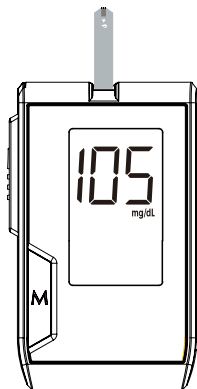


DLAVUE Prudential

BLOOD GLUCOSE MONITORING SYSTEM

**OWNER'S
MANUAL**

Version 3.0 Mar, 2013
311-4254100-003



Dear DIAVUE Prudential System Owner:

Thank you for purchasing the **DIAVUE Prudential** Blood Glucose Monitoring System. This manual provides important information to help you to use the system properly. Before using this product, please read the following contents thoroughly and carefully.

Regular monitoring of your blood glucose levels can help you and your doctor gain better control of your diabetes. Due to its compact size and easy operation, you can use the **DIAVUE Prudential** Blood Glucose Monitoring System to easily monitor your blood glucose levels by yourself anywhere, any time.

If you have other questions regarding this product, please contact the place of purchase or call the Customer Care Line.

IMPORTANT SAFETY PRECAUTIONS

READ BEFORE USE

1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use accessories which are not specified by the manufacturer.
3. Do **NOT** use the device if it is not working properly or if it is damaged.
4. Do **NOT** use the equipment in places where aerosol sprays are being used or where oxygen is being administered.
5. Do **NOT** under any circumstances use the device on newborns, infants, or people who cannot communicate.
6. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only. Always consult your doctor to have the results interpreted.
7. Before using this device to test blood glucose, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
8. Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
9. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
10. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

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BEFORE YOU BEGIN

Important Information

- ▶ Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- ▶ If your blood glucose results are lower or higher than usual, and you do not have any symptoms of illness, first repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare professional.
- ▶ Use only fresh whole blood samples to test your blood glucose. Using other substances will lead to incorrect results.
- ▶ If you are experiencing symptoms that are inconsistent with your blood glucose test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional.
- ▶ We do not recommend using this product on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycaemic-hyperosmolar state, with or without ketosis. Please consult the healthcare professional before use.

Intended Use

The system is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and by health care professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) in fresh whole blood samples (from the finger, palm, forearm, upper arm, calf and thigh).

It should not be used for the diagnosis of diabetes, or testing on newborns.

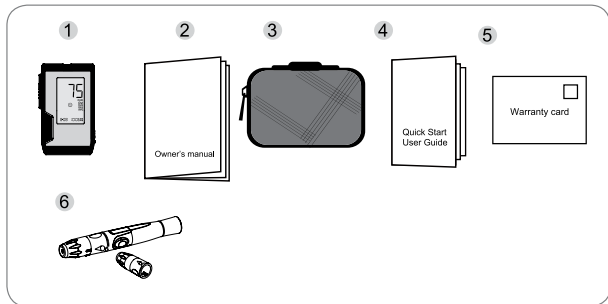
Test Principle

Your system measures the amount of sugar (glucose) in whole blood. The glucose testing 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, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

Contents of System

Your new DIAVUE Prudential system kit includes:

- 1 Blood glucose meter
- 2 Owner's manual
- 3 Protective wallet / carrying bag
- 4 Quick start user guide
- 5 Warranty card
- 6 Lancing device with clear cap for Alternative Site Testing



Test strips, control solutions, or sterile lancets may not be included in the kit (please check the contents on your product box). They can be purchased separately.

NOTE

If any items are missing from your kit or opened prior to use, please contact local customer services or place of purchase for assistance.

Meter Overview

1 Display Screen

2 Test Strip Ejector

Eject the used strip by pushing up this button.

3 Test Slot

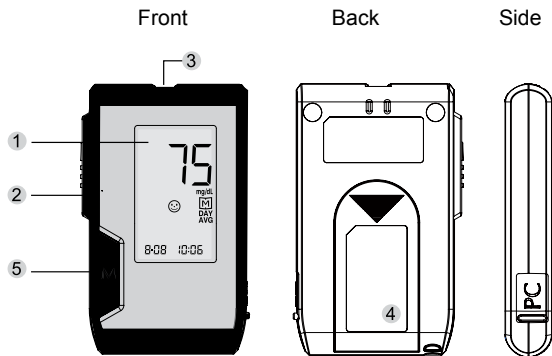
Insert test strip here to turn the meter on for testing.

4 SET Button

Enter and confirm the meter settings.

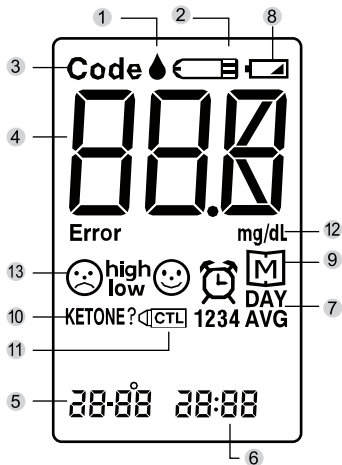
5 M Button

Enter the meter memory and silence a reminder alarm.

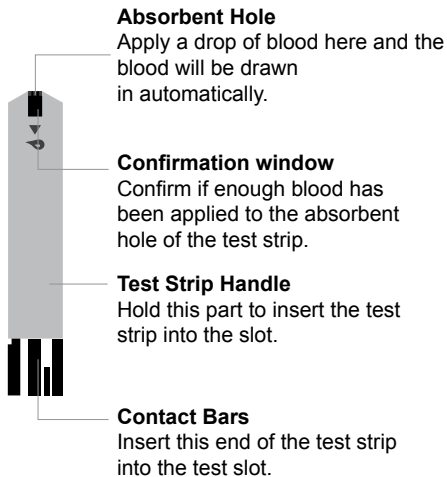


Display Screen

- 1 Blood drop symbol
- 2 Test strip symbol
- 3 Code
- 4 Test result
- 5 Date
- 6 Time
- 7 Day average
- 8 Low battery symbol
- 9 Memory symbol
- 10 Ketone warning
- 11 Control solution mode
- 12 Measurement unit
- 13 Face/Low/High symbol

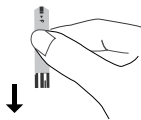


Test Strip

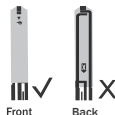


Attention!

Test results might be wrong if the contact bar is not fully inserted into the test slot.



The front side of the test strip should face up when inserting the test strip.



NOTE

The DIAVUE Prudential meter should only be used with DIAVUE Test Strips. Using other test strips with this meter can produce inaccurate results.

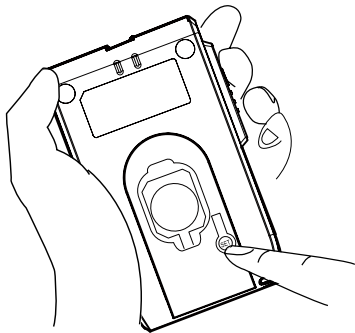
Setting the Meter

Before using your meter for the first time or if you change the meter battery, you should check and update these settings. Make sure you complete the steps below and have your desired settings saved.

Entering the Setting Mode

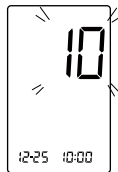
Start with the meter off (no test strip inserted).

Press (and firmly hold) SET for 3 seconds until the meter turns on.

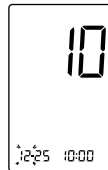


1. Setting the date

With the year flashing, press **M** until the correct year appears. Press Set.



With the month flashing, press **M** until the correct month appears. Press Set.

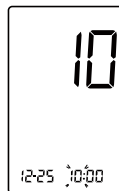


With the day flashing, press **M** until the correct day appears. Press Set.

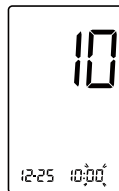


2. Setting the time



With the hour flashing, press **M** until the correct hour appears.
Press Set.







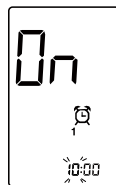
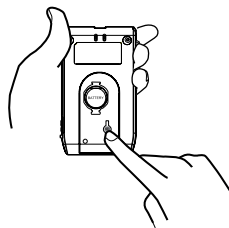
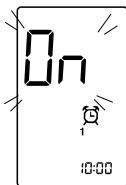
With the minute flashing, press **M** until the correct minute appears.
Press Set.




3. Setting the reminder alarm

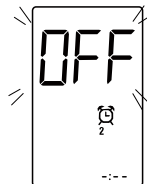
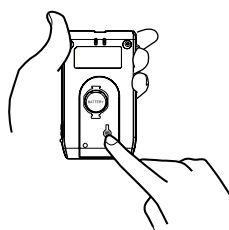
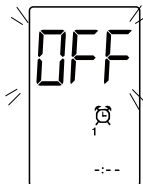
You may set up any or all of the reminder alarms (1-4). The meter displays “On” or “OFF” and  , press  to turn on or turn off to set the first reminder alarm.

Press  to select “On”, then press Set to set the hour. When the hour is flashing, press  to add an hour. Press Set to confirm and go to minutes, press  to add one minute. Hold  longer to add faster. Press Set to confirm and go to the next alarm setting.



If you do not want to set an alarm, press Set to skip this step.

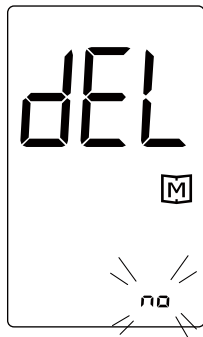
If you want to turn off an alarm, find the alarm number by pressing Set in the setting mode, press  to change from “ON” to “OFF”.



4. Deleting the memory

With “dEL” and a flashing “M” symbol on the display, press **M** and select “No” to keep the results in memory then press Set to skip.

To delete all the results, press **M** twice. “dEL” and “M” are displayed on the meter, which indicates that all data stored is deleted.



BEFORE TESTING

Control Solution Testing

DIAVUE Control Solution contains a known amount of glucose that reacts with test strips and is used to ensure your meter and test strips are working together correctly.

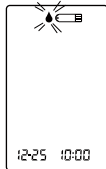
Do a control solution test when:

- you first receive the meter,
- at least once a week to routinely check the meter and test strips,
- you begin using a new vial of test strips,
- you suspect the meter or test strips are not working properly,
- your blood glucose test results are not consistent with how you feel, or if you think the results are not accurate,
- practicing the testing process, or
- you have dropped or think you may have damaged the meter.

Performing a Control Solution Test

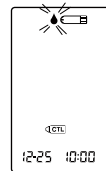
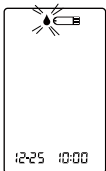
1 Insert the Test Strip to Turn on the Meter

Insert the test strip into the meter. Wait for the meter to display the test strip and blood drop symbols.



2 Press M to mark this test as a control solution test

With "CTL" displayed, the meter will not store your test result in memory. If you press the M button again, the "CTL" will disappear and this test is no longer a control solution test.

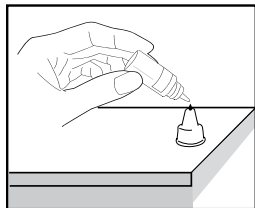


WARNING

When doing the control solution test, you have to mark it so that the test result will not be stored in the memory. Failure to do so will mix up the blood glucose test results with the control solution test results in memory.

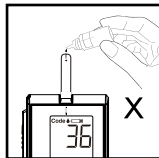
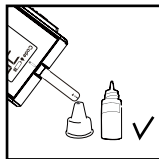
3 Apply Control Solution

Shake the control solution vial thoroughly before use. Squeeze out a drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap.



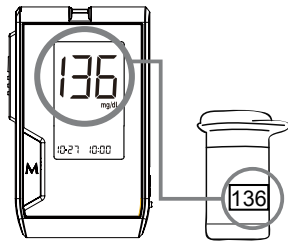
Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down.

To avoid contaminating the control solution, do not directly apply control solution onto a strip.



4 Read and Compare the Result

After counting down to 0, the control solution test result will appear on the display. Compare this result with the range printed on the test strip vial and it should fall within this range. If not, please read the instructions again and repeat the control solution test.



Out-of-range results

If you continue to have test results fall outside the range printed on the test strip vial, the meter and strips may not be working properly. Do NOT test your blood. Contact the local customer service or place of purchase for help.

NOTE

- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose level.
- See the Meter Maintenance section for important information about your control solutions

TESTING WITH BLOOD SAMPLE

WARNING:

To reduce the chance of infection:

- Never share a lancet or the 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.

Preparing the Lancing Device for Blood Testing

Please follow the instructions in the lancing device insert for collecting a blood sample.

If your lancing device differs from the one shown here, please refer to the manufacturer's manual to ensure proper usage.

Preparing the Puncture Site

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

Blood from a site that has not been rubbed 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 the suggestions below before obtaining a drop of blood:

- Wash and dry your hands before starting.
- Select the puncture site either at fingertips or another body parts (please see section “Alternative Site Testing” (AST) on how to select the appropriate sites).
- Clean the puncture site using cotton moistened with 70% alcohol and let it air dry.
- Rub the puncture site for about 20 seconds before penetration.
- Use a clear cap (included in the kit) while setting up the lancing device.

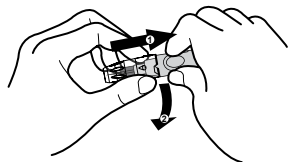
■ Fingertip testing

Press the lancing device’s tip firmly against the side of your fingertip. Press the release button to prick your finger, then a click indicates that the puncture is complete.



■ Blood from sites other than the fingertip

Replace the lancing device cap with the clear cap for AST. Pull the cocking control back until it clicks. When lancing the forearm, upper arm, hand, thigh, or calf, avoid lancing the areas with obvious veins because of excessive bleeding.



NOTE

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- Please consult your health care professional before you begin AST.
- It is recommended that you discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

Alternative Site Testing

IMPORTANT:

There are limitations with AST (Alternative Site Testing).

Please consult your health care professional before you perform AST.

What is AST?

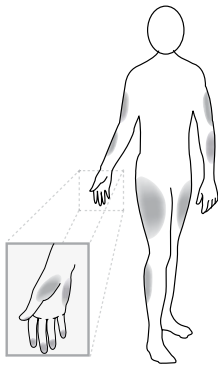
Alternative site testing (AST) means that people use parts of the body other than the fingertips to check their blood glucose levels. This system allows you to test on the palm, the forearm, the upper arm, the calf or the thigh with results equivalent to fingertip testing.

What is the advantage?

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

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. Thus, when testing blood glucose during or immediately after a meal, physical exercise, or any other event, take a blood sample from your finger only.



We strongly recommend that you perform AST **ONLY** at the following times:



- 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.

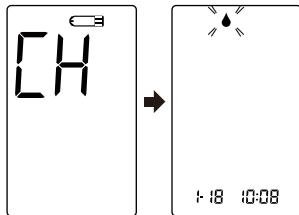
Do NOT use AST if:

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

Performing a blood glucose test

1. Insert the Test Strip to Turn on the Meter

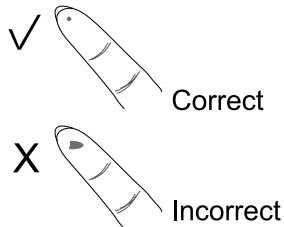
Wait for the meter to display the test strip  and blood drop  symbols with Gen preset.



2. Obtain a Blood Sample

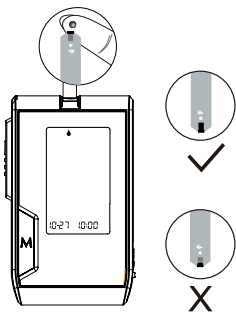
Use the pre-set lancing device to puncture the desired site. After penetration, discard the first drop of blood with a clean cotton swab. Gently squeeze the punctured area to obtain another drop of blood. Be careful NOT to smear the blood sample.

The volume of blood sample must be at least 0.7 microliter (μL) of volume. (. actual size).



3. Apply the Sample

Hold the blood drop to touch the absorbent hole of the test strip. Blood will be drawn in and after the confirmation window is completely filled, the meter begins counting down.

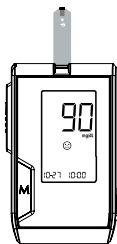


NOTE

- Do not press the punctured site against the test strip or try to smear the blood.
- If you do not apply a blood sample to the test strip within 195 seconds , the meter will automatically turn off. You must remove and reinsert the test strip to start a new test.
- The confirmation window should be filled with blood before the meter begins to count down. NEVER try to add more blood to the test strip after the drop of blood has moved away. Discard the used test strip and retest with a new one.
- If you have trouble filling the confirmation window, please contact your health care professional or the local customer service for assistance.

4. Read Your Result

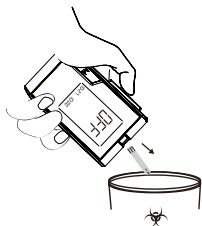
The result of your blood glucose test will appear after the meter counts down to 0. This blood glucose result will automatically be stored in the memory.



5. Eject the used test strip and remove the lancet

To eject the test strip, point the strip at a disposal container for sharp items. The meter will switch itself off automatically after the test strip is ejected.

Always follow the instructions in the lancing device insert when removing the lancet.



WARNING:

The used lancet and test strip may be biohazards. Please discard them carefully according to your local regulations.

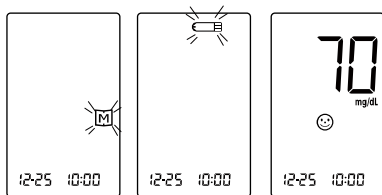
METER MEMORY

The meter stores the 450 most recent blood glucose test results along with respective dates and times in its memory. To enter the meter memory, start with the meter switched off.

Reviewing Test Results

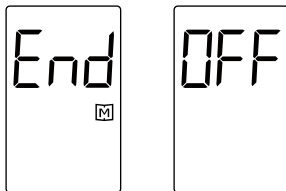
1. Press and release **M**.

M will appear on the display. Press **M** again, and the first reading you see is the last blood glucose result along with date, time and the measurement mode.



2. Press the **M button** to recall the test results stored in the meter each time you press.

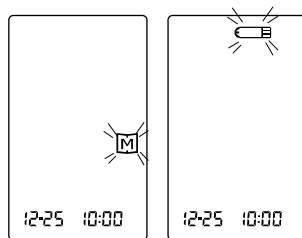
3. Exit the meter memory After the last test results, press M again and the meter will be turned off.



Reviewing Blood Glucose Day Average Results

1. Press and release **M**.

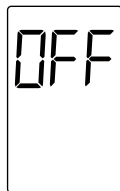
When **M** appears on the display, keep pressing **M** for 3 seconds until the flashing “**M**” appears. Release **M** and then your 7-day average result measured in general mode will appear on the display.



2. Press **M** to review 14-, 21-, 28-, 60- and 90- day average results.

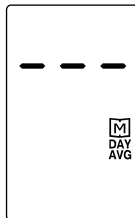
3. Exit the meter memory.

Keep pressing the **M** button and the meter will turn off after displaying the last test result.



NOTE

- Any time you wish to exit the memory, keep pressing **M** for 5 seconds or leave it without any action for 195 seconds. The meter will switch off automatically.
- Control solution results are NOT included in the day average.
- If using the meter for the first time, "---" displays when you recall the test results or review the average result. It indicates that there is no test result in the memory.



Downloading Results onto a Computer

Data Transmission Via Cable

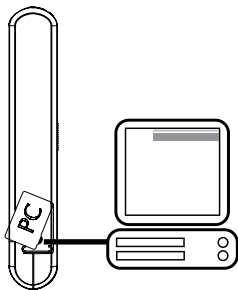
You can use the meter with an interface/ USB cable and the Health Care Software System to view test results on your personal computer. To learn more about the Health Care Software System or to obtain an interface/ USB cable separately, please contact local customer services or the place of purchase for assistance.

1.Obtaining the required cable and installing the software

To download the Health Care Software System, please visit the website: <http://www.DIAVUE.com>.

2.Connecting to a personal computer

Connect the cable to a USB port on your computer. With the meter switched off, connect the other end of the interface/ USB cable to the meter data port. "PC" will appear on the meter display, indicating that the meter is in communication mode.



3. Data transmission

To transmit data, follow the instructions provided with the software. Results will be transmitted with date and time. Remove the cable and the meter will automatically switch off.

WARNING:

While the meter is connecting to the PC, it will be unable to perform a blood glucose test.


MAINTENANCE

Battery


Your meter comes with one 3V CR2032 lithium battery.

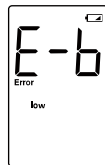
Low Battery Signal

The meter will display one of the messages below to alert you when the meter power is getting low.

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



2. The  symbol appears with E-b, Error and low: The power is not enough to do a test. Please change the batteries immediately.



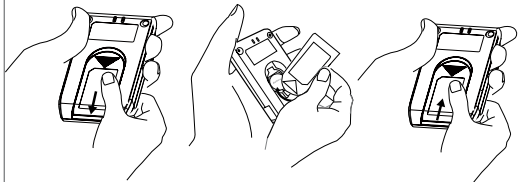
Replacing the Battery

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 one 3V CR2032 lithium battery.
3. Close the battery cover. If the batteries are inserted correctly, you will hear a "beep" afterwards.

NOTE:

- Replacing the batteries does not affect the test results stored in the memory.
- As with all small batteries, these batteries should be kept away from small children. If swallowed, promptly seek medical assistance.
- Batteries might leak chemicals if unused 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).
- Properly dispose of the batteries according to your local environmental regulations.



Caring for Your Meter

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

Cleaning

1. To clean the meter exterior, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do NOT rinse with water.
2. Do NOT use organic solvents to clean the meter.

Meter Storage

- Storage conditions: -20°C to 60°C (-4°F to 140°F) , below 95% relative humidity.
- Always store or transport the meter in its original storage case.
- Avoid dropping and heavy impact.
- Avoid direct sunlight and high humidity.

Caring for Your Test Strips

- Storage conditions: 4°C to 40°C (39.2°F to 104°F) , below 85% relative humidity. Do not freeze.
- Store your test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands.
- Use each test strip immediately after removing it from the vial.
- Write the opening date on the vial label when you first opened it. Discard remaining test strips after 3 months.
- Do not use test strips beyond the expiry date. This may cause inaccurate results.
- 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 may be a choking hazard. If swallowed, promptly see a doctor for help.

For further information, please refer to the test strip package insert.

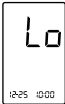


Important Control Solution Information

- Use only DIAVUE control solutions with your meter.
- Do not use the control solution beyond the expiry date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature (20°C to 25°C/68°F to 77°F). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 2°C and 30°C (36°F and 86°F) . Do NOT freeze.



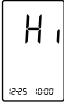
SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service. Do not attempt to repair yourself and never try to disassemble the meter under any circumstances.





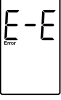
Result Readings

MESSAGE	WHAT IT MEANS
 A digital display showing 'Lo' in large characters. Below it, there is a small icon of a person and the text '12:25 10:00'.	Appears when your result is below measurement limit, which is less than 20 mg/dL (1.1 mmol/L).
 A digital display showing '69' in large characters. Below it, there is a small icon of a person, the text 'mg/dL', and '12:25 10:00'.	Appears when your result is between 20-69 mg/dL (1.1 and 3.8 mmol/L). It indicates the result is below reference range.
These symbols indicate hypoglycemia (low blood glucose) You should seek medical assistance immediately.	
 A digital display showing '70' in large characters. Below it, there is a small icon of a person, the text 'mg/dL', and '12:25 10:00'.	Appears when your result is in the reference range from 70 to 119 mg/dL (3.9 and 6.6 mmol/L).

Result Readings

MESSAGE	WHAT IT MEANS
 <p>A digital display showing the number '121' in large digits. To the right of the number is the unit 'mg/dL'. Below the number is a small warning icon (a circle with a diagonal line) and the text 'mg/dL'. At the bottom of the display, it shows '12:25 10:00'.</p>	Appears when your result is equal to or greater than 120 mg/dL (6.6 mmol/L). It indicates the result is higher than reference range.
 <p>A digital display showing the number '240' in large digits. To the right of the number is the unit 'mg/dL'. Below the number is a small warning icon (a circle with a diagonal line) and the text 'mg/dL'. At the bottom of the display, it shows '12:25 10:00'.</p>	Appears when your result is equal to or higher than 240 mg/dL (13.3 mmol/L). This indicates the possibility of ketone accumulation for type 1 diabetes. Please seek medical assistance immediately.
 <p>A digital display showing the letters 'H I' in large digits. To the right of the letters is the unit 'mg/dL'. Below the letters is a small warning icon (a circle with a diagonal line) and the text 'mg/dL'. At the bottom of the display, it shows '12:25 10:00'.</p>	Appears when your result is higher than the limit of measurement, which is higher than 600 mg/dL (33.3mmol/L).

Error Messages

MESSAGE	WHAT DOES METER SAY?	WHAT IT MEANS	WHAT TO DO
	Battery is dead. Please replace.	Appears when the batteries cannot provide enough power for a test.	Replace the batteries immediately.
	Test strip has been used. Please replace.	Appears when a used test strip is inserted	Repeat with a new test strip.
	Room temperature is out of range. Thus unable to measure.	Appears when ambient temperature is above system operation range.	System operation range is 10°C to 40°C (50°F to 104°F). Repeat the test after the meter and test strip are in the above temperature range.
	Room temperature is out of range. Thus unable to measure.	Appears when ambient temperature is below system operation range.	System operation range is 10°C to 40°C (50°F to 104°F). Repeat the test after the meter and test strip are in the above temperature range.
	Checking internal calibration data available.	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact the customer service for assistance.

Troubleshooting

1. If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO
Battery exhausted.	Replace the battery.
Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
Defective meter or test strips.	Please contact customer services.

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

POSSIBLE 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 automatic switch-off (2 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing "▲" appears on the display.
Defective meter.	Please contact customer services.

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

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and repeat the test again.
Control solution vial was poorly shaken.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiry date of the control solution.
Control solution that is too warm or too cold.	Control solution, meter, and test strips should be at room temperature (20°C-25°C / 68°F-77°F) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact customer services.

DETAILED INFORMATION

Reference values

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that maintaining blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%*1. The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Normal plasma glucose range for people without diabetes (mg/dL)
Fasting and before meal	Less than 100 mg/dL (5.6 mmol/L)
2 hours after meals	Less than 140 mg/dL (7.8 mmol/L)

Source: American Diabetes Association (2008). Clinical Practice Recommendations. Diabetes Care, 31 (Supplement 1): S1-108.

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

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

Comparing Meter and Laboratory Results

The meter provides you with plasma equivalent results. The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results may be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between meter and laboratory results, follow the guidelines below.

Before going to the lab:

- Perform a control solution test to make sure that the meter is working properly.
- Fast for at least eight hours before doing comparison tests, if possible.
- Take your meter with you to the lab.

While staying at the lab:

Make sure that the samples for both tests 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*2. In addition, if you have eaten recently, the blood glucose level from a finger prick 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*3. 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 (dehydration) may also cause a meter result to be different from a laboratory result.








References

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

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

SYMBOL INFORMATION

Symbol	Referent
	In vitro diagnostic medical device
	Do not reuse
	Consult instruction for use
	Keep away from sunlight
	Keep dry
	Temperature limitation
	Use by
	Batch code

Symbol	Referent
	Manufacturer
SN	Serial number
	Caution, consult accompanying documents
	Biological risks
	Authorized representative in the European Community
	CE mark
	Do not use if package is damaged
	Use within 3 months after opening

SPECIFICATIONS

Model No.: DIAVUE Prudential

Dimension & Weight: 90(L) × 52(W) × 15(H)mm, 45.6g

Power source: One CR2032 battery

Display: LCD

Memory: 450 measurement results with respective dates and times

External output: RS232 PC interface

Auto electrode inserting detection

Auto sample loading detection

Auto reaction time count-down

Auto shutdown after 195 seconds of idleness

Temperature Warning

Operating condition: 10°C to 40°C (50°F to 104°F), below 85% R.H.
(no condensing)

Storage/Transportation condition: -20°C to 60°C (-4°F to 140°F), 95% R.H.

Measurement units: mg/dL

Measurement range: 20 to 600mg/dL (1.1 to 33.3mmol/L)

This device has been tested to meet the electrical and safety requirements of:
IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326-1, EN 61326-2-6