Safety Information

- Please use this device only for the intended uses described in this User Guide.

- Before using this system to test your blood glucose, please read instructions thoroughly. Do a quality check on the system following the instructions and consult with your healthcare professional about questions or problems.

- Be aware of the safety of young children or handicapped persons near you when you conduct a glucose test using this system.

- SOLUSmobile test strips can only be used with the SOLUSmobile meter.

- Please keep the test strip bottle away from children. The test strips and bottle cap can present a choking hazard.

- Please be cautious when removing the lancet. Always place the protective cap back on the exposed lancing device.

- Never try to disassemble the meter in any circumstance. If your meter is not working properly, or if you need technical support, please contact our Technical Support Team at (877) 592-3922.

Rev. Date: 06/2012   6131SL-M01A1

1. Introduction

2. Intended Use / Indications for Use

- The SOLUSmobile Blood Glucose Management System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the forearm. It is intended for use by healthcare professionals and people with diabetes mellitus at home and as an aid in monitoring the effectiveness of a diabetes control program. The SOLUSmobile Blood Glucose Management System is not intended for the diagnosis of or screening for diabetes mellitus, nor for use in neonates.

  The alternative site testing (AST) in this system can only be used during steady-state blood glucose conditions.

- This system contains an audible readout function that provides an audible message of test results for users with low vision.

- This User Guide has been prepared to describe the proper use of SOLUSmobile Blood Glucose Management System. Please read this User Guide and the package Insert that accompanies the SOLUSmobile Glucose Test Strips before testing. The system is available as a kit. You can purchase the system supplies from your system provider. Please tell your system provider the system NDC number listed below and marked on the packaging box when you purchase supplies.

  NDC#: 8611-501001

Table of Contents

Chapter 1: Understanding Your New System

SOLUSmobile Audible Blood Glucose Management System

1   Kit Contents

The starter kit of SOLUSmobile Blood Glucose Management System includes the following items:

1. SOLUSmobile Glucose Meter

2. User Guide

3. Quick Start Guide

4. Log Book

5. Protective Case

6. SOLUSmobile Glucose Test Strips

7. SOLUSmobile Control Solution (Low)

8. SOLUSmobile Sterile Lancets

9. SOLUSmobile Lancing Device

10. Package Inserts for Test Strips, Control Solution, and Lancets/Lancing Device

11. Battery Charger and Charging Cable

A single level control solution (Low) is provided in the starter kit. You may purchase High or Low control solution that you need from your system provider.

The SOLUSmobile Glucose Meter uses SOLUSmobile Test Strips only. Neither the meter nor the test strips will work when used with any other brand.

1 – Test Strip Port
2 – LCD Display
5 – Speaker Slot
9 – Micro USB Port
6 – Yes/Up Button
7– No/Down Button
10 – Airplane Mode Switch
8– "Call Me" Button
4 – "R" Right Function Button
3 – "M" Left Function Button
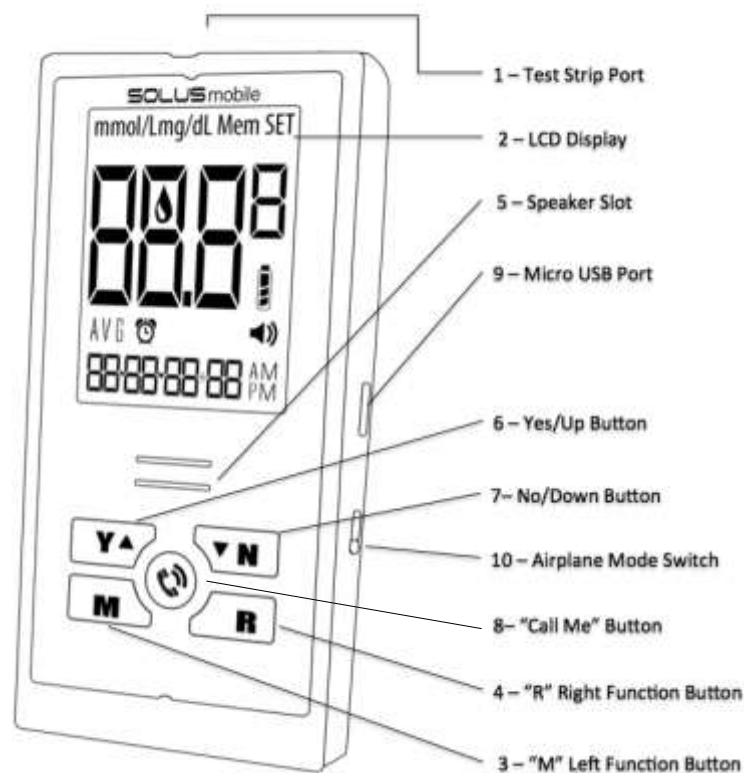
1. Test Strip Port - Insert the test strip here and the meter will turn on automatically for testing.

2. LCD Display - Large screen with large numbers and symbols that makes testing simple and easy. Guides the user through the test using symbols and simple messages.

3. "M" Left Function Button - Powers the meter ON and OFF; in the OFF position, pushing this button allows access to the memory and setting modes.

4. "R" Right Function Button – Allows the user to confirm settings, view averages, and highlight tests before meals and after meals. In the OFF position, push this button to hear the current date and time. (Please refer to manual for detailed function description.)

5. Speaker Slot –Allows the audible output to be heard.

6. Yes/Up Button - Increase the value of the current setting and increases the voice volume. The key is also used to send a "Yes" response to an audible question.

7. No/Down Button - Decreases the value of the current setting and decreases the voice volume. The key is also used to send a "No" response to an audible question.

8. "Call Me" Button – Optional response to certain audible questions. It is an implied request for the patient's healthcare provider to contact the patient.

9. Micro USB Port - This port is where you connect the charging cable to recharge the meter's internal

battery. USB cable provided separately.

10. Airplane Mode Button – A switch to disable the meter's wireless communications capabilities when the meter is carried on board an aircraft. When the switch is in the "On" position, communications capabilities are available. When the switch is in the "Off" position, the communications module is turned off.

2   Charging the Batteries

1. If the meter is on, turn the meter off by pressing and holding the " M " left function button until it says "Goodbye" and you see "OFF" on the screen (see Figure 1-1).

2. Insert the USB connector on the charging cable into the USB port on the right hand side of the meter (see Figure 1-2).

3. Connect the other end of the charging cable to an electrical outlet.

4. Let the meter charge for two (2) hours.
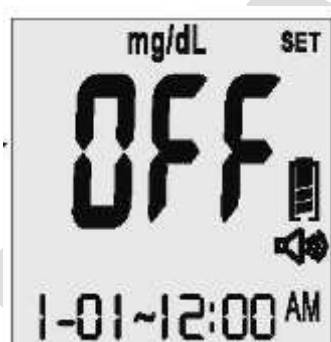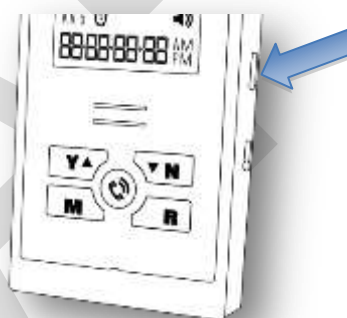
1-1   1-2

IMPORTANT	1. It is suggested you charge the battery when the battery icon appears empty. You will get an Error 3 (E_3) message when the battery does not have enough power to perform a test.
	2. Charging the battery will NOT delete your stored test results.
	3. Charging the battery will NOT change your meter settings.
	4. The meter can be used while charging.

3   Meter Setup

SOLUSmobile allows you to personalize your meter to meet your healthcare needs. Below are features that you can customize:

- Volume Level

- Language
- Date and Time
- Testing Alarm Reminder
- Unit of Measurement
- Before and After Meal Memory

4   Setting the Volume Level

On the front side of the meter, you will find two buttons, the "^" up symbol and the "v" down symbol. Pressing the "^" up symbol ("Up" button) increases the volume; pressing the "v" down symbol ("Down" button) decreases the volume (see Figure 1-4).

When the meter is in the "OFF" position, the voice volume of the meter can be adjusted by pressing the "Up" or "Down" buttons. There are eight (8) different volume settings ranging from OFF (0) to a volume level of seven (7).

To mute the volume, simply set the meter to "0" and you will hear "Voice Off." The speaker icon will disappear from the LCD screen (see Figure 1-5, 1-6).
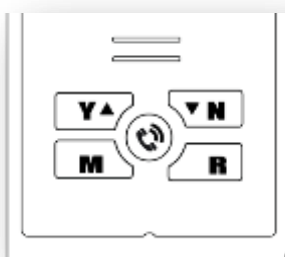
1-4   1-5   1-6

On the right side of the meter, you will find a small switch to turn off and on the meter's communications function, explained below (see Figure 1-7).

Once your current setting is established, the meter will automatically shut off in two (2) seconds and say "Goodbye". The screen will display "OFF" along with the date and time when the meter is turned off. This will not affect the battery life (see Figure 1-9).
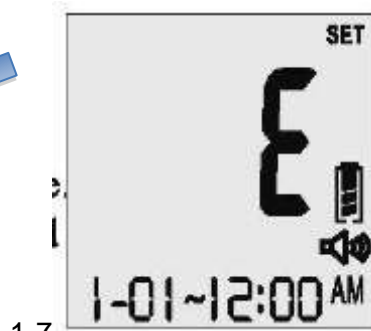
1-7   1-8   1-9

5 LCD Screen Overview

Below is the appearance of the LCD screen:
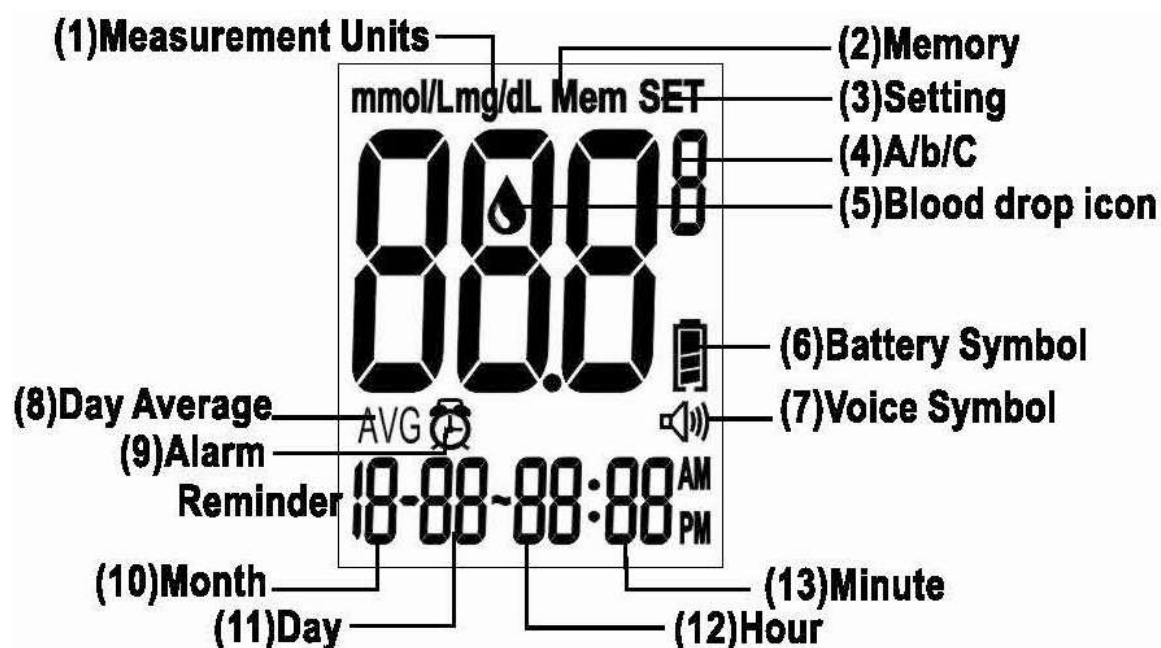
(1) Measurement Units	Appears with the test result either in mg/dL or in mmol/L.
(2) Memory	Appears when you recall the memory.
(3) Setting	Appears when you are in setting mode.
(4) A/b/C: After Meals, Before Meals & Control Test Indicators	When the test is flagged as a control test a "C" appears here. When the test is flagged for a before meal test a "b" appears here. When a test is flagged for an after meal test an "A" appears here.
(5) Blood drop Symbol	Flashes when it is OK to apply the sample.
(6) Battery Symbol	Indicates the remaining battery life.
(7) Voice Symbol	Indicates whether the audio function is "On" or "OFF".
(8) Day Average	Indicates to the user that the current result is an average and not an individual test
(9) Alarm Reminder	Indicates to the user that the Alarm Reminder is "ON".
(10) Month	Month (Note: the year is only displayed in the "setting" mode.)

(11) Day	Day
(12) Hour	Hour
(13) Minute	Minute

The LCD screen for "Power Off": When the meter is in the OFF position, the date, time, measurement unit, battery icon, and the letters "OFF" will still remain on the screen (see Figure 1-10). If the voice is on or the alarm reminder is on, the speaker icon and the alarm icon will be displayed as well.

If the meter contains no test strip and the meter is set to the "OFF" position, you can press the "R" right function button and the meter will audibly speak the current date and time (for example: Two Thousand Eleven, February Twenty-first, Four Forty pm).

1-10

6   Setting the Meter

To SET the meter:

1. <u>Setting Mode</u> - With the meter in the "OFF" position, press the "M" left function button and hold down until you hear "You are now in setting mode." and/or a flashing "12" appears on the screen. This represents the last two digits of the current year. The meter is now in the "Setting" mode. You will hear: "You are now in setting mode. The year is 2012. Please set the year" (see Figure 1-11).

2. <u>Set the Year</u> - Press the "Up" or "Down" button on the right side of the meter until the last two digits of the desired year are displayed. Each time you adjust the year, you will hear "The year is XXX." Press the "R" right function button to confirm the correct year and the meter will move to the next setting. You will hear "The month is XXX. Please set the month" (see Figure 1-12, 1-13, 1-14, 1-15).

3. <u>Set the Month</u> - Press the "Up" or "Down" button on the right side of the meter until the desired month appears. Each time you adjust the month, you will hear "The month is XXX." Press the "R" right function button to confirm the correct month and the meter will move to the next setting. You will hear:

"The day is XX. Please set the day" (see Figure 1-16).
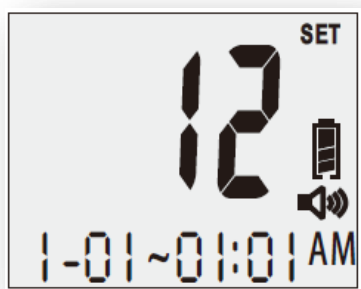
1-11
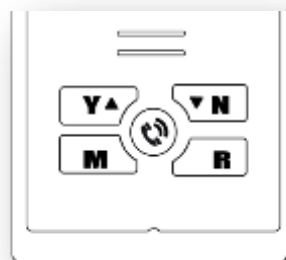
1-12
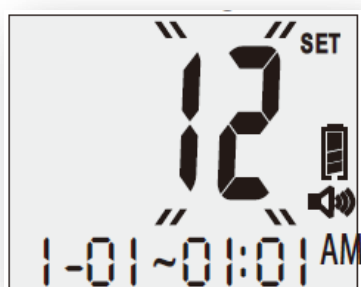
1-13
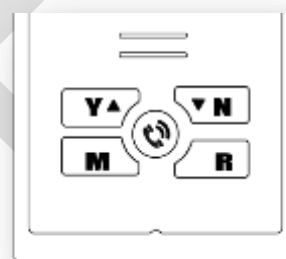
1-14
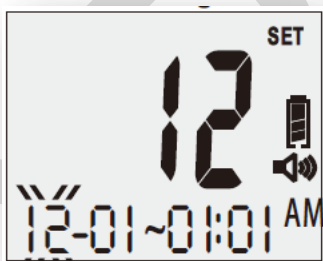
1-15
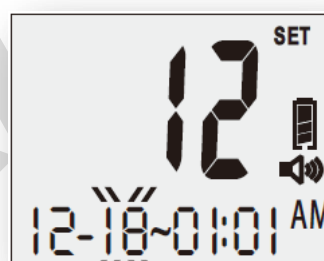
1-16

4. <u>Set the Date</u> - Press the "Up" or "Down" button on the right side of the meter until the desired day appears. Each time you adjust the day, you will hear "The day is the XX." Press the "R" right function button to confirm the correct day and the meter will move to the next setting. You will hear: "The hour is XX a.m. (or p.m.). Please set the hour" (see Figure 1-17).

5. <u>Set the Hour</u> - Press the "Up" or "Down" button on the right side of the meter until the desired hour appears. Each time you adjust the hour, you will hear: "The hour is XX a.m. (or p.m.)"   Press the "R" right function button to confirm the correct hour and the meter will move to the next setting. You will hear: "The minute is XX. Please set the minute" (see Figure 1-18).

6. <u>Set the Minute</u> - Press the "Up" or "Down" button until the desired minute appears. Each time you adjust the minute, you will hear "The minute is XX." Press the "R" right function button to confirm the correct minute and 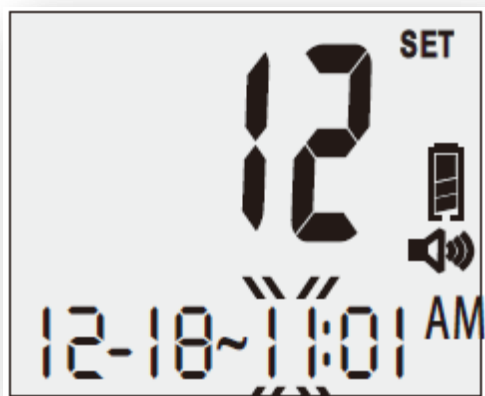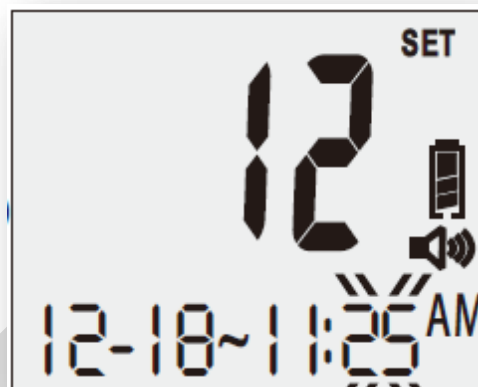the meter will move to the next setting. You will hear: "Please set the alarm." (Does not go to alarm after you set the minute. It goes to Memory)

1-17

1-18

7. <u>Set the Alarm Reminder</u>: You will hear: "Please set the alarm. Alarm off. Press the up button to turn alarm on." or "Please set the alarm. Alarm on. Alarm set for XX:XX. Press the up button to turn alarm off."

   a. <u>Turn Alarm Reminder Off</u>:

   When you hear "Please set the alarm. Alarm on. Alarm set for XX:XX. Press the up button to turn alarm off." Press the up button, alarm will be turned off and you will hear: "Alarm off." Press the "R" right function button to exit alarm setting mode. You will enter the next setting and hear "The unit of measure is milligrams per deciliter. Please set the unit."

   b. <u>Set Alarm Reminder</u>:

   If you do not want to change the current alarm setting, press the "R" right function button to exit the Alarm Setting mode. You will hear "The unit of measure is milligrams per deciliter. Please set the unit."

   Once you press the "UP" button to turn the alarm on, a small alarm clock icon will be displayed on the left side of the screen (see Figure 1-19). You will then hear: "Alarm on. Alarm hour set for XX a.m. (or p.m.). Please set the hour." The hour segment of "00:00" will be flashing on the screen.

   Press the "Up" or "Down" button to change the alarm hour setting until the desired hour appears. Press the "R" right function button to confirm the correct hour for the alarm setting. Each time you adjust the hour, you will hear "The hour is XX a.m. (or p.m.)."

At this point, the minute segment of "00:00" will be flashing on the screen and you will hear: "Alarm minute set for XX. Please set the minute." Press the "Up" or "Down" button until the desired reminder minute appears on the screen. Each time you adjust the minute, you will hear "The minute is XX." Press the "R" right function button to confirm the setting. If you have set the alarm to 8:45 a.m., You will hear "Alarm Reminder is set to 8:45 a.m." and the meter will move to the next setting (see Figure 1-20).

| 1-19 | 1-20 |

NOTE	Once the Alarm Reminder is SET, the meter will beep for 60 seconds every day at the set Alarm Reminder time. To silence the alarm, press the "R" right function button once.

8. Set the measurement unit: Press the "Up" or "Down" button on the right side of the meter until the desired measurement appears. The meter will display either "mg/dL" or "mmol/L" when pressing the "Up" or "Down" button (see Figures 1-21, 1-22). Each time you press the "Up" or "Down" button, you will hear: "Measurement unit in milligrams per deciliter" or "Measurement unit in millimole per liter." Press the "R" right function button to confirm the selection and you will hear: "Ready to delete memory records. Press the "Down" button to delete all records" (see Figure 1-23).
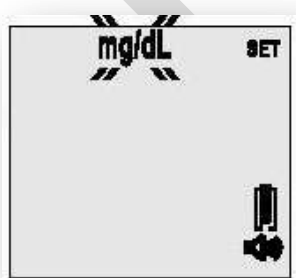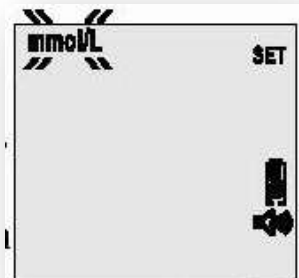
| 1-21 | 1-22 | 1-23 |

WARNING	This meter can show results either in "mg/dL" or "mmol/L" units. Mg/dL is the typical unit of measurement used in the United States, please contact the manufacturer if your meter does not display mg/dL when you turn it on. The factory set default for the meter is mg/dL. In the event that the meter loses power or the batteries are changed, the factory set default is mg/dL. It is critical to use the correct unit of measurement to manage your diabetes. If your meter is set to mg/dL, your results will never have a decimal point. If you obtain your results using the metric system, you will be using the mmol/L unit of measurement. In this case, your results will ALWAYS have a decimal point.

9. Deleting the Memory: To delete your stored results, you will hear: "Ready to delete memory records. Press the down button to delete all records?" Press the "Down" button and you will receive a confirmation: "Are you sure you want to delete all records? Press the down button again to delete all records." Press the "Down" button a second time to delete all records.

NOTE	The user memory can be deleted without affecting the data transmitted to the central data repository.

If you want to skip this memory deletion step, press the "R" right function button when you first hear "Ready to delete memory records." The meter will automatically power off with an audible voice saying "Goodbye". The meter will shut "OFF" (see Figure 1-24).

1-24

Chapter 2: Performing a Control Test

1   Why and When to Perform a Control Test

SOLUSmobile Control Solution contains a known amount of glucose and is used to confirm that the meter and test strips are working properly. A control solution test should be performed every time a new bottle of test strips are opened, or whenever you suspect that the meter or test strips may not be functioning properly.

2   About Control Solution Tests

1. The Control Solution range is found on the bottle of the SOLUSmobile test strips and NOT the control solution itself (see Figure 2-1).

2. Gently roll the control bottle in the palm of your hands as some particles of the solution may have settled to the bottom (see Figure 2-2).

3. Discard the first drop as crystallization may occur.

4. Place a drop of the control solution either on a hard surface or the "dimple" of the control solution cap (see Figure 2-3).

5. Place the meter into "Control" mode (See below) when performing a control test so the readings do NOT get averaged with your other readings.

Figure 2-1   Figure 2-2   Figure 2-3

3   Performing a Control Test

⚠ **Important:**

Press the "R" right function button in order to set the meter to "Control Test" mode. If you leave the meter in the standard mode, the control solution test result will be stored in the memory and affect your average "AVG" results.

1. Insert a strip into the meter and you will hear: "Hello, Solus is ready." You will then hear: "Apply blood now."

2. Press the "R" right function button and you will see a letter "C" in the right-hand corner of the LCD screen to indicate you are in "Control Test" mode. You will then hear: "Apply control solution now." The test result will not be stored in the memory (see Figure 2-4).

3. Squeeze a small amount of control solution onto a flat surface or the "dimple" of the cap and apply it to the front edge of the test strip. You will hear: "Testing in process" (see Figure 2-5).

4. Wait six (6) seconds and the meter will display the result. You will then hear: "The glucose level is [number/unit]" (see Figure 2-6).

5. Remove the used strip. The meter will power off with a display of "OFF" and you will hear: "Goodbye."

6. Compare the reading you received from your meter to the appropriate control range found on the bottle of strips. If the control test falls into range, you know your meter is testing accurately.
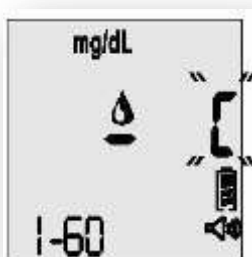
2-4

2-5

2-6

NOTE	1. If the meter, test strips and control solutions are moved from one temperature to another, allow thirty (30) minutes for them to adjust to the new temperature before performing a control test.
	2. You must press the "R" right function button only once to set the meter to "Control Test" mode before running the test. Do not perform the blood test in "Control Test" mode if you want to save the test result in the meter's memory.
	3. Use only SOLUSmobile control solution with the SOLUSmobile Glucose Meter.
	4. SOLUSmobile control solutions are used to confirm the accuracy of the meter and the test strips.
	5. SOLUSmobile control solution contains a known amount of glucose that reacts with test strips. The low- and high-level control solutions are intended to check the management system in different measurement ranges.
	6. To ensure an accurate result, make sure to gently roll the control solution in the palm of your hand. Then discard the first drop.
	7. Use for only three (3) months after first opening the solution. Record the open date on the control solution bottle. Discard after three (3) months.
	8. Compare your control solution test results with the expected range printed on the test strip bottle label. If your glucose control results fall outside the expected range, repeat the test. Results that repeatedly fall outside the expected range may indicate: (1) The control solution test may not be performed correctly. (2) The control solution is expired or contaminated. (3) The test strips are damaged or expired. (4) The meter is malfunctioning.

Chapter 3: Testing Your Blood Sugar

1   Preparing the SOLUSmobile Lancing Device

NOTE	To reduce the chance of infection: Never share a lancet or a lancing device with anyone. Always use a new, sterile lancet. Lancets are for single use only.

1. Pull off the adjustable depth cap or push the ejector forward to remove the adjustable depth cap (see Figure 3-1).

2. Insert a new lancet firmly into the lancet holder (see Figure 3-2).

3. Twist off the protective cover of the lancet (see Figure 3-3).

4. Replace the adjustable depth cap onto the body of the device. Select lancing depth. If necessary, please set the lancing device for a deeper puncture (see Figure 3-4).

5. Slide the lancing device into locking position: gently pull the sliding barrel away from the top of the lancing device until a soft click is heard.

3-1

3-2

3-3
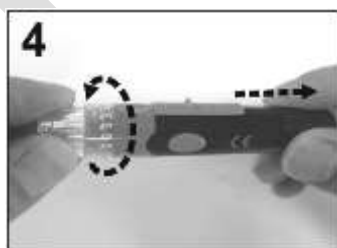
3-4

Important: If you do not obtain enough blood on the strip, you will receive an error message. You will also hear, "No sufficient blood." This is critical for your safety.

2   Performing a Blood Glucose Test

1. If the meter and test strips are moved from one temperature to another, allow thirty (30) minutes for them

to adjust to the new temperature before performing a blood glucose test.

2. Wash your hands with warm, soapy, water (see Figure 3-5).

3. Open the test strip bottle and take out one new test strip (see Figure 3-6). Recap the bottle quickly and firmly.

4. Insert a test strip into the meter while the meter is in the "OFF" position. You will hear: "Hello, Solus is ready" (see Figure 3-7).

5. Retrieve the loaded lancing device or single-use lancet.

6. Apply blood to the front edge of the test strip after you hear: "Apply blood now" (see Figure 3-8). You will also see a flashing blood drop on the LCD screen of your meter. If enough blood is obtained you will hear: "Testing in process."

3-5

3-6

3-7

3-8

3   Important Information on Alternate Site Testing (AST)

a. What is AST?

AST is the sampling from sites on your body other than the fingertip (i.e., forearm, upper arm, thigh, calf,

palm) to check blood glucose levels. This system allows you to test on the forearm with results equivalent to those of fingertip testing.

There are important limitations to AST. Please consult your healthcare professional before you use AST.

b. What is the advantage?

Patients typically feel more pain when lancing their finger pads because they have substantially more nerve endings than other testing sites. It is reported that other testing sites cause less pain; however, there are other limitations. Please speak to your healthcare provider before using this method.

Use Alternate Site Testing (AST) ONLY if:

1. It is more than two (2) hours after the administration of insulin.

2. It is more than two (2) hours after the last meal.

3. It is more than two (2) hours after exercise.

*DO NOT use AST if you are pregnant or if your blood sugars are not stable.

*DO NOT use AST if you think your blood glucose is low or if your AST results do not match the way you feel.

4   Performing an Alternate Site Test (AST)

1. Prepare lancing device for testing

2. Select a puncture site from a fleshy area on the forearm. Rub vigorously until it feels warm. Avoid veins, hair, moles, bones and tendons (see Figure 3-9).

3. Press the clear endcap against the puncture site and then press the blue release button. Keep the device in constant contact with the skin and apply and release pressing slowly pumping up and down 2-3 times without lifting the device away from your skin. Maintain steady pressure until the drop under the endcap reaches appropriate size (see Figure 3-10).

4. Lift the device straight up and away from skin without smearing the blood drop (see Figure 3-11).

5. Apply the blood to the glucose test strip within 20 seconds of puncture (see Figure 3-12).
   Do not test the blood sample if you get:
   ● Smeared blood
   ●Runny blood
   ● Clotted blood
   ● Clear fluid mixed with the blood

6. Wipe the puncture site with a clean, dry tissue and maintain pressure on the site until the bleeding stops (see Figure 3-13).

3-9

3-10

3-11

3-12

3-13

5   Highlighting Your Results as Before and After Meal Tests

1. To flag a before-meal test, press the "R" right function button two (2) times after you hear: "Apply blood now." You will then hear: "Ready for test before meal." Apply blood to the edge of the strip. You will hear "Testing in process" (see Figure 3-14).

2. To flag an after-meal test, press the "R " right function button three (3) times after you hear: "Apply blood now." You will then hear: "Ready for test after meal." Apply blood to the edge of the strip. You will hear "Testing in process" (see Figure 3-15).

3. After a six-second countdown, you will hear: "The glucose level is [number/unit]." For those glucose tests

that were flagged, the screen will display an "A" for an after-meal test and a "b" for a before-meal test (see Figure 3-16).

4. Once you remove the used strip, the meter may ask you one or more questions from your healthcare provider. Use the "Yes" and "No" keys to respond to the questions. If you are uncertain of an answer or want someone to telephone you, push the Language Choice/Call Me button. No further questions will be asked by the meter and your healthcare provider will telephone you. There is no Language Choice/Call Me Button? Remove.

5. As long as the strip is still inserted, press the "R" right function button and the meter will repeat the test results no matter how many times the "R" right function button is pressed until strip is taken out or waiting time runs out.

6. Once you remove the used strip, the meter will turn off automatically and you will hear: "Goodbye." The LCD screen will then display "OFF" (see Figure 3-17).

3-14

3-15

3-16

3-17

6   Understanding Your Test Results[1]

Blood glucose levels are fluid and change all the time depending on food intake, medication dosages, health, stress, and exercise. Consult your physician or healthcare professional for your ideal glucose levels.

Expected plasma blood glucose values for normal, non-diabetic, adults are as follows:

Before Eating; no food intake for eight (8) hours: <100mg/dL (5.6 mmol/L)

Two hours after meals: <140mg/dL (7.8 mmol/L)

Consult your physician or healthcare professional for your appropriate range. If you are experiencing symptoms that are not consistent with your blood glucose results and you have followed all the instructions in this User Guide, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes control programs without speaking to your healthcare professional.

SOLUSmobile meter gives plasma equivalent results.

7   Symptoms of High or Low Blood Sugar

Being aware of the symptoms of high or low blood sugar can help you understand your test results and decide what to do if they seem unusual. Here are some common symptoms:

High blood sugar (hyperglycemia): increased fatigue, increased appetite or increased thirst, frequent urination, blurred vision, headaches, general aching, or vomiting.

Low blood sugar (hypoglycemia): sweating, trembling, blurred vision, rapid heartbeat, numbness around the mouth or fingertips, and irritability

8   Unusual Test Results

If your blood sugar result does not match the way you feel, you should follow these steps:

9   Troubleshooting

1. Check the expiration date of the test strips. This can be found on the strip bottle. If your strips have expired, contact your supplier for a new bottle.

2. Make sure that the test strips have not been opened for longer than ninety (90) days.

3. Perform a control solution test (see Chapter 2) to confirm that the strips and meter are operating correctly.

4. Make sure that you followed all the testing steps located in Chapter 3: "Testing Your Blood Sugar".

5. If your blood sugar results still don't match the way you feel, contact your doctor and follow his or her instructions.

NOTE	Make sure that you always follow your doctor's or healthcare professional's instructions.

If your control test results are outside of the range listed on the test strip bottle, contact the BioSense Medical Devices and speak to one of our customer support representatives at toll free (877) 592-3922 for assistance.

10 Comparing Your Meter Results to Your Lab Result

In order to compare your meter results to a lab result, you must be fasting. You will also need to test your blood sugar with your meter within five (5) minutes of having your blood drawn by a healthcare professional. Keep in mind that the lab uses different technology than your meter and that blood glucose meters for self-testing may read within $\pm$ 20 percent of the lab result, according to FDA guidelines.

Chapter 4: Recalling the Memory, Downloading Results, Communications Functions

1   Recalling the Memory

Your test results will be stored automatically. Your meter can store up to 500 test results at any single point in time. You can also view your averages over the last 7, 14, 28, 60, and 90 days.

To recall the memory:

1   In the "OFF" position, press the "M" left function button once and you will hear: "Recalling the memory." If no results are stored, "---" will be displayed on the screen and you will hear: "Zero memory" (see Figure 4-1 and 4-2).

2   Press the "Down" key to retrieve the latest test first.

3   Press the "Up" key to retrieve the oldest test first.
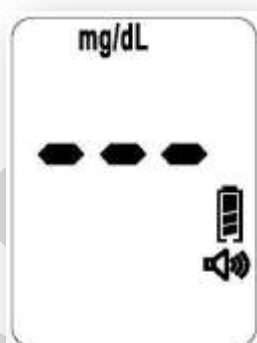
4-1   4-2

2   Viewing the Averages

NOTE	The average will have all test results including those flagged as "Before-Meal" tests, "After-Meal" tests and those not flagged at all. When the meter displays "---" on the screen, it indicates there are no readings stored in memory.

1. Press the "R" right function button once and you will see "AVG" and the number "7" flashing on the lower left corner. The number "7" means that the average was taken over the past seven (7) days. For example, you will hear: "The average for "7" day is 83 milligrams per deciliter." (see Figure 4-3 and 4-4).

2. Press the "R" right function button to incrementally move between the different time-frames for averages

(i.e., the past 7, 14, 28, 60, and 90 days).
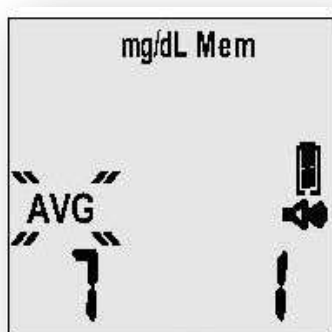
4-3
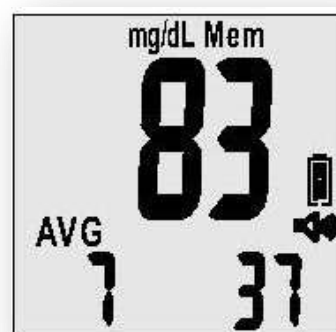
4-4

3   Displaying Averages in Sequential Order

1   Press the "Up" key to see the test averages in the sequence starting with "Before-Meal" test results. For example, you will hear: "The before-meal average for seven days is 83 milligrams per deciliter."

2   Press the "Down" key to see the test averages in the sequence starting with "After-Meal" test results. For example, you will hear: "The after-meal average for seven days is 108 milligrams per deciliter."

The screen will display the average reading with a "b" for "Before-Meal" tests or an "A" for "After-Meal" tests (see Figure 4-5).

4-5

NOTE	1. Out-of-range high and low test results will not be stored in the memory.
	2. Do not insert the strip into the meter when you want to recall test results in memory.
	3. The average readings in the meter memory are calculated from the results obtained during the 7, 14, 28, 60 and 90 calendar days preceding

	the current date and time settings.

4   Communications Functions

1. <u>Airplane Mode</u> - The air plane mode switch is located on the right side of the meter. When in the on position, the communications module will not turn on. Set the meter into airplane mode whenever you board an airplane. Be sure to turn it off again after leaving the airport. Your meter will not transmit test results if left in airplane mode.

2. <u>Answering Customer Service Queries</u> - The meter will use audible prompts for normal customer services that were formerly down via telephone and/or mail. These audible prompts will occur after you perform another action with the meter, such as testing blood sugar or reviewing test results. During the query session, the meter will display "PC". When responding to queries, the keys function as follows: Yes - Top left function key, No – Top right function key, Repeat the question – Bottom left function key, "Call Me" - Request customer service to call you – Center function key, Abort the query session - Right function key. An audible message will inform the patient what action will be taken after all questions have been answered, aborted or the Call Me button has been pressed. Example audible prompts that you may hear include the following:

   - Do you need supplies?

   - Has your address changed?

   - Has your insurance provider changed?

3. <u>Automatic Transmission of Results</u> - Early every morning, between 1:00 AM and 4:00 AM, the SOLUSmobile Wireless Blood Glucose Meter transfers test results and your answers to any audible questions asked after testing stored in its memory to a central repository for review by your healthcare provider. The meter will display "PC" (for communicating) (see Figure 4-6) while transmitting results. The meter does not turn on the display back light or play any messages during this process. It will take between one (1) and five (5) minutes to complete the synchronization process. The meter cannot be used by the patient during this time. The meter still keeps the results in the memory after transmitting. After the synchronization process is complete, the meter will display "OFF" (see figure 4-7).

4. <u>Manual Transmission of Results</u> - The meter may not be able to transmit test results on a daily basis if a patient lives in a location that has poor cell phone coverage. The meter can store 500 test results, which is approximate 3 months of data (testing 5 times a day). No data will be lost provided the meter synchronizes every 500 blood tests.

If a meter fails to upload test results, a customer service representative will contact the patient and ask them to perform a manual synchronization in a location that has cell phone coverage. This could be a doctor's office, local mall or other suitable location.

To perform a manual data synchronization:

1) Ensure the meter is in the "OFF" mode. Press the lower left function button for 2 seconds if needed.

2) Hold the lower left and right function keys down for 2 second until the meter displays "PC" (see Figure 4-6) and plays the message "Ready to transmit data".

3) At completion the meter will indicate if the data was transmitted successfully or not by playing the messages:

   a. Data transmission completed.

   b. Data transmission failed.

4-6   4-7

Chapter 5: Maintenance and Troubleshooting

1   Storing and Handling Your Meter

- Store your test strips in the bottles provided.

- Keep your meter in a clean, dry, place between 46 to 86°F (8 to 30°C).

- When you are not using your meter, keep it stored in the hard, protective case.

- Enforce infection control policies when healthcare professionals are handling your meter.

- Charge your meter at least once per week.

2   Cleaning Your Meter

Cleaning your SOLUSmobile Glucose Meter is easy. We recommend that you clean the meter after every use. Gently wipe and clean its surface with a soft cloth that has been slightly dampened with 70 percent alcohol (ethyl alcohol), or 70 percent rubbing alcohol (isopropyl alcohol).

3   Interpreting Error Messages

Following is a summary of all error messages that appear and can be heard on your meter. These messages help identify certain problems, but do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing an error message or a symbol. In the event of a problem, refer to the information in the table on the next page under Solution.

Error Messages		
Error Message Number	Meaning	Audible Message
E_1	The meter temperature is below its operating range	"The temperature is too low."
E_2	The meter temperature is above its operating range.	"The temperature is too high."
E_3	The battery is low. No further tests can be performed.	"Battery low."
E_4	The blood sample is not sufficient.	"No sufficient blood."
E_5	The test strip is wet or used.	"Strip is wet or used."
E_6	The meter is not working properly, or the test strip is damaged.	"Error in meter or strip."
E_7	The memory has been	"Memory damaged."

Error Messages		
Error Message Number	Meaning	Audible Message
	damaged.	

Other Error Messages		
H I	The test result is higher than 600 mg/dL.	"The glucose level is too high."
LO	The test result is lower than 20mg/dL.	"The glucose level is too low."

4   Troubleshooting Your Meter

5   Error Messages

Message	Audible Message	Possible Cause	Solution
E_1	The temperature is too low.	The meter is operating in an ambient temperature below 10 ^{o}C or 50 ^{o} F, which is the lowest range of operating temperature.	The system operation range is 10 ^{o}C to 40 ^{o}C (50 ^{o} F to 104 ^{o} F). Repeat the test when the temperature is within the range.
E_2	The temperature is too high.	The meter is operating in an ambient temperature above 40 ^{o}C or 104 ^{o} F, which is the cap of operating temperature.	
E_3	Battery low.	The battery is too low to operate the meter.	Charge the battery immediately.
E_4	No sufficient blood.	The blood sample is not sufficient.	Re-test with a new strip and a new blood sample.
E_5	Strip is wet or used.	The inserted test strip has been wet or used.	Re-test with a new test strip and a new blood sample.
E_6	Error in meter or strip.	The meter is not working properly, either because of a defective meter or a defective strip.	Re-test with a new strip. If error message "E_6" is still displayed, contact your local distributor for technical support.
E_7	Memory damaged.	The memory chip of the meter could be damaged or malfunctioning.	Re-test with a new strip. If error message "E_7" is still displayed, contact your local distributor for technical support.

6   Special Messages

Message	Audible Message	Possible Cause	Solution
LO	The test result is lower than 20 mg/dL (1.1 mmol/L)	The test result is lower than the minimum of 20 mg/dL (1.1 mmol/L).	Test again following the user guide for the correct glucose measurement process. If you see "LO" again, please call your medical doctor for advice immediately.
HI	The test result is higher than 600 mg/dL (33.3mmol/L)	The test result is higher than the maximum of 600 mg/dL (33.3 mmol/L).	Test again following the user guide for the correct glucose measurement process. If you see "HI" again, please call your medical doctor for advice immediately.

7 Problem in Operation

Problem	Possible Cause	Solution
The meter will not turn on when a strip is inserted.	1) The meter is defective or the battery is low; or 2) The strip is damaged or not inserted properly.	1) Make sure the arrow on the inserted strip is facing towards the meter, and that blood icon on the strip is facing up. 2) Take a new strip and re-insert it into the meter. 3) Check the battery power or charge the battery, if necessary. 4) Call Customer Service.
The meter does not count down.	The meter is defective or the battery is low.	Charge the battery. If the meter fails to operate, call Technical Support.
The meter display turns off abnormally.	The meter is defective or the battery is low.	Charge the battery. If the meter fails to operate, call Technical Support.
The control test result is out of specified range.	The control solution or test strip may be outdated or defective.	Verify if the control solution or the test strip is expired. If they are not expired, call Customer Service

WARNING	Your meter can show results either in "mg/dL" or "mmol/L" units. Mg/dL is the typical unit used in the United States, please contact the manufacturer if your meter does not display mg/dL when you turn it on. The factory set default for the meter is mg/dL. In the event that the meter loses power, the factory set default is mg/dL. It is very important to use the correct unit of measurement to properly manage your diabetes. If you live in the United States, you should use mg/dL. If you are testing in mg/dL, your results will never have a decimal point. If you use the metric system, you should use mmol/L. Your result will ALWAYS have a decimal point.

8   Accessing Customer Service

BioSense Medical Devices offers 24/7 customer support. If you need assistance with your SOLUSmobile Glucose Management System, please contact:

BIOSENSE MEDICAL DEVICES, LLC

6555 Sugarloaf Parkway,

Suite 307-168,

Duluth, GA 30097

TOLL FREE: 877-592-3922

FAX: 888-620-2345

Chapter 6: Technical Information

1   Methodology of Reagent

When glucose reacts with the reagents on the test strips, an electrical current is produced, which is proportional to the glucose concentration in the blood sample.

The glucose concentration is calculated by the meter type and the amount of electrical current measured.

2   Limitations

1. Do not use for neonatal blood glucose testing.

2. Hematocrits in the range of 32 to 56 percent do not affect the blood glucose results. If you do not know your hematocrit level, consult your healthcare professional.

3. Hemoglobin levels of 500 mg/dL or below will not interfere with blood glucose test results.

4. Cholesterol levels up to 500 mg/dL and Triglycerides up to 1000 mg/dL have been shown not to affect glucose results.

5. Medications: Interference was observed for therapeutic levels of L-Dopa. No interference was shown for uric acid, acetaminophen, ascorbic acid and ibuprofen at normal therapeutic levels; however, higher concentrations in blood may cause incorrect results:
   Uric acid: ＞10.9 mg/dL;
   Acetaminophen: ＞6.2 mg/dL;
   Ascorbic acid: ＞4.5 mg/dL; or
   Ibuprofen: ＞37.5 mg/dL.

6. The test strips may be used at altitudes up to 5,280 feet (1,609m) without effecting test results.

7. If you are suffering from severe dehydration you should have your blood glucose levels tested by a healthcare professional in a hospital or lab setting. Do not test with a home-use blood glucose device when suffering from severe dehydration.

8. Test results below 70 mg/dL indicate low blood glucose (hypoglycemia). Test results greater than 240 mg/dL indicate high blood glucose (hyperglycemia). If you get results below 70 mg/dL or above 240 mg/dL, repeat the test, and if the results are still below 70 mg/dL or above 240 mg/dL, please consult your healthcare professional immediately.[2]

9. Inaccurate results may occur in severely hypotensive individuals or patients in shock. These results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.

Critically ill patients should not be tested with a blood glucose meter.

3 Product Specifications

Test: Glucose

Sample: Whole Blood

Principle of the test method: Amperometric, glucose oxidase.

Test sites: Fingertip, Forearm

Measuring Range: 20–600 mg/dL (1.1–33.3 mmol/L)

Measuring Time: 6 seconds

Code required: No code device

Battery: Internal, not user accessible

Operating Range: 10–40°C (50–104°F)

Humidity: 20–80 % RH

Width: 55 mm.

Length: 100 mm.

Thickness: 18 mm.

Weight: 75 g.

Memory: 500 test results with date and time.

Power: Automatic shut-off after five (5) minutes when a strip is inserted, or one (1) minute if no strip is inserted.

NDC #: 8611-501001

The device has been certified to meet the following standards:

98/79/EC, EN 60601-1 + EN 60601-1-1

ISO 15197

NOTE	This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radi-ate radio frequency energy and, if not in-stalled and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: • Reorient or relocate the receiving antenna. • Increase the separation between the equipment and receiver. • Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. • Consult the dealer or an experienced radio/ TV technician for help.

4   Warranty Information

The SOLUSmobile Glucose Meter is warranted to be free from defects for five (5) years from date of purchase. For warranty assistance, please contact:

BIOSENSE MEDICAL DEVICES, LLC

6555 Sugarloaf Parkway,

Suite 307-168,

Duluth, GA 30097

TOLL FREE: 877-592-3922

FAX: 888-620-2345

References

1. American Diabetes Association : Diabetes Care, January 2007, volume 30 (Suppl. 1) S42-S47

2. American Diabetes Association-Diabetes Forecast (website information http://www.forecast. Diabetes.org/diabetes-101/hyperglycemia.

3. http://www.forecast.diabetes.org/diabetes-101/hypoglycemia.)