### EasyPlus mini MasterDriver<sup>™</sup>

#### Self-Monitoring Blood Glucose System

## **User's Manual**

#### Dear EasyPlus mini MasterDriver<sup>™</sup> SMBG System Owner,

Thank you for choosing the **EasyPlus mini MasterDriver<sup>™</sup>** Self-Monitoring Blood Glucose (SMBG) System. We designed this system to be reliable, use-friendly and efficient to help you monitor your blood glucose on a regular basis.

Please read this manual thoroughly before you begin testing. This manual provides you and your diabetes care team with important information and step-by-step direction to use the EasyPlus mini MasterDriver<sup>™</sup> Self-Monitoring Blood Glucose System.

Once again, thank you for choosing the **EasyPlus mini MasterDriver<sup>™</sup>** SMBG System.

#### **Intended Use**

The **EasyPlus mini MasterDriver<sup>™</sup> Self Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in fresh capillary whole blood from fingertips, palm or forearm. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for self-testing (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.



Although the Master Driver<sup>™</sup> SMBG System is easy to use, you may need to consult your healthcare professional (this may be your doctor, pharmacist or diabetes nurse educator) for instructions on how to use the system. Only the correct use of the system will ensure accurate results.

#### **Standard Accessories**

Your new **EasyPlus mini MasterDriver<sup>™</sup>** Blood Glucose meter and accessories work together to measure the amount of glucose in your blood. The system includes:

- Blood Glucose Meter
- Test Strip x 10 ct.
- Normal Control Solution
- Carrying Case
- Control Solution Instructions
- Lancet x 5 ct.
- Lancing device

- AST Lancing Device Cap
- User's Manual
- Quick Reference Guide
- Log Book
- Test Strip Instructions
- CR2032 Battery x 1

#### Why is it so important to test blood glucose regularly?

Testing your blood glucose regularly can make a big difference in how you manage your diabetes every day. We've made this SMBG system as simple as possible to help you to use it regularly. Your meter is easy to use, and you can adjust the lancing device for your comfort.

#### Do you need Help?

If you have questions or need assistance, please contact your healthcare professional.

#### Important Information About Your New MeterDriver™

- EasyPlus mini MasterDriver<sup>TM</sup> blood glucose meter is designed and approved for testing fresh capillary whole blood samples from your fingertips, palm and forearm. The meter is for in vitro diagnostic use ONLY (for testing outside the body). It should not be used to diagnose diabetes.
- EasyPlus mini MasterDriver<sup>™</sup> blood glucose meter can only be used with EasyPlus mini MasterDriver<sup>™</sup> Blood Glucose Test Strips. Other test strips will give inaccurate results.
- Testing is not valid for neonatal blood specimen.
- Do not disassemble the meter as this may cause damage to the components resulting in incorrect reading. Disassembling the meter will also void the warranty.
- Always keep the meter clean and store it in a safe place. Protect the meter from direct sunlight to ensure a longer lifespan.
- You should not store the meter and test strips in a car or a bathroom, or refrigerator.
- Keep the meter, test strips and lancing device away from children and pets.
- You should not test critically ill patients with home-use blood glucose meters.
- Elevated levels of acetaminophen, uric acid, gentisic acid, levodopa, dopamine, ascorbic acid and methyldopa may affect results.

- Incorrect results may occur when performing the test. If you believe you are not feeling well, please contact your healthcare professional.
- Remove batteries if the meter will not be used for one month or more.
- Warning for potential biohazard: Healthcare professionals using this system on multiple patients should be aware that all products or objects that come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral disease.

# À

- Consult with your healthcare professional before testing on your palm or forearm.
- Do not touch the strips with wet hands.
- Do not use expired strips (the expiration date is shown on the bottle.)
- Do not bend, cut or twist the strips.
- Altitude up to 3,048 meters above sea level has no effect on readings.

#### **Health-Related Information**

- If you are very dehydrated, urinating frequently, have low blood pressure, in shock or hyperosmolar hyperglycemic nonketotic coma (HHNKC), you may get a test result that is lower than what your blood glucose really is. If you think you are dehydrated, call your doctor right away.
- If you have followed the steps in the user's manual, but still have symptoms that don't seem to match your test results, or if you have questions, please contact your healthcare provider.
- Please read your test strip instructions carefully for additional health-related information.

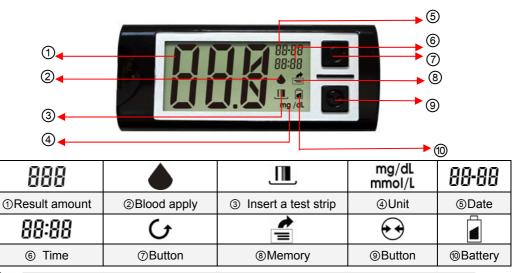
## Â

Warning for potential biohazard:

Healthcare professionals using this system on multiple patients should handle all products or objects in contact with human blood carefully to avoid transmitting viral disease, even after cleaning.

#### **Explanation of Symbols**

ĺ	Consult instructions for use	$\wedge$	Caution
LOT	Batch code	$\otimes$	Do not re-use
IVD	In vitro diagnostic medical device	+ CR2032 3V x 1	3V (CR2032) x 1 battery only
X	Use by		Temperature limitation
***	Manufacturer	REF	Catalogue number
SN/	Serial number	CONTROL	Control
$\Sigma < n >$	Sufficient for	EC REP	Authorized representative in the European Community
CE	This product meets the requirements of Directive 98/79/EC in vitro diagnostic medical devices		





The unit of Blood Glucose Meter is set at mg/dL.

#### **Table of Contents**

Chapter 1: Understanding Your Meter	14
The EasyPlus mini MasterDriver <sup>™</sup> Blood Glucose Meter	14
The EasyPlus mini MasterDriver <sup>™</sup> Blood Glucose Test Strip andAccessorie	
Inserting Batteries	16
Setting The Time And Date	17
Using <b>EasyPlus mini MasterDriver</b> <sup>™</sup> Blood Glucose Test Strip	18
Chapter 2: Control Solution Test	19
Why Run a Control Solution Test	19
About The Control Solution	20
Running A Control Solution Test	21

Chapter 3: Testing Your Blood Glucose	25
Using The Lancing Device	25
Inserting A Lancet into the Lancing Device	
Running A Blood Glucose Test With Blood From Your Fingertip	
Alternate Site Testing (AST)	
Running A Blood Glucose Test With Blood From Your Forearm	
Running A Blood Glucose Test with Blood from Your Palm	34
Discarding Used Lancets	35
Understanding Your Test Results	
Unusual Test Results	
Symptoms of High or Low Blood Glucose	
Comparing Your Meter Result To A Lab Result	40

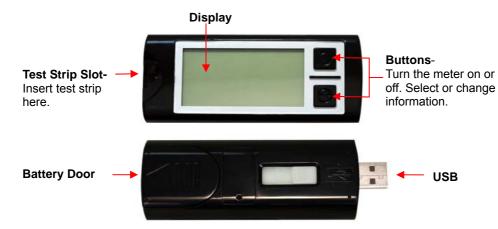
Chapter 4: Meter Memory, Setup	41
Memory, Storing Test Result	41
Viewing & Deleting Test Results	

Chapter 5: Maintenance And Troubleshooting	44
Inserting Batteries	
Cleaning Your Meter	
Cleaning Your Lancing Device	
Maintenance And Testing	
Screen Messages And Troubleshooting	

Chapter 6: Technical Information	
Specifications	
Running With Your Computer	
Limitation	
Device Information	
Warranty	

#### **Chapter 1: Understanding Your Meter**

#### EasyPlus mini MasterDriver<sup>™</sup> Blood Glucose Meter



## The EasyPlus mini MasterDriver<sup>™</sup> Blood Glucose Test Strip and Accessories



#### **Inserting Batteries**



**1.** Open the battery door of the meter by slipping the tab in the direction of the arrow.



2. Insert a battery and the meter beeps.



**3.** Put the battery door back in place and snap it closed. The meter turns on automatically.

#### Setting The Time and Date—First Time Use

Setting the current time and date in your meter is important if you intend to use the meter memory or if you want to download your results to a computer.







**1.** Insert a new battery, the meter beeps and turns on automatically.

**3.** Repeat step 2 to set the date and time. The flashing field is the one you are currently setting. When finishing the setting, the display shows **OK** and the meter beeps.

#### Using EasyPlus mini MasterDriver<sup>™</sup> Blood Glucose Test Strip

- Use only with **EasyPlus mini MasterDriver**<sup>TM</sup> Blood Glucose Meter.
- Run a control solution test every time you open a new box of test strips (See Chapter 2 "Control Solution Testing.")
- Keep the test strips in their original bottle.
- After you take a test strip out of the bottle, close the bottle immediately.
- Use the test strip within 3 minutes after you taking it out of the bottle.
- The test strip is for single use only. Do not reuse it.
- Write down the date on strip bottle when the strip bottle is first time opened. Be sure to check the expiration date on the test strip bottle. The test strip will be expired either in three months after the date of the bottle is opened or till the expiration date printed on the bottle.
- Store the test strip bottle and your meter in a shady and arid place.
- Store the test strips between 2°C 30°C (36°F- 86°F). Do not freeze.
- Do not apply blood or control solution to the test strip before you insert it into the meter.
- Do not touch the test strip with wet hands. Do not bend, cut, or twist the test strips.

#### **Chapter 2: Control Solution Testing**

#### Why Run A Control Solution Test

We recommend that you run the **EasyPlus mini MasterDriver**<sup>TM</sup> Normal control test because it lets you know that your meter and test strips are working properly to give you reliable results. You should run the control solution test when:

- You use the **EasyPlus mini MasterDriver**<sup>TM</sup> Blood Glucose Meter for the first time.
- You open a new bottle of test strips.
- You think the meter or test strips may be working incorrectly.
- You drop the meter.
- You have repeated a test and the test results are still lower or higher than expected.
- You are practicing the test procedure.



Professional users are instructed to follow federal, state, and local guidelines.

#### **About The Control Solution**

- Use only with **EasyPlus mini MasterDriver**<sup>TM</sup> test strips.
- Write the date you opened the control solution bottle on the bottle label. The control solutions are good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Do not use a control solution that is past the expiration date.
- Control solution can stain clothing. If you spill it, wash your clothes with soap and water.
- Close the bottle tightly after every use.
- Left over control solution should not be added back into the control bottle.
- Store control solution at room temperature, between 2°C- 30°C (36°F 86°F). Do not freeze.

#### **Running A Control Solution Test**

You need the meter, a test strip, and control solution.



1. Put a test strip into the meter in the direction of the arrow.

2. The meter beeps and turns on automatically. The icon
♦ and III shows itself.



- **3.** Place the meter on a flat surface, like a table.
- **4.** Remove the control solution bottle cap and wipe the tip of the bottle with a tissue.





- **5.** Squeeze the bottle until a tiny drop forms at the tip of the bottle.
- Fouch the drop to the Blood collection area at the tip of the test strip. Do not put control solution on top of the test strip. When you hear beeps, you have enough control solution in the test strip.
- **7.** The meter starts to count down from 5 seconds, the display shows "**Ok**", and then shows the test result.
- **8.** Do not remove the test strip yet. Check if the reading falls within the range printed on the test strip bottle.



**9.** Remove the test strip and throw it away after you have compared the reading to the range printed on the test strip bottle.

#### **Understanding Control Solution Test Results**

The label on your test strip bottle shows the acceptable ranges for the Control Solutions. The result you get should be inside the acceptable range for the appropriate control solution level. Make sure you compare the result to the correct level of control.

When the control solution result is inside the range on the test strip bottle, your test strips and your meter are working properly.

If your control solution result is not inside the acceptable range (printed on your test strip bottle), here are some things you can do to solve the problem:



Control Solution values will be included in the memory and averages. Refer to the section "Viewing & Deleting Test Results" to delete the control solution values before averaging vour test results.

#### Troubleshooting Checks

- ✓ Was the test strip exposed to open air for a long period of time?
- ✓ Does test strip cap close tightly? Or was test strip cap left open?
- ✓ Is the meter functioning well?
- ✓ Is the control solution expired or contaminated?
- ✓ Were test strips and control solutions stored in cool, dry places?
- ✓ Did you follow the testing steps properly?

#### Action

If yes, repeat the control test with properly stored strips.

If the cap was not tight, or the bottle was left uncapped, open a new bottle of test strips. Do not reuse the strips from the affected bottle.

You can use control solution to verify the meter's functions. (Chapter 2)

If yes, replace with new control solution to check the performance of SMBG system.

If no, repeat the control test with properly stored strips or control solutions.

Read Chapter 2 "Control Solution Testing" and test again. Stop using the meter if you continue to obtain the inaccurate results. If you have questions or need assistance, please contact your healthcare professional.

#### **Chapter 3: Testing Your Blood Glucose**

#### **Using The Lancing Device**

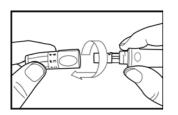
- The best depth setting is the lowest number that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your lancing device with anyone. And always use a new, sterile lancet. Lancets are for one time use only.

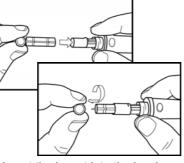
# Â

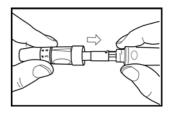
Used test strips and lancets are considered bio-hazardous waste in accordance with local regulations and should be handled as if capable of transmitting infection. Users may discuss methods for disposing of used test strips and lancets with their doctor.

#### Inserting A Lancet Into The Lancing Device

You must first load the lancet into the lancing device to get it ready for use.





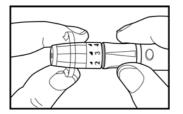


1. Unscrew the Cap.

- 2. Insert the lancet into the lancing device firmly then twist off the protective cover.
- 3. Recap the front cap.

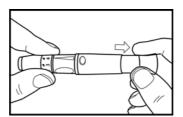


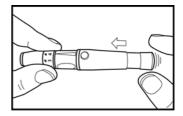
Lancets are for use only and a new, sterile lancet should be used each time you perform a test.



**4.** Select the desired penetration depth.







5. Pull on the sliding barrel of the lancing device until it clicks and then release.

Now the lancing device is ready. Do not prick your finger until your meter and strip are prepared. 6. Set the lancing device aside until later in the test.

- 1. Select 1-2 for soft or thin skin, 3 for average, and 4-5 for thick or calloused skin.
- 2. Lancing device and lancets are not to be shared between users. Sharing lancing devices and lancets may transmit blood borne pathogens, such as viral hepatitis.

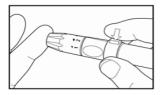
#### Running A Blood Glucose Test With Blood From Your Fingertip



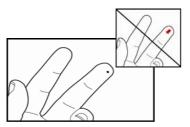
**1.** Wash your hands with soap and warm water. Rinse and dry thoroughly.



- **2.** Put a test strip into the meter in the direction of the arrow. The meter beeps and turns on automatically.
- **3.** When the blood drop flashes on the display, using the lancing device.



**4.** Hold the lancing device firmly against the side of your finger. Press the trigger button. Then remove the lancing device from your finger.







**5.** Gently squeeze and/or massage your fingertip until a round drop of blood on your fingertip.

6. Touch the blood drop at the tip of the transparent window of the test strip. Do not put blood on top of the strip. When you hear beeps, you have enough control solution in the test strip.

Be sure to get enough blood in the test strip. Otherwise, an inaccurate reading may result.

- **7.** The meter starts to count down from 5 seconds, the display shows "Ok", and then shows the test result.
- **8.** Remove the test strip and the meter turns off automatically.

#### Alternate Site Testing (AST)

**Understanding Alternate Site Testing** 

What is AST? Besides the fingertip, you can test the forearm. What is the advantage of AST? You have the option of testing other places on your body besides the fingertip.

Consult your health care professional before you begin using the forearm or palm for testing. Blood glucose test results obtained from your forearm or palm may differ significantly from fingertip samples.

#### We strongly recommend that you:

Do AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

#### Do NOT use AST if:

- You think your blood glucose is low.
- You are unaware of hypoglycemia.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.

#### Fingertip test only:

- If sick
- If blood glucose is low
- After exercising
- Two hours or less after eating
- When you have just taken insulin
- After injecting rapid-acting insulin (two hours or less)
- If you often do not notice when your blood glucose is low, do a fingertip test.

#### **AST Results:**

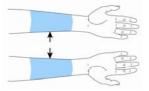
- If the blood glucose test result from the alternate site test does not match how you feel, do a fingertip test to confirm the result again.
- Do NOT change your treatment just because of an alternate site result, do a fingertip test to confirm the result.



- Talk with your healthcare professional before you test with your palm or forearm.
- Do NOT ignore symptoms of high or low blood glucose.
- Fingertip samples are able to show the rapid change of glucose faster than forearm samples.
- Do NOT change your treatment just because of a result.

#### Running a Blood Glucose Test with Blood from Your Forearm

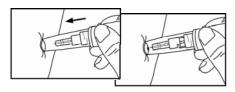
Please use the clear cap with the lancing device for AST testing.



**1.** Massage the puncture area of forearm for a few seconds.



**2.** Press and hold the device with clear adjustable tip against the forearm.



- **3.** Press the trigger button to activate the lancing device.
- **4.** Hold the device against forearm and increase pressure until the blood sample size is sufficient.

#### Running a Blood Glucose Test with Blood from Your Palm



**1.** Massage the puncture area of palm for a few seconds.

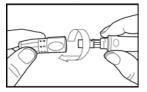
**2.** Press and hold the device with one clear adjustable tip against the palm.

 Press the trigger button to activate the lancing device.
Hold the device against forearm and increase pressure until the blood sample size is sufficient.
Check with your healthcare professional before



Check with your healthcare professional before testing other sites than fingertip.

#### **Discarding Used Lancets**



1. Unscrew and remove the cap.



**2.** Without touching the used lancet, stick the lancet tip into its protective cover.



**3.** Pointing the lancing device toward a container for sharp or biohazard material, slide the ejection button down to release the covered lancet into the container.

#### **Understanding Your Test Results**

The **EasyPlus mini MasterDriver**<sup>™</sup> Blood Glucose test strips are plasma referenced and calibrated for easier comparison to lab results. The normal fasting blood glucose range for an adult with diabetes is 70-130 mg/dL (3.9~7.2 mmol/L)\*. Two hours after meals, the blood glucose range for an adult with diabetes is less than 180 mg/dL (10.0 mmol/L). For further queries about diabetes: please consult your healthcare professional for the blood glucose range appropriate for you.

\* Reference: American Diabetes Association. Standards of medical care in diabetes-Table 10. Diabetes care. 2011; Vol. 34, Suppl 1, S21.

## **Unusual Test Results**

If your test result doesn't match the way you feel, please follow these steps:

- 1. Run a control solution test, Chapter 2 "Control Solution Testing."
- 2. Repeat a blood glucose test, Chapter 3 "Testing Your Blood glucose."
- 3. If your test results still don't reflect the way you feel, call your healthcare professional immediately.



- 1. Extremely high humidity may affect the test results. A relative humidity greater than 90% may cause inaccurate results.
- 2. Hematocrit below 30% may cause higher results. Hematocrit above 55% may cause lower results.
- 3. Some studies have shown that electromagnetic fields may affect results. Do not test near an operating microwave oven.

## Symptoms Of High Or Low Blood Glucose

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

#### Greater than 240 mg/dL (13.33 mmol/L)

#### What It Means:

The test result is higher than reference normal range. (70-130 mg/dL or 3.89-7.22 mmol/L)

#### Symptoms:

Fatigue, increased appetite or thirst, frequent urination, blurred vision, headache, general aching, or vomiting.

#### What to Do:

- If you are experiencing any of these symptoms, test your blood glucose.
- If the result displayed is greater than 240 mg/dL (13.33 mmol/L) and you have symptoms of high blood glucose, contact your healthcare professional instantly.
- If the result does not match how you feel, follow the steps under "Unusual Test Results."

#### Below 60 mg/dL (3.33 mmol/L)

#### What It Means:

The test result is lower than reference normal range. (70-130 mg/dL or 3.89-7.22 mmol/L)

#### Symptoms:

Sweating, trembling, blurred vision, rapid heartbeat, tingling, or numbness around mouth or fingertips.

#### What to Do:

- If you are experiencing any of these symptoms, test your blood glucose.
- If the result displayed is below 60 mg/dL (3.33 mmol/L) and you have symptoms of low blood glucose, contact your healthcare professional instantly.
- If the result does not match how you feel, follow the steps under "Unusual Test Results."

## **Comparing Your Meter Result To A Lab Result**

A common question is how the blood glucose results on your meter compare to the lab results. Your blood glucose can change quickly, especially after eating, taking medication, or exercising. If you test yourself in the morning, then go to the doctor's office for a blood glucose test. The results will probably not match, even if you are fasting. This is typically not a problem with your meter, it just means that time has elapsed and your blood glucose has changed.

If you want to compare your meter result to the lab result, you must be fasting. Bring your meter to the doctor's office, and test yourself by fingertip within five minutes of having blood drawn from your arm by a healthcare professional. Keep in mind that the lab could use different technology than **EasyPlus mini Master Driver<sup>™</sup>** blood glucose meter, and that blood glucose meters for self testing generally read somewhat lower or higher than the lab result.

For accuracy and precision data and for important information on limitations, see the instructions that come with your test strips.

## Chapter 4: Meter Memory, Setup

## Memory, Storing Test Results

Your meter stores a maximum of 480 test results with the time and date of the test. You can review them at any time. When the memory is full, the oldest result is dropped as the newest is added, so it is very important to have the correct time and date set in the meter.



- 1. Do not change your therapy based on one individual result in memory.
- 2. The memory is not lost when you replace the battery. You do need to check that the time and date are still correct. See Section "Setting the time and date" in Chapter 1.
- 3. Once 480 results are in memory, adding a new result causes the oldest one to be deleted.
- 4. Control Solution values will be included in the memory and averages. Refer to the section "Viewing & Deleting Test Results" to delete the control solution values before averaging your test results.

## **Viewing & Deleting Test Results**



Press to turn the meter on.
Press to enter memory mode. The meter shows the total number of the stored results first and then shows the latest result.



3. Press G to view the test result from latest to oldest.



Or press  $\boldsymbol{G}$  to cancel the deletion and go back to the total number of the stored results.



- 5. Press 💓 for 1 second to go back to the total number of the stored results.
- Press for 3 seconds to turn off the meter, or the meter turns off automatically in 90 seconds.

## **Chapter 5: Maintenance and Troubleshooting**

## **Inserting Battery**



The meter uses one CR2032 Battery. Battery will normally last for more than 1000 tests. Other types of CR2032 batteries are also acceptable, but the capacity of test times may differ. Insert the battery when you first use the meter or replace with new battery when the "LP" (low power) message and the low battery symbol appear on the display. The meter will not turn on the first time the

battery is inserted. Please press and hold " 💓" button or insert the test strip to turn your meter on. The meter will turn off automatically. Or you can press and hold " 🔶 " button to turn your meter off.



- 1. The meter won't delete earlier records after you replace the battery.
- 2. You should reset the time and date again after you replace the battery.
- 3. CR2032 Lithium Battery is available at most stores. You may take the old battery with you for replacement.
- 4. Remove the battery when you will not be using the meter for one month or more.

## **Cleaning Your Meter**

Caring for your **EasyPlus mini MasterDriver**<sup>™</sup> SMBG system does not require special cleaning. Please keep the meter free of dirt, dust, bloodstain, and water stains. Follow these guidelines carefully to help you get the best performance possible:

#### Do:

- Make sure the meter is turned off.
- Gently wipe the meter's surface with a soft cloth slightly dampened.

#### Do Not:

- Get any moisture in the test strip slot.
- Spray any cleaning solution directly onto the meter.
- Put the meter under water or liquid.
- Pour liquid into the meter.

## **Cleaning Your Lancing Device**

- To clean the lancing device, wipe it with a soft cloth dampened with water and mild detergent. DO NOT places the entire device under water.
- To disinfect the cap after cleaning, place it in 70%-75% rubbing alcohol for 10 minutes at least once a week. Allow the cap to air-dry after disinfecting.

## **Maintenance And Testing**



Your meter needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong. (See "Screen Messages" and what to do about them.)

To make sure the display is working properly, turn off the meter. Press and hold "  $\bigcirc$  " to see the complete display. All the indicators should be clear and look exactly like the

picture to the left. If not, please contact your healthcare professional.

## Screen Messages and Troubleshooting

Never make treatment decisions based on an error message. If you have any concerns, please contact your healthcare provider.

Message What it means?		What to do?	
	Humidified / Used strips The meter has detected a problem with the test strip.	<b>Repeat the test with a new strip.</b> Refer to pages 28-29 for information on sample application.	
	<b>Low power</b> The meter batteries do not have enough power to perform a test.	Replace the new batteries.	
<b>E</b> rr*	<b>Volume detector error</b> The volume of blood or control solution is NOT enough.	<b>Replace with a new strip.</b> If <b>Err</b> appears again, please contact your local dealer.	

Message	What it means?	What to do?
}	Test result is higher than 630 mg/dL (35.0 mmol/L).	<b>Re-check your glucose level.</b> If the result is <b>HI</b> again, obtain and follow instructions from your healthcare professional without delay.
	The test result is lower than 20 mg/dL (1.1 mmol/L).	This may require immediate treatment according to your healthcare professional's recommendations. Although this message could be due to a test error, it is safer to treat first and then do another test.
	The meter is connecting to the computer.	You can start to use the embedded software. Please read <b>GlucoManager<sup>™</sup> Data</b> <b>Management Software (GDMS)</b> User's Manual for more information. 48

## **Chapter 6: Technical Information**

#### Specification

Brand name	Brand name EasyPlus mini MasterDriver <sup>™</sup> Blood Glucose Met		
Range		20~630 mg/dL (1.1~35.0 mmol/L)	
Test time		5 seconds	
Memory sets	Run with PC	10000	
	Embedded Memory	480	
Operating	Temp.	10°C - 40°C (50°F - 104°F)	
condition	Relative Humidity	R.H. ≦ 90%	
Blood sample		0.6 µL	
		Fresh blood from fingertips, palm or forearm	
Hematocrit (Hct)		30-55%	
Power		CR2032 Lithium Battery	
Battery life		1000 tests	
Display dimension		1.93" x 0.94" (49 × 24.0 mm)	
Device dimension H × W × D (mm)		3.5" x 1.5" x 0.6" (89.0 × 38.0 × 16.5 mm)	
Weight		1.2 oz (34.3 grams) w/o batteries	
Principles		Electrochemical biosensor technology	
Embedded Software		Auto-Run GlucoManager	

## **Running With Your Computer**



1. Plug the EasyPlus mini MasterDriver<sup>™</sup> meter into a USB port on your PC.

 The display shows "PC" and the GlucoManager<sup>™</sup> software runs automatically.



For more information, please read GlucoManager<sup>™</sup> Data Management Software (GDMS) User's Manual.

- 1. Make sure you had exited from GlucoManager<sup>™</sup> software, otherwise DO NOT plug out meter.
- 2. Do not insert strip while meter connect on PC.
- 3. The suggested monitor for the software is 1024 x 768 dpi.

### Limitation

The test strips are used for fresh capillary whole blood samples.

- 1. DO NOT use neonate blood sample.
- 2. Extreme humidity may affect the results. A relative humidity greater than 90% may cause incorrect results.
- 3. The system should be used at a temperature between 10°C 40°C (50°F 104°F). Outside this range, the system may get incorrect results.
- 4. DO NOT reuse the test strips. The test strips are for single use only.
- 5. Red blood cell count (Hematocrit); Hematocrit levels between 30% and 55% will not significantly affect the results, Hematocrit levels below 30% may cause higher results, Hematocrit levels above 55% may cause lower results. If you do not know your hematocrit level, please consult with your healthcare professional.
- 6. Altitude up to 3048 meters above sea level has no effect on readings.

Healthcare Professionals - Please note these additional Limitations

- 7. Patients undergoing oxygen therapy may have inaccurate results.
- 8. If the patient has the following conditions, the result may fail:
  - Severe dehydration
  - Severe hypotension (low blood pressure)
  - Shock
  - A state of hypoglycemic-hyperosmolar state (with or without ketosis)
- Lipemic samples: Cholesterol level up to 500 mg/dL and triglycerides up to 3,000 mg/dL do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with EasyPlus mini MasterDriver<sup>™</sup> Glucose Meter.
- 10. Critically ill patients should not be tested with home-use blood glucose meters.
- 11. Interfering Substances depend on the concentration. The below substances up to the test concentration will not affect the test results.

Interfering , Substance	Test Concentration mg/dL	Bias at 50±5 mg/dL	% Bias at 250±5 mg/dL	% Bias at 500±5 mg/dL
Acetaminophen	8	10.2	6.5	3.8
Ascorbic Acid	2.5	11.8	-6.8	5.3
Dopamine	2	4.3	12.9	6.3
Gentisic Acid	6	7.8	2.8	-4.3
L-Dopa	2	3.8	-1.2	-1.8
Methyldopa	2	5.2	-2.3	4.1
Uric Acid	13	7.6	3.9	3.8

## **Device Information**

EasyPlus mini MasterDriver<sup>™</sup> SMBG System, EasyPlus mini MasterDriver<sup>™</sup> Blood Glucose Test Strips, EasyPlus mini MasterDriver<sup>™</sup> Blood Glucose Meter, EasyPlus mini MasterDriver<sup>™</sup> Normal Control Solution, EasyPlus mini MasterDriver<sup>™</sup> High Control Solution.



Manufacturer: EPS BIO TECHNOLOGY CORP. No.8, R&D RD. III, Hsinchu Science Park, Hsinchu, Taiwan 30077

## Warranty

EPS warrants the original purchaser for a period of 3 years from the date of purchase. This means during the warranty period if your Self-Monitoring Blood Glucose System does not work for any reason (other than obvious abuse), EPS will replace it with a new system or an equivalent product free of charge.

#### Lancing Device

Meets the requirements of MDD 93/42/EEC

## Manufacturer:

STERILANCE MEDICAL (SUZHOU) INC.

No. 32 Xinlian RD. Pingjiang Suzhou P.R. China 215031 TEL : 0086 (512) 67217661 FAX : 0086 (512) 67217663 E-mail : guopings@xinda-medical.com

#### Lancet

Meets the requirements of MDD 93/42/EEC

## Manufacturer: SAE HAN MEDICAL CORP.

# 700-113 PUB GOT-DONG, IL SAN-GU, GOYANG-CITY, KYUNGGI-DO, KOREA TEL : 82-31-923-4330 FAX : 82-31-923-4331 E-mail : saehan@saehanmed.com



Obelis s.a.

34, Av. de Tervuren, bte 44, B-1040 Brussels, Belgium

TEL: (32) 2.732.59 54 FAX: (32) 2.732.60 03

E-mail: mail@obelis.net

# **CE**0537

P/N. 718039000\_0373\_02