
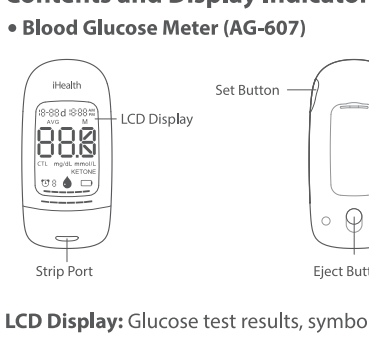
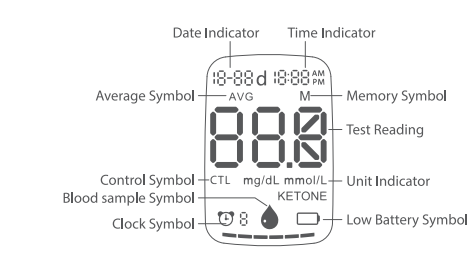
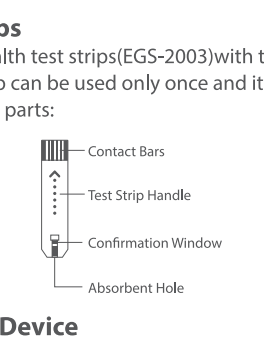
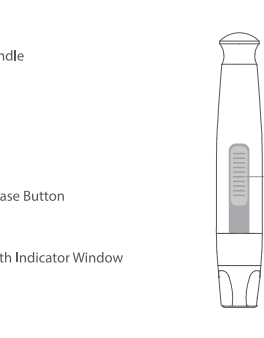
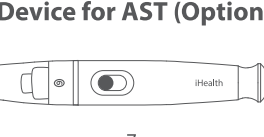
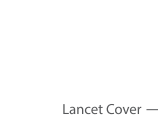

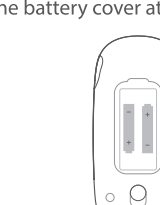

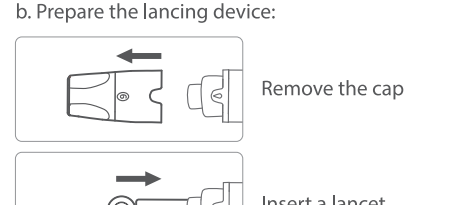





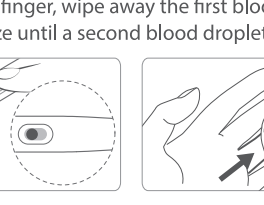
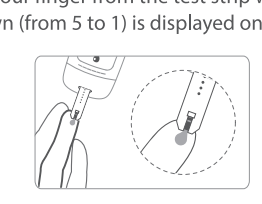
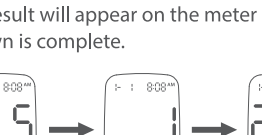

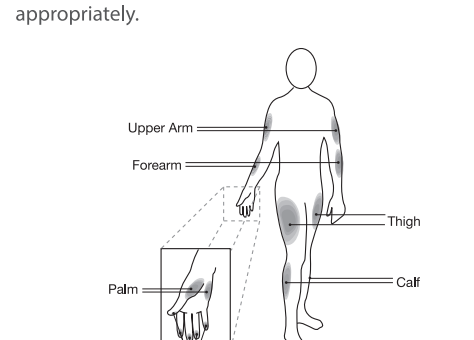
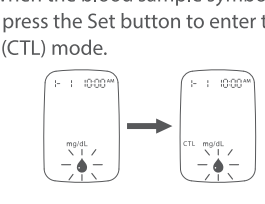


<p><b>iHealth Acacia</b> Blood Glucose Monitoring System Model: AG-607</p>  <p><b>INSTRUCTION MANUAL</b> For in vitro diagnostic use only. Read instructions before use for self-testing.</p>	<p><b>Table of Contents</b></p> <p>Introduction ..... 1 Intended Use ..... 1 Important Safety Instructions ..... 2 Limitations of Use ..... 3 Box Contents ..... 4 Contents and Display Indicators ..... 4 Test Principle ..... 5 Important Test Information ..... 5 Setup and Operation ..... 9 Cleaning and Disinfection ..... 10 Information about Alternative Site Testing (AST) ..... 22 Important Information about Control Solution Tests ..... 24 Comparing Glucose Meter Test Results with Laboratory Results ..... 27 Specifications ..... 28 Maintenance and Troubleshooting ..... 30 Electromagnetic Compatibility Information ..... 34 Explanation of Symbols ..... 41</p>	<p><b>Introduction</b></p> <p>Thank you for purchasing the Health Acacia Blood Glucose Monitoring System. This manual provides important information to help you use the system properly. Before using this product, please read the instruction manual thoroughly. If you have questions regarding this product, please contact customer service or your care provider.</p> <p><b>Intended Use</b></p> <p>The Health Acacia Blood Glucose Monitoring System is intended to be used for:</p> <ul style="list-style-type: none"> <li>Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf, or thigh.</li> <li>The Health Acacia Blood Glucose Meter (AG-607), to check that the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.</li> </ul> <p><b>Important Safety Instructions</b></p> <p>Please read the following information carefully before using the Acacia Blood Glucose Monitoring System. Always keep these instructions in a safe place for reference.</p> <ul style="list-style-type: none"> <li>The glucose meter and lancing device are for single patient use. Do not use either on multiple patients.</li> <li>Do not share the meter or lancing device with anyone, including other family members.</li> <li>Do not place the blood glucose monitoring system in or near liquid.</li> <li>Use the blood glucose monitoring system only for the purpose described in the instruction manual.</li> <li>Use only accessories (i.e., test strips, control solution, lancing device, and lancets) that are supplied by the manufacturer.</li> <li>Do not use the blood glucose monitoring system if it</li> </ul>	<p>(AG-607) to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf, or thigh.</p> <ul style="list-style-type: none"> <li>The control solutions (Level II) are intended for use with the Health Acacia Blood Glucose Meter (AG-607), to check that the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.</li> </ul> <p><b>Important Safety Instructions</b></p> <p>Please read the following information carefully before using the Acacia Blood Glucose Monitoring System. Always keep these instructions in a safe place for reference.</p> <ul style="list-style-type: none"> <li>The glucose meter and lancing device are for single patient use. Do not use either on multiple patients.</li> <li>Do not share the meter or lancing device with anyone, including other family members.</li> <li>Do not place the blood glucose monitoring system in or near liquid.</li> <li>Use the blood glucose monitoring system only for the purpose described in the instruction manual.</li> <li>Use only accessories (i.e., test strips, control solution, lancing device, and lancets) that are supplied by the manufacturer.</li> <li>Do not use the blood glucose monitoring system if it</li> </ul>	<p>has sustained any damage or is not working properly.</p> <ul style="list-style-type: none"> <li>Do not block test ports or place the blood glucose monitoring system on soft surfaces that may block them. Keep test ports free from lint, hair, debris, etc.</li> <li>Do not place anything on top of the blood glucose monitoring system.</li> <li>Do not insert any objects other than test strips into the opening of the blood glucose system.</li> <li>All parts of the system are considered biohazards and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.</li> <li>Please refer to the resources identified below for detailed information: <ul style="list-style-type: none"> <li>“CDC. Clinical Reminder: Use of Fingertick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens” <a href="http://medlib.iahm.mod.edu/enr/cdc/www.cdc.gov/infectioncontrol/guide/guide/guide.html">http://medlib.iahm.mod.edu/enr/cdc/www.cdc.gov/infectioncontrol/guide/guide/guide.html</a></li> <li>“Infection Prevention during Blood Glucose Monitoring and Insulin Administration” <a href="https://www.cdc.gov/clic/dccs/addenda/dcc0313/07B_CLIC_2013March_Glucose_Monitoring.pdf">https://www.cdc.gov/clic/dccs/addenda/dcc0313/07B_CLIC_2013March_Glucose_Monitoring.pdf</a></li> </ul> </li> </ul> <p><b>Limitations of Use</b></p> <ul style="list-style-type: none"> <li>The Acacia Blood Glucose Monitoring System is not intended for use on neonates.</li> </ul>	<ul style="list-style-type: none"> <li>The meter is not intended for use on an artery blood, serum, plasma, and venous blood samples.</li> <li>The system should be only used with the EG-2003 test strips.</li> <li>The system cannot be used above an altitude of 10,744 feet (3275 meters).</li> <li>Drugs containing acetaminophen (e.g., Tylenol®) and other medications containing acetaminophen, blood concentrations &gt;5 mg/dL and Vitamin C (ascorbic acid, blood concentrations &gt;4 mg/dL), at doses higher than recommended, may interfere with your glucose meter and deliver inaccurate results.</li> <li>Not for use in patients in a hyperglycemic hyperosmolar state, with or without ketosis.</li> <li>Not for use on critically ill patients.</li> <li>Not to be used for patients who are dehydrated, hypertensive, hypotensive, or in shock.</li> <li>Do not use during, or soon after, xylene absorption testing.</li> </ul> <p><b>Box Contents</b></p> <p>Package contents may vary depending on sales channels. Please refer to the contents listed on the package.</p> <ol style="list-style-type: none"> <li>Blood Glucose Meter (AG-607)</li> <li>2 x AAA Batteries</li> <li>Test Strips (EG-2003) x 3</li> <li>Lancing Device</li> <li>Lancet x 1</li> </ol>	<p>6. Control Solution (Level II)® 7. Instruction Manual 8. Carrying Bag * The package contents may vary across different sales channels.</p> <p><b>Contents and Display Indicators</b></p> <p>• <b>Blood Glucose Meter (AG-607)</b></p>  <p><b>LCD Display:</b> Glucose test results, symbols, and messages appear here.</p> <p><b>Strip Port:</b> Insert the test strip into the strip port to automatically turn on the meter.</p> <p><b>Set Button:</b> Located on the left side of the meter. It is used to turn on the meter and set the meter's parameters.</p> <p><b>Mem Button:</b> Located on the right side of the meter. It is used to turn on the meter and view past test results.</p> <p><b>Eject Button:</b> Located on the back side of the meter. It is used to automatically remove the test strip.</p>	 <p><b>Date Indicator:</b> Displays the meter's date.</p> <p><b>Time Indicator:</b> Displays the meter's time.</p> <p><b>Average Symbol:</b> Displays the 7, 14, 28, 60, 90 day averages.</p> <p><b>Memory Symbol:</b> Appears when checking the past test results.</p> <p><b>Test Reading:</b> Displays glucose results.</p> <p><b>Control Symbol (CTL):</b> Appears when doing a control solution test and indicates that the result will not be stored in the memory.</p> <p><b>Unit Indicator:</b> Appears with test results in mg/dL.</p> <p><b>Blood Sample Symbol:</b> Flashes when it is ready to apply the sample.</p> <p><b>Check Symbol:</b> Indicates alarm is set; up to four alarms can be stored.</p> <p><b>Low Battery Symbol:</b> Appears when the batteries are low to indicate time for replacement.</p>																																																																																																																								
<p>• <b>Test Strips</b></p> <p>Use only Health test strips (EG-2003) with the meter. Each test strip can be used only once and it consists of the following parts:</p>  <ul style="list-style-type: none"> <li>Contact Bars</li> <li>Test Strip Handle</li> <li>Confirmation Window</li> <li>Absorbent Pad</li> </ul> <p>• <b>Lancing Device</b></p>  <ul style="list-style-type: none"> <li>Head</li> <li>Release Button</li> <li>Cap</li> <li>Depth Indicator Window</li> <li>Eject Button</li> </ul> <p>• <b>Lancing Device for AST (Optional)</b></p> 	<p>• <b>Lancets</b></p>  <p>• <b>Control Solution (Level II)</b></p>  <p><b>Note:</b></p> <p>1. If any items printed on the package are missing from your package, or if the package appears to have been opened prior to your use, please contact customer service. The package contents may vary across different sales channels. Please verify the contents using your package label.</p> <p><b>Test Principle</b></p> <p>Testing with the Acacia Blood Glucose Monitoring System is based on the measurement of electrical currents generated by the reaction of glucose with the reagent of the strip. The system measures the current and converts it to the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.</p>	<p><b>Important Test Information</b></p> <p><b>Please read the following:</b></p> <ol style="list-style-type: none"> <li>Severe dehydration and excessive water loss may cause inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.</li> <li>Inaccurate results may occur in severely hypertensive individuals or patients who are in shock. Test results that are lower than actual values may occur in individuals who are in a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.</li> <li>If you think your blood glucose results are inconsistent with how you are feeling or the symptoms that you are experiencing, repeat the test. If you continue to experience symptoms and/or similar results, follow the treatment advice of your healthcare professional.</li> <li>If you are experiencing symptoms that are inconsistent with your blood glucose test, and you have followed all of the instructions provided in this Instruction Manual, consult your healthcare professional immediately.</li> <li>Use only fresh, whole blood samples to test your blood glucose.</li> <li>Do not use test strips that are expired or appear to be damaged, as they may return inaccurate results.</li> <li>The lancing device is for self-use only. Do not share or reuse lancets. Please refer to the Lancing Device Manual for the detailed procedure.</li> </ol>	<p><b>Setup and Operation</b></p> <p><b>Setup</b></p> <p>• Open the battery cover at the back of the meter.</p>  <p>• Insert two "AAA" batteries. Make sure the batteries are inserted according to the positive and negative marks ("+" and "-") printed in the battery housing compartment.</p> <p>• Place the battery cover back on the device.</p> <p>• <b>Disposal</b> - Electrical products should not be disposed of with household waste. Please recycle your device, along with your local authority or retailer for recycling advice.</p> <p><b>2. Time and date setup</b></p> <p>Check your update time and date settings prior to using your system for the first time, or when batteries have been replaced.</p>	<p>a. Press the Set button for two seconds to turn on the meter. A beeping sound will occur and enter the setting mode.</p> <p>b. With the year display flashing, press the Mem button to cycle through the year values.</p> <p>c. Press the Set button to lock your choice and proceed to the next setting screen. The order of setting is "Year/Month/Day/Hour/Minute". Refer to the following:</p>  <p>3. <b>Deleting memory (optional)</b></p> <p>After setting the time and date, the meter will automatically proceed to the memory deletion screen.</p> <p>a. When "DEL" is flashing and the "0" symbol is solid on the screen, press the Mem button to delete all stored memory.</p> <p>b. The meter will then display a flashing "--" and a solid "0" symbol to indicate all memory has been deleted.</p> <p>c. If you do not wish to delete the memory, press the Set button while "DEL" is flashing and the "0" symbol is solid to skip to the alarm settings.</p> <p>4. <b>Alarm settings (optional)</b></p> <p>Repeat steps 3 through e, for the next alarm. You may set up to four alarms at one time.</p> <p>e. Repeat steps 3 through e, for the next alarm. You may set up to four alarms at one time.</p> <p>If you do not wish to set an alarm, press the Set button to skip this step.</p> <p>g. To turn off an alarm, enter the setting mode by</p>	<p>4. <b>Alarm settings (optional)</b></p> <p>Repeat steps 3 through e, for the next alarm. You may set up to four alarms at one time.</p> <p>e. Repeat steps 3 through e, for the next alarm. You may set up to four alarms at one time.</p> <p>If you do not wish to set an alarm, press the Set button to skip this step.</p> <p>g. To turn off an alarm, enter the setting mode by</p>	<p>pressing the Set button for 2 seconds, then press the Mem button to change the alarm status from "On" to "Off". Use the Set button to confirm.</p> <p>When the alarm activates, the meter will beep and automatically turn on. You can insert a test strip to begin testing. If you do not wish to test at this time, press the Set button to turn off the meter. If you do not press the Set button, the meter will beep for 60 seconds before automatically turning off.</p> <p><b>Note:</b></p> <p>The data, time, memory deletion, and alarm can only be changed in a clean, dry work surface.</p> <p><b>Operation</b></p> <p>1. <b>Prepare your measurement</b></p> <p><b>CAUTION:</b></p> <p>To reduce the chance of infection:</p> <ol style="list-style-type: none"> <li>Choose a clean, dry work surface.</li> <li>Never share a lancing device or lancet with another person.</li> <li>Always use a new and sterile lancet.</li> <li>Always use a new test strip. The test strips are designed for single use only.</li> <li>Avoid getting lotion, oils, dirt, or debris in or on the lancet and lancing device.</li> </ol>	<p>a. Lay out your Acacia Meter, test strips, lancing device, and lancet on a clean, dry work surface.</p> <p>b. Prepare the lancing device.</p>  <p>Remove the cap</p>  <p>Insert a lancet</p>  <p>Twist the lancet cover off (do not touch the lancet tip)</p>  <p>Place the cap back on</p>  <p>Adjust the puncture depth (Recommended starting with level 4)</p> <ul style="list-style-type: none"> <li>1-2 for normal skin</li> <li>3-4 for normal arm</li> <li>5-6 for normal calf</li> </ul>  <p>Pull the handle until it clicks (do not touch the lancet tip)</p>																																																																																																																								
<p><b>Note:</b> The lancet is for individual use only. Never share the meter or lancing device with anyone, including family members.</p> <p>c. Wash your hands with warm, soapy water and dry thoroughly.</p> <p>d. Take a new test strip out by holding the handle, without touching the absorbent hold or the contact bars.</p> <p>e. With the arrow facing the meter, insert the test strip into the meter's strip port. All test strips will power on the device and display all symbols, then the blood sample symbol will be flashing.</p> <p>2. <b>Obtain a blood sample</b></p> <p>a. Place the lancing device against your fingertip and press the release button to lance.</p> <p>b. Squeeze your finger until a droplet of blood forms. Using your finger, wipe away the first blood droplet and squeeze until a second blood droplet forms.</p> 	<p>3. <b>Apply the blood sample and read the test results.</b></p> <p>a. Carefully bring the absorbent hold of the test strip close to the blood droplet at an angle, allowing it to naturally draw in the sample. Make sure the confirmation window of the test strip is filled completely with the blood sample.</p> <p>b. Remove your finger from the test strip when the countdown (from 5 to 1) is displayed on the meter.</p>  <p>c. The test result will appear on the meter after the countdown is complete.</p>  <p><b>Note:</b> The results obtained from the glucose meter are plasma-calibrated. These values and your physician, or other qualified healthcare provider, to compare your meter results with laboratory tests. Refer 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.</p>	<p>4. <b>Dispose and clean</b></p> <p>Push the eject button on the back of the meter and discard the lancet completely with an appropriate container to avoid contaminating other articles.</p> <p>Remove the lancing device cap and insert the device cap into the lancing device cap to avoid exposing the needle tip.</p> <p>Push the eject button slightly and discard the lancet.</p> <p>To clean, use an isopropyl alcohol pad to wipe the entire surface of the meter and a lancing device for 10 seconds, removing all visible soil from the surface.</p>	<p><b>Source:</b> American Diabetes Association: Classification and Diagnosis of Diabetes (Position Statement). Diabetes Care 39 (Suppl. 1): S15, 2016.</p> <p>Please consult your healthcare provider to determine a target range that is best for you.</p> <p><b>Color bar indication</b></p> <p>On the panel of the Acacia Blood Glucose Meter, there is a color bar. It is used for indicating the blood glucose value range. The color bar is shown in:</p>  <p>The black block indicates the present blood glucose value range according to the list below.</p> <table border="1"> <thead> <tr> <th>Value of Blood Glucose (mg/dL)</th> <th>Block in Color Bar (from left to right)</th> </tr> </thead> <tbody> <tr> <td>&lt;70</td> <td>Change Block</td> </tr> <tr> <td>70&lt;N&lt;110</td> <td>1<sup>st</sup> Blue Block</td> </tr> <tr> <td>110&lt;N&lt;126</td> <td>2<sup>nd</sup> Blue Block</td> </tr> <tr> <td>126&lt;N&lt;140</td> <td>1<sup>st</sup> Purple Block</td> </tr> <tr> <td>140&lt;N&lt;200</td> <td>2<sup>nd</sup> Purple Block</td> </tr> <tr> <td>&gt;200</td> <td>3<sup>rd</sup> Purple Block</td> </tr> </tbody> </table>	Value of Blood Glucose (mg/dL)	Block in Color Bar (from left to right)	<70	Change Block	70<N<110	1 <sup>st</sup> Blue Block	110<N<126	2 <sup>nd</sup> Blue Block	126<N<140	1 <sup>st</sup> Purple Block	140<N<200	2 <sup>nd</sup> Purple Block	>200	3 <sup>rd</sup> Purple Block	<p>6. <b>Reviewing saved test results</b></p> <p>a. Hold the Mem button for two seconds to view the test results stored in the meter. The test reading is read and the newest result is added.</p> <p>b. Press the Mem button to review 14, 21, 28, 60, and 90-day averages stored in the meter.</p> <p>c. After reviewing the 90-day average results, press the Mem button again to view the blood glucose result, along with the date and time.</p> <p>d. Continue pressing the Mem button to recall additional tested results stored in the meter.</p> <p><b>Note:</b> When the result is full, the oldest result is erased and the newest result is added.</p> <p>e. After reaching the last test result, "End" will display and the meter will turn off automatically.</p>	<p><b>Cleaning and Disinfection</b></p> <p>Cleaning and disinfection are absolutely necessary for the device to ensure the meter works optimally (e.g., display will be visibly clear after cleaning) and to prevent infection and/or cross-contamination. The meter and lancing device should be cleaned and disinfected following each use. We suggest that you use CavWipes® (Metrex® Research Corporation, EPA Reg. No. 467818, EPA Est. No. 56925W-001), CavWipes Multi-Surface and disinfecting/antibacterial/ethoxyethyl dimethyl benzyl ammonium chloride as the active ingredient, have been shown to be safe for use with the meter and lancing device. You can purchase this product from the suppliers listed below:</p> <ol style="list-style-type: none"> <li>Visit the website <a href="http://www.metrex.com">www.metrex.com</a>, or contact Metrex at 800-841-1428 for product or technical information.</li> <li>Visit retail stores, such as Walmart.</li> <li>Visit the following websites: Amazon.com; <a href="http://www.amazon.com/s?ref=nb_sb_noss?__search-alias=aps&amp;pf_rd_p=key-words=CavWipes">www.amazon.com/s?ref=nb_sb_noss?__search-alias=aps&amp;pf_rd_p=key-words=CavWipes</a>; Costco and disinfected/antibacterial/ethoxyethyl dimethyl benzyl ammonium chloride as the active ingredient, have been shown to be safe for use with the meter and lancing device. You can purchase this product from the suppliers listed below:</li> </ol> <p>The meter and the lancing device are for single - patient use. If you use test six times per day, the meter and lancing device should be cleaned and disinfected six times per day, which equals 10,950 cycles over the five-year</p>	<p>lifespan of the device. The meter and lancing device were validated for 11,000 cycles, which could support up to six cleaning and disinfection cycles per day. Below are the steps on how to clean and disinfect the meter and lancing device.</p> <ol style="list-style-type: none"> <li>Wash your hands thoroughly with soap and water.</li> <li>Use one CavWipe to carefully clean the entire external surface of the meter.</li> <li>Then, wipe the entire external surface of the meter with a new wipe until the surface wet for three minutes.</li> <li>Using the same method, use CavWipes to clean and disinfect the lancing device.</li> </ol> <p><b>Note:</b></p> <ol style="list-style-type: none"> <li>Wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.</li> <li>Only the surface of the meter can be cleaned and disinfected with the disinfecting towelette. Do not insert the disinfecting towelette into the test strip port and the metal connector, or the performance of the meter may be negatively affected.</li> <li>If you have any questions, call customer service.</li> <li>If the meter is being tested by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the person providing assistance.</li> </ol>	<p><b>Information about Alternative Site Testing (AST)</b></p> <p><b>What is AST?</b></p> <p>AST is checking blood glucose levels using other parts of the body besides a fingertip. The Acacia Blood Glucose Monitoring System allows you to test on the palm, forearm, upper arm, calf, or thigh, producing equivalent results to fingertip testing when used appropriately.</p>  <p>AST has limitations. Please consult your healthcare professional before you conduct AST. The Acacia Blood Glucose Monitoring System should only be used for AST under steady-state blood glucose conditions.</p>																																																																																																										
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<p><b>What Is the Advantage of AST?</b></p> <p>The advantage of AST is potential pain reduction. Pain is felt more readily on the fingertips because they are full of nerve endings (receptors). At other body sites, the nerve endings are not as condensed, pain is not felt as acutely.</p> <p><b>When AST Be Used?</b></p> <p>Food, medication, illness, stress, and exercise can affect blood glucose levels. Capillary blood from the fingertips reflects these changes faster than capillary blood from other sites. Therefore, when testing blood glucose levels during or immediately after meals, exercise, or when one of the above-noted conditions applies, take a blood sample from your fingertips only. AST should be used only during steady-state times when glucose levels are not changing rapidly.</p> <p>Blood glucose results from the forearm, upper arm, hand, thigh, and calf are not always the same as results from fingertips. AST is suitable in the following instances:</p> <ul style="list-style-type: none"> <li>In a pre-meal or fasting state (i.e., two or more hours have passed since last meal).</li> <li>Two or more hours after taking insulin.</li> <li>Two or more hours after exercising.</li> </ul> <p><b>Caution:</b> Do not use sites other than the fingertips for testing when blood glucose is rapidly rising or falling. Within two hours of eating, after taking insulin, immediately after exercise, or when you are ill or under stress, AST should not be used to calibrate Continuous</p>	<p>Glucose Monitoring Systems (CGMs). Results from AST should not be used in insulin dose calculations. Do not use AST if:</p> <ul style="list-style-type: none"> <li>You think your blood glucose is low.</li> <li>You are unaware that you might have hypoglycemia.</li> <li>You are testing for hypoglycemia.</li> <li>Your AST results do not match the way you feel.</li> <li>Your routine glucose results fluctuate often.</li> </ul> <p><b>Note:</b> The Lancing Device for AST is sold separately. It is not included in your kit, contact customer service to purchase.</p> <p><b>Important Information about Control Solution Tests</b></p> <p>Control solution contains a known amount of glucose that reacts with test strips and is used to check that your meter and test strips are working together properly. Blood glucose results from the forearm, upper arm, hand, thigh, and calf are not always the same as results from fingertips. 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When the blood sample symbol appears on the screen, hold the test button to enter the control solution (CTL) mode. </li></ol> <p><b>Note:</b> Be sure to test the meter on the CTL mode before performing a control solution test. The control test result will not be saved in the meter. Press the Set button again to turn off the CTL mode and switch back to the regular testing mode.</p>  <p>3. Apply the control solution.</p> <p>4. Shake the control solution vial before each use.</p> <p>5. Squeeze a droplet of control solution into the vial cap.</p>	<p>4. Head and compare the results.</p> <p>After the meter counts down to "1" the control solution test result will appear on the meter display. The result of the control solution test should be within the range printed on the test strip vial label. If the test result falls outside the specified range, repeat the test, carefully following the steps above.</p> <p><b>Out-of-Range Results</b></p> <p>Results falling outside the specified range may be caused by:</p> <ul style="list-style-type: none"> <li>Bubbles in the test.</li> <li>Expired or contaminated control solution.</li> <li>An expired or contaminated test strip.</li> <li>Meter malfunction.</li> </ul> <p>If you continue to get control solution test results that fall outside of the range printed on the vial, the meter may not be working properly. Discontinue use and contact customer service.</p>	<p>contact customer service. To purchase additional control solution, please visit <a href="http://www.healthlabs.com">www.healthlabs.com</a>.</p> <p><b>Note:</b> Do not use expired control solution.</p> <p><b>Note:</b> When the result is full, the oldest result is erased and the newest result is added.</p> <p><b>Comparing Glucose Meter Test Results with Laboratory Results</b></p> <p>The results obtained from the glucose meter are plasma-calibrated. These values and your physician, or other qualified healthcare provider, to compare your meter results with laboratory tests. Refer 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.</p> <p><b>Before the Lab Test</b></p> <ul style="list-style-type: none"> <li>Perform a control solution test to make sure that the meter is working properly.</li> <li>If possible, fast at least eight hours before conducting a comparison test.</li> <li>Take your meter to the lab.</li> </ul>	<p><b>Specifications</b></p> <p>Model: AG-607</p> <p>2. Machine size: 4.3" x 2.05" x 0.81" (110 mm x 52 mm x 20.5 mm)</p> <p>3. Measuring method: Amperometric technology using glucose dehydrogenase</p> <p>4. Result range: 20 mg/dL - 600 mg/dL (1.1 mmol/L - 33.3 mmol/L)</p> <p>5. Storage condition: 2x1.5V size AAA</p> <p>6. Power source: 2x1.5V size AAA</p> <p>7. Operating conditions: 50°F - 104°F (10°C - 40°C) and 25% - 80% RH</p> <p>8. Blood source: Fresh capillary whole blood</p> <p>10. Blood volume: Minimum 0.7 microliter</p> <p>11. Life span: Five years</p> <p>12. Drugs containing acetaminophen (e.g., Tylenol®) and other medicines containing acetaminophen, blood concentrations &gt;5 mg/dL and Vitamin C (ascorbic acid, blood concentrations &gt;4 mg/dL), at doses higher than recommended, may interfere with your glucose meter and deliver inaccurate results.</p> <p>13. System Accuracy: The System was tested on 350 capillary blood samples, and this is the accuracy in the hands of the user.</p> <p>Regression Analysis Between the Meter and YSI Reference</p> <table border="1"> <thead> <tr> <th></th> <th>Finger</th> <th>Forearm</th> <th>Upper Arm</th> <th>Calf</th> <th>Thigh</th> </tr> </thead> <tbody> <tr> <td>Slope (comparison with YSI)</td> <td>0.9883</td> <td>0.9964</td> <td>0.9809</td> <td>0.9853</td> <td>0.9856</td> </tr> <tr> <td>Intercept (comparison with YSI)</td> <td>1.0011</td> <td>-2.2901</td> <td>-0.6385</td> <td>-0.7838</td> <td>-0.5727</td> </tr> <tr> <td>R<sup>2</sup> (comparison with YSI)</td> <td>0.9813</td> <td>0.9829</td> <td>0.9844</td> <td>0.9812</td> <td>0.985</td> </tr> </tbody> </table> <p>System Accuracy Results for Glucose Concentrations &lt;75mg/dL</p> <table border="1"> <thead> <tr> <th>Anatomical Site</th> <th>Within 5%</th> <th>Within 5% to 10%</th> <th>Within 10% to 15%</th> <th>Within 15% to 20%</th> <th>Within 20% to 25%</th> </tr> </thead> <tbody> <tr> <td>Finger</td> <td>124/295 (42%)</td> <td>242/295 (82%)</td> <td>292/295 (100%)</td> <td>292/295 (100%)</td> <td>292/295 (100%)</td> </tr> <tr> <td>Palm</td> <td>122/294 (41%)</td> <td>232/294 (79%)</td> <td>286/294 (97%)</td> <td>294/294 (100%)</td> <td>294/294 (100%)</td> </tr> <tr> <td>Forearm</td> <td>136/295 (46%)</td> <td>245/295 (83%)</td> <td>295/295 (100%)</td> <td>295/295 (100%)</td> <td>295/295 (100%)</td> </tr> <tr> <td>Upper Arm</td> <td>122/297 (41%)</td> <td>245/297 (82%)</td> <td>282/297 (95%)</td> <td>297/297 (100%)</td> <td>297/297 (100%)</td> </tr> <tr> <td>Thigh</td> <td>136/295 (46%)</td> <td>246/295 (83%)</td> <td>296/295 (100%)</td> <td>295/295 (100%)</td> <td>295/295 (100%)</td> </tr> </tbody> </table>		Finger	Forearm	Upper Arm	Calf	Thigh	Slope (comparison with YSI)	0.9883	0.9964	0.9809	0.9853	0.9856	Intercept (comparison with YSI)	1.0011	-2.2901	-0.6385	-0.7838	-0.5727	R <sup>2</sup> (comparison with YSI)	0.9813	0.9829	0.9844	0.9812	0.985	Anatomical Site	Within 5%	Within 5% to 10%	Within 10% to 15%	Within 15% to 20%	Within 20% to 25%	Finger	124/295 (42%)	242/295 (82%)	292/295 (100%)	292/295 (100%)	292/295 (100%)	Palm	122/294 (41%)	232/294 (79%)	286/294 (97%)	294/294 (100%)	294/294 (100%)	Forearm	136/295 (46%)	245/295 (83%)	295/295 (100%)	295/295 (100%)	295/295 (100%)	Upper Arm	122/297 (41%)	245/297 (82%)	282/297 (95%)	297/297 (100%)	297/297 (100%)	Thigh	136/295 (46%)	246/295 (83%)	296/295 (100%)	295/295 (100%)	295/295 (100%)	<p>concentrations &gt;5 mg/dL and Vitamin C (ascorbic acid, blood concentrations &gt;4 mg/dL), at doses higher than recommended, may interfere with your glucose meter and deliver inaccurate results.</p> <p>13. 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Dropping or throwing the meter may cause damage.</li> <li>Always wash your hands with soap and water, rinse, and dry them completely before handling the AG-607 Blood Glucose Meter and test strips.</li> </ul> <p><b>Signs of Potential Physical and Performance Deterioration</b></p> <p>If you start experiencing one of the following, stop using and contact customer service, or the place of purchase, for assistance.</p> <ol style="list-style-type: none"> <li>The device does not work.</li> </ol>
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<p>2. Discoloration of the meter casing or lancing device (e.g., it is difficult to read the labeling information).</p> <p>3. Corrosion, crazing (fine cracks), embrittlement, and/or cracking of the meter casing or lancing device.</p> <p><b>Display Message</b></p> <p>If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please contact customer service. Do not attempt to repair the meter by yourself and never try to disassemble the meter under any circumstances.</p> <p><b>Message</b></p> <p><b>What It Means</b></p> <p><b>LO</b> Blood glucose level is lower than 20 mg/dL (1.1 mmol/L).</p> <p><b>H</b> Blood glucose level is higher than 600 mg/dL (33.3 mmol/L).</p> <p><b>B</b> The batteries in your meter are low power.</p> <p><b>Problem with the meter.</b></p>	<p>Problems have occurred that are related to test strips.</p> <p><b>EE3</b> Test strips may be wet or test strips may have been used more than once.</p> <p><b>EE4</b> The test strip has not been fully inserted into the meter.</p> <p><b>EE5</b> The environmental temperature is lower than 50°F (10°C).</p> <p><b>EE6</b> The environmental temperature is higher than 104°F (40°C).</p> <p><b>Problem with the meter.</b></p> <p><b>EE7</b> The environmental temperature is lower than 50°F (10°C).</p> <p><b>EE8</b> The environmental temperature is higher than 104°F (40°C).</p> <p><b>Problem with the meter.</b></p> <p><b>EE9</b> The environmental temperature is lower than 50°F (10°C).</p> <p><b>EE10</b> The environmental temperature is higher than 104°F (40°C).</p> <p><b>Problem with the meter.</b></p> <p><b>EE11</b> The environmental temperature is lower than 50°F (10°C).</p> <p><b>EE12</b> The environmental temperature is higher than 104°F (40°C).</p> <p><b>Problem with the meter.</b></p> <p><b>EE13</b> The environmental temperature is lower than 50°F (10°C).</p> <p><b>EE14</b> The environmental temperature is higher than 104°F (40°C).</p> <p><b>Problem with the meter.</b></p> <p><b>EE15</b> The environmental temperature is lower than 50°F (10°C).</p> <p><b>EE16</b> The environmental temperature is higher than 104°F (40°C).</p> <p><b>Problem with the meter.</b></p> <p><b>EE17</b> The environmental temperature is lower than 50°F (10°C).</p> <p><b>EE18</b> The environmental temperature is higher than 104°F (40°C).</p> <p><b>Problem with the meter.</b></p> <p><b>EE19</b> The environmental temperature is lower than 50°F (10°C).</p> <p><b>EE20</b> The environmental temperature is higher than 104°F (40°C).</p> <p><b>Problem with the</b></p>																																																																																																																														