (the date opened plus 90 days) on the vial label when you first open it. Discard remaining test strips 90 days after first opening date.



- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip can be a potential choking hazard. If swallowed, please seek medical assistance immediately.

3. Control solution storage



- Storage condition: Store the control solution tightly closed at temperatures below 86°F (30°C). Do not refrigerate.
- Record the discard date (date opened plus 90 days) on the control solution vial. Discard after 90 days.




PROBLEM-SOLVING GUIDE

The following is a summary of some display messages and symbols. These 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".

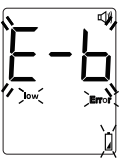

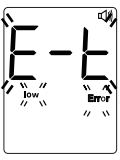
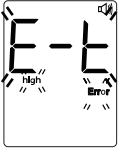
Never try to disassemble the meter in any circumstances. If you encounter any error messages not listed below or if you have followed the actions recommended but the problem remains unsolved, please call the Technical Support 1-800-243-2636.



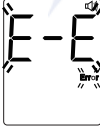
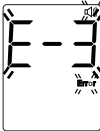



• Special Message

MESSAGE	WHAT IT MEANS	ACTION
	<p>Appears when your result is below measurement limit, which is less than 20 mg/dL. (1.1 mmol/L)</p>	<p>This indicates hypoglycemia (<i>low blood glucose.</i>)</p> <p>You should immediately treat hypoglycemia as recommended by your healthcare professional.</p>
	<p>Appears when your result is above measurement limit, which is higher than 600 mg/dL. (33.3 mmol/L)</p>	<p>This indicates severe hyperglycemia (<i>high blood glucose.</i>)</p> <p>Please seek medical assistance immediately.</p>
	<p>KETONE? appears when your result is equal or higher than 240 mg/dL. (13.3 mmol/L)</p>	<p>This indicates there is a possibility of ketone accumulation if you have Type 1 diabetes.</p> <p>Please seek medical assistance immediately.</p>

• Error Message

MESSAGE	WHAT DOES METER SAY?	WHAT IT MEANS	ACTION
	Battery is dead. Please replace.	Appears when the batteries cannot provide enough power for a test.	Replace the batteries immediately.
	Strip has been used. Please replace.	Appears when inserting a used test strip.	Test with a new test strip.
	The room temperature is out of range. Thus unable to measure.	Appears when ambient temperature is below system operation range. 50° F (10° C)	System operation range is 50°F~104°F (10°C~40°C). Repeat the test after the meter and test strip have reached the above temperature.
		Appears when ambient temperature is above system operation range. 104° F (40° C)	

MESSAGE	WHAT DOES METER SAY?	WHAT IT MEANS	ACTION
	<p>Please ensure proper operation then try again.</p>	<p>Remove the strip after applying blood to the absorbent channel.</p>	<p>Re-test with a new test strip.</p>
	<p>Please remove strip.</p>	<p>Test strip is inserted after the meter turns off.</p>	<p>Remove the test strip.</p>
  	<p>Meter malfunction. Please contact local distributor.</p>	<p>Problem with the meter.</p>	<p>Review the instructions and re-test with a new test strip. If the above steps do not work, please contact technical support for help.</p>

• Problem in Operation**1. If the meter does not display a message after inserting a test strip:**

PROBABLE CAUSE	WHAT TO DO
Battery exhausted.	Replace the batteries.
Battery incorrectly installed or absent.	Check that the battery is correctly installed.
Test strip inserted upside down, incompletely or incorrectly.	Insert the test strip correctly with the contact bars end first and facing up.
Defective meter.	Please contact Technical Support for help.

2. If the test does not start after applying the sample:

PROBABLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatically shut off (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing blood symbol appears on the display.
Defective meter.	Please contact Technical Support for help.



3. If the control solution test result is out of range.

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read the instruction thoroughly and repeat the test again.
Did not shake the control solution bottle very well.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiration date or the discarded 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.	Repeat the test with a new test strip.
Meter malfunction.	Please contact Technical Support for help.



SPECIFICATIONS

Model No.: 51900

Dimension & Weight: 3.74"(L) x 2.17"(W) x 0.71(H) 2.6 oz.

95mm(L) x 55mm(W) x 18mm(H), 75 g

Power Source: two(2) 1.5V AAA alkaline batteries

Display: LCD

Memory: 450 measurement results with date and time

External output: RS232 PC interface

Auto electrode inserting detection

Auto sample loading detection

Auto reaction time count-down

Auto turn-off after 3 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~104°F (4°F~40°F), below 85% R.H.

Measurement Units: either mg/dL or mmol/L

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

The specifications may be changed without prior notice.

The device has been certified to meet the electrical and safety requirements of:

IEC 60601-1, EN 60601-1, IEC 61010-1, EN 61010-1, EN 61010-2-101, EN 60601-1-2, EN 61326.



