IMPORTANT: Please read this information and the Owner's Guide that came with your meter before using BGStar Test Strips.

IMPORTANT: Only use BGStar Test Strips with the BGStar Systems. BGStar Test Strips are designed for use with the BGStar family of meters.

INTENDED USE AND TEST PRINCIPLE

The BGStar family of blood glucose monitoring systems should be used:
- As indicated for single patient use (one-lot counterfeit tests) by patients with diabetes, as an aid to monitor the effectiveness of diabetes control.
- For measuring blood glucose levels from fresh capillary whole blood samples taken from the finger, palm (at the base of the thumb), or forearm (see Owner's Guide for exact locations).
- For in vitro (i.e., outside of the body) diagnostic use only.
- With BGStar Test Strips and BGStar Control Solution only. Do not use other brands of test strips and control solution with this meter. This may produce inaccurate results.

Do not use the BGStar family of blood glucose monitoring systems for:
- The diagnosis of diabetes.
- Testing the glucose levels of neonates (children under 1 week).
- Testing glucose levels of arterial or venous blood.
- Testing glucose from sites other than the finger, palm (at the base of the thumb), or forearm.

How it Works:

Glucose in a blood sample mixes with special test strip reagent where a small electrical signal is produced. The meter then detects the electrical signal, interprets it, and presents the result on the test strip. The amount of signal produced corresponds with the amount of glucose in the blood sample.

METER AND TEST STRIP PERFORMANCE CHECK WITH BGSTAR CONTROL SOLUTIONS

BGStar Control Solution (Normal and High) contains a known amount of glucose that reacts with a BGStar Test Strip in combination with a blood glucose meter from the BGStar family of meters to make sure they are working together properly.

Control solution tests should be performed when:
- First get your meter.
- Snap that your meter or test strips are not working properly.
- Think that your test results are not accurate.
- Have dropped or damaged your meter or expressed your meter to liquids.
- Are advised by your healthcare professional to do so.

If your control solution test results do not fall within the target range printed on the test strip and for the control solution you are using (Normal or High), repeat the test. Out of range results may be due to one or more of the following factors:
- Expired or defective control solution.
- Expired or defective test strip.
- Error in performing test.
- Improper use of control solution.
- METER malfunction.
- Control solution test done outside of the system operating temperature of 59°F to 104°F (15°C to 40°C).
- Failure to shake the control solution bottle vigorously before using.
- Failed to discard the first drop of control solution and to wipe the bottle tip clean.

If results continue to fall outside the appropriate target range printed on your BGStar Test Strips, the test strip and meter may not be working properly. If so, do not use your system and contact 24-Hour Customer Service toll free 1-800-653-1610.

TEST PROCEDURE

1. To ensure accurate results, wash your hands with soap and water. Make sure there is no grease, oil, or lotion on the test site. Thoroughly dry your hands.
2. Snap the cap off the BGStar Lancing Device, insert a new lancet and twist off the lancet cover. Replace the lancing device cap, set the lancing level and cock the handles.
3. Insert a new test strip.
4. Press the meter display until the blood drop symbol, bring the blood sample to the tip of the BGStar Test Strip.
5. When the meter displays the blood drop symbol, bring the blood sample to the tip of the BGStar Test Strip.
6. When your blood glucose test result with time and date is shown on the display, the test is completed and saved in the memory.
7. Remove the used BGStar Test Strip from the meter and dispose of safely.


WHAT DO YOUR TEST RESULTS MEAN?

Results below 20 mg/dL: If the test result is below 20 mg/dL, a message will appear on the display indicating hypoglycemia (low blood glucose). See your Owner’s Guide for details. You should perform another test immediately. If your result is below 20 mg/dL, again, follow the treatment plan recommended by your healthcare team and contact your healthcare professional immediately.

Results above 600 mg/dL: If the test result is above 600 mg/dL, a message will appear on the display indicating hyperglycemia (high blood glucose). See your Owner’s Guide for details. You should perform another test immediately. If your result is above 600 mg/dL, again, follow your healthcare professional’s recommendations to treat hyperglycemia. Checking ketones may be advisable.

The normal fasting adult blood glucose range for a person without diabetes is 70 to 99 mg/dL.

Always consult your healthcare professional for your recommended target ranges.

WARNING: Alternate Site Testing (AST)

Physiological differences in circulation between the finger, palm (at the base of the thumb), or forearm may result in differences in blood glucose measurements between these sites. Differences in glucose concentrations may be observed after eating, taking insulin medication, or exercise. Changes in blood glucose may be detected in the fingerpits before the palm (at the base of the thumb) or forearm.

It is recommended that you use a fingerpits sample if:
- you are checking for hypoglycemia and you suffer from hypoglycemia unawareness.
- you are checking your blood glucose within 2 hours of eating, taking insulin, medication, exercise, or
- your blood glucose results obtained from the palm (at the base of the thumb) or forearm are not consistent with the way you feel.

TESTING PRECAUTIONS

- Inaccurate results may occur in severely hypoventilated individuals or patients in shock. Inaccurate line results may occur for individuals experiencing a hypoglycemic or hyperglycemic state, with or without ketosis. Severely ill patients should not be tested with blood glucose meters.
- Severe dehydration and excessive water loss may yield inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- Diabetics undergoing a dietary or pharmacological regimen may receive inaccurate results.
- Results below 70 mg/dL, may mean low blood glucose levels (hypoglycemia). Results over 240 mg/dL, may mean high blood glucose levels (hyperglycemia). Checking ketones may be advisable.
- If you get results below 70 mg/dL or above 240 mg/dL, and do not have symptoms of hypoglycemia or hyperglycemia, repeat the test. If you have symptoms, or continue to get results that fall below 70 mg/dL, or rise above 240 mg/dL, follow the treatment plan recommended by your healthcare team and contact your healthcare professional immediately.
- If you are experiencing symptoms that are not consistent with your blood glucose test and you have followed all instructions described in the Owner’s Guide, follow your healthcare professional’s recommendations.
- Do not use test strips that are expired or appear to be damaged as they may return inaccurate results.
- Healthcare professionals should follow their institutions infection control protocols.
- Always follow your healthcare professional’s recommendations.
STORAGE AND HANDLING
- Store the BGStar Test Strips in a cool, dry place at 46°F to 86°F (8°C to 30°C).
- Use BGStar Test Strips only within the system operating temperature range of 50°F to 104°F (10°C to 40°C).
- Keep away from direct sunlight and heat.
- Store your BGStar Test Strips in their original vial only; never move them to another vial or any other container, or outside the vial.
- After removing a BGStar Test Strip from the vial, immediately close the vial cap tightly.
- With clean, dry hands, you may gently handle the BGStar Test Strip when removing it from the vial or expectant to inspect the meter.
- Do not use BGStar Test Strips beyond the expiration date or 60 days after first opening the vial. This may cause inaccurate results. Write the discard date 90 days from the first opening on the test strip vial.
- Do not bend, cut, or alter BGStar Test Strips.
- Apply only fresh capillary blood or control solution to the sample area of the BGStar Test Strip.

WARNINGS AND PRECAUTIONS
- Keep test strips and test strip vial away from children. The test strips may be choking hazards. The vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.
- Test strips are for single use only. Do not reuse. Discard used test strips properly.
- If test strip will not receive a blood sample, contact 24-Hour Customer Service toll free: 1-800-633-1610.

PERFORMANCE CHARACTERISTICS
The performance of the BGStar System was tested in both clinical and laboratory settings.

Accuracy
The accuracy of the BGStar System was evaluated by comparing blood glucose results obtained from whole blood samples. The system is calibrated to yield results equivalent to plasma glucose concentrations. Whole blood glucose results obtained with the BGStar System were compared to the plasma glucose results obtained using the YSI Model 2300 Glucose Analyzer.

The results were:
- Slope: 0.992
- Y-intercept: 1.4 mg/dL (0.08 mmol/L)
- Correlation coefficient: 0.995
- N = 200

Range of reference values: 32.7 to 490.5 mg/dL (1.8 to 27.2 mmol/L)

Finger-stick summary of system accuracy results for glucose concentration less than 75 mg/dL (4.2 mmol/L):

<table>
<thead>
<tr>
<th>Within ± 10 mg/dL (0.54 mmol/L)</th>
<th>Within ± 15 mg/dL (0.83 mmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>97%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Finger-stick summary of system accuracy results for glucose concentrations greater than or equal to 75 mg/dL (4.2 mmol/L):

<table>
<thead>
<tr>
<th>Within ± 1%</th>
<th>Within ± 15%</th>
<th>Within ± 20%</th>
</tr>
</thead>
<tbody>
<tr>
<td>91%</td>
<td>98%</td>
<td>99%</td>
</tr>
</tbody>
</table>

The total number of acceptable results for all glucose concentrations is 199/200 (99.5%).

Conclusion: Results meet ISO 15197 requirements.

Finger-stick alternate site testing results for use as compared to interdactal results obtained by Healthcare Professional:
All results were within the clinically acceptable A and B zones of the Parkers Error Grid, with 99% falling within zone A.

Finger-stick alternate site testing results for use as compared to interdactal results obtained by Healthcare Professional:
All results were within the clinically acceptable A and B zones of the Parkers Error Grid, with 99% falling within zone A.

PRECISION
The repeatability of the strips was evaluated with various blood samples and control solution in the laboratory.

Within-Run Precision:
- Blood average: 50 mg/dL
- Blood average: 225 mg/dL
- Blood average: 201 mg/dL
- Control average: 108 mg/dL
- Control average: 365 mg/dL

Chemical Composition:
- Each BGStar Test Strip contains:
  - Glucose reagent (2.74%)  
  - N-higher reagent (8%)  
  - Other ingredients (1.6%)  

Interfering Substances:
- Substance found in the blood naturally (e.g., uric acid, bilirubin) or from therapeutic treatment (e.g., aspirin, etc.) should not significantly affect the test results.

The limiting concentrations of certain compounds are:
- Acetaminophen: 20 mg/dL
- Aspirin: 2 mg/dL
- Bilirubin: 15 mg/dL
- Creatinine: 6 mg/dL
- Cholesterol: 400 mg/dL
- Fructos: 18 mg/dL
- Glucose: 1.25 mg/dL
- Iodium: 50 mg/dL
- Lactic acid: 10 mg/dL
- Lipids: 0.2 mg/dL
- Malondialdehyde: 0.5 mg/dL
- Salicylate: 60 mg/dL
- Superoxide: 20 mg/dL
- Taurine: 3.5 mg/dL
- Uric acid: 500 mg/dL
- Xylitol: 120 mg/dL

Manufacturer: AgerLink, Inc.
Distributed by:
- Landmark U.S., LLC
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- Salem, NH 03079 USA

References:

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