



sanofi aventis

OWNER'S GUIDE

Key Features of the BGStarTM

No Coding Required – The BGStar doesn't require you to enter a code. Insert a test strip and you are ready to start the test.

Pre/Post Meal Tagging – After you test, tag your reading with the mealtime. You can organize your data, and see how your test results change before and after meals.

Positive Feedback – The BGStar will also display a smiley face icon if your result is within the target range.

BG*STAR*

Toll free sanofi-aventis 24 hour support Tel.: 1-888-852-6887 or visit us at www.bgstar.ca In case of emergency, contact your health professional or emergency medical response.



Manufactured by AgaMatrix Inc., 7C Raymond Avenue, Salem NH 03079 USA For sanofi-aventis Canada Inc., 2150 St. Elzear Blvd. West, Laval (Quebec) Canada H7L 4A8 www.bgstar.ca

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Meter Firmware ©2011AgaMatrix, Inc.

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CHAPTER 1 Getting Started

Unpack your BGStarTM System Kit. Dispose of the packing material properly.

IMPORTANT: To ensure accurate use of meter, verify the time, date and units of measure.

For step-by-step instructions on changing the time and date settings, please refer to chapters 13 and 14.

CHAPTER 2 Important Health-related Information

Please Read the Following:

- [1] Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- [2] Severe dehydration and excessive water loss may yield inaccurate results. If you believe you are suffering from severe dehydration, consult your health professional immediately.
- [3] Patients undergoing oxygen therapy may receive inaccurate results.
- [4] Results below 3.9 mmol/L may mean low blood glucose levels (hypoglycemia).
- [5] Results over 13.3 mmol/L may mean high blood glucose levels (hyperglycemia). Checking ketones may be advisable.
- [6] If you get results below 3.9 mmol/L or above 13.3 mmol/L and do not have symptoms of hypoglycemia or hyperglycemia, repeat the test. If you have symptoms, or continue to get results below 3.9 mmol/L or above 13.3 mmol/L, contact your health professional immediately.
- [7] If you are experiencing symptoms that are not consistent with your blood glucose test and you have followed all instructions described in the BGStar Owner's Guide, follow the treatment plan recommended by your health professional team or contact your health professional immediately.
- [8] Do not use test strips that are expired or appear to be damaged as they may return inaccurate results.
- [9] Health professionals should follow their institution's infection control protocols.
- [10] Always follow your health professional's recommendations.

CHAPTER 3 Important Information about Your BGStar System

The BGStar System should be used:

- [1] For quantitative measuring of blood glucose levels from fresh capillary whole blood samples taken from the fingertip, palms (at the base of the thumb), or forearms.
- [2] For *in vitro* diagnostic (i.e. outside of the body) use only.
- [3] 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.
- [4] For use at home (over the counter (OTC)) by persons with diabetes, or in a clinical setting by health professionals, as an aid to monitor the effectiveness of diabetes control.

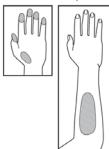
Do not use the BGStar System for:

- [1] The diagnosis of diabetes.
- [2] Testing the glucose levels of neonates (children under 4 weeks).
- [3] Testing glucose levels of arterial or venous blood.
- [4] Testing glucose from sites other than the fingertip, palm (at the base of the thumb), or forearm.

Possible test sites:

The BGStar System requires only $0.5~\mu L$ of blood to perform a glucose test. For best results, test using blood from the tip of any finger. The palm (at the base of the thumb) and forearm are alternate, but less accurate test sites. Only select soft and fleshy areas to lance. Avoid lancing any bony areas, obvious veins and moles.

Physiological differences in circulation between the fingertip, palm (at the base of the thumb), and 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 at the fingertips before the palm (at the base of the thumb) and forearm.



It is recommended that you use a fingertip sample if:

[1] you are testing for hypoglycemia or if you suffer from hypoglycemia unawareness;

- [2] you are testing your blood glucose within 2 hours of eating, taking insulin or medication, exercising; or
- [3] your blood glucose results obtained from the palm (at the base of the thumb) or forearm are not consistent with the way you feel.

CAUTION: Please read all the instructions provided in this Owner's Guide and practice the testing procedures before using the BGStar Blood Glucose Monitoring System. Blood glucose monitoring should be done under the guidance of your health professional.

CHAPTER 4 About the BGStar System

Your BGStar System includes:

- BGStar Blood Glucose Meter
- Two Pre-installed CR2032, 3 Volt, Lithium Batteries
- Lancing Device with Gray Cap
- Clear Alternate Site Testing (AST) Lancing Device Cap
- 10 Sterile Lancets (Gauge 33)
- Carrying Case
- Owner's Guide
- Ouick Reference Guide
- Warranty Card

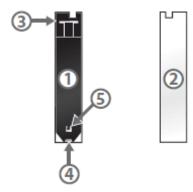
Test Strips and Control Solution are sold separately.

About the BGStar Test Strip

With your BGStar System, you can test your blood glucose on your fingertips, palms (at the base of the thumb) or forearms. Testing with the BGStar System requires a small sample size, $0.5~\mu L$ of blood, about the size of a pinhead.

- (1) Front of the Test Strip: The front of the test strip is black in color. Ensure that the front (black-colored) side of the test strip is facing up when inserting a test strip into the meter's test strip port.
- (2) Back of the Test Strip: The back of the test strip is white in color. Ensure that the back (white-colored) side of the test strip is facing down when inserting a test strip into the meter's test strip port.
- (3) Contact Bars: This end is inserted, front of the test strip facing up, into the meter's test strip port.
- (4) Sample Area: Blood or control solution should be applied to the tip of the test strip here.
- (5) Visual Fill Window: This window will turn red when enough blood has been applied or blue when enough control solution has been applied.

Application number: 184338 Date of revision: August 18, 2011 s-a Version 2.1 dated August 26, 2011



CAUTION: Dispose used test strips properly.

IMPORTANT: Use a BGStar Test Strip only once.

IMPORTANT: Only use BGStar Test Strips with the BGStar or iBGStar TM System.

Important Test Strip Information:

- [1] Store the BGStar Test Strip vial in a cool, dry place at 8°C to 30°C.
- [2] Use BGStar Test Strips only within the system operating temperature range of 10°C to 40°C.
- [3] Keep away from direct sunlight and heat.
- [4] Store your BGStar Test Strips in their original vial only; never store them in another vial, any other container, or outside the vial.
- [5] With clean, dry hands you may gently handle the BGStar Test Strip when removing it from the vial or inserting it into the meter.
- [6] After removing a BGStar Test Strip from the vial, immediately close the vial cap tightly.
- [7] Do not use BGStar Test Strips beyond the expiration date or 90 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.
- [8] Do not bend, cut or alter BGStar Test Strips.
- [9] Apply only fresh capillary blood or control solution to the sample area of the BGStar Test Strip.

About the BGStar Meter



- (1) **Display:** Glucose test results, symbols, messages, and graphs appear here.
- (2) **CHECK** (**Button:** Use the CHECK button to confirm an option or make a selection in a menu.
- (3) **UP Arrow** (**Button:** Use the UP arrow button to scroll backward through options.
- (4) **DOWN Arrow** () **Button:** Use the DOWN arrow button to scroll forward through options.
- (5) **BACKLIGHT** () **Button:** Use the BACKLIGHT button to turn the backlight ON and OFF.
- (6) **Test Strip Port:** Insert the BGStar Test Strip, with the contact bars facing up, into the strip port.

About the BGStar Meter Display Symbols/Messages



(1) **Date and Time:** Appears here, including when the meter is deactivated. For details on setting the date, refer to chapter 14.



(2) Glucose Test Results



(3) Low Battery Message: Appears when battery #2 in your meter is running low.



(4) **Dead Battery Message:** Appears when battery #2 in your meter is dead.



(5) **Temperature Symbol:** Appears when the meter is outside its operating temperature range of 10°C to 40°C.

TEMP

(6) **Ketone Symbol:** Appears when your glucose test results are higher than 13.3 mmol/L.



(7) **Control Solution message:** Appears after you have performed a control solution test.

[E -]

(8) Units of Measurement symbol: Results will be displayed in mmol/L.

mmol/L

(9) **Apply Sample to Test Strip message:** The flashing droplet symbol and the word "fill" will signal you to apply a sample to the test strip.

 $F_1()$



(10) **Volume Message:** Can be set to ON or OFF.

ЬЕЕР

(11) **1 Month, 2 Week, 3 Day Indicators:** The appropriate number of days will appear when viewing graphical averages.



(12) **1,2,3 Countdown:** The 1, 2 and 3 symbols will appear during a glucose test.



(13) **Graphing Area:** Areas of the dot matrix will appear during a test and when displaying graphs.



(14) **Happy Face Symbol:** The happy face is displayed with glucose test results that fall within specific pre and post meal target ranges.



(15) **Mealtime Tags:** The mealtime tags appear after a test is complete and will help categorize your results.



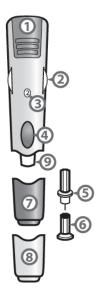
(16) **/D, SD, and AVG Symbols:** These symbols appear in the meter's data management functions.

/D

SD

AVG

About the BGStar Lancing System



- (1) **Arming Handle:** Arms the device so it is ready to lance.
- (2) **Depth Adjustment Dial:** Adjusts how deep the lancet will lance the skin.

- (3) **Depth Indicator Window:** Displays the depth setting of the lancing device.
- (4) **Release Button:** Fires the lancet.
- (5) **Lancet:** Lances the skin to produce a drop of blood.
- (6) Lancet Cover: Covers the lancet for safety.
- (7) **Lancing Device Cap:** Covers the lancet when in lancing device.
- (8) **Alternate Site Testing Cap:** An AST clear lancing device cap used for obtaining a blood sample on the palm (at the base of the thumb) or forearm.
- (9) Lancet Holder Cup: Holds the lancet in place inside the lancing device.

CHAPTER 5 Meter Basics

METER SYSTEM CHECK



Each time your meter is activated, it will perform a meter system check. All display segments and the backlight will briefly flash ON.

IMPORTANT: If all the display segments DO NOT flash ON (each time your meter is activated), do not use the meter. Call sanofi-aventis toll free immediately at 1-888-852-6887.

HOW TO ACTIVATE THE METER AND ENTER MENU MODE

- [1] When your meter is deactivated, press the CHECK (button to enter the menu mode.
- [2] Press the DOWN () or UP () arrow buttons to view the options: MEM, STATS, AVG, MEAL, GRAPH, TIME, DATE, TAG, RANGE, BEEP, HYPO, HYPER, and ALARM. To view/alter any of these options or settings press the CHECK () button.

HOW TO ACTIVATE THE METER AND VIEW INDIVIDUAL RESULTS

- [1] When your meter is deactivated, press the CHECK (button to enter menu mode. The word "MEM" is displayed. Press the CHECK (button again to see your most recent test result.
- [2] Press the DOWN (or UP (arrow buttons repeatedly to scroll through every test result, starting from the most recent and ending with the oldest.

HOW TO ACTIVATE THE METER AND VIEW MEALTIME AVERAGES

- [1] When your meter is deactivated, press the CHECK () button once to enter Menu mode. The word "MEM" is displayed. Press the DOWN () or UP () arrow buttons until the word "MEAL" appears in the lower part of the display. Press the CHECK () button again to see your most recent test result.
- [2] Press the DOWN () or UP () arrow buttons repeatedly to scroll through your Breakfast, Lunch, Dinner, and Bedtime Averages.

HOW TO DEACTIVATE THE METER

To deactivate the meter, press and hold the CHECK () button for 2 seconds. If the meter is inactive for 3 minutes, the meter will be deactivated automatically.

HOW TO ACCELERATE THROUGH OPTIONS

Hold down the DOWN (►) or UP (►) arrow buttons to accelerate through options or results.

CHAPTER 6 Preparing For a Test With Your BGStar Meter

[1] **Insert a BGStar Test Strip:** Insert a new BGStar Test Strip into the meter. Make sure you insert the test strip, with the contact bars facing up, into the strip port. The meter will be activated automatically.



Note: If you do not start the test within 5 minutes, the meter will be deactivated. To reactivate your meter, remove the unused BGStar Test Strip and reinsert it into the meter.

[2] **Meter Ready for Test:** The meter now displays the blood drop symbol and the word "Fill". The BGStar System is now ready for you to apply control solution or blood.

CHAPTER 7 Performing a Control Solution Test

The control solution is used to:

- [1] Ensure that your BGStar Meter and Test Strips are working together properly.
- [2] Practice testing without having to use your own blood.

Control solution tests should be performed when you:

[1] First get your meter.

- [2] Suspect that your meter or test strips are not working properly.
- [3] Think your test results are not accurate.
- [4] Have dropped or damaged your meter or exposed your meter to liquids.
- [5] Are advised by your health professional to do so.

Control solution should only be used for 90 days after first opening the bottle or until the expiration date printed on the label, whichever comes first.

IMPORTANT: Count forward 90 days from the date you open a new bottle of BGStar Control Solution. This is your discard date. Write the discard date on the BGStar Control Solution bottle.

Important BGStar Control Solution information:

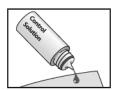
- [1] Use only BGStar Control Solution with your BGStar System.
- [2] Always replace the cap on the control solution bottle immediately after use.
- [3] Do not add water or any other liquid to control solution.
- [4] Control solution tests should be performed within the system operating temperature range of 10°C to 40°C.

How to perform a control solution test:

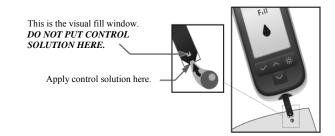
[1] **Inserting a BGStar Test Strip:** Insert a new BGStar Test Strip into the meter. The meter will be activated when the test strip is fully inserted.

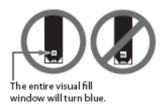


- [2] **Meter Ready for Test:** The meter now displays the droplet symbol and the word "Fill". The BGStar System is now ready for you to apply control solution. You do not need to set a calibration code for this meter.
- [3] **Applying Control Solution:** Shake the control solution bottle. Discard the first drop of control solution and wipe the bottle tip clean using a clean tissue or paper towel. Dispense a second drop onto a clean surface, such as an unused resealable plastic bag.

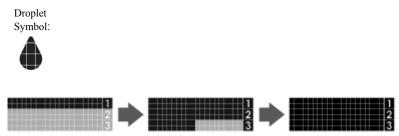


Bring the tip of the test strip to the control solution sample. The BGStar System will automatically detect if a test is performed with BGStar Control Solution.





When control solution is applied, the visual fill window on the BGStar Test Strip turns blue. Your meter will beep once indicating that you should remove the tip of the BGStar Test Strip from the control solution sample. On the meter display, the droplet symbol fills. The scrolling bar and 1-2-3 indicates that the meter is calculating your results.



[4] **Viewing Control Solution Test Result:** The result will appear on the display and, if the volume is enabled, your meter will beep. The date and the abbreviation "Ctrl" will also appear on the display.

Compare the result of your control solution test to the range printed on the BGStar Test Strip vial label for the control solution level that you used. Your control solution result should fall within this range. The control solution test result is stored in memory.





To deactivate the meter, remove the used BGStar Test Strip. Dispose of used materials properly.

If your control solution test results are out of the range, repeat the test. If the results from the control solution tests continue to fall outside that range, do not use the BGStar System to test your blood glucose. Call sanofi-aventis toll free at 1-888-852-6887.

IMPORTANT: Out-of-range test results may be due to one or more of the following factors:

- [1] Expired or defective control solution.
- [2] Expired or defective test strip.
- [3] Error in performing test.
- [4] Watered-down control solution.
- [5] Meter malfunction.
- [6] Control solution test done outside the system operating temperature of 10°C to 40°C.
- [7] Failure to shake the control solution bottle vigorously before using.
- [8] Failure to discard the first drop of control solution and to wipe the bottle tip clean.

CAUTION: Results from control solution tests do not reflect your blood glucose level. The control solution range is a target range for control solution only. It is not a target range for your blood glucose level. Control results are not included in the pre and post meal time, 14, 30 and 90 day averages.

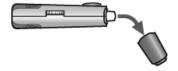
CHAPTER 8 How to Test Your Blood Glucose Level

CAUTION: To ensure accurate results, wash your hands with warm, soapy water and dry before every test. Make sure there is no grease, oil or lotion on the test site. Use lancets only once. Do not use any lancet or lancing device that has been used by another person. Unwashed hands may lead to inaccurate results.

How to test your blood glucose level:

[1] **Preparing the BGStar Lancing Device:** Use the gray cap for testing on a fingertip and the clear cap for testing on the palm (at the base of the thumb) or forearm.

Remove Lancing Device Cap: Snap off the cap from the lancing device.



Insert New Lancet: Insert a new BGStar Lancet firmly into the lancet holder cup. Pushing the



lancet into the lancet holder cup may arm the device; this is OK.

Twist the Lancet Cover Off: Hold the lancet firmly in place with one hand and use your other hand to twist off the lancet cover. Do not discard the lancet cover. It should be used when discarding your used lancet.



Replace Lancing Device Cap: Replace the lancing device cap until it snaps into place. Be careful not to touch the exposed needle on the lancet.



Set the Lancing Level: The BGStar Lancing Device offers 8 depth settings. Rotate the dial to the desired setting as shown in the depth indicator window. Level 1 is the most shallow; level 8 is the deepest. If you have never lanced before, it is recommended that you start at level 3. If necessary, set the depth level to a deeper setting to produce enough blood to fill the test strip $(0.5 \,\mu\text{L})$.



Application number: 184338 Date of revision: August 18, 2011 s-a Version 2.1 dated August 26, 2011 **Arm the Handle:** Pull the arming handle out until it clicks. You may have already armed the handle accidentally while inserting the lancet; this is OK. The lancing device is now ready for use.



[2] **Insert a BGStar Test Strip:** Insert a new BGStar Test Strip into the strip port of the meter. Make sure you insert the test strip, with the contact bars facing up, into the test strip port. The meter will be activated when the test strip is fully inserted.



Note: If you do not start the test within 5 minutes, the meter will be deactivated. To reactivate your meter, take out the unused BGStar Test Strip and reinsert it into the meter.

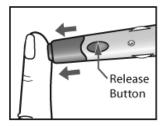
Meter Ready for Test: The meter now displays the droplet symbol and the word "Fill". The BGStar System is now ready for you to apply blood. You do not need to set a calibration code for this meter.

[3] **Lancing:** To ensure accurate results, wash hands with warm, soapy water and dry before every glucose test. For details on possible test sites, refer to chapter 3.

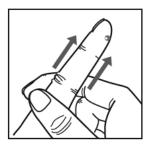
For instructions on how to test on your palm or forearm, please refer to chapter 9.

Note: Keep your hand warm or gently massage the site you are lancing to stimulate blood flow.

Lance Test Site: Press the lancing device against the site to be lanced. Press the release button.



Obtain Blood Drop: When testing on a finger tip, wipe away the first blood drop that appears using a clean tissue or paper towel. Squeeze from the base of your finger up towards the tip, until a second small blood drop forms.



Do not squeeze directly around the lanced area.

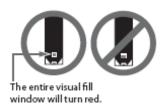
If necessary, set the lancing device to a deeper setting or use a larger lancet to produce enough blood.

[4] Applying Blood Sample

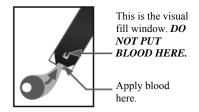
Bring Test Strip to Blood Sample: The meter now displays the droplet symbol and the word "Fill". This means your BGStar System is now ready for you to apply blood. Immediately bring the BGStar Test Strip to the blood sample.



The test strip fills from the tip. Do not apply blood on the top surface of the test strip. The BGStar Test Strip acts like a sponge and draws the blood into the test strip through the sample area. The visual fill window of the BGStar Test Strip will turn red.



WARNING: If the visual fill window does not completely fill, you may get an inaccurate result. Retest using a new test strip and ensure that the visual fill window is completely full.



IMPORTANT:

- [1] Remove the test strip from the blood sample as soon as you hear the beep.
- [2] Do not press the BGStar Test Strip against the test site.
- [3] Do not scrape blood onto the BGStar Test Strip.
- [4] Do not apply blood to the top side of the BGStar Test Strip.
- [5] Do not apply blood to the BGStar Test Strip when the test strip is out of the meter.
- [6] Do not put blood or foreign objects into the BGStar strip port. Doing so may lead to system failure.
- [7] Do not apply more blood after beep.
- [8] Carefully read the test results on the display before making any treatment decisions.

Remove Test Strip from Blood Sample when you hear the beep: Your meter will beep once, when you should remove the tip of the BGStar Test Strip from the blood sample.



On the meter display, the droplet symbol fills. The scrolling bar and 1-2-3 indicates that the meter is calculating your results.

Droplet Symbol:





Your test is completed when your blood glucose test result with time and date is shown on the display. If the volume is ON, you will hear a beep. Your test result is now stored in the memory.



[5] Test Result Mealtime Tagging and Feedback

If the Mealtime Tag Feature is Enabled: The BGStar Meter allows you to add a tag to your test result. Tagging results allows you to view averages before and after meals to see what effect food has on your blood glucose levels.

After your result appears, a tag will flash on the display suggesting a mealtime tag (Breakfast, Post Breakfast, Lunch, Post Lunch, Dinner, Post Dinner, and Night). For example, if you test at 12:30, the meter will flash the word "POST LUNCH."

If the tag is incorrect, you can change it by pressing the DOWN () or UP () arrow buttons. Pressing the UP () arrow button would change the tag to Lunch, pressing the DOWN () arrow button would change the tag to Dinner. Pressing the CHECK () button confirms the mealtime tag and it stops flashing. Your test result's mealtime tag is now stored in the memory.

Example of Mealtime Tag:



You can still change this setting by pressing the DOWN () or UP () arrow buttons, if you haven't removed the test strip from the meter yet.

Example of Mealtime Tag: POST BREAKFAST



If you don't want to tag a reading, scroll through the options by pressing the DOWN () or UP () arrow buttons. One of the options will leave the tag field blank. If you do not want to tag meals, this feature can be turned OFF in the menu mode.

Example of Mealtime Tag: NO TAG (BLANK)



Tagging Values: The BGStar Meter suggests mealtime tagging values according to this chart:

Preakfast: 5:00 - 7:59
Post Breakfast: 8:00 - 9:59
Lunch: 10:00 - 11:59
Post Lunch: 12:00 - 14:59
Dinner: 15:00 - 17:59
Post Dinner: 18:00 - 20:59
Night: 21:00 - 4:59

Feedback: Depending on the mealtime tag and your test result, the meter will display positive feedback in the form of a happy face. The happy face symbol is displayed with glucose test results that fall within specific pre and post meal target ranges.



[6] Final Steps

Remove the Test Strip: Remove the used BGStar Test Strip. The BGStar Meter will automatically deactivate.



IMPORTANT: If you do not remove the used test strip after 3 minutes of testing, the meter will deactivate. To activate your meter with a used test strip still in the meter, press the CHECK () button once. Do not attempt to apply blood or control solution to an already used test strip.

Remove the Lancet: When you have finished testing, snap off the cap from the lancing device.



While the lancet is still in the lancing device, replace the lancet cover onto the lancet. You can then safely handle the used lancet.



Extract the lancet from the lancet holder cup by pulling on the plastic collar of the lancet (near the middle of the lancet).



Replace the lancing device cap onto the lancing device until it snaps or clicks into place.



Discard Properly: Discard the used BGStar Test Strip and Lancet properly.



WARNING: The lancing device and lancets should only be used by one person. Never share lancing devices or lancets. Used test strips, lancets, and lancing devices may be considered biohazardous or medical waste in your city or town. Follow recommended safety measures for removal and disposal of test strips and lancets (e.g. contact your health professional) in order to reduce the risk of accidental lancet injury and transmission of infectious diseases. Used test strips and lancets should be placed in sharps containers (such as biohazard containers), hard plastic containers (such as detergent bottles), or metal containers (such as an empty coffee can). Such containers should be sealed and disposed of properly.

CHAPTER 9 Testing on Your Palm or Forearm

Testing glucose levels with blood obtained from the palm (at the base of the thumb) or forearm may reduce the pain of testing. The technique for testing on the palm and forearm is slightly different than testing on the finger. Always discuss changes to your testing habits with your health professional.

Application number: 184338 Date of revision: August 18, 2011 s-a Version 2.1 dated August 26, 2011 IMPORTANT: When testing on the palm (at the base of the thumb) or forearm, you may need to set the lancing device to a deeper setting or use a larger lancet to obtain enough whole blood to perform a test. Consult your health professional for a recommendation.

CAUTION: To ensure accurate results, wash your hands and test site with warm, soapy water and dry before every test. Clean and make sure there is no grease, oil or lotion on the test site.

Follow Chapter 8, steps 1-2, to begin blood glucose testing.

For testing on your palm or forearm:

- [1] **Prepare Lancing Device:** Always use the AST clear lancing device cap on the lancing device.
- [2] Rub Test Site: To increase the blood flow in your palm (at the base of the thumb) or forearm, rub the area that you will be testing. Ensure that your palm or forearm is facing up and held level.

Palm:



Forearm:

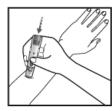


[3] Lance Test Site: Press the tip of the clear cap against your skin on the palm of your hand (at the base of the thumb) or forearm. Hold the tip to the test site for a few seconds before pressing the release button.

Palm:



Forearm:



Release Button

[4] Obtain Blood Drop: After lancing, hold the lancing device against your skin until a blood droplet forms. Make sure the blood drop is large enough to completely fill the visual fill window of the test strip. Pull the lancing device directly off your palm or forearm to ensure that you do not smear the blood drop.



Return to Chapter 8, step 4 to continue with testing instructions.

CHAPTER 10 Data Management Features

IMPORTANT: Results, averages and graphs stored in memory should only be used as a reference. Do not make treatment decisions based solely on stored results, averages and graphs. Consult with your health professional regarding treatment options.

This chapter covers the steps on how to view your:

- Individual Results (1865 past results, with time and date)
- 14 Day Statistics
- 14, 30 and 90 Day Averages
- Pre/Post Mealtime Averages and Glucose Variability Tracking
- 1 Month, 2 Week, 3 Day Trend Graphs

How to access all data management features:

All past test results are accessed the same way. The following instructions will explain how to get to the different types of data.

- [1] When your meter is deactivated, press the CHECK () button to enter menu mode. The word "MEM" is displayed.
- [2] Press the DOWN () arrow button to scroll forward and press the UP () arrow button to move backward through the categories of data.
- [3] Press the CHECK (button to enter into a category and view features.

About averages and standard deviations:

Control solution, out-of-temperature-range results, and results without a valid time or date are not included in averages, standard deviations and trend graphs. Hi and Lo test results will be included in averages as values of 33.3 mmol/L and 1.1 mmol/L, respectively. 14, 30 and 90 day averages and trend graphs are calculated by taking the average of all readings within the respective time period. Standard deviations, averages and trend graphs do not include the current day in their calculations.

The standard deviation is an expression of the variation of readings from the average reading. The greater this value the more variation exists between individual readings and the average. The standard deviation feature is a way to track your glucose variability.

You can transfer your stored results to a computer to track, identify patterns and print. For information on how to order the BGStar Diabetes Management Software please call toll free sanofi-aventis 24 hour support Tel.: 1-888-852-6887 or visit us at www.bgstar.ca

10.1 Viewing Individual Results

[1] When your meter is deactivated, press the CHECK (button once to enter menu mode. The word "MEM" is displayed.



[2] Press the CHECK (button again to enter the individual results section.



[3] Press the DOWN () arrow button to scroll through the individual readings. Press the UP () arrow button to scroll backwards.

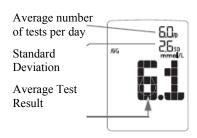
Note: When scrolling through, the oldest test result will cycle back to the most recent test result. To return to the menu, press the CHECK (button.

10.2 Viewing 14 Day Statistics

The stats feature allows you to compare your average test result, the standard deviation between test results, and the average number of tests per day over the last 14 day period.

- [1] When your meter is deactivated, press the CHECK (button once to enter menu mode. The word "MEM" is displayed.
- [2] Press the DOWN () or UP () arrow buttons until the word "STATS" appears on the display.

[3] Press the CHECK (button again to enter the statistics section.

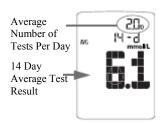


Note: To return to the menu, press the CHECK (button.

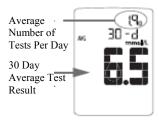
10.3 Viewing 14, 30 and 90 Day Averages

- [1] When your meter is deactivated, press the CHECK (button once to enter menu mode. The word "MEM" is displayed.
- [2] Press the DOWN () arrow button until the word "AVG" appears in the lower part of the display.

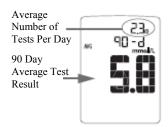
[3] Press the CHECK (button again to enter the 14, 30 and 90 day averages section. The display now shows your 14 day average and average number of tests per day.



[4] Press the DOWN (arrow button. The display now shows your 30 day average and average number of tests per day.



[5] Press the DOWN () arrow button. The display now shows your 90 day average and average number of tests per day.



Note: Press the UP () arrow button to scroll backwards. When scrolling, you will cycle through the 14, 30 and 90 Day Averages. To return to the menu, press the CHECK () button.

10.4 Viewing Pre/Post Mealtime Averages & Glucose Variability Tracking

The BGStar Meter categorizes readings as happening before or after meals. These averages allow you to see how your blood glucose levels vary by time of day. The pre/post mealtime averages and standard deviations only include the first instance of a particular mealtime tag (breakfast, post breakfast, lunch, post lunch, etc.) per day over the last 14 day period. The second and subsequent tests marked with the same time tag (on the same day) are not included. The standard deviation feature is a way to track your glucose variability.

Note: Standard deviation is always displayed with a decimal point.

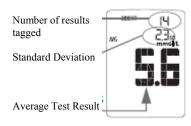


Example of a standard deviation of 2.0

- [1] When your meter is deactivated, press the CHECK (button once to enter menu mode. The word "MEM" is displayed.
- [2] Press the DOWN (or UP (arrow buttons until the word "MEAL" appears in the lower part of the display.

MEAL

[3] Press the CHECK (button again to enter the mealtime averages section. The display now shows your breakfast average.



[4] Press the DOWN (arrow button. The display now shows your post breakfast average



[5] Press the DOWN () arrow button. The display now shows your lunch average.



[6] Press the DOWN (arrow button. The display now shows your post lunch average.



[7] Press the DOWN () arrow button. The display now shows your dinner average.



[8] Press the DOWN () arrow button. The display now shows your post dinner average.



[9] Press the DOWN () arrow button. The display now shows your bedtime average.



Note: Press the UP () arrow button to scroll backwards. When scrolling, you will cycle through the Pre/Post Mealtime Averages. To return to the menu, press the CHECK () button.

10.5 Viewing 1 Month, 2 Week, and 3 Day Trend Graphs

- [1] When your meter is deactivated, press the CHECK (button once to enter menu mode. The word "MEM" is displayed.
- [2] Press the DOWN () or UP () arrow buttons until the abbreviation "GRAPH" appears in the lower part of the display.



[3] Press the CHECK (button again to enter the graph section. The display now shows your 1 month graph.



[4] Press the DOWN () arrow button. The display now shows your 2 week trend graph.

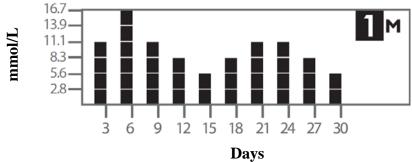


[5] Press the DOWN () arrow button. The display now shows your 3 day trend graph.



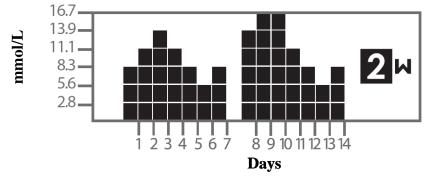
Note: Press the UP (\triangle) arrow button to scroll backwards. When scrolling, you will cycle through the Trend Graphs. To return to the menu, press the CHECK (\triangleleft) button.

1 Month Trend Graph:



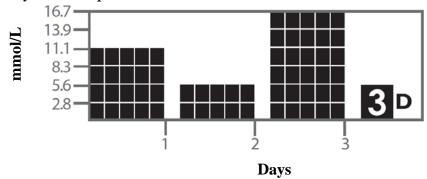
Each bar represents a test result average from 3 days. Each vertical unit represents about 2.8 mmol/L. *The most recent result is on the right side of the screen.*

2 Week Trend Graph:



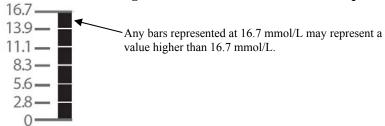
Each bar represents a test result average from 1 day. Each vertical unit represents about 2.8 mmol/L. *The most recent result is on the right side of the screen*.

3 Day Trend Graph:



Each bar represents a test result average from 1 day. Each vertical unit represents about 2.8 mmol/L. *The most recent result is on the right side of the screen.*

IMPORTANT: Averages above 16.7 mmol/L will not be represented in the trend graphs.



CHAPTER 11 Setting the Mealtime Tag

The BGStar Meter allows you to turn ON or OFF the feature that tags results as having occurred before or after a meal.

[1] When your meter is deactivated, press the CHECK (button once to enter menu mode. The word "MEM" is displayed.

[2] Press the DOWN () or UP () arrow buttons until the word "TAG" is displayed.



[3] Press the CHECK (button to enter and edit the tag setting.

[4] Turn the tagging feature ON or OFF with the DOWN () or UP () arrow buttons. Your selection will be highlighted by the blinking of the symbol. Press the CHECK () button to confirm your selection and return to the menu.



CHAPTER 12 Setting Meter Volume

- [1] When your meter is deactivated, press the CHECK (button once to enter menu mode. The word "MEM" is displayed.
- [2] Press the DOWN (or UP (arrow buttons until the word "BEEP" is displayed.



- [3] Press the CHECK (button to enter and edit the alarm volume setting.
- [4] Turn the volume ON or OFF with the DOWN () or UP () arrow buttons. Your selection will be highlighted by the blinking of the symbol. Press the CHECK () button to confirm your selection and return to the menu.

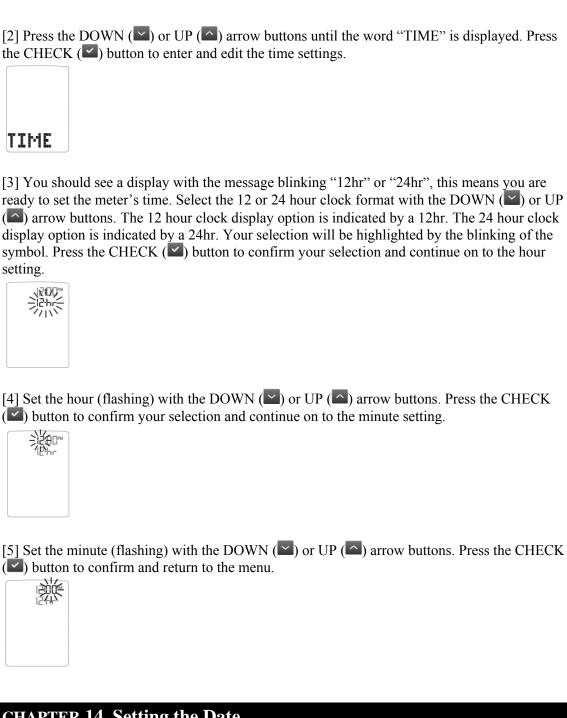


Note: The meter will always produce a beeping sound after you have applied blood or control solution to a test strip. This sound lets you know when to take your blood sample or control solution away from the test strip. You will hear this sound if the volume is set to ON or OFF.

CHAPTER 13 Setting the Time

IMPORTANT: Check the Time and Date settings before testing. In order to properly use the meter it is important to ensure that the time and date are set correctly.

[1] When your meter is deactivated, press the CHECK (button once to enter menu mode. The word "MEM" is displayed.

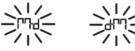


CHAPTER 14 Setting the Date

- [1] When your meter is deactivated, press the CHECK (button once to enter menu mode. The word "MEM" is displayed.
- [2] Press the DOWN () or UP () arrow buttons until the word "DATE" is displayed. Press the CHECK (button to enter and edit the date settings.



[3] You should see a display with the message blinking "M-d" or "d-M", this means you are ready to set the meter's date. Select the M-d (Month-Day) or d-M (Day-Month) date format with the DOWN () or UP () arrow buttons. Your selection will be highlighted by the blinking of the symbol. Press the CHECK () button to confirm your selection and continue on to the year setting.



[4] Set the year (flashing) with the DOWN () or UP () arrow buttons. Your selection will be highlighted by the blinking of the symbol. Press the CHECK () button to confirm your selection and continue on to the month setting.



[5] Set the month (flashing) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm your selection and continue on to the day setting.



[6] Set the day (flashing) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm your selection and return to the menu.



CHAPTER 15 Setting Hypoglycemic Warning Alarms

The Hypoglycemic Warning Alarm alerts you when your glucose test results are below the hypoglycemic threshold you have set. The meter is pre-set to a hypoglycemic threshold of 3.9 mmol/L. Always consult your health professional for your recommended target ranges. When your glucose test results are below your set hypoglycemic threshold, the meter display will flash your test results, the abbreviation "HYPO," time, and date repeatedly.

WARNING: Your health professional should recommend what your hypoglycemic limit is.

- [1] When your meter is deactivated, press the CHECK (button once to enter menu mode. The word "MEM" is displayed.
- [2] Press the DOWN () or UP () arrow buttons until the abbreviation "HYPO" is displayed.
- [3] Press the CHECK (button to enter and edit the Hypoglycemic Warning Alarm settings.
- [4] Set the Hypoglycemic Alarm ON or OFF with the DOWN () or UP () arrow buttons. Your selection will be highlighted by the blinking of the symbol. Press the CHECK () button to confirm your selection and move on to the hypoglycemic threshold setting.



[5] Set the hypoglycemic threshold (flashing) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm your selection and return to the menu.



CHAPTER 16 Setting Hyperglycemic Warning Alarms

The Hyperglycemic Warning Alarm alerts you when your glucose test results are above the hyperglycemic threshold you have set. The meter is pre-set to a hyperglycemic threshold of 13.3 mmol/L. Always consult your health professional for your recommended target ranges. When your glucose test results are above your set hyperglycemic threshold, the meter display will flash your test results, the abbreviation "HYPr," time, and date repeatedly.

Application number: 184338 Date of revision: August 18, 2011 s-a Version 2.1 dated August 26, 2011 WARNING: Your health professional should recommend what your hyperglycemic limit is.

- [1] When your meter is deactivated, press the CHECK (button once to enter menu mode. The word "MEM" is displayed.
- [2] Press the DOWN (or UP (arrow buttons until the abbreviation "HYPER" is displayed.

HYPER

- [3] Press the CHECK (button to enter and edit the Hyperglycemic Warning Alarm settings.
- [4] Set the Hyperglycemic Alarm ON or OFF with the DOWN () or UP () arrow buttons. Your selection will be highlighted by the blinking of the symbol. Press the CHECK () button to confirm your selection and move on to the hyperglycemic threshold setting.



[5] Set the hyperglycemic threshold (flashing) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm your selection and return to the menu.



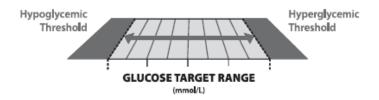
CHAPTER 17 Setting The Glucose Target Range

The BGStar includes a unique positive feedback feature where a happy face symbol is displayed with test results that fall within the glucose target range. By setting a target range for what your glucose levels should be before or after a meal, you customize when this symbol appears. Always consult your health professional for your recommended target ranges.

IMPORTANT: First set the hypoglycemic and hyperglycemic warning alarms to your recommended thresholds before making changes within the glucose target range menu (refer to chapters 15-16 for setting these alarms).

Note: The glucose target range is limited by the values set for your hypoglycemic and hyperglycemic warning alarms. Your meter will not allow you to select a number beyond these alarm settings, even if the warning alarm is turned off. For example: If you want the premeal target range to begin at 5.0 mmol/L, then the hypoglycemic alarm needs to be set at 5.0 mmol/L

Application number: 184338 Date of revision: August 18, 2011 s-a Version 2.1 dated August 26, 2011 or less; or if you want the postmeal target range to end at 10.0 mmol/L, then the hyperglycemic alarm needs to be set at 10.0 mmol/L or higher.



- [1] When your meter is deactivated, press the CHECK (button once to enter menu mode. The word "MEM" is displayed.
- [2] Press the DOWN () or UP () arrow buttons until the word "RANGE" is displayed.



- [3] Press the CHECK (button to enter and edit the glucose target range settings.
- [4] Set the lower limit of the premeal glucose target range (flashing) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm your selection and continue on to the upper limit premeal setting.



[5] Set the upper limit of the premeal glucose target range (flashing) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm your selection and continue on to the lower limit postmeal setting.



[6] Set the lower limit of the postmeal glucose target range (flashing) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm your selection and continue on to the upper limit postmeal setting.



[7] Set the upper limit of the postmeal glucose target range (flashing) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm your selection and return to the menu.



CHAPTER 18 Setting Alarms

There are 7 alarms you can set to remind you when to test your glucose levels.

When alarms are activated:

- [1] If an alarm is set and the BGStar Meter is deactivated, the alarm will activate the meter. "AL1" through "AL7" (depending which alarm is set) is displayed. The display backlight flashes, and the meter will beep repeatedly for 15 seconds.
- [2] You can turn the alarm OFF by pressing any button.
- [3] The alarms will not appear during menu and test modes. If an alarm is set to sound or flash while using these modes, it will alarm after the meter is deactivated.

CAUTION: Follow your health professional's recommendations on when and how often to test your glucose.

How to set alarms:

- [1] **Enter MEM Mode:** When your meter is deactivated, press the CHECK (\checkmark) button once to enter menu mode. The word "MEM" is displayed.
- [2] **Enter Alarm Option:** Press the DOWN ($\stackrel{\smile}{}$) or UP ($\stackrel{\frown}{}$) arrow buttons until the word "ALARM" is displayed. Press the CHECK ($\stackrel{\smile}{}$) button to enter and set an alarm.



[3] **Select An Alarm to Set:** Choose the alarm you want to set with the DOWN () or UP () arrow buttons. If this is your first time setting an alarm, use AL1. Press the CHECK () button to confirm your selection and advance to the alarm ON or OFF section.



[4] **Turning Alarms ON or OFF:** Turn the alarm ON or OFF with the DOWN () or UP () arrow buttons. Your selection will be highlighted by the blinking of the symbol. Press the CHECK () button to confirm your selection and move to the set alarm time section.



[5] **Set Alarm Time:** You can now set the alarm time. First, set the hour (flashing numbers) with the DOWN () or UP () arrow buttons. Accelerated change is possible by holding down the arrow buttons. Press the CHECK () button to confirm the hour and advance to the minutes.



Set the minute (flashing numbers) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm the minutes and return to the MENU Mode.



Note: The volume of an alarm will be affected by your meter's volume setting, which can be changed in the meter's "BEEP" option. If your meter has the volume turned OFF, then the alarm will not sound, but the backlight will flash.

[6] **Setting Multiple Alarms:** To set other alarms, press the DOWN () or UP () arrow buttons until the alarm you want to set (AL1 to AL7) is displayed. Follow the previous steps in this section.

CHAPTER 19 Errors and Troubleshooting

The BGStar Blood Glucose Monitoring System has been designed to work accurately under normal conditions. On rare occasions, the meter will display an error message instead of a glucose result. The BGStar System is able to detect specific problems which may allow you to determine the cause of the error without wasting valuable test strips. When you are presented with an error message, check for common problems within this chapter that may explain the source of the error.

CAUTION: In certain cases, the meter may return an error code or provide an inaccurate result if it is being used near electrical equipment, like a power generator or a computer monitor. If this is the case, move the meter away from the source of electrical interference.

ER.1

Error 1:

Problems have occurred that are related to test strip use.

- [1] If this message appears the moment the test strip is inserted, the test strip may be wet or damaged.
- [2] If the message appears during a test, the test strip may have been removed too early.
- [3] If this message appears after the last progress bar instead of a result, it may indicate that you applied more blood after testing began.

ER.2

Error 2:

The meter has detected an irregularity with the sample.

- [1] The test strip may be partially filled; you should check the window of the test strip to confirm that it is full.
- [2] The sample may not be blood or control solution.

ER.3

Error 3:

The meter has detected that the test strip is in poor condition.

- [1] The test strip may have been improperly stored (e.g. hot, humid conditions) or may be expired.
- [2] The test strip may have been mishandled by vigorous bending or shaking.
- [3] Parts of the test strip may have become covered in grease, oil, or lotion.

[4] The strip port connector may be dirty.

ER.4

Error 4:

Unusual test strip problems have occurred that may be related to extreme conditions.

[1] Retest where it is closer to a room temperature of 21°C to 24°C.

ER.5

Error 5:

The meter was unable to produce a reliable result.

- [1] This may be caused by a non-blood sample, or a combination of high glucose and other medical conditions.
- [2] If this error code persists on retesting, consult your health professional.

ER.5

Error 6:

The test strip has taken too long to generate a signal.

- [1] This may be caused by a combination of cold operating temperature and high hematocrit levels. Retest in a warmer location.
- [2] If this error code persists on retesting, consult your health professional.

ER.7

Error 7:

Meter problems have occurred that are beyond your control.

Call sanofi-aventis toll free at: 1-888-852-6887 for assistance.

TEMP

Temp Icon:

Test was performed outside the system operating temperature range of 10°C to 40°C.

Move to an area with an ambient temperature of 10° C to 40° C. Wait for the meter and test strips to reach the new temperature (usually 10-20 minutes) and retest.



Battery Icon:

Battery #2 has died during test.

Replace battery #2 immediately before retesting.

Troubleshooting Situation #1: Meter does not enter the test mode after inserting a BGStar Test Strip.

- [1] **CAUSE:** The batteries have insufficient power. **ACTION:** Replace the batteries, set time and date, and test.
- [2] **CAUSE:** The batteries are installed incorrectly or there are no batteries in the meter. **ACTION:** Check that both batteries are installed correctly, with the positive (+) sign facing up towards you.
- [3] **CAUSE:** BGStar Test Strip has been inserted upside down, wrong end in, or incompletely inserted into the meter. **ACTION:** Insert the BGStar Test Strip with the black side up and the contact bars of the test strip in the meter. Ensure that the test strip is fully inserted.
- [4] **CAUSE:** Defective meter or defective BGStar Test Strips. **ACTION:** Call sanofi-aventis toll free at: 1-888-852-6887.
- [5] **CAUSE:** Blood or foreign objects introduced into the BGStar Meter strip port. **ACTION:** Please refer to chapter 22. If problem persists, call sanofi-aventis toll free at: 1-888-852-6887 and have the meter serial number available (located on back of the meter).

Troubleshooting Situation #2: The glucose test sequence does not start after applying the blood sample.

- [1] **CAUSE:** Defective test strip. **ACTION:** Repeat the test with a new BGStar Test Strip. If problem persists, call sanofi-aventis toll free at: 1-888-852-6887 and have the test strip LOT number available (located on the test strip vial).
- [2] **CAUSE:** Sample applied after meter times out and deactivates. **ACTION:** Repeat the test using a new BGStar Test Strip. Wait until you see the blood and test strip symbols on the display before you apply the blood sample.
- [3] **CAUSE:** Sample not applied to the tip of the test strip. **ACTION:** Repeat the test using a new BGStar Test Strip.
- [4] **CAUSE:** Defective meter. **ACTION:** Call sanofi-aventis toll free at: 1-888-852-6887 and have the meter serial number available (located on the back of the meter).

CHAPTER 20 Display Messages

CAUTION: Low or high blood glucose test results can indicate a potentially serious medical condition. Follow your health professional's recommendations.

LO MESSAGE: Flashing message, with double beep (if volume is enabled).

MEANING: Glucose test result is lower than 1.1 mmol/L. This Lo result may indicate hypoglycemia (low blood glucose). The Lo result is stored in the memory with time and date. It will be included in averages as a value of 1.1 mmol/L.

ACTIONS: If you feel symptoms such as weakness, sweating, nervousness, headache or confusion, follow your health professional's recommendations. If you get a Lo glucose test result but have no symptoms of low blood glucose, then retest with a new BGStar Test Strip. If you still get a Lo test result, follow the treatment plan recommended by your health professional team or contact your health professionnal immediately.

HI MESSAGE: Flashing message, with double beep (if volume is ON).

MEANING: Glucose test result is above 33.3 mmol/L. This Hi result may indicate hyperglycemia (high blood glucose). The Hi result is stored in the memory with time and date. It will be included in averages as a value of 33.3 mmol/L.

ACTIONS: If you feel symptoms such as fatigue, thirst, excessive urination, or blurry vision, follow your health professional's recommendations. If you get a Hi glucose test result but have no symptoms of high blood glucose, then retest with a new BGStar Test Strip. If you still get a Hi glucose test result, follow your health professional's recommendations. Checking ketones may be advisable.

HYPOGLYCEMIC WARNING ALARM: Flashing message with the time. Test result flashes, with double beep (if volume is ON).

HYPO

MEANING: If the Hypoglycemic Warning Alarm is set, your glucose test result is lower than the pre-set threshold.

HYPERGLYCEMIC WARNING ALARM: Flashing message with the time. Test result flashes, with double beep (if volume is ON).

H닉Pr

MEANING: If the Hyperglycemic Warning Alarm is set, your glucose test result is higher than the pre-set threshold.

KETONE MESSAGE: Flashing message, with double beep (if volume is ON).

K

MEANING: The result of the glucose test is higher than 13.3 mmol/L.

ACTIONS: You should check ketones. Follow your health professional's recommendations.

TEMPERATURE MESSAGE: Flashing message, with double beep (if volume is ON).

TEMP

MEANING: The test has been performed outside the operating temperature range. **ACTIONS:** Move to an area with an ambient temperature of 10°C to 40°C. Wait for the meter and test strips to reach the new temperature (usually 10-20 minutes) and retest.

LOW BATTERY MESSAGE: Flashing message



MEANING: Battery #2 in your meter is low.

ACTIONS: If the low battery symbol appears, battery #2 must be replaced. Battery numbers are indicated by the numbers printed on the pull tabs.

DEAD BATTERY MESSAGE: Flashing message



MEANING: Battery #2 in your meter is dead.

ACTIONS: If the dead battery symbol appears, the dead battery must be replaced.

LOW BACKLIGHT BATTERY: Backlight flashes when user presses the BACKLIGHT (*) button.

MEANING: Battery #1, which powers the backlight, is low.

ACTIONS: If the backlight flashes when user presses the BACKLIGHT (button, battery #1 must be replaced. If the backlight does not turn on, battery #1 is dead and must be replaced. (Battery numbers are indicated by the numbers printed on the pull tabs).

CHAPTER 21 Batteries

CAUTION: When the battery symbol appears, you should replace the batteries immediately. Only use CR2032 batteries.

Your BGStar Meter comes with two pre-installed, CR2032, 3 volt, lithium batteries. Battery #1 powers the backlight and battery #2 powers the basic meter functions. When the power from battery #2 is low, the low battery symbol or dead battery symbol will be displayed on the screen until you change battery #2. When replacing battery #2, the time and date information may be lost after the battery is removed from the meter. If this happens, activate the meter after installing the new battery and it will prompt you to set the time and date. Correct time and date settings are needed to get correct averages. Removing the batteries does not affect the meter's memory or previously stored user settings, such as time format, alarms, etc.

Note: Dispose of used batteries according to your local environmental regulations. Your meter is an electronic device. When disposing of your meter follow all local environmental regulations.

Application number: 184338 Date of revision: August 18, 2011 s-a Version 2.1 dated August 26, 2011

Replacing the Batteries

[1] **Open Battery Door:** Make sure the meter is deactivated. Turn the meter so you are looking at the battery door. Press the battery door clip to open. Remove the battery door. Be careful not to misplace the battery door.



[2] **Remove and Install the meter battery:** To remove the used battery, pull the appropriate tab to pop out the battery. Install the new battery with the positive (+) sign facing up towards you.



[3] **Remove and Install the backlight battery:** To remove the used battery, pull the appropriate tab to pop out the battery. Install the new battery with the positive (+) sign facing up towards you.



[4] **Close Battery Door:** Angle the battery door back onto the meter and swing down until it snaps gently into place. Make sure that the battery door is completely closed before using.



IMPORTANT: When the meter is deactivated and you are replacing battery #2, the time and date information may be lost after the battery is removed from the meter. If this happens, activate the meter after installing the new battery and it will prompt you to set the time and date.

Time and Date Setting After Battery Replacement

If the date and time need to be set, the word "SET" will be displayed the first time the meter is activated.

Note: The meter retains the date and time format [24 or 12 hour time, M-d (Month-Day) or d-M (Day-Month)]

[1] Set the year (flashing) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm your selection and continue on to the month setting.



[2] Set the month (flashing) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm your selection and continue on to the day setting.



[3] Set the day (flashing) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm your selection and continue on to the hour setting.



[4] Set the hour (flashing) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm your selection and continue on to the minute setting.



[5] Set the minute (flashing) with the DOWN () or UP () arrow buttons. Press the CHECK () button to confirm your selection. If the meter was activated via strip insertion, pressing CHECK () allows you to perform a test. If the meter was activated via the CHECK () button, the meter will enter menu mode.



CHAPTER 22 Caring For Your Meter and Lancing Device

When using your meter, avoid getting dirt, dust, blood, control solution, water or any other liquid into the strip port and battery compartment. Clean the outside of the meter or the lancing device

using a cloth dampened with mild detergent or mild soap. If you wish to clean the lancing device cap only, remove the cap, wash it in warm water, rinse well, and dry.

CAUTION: Never immerse the meter or the body of the lancing device in water or any other liquid solution.

CHAPTER 23 Meter Specifications

Assay Method: Dynamic Electrochemistry *Maximum Altitude:* 3,048 meters (10,000 feet)

Calibration: Plasma equivalent

Coding: No Code

Reference Number: 8000-06968 **Sample:** Whole blood, capillary Sample Size: 0.5 microliters

Average Glucose Test Time: 6 seconds

Measurement Units: mmol/L *Alarms:* 7 programmable alarms **Result Range:** 1.1 to 33.3 mmol/L

Hematocrit: 20% to 60%

Operating Relative Humidity: Up to 90% *Operating Temperature:* 10°C to 40°C

Control Solution Storage Temperature: 2°C to 30°C

Test Strip Storage Temperature: 8°C to 30°C

Memory: 1865 blood glucose and control solution test results with date, time, and averaging (14,

30, 90 days and mealtimes)

Power Source: Two replaceable CR2032, 3 volt, lithium batteries

Automatic Deactivation: 3 minutes after last user action Size: 8.6 cm x 4.6 cm x 1.6 cm (1.81" x 3.39" x 0.63")

Weight: 48 g (including batteries)

Equipment not suitable for use in the presence of flammable mixtures.

This meter complies with the applicable standards for Electromagnetic Compatibility; however it is not recommended that it be used in the presence of strong electromagnetic fields. When using this meter, keep away from sources of electromagnetic disturbances such as electric motors or radio transmitting equipment. This meter should not affect the normal operation of other devices. If this does occur, provide more distance between the meter and the affected device.

CHAPTER 24 Symbols

The following symbols may appear on the equipment packages or in the documents.

Serial Number: SN

Manufacturer:

In Vitro Diagnostic Medical Device: IVD

Application number: 184338 Date of revision: August 18, 2011 s-a Version 2.1 dated August 26, 2011 Page 47 of 48

Batch Code: LOT

Consult Instructions For Use:

Do Not Reuse: ②

Temperature Limitation: 8°C 1 30°C

Use By:

Reference Number: REF