CLEVER CHOICE™ Voice+

BLOOD GLUCOSE METER

Owner's Manual

Distributed by
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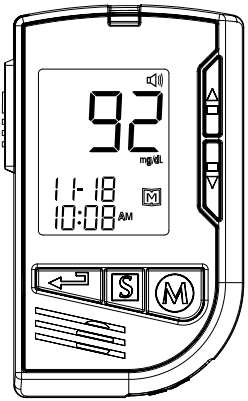
Simple Diagnostics

For in vitro diagnostic use only
Read instructions before use
For self-testing

CLEVER CHOICE™ Voice+

BLOOD GLUCOSE METER



OWNER'S MANUAL

June 2011 Versión 1.0

Dear **CLEVER CHOICE Voice+** Blood Glucose Meter Owner:

Thank you for purchasing the **CLEVER CHOICE Voice+** Blood Glucose Meter. 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 **CLEVER CHOICE Voice+** Blood Glucose Meter 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 Customer Service at 1-877-DIABETK (1-877-342-2385) for support.

IMPORTANT SAFETY PRECAUTIONS
READ BEFORE USE

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For more information, please visit

1."FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

2."CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) http://www.cdc.gov/injectionsafety/FingerstickDevicesBGM.html

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 neonates.

6. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only.
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. This system is not intended for use in the diagnosis or screening of diabetes mellitus.

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 hyperglycemic-hyperosmolar state, with or without ketosis. Please consult the healthcare professional before use.
- Critically ill patients should not be tested with a blood glucose meter.

Intended Use

The **CLEVER CHOICE Voice+** Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative site testing in this system can be used only during steady-state blood glucose conditions.

The **CLEVER CHOICE Voice+** Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system contains a speaking functionality which provides step by step instructions to aid visually impaired persons.

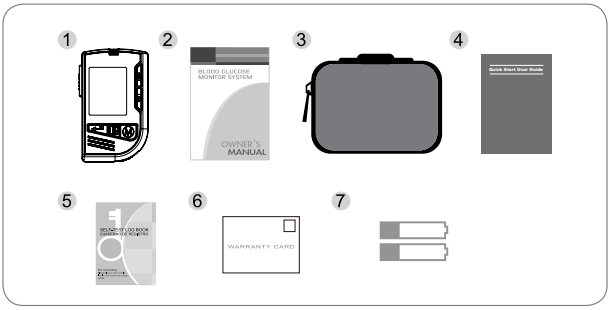
Test Principle

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 **CLEVER CHOICE Voice+** Blood Glucose Meter kit includes:

1. Meter
2. Owner's Manual
3. Protective Wallet
4. Quick Start User Guide
5. Daily Log Book
6. Warranty Card
7. 2 x 1.5V AAA alkaline batteries

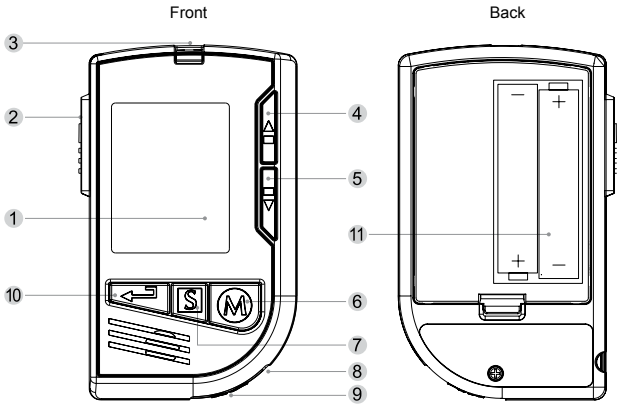


Test strips, control solution, or sterile lancets may be purchased separately.

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.
- There are two levels of CLEVER CHOICE control solution available, normal and high. Please contact the place of purchase for more information.
- This **CLEVER CHOICE Voice+ Blood Glucose Meter** must be used with **CLEVER CHOICE Voice+** Test Strips.

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 **Up Button &** 5 **Down Button**

Select or change information.

6 Ⓜ **Button**

Enter the meter memory and silence a reminder alarm.

7 Ⓢ **Button**

Enter and confirm the meter settings.

8 **Earphone Port**

Insert earphones to listen the voice messages.

9 **Data Port**

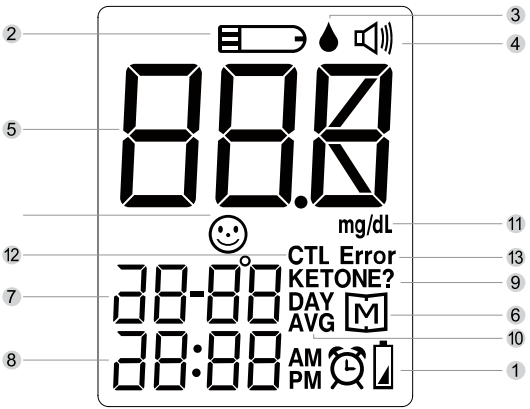
Download test results with a cable connection.

10 **Repeat Button**

Replay the previous recording while operating the meter.

11 **Battery Compartment**

Display Screen



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

Test Strip

Absorbent Hole
Apply a drop of blood here and the blood will be drawn in automatically.

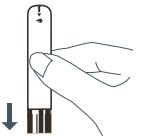
Confirmation window
Confirm if enough blood has been applied to the absorbent hole of the test strip.

Test Strip Handle
Hold this part to insert the test strip into the slot.

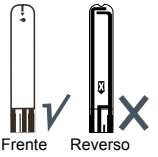
Contact Bars
Insert this end of the test strip into the test slot.

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 **CLEVER CHOICE Voice+ Blood Glucose Meter** should only be used with **CLEVER CHOICE Voice+ Test Strips**. Using other test strips with this meter can produce inaccurate results.

Speaking Function

CLEVER CHOICE Voice+ Blood Glucose Meter “speaks” aloud with step by step instructions to guide you through the process of setting up your meter and blood glucose testing. The following table tells you when and what the meter “speaks”.

WHEN does the meter speak?	**WHAT** does the meter speak?
Setting up the meter	
Choosing the language	You are now in setting mode. Thank you for using this product.
Setting the voice volume	Voice volume is (number).
Setting the year	The Year is (number).
Setting the month	The month is (month).
Setting the date	The date is the (number).
Setting the hour	The hour is (number) PM/AM.
Setting the minutes	The minutes are (number).
Deleting the memory	1. Delete memory record function. Press Up key to clear all records. 2. Are you sure you want to clear ALL records? Press Up key again to clear all records. 3. All memory record have been deleted.

Setting the alarm	1. The (first/second/third/fourth) alarm is disabled/enabled. 2. The (first/second/third/fourth) alarm hour is (number) AM/PM. 3. The (first/second/third/fourth) alarm minutes are (number).
At the end of the meter setting	1. Today's date is (week day) (month) (day), (year). 2.The time is (hour minute) AM/PM. 3.Blood glucose unit is milligrams per deciliter. 4.Voice volume is (number) 5.First alarm is enabled for (time) AM/PM. Second alarm is enabled for (time) AM/PM. Third alarm is enabled for (time) AM/PM. Fourth alarm is enabled for (time) AM/PM. 6.Have a nice day.

WHEN does the meter speak?	**WHAT** does the meter speak?
Using the meter	
When switching on the meter	Thank you for using this product.
When room temperature is outside operating range, which is 50°F-104°F(10°C-40°C).	Room temperature is out of range, thus unable to measure.

Insert test strip When the meter is ready to test. (symbol appears on display)	1. Test strip inserted. 2.Today's date is (week day) (month) (day), (year). 3.The time is (hour minute) PM/ AM. 4.Please apply blood onto the test strip.
After sample is applied onto the test strip	Now testing.
When the test is completed. (result appears on display)	Your blood glucose is (number) milligrams per deciliter.
When the test result is < 20 mg/dL	Your blood glucose is less than 20 milligrams per deciliter.
When the test result is > 600 mg/dL	Your blood glucose is over 600 milligrams per deciliter.
When selected CTL for control solution testing	You are now in control solution mode.
Recall the Stored Test Results	1. Thank you for using this product. 2. Today's date is (week day) (month) (day), (year). 3. The time is (hour minute) AM/ PM. 4. Press M key for memory recall mode. 5. Memory record for (week day) (month) (day), (year) (hour minute) AM/PM. 6. Your blood glucose was (number) milligrams per deciliter.

Reading the Average of Blood Glucose Results	1. Thank you for using this product. 2. Today's date is (week day) (month) (day), (year). 3. The time is (hour minute) AM/PM. 4. Press M key for memory recall mode. 5. The (number) day blood glucose average is (number) milligrams per deciliter for (number) records.
If no results stored in memory	No memory record available.
Downloading results from your meter onto the computer	Connecting to your computer.

NOTE

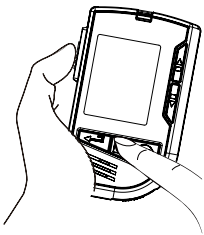
If you would like to listen to the voice messages by earphone, you can plug the earphone into the earphone port on the side of your meter.

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.

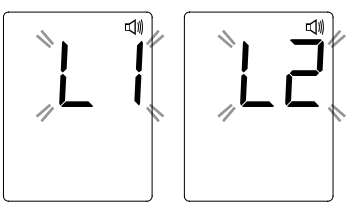
Entering the Setting Mode

Start with the meter off (no test strip inserted). Press and firmly hold S for 3 seconds until the meter turns on.



1. Choosing a Language

Press ▲ or ▼ to select L1/L2.The default language for the meter is L1, which is English. L2 is Spanish. To confirm your selection, press S .



2. Setting the speaking volume

There are seven (7) speaking volume options to choose from. Press ▲ or ▼ until the desired speaking volume appears. To confirm your selection, press S .

Volume 0 indicates that the speaking function is turned off, and " 🔊 " will not display during testing. Volume 1 to 7 indicates speaking volume from low to high, and " 🔊 "will be displayed throughout the testing.

3. Setting the date

With the year flashing, press ▲ or ▼ until the correct year appears. Press S .

With the month flashing, press ▲ or ▼ until the correct month appears. Press S .

With the day flashing, press ▲ or ▼ until the correct day appears. Press S .

4. Setting the time

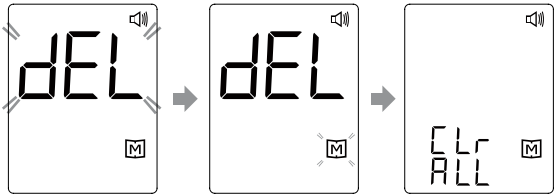
With the hour flashing, press ▲ or ▼ until the correct hour appears. Press S .

With the minute flashing, press ▲ or ▼ until the correct minute appears. Press S .

5. Deleting the memory

With “**dEL**” and a flashing “ M ” symbol on the display, press S to keep the results in memory.

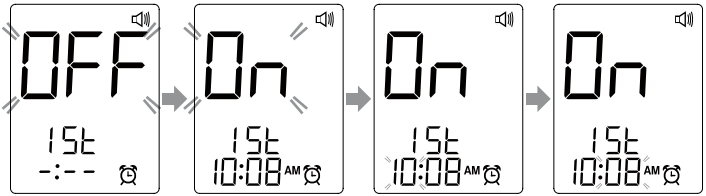
To delete all the results, press ▲ twice. “ CLr ALL ” and “ M ” are displayed on the meter, which indicates that all data stored is deleted.



6. Setting the reminder alarm

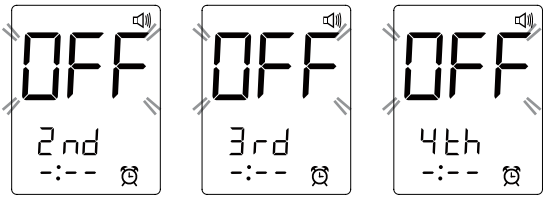
You may set up the reminder alarm. The meter displays “**OFF**” or “**On**” with ⏰ , press ▲ or ▼ to turn on or turn off to set the reminder alarm.

Press ▲ or ▼ to select “**On**”, then press S to set the hour. When the hour is flashing, press ▲ or ▼ to add an hour. Press S to confirm and go to minutes, press ▲ or ▼ to add one minute. Hold ▲ or ▼ longer to add faster. Press S to confirm the first alarm setting.



If you do not want to set an alarm, press S and select "**OFF**" to skip this step.

Setup the remaining three reminder alarms by following instructions above.

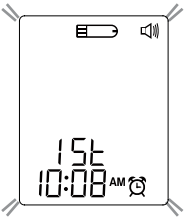


Press S to turn off the meter. The meter repeats all your settings before shutdown.

Congratulations! You have completed all settings!

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

At the time of your alarm, the meter will beep and automatically turn on. You can press M to silence the alarm and insert a test strip to begin testing. If you do not press M , the meter will beep for 2 minutes then switch off. If you do not want to test at this time, press M to switch off.



NOTE

- These parameters can **ONLY** be changed in the setting mode.
- If the meter is idle for 3 minutes during the setting mode, it will switch off automatically.

BEFORE TESTING

Control Solution Testing

CLEVER CHOICE 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.

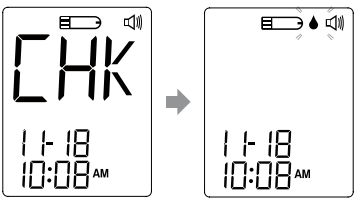
Do a control solution test when:

- 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

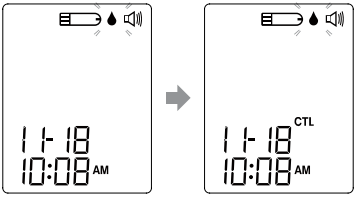
1. Insert the test strip to turn on the meter

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



2. Press Ⓜ 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 Ⓜ again, the "**CTL**" will disappear and this test is no longer a control solution test.



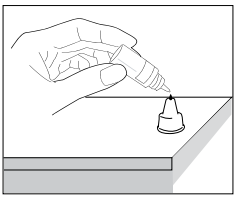
WARNING

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

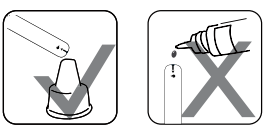
Shake the control solution vial thoroughly before use.

Squeeze out a drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap.



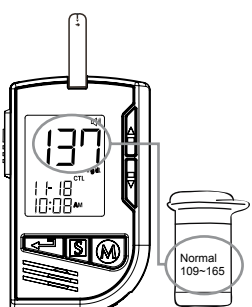
Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down.

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 **Maintenance** section for important information about your control solutions.

TESTING WITH BLOOD SAMPLE

Overview of the Lancing Device

Please refer to the manufacturer's instructions for the lancing device to collect a 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.
- Wash and dry your hands thoroughly after handling the meter, lancing device and test strips to prevent infection. For more information, please refer to the "Cleaning and Disinfection" section.
- If the 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.

Sharing the lancing device and lancets may increase the risk of contracting infectious diseases. Lancing device must not be used for more than one person.

Preparing the Puncture Site

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

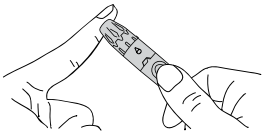
Blood from a site that has not been rubbed exhibits a measurably different glucose concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

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 for AST while setting up the lancing device.

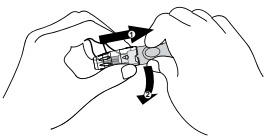
▶ Fingertip testing

Press the lancing device's tip firmly against the lower 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

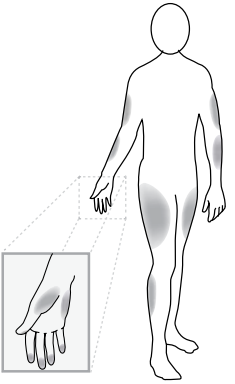
- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- Please consult your health care professional before you begin AST.
- It is recommended that you discard the first drop of blood as it might contain tissue fluid, which may affect the test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

Alternative Site Testing

Important: There are limitations with AST (Alternative Site Testing). The alternative site testing of the system can be used in only during steady-state blood glucose conditions. Please consult your health care professional before you perform AST.

Alternative site testing (AST) should not be used to calibrate continuous glucose monitoring systems (CGMs).

Results from alternative site testing should not be used in insulin dose calculations.



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.

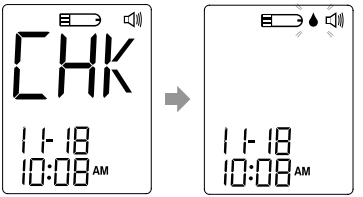
Do **NOT** use AST if:

- 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

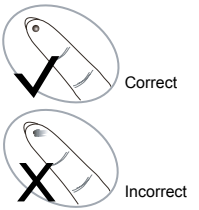
1. Insert the test strip to turn on the meter

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



2. Obtaining a blood sample

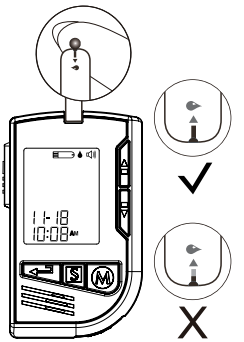
Use the pre-set lancing device to puncture the desired site. After penetration, discard the first drop of blood with a clean cotton swab. Gently squeeze the punctured area to obtain another drop of blood. Be careful NOT to smear the blood sample.



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 3 minutes, 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.

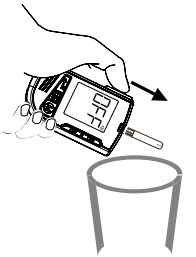
4. Read Your Result

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.

Wash your hands thoroughly with soap and water after handling the meter, lancing device and test strips to avoid contamination. For more information, please refer to the “Cleaning and Disinfection” section.

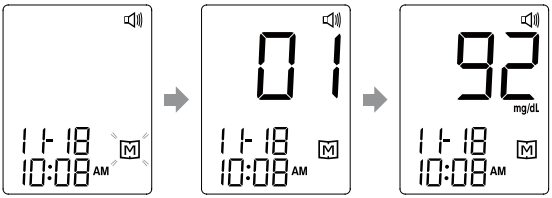
METER MEMORY

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**.

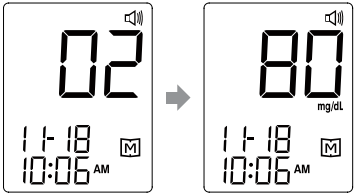
Reviewing Test Results

1. Press and release Ⓜ.

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



2. Press ▲ or ▼ to recall the test results stored in the meter each time you press.



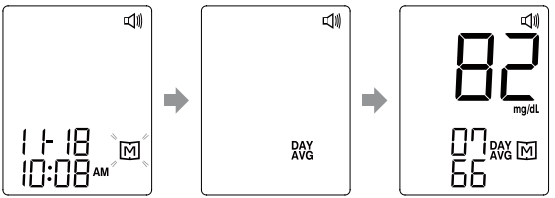
3. Exit the meter memory

After the last test results, keep pressing Ⓜ and the meter will be turned off.

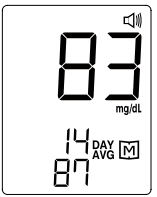
Reviewing Blood Glucose Day Average Results

1. Press and release Ⓜ.

When Ⓜ appears on the display, keep pressing Ⓜ for 3 seconds until the flashing DAY AVG appears. Release Ⓜ and then your 7-day average result will appear on the display.



2. Press ▲ or ▼ to review 14-, 21-, 28-, 60- and 90- day average results stored in memory.

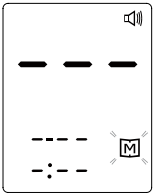


3. Exit the meter memory

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

NOTE

- Any time you wish to exit the memory, keep pressing Ⓜ for 5 seconds or leave it without any action for 3 minutes. 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

You can use the meter and download your test results to view on your personal computer. Please download the software from the Simple Diagnostics website at http://www.SimpleDiagnostics.com and install on your computer first. Follow instructions below to transmit the data.

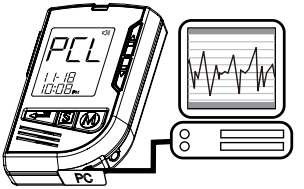
If you have any question about the installation of software or using a interface cable, please contact local customer service or the place of purchase for assistance.

1. Obtaining the required cable and installing the software

Download the software from the website. To install the Health Care system software on your computer, please follow the instructions given on the screen.

2. Connecting to a personal computer

Connect the meter to a USB port on your computer with an interface cable. With the meter switched off, connect the other end of the interface cable to the meter data port. "**PCL**" 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 two1.5V AAA size alkaline batteries.

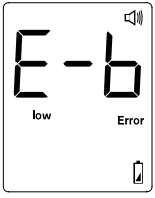
▶ Low Battery Signal

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:

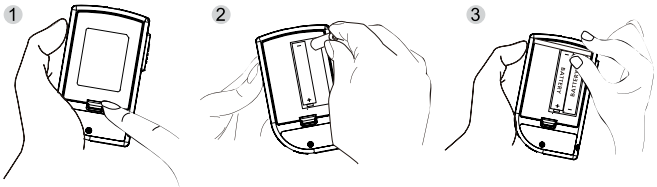
The power is not enough to do a test. Please change the batteries immediately.



▶ 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 two 1.5V AAA size alkaline batteries.
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 hands thoroughly with soap and water before and after use.

▶ Why the cleaning and disinfection should be performed

Cleaning and disinfection are different. Cleaning is the process of removing dirt (e.g. food debris, grease, dust), disinfection is the process of killing germs (e.g. bacteria and viruses).

▶ When to clean and disinfect the meter

Clean the meter when you see any dirt on it. You should disinfect the meter at least once a week to prevent infection.

▶ How to clean and disinfect the meter

The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt or blood or any other body fluid with the wipe. Use a second wipe to disinfect the meter. Do **NOT** use organic solvents to clean the meter.

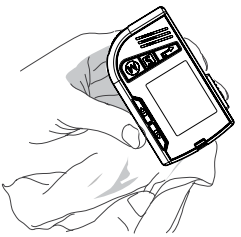
We recommend for meter cleaning and disinfection you should use the disinfecting wipe/towelette from below. The following product with isopropyl alcohol as the active ingredient has been shown to be safe for use with the **CLEVER CHOICE Voice+** meter.

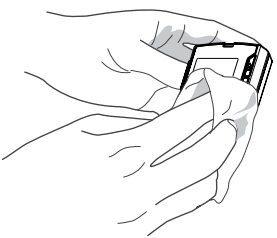
Micro-Kill+™ (Micro-Kill Plus™) by Medline (EPA Reg. No. 59894-10-37549)

To obtain disinfecting wipes and other information, please contact Medline at 1-800-MEDLINE (1-800-633-5463) or visit www.medline.com.

▶ Disinfecting Procedures

1. Take out one disinfecting wipe from the package and squeeze out any excess liquid in order to prevent damage to the meter.
2. Wipe all meter's exterior surface display and buttons. Hold the meter with the test strip slot pointing down and wipe the area around the test slot but be careful not to allow excess liquid to get inside. Avoid the earphone port and wipe the surface around the area because the liquid may go inside the port and damage the electrical components inside the meter. Keep meter wet with disinfection solution contained in the wipe for a minimum of 2 minutes for Micro-Kill+™ wipes. Follow the instructions on the package label of disinfecting wipe.





3. Remove the wipe. Allow the meter surface to dry completely.
4. Discard the used wipes and never reuse them. Wash your hands thoroughly with soap and water after handling the meter, lancing device and test strips to avoid contamination.

Improper system cleaning and disinfection may result in meter malfunction. If you have a question, please contact customer service at 1-877-DIABETK (1-877-342-2385) for assistance.

This device has been validated to withstand up to 5,000 cleaning and disinfection cycles using the recommended disinfecting wipe/ towelette. The tested number of cycles is estimated by a minimum of 1 cleaning and disinfection per week, plus any additional cleanings over 5 years, the expected life of the device. The meter should be replaced after the validated number of cleaning and disinfection cycles or the warranty period, which ever comes first.

Stop using the meter if you see any signs of deterioration. For example:

- meter can not be turned on,
- LCD display cracks or becomes cloudy,
- buttons no longer function,
- meter outer casing cracks,
- speaking malfunctions,
- earphone port is not working,
- data can not be transmitted to PC,
- color or paint/printing on housing is abnormal, or
- scratches or abrasions on meter are higher than acceptable.

Please contact the customer service or call at 1-877-342-2385 for a replacement meter if any of the signs of deterioration are noticed.

NOTE

- Do **NOT** clean and disinfect the meter while performing tests.
- If the meter is being operated by a second person, the meter and lancing device should be decontaminated prior to use by the second person.
- Do **NOT** allow cleaning and disinfecting solution to get in the test slot, battery compartment, or strip-ejection button.
- If you do get moisture in the test strip slot, wipe it away with a corner of tissue.
- Always dry the meter thoroughly before using it.
- Do not spray the meter directly with cleaning solutions especially those containing water (i.e. soapy water), as this could cause the solution to enter the case inside and damage the electronic components or circuitry.

▶ Meter Storage

- Storage conditions: -4°F to140°F (-20°C to 60°C), 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: 39.2°F to 104°F (4°C to 40°C), 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 expiration 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.

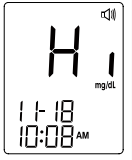
Important Control Solution Information

- Use only CLEVER CHOICE control solutions with your meter.
- Do not use the control solution beyond the expiration 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 (68°F to77°F/20°C to 25°C). 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 36°F and 86°F (2°C and 30°C). Do NOT freeze.

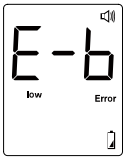
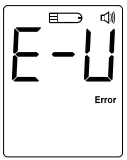
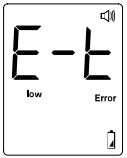
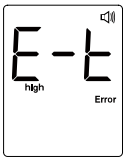
SYSTEM TROUBLESHOOTING

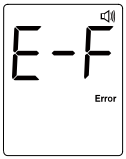
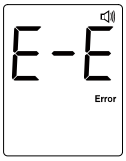
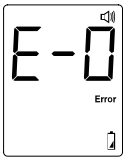
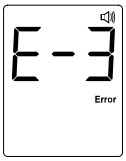
If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service. Do not attempt to repair yourself and never try to disassemble the meter under any circumstances.

Result Readings

MESSAGE	WHAT IT MEANS
	Appears when your result is below measurement limit, which is less than 20 mg/dL (1.1 mmol/L).
This symbol indicates hypoglycemia (low blood glucose) You should seek medical assistance immediately.	
	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.
	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. Please replace.	Replace the batteries immediately.
	Strip has been used.	Appears when a used test strip is inserted. Please replace.	Repeat 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.	System operation range is 10°F to 40°F (50°C to 104°C). Repeat the test after the meter and test strip are in the above temperature range.
		Appears when ambient temperature is above system operation range.	

MESSAGE	WHAT DOES METER SAY?	WHAT IT MEANS	WHAT TO DO
	Please ensure proper operation then try again.	Remove the strip after applying blood to the absorbent hole.	Re-test with a new test strip.
 	Meter malfunction. Please contact local distributor.	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.
	---	Voice chip error.	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
Batteries exhausted.	Replace the batteries.
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 (3 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 (68°F-77°F/20°C-25°C) 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 (2010). Clinical Practice Recommendations. Diabetes Care, 31 (Supplement 1): S1-108.

Please consult 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 whole blood 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.

SPECIFICATIONS

Model No.: TD-4248

Dimension & Weight: 93.9 (L) x 57.2 (W) x 20 (H) mm, 80.6 g

Power Source: two 1.5V AAA alkaline batteries

Display: LCD

Memory: 450 measurement results with respective date and time

External output: RS232 PC interface

Auto electrode insertion detection
Auto sample loading detection
Auto reaction time count-down
Auto switch-off after 3 minutes without action
Temperature Warning
Operating Condition: 50°F to 104°F (10°C to 40°C), below 85% R.H. (non-condensing)

Storage/Transportation Conditions:-4°F to 140°F (-20°C to 60°C), below 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, IEC/EN 61326-2-2.

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NOTE