

American Health Gate

BLOOD GLUCOSE MONITORING SYSTEM AHG-427B

INSTRUCTION MANUAL

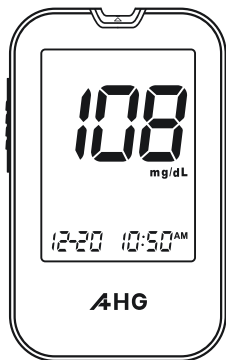


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BLOOD GLUCOSE MONITORING SYSTEM

Thank you for choosing the AHG-427B Blood Glucose Monitoring System. This Owner's Manual provides important information to help you use the system safely and accurately. Please read this manual thoroughly before using the system and keep it for future reference.

The system is designed with a no-coding feature and does not require user calibration.

Intended Use

The AHG-427B Blood Glucose Monitoring System is an in vitro diagnostic medical device intended for the quantitative measurement of glucose in fresh capillary whole blood samples obtained from the fingertip. Alternative site testing (palm or forearm) may be performed only under steady-state conditions when blood glucose levels are not changing rapidly.

The system is intended for self-testing by individuals with diabetes at home environment and for use by healthcare professionals in clinical settings as an aid in monitoring blood glucose levels.

The system is intended for single-patient use only and must not be shared to reduce the risk of infection. This system is not intended for the diagnosis or screening of diabetes, or for testing neonates.

Important Safety Instructions

- The meter is for single-patient use only. Do not share with others, including family members, to avoid infection risk.
- Disposable sterile safety lancets are for single use only. Use a new lancet each time; do not reuse or share.
- Used test strips and lancets are biohazardous and may transmit infectious diseases. Dispose according to local regulations.
- Changes or modifications not approved by the manufacturer may void compliance and user authority to operate the device.
- For use exclusively with AHG-427BS Blood Glucose Test Strips.

Read This Before Using

▲ WARNING: Misuse of this electrical device may cause electric shock, burns, fire, or other hazards.

Failure to follow these instructions may lead to inaccurate test results or injury. Close supervision required for use by children, elderly persons, or those with physical/cognitive limitations.

Safety Precautions

1. Do not immerse the meter in liquid or allow liquid to enter the device.
2. Use the meter only for its intended purpose as described in this manual.
3. Use only manufacturer-recommended accessories/components.
4. Do not use the meter in areas where aerosol sprays are being used or near excessive heat/hot surfaces.
5. Do not use the meter if it has been damaged or is not functioning properly.
6. Practice the testing procedure and perform all quality control checks as directed before testing blood glucose.
7. Consult a healthcare professional if you have questions regarding your results.

About Alternative Site Testing (AST)

Alternative site testing (AST) with this system may be performed only during steady-state blood glucose conditions, as described in this section.

Important: Alternative site testing has limitations. Please consult your healthcare professional before using AST.

What Is AST?

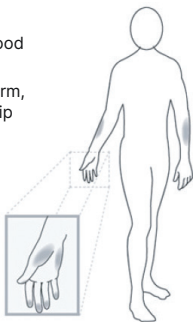
Alternative site testing (AST) refers to testing blood glucose using sites other than the fingertip.

This system allows testing from the palm or forearm, which may provide results comparable to fingertip testing when blood glucose levels are stable.

Advantages of AST

Fingertips contain a high concentration of nerve endings and may be more sensitive to pain.

Alternative sites such as the palm or forearm generally have fewer nerve endings and may be less painful than fingertip testing.



When to Use AST

Blood glucose levels can change rapidly due to food intake, medication, illness, stress, or exercise. Glucose changes appear faster in fingertip blood than in blood from alternative sites.

For this reason, use fingertip testing only:

- During or immediately after a meal
- During or after physical exercise
- When blood glucose levels may be changing rapidly

AST should be performed **ONLY** under the following conditions:

- In a fasting state or more than 2 hours after a meal
- Two (2) hours or more after insulin administration
- Two (2) hours or more after exercise

Limitations of AST

- Alternative site testing must not be used to calibrate continuous glucose monitoring (CGM) systems.
- Results obtained from AST must not be used for insulin dose calculations.

Do not use AST if:

- You suspect your blood glucose is low
- You are unaware of hypoglycemia
- You are testing for hyperglycemia
- Your test results do not match how you feel
- Your blood glucose levels are frequently fluctuating

Test Principle

The test is based on the measurement of an electrical current generated by the reaction between glucose in the blood sample and the reagents on the test strip. The meter measures this current and displays the corresponding blood glucose concentration.

The magnitude of the electrical current produced is proportional to the amount of glucose present in the blood sample.

Contents of the Kit

- 1 AHG-427B Blood Glucose Meter
- 30 AHG Disposable Safety Lancets
- 25 AHG-427BS Blood Glucose Test Strips
- 25 Alcohol Pads
- 2 AAA Alkaline Batteries
- 1 Instruction Manual

Note:

Optional items may not be included in all packages. Please verify the contents with your supplier. If any items are missing or appear damaged or opened, contact the place of purchase or refer to the warranty card.

Safety Lancet Warnings:

- *Use AHG Disposable Sterile Safety Lancets only before the labeled expiration date.*
- *Do not use the lancet if the protective cap is missing or damaged.*
- *Use with caution in individuals with bleeding or coagulation disorders. Consult a healthcare professional if unsure.*
- *Keep out of reach of children.*
- *For single use only. Do not reuse or re-sterilize.*

Meter Overview

STRIP PORT

Insert the test strip into the strip port. The meter will turn on automatically.

STRIP EJECTOR

Slide forward to eject the test strip after the test.

LCD DISPLAY

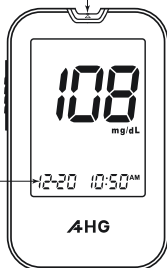
Displays symbols and simple messages to guide you through the test.

"M" BUTTON

Used to turn on the meter and enter memory mode.

"S" BUTTON

Used to set up the meter.



Test Strip Description

Each strip is single-use only. The test strip includes the following parts:

ABSORBENT HOLE

Apply a drop of blood here. The blood will be drawn into the strip automatically.

TEST STRIP HANDLE

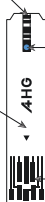
Hold this part to insert the strip into the meter's slot.

CONFIRMATION WINDOW

Confirms whether enough blood has been drawn into the absorbent hole.

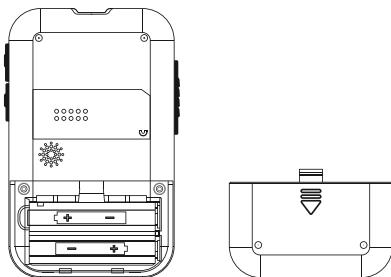
CONTACT BARS

Insert this end into the meter, pushing firmly until it stops.



Installing the Battery

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

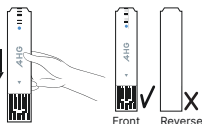


Environment Protection:

Waste electrical products must not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice.

Important Notes:

- Use each test strip only once. Do not bend, cut, or reuse test strips.
- Test results may be inaccurate if the contact bars are not fully inserted into the test strip port.
- Ensure that the front side of the test strip faces upward when inserting it into the meter.



Meter Screen Display Messages

TEST STRIP SYMBOL

Appears when the meter is turned on.

BLOOD DROP SYMBOL

Flashes when the meter is ready for a blood sample.

KETONE REMINDER

Appears when blood glucose is above 240 mg/dL.

MEASURING MODES

Indicates the selected measuring mode (General, AC, PC, or CTL).

DATE

Displays the test date.

BLUETOOTH SYMBOL

Indicates Bluetooth connection status.

TEST RESULT

Displays the blood glucose result.

LOW BATTERY SYMBOL

Indicates low battery power.

MEASUREMENT UNIT

Displays the measurement unit (mg/dL or mmol/L).

CTL SYMBOL

Appears during a control solution test.

MEMORY SYMBOL

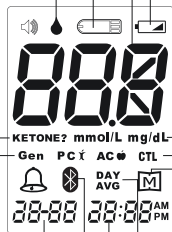
Appears when reviewing stored test results.

AVERAGE VALUE

Indicates the displayed value is an average result.

TIME

Displays the test time.



How to Connect AHG-427B with MedM Health App

1. Download and install the App

Search for "MedM Health" on Google Play, App Store, or download the Android APK directly from:

<https://www.medm.com/apps/health.html>



All-in-One Health Monitoring Diary App
All-in-one health monitoring tool for personal and family use

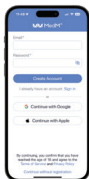


2. Register and Log In

Open the app, create an account, and log in as prompted.



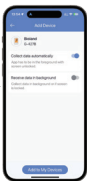
Get your app



3. Add your device

Tap "My Devices" in the left menu, then select "Add New." Turn on the AHG-427B Blood Glucose Meter to enable Bluetooth.

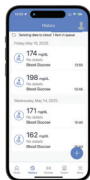
The app will automatically search for the device and display it in the list. Select it to complete pairing.



4. Start Measurement

Once connected, you can begin testing your blood glucose.

The test results and charts will automatically appear in the app.



Tip 1: To change the unit of measurement, go to the app's Settings → Units and select mg/dL or mmol/L.

Tip 2: For more information on app functions, refer to the "Help" section in the left menu of the app.

Setting the Meter and Deleting the Memory

1. Setting the Date and Time

1.1 Setting the Year

Press and hold the "S" button for 3 seconds until the last two digits of the year flash on the display.

Press the "M" button until the correct year appears, then press "S" to confirm and proceed.



1.2 Setting the Month

When the month flashes, press the "M" button to select the correct month. Press "S" to confirm.



1.3 Setting the Day

When the day flashes, press the "M" button to select the correct day. Press "S" to confirm.



1.4 Setting AM/PM

When AM or PM flashes, press the "M" button to select the correct setting. Press "S" to confirm.



1.5 Setting the Hour

When the hour flashes, press the "M" button to select the correct hour. Press "S" to confirm.



1.6 Setting the Minute

When the minute flashes, press the "M" button to select the correct minute. Press "S" to confirm.



2. Setting the Measurement Unit (mg/dL or mmol/L)

1. Press the "S" button.
The measurement unit (mg/dL) will flash on the display.
2. Press and hold the "M" button for 2 seconds to switch between mg/dL and mmol/L.
3. Select the desired unit and press "S" to confirm.

Once the unit is selected, all test results will be displayed in the chosen unit.



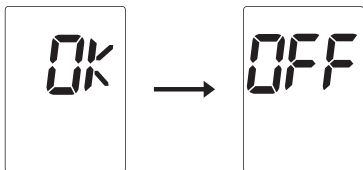
3. Deleting the Memory

1. Press the "S" button until "dEL" appears on the display and the "M" icon flashes.
2. Press the "M" button once to enter delete mode.
3. Press the "M" button again to delete all stored results.

The meter will display "OK" to confirm that all memory has been deleted.



- If you do not want to delete the memory, press the "S" button to skip this step.
- The meter will automatically turn OFF, and the setup process will be completed.



Notes:

- *Date, time, unit, and memory deletion can only be set while the meter is in Setting Mode.*
- *If no button is pressed for 3 minutes while in Setting Mode, the meter will automatically turn OFF.*

Four Measuring Modes

The AHG-427B Blood Glucose Meter provides four (4) measuring modes: General (GEN), AC, PC, and CTL.

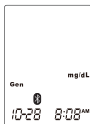
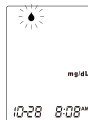
The **CTL mode** is used when testing with a control solution.

Refer to the table below for details.

Modes	Use When
General	Testing at any time of day, regardless of meal time.
AC	For testing before a meal.
PC	For testing after a meal.
CTL	Testing with control solution.

Selecting a Measuring Mode

1. Start with the meter turned off.
2. Insert a test strip to turn on the meter. The display will show a flashing blood drop symbol.
3. Short press the "S" button to switch between General (GEN), AC, and PC modes.
4. Long press the "S" button to select CTL mode.



AHG Disposable Sterile Safety Lancets Overview

The AHG Disposable Sterile Safety Lancet is a sterile, single-use medical device designed for capillary blood sampling. It features:

- Gauge: 28G
- Needle Diameter: 0.36 mm
- Penetration Depth: 1.8 mm
- Color: Transparent
- Safety Feature: Pre-loaded needle automatically retracts after use to prevent reuse.
- Sterilization: Sterilized using irradiation.
- Shelf Life: 5 years from manufacture date if stored properly.

Storage:

- Store in a cool, dry, well-ventilated area, below 30°C (86°F).
- Keep away from direct sunlight, moisture, and corrosive substances.

Warning:

- *Never share an AHG Sterile Disposable Safety Lancet with another person.*
- *Use a new lancet for each test (single-use only).*
- *Avoid getting lotion, oils, dirt, or debris on the lancet.*
- *Do not use if the protective cap is missing or damaged.*



Setting Up the AHG Disposable Sterile Safety Lancet

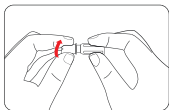
Fingertip Testing Using the AHG Disposable Sterile Safety Lancet:

Follow the steps below to safely obtain a capillary blood sample using the AHG Disposable Sterile Safety Lancet:

Note: Wash your hands thoroughly with soap and warm water. Dry them well.

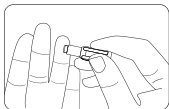
1. Prepare the Lancet:

- Hold the device firmly and twist off the protective cap.
- Do not pull or force the cap to avoid damaging the lancet.



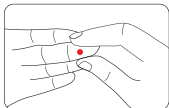
2. Position the Lancet:

- Gently press the lancet tip against the blood collection site (e.g., fingertip or approved alternate site).



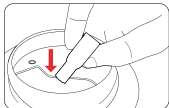
3. Activate the Lancet:

- Press down firmly to puncture the skin and collect the blood sample.



4. Dispose of the Lancet:

- Immediately discard the used lancet into a designated sharps container in accordance with local regulations.



Potential Biohazard

Dispose of the used test strips as medical waste.

Performing a Blood Glucose Test

Step 1: Wash your hands with soap and warm water. Dry thoroughly.

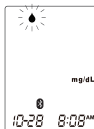
Step 2: Remove one test strip from the vial. With clean, dry hands, you may touch the test strip anywhere on its surface. Do not bend, cut, or modify the test strip. Use the test strip immediately after removing it from the vial.

Step 3: Insert the test strip into the test strip port of the meter. The meter will turn on automatically, and the date and time will appear on the display.

Note:

- Use only AHG-427BS Blood Glucose Test Strips; other strips may produce inaccurate results.

Step 4: When the blood drop symbol flashes on the display, select the appropriate measuring mode if needed. Refer to the section "Measuring Modes" for details on selecting General or Control (CTL) mode.



Step 5: Obtain a blood sample using AHG disposable sterile safety lancet, and apply the blood to the absorbent opening of the test strip.

Step 6: When enough blood has filled the confirmation window, the meter will beep, indicating the test has started. A 5-second countdown will appear on the display.



Note: Ensure that the confirmation window is completely filled with blood.

Step 7: The blood glucose result, along with the date and time, will appear on the display. Test results are automatically stored in the meter memory.



- If Bluetooth is enabled and connected, the Bluetooth symbol will flash while the meter transmits the test result to a compatible device.

Important Information About Test Results

The results obtained from this meter are plasma-calibrated. This allows comparison of your meter results with laboratory measurements.

Always follow the instructions provided by your physician or healthcare professional. Do not change your treatment or medication based on test results without consulting a healthcare professional.

Step 8: Eject the used test strip and dispose of it according to local regulations. The meter will automatically turn OFF after the test strip is ejected.

Reference Ranges:

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.

Note: Please consult with your healthcare provider to determine the target blood glucose range that is appropriate for you.

Control Solution Test

Materials needed:

- AHG-427B Blood Glucose Meter
- AHG 427BS Test Strips
- AHG Glucose Control Solution

When to perform a control solution test:

- When you suspect the meter or test strips are not working properly.
- When blood glucose results do not match how you feel.
- After test strips have been exposed to extreme temperatures or humidity.
- After dropping or damaging the meter.
- When using a new vial of test strips.

The control solution test verifies that the meter and test strips are working together properly and that you are performing the test correctly.

Performing a Control Solution Test

Step 1: Insert a test strip into the meter to turn it on. Wait until the blood drop symbol appears on the display.

Step 2: Long press the “S” button to select CTL mode. For more information, refer to the section “The Four Measuring Modes.”

Step 3: Apply the control solution:

- Shake the control solution vial well before use.
- Squeeze out and discard the first drop.
- Squeeze a second drop and place it on the tip of the vial cap.
- Touch the absorbent hole of the test strip to the drop.
- When the confirmation window is completely filled, the meter will begin counting down automatically.



Important: To avoid contaminating the control solution, do not apply the control solution directly onto the test strip.

Step 4: The result of the control solution test will appear on the display. Results obtained in CTL mode are not stored in the meter memory.

The control solution test result must fall within the range printed on the test strip vial label. If the result is outside this range, repeat the test.

Results outside the specified range may be caused by:

- Errors in performing the test
- Expired or contaminated control solution
- Expired or contaminated test strips
- Meter malfunction

If control solution results continue to fall outside the acceptable range, do not use the meter. Contact your distributor or customer support immediately.

Viewing Stored Results

The meter stores up to 500 blood glucose test results, including the date and time. It also provides 7-, 14-, 21-, 30-, 60-, and 90-day averages of blood glucose results.

Note: Control solution test results are not included in the average calculations.

Recalling Stored Test Results

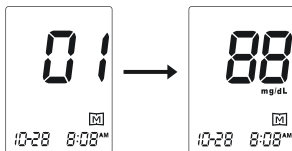
1. With the meter turned off, press the "M" button to turn it on.
2. The "M" symbol will flash, and the date and time will be displayed on the screen. Press the "M" button again to display the most recent test result with date and time.



Each time you press and release the "M" button, the next most recent result will appear. The meter can recall up to 500 stored test results, displayed in chronological order.

When the memory is full, the oldest result is automatically deleted and the newest result is stored.

3. Press the "S" button to turn off the meter.

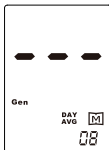


Reading the Average of Blood Glucose Results

With the meter turned off, press and hold the "M" button until "DAY AVG" flashes on the screen, then release the button.

- The 7-day average in General mode will be displayed first.
- Press the "M" button again to view the 7-day average in PC mode.
- Press the "M" button again to view the 7-day average in AC mode.

The same procedure applies to viewing 14, 21, 30, 60, and 90-day averages under each measurement mode.



Comparing Meter and Laboratory Results

The AHG-427B Blood Glucose Meter provides plasma-equivalent results. Results may differ from laboratory measurements due to normal biological variation and different testing methods. Meter results can also be affected by conditions that do not influence laboratory equipment.

To ensure an accurate comparison between your meter and laboratory results, follow these guidelines:

Before Visiting the Laboratory:

- Confirm the meter and test strips are functioning correctly by performing a control solution test.
- If possible, fast for at least 8 hours before testing.
- Take the meter with you to the laboratory for side-by-side testing.

At the laboratory:

- Ensure that the blood samples for the laboratory and the meter are collected and tested within 15 minutes of each other.
- Wash hands thoroughly before obtaining a blood sample.
- Use fresh capillary whole blood only.
- Do not use the meter with blood collected in gray-top test tubes or with anticoagulant-treated samples.

Care and Storage

Handle the meter with care; dropping or impacting the device may cause damage. Do not expose the monitoring system, test strips, or control solution to extreme conditions, such as:

- High humidity or excessive dust.
- Extreme temperatures (heat or freezing).

Storage Conditions:

- Test Strips: 4 °C to 30 °C; humidity < 80%
- Meter: -20 °C to 55 °C; relative humidity ≤ 93%

Always wash and dry your hands thoroughly before handling the meter or strips. Discard used disposable sterile safety lancets in an approved sharps container.

Cleaning and Disinfection

Cleaning and disinfection are essential to ensure device performance and to reduce the risk of infection and cross-contamination.

Use CaviWipes® (EPA Registration No. 46781-8) or an equivalent disinfectant approved for medical devices, following the manufacturer's instructions for use.

Ensure the meter is completely dry before performing a test.

Cleaning and Disinfection Frequency

- Single-Patient Use: The meter may be cleaned and disinfected up to 5–6 times per day.
- The meter is designed to withstand approximately 11,000 cleaning and disinfection cycles (1 cycle = 1 cleaning + 1 disinfection) over its 5-year expected service life.

Cleaning and Disinfection Procedure

1. Before testing, wash hands thoroughly with soap and water. If assisting another person, the caregiver shall wear disposable gloves.
2. Cleaning: After testing, use one disinfectant wipe to scrub the meter housing, buttons, display lens, markings, USB cover, and support areas (front and back) for at least 10 seconds until all visible soil is removed.
3. Use a new disinfectant wipe to disinfect the same surfaces. Ensure all surfaces remain visibly wet for a minimum of 2 minutes.
4. Remove and discard gloves in accordance with local healthcare waste regulations.

Important Notes:

- *Each disinfection step must always be preceded by a cleaning step.*
- *If the meter is handled by another person providing testing assistance, it must be cleaned and disinfected before the next use.*
- *Wash hands thoroughly with soap and water after handling the meter, test strips, or disposable sterile safety lancets.*

Error Messages and Symbols

Message	What It Means	What You Should Do
	Blood glucose level is below 20 mg/dL.	Indicates severe hypoglycemia. Contact your healthcare professional immediately.
	Blood glucose level is above 600 mg/dL.	Indicates severe hyperglycemia. Seek immediate medical attention.
	Meter is ready to perform a control solution test.	Apply a drop of control solution to the test strip.
	Battery power is low.	Replace the batteries as soon as possible.
	A used or contaminated test strip was detected.	Discard the strip. Use a new test strip and repeat the test.
	Test strip was removed too early or insufficient blood was applied.	Repeat the test using a new test strip.
	Meter malfunction or system error.	Repeat the test with a new test strip. If the error persists, contact customer support.
	Ambient temperature is outside the operating range (below 10°C (50°F) or above 40°C (104°F)).	Perform the test in an environment between 10°C–40°C (50°F–104°F).

Troubleshooting

Problem	Causes	Solutions
Display remains blank after inserting the test strip.	1. Batteries are installed incorrectly. 2. Batteries are depleted. 3. Excessive delay between inserting strip and testing. 4. Test strip not fully inserted.	1. Install battery correctly. 2. Replace with new batteries. 3. Reinsert the strip and perform the test promptly. 4. Fully insert the test strip.
Test results are inconsistent or control solution results are outside the specified range	1. Insufficient blood or control solution sample. 2. Expired test strip or control solution. 3. Test strip damaged by heat or humidity. 4. Testing environment outside recommended temperature range.	1. Repeat the test with a new strip; ensure enough sample is applied. 2. Repeat the test using unexpired materials. 3. Perform a control solution test with a new test strip. Replace the test strip vial if results remain out of range. 4. Move the system to a room-temperature environment and wait 30 minutes before retesting.
Meter countdown does not start.	Test strip was not inserted correctly or is damaged.	Remove the strip and repeat the test using a new strip.

System Specifications

Feature	Specification
Model	AHG-427B (For use with AHG-427BS Blood Glucose Test Strips and AHG Glucose Control Solution)
Measuring Method	Amperometric technology using glucose oxidase
Measuring Range	20–600 mg/dL (1.1–33.3 mmol/L)
Blood Sample	Fresh capillary whole blood
Minimum Sample Volume	0.7 µL
Memory Capacity	Stores up to 500 blood glucose results
Display	LCD with backlight
Power Source	DC 3 V (2 × AAA alkaline batteries)
Battery Life	Approximately 500 tests under normal use
Dimensions	90 mm (L) × 54 mm (W) × 13 mm (H)
Weight	Approx. 48 g (excluding batteries)
Operating Conditions	10°C–40°C (50°F–104°F), relative humidity ≤80%
Storage Conditions (Meter)	–20°C–55°C (–4°F–131°F), relative humidity ≤93%
Storage Conditions (Test Strips)	4°C–30°C (39°F–86°F), relative humidity <80%
Service Life	Lifetime international warranty
Compatible App	MedM Health (available on iOS and Android)

Performance Characteristics

Measurement Precision

Repeatability

Mean Glucose (mg/dL)	40.3	82.0	130	202	325
SD (mg/dL)	2.6	3.7	5.1	6.6	8.4
CV (%)	-	4.5	3.9	3.3	2.6

Measurement Precision

Mean Glucose (mg/dL)	44.4	108.1	342
SD (mg/dL)	3.2	3.3	7.1
CV (%)	-	3.3	2.0

System Accuracy

For glucose concentrations < 100 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
86/180 (47.8%)	149/180 (82.8%)	176/180 (97.8%)

For glucose concentrations ≥ 100 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
203/420 (48.3%)	360/420 (85.7%)	415/420 (98.8%)

For glucose concentrations between 40.7 mg/dL and 549 mg/dL:

Within ±15 mg/dL or ±15%	Within (±0.83 mmol/L or ±15%)
591/600 (98.5%)	

Limitations of Use

- The Blood Glucose Monitoring System is not intended for use in neonates and is not designed for use with arterial blood, serum, or plasma.
- The meter should be used exclusively with AHG-427BS Blood Glucose Test Strips.
- Do not use the device at altitudes above 10,744 feet (3,275 m). Use outside specified environmental conditions may result in inaccurate results.
- Certain substances, when present at levels higher than normal or therapeutic concentrations, may cause significant interference, with results differing by more than $\pm 10\%$. These substances include ascorbic acid (vitamin C), uric acid, hemoglobin, acetaminophen (paracetamol), dopamine, L-dopa, and tolbutamide. At normal concentrations, these substances do not affect test results.
- Do not use samples with severe hemolysis, icterus, or high lipemia, as inaccurate results may occur.

Interfering Substances

The following compounds may produce inaccurate blood glucose results when present at concentrations greater than the levels listed below.

Compound	Limitations
Acetaminophen	≤ 8.0 mg/dL
Ascorbic Acid (Vitamin C)	≤ 5.0 mg/dL
Bilirubin	≤ 90 mg/dL
Cholesterol	≤ 500 mg/dL
Creatinine	≤ 5.0 mg/dL
Dopamine	≤ 2.0 mg/dL
EDTA	≤ 360 mg/dL
Galactose	≤ 900 mg/dL
Gentisic Acid	≤ 5.0 mg/dL
Glutathione	≤ 53 mg/dL
Hemoglobin	≤ 500 mg/dL
Heparin	$\leq 8,000$ U/dL

Compound	Limitations
Ibuprofen	≤ 50 mg/dL
Icodextrin	≤ 10 mg/dL
L-Dopa	≤ 900 mg/dL
Maltose	≤ 3.0 mg/dL
Methyldopa	≤ 25 mg/dL
Pralidoxime Iodide	≤ 60 mg/dL
Salicylate	≤ 100 mg/dL
Tolazamide	≤ 400 mg/dL
Tolbutamide	$\leq 2,000$ mg/dL
Triglycerides	≤ 8.0 mg/dL
Uric Acid	≤ 100 mg/dL
Xylose	≤ 50 mg/dL

Traceability

Results obtained using the AHG-427B Blood Glucose Monitoring System with AHG-427BS Test Strips were compared to parallel measurements performed using the YSI 2300 STAT Plus Glucose Analyzer, which is traceable to a recognized reference method.

User Performance Evaluation

A study conducted with 100 lay users testing fingertip, palm, and forearm capillary blood samples demonstrated:

- **Glucose < 100 mg/dL:**
Fingertip 96.3%, Palm 96.3%, Forearm 96.3% within ± 15 mg/dL of laboratory values.
- **Glucose $\geq$ 100 mg/dL:**
Fingertip 99.3%, Palm 98.6%, Forearm 98.6% within $\pm 15\%$ of laboratory values.

The system meets the requirements of EN ISO 15197:2015.

Electrical and Safety Standards

This meter complies with:

- CISPR 11, Class B (Radiated Emissions Only)
- IEC 61326-1 / IEC 61326-2 (Immunity requirements)
- EN ISO 15197:2015 (Electrical immunity related to glucose monitoring systems)

Caution: Do not use the equipment in the presence of aerosol sprays or when oxygen is being administered.

FCC ID: 2AHLE-BGMB002

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

Index of Symbols

These symbols may appear on the packaging and in the instructions for the AHG system.

Symbol	Description	Symbol	Description
	In vitro diagnostic use only		Medical device
	Caution		Sterilized using irradiation
	Consult instructions for use		Manufacturer
	Batch code		Model number
	Catalog number		Unique device identification
	Date of manufacture		Temperature limitations
	Use-by		Control
	Keep away from sunlight		Authorized representative in the EU
	Keep dry		Series number
	Do not reuse		Dispose of according to local regulations

American Health Gate Co., LLC Limited Warranty

Limited Warranty. American Health Gate Co., LLC ("AHG") warrants AHG Glucose Monitoring System AHG-427B (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 [batteries, test strips, safety lancets, 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