SAP-Nummer	521873	Abmessungen	Format (B x H) 101,6 x 139,7 mm
Sprachvariante	103	Farbe	Cyan Magenta
Erstellversion	4		Yellow Black
Packmittel erstellt am	24.09.2013 / Keim		
Packmittel geändert am	09.10.2013 / Perleth		

MyStar Extra®

BLOOD GLUCOSE MONITORING SYSTEM

OWNER'S GUIDE

MyStar
SANOFI DIABETES

CAUTION: Please read all the instructions provided in this Owner's Guide and practice the testing procedures before using the MyStar Extra® Blood Glucose Monitoring System. Self blood glucose monitoring should be done under the guidance of a healthcare professional.

Key Features of MyStar Extra®:

No Coding Required: The MyStar Extra® doesn't require you to enter a calibration code. Insert a BGStar® Test Strip and you are ready to test.

Pre/Post-Meal Tagging: After you test, your result is tagged with the mealtime. You can organize your data and see how your test results change before meals, after meals, and when fasting.

Estimate A1c: Use the estimated A1c (~A1c) tool to facilitate a meaningful dialogue between patients and the healthcare professional in between laboratory haemoglobin A1C tests.

MyStar Extra®

Blood Glucose Monitoring System

Toll-Free, 24-Hour Customer Service: 08000 35 25 25

In case of emergency, contact your healthcare professional or emergency medical response.

CE 0123

Manufacturer:
AgaMatrix, Inc.
7C Raymond Avenue
Salem, NH 03079, USA

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Distributed by:
Sanofi UK,
One Onslow Street,
Guildford, Surrey, GU1 4YS

Date of revision: September 2013

SANOFI

<MAT>521873

Contents

CHAPTER 1 Important Information About Your MyStar Extra® Blood Glucose Monitoring System

The MyStar Extra® System should be used:

[1] As indicated for single-patient use for self testing (over the counter [OTC]) by persons with diabetes, as an aid to monitor the effectiveness of diabetes control.

[2] For measuring blood glucose levels from fresh capillary whole blood samples taken from the fingertip.

[3] For *in vitro* (i.e. outside of the body) diagnostic use only.

[4] With BGStar® Test Strips and Control Solution only. Do not use other brands of test strips and control solution with this meter. This may produce inaccurate results. BGStar® Test Strips are designed for use with the Sanofi family of meters.

Do not use the MyStar Extra® System for:

[1] The diagnosis of diabetes.

[2] Testing the glucose levels of neonates (children younger than 4 weeks of age).

[3] Testing the glucose levels of pregnant women.

[4] Testing glucose levels of arterial or venous blood.

[5] Testing glucose from sites other than the fingertip.

Test site:

The MyStar Extra® System requires only a small droplet of blood (0.5 microliters), about the size of a pinhead, to perform a glucose test. Test using blood from the tip of any finger.

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

The MyStar Extra® Blood Glucose Meter has small parts, store meter away from children.

CHAPTER 2

Important Safety Instructions

The meter and lancing device are for single-patient use. Do not share them with anyone, including other family members! Do not use on multiple patients!

All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed disinfection.

For important instructions for disinfecting your meter and lancing device, please read Chapter 5.

CHAPTER 3

Getting Started

Your MyStar Extra® Blood Glucose Monitoring System MyStar Extra® System) Kit contains:

- MyStar Extra® Blood Glucose Meter (Referred to as "MyStar Extra® Meter" or "the meter")
- Two pre-installed CR2032, 3 volt lithium batteries
- One Lancing Device with Cap
- Three bags of 10 33 gauge Lancets
- One Vial of 25 count BGStar® Blood Glucose Test Strips
- BGStar® Control Solution (control solution)
- MyStar Extra® Owner's Guide
- One Set of Flashcards
- One Warranty Card
- One MyStar Extra® Compact Carrying Case

Dispose of packing material properly after unpacking your MyStar Extra® System Kit.

Store the MyStar Extra® Blood Glucose Meter in the Carrying Case when not in use.

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

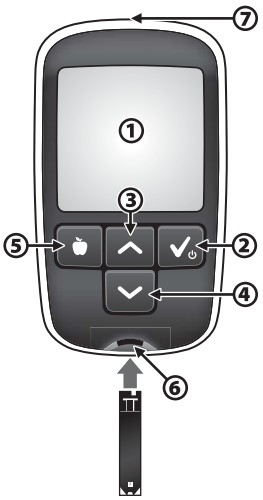
For step-by-step instructions on changing the time and date settings, please refer to Chapter 8.

CHAPTER 4

About the MyStar Extra® Blood Glucose Monitoring System

The MyStar Extra® Blood Glucose Monitoring System is made up of the MyStar Extra® Blood Glucose Meter, BGStar® Test Strips, BGStar® Control Solution, and a lancing system.

About the MyStar Extra® Meter



(1) Display: Glucose test results, icons, calculations, and error messages appear here.

(2) CHECK ( ) Button: Use the CHECK button to activate and deactivate the meter, access the settings menu, confirm a selection, navigate between modes and activate the backlight.

(3) UP ( ) Arrow Button: Use the UP arrow button to scroll backward through options.

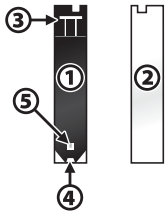
(4) DOWN ( ) Arrow Button: Use the DOWN arrow button to scroll forward through options.

(5) MEALTIME ( ) Button: Use the MEALTIME button to select mealtime tags for readings.

(6) Test Strip Port: Insert the BGStar® Test Strip, with the contact bars facing up, into the test strip port.

(7) Mini-USB Port: Use for communication with Sanofi approved software and devices (where available). Do not connect other cables or devices into this port.

About the BGStar® Test Strip



(1) Front of the Test Strip: The front of the test strip is black in colour. Ensure that the front (black-coloured) side of the test strip is facing towards you when inserting a test strip into the meter test strip port.

(2) Back of the Test Strip: The back of the test strip is white in colour. Ensure that the back (white-coloured) side of the test strip is facing away from you when inserting a test strip into the meter test strip port.

(3) Contact Bars: This end is inserted, front of the test strip facing towards you, into the meter 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.

IMPORTANT: Use test strips only once. Use only BGStar® Test Strips with your MyStar Extra® Meter.

Important test strip information:

[1] Store the BGStar® Test Strip vial in a 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 test strips in their original vial only. Never store them in another vial, in any other container, or outside the vial.

[5] Handle the test strip with clean, dry hands.

[6] After removing a test strip from the vial, immediately close the vial cap tightly.

[7] Do not use test strips beyond the expiration date or 180 days after first opening the vial. This may result in inaccurate readings. Write the discard date (180 days from the first opening) in the space provided on the test strip vial.

[8] Do not bend, cut, or alter test strips.

[9] Apply only fresh capillary whole blood or control solution to the sample area of the test strip.

About the BGStar® Control Solution

The MyStar Extra® System has 2 different levels of control solution available – Normal and High. The Normal Control Solution is provided with the MyStar Extra® System Kit. If you would like to use High Control Solution, please contact Customer Service at 08000 35 25 25

Control solution should be used only 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 control solution. This is your discard date. Write the discard date on the control solution bottle.

The control solution is used to:

[1] Ensure that your meter and test strips work properly together.

[2] Practice testing without having to use your own blood.

Important BGStar® Control Solution information:

[1] Use only BGStar® Control Solution with your MyStar Extra® Meter.

[2] Always shake the control solution bottle before use.

[3] Always discard the first drop of control solution and wipe the bottle tip clean using a clean tissue or paper towel.

[4] Replace the cap on the control solution bottle immediately after use.

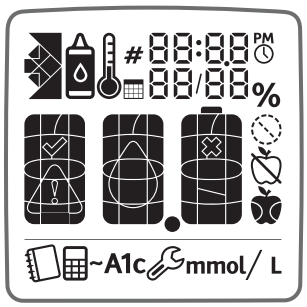
[5] Do not add water or any other liquid to control solution.

[6] Control solution tests should be performed within the system operating temperature range of 10°C to 40°C.

About the Lancing System

Note: Lancing devices and lancets are only intended for a single user and should not be shared between users.

About the MyStar Extra® Meter Display and Icons



Backlight: The backlight is illuminated whenever the meter is activated. It will deactivate after thirty seconds of inactivity. The backlight will be reactivated by pressing any button before advancing screens.

(1) Date and Time: The date and time appear on each reading in your meter.

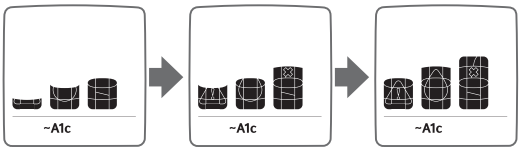
(2) Units of Measurement: Results will be displayed in mmol/L.

(3) Control Solution Icon: Appears to the left of the date when viewing a control solution test result.

(4) Apply Sample to Test Strip Message: After inserting a new test strip, a flashing droplet icon will appear on the meter display as well as the current date and time. This means that the meter is ready and you can now apply a sample to the test strip. A sample may be either control solution or blood.

(5) Calculating Animation: An animated sequence of "1, 2, 3" will appear on the meter display after a sample has been applied to the test strip. This means the meter is calculating the test result.

(6) Calculating ~A1c Animation: An animated sequence of appearing and disappearing bars will appear on the meter display while an ~A1c result is being calculated.



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

There are four icons for Mealtime tags:

Tag Icons:

- No Tag
- Fasting
- Pre Meal
- Post Meal

(8) Menu Icons: These icons represent the four different modes:

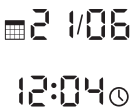
 1. Logbook

 2. Averages

~A1c 3. Estimated A1c

 4. Settings

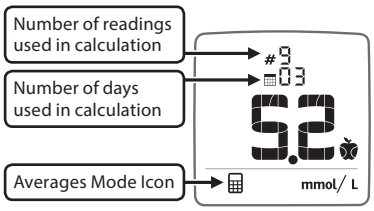
(9) Date and Time Icons: The date icon () and the time icon () are displayed next to the date and time when you are in the settings screen.



(10) Number of Days used for Average Calculations: The date icon () is displayed on the averages screen to indicate the number of days used in the average calculation.

(11) Number of Days remaining until your next profile is needed: The date icon () is displayed on the ~A1c results screen indicating the number of days remaining until your next profile is needed.

(12) Number of Readings used in Calculations: The number of readings used in the average calculation is indicated next to the number icon (#).



(13) Trending Arrows: Trending arrows may be seen in the Logbook as well as the ~A1c results screen. The trend arrows in the logbook illustrates the direction of your average fasting glucose reading from the past 3 days as compared to the median fasting value over the 7 days before. The trend arrows in the ~A1c results screen indicate the trend of your A1c result compared to two weeks ago.

1. Trending up
2. Trending down
3. Steady

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

(15) Low Battery Icon: Appears when battery #2 (see Chapter 12) in your meter is running low. For complete instructions on identifying and changing your meter batteries, refer to Chapter 12.

(16) Dead Battery Icon: Appears when battery #2 in your meter is dead. For complete instructions on identifying and changing your meter batteries, refer to Chapter 12.

CHAPTER
5 Important Disinfection Procedures

When using your meter, avoid getting dirt, dust, blood, control solution, water, or any other liquid inside the test strip port, battery compartment and mini-USB port. You should wash your hands thoroughly after handling the meter, lancet, lancing device, and test strips. Your meter and lancing device should be disinfected periodically. Cleaning and disinfecting will kill the bacteria and viruses that you cannot see.

Cleaning and disinfecting your meter and lancing device

CAUTION: Never immerse the meter or the body of the lancing device in water or any other liquid solution. Be careful when cleaning and disinfecting your meter. Avoid getting liquid inside the test strip port and mini-USB port.

When should you clean and disinfect your meter, and lancing device?

We recommend that you clean and disinfect your meter and lancing device once a week because you are the only person operating the meter and components. If the meter is being operated 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 second person. The disinfection instructions in this chapter were validated for 260 cleaning and disinfection cycles, for a total of 520 wipes (260 cleaning wipes plus 260 disinfecting wipes) on the lancing device and MyStar Extra® Meter. The life of the MyStar Extra® Meter, defined as 5,000 test strip insertions, is between 3 to 5 years, depending on use. The number of cleaning and disinfecting wipes used simulates cleaning and disinfecting your meter once a week for 5 years.

What can you use to clean and disinfect your meter and lancing device?

See the table below for the suggested disinfecting wipe. You should use wipes that are pre-saturated with disinfectant. Do not immerse your meter or the body of the lancing device in any liquid solution.

If you suspect your meter is not working properly after disinfecting, verify that your system is working properly by performing a control solution test. If your control solution test result falls outside of the control range, call Customer Service at 08000 35 25 25
If you should notice any signs of deterioration on the meter or lancing device (such as clouding on the meter, corrosion or erosion of meter, lancing device plastic housing or cracking of plastic housing, display, or button) or if the meter does not turn on, or if the lancing device does not work after cleaning and disinfection, discontinue use of the system and contact Customer Service at 08000 35 25 25

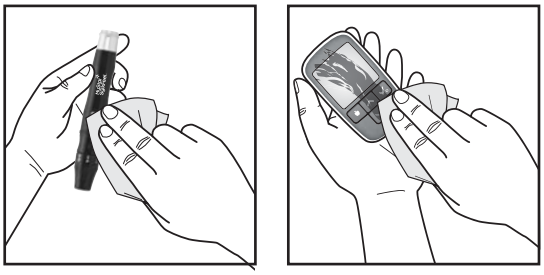
Availability of disinfecting wipe may vary. For updated information, call Customer Service at 08000 35 25 25

EPA #	Brand Name	Manufacturer	Available at	Contact Time
9480-4*	Super Sani-Cloth Germicidal Disposable Wipes	Professional Disposables International, Inc. (PDI)	Online: Amazon.com Officedepot.com	2 minutes

*Active ingredient: Quaternary ammonium chlorides and isopropanol.

How do you clean and disinfect your meter and lancing device?

1. Before you clean and disinfect your meter and lancing device, pre-clean the outside of the meter and lancing device with a disinfecting wipe.
2. With a new disinfecting wipe, clean and disinfect your meter and lancing device. Use the disinfecting wipe listed in the table above and follow the instructions below. In addition, follow the instructions on the disinfecting wipe container label for safe handling of the wipes.
3. Wipe each side of your meter and lancing device with moderate pressure 3 times using the following method:
   a. Wipe up and down 3 times.
   b. Wipe left and right 3 times.
   c. Avoid getting disinfectant inside the test strip port and the mini-USB port.
4. After 2 minutes of contact time, let air dry.



You should wash your hands thoroughly with soap and water after handling the meter, lancet, lancing device, and test strips.

If you have any questions about cleaning and disinfecting your meter or lancing device, call Customer Service at 08000 35 25 25

CHAPTER

6 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 healthcare 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 that fall below 3.9 mmol/L or rise above 13.3 mmol/L, follow the treatment plan recommended by your healthcare team or contact your healthcare professional immediately.

[7] If you are experiencing symptoms that are not consistent with your blood glucose test result and you have followed all instructions described in this Owner's Guide, follow your healthcare professional's recommendations.

[8] If you get repeated error messages and are experiencing symptoms of hypo or hyperglycemia, contact your healthcare professional immediately as this may indicate low or high glucose. If this error code persists on retesting, consult your healthcare professional.

[9] Do not use test strips that are expired or appear to be damaged as they may return inaccurate results.

[10] Healthcare professionals should follow their institution's infection control protocols.

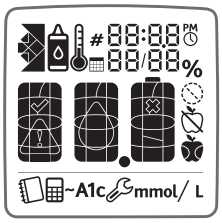
[11] Always follow your healthcare professional's recommendations.

The normal fasting adult blood glucose range for a person without diabetes is 3.9-5.5 mmol/L.

Treatment goals are individualized for each patient. Speak with your healthcare professional about the target blood glucose ranges that are right for you.

CHAPTER
7 MyStar Extra® Meter Basics

METER SYSTEM CHECK



Each time your meter is activated, the meter will perform a meter system check. All display segments 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 Customer Service immediately at 08000 35 25 25

HOW TO ACTIVATE THE METER AND VIEW INDIVIDUAL RESULTS

[1] When your meter is deactivated, press the CHECK ( ) button to activate the meter.

[2] Press the DOWN ( ) or UP ( ) arrow button repeatedly to scroll through each test result, starting from the most recent and ending with the oldest.

HOW TO ACTIVATE THE METER AND VIEW , MEALTIME AVERAGES, AND ~A1c

[1] Press the CHECK ( ) button again to reach Averages and ~A1c.

HOW TO DEACTIVATE THE METER

To deactivate the meter, press and hold the CHECK (✓) button for 2 seconds. If the meter is inactive for one minute, it will deactivate automatically.

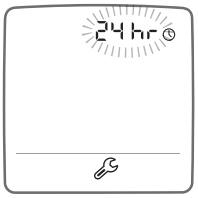
CHAPTER

8 Setting the Time and Date

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.

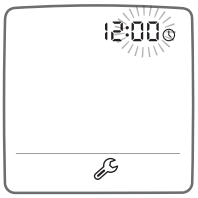
[1] When your meter is deactivated, press and hold the CHECK ( ) button to enter settings mode. The settings icon ( ) will appear with the "24 hr" flashing next to the time icon ( ).

[2] Press the DOWN ( ) or UP ( ) arrow button to choose between 12 hour and 24 hour time format settings. Press the CHECK ( ) button to confirm your selection and continue on to the hour setting.



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

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



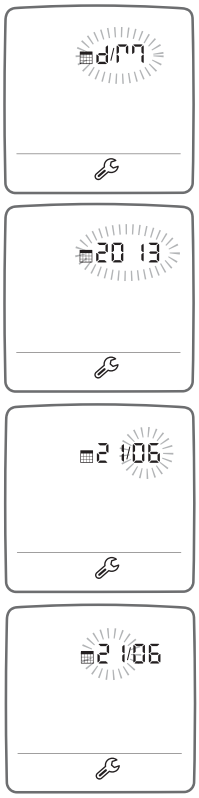
[5] Set the day-month format setting (flashing) with the DOWN ( ) or UP ( ) arrow button to choose between Month-day or Day-Month format. Press the CHECK ( ) button to confirm your selection and continue on to the year setting.

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

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

[8] Set the day (flashing) with the DOWN ( ) or UP ( ) arrow button. Press the CHECK ( ) button to confirm your selection.

[9] Press and hold the CHECK ( ) button to exit the settings mode.



CHAPTER

9 Performing a Control Solution Test

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.

Important BGStar® Control Solution information:

[1] Use only BGStar® Control Solution with your MyStar Extra® Meter.

[2] Do not add water or any other liquid to control solution.

[3] Control solution tests should be performed within the system operating temperature range of 10°C to 40°C.

Control solution should be used only 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 control solution. This is your discard date. Write the discard date on the control solution bottle.

The control solution is used to:

[1] Ensure that your meter and test strips work properly together.

[2] Practice testing without having to use your own blood.

Control solution tests should be performed when you:

[1] First get your meter and want to practice a test first.

[2] Suspect that your meter or test strips are not working properly.

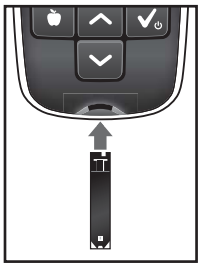
[3] Think your test results are not accurate.

[4] Have dropped or damaged your meter or exposed your meter to liquids.

[5] Are advised by your healthcare professional to do so.

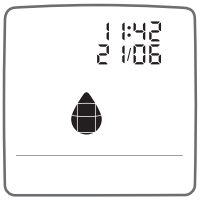
HOW TO PERFORM A CONTROL SOLUTION TEST

[1] Insert a BGStar® Test Strip



Insert a new Test Strip with the contact bars facing towards you into the meter test strip port. The meter will activate when the test strip is fully inserted. All segments will briefly flash on.

[2] Meter Ready for Test



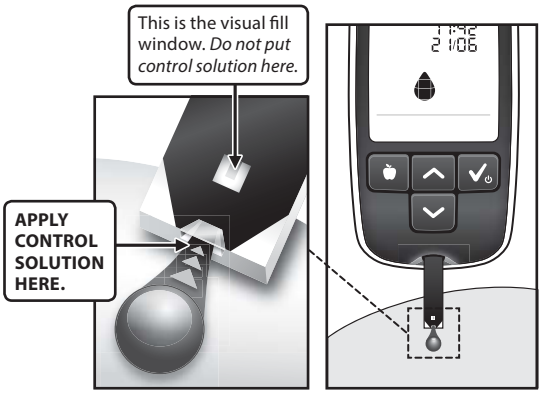
The meter now displays time and date and a flashing droplet icon.

The meter is now ready for you to apply control solution. You do not need to set a calibration code for the MyStar Extra® Meter (no coding required).

Note: If you do not start the test within 2 minutes of inserting a test strip, the meter will deactivate. To reactivate your meter, take out the unused test strip and reinsert it into the meter. Avoid touching the test strip sample area (where control solution should be applied).

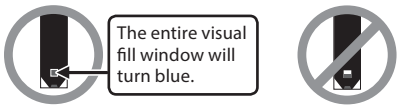
[3] Apply Control Solution

- Shake the control solution bottle.
- Discard the first drop of control solution.
- Wipe the bottle tip clean using a clean tissue or paper towel.
- Dispense a second drop onto a clean surface, such as an unused re-sealable plastic bag.
- Bring the tip of the test strip to the control solution sample.



The MyStar Extra® Meter will automatically detect if a test is performed with BGStar® Control Solution.

[4] Remove Test Strip From Control Solution Sample When the Test Strip Visual Fill Window Completely Turns Blue



When the meter beeps you should move the test strip away from the control solution sample. The Calculating Animation (a sequence of the numbers 1, 2, 3) will begin on the meter display. This animation means that a sample has been applied to the test strip and the meter is calculating the control solution test result.

Calculating Animation:

[5] View Control Solution Test Result

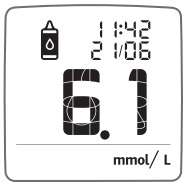
The control solution test result will appear on the meter display. The date, time and control solution icons will also appear on the display. The control solution test result is stored in the memory of your meter but is not included in Averages or ~A1c calculations.

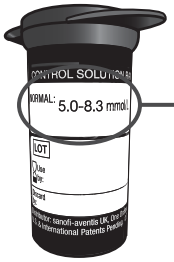
Example:

[6] Check if Result Is in Range

Compare the result of your control solution test to the range printed on your BGStar® Test Strip vial label. Your control solution result should fall within this range.

Example:





Normal: 5.0-8.3 mmol/L

FOR EXAMPLE ONLY.
Refer to your test strip vial label for corresponding range.

If your control solution test result is 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 MyStar Extra® Meter to test your blood glucose. Call Customer Service at 08000 35 25 25. The phone number is also printed on your meter label.

IMPORTANT: Out-of-range test results may be caused by 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] Failure to shake the control solution bottle vigorously before using.

[7] Failure to discard the first drop of control solution and to wipe the bottle tip clean.

[8] Control solution test done outside the system operating temperature range of 10°C to 40°C.

[7] Remove the Used Test Strip From the Meter Test Strip Port

The control solution test result will be stored in memory.

Removing the used test strip will deactivate your meter.

[8] Dispose of Used Materials Properly

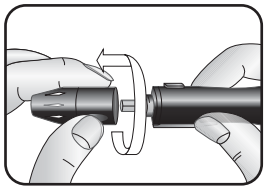
Follow your healthcare provider's instructions for disposal.

CHAPTER
10 How to Test Your Blood Glucose Level

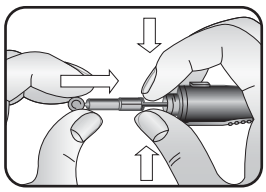
CAUTION: To ensure accurate results, wash your hands and the test site with warm, soapy water and dry before every test. Unwashed hands and test sites may lead to inaccurate results. Make sure there is no grease, oil, or lotion on the test site. Use lancets only once. Do not use any lancet or lancing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

The meter and lancing device are for single-patient use. Do not share them with anyone, including other family members! Do not use on multiple patients!
All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

Instructions for cleaning and disinfecting your meter and lancing device are in Chapter 5.

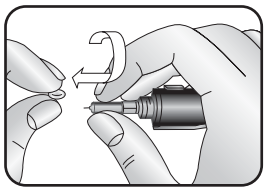


1. Removing the cap: Twist the cap off the lancing device by turning it counter-clockwise while holding the base firmly.

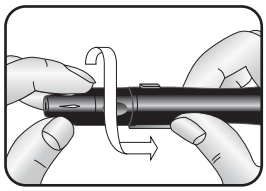


2. Load a new sterile lancet directly into the bottom of lancet carrier.

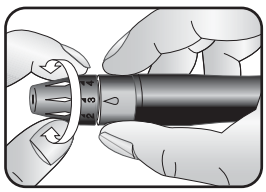
   Note: *In case you accidently cock the device at this point, press the release button before you move on.*



3. While holding the lancet firmly, remove the lancet cap; be careful not to touch the lancet tip.

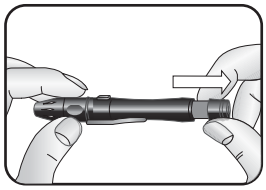


4. Put the cap of the lancing device back on and turn it clockwise until it is fully into place.



5. The lancing device can be set to the sensitivity of your skin. You can adjust the tip to 5 different lancing depths. Twist the cap end in the appropriate direction until the arrow is pointing to the number for the lancing depth you want.

   1-2 for soft or thin skin,
   3 for average skin,
   4-5 for thick or calloused skin.

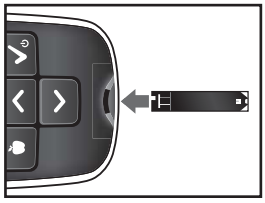


6. Hold the cap firmly in one hand then pull out the sliding barrel with the other hand until it clicks into place. This will cock the lancing device.

Note: *Do not lance your finger before the meter and test strips are ready to use.*

---

[1] Insert a New BGStar® Test Strip



Insert a new Test Strip with the contact bars facing towards you into the meter test strip port. The meter will activate when the test strip is fully inserted. All segments will briefly flash on.

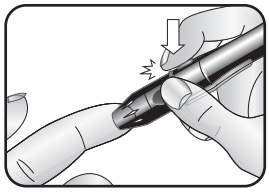
[2] Meter Ready for Test

The meter now displays the time and date with a flashing droplet icon.

The meter is now ready for you to apply blood. You do not need to set a calibration code for the MyStar Extra® Meter (no coding required).

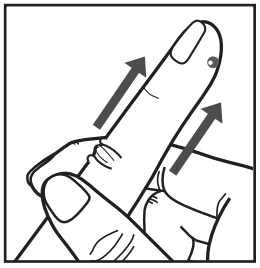
Note: If you do not start the test within 2 minutes of inserting a test strip, the meter will deactivate. To reactivate your meter and continue testing, take out the unused test strip and reinsert it into the meter. Avoid touching the test strip sample area (where blood should be applied).

[3] Lance Finger



Hold the MyStar Sylkfeel® lancing device firmly against the side of the fingertip, with the cap resting on the fingertip (Note: the harder you press MyStar Sylkfeel® lancing device against the finger the deeper the puncture). Press the release button to get a blood sample.

Obtain a Drop of Blood



- Squeeze from the base of your finger up towards the tip until a small blood drop forms. Do not squeeze the lanced area directly.

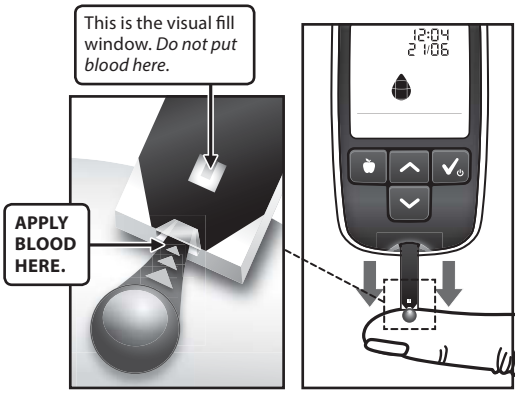
If necessary, set the lancing device to a deeper setting or use a larger lancet to produce enough blood.

[4] Apply Blood Sample

The meter should still display the time and date with the flashing droplet icon. If it does not, reinsert the test strip.

Bring Test Strip to Blood Sample

Immediately bring the test strip to the blood sample. The test strip fills from the tip. Do not try to smear blood on the top surface.



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 test strip will turn red.

WARNING: If the visual fill window does not completely turn red, you may get an inaccurate result. Retest and ensure that the visual fill window completely turns red.

IMPORTANT:

[1] Move the test strip away from the blood sample as soon as you hear the beep.

[2] Do not press the test strip against the finger.

[3] Do not scrape blood onto the test strip.

[4] Do not apply blood to the top side of the test strip.

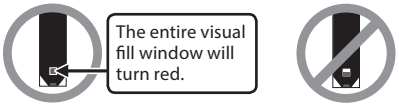
[5] Do not apply blood to the test strip when the test strip is out of the meter.

[6] Do not put blood or foreign objects into the meter test strip port. Doing so may lead to system failure.

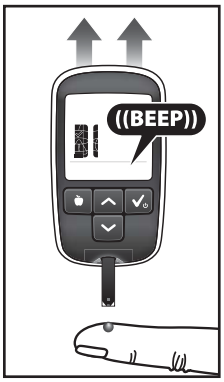
[7] Do not apply more blood after beep.

[8] Carefully read the test result on the meter display before making any treatment decisions.

[5] Remove Test Strip From Blood Sample When the Test Strip Visual Fill Window Completely Turns Red



Your meter will beep once when you should remove the test strip from the blood sample.



The Calculating Animation (a sequence of the numbers 1, 2, 3) will begin on the meter display. This animation means that a sample has been applied to the test strip and the meter is calculating the blood glucose test result.

Calculating Animation:

[6] View Blood Glucose Test Result

The blood glucose test result will appear on the meter display. Your test result is stored in the memory of your meter.

Example of Blood Glucose Test Result:

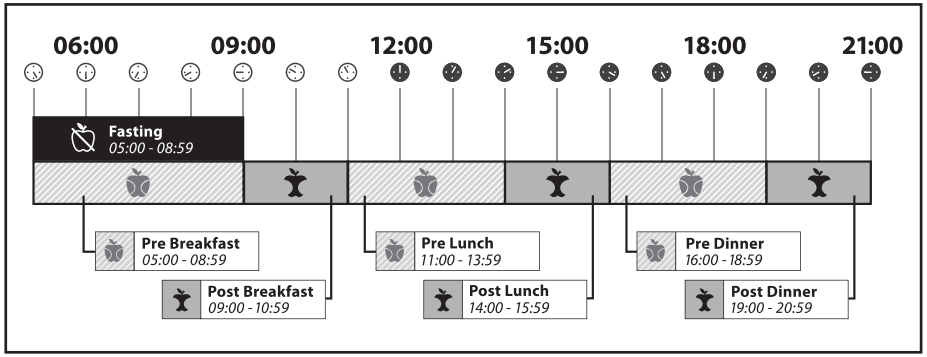
[7] Test Result Mealtime Tagging

The MyStar Extra® Meter automatically tags results as before meal, after meal, or fasting, based on the default mealtime settings (see below). Tagging enables you to view averages to see what effect your meals have on your blood glucose levels. The meter adjusts to your habits and adapts to your schedule.

When a reading is taken during preset meal times the meter will flash the suggested tag until the tag is confirmed. The tag is confirmed either by pressing CHECK (✓), removing the used strip, or when the meter deactivates. Once confirmed, the test result and mealtime tag are stored in the memory of your meter.

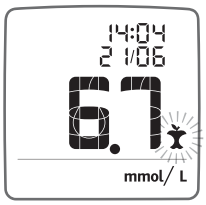
If the tag assigned to your reading is not correct, you can change the mealtime tag within the next 48 hours by pressing the MEALTIME button (🍎) to select the appropriate tag. Once the appropriate tag is chosen, confirm by pressing the CHECK (✓) button. The icon will then stop flashing.

Mealtime Tag: By default, the MyStar Extra® Meter suggests mealtime tags according to this schedule:



Example of Pre Meal Tag Reading:

Example of Post Meal Tag Reading:



Fasting Tag:

Default Fasting Time: 5:00 h to 8:59 h.

The fasting tag is used for readings taken while no food or drink (except water) has been consumed over a period of 6-8 hours. The default fasting time period is from 5:00 h to 8:59 h. The fasting tag will automatically be suggested for readings that fall within this time period.

Example of Fasting Tag Reading:

The fasting tag can only be assigned to one reading per day. If an additional reading is taken during the fasting time period, the suggested tag will be based on the mealtime tagging schedule. The fasting tag icon will be unavailable unless the fasting tag is removed from the previously marked reading.

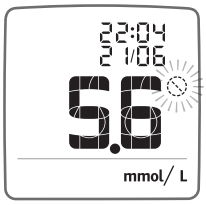
The MyStar Extra® adjusts to your fasting habits. It will automatically adjust the default fasting time period (5:00 h to 8:59 h) to fit your schedule.

No Tag:

Default No-Tag Time: 21:00 h to 4:59 h.

Any readings taken outside of a mealtime or a fasting time will be automatically tagged as No-Tag. You can also choose to not tag a reading by selecting this tag. To do this, scroll through the tagging options by pressing the MEALTIME ( ) button until you see the "No Tag" icon. Press the CHECK ( ) button to confirm.

Example of No-Tag Reading:

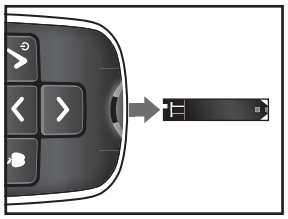


[8] Remove the Used Test Strip From the Meter Test Strip Port

Avoid touching the test strip sample area (where blood was applied).

Removing the used test strip will deactivate your meter.

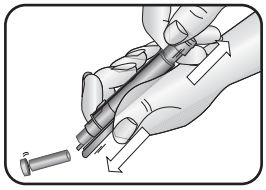
IMPORTANT: If you do not remove the used test strip within 1 minute of testing, the meter will deactivate. Do not attempt to apply blood or control solution to an already used test strip.



[9] Final Steps

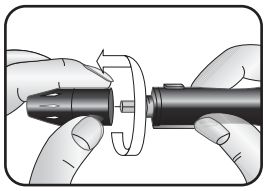
Removing the cap: Twist the cap off the lancing device by turning it counter-clockwise while holding the base firmly.

Push lancet into the cap.



Push the lancet ejector forward with the thumb and simultaneously pull out the sliding barrel to dispose of the used lancet in a safe way, e.g. directly in a puncture resistant container, according to local regulations.

Note: *In case the lancet does not fall out, carefully pull the lancet body out of the lancet holder.*



[10] Discard the used test strip and lancet properly

Follow your healthcare provider's instructions for disposal.

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 your healthcare provider's instructions for disposal. You should wash your hands thoroughly with soap and water after handling the meter, lancet, lancing device, and test strips.

CHAPTER
11 Data Management Features

IMPORTANT: Results and averages stored in memory should be used only as a reference. Do not make treatment decisions based solely on stored results and averages. All health-related decisions should be made in conjunction with the advice of a qualified healthcare professional.

The MyStar Extra® Meter will store up to 1865 of the most recent blood glucose and control solution test results with date and time. When the meter needs to save a new test result and has already stored 1865 test results, the oldest test result will be deleted and a new test result will be saved.

This chapter covers the steps on how to view your:

- Logbook showing individual results
- 3-, 7-, and 30-Day Averages
- Estimated A1c (~A1c) value

HOW TO ACCESS ALL DATA MANAGEMENT FEATURES

[1] When your meter is deactivated, press the CHECK ( ) button to activate the meter. The most recent result is displayed.

[2] Press the CHECK ( ) button to scroll through the data management features: Logbook, Averages, ~A1c.

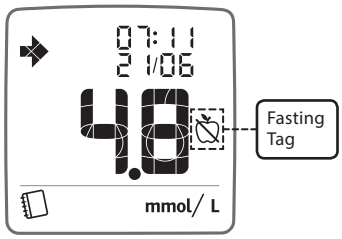
11.1 Logbook

Viewing Individual Results

[1] When your meter is deactivated, press the CHECK ( ) button to enter the Logbook. Your most recent result is shown. The logbook displays all the individual glucose and control solution readings.

[2] Press the UP ( ) and DOWN ( ) arrow buttons to scroll through the Logbook. Press and hold the UP or DOWN arrow buttons to scroll quickly through the Logbook.

Example of a Blood Glucose Result with a Fasting Tag:



Changing Mealtime Tags

You can change the mealtime tags of readings for up to 48 hours after a reading was taken when you view them in the Logbook.

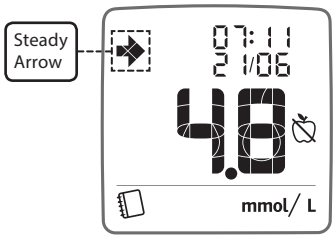
[1] Press the MEALTIME ( ) button. The mealtime tag on the reading you are viewing will start to flash. Press the MEALTIME ( ) button again to scroll through the mealtime tag icons. Press the CHECK ( ) button to confirm your desired mealtime tag.

Fasting Trend Arrows
Readings in the Logbook may also include a trend arrow icon to give you a general idea of your fasting glucose trend. The trend arrow illustrates the direction of your average fasting glucose reading from the past 3 days as compared to the median fasting value over the 7 days before the 3-day average. If your 3 day average is less than 6.9 mmol/L, then the arrows will show either an upward or downward trend if there is greater than 1.4 mmol/L difference between the 3 day average and the 7 day median. If your 3 day average is greater than 6.9 mmol/L, then the arrows will show either an upward or downward trend if the difference between the 3 day average and the 7 day median is greater than 20% of the 3 day average.

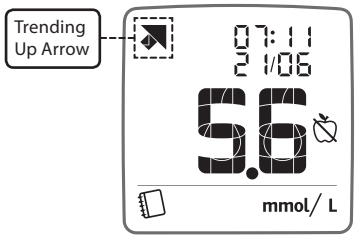
Note: For information on ~A1c trend arrows, please see section 11.3.

The Fasting Trend Arrow information should not be used to assess the fasting glucose trend in pregnant women.

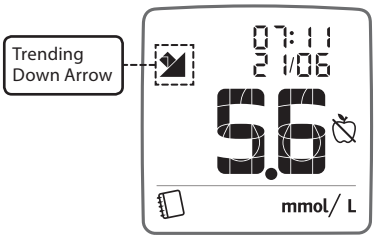
Steady Arrow: a steady arrow will appear above your readings if your current 3-day fasting glucose average is similar to your 7 day fasting glucose median from 3 days ago.



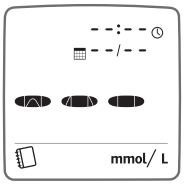
Trending Up Arrow: an arrow pointing up will appear above your reading if your current 3-day fasting glucose average is somewhat greater than your 7-day fasting glucose median.



Trending Down Arrow: an arrow pointing down will appear above your reading if your current 3-day fasting glucose average is somewhat less than your 7-day fasting glucose median.



NOTE: If your meter shows dashes in the place where the reading, time and date should appear, it means there are no readings yet in the meter.



11.2 Averages

The MyStar Extra® categorizes readings based on the selected mealtime tag and displays the corresponding average at 3, 7 and 30 days. These averages allow you to see how your blood glucose levels vary by time of day and over the course of several days.

Averages are categorized as the following:

- All (no mealtime tag icon): includes all readings (tagged and untagged) for the specified number of days.
- Fasting: includes all tagged fasting readings for the specified number of days.
- Pre-meal: includes all tagged Pre-meal readings for the specified number of days.
- Post-meal: includes all tagged Post-meal readings for the specified number of days.

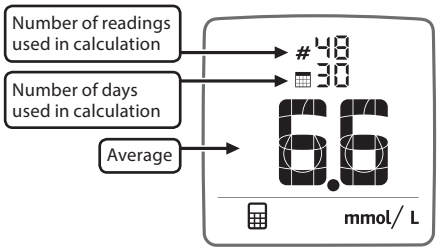
Symbols:

No Tag
Fasting
Pre Meal
Post Meal
All readings *(no symbol)*

Viewing Averages

[1] When your meter is deactivated, press the CHECK ( ) button to activate the meter. The most recent result is displayed.

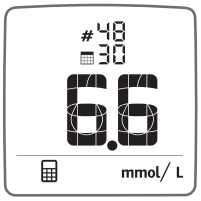
[2] Press the CHECK ( ) button again to enter the Averages mode. The calculator icon on the bottom of the screen indicates Averages mode. The Averages mode displays the number of readings used in the calculation, the number of days used in the calculation, and the average of those readings within that time frame.



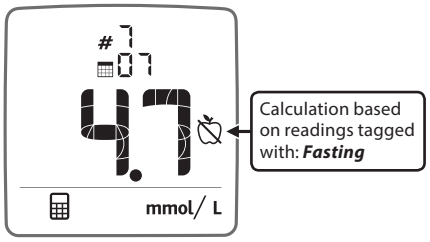
[3] Press the MEALTIME ( ) button to scroll through the four categories: All readings (no icon), Fasting readings, Pre-meal readings, Post-meal readings. The corresponding mealtime icon is displayed beside the calculated average. If no icon is displayed, then the average is calculated for all readings.

[4] Press the UP ( ) or the DOWN ( ) arrow buttons to scroll through the 3, 7, and 30 day averages.

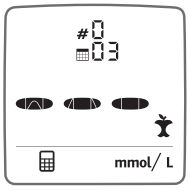
This screen shows the 30-day average of all readings. There are 48 total readings and the average is 6.6 mmol/L.



This screen shows the 7-day average of all Fasting readings. There are 7 total readings and the average is 4.8 mmol/L.



There must be at least two readings to calculate an average. A screen with dashes will display if there are insufficient readings to calculate an average.



Note: Control solution results are not included in averages. High (Hi) and Low (Lo) test results will be included in averages as values of 33.3 mmol/L and 1.11 mmol/L, respectively. Displayed averages include all stored glucose readings in the calculation.

11.3 Estimated A1c (~A1c)

The MyStar Extra® contains a tool that estimates A1c. The estimated A1c tool is intended for at home use by people with Type 1 and Type 2 diabetes to monitor average glycemic control. The estimated A1c is intended to raise A1c awareness by providing an estimated A1c value and trend in between HCP visits.

IMPORTANT:
Do not use these ~A1c values to make treatment decisions. Any changes in treatment must be done in consultation with your physician.

Notice to physicians: extreme care should be used when making dosing decisions for medications for which hypoglycemia is a potential side effect, for example sulfonylureas, mitiglinide and repaglinide.
No dosing changes should ever be made for insulin based on ~A1c results.

What is an estimated A1c (~A1c)?
The ~A1c tool provides an estimation of Haemoglobin A1c calculated from glucose readings.
The estimated A1c tool is indicated for use as an adjunctive tool to complement, not replace, a laboratory Haemoglobin A1c test and is not intended to suggest changes in treatment decisions or to be used as a substitute for professional healthcare advice.
The ~A1c is a calculated percentage based on fasting glucose values and a glucose profile (see "To get an ~A1c result"). The number of blood glucose tests you perform each day and the timing of when those tests are performed (i.e. fasting, pre-meal or post-meal) should be discussed with your healthcare professional.

How is the ~A1c useful in my treatment plan?
The ~A1c is another tool you can use along with your averages to monitor the effectiveness of your treatment plan. The purpose of the ~A1C is to facilitate increased dialogue between patient and HCP and as a reminder of the importance of glycemic control.

What is HbA1c?
HbA1c is formed when haemoglobin (a component in your red blood cells) binds to glucose.

What is the HbA1c lab test?
The HbA1c lab test measures HbA1c. It is used to show blood glucose level control over the past 2 to 3 months[1]. The HbA1c lab result is expressed as a percentage of haemoglobin bound to glucose. For example, an HbA1c of 7% means 7% of your haemoglobin is bound to glucose. The higher your blood glucose level, the more glucose binds to the haemoglobin in your blood and the greater your HbA1c test result.

The MyStar Extra® does not give you an HbA1c value. It only gives an ~A1c value and may differ substantially from an actual HbA1c result that you get when you visit your healthcare professional and have blood drawn in the laboratory. The ~A1c should not be used to predict your actual HbA1c.

WARNING: This tool uses blood glucose readings to estimate your A1c based on a mathematical formula. It is not a substitute for a laboratory test performed by your healthcare professional. Your ~A1c value may differ substantially from results obtained through an HbA1c test. **Do not use the ~A1c to make treatment decisions.**

If you have questions about your ~A1c, please contact your healthcare professional.

[1)] http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/a1c/

Obtaining an ~A1c result

Before you can obtain an ~A1c result for the first time, you must perform the following steps in order:

[1] Create a "Profile"
[2] Confirm that a "Profile" was created
[3] Take "Fasting" blood glucose tests every day for the next 6 days after your "Profile" day

The MyStar Extra® will not show an ~A1c result if you did not successfully complete these three steps.

[1] Create a "Profile"
A "Profile" consists of 7 blood glucose tests taken in one day.

- Take the 7 blood glucose tests using the **"Profile" Schedule**. Blood glucose tests **must** be taken within the specified time periods and correctly tagged in order to create a "Profile".

- During a blood glucose test, the meter will suggest a mealtime tag depending on the time of your blood glucose test. Make sure this suggested tag is appropriate for the blood glucose test (e.g. pre-meal reading is tagged with the pre-meal symbol). If the suggested tag is not appropriate for the blood glucose test, you must change the tag. A tag can be changed by pressing the ( ) button on the meter until the desired tag is displayed. Confirm the appropriate tag by pressing the ( ) button.

"Profile" Schedule

Between **5:00 h and 10:59 h:**

1. **Fasting:** Take a "Fasting" blood glucose test when you have not had any food or drink (except water) for at least 6-8 hours (usually immediately upon waking up). Confirm the fasting tag. A Pre Breakast tag can also be used.
2. **Post Breakfast:** Eat breakfast, and take a post breakfast blood glucose test about 2 hours after the start of your meal. Confirm the post meal tag.

Between **11:00 h and 15:59 h:**

3. **Pre Lunch:** Take a pre lunch blood glucose test immediately before eating lunch. Confirm the pre meal tag.
4. **Post Lunch:** Eat lunch, and take a post lunch blood glucose test about 2 hours after the start of your meal. Confirm the post meal tag.

Between **16:00 h and 20:59 h:**

5. **Pre Dinner:** Take a pre dinner blood glucose test immediately before eating dinner. Confirm the pre meal tag.
6. **Post Dinner:** Eat dinner, and take a post dinner blood glucose test about 2 hours after the start of your meal. Confirm the post meal tag.

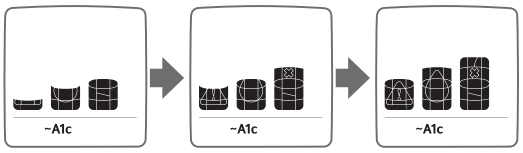
Between **21:00 h and 23:59 h:**

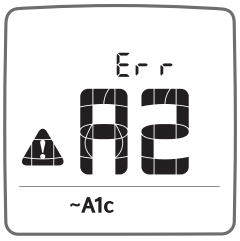
7. Bedtime: Take a bedtime blood glucose test. Confirm the bedtime result as no tag.

Use the chart as a worksheet for testing and tagging your readings.

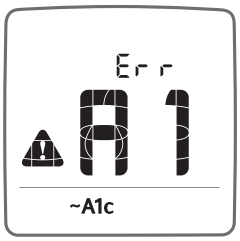
Profile Measurement Number	Tag	Check Box when Complete
1. Fasting (5h00-10h59)	Fasting	
2. Post breakfast (5h00-10h59)	Post-meal	
3. Pre Lunch (11h00-15h59)	Pre-meal	
4. Post Lunch (11h00-15h59)	Post-meal	
5. Pre Dinner (16h00-20h59)	Pre-meal	
6. Post Dinner (16h00-20h59)	Post-meal	
7. Bedtime (21h00-23h59)	No tag	

[2] Confirm that a "Profile" was Created
Activate the meter by pressing the (☑) button.
The "Logbook" screen will appear (📖) displaying your most recent blood glucose test result.
Press the (☑) button twice more until you see the following animation.





"Profile" Created
If message "A2" is displayed, you have successfully created your "Profile" and are now required to take 6 "Fasting" blood glucose tests (refer to section [3] **Take "Fasting" Blood Glucose Tests).**



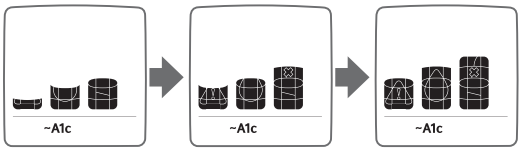
"Profile" *Not* Created
If message "A1" is displayed, refer to **"Profile" Troubleshooting.**

"Profile" Troubleshooting
Review your blood glucose tests and tags in the Logbook. Confirm that you have taken and tagged the blood glucose tests per the **"Profile" Schedule.**
If a blood glucose test is tagged incorrectly but was taken within the last 48 hours, manually change the tag:
- Locate the blood glucose test in the Logbook
- Press the ( ) button on the meter
- Continue to press the ( ) button until the desired tag is displayed
- Confirm the appropriate tag by pressing the ( ) button.

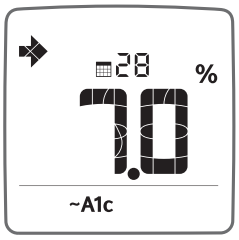
Follow the steps at the beginning of section [2], **Confirm that a "Profile" was Created.**
If message "A1" continues to be displayed, follow the steps at the beginning of section [1], **Create a "Profile".**

[3] Take "Fasting" Blood Glucose Tests
After you have confirmed that a "Profile" was created, take a "Fasting" blood glucose test every day for the next 6 days.
Take a "Fasting" blood glucose test when you have not had any food or drink (except water) for at least 6-8 hours (usually immediately upon waking up).
Tag the "Fasting" blood glucose test by pressing the ( ) button on the meter until the ( ) is displayed.

View Your ~A1c Result
Activate the meter by pressing the ( ) button. The "Logbook" screen will appear ( ) displaying your most recent blood glucose test result.
Press the ( ) button twice more until you see the following animation.



If you have taken enough "Fasting" blood glucose tests, an ~A1c result is displayed (example ~A1c).



If message "A2" is displayed, go to **"Fasting" Troubleshooting.**

"Fasting" Troubleshooting
Review the blood glucose test results and their tags. Confirm that you have taken a "Fasting" blood glucose test every day for the past 7 days and all the tests have a "Fasting" (⏱) tag.
If a blood glucose test is tagged incorrectly but taken within the last 48 hours, manually change the tag:
- Locate the blood glucose test result in the Logbook
- Select the (🍎) button on the meter
- Continue to press the (🍎) button until the desired tag is displayed.
- Confirm the appropriate tag by pressing the (✓) button.

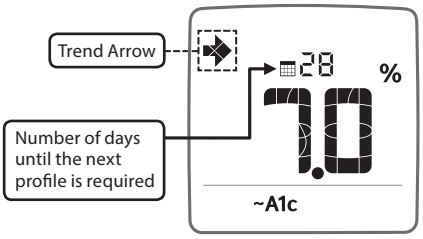
Follow the steps to **View Your ~A1c Result.**
If message "A2" continues to be displayed, follow the steps at the beginning of section [3], **Take "Fasting" Blood Glucose Tests.**
If you miss taking your "Fasting" blood glucose test you should take your "Fasting" blood glucose test the next day.

Continue to Obtain ~A1c Results
To continue to obtain ~A1c results, you must continue to use your meter and:
- Take at least 7 fasting readings in the last 14 days
- Have at least 1 fasting reading taken in the last 6 days
- Have created a "profile" at least once in the last 32 days.

If the time and date is changed more than 48 hours, then a new profile and fasting values will be required to calculate your ~A1c.

For additional information see Chapter 14 "Error Messages and Troubleshooting".

~A1c Additional Information

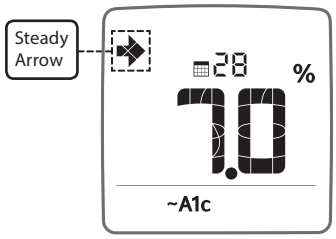


Note: Control solution results are not included in the ~A1c calculation. High (Hi) and Low (Lo) test results will be included in the ~A1c calculation as values of 33.3 mmol/L and 1.11 mmol/L, respectively. The ~A1c includes the most recent stored fasting glucose readings in the calculation, including those just taken.

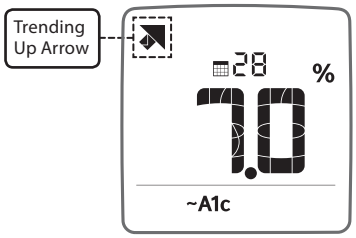
~A1c Trend Arrows

~A1c Trend Arrows display the trending of your current ~A1c results as compared with the results from at least two weeks ago. The trend arrows will display if your ~A1c value has increased or decreased by more than 0.14.

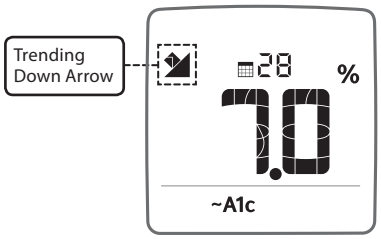
Steady Arrow: a steady arrow will appear above your ~A1c result if an upward or downward trend from your ~A1c result from two weeks ago has not been detected.



Trending Up Arrow: an arrow pointing up will appear above your ~A1c result if your current ~A1c is greater than your ~A1c from at least two weeks ago by more than 0.14.



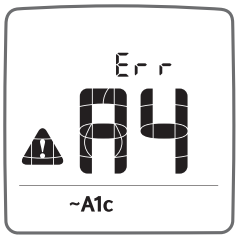
Trending Down Arrow: an arrow pointing down will appear above your ~A1c result if your current ~A1c is less than your ~A1c from at least two weeks ago by more than 0.14.



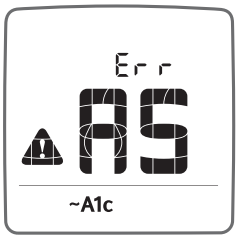
Results Displayed (A4 and A5)

Only ~A1c values between 6% and 10% will be displayed.

~A1c results below 6% will be displayed as A4:



~A1c results above 10% will be displayed as A5:



CHAPTER
12 Batteries

Your MyStar Extra® 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 or the battery is dead, the low battery icon or dead battery icon 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 blood glucose averages. Removing the batteries does not affect the meter memory.

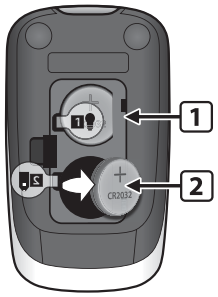
CAUTION: When the low battery icon appears, you should replace the batteries immediately. Use only CR2032 batteries.

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

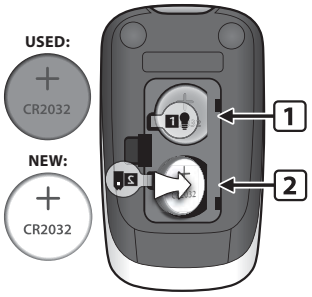
HOW TO REPLACE THE BATTERIES

[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, being careful not to misplace it.

[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 the meter.

Time and Date Setting After Battery Replacement

If the time and date need to be set, the meter will enter the settings screen upon activation. See Chapter 8 for detailed instructions on how to set the time and date.

CHAPTER

13 Display Messages

Messages occurring while a test strip is inserted are displayed until the test strip is removed or the meter automatically deactivates. Messages occurring when no test strip is inserted are displayed until the meter deactivates or you insert a strip.

CAUTION: Low or high blood glucose test results can indicate a potentially serious medical condition. Follow your healthcare professional's recommendations. These results represent the meter operating range. Consult your healthcare professional for appropriate target ranges.

LO MESSAGE

MEANING: Glucose test result is lower than 1.11 mmol/L. A Lo result may indicate hypoglycemia (low blood glucose). The Lo glucose test result is stored in the meter with time and date. It will be included in Averages and ~A1c as a value of 1.11 mmol/L.

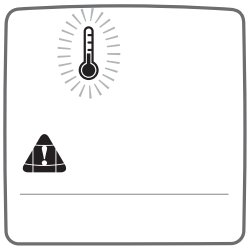
ACTIONS: If you feel symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your healthcare professional's recommendations. If you get a Lo glucose test result but have no symptoms of low blood glucose, retest with a new test strip. If you still get a Lo glucose test result,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

HI MESSAGE

MEANING: Glucose test result is above 33.3 mmol/L. A Hi result may indicate hyperglycemia (high blood glucose). The Hi glucose test result is stored in the meter with time and date. It will be included in Averages and ~A1c as a value of 33.3 mmol/L.

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

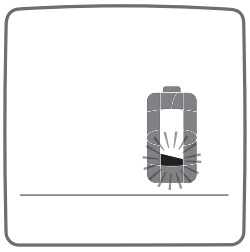
TEMPERATURE ICON: Flashing temperature icon.



MEANING: The meter is outside its operating temperature range of 10°C to 40°C or the test was performed outside the system operating temperature range of 10°C to 40°C.

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) before using the meter or performing a test.

LOW BATTERY MESSAGE: A low battery icon flashes for two seconds.



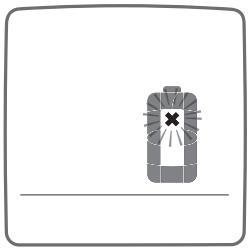
MEANING: The meter can perform less than 20 tests before the battery dies. Battery #2 in your meter is low.

ACTIONS: If the low battery icon appears, battery #2 must be replaced. Battery numbers are indicated by the numbers printed on the pull-tabs. For details about replacing your batteries, refer to Chapter 12.

DEAD BATTERY MESSAGE: A dead battery icon flashes for three seconds and then the meter turns off.

MEANING: Battery #2 in your meter is dead.

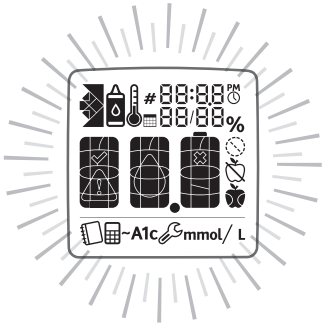
ACTIONS: If the dead battery icon appears, battery #2 must be replaced. Battery numbers are indicated by the numbers printed on the pull-tabs. For details about replacing your batteries, refer to Chapter 12.



LOW BACKLIGHT BATTERY: Backlight flashes twice on startup.

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

ACTIONS: If the backlight flashes when the meter is activated, battery #1 must be replaced. Battery numbers are indicated by the numbers printed on the pull-tabs. For details about replacing your batteries, refer to Chapter 12.



CHAPTER

14 Error Messages and Troubleshooting

The MyStar Extra® Blood Glucose Monitoring System has been designed to work accurately under most usual conditions. On rare occasions, the meter will display an error message instead of a glucose result.

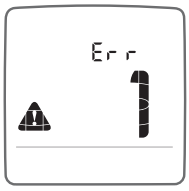
The meter is able to detect specific problems, which may allow you to determine the cause of the error without wasting valuable test strips. When you are presented with an error message, check for possible problems related to each message listed in this chapter.

Messages occurring while a test strip is inserted are displayed until the test strip is removed or the meter automatically deactivates. Messages occurring when no test strip is inserted are displayed until the meter deactivates or you insert a strip.

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.

CAUTION: If you get repeated error messages and are experiencing symptoms of hypo or hyperglycemia, contact your healthcare professional immediately as this may indicate low or high glucose. If this error code persists on retesting, consult your healthcare professional.

Error 1: Problems have occurred that are related to test strip use.

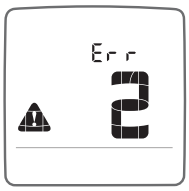


[1] If this message appears the moment the test strip is inserted, the test strip may be wet or damaged. Retest using a new test strip.

[2] If this message appears during a test, the test strip may have been removed too early. Retest using a new test strip.

[3] If this message appears after the calculating animation instead of a result, it may indicate that you applied more blood after testing began. Retest using a new test strip.

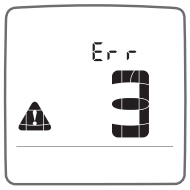
Error 2: The meter has detected an irregularity with the sample.



[1] The test strip may be partially filled. You should check the window of the test strip to confirm that it is full. Retest using a new test strip. Ensure that enough blood is applied to the test strip when retesting.

[2] The sample may not be blood or control solution. Retest using a new test strip. Ensure that the test site is clean prior to performing a blood glucose test or that the control solution bottle tip is wiped clean prior to performing a control solution test.

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. Check the test strip vial for the expiration date. Do not use test strips beyond the expiration date or 180 days after first opening the vial. You may need to retest using a new test strip from a new vial of test strips.

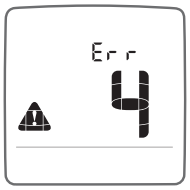
[2] The test strip may have been mishandled by vigorous bending or shaking. Retest using a new test strip.

[3] Parts of the test strip may have become covered in grease, oil, or lotion. Retest using a new test strip.

[4] The test strip port connector may be dirty. Call Customer Service at 08000 35 25 25. The phone number is also printed on your meter label.

Error 4: The meter was unable to produce a result or unusual test strip problems have occurred that may be related to extreme conditions.

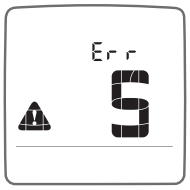
[1] This error may be caused by extremely high glucose. If you are experiencing symptoms of hyperglycemia, contact your healtcare professional immediately. If this error code persists on retesting, consult your healthcare professional.



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

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.

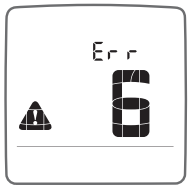


[2] If this error code persists on retesting, call Customer Service at 08000 35 25 25

Error 6: The test strip has taken too long to generate a signal.

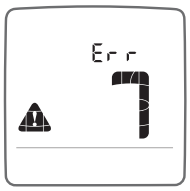
[1] This may be caused by a combination of cold operating temperature and high hematocrit levels. Retest in a warmer location.

[2] If this error code persists on retesting, call Customer Service at 08000 35 25 25. The phone number is also printed on your meter label.



Error 7: Meter problems have occurred that are beyond your control.

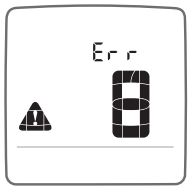
[1] If this error code persists on retesting, call Customer Service at 08000 35 25 25. The phone number is also printed on your meter label.



Error 8: A problem has occurred related to the meter hardware.

[1] This may be caused by connecting a cable to the meter while testing. Disconnect the cable and retest.

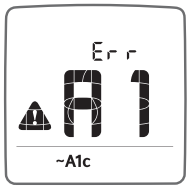
[2] If this error code persists on retesting, call Customer Service at 08000 35 25 25. The phone number is also printed on your meter label.



~A1c Errors

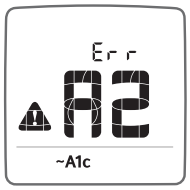
Error A1: No profile available to calculate ~A1c.

[1] This message indicates that a new profile is required to calculate ~A1c. Follow the instructions for Obtaining an ~A1c Result, section 11.3, [1] Create a "Profile".



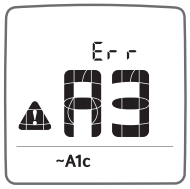
Error A2: Insufficient number of fasting readings to calculate ~A1c.

[1] This message indicates that there are not sufficient fasting readings to calculate an ~A1c. Follow the instructions for Obtaining an ~A1c Result, section 11.3, [3] Take "Fasting" blood glucose tests.



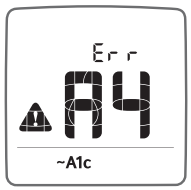
Error A3: Unable to calculate ~A1c.

[1] An unspecified error occurred that prevented the calculation of ~A1c.



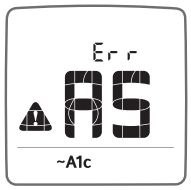
Error A4: ~A1c result below 6%.

[1] Your calculated ~A1c result is below 6%.



Error A5: ~A1c result above 10%.

[1] Your calculated ~A1c result is above 10%.



Call Customer Service at 08000 35 25 25. The phone number is also printed on your meter label.

TROUBLESHOOTING SITUATION #1

Meter does not enter test mode after inserting a BGStar® Test Strip.

[1] CAUSE: The meter batteries have insufficient power.
ACTION: The meter batteries must be replaced immediately. For details about replacing your batteries, refer to Chapter 12. The time and date information may be lost. 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 blood glucose averages. See Chapter 8 for instructions on setting time and date after battery replacement.

[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: The test strip has been inserted upside down or wrong end in, or incompletely inserted into the meter.
ACTION: Remove the test strip from the meter test strip port. Reinsert the test strip with the black side up and the end of the test strip with contact bars inserted into the meter test strip port. Ensure that the test strip is fully inserted.

[4] CAUSE: Defective meter or defective test strips.
ACTION: Call Customer Service at 08000 35 25 25. The phone number is also printed on your meter label. Have the meter serial number (located on the back of the meter) and test strip LOT number (located on the test strip vial) available.

[5] CAUSE: Blood or foreign objects put into the meter test strip port.
ACTION: Call Customer Service at 08000 35 25 25. The phone number is also printed on your meter label. Have the meter serial number (located on the back of the meter) available.

TROUBLESHOOTING SITUATION #2

After applying the blood sample, the meter doesn't begin the Calculating Animation (1, 2, 3) and no test result is displayed.

[1] CAUSE: Defective test strip.
ACTION: Repeat the test with a new test strip. If the problem persists, call Customer Service at 08000 35 25 25. The phone number is also printed on your meter label. Have the test strip LOT number (located on the test strip vial) available.

[2] CAUSE: Sample was applied after 2 minutes of inserting a test strip.
ACTION: Repeat the test using a new test strip. Wait until the flashing droplet appears on the meter 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 test strip.

[4] CAUSE: Defective meter.
ACTION: Call Customer Service at 08000 35 25 25. The phone number is also printed on your meter label. Have the meter serial number (located on the back of the meter) available.

CHAPTER 15

Caring for Your MyStar Extra® Meter and Lancing Device

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

CHAPTER
16 MyStar Extra® Meter Specifications

Assay Method: Dynamic Electrochemistry

Maximum Altitude: 10,000 feet (3,048 meters)

Calibration: Plasma equivalent

Coding: No code

Sample: Whole blood, capillary

Sample Size: 0.5 microliters

Average Glucose Test Time: 5 seconds

Measurement Units: mmol/L

Result Range: 1.11 mmol/L to 33.3 mmol/L

Hematocrit: 20% to 60%

Operating Relative Humidity: 25% 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 (3, 7, 30 days and mealtimes)

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

Automatic Deactivation: 1 minute after last user action, two minutes when a test strip is inserted

Size: Width 2.00" x Length 3.54" x Height 0.67"
(5.1 cm x 9.0 cm x 1.7 cm)

Weight: 51 g (including batteries)

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

The MyStar Extra® Blood Glucose 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. The meter should not affect the normal operation of other devices. If this does occur, provide more distance between the meter and the affected device. Your meter is an electronic device. When disposing of your meter, follow all local regulations.

Studies have shown that 95% of ~A1c values fall within ±17% of a standard lab reference measurement.

CHAPTER

17 Symbols

Serial Number: SN

Manufacturer: 

In Vitro Diagnostic Medical Device: IVD

Batch Number: LOT

Consult Instructions For Use: 

Do Not Reuse: 

Temperature Limitation: 

Use By: 

Catalogue Number: REF

European Authorized Representative: EC REP

Sterile: STERILE R

<MAT>521873