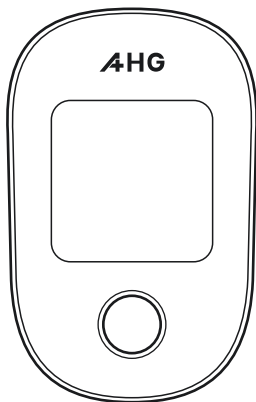


American Health Gate

BLOOD GLUCOSE MONITORING SYSTEM AHG-2022

INSTRUCTION MANUAL



Blood Glucose Monitoring System

The AHG blood glucose monitoring system is designed for easy testing of blood glucose and helps you keep your blood glucose under control. The AHG system complies with the requirements of the EN ISO 15197:2015 international standard.

Read these Instructions for Use carefully before using the system. The information provided will help you become familiar with the proper operation of the device and ensure accurate, reliable test results. Keep these Instructions for Use in a safe place for future reference.

Principle and Intended Use

The AHG-2022 system is designed for the quantitative measurement of glucose concentration in fresh capillary whole blood samples drawn from the fingertips.

The system measures glucose using electrochemical technology. When a blood sample is applied to the test strip, it is drawn into the reaction zone by capillary action. Glucose in the blood reacts with the enzyme and mediator on the test strip electrode, generating electrons and producing an electrical current proportional to the glucose concentration. The meter then calculates and displays the glucose concentration as a plasma-equivalent result.

The AHG Blood Glucose Monitoring System is intended for self-testing by individuals with diabetes at home as an aid to monitor their diabetes management. The device is for in vitro diagnostic use only.

This system is not intended for neonatal use, nor for the diagnosis of or screening for diabetes. The device is intended for single-patient use only and must not be shared.

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Your Meter System Overview

The AHG Blood Glucose Meter and AHG Blood Glucose Test Strip.

Sample tip:

where the blood is drawn in.

Electrode end:

This end is inserted into the test strip port on the meter with facing upwards, in the direction of the arrows.

Test strip port

Display

Button

Charging port

Your Meter Display

The picture below shows all the symbols that appear on your meter display. Please make sure the display is working properly before testing. When the meter is off, press "ⓘ" and hold to see the complete display. All display segments will appear exactly like the picture below. If not, contact your local distributor for help.



Icon	What it Means
	The top right area on the screen indicates the date.
	The top left area on the screen indicates the time.
	Indicates that the battery is empty or needs to be recharged.
	The center area on the display, this shows test results or error codes.
	Indicates the system is ready to do a test.
	Control test result.
mg/dL mmol/L	Test results are displayed in mg/dL or mmol/L, depending on the country in which the device is distributed.
	Indicates successful Bluetooth communication.
	The meter failed to sync with the Smartphone.
M	Memory.

Notes:

Your AHG meter is pre-set with a beep sound function, the meter will beep when:

- Turn on the meter.
- Insert the test strip and it is ready for blood or control solution to be applied.
- Sufficient blood or control solution is drawn into the test strip.
- It is time to perform a test if you set the test alarms.
- If any error occurs during operation.

Meter Use and Precautions

- The meter is pre-set to display blood glucose results in either millimoles per litre (mmol/L) or milligrams per decilitre (mg/dL), depending on the unit of measurement standard in your country. This unit of measurement cannot be adjusted.
- Do not allow water or other liquids to enter the meter.
- Keep the strip port area clean.
- Keep the meter dry and avoid exposing it to extreme temperatures or humidity. Do not leave it in your car.
- Do not drop the meter or allow it to become wet. If the meter is dropped or becomes wet, perform a quality control test. Refer to the "Quality Control Test" section for instructions.
- Do not disassemble the meter. Disassembling the meter will void the warranty.
- Refer to the "Caring for Your Meter" section for cleaning instructions.
- Keep the meter and all associated components out of reach of children.

Note: Follow proper precautions and all local regulations when disposing of the meter and used batteries.

EMC Precautions (Electromagnetic Compatibility)

1. This meter has been tested for immunity to electrostatic discharge in accordance with IEC 61000-4-2. However, use of the meter in a dry environment, particularly where synthetic materials are present (e.g., synthetic clothing or carpets), may generate static discharges that could result in inaccurate readings.
2. This device complies with the emission and immunity requirements of EN 61326-1 and EN 61326-2-6. Do not use the meter in close proximity to sources of strong electromagnetic radiation, as this may interfere with its proper operation.
3. For professional use, the electromagnetic environment should be evaluated prior to operating the meter.

Important Safety Information

- Always keep the test strips in the original vial. Tightly close the vial immediately after removing a test strip.
- Do not use the meter if it has been dropped into water or exposed to splashing water.
- Wash and dry your hands thoroughly before and after testing.
- Test strips and safety lancets are for single use only.
- Do not apply blood to the flat surface of the test strip.
- Check the expiration date and discard date on the test strip vial label and control solution bottle label.
- Use only AHG Blood Glucose Test Strips with your AHG Blood Glucose Meter.
- Use only AHG control solution with your AHG system.
- Contact your physician or diabetes healthcare professional before making any changes to your therapy or diet based on test results.
- If the system is used in a manner not specified by the manufacturer, the protection provided by the system may be impaired.



Potential Biohazard

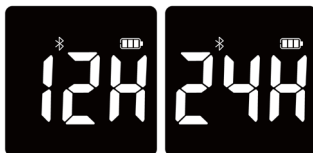
Healthcare professionals or persons using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects, which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral disease.

Before you use your meter for the first time, you must check and update your meter settings.

Set the Time and Date

1. Set the Clock

When the meter is off, press and hold  until the meter beeps to enter the set up mode. Then set the clock for either 12 or 24 hour mode. Press  to adjust it then press and hold  to save your choice and start setting the year, month and date.



2. Set the Date

The year will now flash. Press  to adjust it then press and hold  until the meter beeps to set. Then it will shift to next digit for setting. Repeat the above action until the year setting is completed.



The month will now flash. Press  to adjust the month, press and hold  until the meter beeps to set.



The date will now flash. Press  to adjust the date, press and hold  until the meter beeps to set. Then it will shift to next digit for setting. Repeat the above action until the year setting is completed.



Note: Before using your meter system for the first time, please adjust the meter settings to set the correct date and time. This ensures that all results stored in memory are recorded with the accurate date and time.

3. Set the Time

If you select 12 hour mode, you could select "AM" or "PM" before you setting the hour. The hour will now flash. Press  to adjust the current hour, press and hold  until the meter beeps to set. Then it will shift to next digit for setting. Repeat the above action until the hour setting is completed.

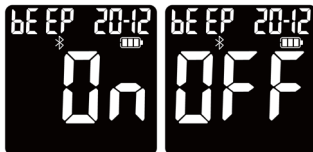


The minute will now flash. Press  to adjust the minute, press and hold  to set.



4. Set the Audio Feature

After setting the time, press  to select "On" or "OFF". Press and hold  to confirm.



Now you have completed the meter set up. A symbol of a test strip appears letting you know the meter is ready to test.



Pairing Your Meter with the Smartphone

Pairing prepares your AHG Meter and smartphone to communicate with each other. The devices must be within 5 meters of each other to pair and sync. Download the MedM app before pairing your meter and smartphone.

Note: *it's compatible with Android 4.3 or above, and iOS 8.0 or above.*



WARNING: *Do Not pair another person's meter with your smartphone.*

Syncing to Send Results Wirelessly to the App

The first time you sync, the smartphone will set the time in the meter. The Smartphone checks and updates the date and time in your meter each time you sync. Check the date and time on your smartphone often to be sure they are correct.

Note: *It is important to sync the meter and app before testing for the first time. This will ensure that the correct date and time are attached to your test results. Any glucose results from tests taken before your initial sync will never be sent to the app.*

To pair the smartphone with your meter, turn your meter on and follow these steps:

1. When you turn on your meter, the (⌘) symbol will appear to indicate Bluetooth® is on.
2. To turn on Bluetooth® on your smartphone.
3. Open the MedM app on the smartphone.
4. "✓" will appear on the app to notify you that the meter is communicating with the app.

After syncing, the app will display a list of any new blood glucose results sent from the meter.

Using Your Meter Without the App

The meter can be used without a smartphone or the app. You can still test your blood glucose and review your last result on the meter screen. To review additional results in the meter memory, you can download the results to a computer.

However, date and time will not appear with your test results unless you have installed the app, paired your meter with your smartphone, and completed an initial sync.

Set up your meter correctly and have all the materials you will need ready before you begin the testing. This includes your AHG meter, the AHG test strips and AHG lancing device with AHG lancets.

Preparing the Test Strip

1. Wash and dry your hands well before testing.
2. Remove a test strip from the test strip vial. Tightly close the vial cap immediately after you have removed the test strip.
3. Insert the test strip into the meter in the direction of the arrows. The meter turns on after a beep.



4. A symbol with a test strip with a flashing blood drop will appear letting you know the meter is ready to test.



Note:

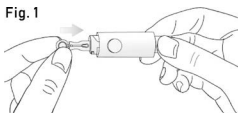
Check the expiration and discard dates on the test strip vial. All expiration dates are printed in Year-Month format. 2025-01 indicates January, 2025. Your AHG test strips have 6 months shelf life after you first open the test strip vial. Write the discard date on the vial label when you first open it. Make sure the test strip does not appear damaged. Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water wash hands to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.

Preparing the Lancing Device

INSERTING THE LANCET

Insert a new lancet into the lancet holder and push down firmly until it is fully inserted. Remove the protective cap by twisting it away from the body of the lancet (fig. 1).

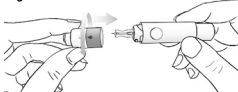
Fig. 1



REPLACING THE DEPTH ADJUSTER

Replace the depth adjuster assembly onto the AHG lancing device by twisting it on (fig. 2).

Fig. 2



SETTING THE PENETRATION DEPTH

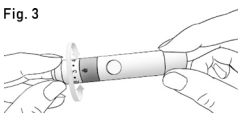
Adjust the penetration depth as necessary. Hold the white depth adjuster collar between thumb and forefinger and twist until the required depth setting lines up with the penetration depth indicator.

"1" provides the minimum penetration depth and, "6" provides the maximum penetration depth.

"." provides the middle penetration depth between two depths.

It is recommended you start at the minimum depth (fig. 3).

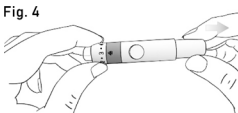
Fig. 3



PREPARING TO TAKE THE SAMPLE

Hold the main body of AHG lancing device with one hand and the device sleeve with the other and pull the two apart until you hear a click. This primes the device ready for use (fig. 4).

Fig. 4

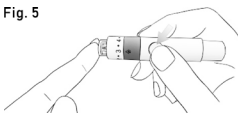


OBTAINING THE SAMPLE

Hold the front end of AHG lancing device firmly against the sample site (fig. 5).

Press the release button and then remove AHG lancing device from the sampling site. Wait a moment for the blood to flow freely from the puncture site. Massage the site if necessary, from the palm to the fingertip, with the hand held downwards, until a sufficient blood sample is acquired.

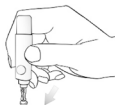
Fig. 5



COVERING THE NEEDLE TIP

Twist off the depth adjuster assembly to remove it from the AHG lancing device. Push the lancet until needle tip is totally covered by protective cap. Don't touch the exposed lancet needle (fig. 6).

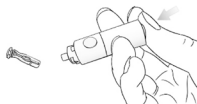
Fig. 6



EJECTING THE LANCET

Push the sleeve until eject lancet. It is important to discard the used lancet carefully in a suitable sharps container. Do not reuse lancet. Replace the depth adjuster assembly onto the AHG lancing device by twisting it on (fig. 7).

Fig. 7

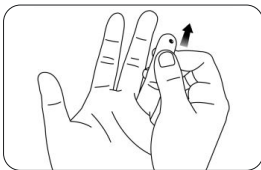
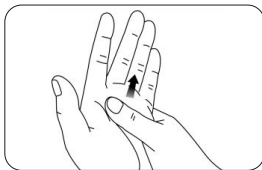


Potential Biohazard:

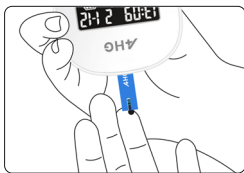
Always dispose of the used lancet properly to prevent injury or contamination to others.

Getting a Blood Drop and Testing

1. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the blood drop. Lance on the side or the fingertip to help reduce any pain. Test immediately after a good blood drop has formed.

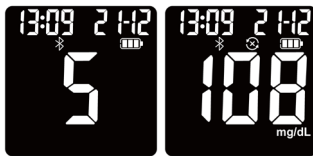


2. Immediately touch the tip of the test strip to the blood drop and allow the sample to be drawn in by capillary action. Make sure that the blood sample has fully filled the sample tip on the test strip. Hold the tip of the test strip in the blood drop until the meter beeps.



Note: If the blood sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.

- The meter counts down for 5 seconds, and your result appears on the display after a beep. The test result is automatically stored in the meter memory. Do not touch the test strip during the countdown, as this may cause an error.



Discard the Used Test Strip

You can discard the used test strip by sliding the strip ejector forwards. The meter turns off automatically after a beep.

⚠ Potential Biohazard: Dispose of the used test strips as medical waste.

Expected Diabetes Control Goal:

Blood glucose values will vary depending on food intake, medication dosages, health, stress, or exercise. Ideally, to control the glucose level as close to a normal (non-diabetic) blood glucose level as you safely can.

The American Diabetes Association suggests the following targets for most non-pregnant adults with diabetes. More or less stringent glycemic goals may be appropriate for each individual. Blood glucose targets should be determined in consultation with a healthcare professional.

CHAPTER 3 – TAKING A TEST

Expected blood glucose levels for most non-pregnant adults with diabetes:

Time of Day	Range, mg/dL	Range, mmol/L
Fasting and before Meals	80 – 130	4.4 – 7.2
2 hours after meal	Less than 180	Less than 10

Reference:

1. ADA Clinical Practice Recommendation, 2014

Warnings:

- If your blood glucose reading is under 50 mg/dL (2.8 mmol/L) or you see LO (less than 10 mg/dL (0.6 mmol/L)) on the meter display, contact your health care professional as soon as possible.
- If your test result is above 250 mg/dL (13.9 mmol/L) or you see HI (greater than 600 mg/dL (33.3 mmol/L)) on the meter display, contact your health care professional as soon as possible.
- Do not change your medication therapy based on AHG test result. Consult a healthcare professional before making changes to medication or treatment.

Questionable or Inconsistent Results:

If your blood glucose result does not match how you feel, please:

- Check the expiration and discard dates of the test strip. Make sure that the test strip vial has not been opened for more than 6 months.
- Confirm the temperature in which you are testing is between 5 and 45°C (41-113°F).
- Make sure that the test strip vial has been tightly capped.
- Make sure the test strip has been stored in cool, dry place.
- Make sure the test strip was used immediately after removing from the test strip vial.
- Make sure that you followed the test procedure correctly.
- Perform a control solution test (See Performing a Control Test for instructions).

After checking all of the conditions listed above, repeat the test with a new test strip. If you are still unsure of the problem, please contact your local dealer.

Cautions:

- *Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.*
- *Do not use the lancet if the needle is bent.*
- *Take care whenever the lancet needle is exposed.*
- *Never share lancets or the lancing device with other people in order to prevent possible infections.*
- *In order to reduce the risk of infection from prior use or the instrument, always use a new, sterile lancet. Do not reuse lancets.*
- *Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt or debris.*

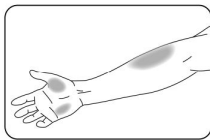
Alternative Site Testing

Blood samples for glucose testing may be taken from sites other than your fingertips. Alternative site testing using blood from the forearm or palm may produce results that differ from fingertip testing. Differences occur when blood glucose levels are changing rapidly, such as after a meal, after insulin, and during or after exercise. Consult a healthcare professional before using alternative site testing.

The forearm and palm areas have less nerve endings than the fingertip. You may find obtaining blood from these sites less painful than from the fingertip. The procedure for forearm and palm sampling is different. You need the clear cap to draw blood from these sites.

Note: *If you use a lancing device with clear cap, please follow the manufacturer's instructions.*

1. Insert a new lancet into the lancet holder and push down firmly until it is fully inserted. Remove the protective cap by twisting it away from the body of the lancet.
2. Screw the clear cap onto the lancing device.
3. Choose a puncture site on the forearm or palm. Select a soft and fleshy area of the forearm or palm that is clean and dry, away from bone, and free of visible veins and hair. To bring fresh blood to the surface of the puncture site, massage the puncture site vigorously for a few seconds until you feel it getting warm.



4. Place the lancing device against the puncture site. Press and hold the clear cap against the puncture site for a few seconds. Press the release button of the lancing device, but do not immediately lift the lancing device from the puncture site. Continue to hold the lancing device against the puncture site until you can confirm a sufficient blood sample has formed.

Notes:

- *Consult your doctor or health care professional to determine if alternative site setting is right for you.*
- *Alternative site testing is not recommended if you have hypoglycemic unawareness (you do not recognize the symptoms of or cannot tell when you have low blood glucose). Please consult with your doctor or health care professional if you have a low blood glucose level.*
- *Select a soft, fleshy area or skin that is free from hair, moles and visible veins for alternative site testing. Wash the site with soap and warm water then rinse and dry thoroughly.*
- *Use alternative site testing for blood glucose tests only when it is more than 2 hours after: A meal, Taking medication, Exercise*

Testing with Control Solution

Why Perform Control Tests

Performing a control test confirms you know that your meter and test strips are functioning properly and will give reliable test results.

You should perform a control test when:

- At least once a week
- When you open a new box of test strips
- When you want to check the meter and test strips
- If your test strips were stored in extreme temperature or humidity
- If you dropped the meter
- If your test result does not match with how you feel

About the Control Solutions

- Only use AHG Control Solutions (Low, Normal or High) to practice on the system.
- Your meter automatically recognizes the control solution.
- The control solution results are not included in the average value calculation.
- All expiration dates are printed in Year-Month format. 2025-01 indicates January, 2025.
- Do not use a control solution that is past the expiry date or discard date (the control solution will expire 6 months after the bottle is opened for the first time).
- Shake the bottle well before use.
- Close the bottle tightly after use.

Performing a Control Test

1. Remove test strip from the test strip vial. Tightly close the vial cap immediately after you have removed the test strip.
2. Insert a test strip into the meter in the direction of the arrows.

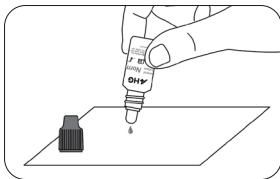


Note: Check the expiration and discard dates of the test strips. Do not use the expired test strip.

3. The meter turns on after a beep. An image of a test strip with a flashing blood drop will appear letting you know the meter is ready to test.

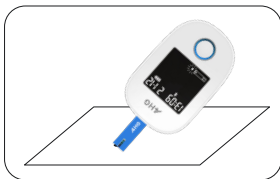


4. Shake the control solution bottle thoroughly. Gently squeeze the bottle to discard the first drop, then squeeze out a second small drop onto a clean, nonabsorbent surface.



Note: Do not apply control solution to the test strip directly from the bottle.

5. Immediately touch the tip of the test strip to the drop of control solution. The control solution is pulled into the test strip through the strip tip.



Note: If the control solution sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.

- Hold it in the drop until the meter beeps, and then you see the meter count down on the screen and followed with your control test result after a beep.



Understand Your Control Test Result

Compare your control test result with the ranges printed on the test strip vial label.

Notes: If your control test result is out of range:

- Check the expiry dates and discard dates of the test strip and control solution. Make sure that the test strip vial has not been opened for more than 6 months and the control solution bottle has not been opened for more than 6 months. Discard any expired test strips or control solution.
- Confirm the temperature in which you are testing is between 15°C – 40°C (59°F – 113°F).
- Make sure that the test strip vial and the control solution bottle have been tightly capped.
- Make sure the test strip was used immediately after removing it from the test strip vial.
- Make sure the control solution was mixed well.
- Confirm that you are using AHG brand control solution.
- Make sure that you followed the test procedure correctly.



After checking all of the conditions listed above, repeat the control solution test with a new test strip. If your results still fall out of the range indicated on the test strip vial label, your meter or test strips may not be working properly.

DO NOT use the system to test blood. Contact your distributor for help.

To turn your meter off, just remove the test strip. Dispose of the used test strips as medical waste. The result will be automatically marked and stored in the meter memory. Control results will be not included in your blood glucose averages.

Using the Meter Memory

Your meter automatically stores up to 500 results with the time and date. Test results are stored from the newest to the oldest.

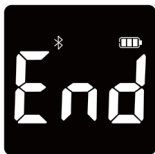
Notes:

- *If there are already 500 records in memory, the oldest record will be erased to make room for a new one.*
- *It is very important to set the correct time and date in the meter, please make sure the time and date are correct after you change your batteries.*

Viewing Your Test Results

When your meter is off, press  to turn meter on. After a beep, a symbol of strip flashes on the display. Continue to press  to review previous results in order. Results will be shown starting with the most recent. Each result will show the date and time the test was taken.

When **END** appears on the display, you have viewed all of the results in the memory.



Proper maintenance is recommended for best results.

Recharging the Battery

When the meter needs to be recharged, the Empty Battery () will appear. When the Empty Battery symbol () appears by itself on the screen, the meter cannot be used. You must recharge the battery before using your meter.

Notes:

The meter battery may be charged using one of the following options:

- *Micro USB cable (computer charging).*
- *Micro USB cable with the AC adapter (wall charging).*

If you need the Micro USB cable or AC adapter which are not included in your kit, please contact your local dealer.



Cautions:

- *Do not charge the meter outdoors or in wet environments.*
- *Do Not use the Micro USB cable, AC adapter or meter if it is damaged, discolored, abnormally hot, or has an unusual odor. Contact your local dealer.*
- *Do Not plug the AC adapter into wall outlet and leave it unattended.*
- *Verify that the wall outlet voltage matches the AC adapter voltage.*
- *Do Not allow unsupervised children to charge the meter battery.*



Cautions:

- *Do Not insert a test strip while the meter is connected to a computer or wall outlet.*

Notes:

- *Using the Micro USB cable or AC adapter charges the battery in about 2 hours.*
- *When using the USB port on your computer to charge the battery, be sure the computer is turned on and not in standby mode. If the meter does not charge, try using another USB port on your computer.*
- *To optimize battery life, it is best to recharge the battery when the Low Battery symbol () appears.*

Cautions:

- *If you use the AC adapter which not provided by American Health Gate, be sure it should match EN 60950-1;*
- *If you use the USB port on your computer to charge the battery, be sure it should match IEC60950.*

Caring for Your Glucose Monitoring System

Blood Glucose Meter

Your AHG Blood Glucose Meter does not require special maintenance or cleaning. A damp cloth and a mild detergent solution can be used to wipe the outside of the meter. Take care to avoid getting liquids, dirt, blood or control solution into the meter through the strip or data ports. It is recommended that you store the meter in the carrying case after each use.

The AHG Blood Glucose Meter is a precision electronic instrument. Please handle it with care. **Do not immerse the device in water or any cleaning solution.**

Lancing Device

Clean the lancing device using a soft cloth with mild soap and warm water as required. Use 70% Isopropyl Alcohol to disinfect the lancing device. Carefully dry the lancing device. **Do not immerse the lancing device in water or any cleaning solution.**

Troubleshooting Guide

What You See	What It Means	What You Should Do
	Blood or control solution was applied to the test strip before the flashing drop appeared on the display.	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
	The meter is sensing the use of a used or contaminated test strip.	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
	Incorrect test strip.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using an AHG test strip.
	Incorrect sample.	Discard the test strip and repeat the test with a new test strip. Make sure that only human capillary blood and AHG control solution can be used for the test.
	Temperature out of range.	Move to an area that is within the operating temperature for the meter. Let the meter adjust to this temperature for 20 minutes before performing a test.
	Potential hardware issue.	Restart the meter. If the problem continues, contact your local dealer.

Troubleshooting Guide

What You See	What It Means	What You Should Do
	Insert a test strip while the meter is connected to a computer or wall outlet.	When the charge is completed (about 2 hours when charging an empty battery), remove the Micro USB cable from the meter, and then take a test.
	Insufficient sample.	Repeat test and apply enough sample to fill the test strip check window.
	Test result is above 600 mg/dL (33.3 mol/L).	Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes HI, contact your health care professional as soon as possible.
	It's failed to syncing Smartphone.	Turn on the meter, Smartphone's Bluetooth and the app, and try to pair again. If the problem continues, contact your local dealer.
	Test result is below 10 mg/dL (0.6 mmol/L).	Repeat the test using a new test strip. If your result still flashes LO, contact your health care professional as soon as possible.

Symptoms of High or Low Blood Glucose

You can better understand your test results by being aware of the symptoms of high or low blood glucose. According to the American Diabetes Association, some of the most common symptoms are:

Low blood glucose (Hypoglycaemia):

- Shakiness
- Sweating
- Fast heartbeat
- Blurred vision
- Confusion
- Fainting
- Irritability
- Seizure
- Extreme hunger
- Dizziness

High blood glucose (Hyperglycaemia):

- Frequent urination
- Excessive thirst
- Blurred vision
- Increased fatigue
- Hunger

Ketones (ketoacidosis):

- Shortness of breath
- Nausea or vomiting
- Very dry mouth

Limitations

The AHG Meter, AHG Test Strips, and AHG Control Solution have been designed, tested, and validated for use together to provide accurate blood glucose measurements. Do not use components from other manufacturers.

- Fresh capillary blood may be collected into test tubes containing sodium heparin or lithium heparin, provided the sample is tested within 10 minutes. Do not use sodium fluoride/oxalate or other anticoagulants or preservatives.
- Use only with whole blood. Do not use with serum or plasma samples.
- For use with whole blood only. Do not use serum or plasma samples.
- Very high (above 70%) or very low (below 20%) haematocrit levels may cause inaccurate results. Consult your doctor or healthcare professional to determine your haematocrit level.
- Abnormally high levels of vitamin C (ascorbic acid) or other reducing substances may cause falsely elevated blood glucose results.
- The system has been tested to measure glucose in whole blood within the range of 10 to 600 mg/dL (0.6–33.3 mmol/L).
- Triglycerides up to 3,000 mg/dL or cholesterol up to 500 mg/dL have no clinically significant effect on blood glucose results.
- The AHG Blood Glucose Monitoring System has been tested and shown to operate properly at altitudes up to 10,000 ft (3,048 metres).
- The system is not intended for use in severely ill patients.
- The system is not recommended for use in patients undergoing oxygen therapy.
- Blood samples from patients in shock, with severe dehydration, or in a hyperosmolar state (with or without ketosis) have not been evaluated and are not recommended for testing with this system.
- Dispose of blood samples and used materials carefully. Treat all blood samples as potentially infectious. Follow appropriate infection control procedures and comply with applicable local regulations when disposing of materials.

System Specifications

Feature	Specification
Measurement range	10 to 600 mg/dL (0.6-33.3 mmol/L)
Test measurement	Plasma-equivalent
Sample	Fresh capillary whole blood
Sample volume	About 0.5 μ L
Test time	5 seconds
Power source	Rechargeable 3.7 Volt Lithium-Ion battery
Charging current	100mAh, === Direct current
Battery type	Rechargeable, non-serviceable, 250mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)
Glucose units of measurement	Test results are displayed in mg/dL or mmol/L, depending on the country in which the device is distributed.
Memory	Up to 500 records with date and time
Automatic shutoff	2 minutes after last action
Dimensions	83 mm $\times$ 52 mm $\times$ 18.7 mm
Display size	32mm $\times$ 32 mm
Weight	Approximately 53g
Operating temperature	5-45°C
Operating relative humidity	10-90% (non-condensing)
hematocrit range	20-70%
Charging port	Micro USB
Bluetooth	Bluetooth Low Energy (BLE)

Index of Symbols

The following symbols may appear on the packaging and in these instructions for use.

Symbols	Explanation
	Consult instructions for use
	For in vitro diagnostic use only
	Manufacturer
	Temperature limitations
	Contains sufficient for <n> tests
	Use by
	Lot Number
	Authorized Representative
	Sterilized using irradiation
	Control range
	Catalogue number
	Model number
	Do not re-use
	Caution, consult accompanying documents
	Dispose of items according to local relevant laws regarding disposal and recycling
	Use by 6 months from the opening
	Series number
	Keep away from sunlight and heat

American Health Gate Co., LLC Limited Warranty

Limited Warranty. American Health Gate Co., LLC ("AHG") warrants AHG Blood Glucose Monitor AHG-2022 (the "Product") purchased from AHG, an AHG affiliate or an authorized AHG dealer at the point of original sale, shall be free of manufacturing defects in workmanship and material for the lifetime of the original retail purchaser (the "**Purchaser**") from the date of the original purchase (the "Warranty Period").

Non-Transferable. This Limited Warranty is to the Purchaser only and is not transferable to any other person or entity.

Exclusions from Warranty Coverage. AHG has no obligation under this Limited Warranty with respect to any defect or damage to the Product arising from any abuse, improper use or mishandling of the Product. The Limited Warranty shall not apply to any claimed defect or damage arising out of or being caused by any of the following, including, but not limited to:

- Failure to use the Product in accordance with AHG instructions or recommendations;
- Failure to assemble or install the Product according to AHG's instructions;
- Damage to the outside shield;
- Damage that has occurred during shipping;
- Removal, defacement or alteration of the serial number/QC seal;
- Routine maintenance items, normal wear and tear, cosmetic deterioration or electrical components damaged as a result of fluctuations in electric current;
- Warranty repairs made by anyone other than AHG or an authorized and qualified AHG dealer or designee;
- Damage or loss resulting from acts of nature, vandalism, theft, war or other events over which AHG has no control; or
- Exhaustion or depletion of consumable parts of the Product, including [lancets, test strips, USB-C charging cable, and packaging].

Warranty Process; Basis of Warranty. In the event that the Product appears to have defects in materials and/or workmanship under everyday use and service, Purchaser shall: (1) submit a claim for warranty online at: <https://americanhealthgate.com/contact-us> or via electronic mail or telephone, (2) provide the applicable information on the warranty card included in the instruction

manual accompanying the Product and submit such warranty card to AHG or an authorized AHG dealer via postal mail, or (3) present the Product to AHG or to an authorized agent, dealer or distributor of AHG where Purchaser purchased the Product (the "Place of Purchase"). In the event Purchaser delivers the defective Product to the Place of Purchase, an authorized agent at the Place of Purchase shall inspect the Product to determine eligibility for replacement under the terms of this Limited Warranty. The authorized agent at the Place of Purchase shall submit a claim to AHG to confirm that any defects in the Product are covered under this Limited Warranty. Upon determination that defects in the Product are covered by the terms of this Limited Warranty, the Purchaser's recovery shall be in the form of replacement of the Product. The cost of shipping and packaging to return the Product to AHG or to an authorized AHG dealer will be the sole responsibility of the Purchaser.

Remedy. Purchaser's sole and exclusive remedy under this Limited Warranty in the event of a defect in material or workmanship in the Product or any part or component thereof, during the Warranty Period is that AHG or an authorized AHG dealer will replace the Product. In the event a specific model of a Product has been discontinued and replacement with an identical model is not possible, AHG or an authorized AHG dealer will replace the defective Product with the latest model of such Product. This Limited Warranty shall be deemed null and void if repairs are undertaken by persons not authorized by AHG and if original AHG parts are not used in the repair of such defective Product. This exclusive remedy will not be deemed to have failed of its essential purpose so long as AHG has made reasonable efforts to replace the defective parts.

LIMITATIONS ON LIABILITY. THIS WARRANTY IS GIVEN BY AHG IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE, WHETHER EXPRESS OR IMPLIED BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE. THE REPLACEMENT OF THE PRODUCT IS THE EXCLUSIVE REMEDY. AHG SHALL NOT BE LIABLE TO THE PURCHASER OR ANYONE ELSE FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, INDIRECT, OR PUNITIVE DAMAGES, INCLUDING WITHOUT LIMITATION PERSONAL INJURY, DEATH, PROPERTY DAMAGE, LOST PROFITS, LABOR COSTS, OR ANY OTHER PECUNIARY DAMAGE, WHETHER DUE TO ANY DEFECT, DELAY, NONDELIVERY, NONPERFORMANCE, RECALL, BREACH BY AHG, OR OTHER REASON, ALL CLAIMS IN TORT, STRICT LIABILITY, AND FAILURE OF ESSENTIAL PURPOSE ARE WAIVED AND EXCLUDED, INCLUDING CLAIMS OF AHG'S NEGLIGENCE. AHG SHALL NOT BE LIABLE TO THE PURCHASER OR ANYONE ELSE IN TORT, STRICT LIABILITY, OR ANY OTHER LEGAL OR EQUITABLE THEORY FOR ANY ALLEGED DEFECT IN THE DESIGN OR MANUFACTURE OF THE PRODUCT OR FOR THE OMISSION OR ALLEGED INADEQUACY OF ANY WARNING. EXCEPT FOR THE LIMITED WARRANTY HEREIN, THE PURCHASER ACCEPTS THE PRODUCT "AS IS" WITH ALL FAULTS AND ASSUMES THE RISK OF LOSS FOR ANY DEFECT OR NONCONFORMITY. PURCHASER WAIVES, RELIEVES

AND RELEASES AHG FROM ANY AND ALL CLAIMS, CAUSES OR RIGHTS OF ACTION, AND LIABILITY FOR ANY REDHIBITORY, PATENT, OR LATENT VICES, WHETHER BY STATUTE OR COMMON LAW, OBVIOUS OR UNKNOWN, EASILY DISCOVERABLE OR HIDDEN, EXCEPT AS SPECIFICALLY PROVIDED IN THE WARRANTY. UNDER NO CIRCUMSTANCES SHALL AHG'S LIABILITY FOR ANY DEFECT IN THE PRODUCTS, WHETHER BASED ON CONTRACT, TORT, WARRANTY, STRICT LIABILITY, OR ANY OTHER THEORY, EXCEED THE PURCHASE PRICE OF THE DEFECTIVE PRODUCT. THERE ARE NO THIRD-PARTY BENEFICIARIES TO THIS AGREEMENT.

PURCHASER ACKNOWLEDGES AND DECLARES THAT PURCHASER HAS READ AND UNDERSTANDS ALL TERMS AND AGREES TO BE SO BOUND, AND THAT PURCHASER'S RECEIPT OF THE WARRANTY AND PRODUCT, AND ANY PAYMENT FOR THESE, SIGNIFIES THAT PURCHASER HAS VOLUNTARILY AND KNOWINGLY CONSENTED TO ALL TERMS, INCLUDING THE WAIVERS AND LIMITATIONS CONTAINED HEREIN.

Legal Rights. Some countries and/or states do not allow limitation on how long an implied warranty lasts or the exclusion or limitation of incidental or consequential damages, so the above limitations may not apply to Purchaser. This Limited Warranty gives you, the Purchaser, specific legal rights, which may vary from country to country and/or state to state. This Limited Warranty is understood to be the exclusive agreement between the parties relating to the subject matter hereof. No employee or representative of AHG is authorized to make any warranty in addition to those made in this agreement.

**American
Health
Gate**

American Health Gate Warranty Card

Please complete the warranty card that came with this product and mail it to:

American Health Gate LLC

450 Alaskan Way S., Suite 200, Seattle, WA 98104, USA

AHG Customer Support: +1 888 881 3479

www.americanhealthgate.com

Customer Name: _____

Telephone Number: _____

Email Address: _____

Where purchase: _____

Date of purchase: _____

Model: _____ Batch NO.: _____



Head office:

American Health Gate LLC

450 Alaskan Way S., Suite 200, Seattle, WA 98104, USA

www.americanhealthgate.com