CLEVER CHOICE™ Voice HD

BLOOD GLUCOSE MONITORING SYSTEM



Owner's manual

Distributed by
Simple Diagnostics
P.O.Box 128,Williston Park,NY 11596 USA
24-HOUR TOLL-FREE TELEPHONE ASSISTANCE
1-877-DIABETK 1-877-342-2385
www.SimpleDiagnostics.com

Simple Diagnostics

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



Manual del Usuario

CLEVER CHOICE™ Voice HD

Sistema de Vigilancia de la Glucosa en Sangre

Distribuido por:
Simple Diagnostics
P.O.Box 128,Williston Park,NY 11596 USA
LINEA DE ATENCION AL CLIENTE LAS 24-HORAS AL DIA
(GRATUITO)
1-877-DIABETK 1-877-342-2385
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Simple Diagnostics

Para uso diagnostico in-vitro
Lea las instrucciones antes de utilizar
Para autoanalisis

Dear CLEVER CHOICE Voice HD Blood Glucose Monitoring System Owner:

Thank you for choosing this system!

This manual contains important information you must know about the system.

Please read it thoroughly and carefully.

The system provides No Code function which means that you don't need to calibrate your meter, making it easier for the user to monitor blood glucose at home.

IMPORTANT SAFETY INSTRUCTIONS

- 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.

You should refer to the following linkages for more information:

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

READ THIS BEFORE USING

DANGER - Misuse of this electrical device can cause electrocution, burns, fire and other HAZARDS.

Basic safety precautions should always be taken, including all those listed below.

Close supervision is necessary when equipment is used by, on, or near children, handicapped persons or invalids.

The following basic safety notice should always be taken:

1. Do not place the device in liquid, nor put it where it could fall into liquid.
2. The following basic safety notice should always be taken.
3. Use the device only for the intended use described in this manual.
4. Do not use adjunct which are not supplied by the producer.
5. Do not make the device come into contact with surfaces which are too hot to touch.
6. Do not use the device where aerosol sprays are being used.
7. Do not use the device if it is not working properly, or if it has been damaged.
8. Read all the manual, and practice the test, and then use the product to test your blood glucose. Do all quality control checks as directed and consult with a diabetes expert.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

Table of Contents

BEFORE YOU BEGIN……5

ABOUT YOUR SYSTEM……6

INTRODUCTION TO THE SYSTEM……...6

ABOUT ALTERNATIVE SITE TESTING (AST)……..…....7

CONTENTS OF THE KITS……9

SETTING THE METER AND DELETING THE MEMORY.....13

1. Setting the Language and voice volume……13

2. Setting the date and time……13

3. Deleting the Memory ……..15

4. Speaking Function ……...16

THE TWO MEASURING MODES……....18

TESTING WITH BLOOD SAMPLE……18

Comparing Meter and Laboratory Results……24

CONTROL SOLUTION TEST……25

VIEWING RESULTS ON THE METER……26

Recalling the Stored Test Results……27

Reading the Average of Blood Glucose Results……27

CARE AND STORAGE FOR YOUR SYSTEM……28

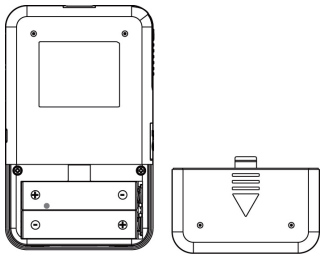
Cleaning and Disinfection……28

METER SPECIFICATION……30

DISPLAY MESSAGE……..…33

BEFORE YOU BEGIN

Installing the battery



1. Open the battery cover on the back of meter.
2. If replacing the batteries, please remove the used batteries.
3. Insert 2 new (AAA) batteries with correct +/- direction.
4. Close the battery cover.



Environment Protection – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice.

ABOUT YOUR SYSTEM

INTRODUCTION TO THE SYSTEM

Intended Use

- The system is intended for use outside the body (in vitro diagnostic use). It is for single-patient use. It should be used only for testing glucose (sugar) and only with fresh capillary whole blood samples taken from the finger and the alternative sites including the palm, the forearm, the upper arm, the calf and the thigh. The system is intended for use at home. It should not be used for the diagnosis of diabetes or for the testing of newborns.
- The System is to be used by a single person and should not be shared.
- The System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).
- The “CLEVER CHOICE” Test Strips are for use with the Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.
- The CLEVER CHOICE control solutions is intended for use with the System, to check that the glucose meter and test strips are working properly and that you are doing the test correctly. These solutions contain a known range of glucose, as indicated on the strips vial bottles.

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

Test principle

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.

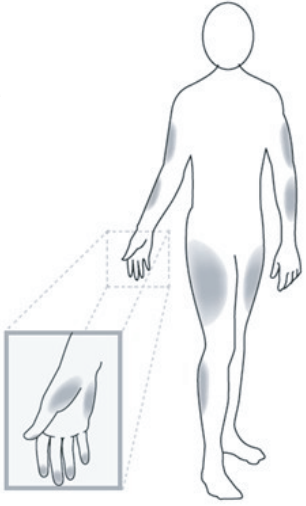
ABOUT ALTERNATIVE SITE TESTING (AST)

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 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 the equivalent results to fingertips testing.



What’s 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 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 a blood sample from your finger only.

You do AST **ONLY** in the following instances:

- 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 exercising.

NOTE:

- 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 doses calculations.

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 are often fluctuating.

CONTENTS OF THE KITS

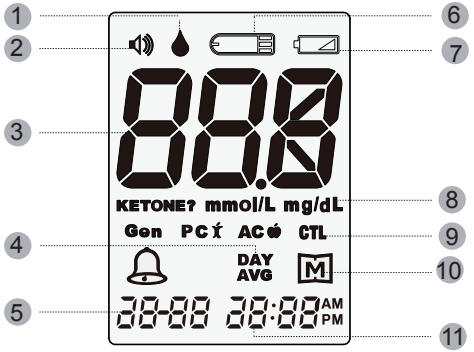
- A Meter
- Carry case
- Owner's Manual
- Daily Log Book
- Two AAA Alkaline Batteries
- Clever Choice Test strip(optional)
- Lancing Device(optional)
- Sterile Lancet(optional)
- Clever Choice Control solution (Optional)

NOTE:

- The Lancing Device can be used for several times however the lancet should be changed after each use.
- Adjustable Automatic Lancing Device, sterile lancet and test strips are not included in the standard kit.
- There are three levels for the control solutions: low, normal and high available, please contact the place of purchase for more information.
- You can toll free service hotline: 1-877-342-2385, Available 24 hours a day/7 days a week, except USA Federal Holidays (Simple Diagnostics) to buy all of the items.

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 Screen Display Message



1. BLOODDROP SYMBOL
   Flashes when it is ready to apply the blood sample
2. VOICE SYMBOL
   Appears when voice enable at volume 1~7, and at "0" voice turned off
3. TEST RESULT AREA
   Displays glucose results.
4. DAY AVERAGE
   Indicate that the displayed test result is an average value
5. DATE
6. TEST STRIP SYMBOL
   Appears when the meter is turned on
7. LOW BATTERY SYMBOL
   Appears when the battery power is low
8. MEASUREMENT UNIT
   Appears with the test result in mg/mL
9. CTL SYMBOL
   Appears when doing a control test and indicates that the result won't be stored in the memory.
10. MEMORYSYMBOL
    Appears when you review the memory
11. TIME

Blood Glucose Meter



1. STRIP PORT
   Where you insert the test strip. The meter will turn on automatically

2. DATA PORT
   Located at the side, is for cable connection.

3. STRIP EJECTOR
   Slide forward to eject the test strip after test

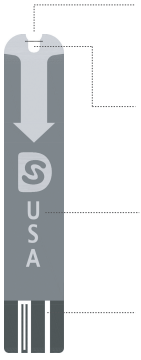
4. LCD DISPLAY
   It guides you through the test using symbols and simple messages

5. "M" Button
   It is used to turn on the meter, enter the memory mode

6. "S" BUTTON
   It is used to set up the meter

Test Strip

Each strip can be used only once. The test strip consists of the following parts:



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

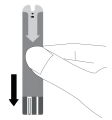
Confirmation window
This is where you confirm if enough blood has been applied to the absorbent hole of the strip.

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

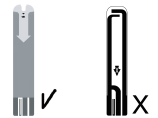
Contact bars
Insert this end of the test strip into the meter. Push it in firmly until it will go no further.

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.



SETTING THE METER AND DELETING THE MEMORY

1. Setting the Language and Voice volume.

1.1 Setting the Language

Press and Hold “S” button for 3 seconds, until the Eng or ESP is flashing. Press “M” button to select a language you desire. Press “S”.



OR



1.2 Setting the Volume

With the Volume level number flashing , Press “M” button to select level between “0” ~ “7” (set “0” to turned off voice). Press “S”.



2. Setting the date and time

2.1 Setting the Year

Press and Hold “S” button for 3 seconds, until the last two digits of the year will flash on the screen (for example, “14” equals 2014).Press “M” button until the correct year appears. Press “S”.



2.2 Setting the month

With the month flashing, press “M” until the correct month appears. Press “S”.



2.3 Setting the day

With the day flashing, Press “M” until the correct day appears. Press “S”.



2.4 Setting the AM/PM

With the AM or PM flashing, Press “M” until the correct one appears. Press “S”



2.5 Setting the hour

With the hour flashing,Press“M” until the correct hour appears.Press “S”.



2.6 Setting the minute

With the minute flashing, Press “M” until the correct minute appears. Press “S”.

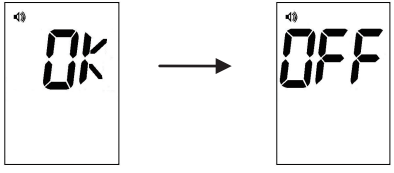


3. Deleting the Memory

The "dEL" will display with flashing "M" .



Press “M”once, to confirm delete, press“M” button again to delete ALL memory. The meter then displays “OK”, which means that the memory is deleted. If you don’t want to delete the memory, press the S button to skip this step. Then meter auto turned “OFF” completed the setting.



NOTE:

- The date, time, unit and memory deletion can ONLY be set in the setting mode.
- When the meter is in setting mode, if no button is pressed within 3 minutes, the meter will turn off.
- The meter equiped with real time backup timer, it keep running even without installing battery. When replace new batteries, no need to reset the date and time.

4. Speaking Function

Clever Choice Voice HD meter “speaks” with step by step instructions to guide you through the process of setting up your meter and blood glucose testing. The folloing 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	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 AM/PM	AM/PM
Setting the hour	The hour is (number)
Setting the minutes	The minutes are (number)
Deleting the memory	1. Delete all record mode. Press “M” key to delete all records. 2. Are you sure? Yes, to press “M” key again. 3. All memory record have been deleted
At the end of the meter setting	1. Today’s date is (month)(day), (year) 2. The time is (hour minute) AM/PM 3. Thank you for using this product

WHEN does the meter speak?	WHAT does the meter speak?
Using the meter	
Insert test strip When the meter is ready to test.	1. Test strip inserted 2. Today's date is (month)(day), (year). 3. The time is (hour minute) AM/PM 4. Please apply blood onto the test strip.
After sample is applied onto the test strip	Beep
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
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	Control solution mode
Recall the stored test result (press M key to turn on)	1. Today's date is (month)(day), (year) 2. The time is (hour minute) AM/PM 3. Press M key for memory recall mode 4. Memory record for (month) (day), (year) (hour minute)AM/PM 5. Your blood glucose was (number) milligrams per deciliter
Recall the Average of blood glucose results	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 computer
When display E-b	The battery is dead, please replace
When inserted an used strips	Strip has been used
When room temperature is outside operating range, which is 50°F ~ 104°F (10°C ~ 40°C).	Temperature is out of range
When error message appear	Unable to measure

THE TWO MEASURING MODES

The meter provides you with two modes for measuring, General and CTL. The CTL mode should be used when a control solution is being tested. See the table below.

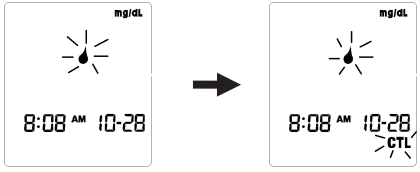
Modes	Use when
General tests (not display)	any time of day without regard to time since last meal
CTL	testing with the control solution

You can switch between each mode by:



1. Start with the meter turned off. Insert a test strip to turn on the meter, the screen will display a flashing blood drop.

2. Press M to select General or CTL mode.



TESTING WITH BLOOD SAMPLE

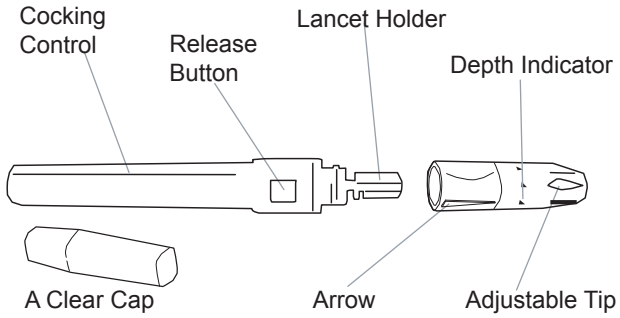
CAUTION:

To reduce the chances of infection:

- **Choose a clean, dry work surface.**
- **Never share a lancing device and lancet with another person.**
- **Always use a new and sterile lancet. Lancets are for single use only.**
- **Always use a new test strip. Test strips are for single use only.**
- **Avoid getting lotion、oils、dirt or debris in or on the lancet and lancing device.**

Note: Before testing, please read the following steps thoroughly and carefully, please relax and do the test step by step. Simplifying or changing the test procedure may produce inaccurate results.

Overview of the Lancing Device



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

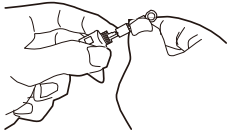
NOTE:

To reduce the chance of infection:

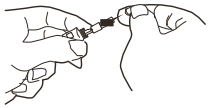
- Never share a lancet or the lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris when handling the lancets.

Setting Up the Lancing Device

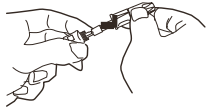
Screw off the cap of the lancing device. Insert a lancet into the lancet holder and push down firmly until it is fully in place.



Twist the protective disk until it separates from the lancet.



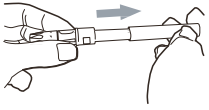
Replace the lancing device cap. Turn the cap until it is snug but not too tight.
The adjustable tip offers 5 levels of skin penetration.
Twist the adjustable tip in either direction until the number lines up with the arrow:
1-2 for soft or thin skin,
3 for average skin,
4-5 for thick or calloused skin.



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



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



Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site prior to 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:

- Rub the puncture site for about 20 seconds before penetration.
- Use a clear cap while setting the lancing device for AST. Wash and dry your hands before starting.
- Select the puncture site either at the fingertips or another body part (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.

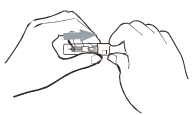
Fingertip testing

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.



Blood from sites other than the fingertip

A clear cap, together with 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 lancing device cap with the clear cap. Turn the clear cap until it is snug but not too tight, and then slide the cocking control back until it clicks.



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 to discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

Performing a Blood Glucose Test

Step 1.

Wash hands with soap and warm water.

Step 2.

Remove a test strip from its vial. With clean, dry hands, you may touch the test strip anywhere on its surface. Do not bend, cut or modify the test strips in any way. Remove the test strip from the vial and use it instantly.

Step 3.

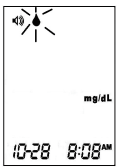
Insert the test strip into the meter's test port and the meter is turned on. The time and date appears on the screen.

NOTE: Be sure to use CLEVER CHOICE test strips, other test strips may not produce accurate results.



Step 4

When the blood drop symbol flashes on the screen, you may select the appropriate measurement mode, for selecting the measurement mode of Control(CTL) or General, please refer to the “THE TWO MEASURING MODES” section.



Step 5

Apply your blood to the absorbent hole of the test strip.

Step 6

As soon as enough blood has filled the confirmation window of the test strip, you will hear a beep letting you know the test has begun. A countdown of 5 seconds starts.



Note: make sure the confirmation window of the Test Strip is completely filled with your blood sample.

Step 7

Your blood glucose level, along date and time appears on the display. Blood glucose results are automatically stored in the memory.

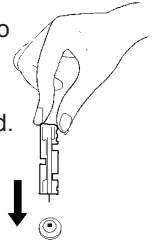


NOTE:

The results obtained from this meter are plasma-calibrated. This helps you and your physician or other qualified healthcare provider to compare your meter results with laboratory tests. Reference to the instructions given by your physician or other qualified healthcare provider, do not deviate from these instructions on the basis of the result without first consulting your physician.

Step 8

Eject the used test strip and remove the lancet. To eject the test strip, point the strip at a disposal container for sharp objects. The meter will switch itself off automatically after the test strip is ejected.



Please wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

Reference value:

Time of day	People without diabetes
Before breakfast (fasting)	<100 mg/dL
Two hours after meals	<140 mg/dL

Source: American Diabetes Association. Standards of Medical Care in Diabetes-2012.Diabetes Care 2012,35（Suppl.1)S11-S63. Please work with your doctor to determine a target range that works best for you.

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 can 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:

- Do a control solution test to make sure that the meter is working properly.
- Fast for at least eight hours and then do 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 test are taken and tested within 15 minutes of each other.

- Wash your hands and then obtain a blood sample
- Never use your meter with blood that has been collected in a gray top test tube.
- Use fresh capillary blood only.

CONTROL SOLUTION TEST

Material needed:

- Glucose Meter
- Clever Choice Test strips
- Clever Choice Control solution

When to do a control solution test:

- When you open a new vial of test strips
- When you suspect that the meter or test strips are not working properly.
- If your blood glucose test results are not consistent with how you feel.
- After the test strips are exposed to extreme conditions.
- After dropping the meter.

The control solution is to check that the meter and the test strips can work together as a system and work correctly.

Step 1

Insert the test strip to turn on the meter. Insert the test strip into the meter. Wait for the meter to display the drop symbol.

Step 2

You may press “M” button to select CTL mode, for selecting the CTL mode, please refer to the “THE TWO MEASURING MODES” section.



Step 3

Apply the control solution

Shake the control solution vial thoroughly before use.

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

Hold the meter to move the absorbent hole of test strip so it touches 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.

Step 4

The result of the control solutions test appears on the display. The result will not be stored under CTL mode.

The result of the control solutions test should be within the range printed on the test strip vial label. If the test results falls outside the specified range printed on test strip vial label, repeat the test. Results falling outside the specified range may be caused by:

- Error in performing the test
- Expired or contaminated Control Solution
- Expired or contaminated Test Strip
- Malfunction of your Meter

If you continue to get control solution test results that fall outside of the range printed on the vial, the system may not be working properly, Do not use the meter. Please contact your customer support immediately. 24-hour toll free service hotline: 1-877-342-2385

NOTE: Do not use the expired control solution.

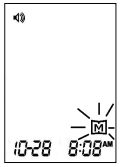
VIEWING RESULTS ON THE METER

Your meter stores the 500 most recent blood glucose test results with dates and times. It also provides 7-, 14-, 21-, 28-, 60- and 90 -day averages of your blood glucose test results.

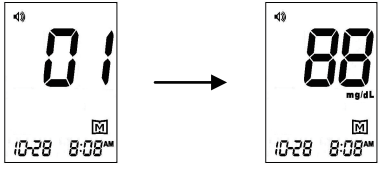
Note: The control solution readings are not included in the average of your results.

Recalling the Stored Test Results

1.Start with the meter off, press the M button to turn on the meter.The “ M ” symbol will flash with the time and date displayed on the screen.



2.Press **M** again, the most recent test results with date and time will display. Press “M” once more and the next most recent test results will appear. Each time you press and release “M”, the meter will recall up to your last 500 test results in order. Press the “S” to turn off the meter. When the memory is full, the oldest result is dropped and the newest result is added.



Reading the Average of Blood Glucose Results

When the meter is off, press and hold the “M” button until the screen turn on with DAY AVG appears, release button then 7-day average results appear with “a024” (means 24 records to be averaged) on the screen. Press the “M” button to review the 14-, 21-,28-, 60- and 90-day general averages. Press the S button to turn off the meter.

Note: The control solution readings are not included in the average of your results.



CARE AND STORAGE FOR YOUR SYSTEM

- Handle the meter with care. Dropping or throwing the meter may cause damage to the device.
- Don't expose the Blood Glucose Monitoring System, Test strip, and Control Solution, to extreme conditions, such as high humidity, heat, freezing cold or dust. The storage conditions for the test strips are 39˚F～86˚F, Humidity＜85%RH. Storage conditions for the meter are -40˚F～131˚F, Humidity＜80%RH.
- Always wash your hands with soap and water and rinse and dry completely before handling the Blood Glucose Monitoring system and Test strip.
- Use CaviWipes (see below) to clean the Blood Glucose Monit oring System.
- Discard the used lancet into a container for sharp objects.

Cleaning and Disinfection

The cleaning and disinfection is absolutely necessary for the test procedure, because cleaning can insure the meter works well (for example, display will be clear to see after cleaning); and disinfection can avoid the infection to you or to the other people, and the cross-infection. We strongly warn that the device should be cleaned and disinfected following use on every patient. And we suggest you use the following product: CaviWipes (EPA registration number：46781-8）. You can purchase this product according to the following information: visit the web site: www.metrex.com or contact Metrex at 800-841-1428 for product or technical information. CaviWipes are also available at www.amazon.com or via a Google search.

The meter for single-patient use and the lancing devices may be cleaned 5-6 times per day (Test 5-6 times every day),

so the meter will be cleaned and disinfect about 11000 cycles that include cleanings plus disinfections (1 cycle = 1 cleaning + 1 disinfection) during its 5 years life cycle.

1. Before the test, the user should clean and wash hands. If you are a caregiver, (not the patient), the please use disposable gloves.
2. After test, take one wipe to clean the meter's housing, buttons, lens, mark, usb cover and support block, including its front and back for 10 seconds for cleaning until there is no soil on the surface. Then disinfect the meter's housing, buttons, lens, mark, usb cover and support block use another wipe for 2 min, keep the surface wet for 2 min.
3. Take off the glove; discard carefully according to your health-care provider's instruction.

Note:

1. Each disinfection step requires a pre-cleaning step.
2. If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device shall be cleaned and disinfected first.
3. The users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
4. If you have any questions you can dial the number 1-877-342-2385
5. Please refer to the following linkage for detail information: "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

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

6. **Table: A list of the signs of potential deterioration (Physical and in performance)**

What do you see?	What to do?
The buttons do not work	Stop using and contact local customer services or place of purchase for assistance, or toll free service hotline: 1-877-342-2385
The device does not work	Stop using and contact local customer services or place of purchase for assistance, or toll free service hotline: 1-877-342-2385
Discoloration of the buttons , meter casing or lancing device	Stop using and contact local customer services or place of purchase for assistance, or toll free service hotline: 1-877-342-2385
Corrosion, crazing, embrittlement, cracking of the buttons, meter casing, display or lancing device	Stop using and contact local customer services or place of purchase for assistance, or toll free service hotline: 1-877-342-2385
Cloudiness of the lens	Stop using and contact local customer services or place of purchase for assistance, or toll free service hotline: 1-877-342-2385

METER SPECIFICATION

1. Model: CLEVER CHOICE Voice HD (with "Clever Choice" test strip and Clever Choice control solution)
2. Machine size: 90mm (L)×54mm (W)×13mm(H)
3. Weight: 50g (excluding batteries)
4. Measuring method: Amperometric technology using glucose oxidase

5. Result range: 20 mg/dL ~600 mg/dL(1.1 mmol/L ~33.3mmol/L)
6. Glucose Units: Either mg/dL or mmol/L (USA version preset mg/dL only)
7. Memory : 500 blood glucose tests
8. Display: LCD display with backlight
9. Power source: DC 3V (AAA×2 alkaline batteries)
10. Battery Life: Approx. 500 normal tests
11. Storage Condition: Blood glucose Monitoring system (meter and test strips): 39°F ～ 86°F , Humidity＜80%RH.
12. Storage Condition (meter): -40°F～131°F, Humidity＜80%RH
13. Operating conditions: 50°F ～ 104°F , Humidity:25%~80%RH
14. Blood Source: Fresh capillary whole blood
15. Blood Volume: Minimum 0.7 micro liter.
16. Use life: five years

NOTE: Factors affecting the life of the meter

The factor	The indication	Do this:
The aging of the strip connector	The meter cannot be turned on when Inserting the test strip several times.	please contact local customer services or place of purchase for assistance, or toll free service hotline: 1-877-342-2385
The clouding of the lens	The content displayed on the lens cannot be recognized clearly.	please contact local customer services or place of purchase for assistance, or toll free service hotline: 1-877-342-2385
The aging of the electronic components	The results are not accurate when the test strips are in normal mode.	please contact local customer services or place of purchase for assistance, or toll free service hotline: 1-877-342-2385

★Limitations of use:

※ The blood Monitoring System is not intended for use on neonates.

※ The blood Monitoring System is not intended for use on artery blood, neonates' serum and plasma.

※ The Blood Glucose Meter should be used with "CLEVER CHOICE" test strip.

※ The system can be used up to an altitude of 10744 feet.

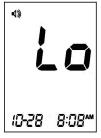
※ The following substances at levels greater than normal or therapeutic levels may cause significant interference (affect the result by greater than 10%) resulting in an inaccurate result: ascorbic acid, uric acid, hemoglobin， acetaminophen, Dopamine, L-dopa, L-dopa and Tolbutamide etc. These substances do not affect test results in normal concentration but may affect test results in high concentration. Do not use haemolysis sample, icterus sample or high lipemia samples.

※ The following compounds, when determined to in excess of their limitation, may produce inaccurate results:

Compound	Limitation
Ascorbic acid	＞2mg/dL
Uric acid	＞10mg/dL
Acetaminophen	＞5mg/dL
Bilirubin	＞15mg/dL
Dopamine	＞0.03mg/dL
L-dopa	＞0.45mg/dL
Methyldopa	＞0.75mg/dL
Tolbutamide	＞24mg/dL
Triglycerides	＞2000mg/dL
Hemoglobin	＞250mg/dL

※ Patients undergoing oxygen therapy may yield falsely lower results.
※ Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
※ Not for use on critically ill patients.
※ Not to be used for patients who are dehydrated, hypertensive, hypotensive or in shock.
※ Very low (less than 20%) or very high (more than 60%) red blood cell count (hematocrit) can lead to incorrect test results. If you do not know your hemarocrit level, please consult your health care provider.

DISPLAY MESSAGE

MESSAGE	WHAT IT MEANS	ACTION
	Blood glucose level is lower than 20mg/dl (1.1mmol/L)	The message indicates very low blood sugar. You should consult with your healthcare professional.
	Blood glucose level is higher than 600 mg/dl (33.3mmol/L)	This indicates sever severe hyperglycemia (high blood glucose). You should seek immediate medical assistance.
	Meter is ready to test control solution under the CTL state.	Please place a drop of control solution onto the test well of test strip.
	Battery power is dead.	Please change the battery.

MESSAGE	WH AT IT MEANS	ACTION
	Use a used test strip.	Please use a new strip and re-test.
	Error massage indicates that you may remove the strip after applying blood to the absorbent hole.	Try again with a new test strip.
 	Problem with the meter.	Re-test with a new test strip. If the problem is still unsolved, please call the Customer Care Line for help.
	Environmental temperature is lower than 10℃(50℉) or higher than 40℃(104℉)	Please test at an environmental temperature within 10~40℃ (50~104 ℉) operation range.

Problems

Problems	Causes	Solutions
Display remains blank after the test strip has been inserted into the Meter.	1. Battery may be installed improperly. 2. Battery power is too low for use. 3. Too much time has passed between inserting the Test Strip and performing the test.	1.Install the Battery correctly. 2.Replace with new Battery. 3.Reinsert the Test Strip into the Meter.

Problems	Causes	Solutions
	4. Test Strip has not been fully inserted into the Meter.	4. Reinsert the Test Strip into the Meter.
Test results are incon sistent or Control Solution test results are not within the specified range.	1. Not enough sample in the Test Strip. 2. Test Strip or Control Solution has expired. 3. Test Strip has been damaged due to heat or humidity so that sample cannot be applied or the speed of applying sample is too slow. 4. System is not performing due to the environment being above or below room temperature.	1. Redo test with new test strip and make sure that enough sample has been added. 2. Redo test with new test strip. 3. Perform a Control Solution test using a new Test Strip. If results are still out of range, replace with new vial of Test Strips. 4. Bring System to a room temperature environment and wait approximately 30 minutes before performing a new test.
The Meter countdown did not start.	Test Strip has not been inserted correctly.	Use a new Test Strip and redo the test.

Manufactured for
Simple Diagnostics
P.O. Box 128
Williston Park, NY 11596

USA
TEL : 877-342-2385
FAX: 800-865-9155
(Available 24 hours a day/7 days a week, except USA Federal Holidays)

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