DCD 2IN1

Self-Monitoring Blood Glucose System

User's Manual

(Model Name: EasyPlus mini 2IN1)

Dear DCD 2IN1 SMBG System Owner,

Thank you for using the **DCD 2IN1** Self-Monitoring Blood Glucose (SMBG) System. We designed this system to be dependable, easy-to-use, compact, lightweight and portable 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 **DCD 2IN1** Self-Monitoring Blood Glucose System.

Thanks again for choosing the **DCD 2IN1** SMBG System.

Intended Use

The **DCD 2IN1 Self Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professional, as an aid to monitor the effectiveness of diabetes control.

Although the DCD 2IN1 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 **DCD 2IN1** Blood Glucose meter and accessories work together to measure the amount of glucose in your blood. The system includes:

- **Blood Glucose Meter**
- **Carrying Case**
- **Test Strip x 10 ct.**
- **Normal Control Solution**
- **Control Solution Instructions**
- **Lancet x 5 ct.**
- **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 the meter 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. You can also visit www.epsbio.com for diabetes management tools and product demonstrations.

Please complete your warranty card and mail it, so you receive the best customer service possible and product update news.

Important Information About Your New DCD 2IN1

- The **DCD 2IN1** blood glucose meter is designed and approved for testing fresh capillary blood from fingertip. The meter is for outside the body (in vitro) use. It should not be used to diagnose diabetes.
- Only use **DCD 2IN1** blood glucose meter with the **DCD 2IN1** 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, a bathroom or a refrigerator.
- Keep the meter and test strips away from children and pets.
- You should not test critically ill patients with home-use blood glucose meters.
- Elevated levels of acetaminophen, uric acid, gentisica 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.
- 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 10,000 feet above sea level has no effect on readings.

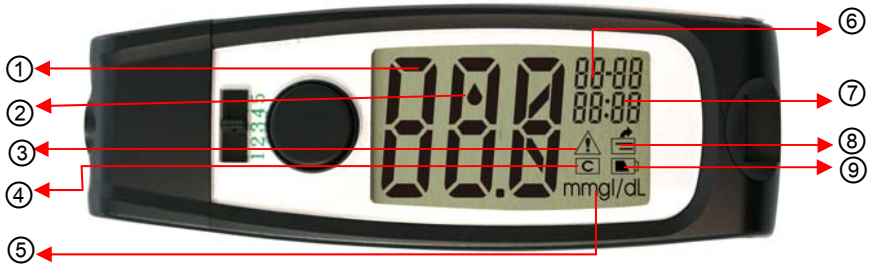
Health-Related Information

- If you are very dehydrated, urinating frequently, low blood pressure, 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 talk to your doctor.
- Please read your test strip instructions carefully for additional health-related information.

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

	Consult instructions for use		Caution
	Batch code		Do not reuse
	In vitro diagnostic medical device		3V (CR2032) x 1 battery only
	Use by		Temperature limitation
	Manufacturer		Catalogue number
	Serial number		Control
	Sufficient for		Authorised representative in the European Community
	This product meets the requirements of Directive 98/79/EC in vitro diagnostic medical devices		



888			C	mg/dL mmol/L
①Result amount	②Blood apply	③ Hypo	④Control Solution	⑤Unit
88-88	88:88			
⑥Date	⑦Time	⑨Memory	⑩Battery	

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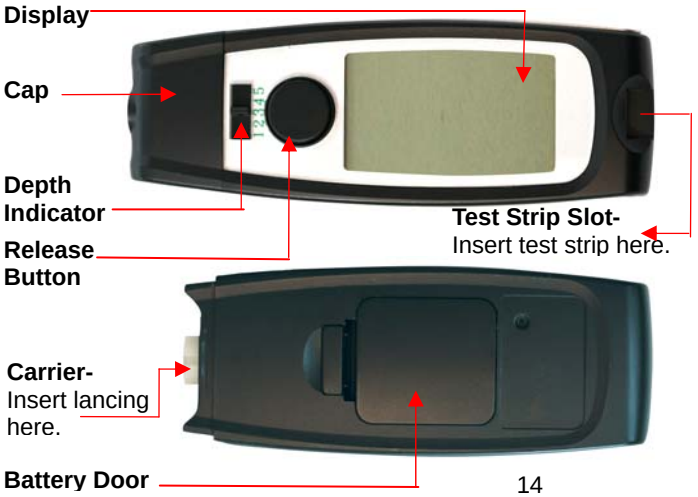
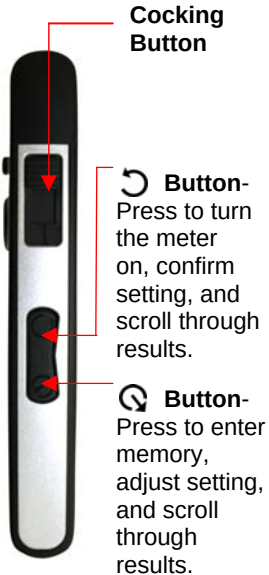
Chapter 1: Understanding Your Meter

DCD 2IN1 Blood Glucose Meter





Installing Batteries

1. Flip open the battery door by pushing the tab in the direction of the arrow and pulling the door up.

2. Insert a battery.

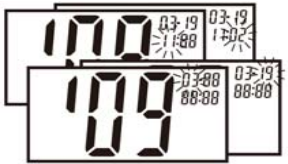
3. Put the battery door back in place and snap it closed. The meter beeps and turns on automatically.

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. If your meter does not turn on automatically, press ↺ for 3 seconds to turn on the meter.

2. The last 2-digits of the year flash at the center of the display. Press ⟳ to adjust the year and press ↺ to confirm the setting.



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 meter beeps.

Using DCD 2IN1 Blood Glucose Test Strip

- Use only with **DCD 2IN1** 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.
- Close the bottle tightly right away, after you take a test strip out. This keeps the test strip dry.
- Use the test strip within three minutes after you take it out of the bottle.
- The strip is for single use only. Do not reuse it.
- Record the date you open the test strip bottle. Be sure to check the “Expiration date” on the test strip bottle. The test strip is good for three months from the date the bottle is opened or until the expiration date on the bottle, whichever comes first.
- Store the test strip bottle and your meter in a cool dry place.
- Store the test strips between 2°C - 30°C (35.6°F- 86°F). Do not freeze.
- Do not apply blood or control solution to the test strip until 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 **DCD 2IN1** 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 **DCD 2IN1** 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 **DCD 2IN1** test strips.
- Write the date you opened the bottle on the bottle label. The control solution is 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.
- The 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 the bottle of control solution at room temperature, between 2°C- 30°C (35.6˚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 shows itself.

3. Press the , the icon C shows and the meter is ready to run a Control Solution Test.
Or press to cancel the Control Solution Test Mode.

4. Place the meter on a flat surface, like a table.

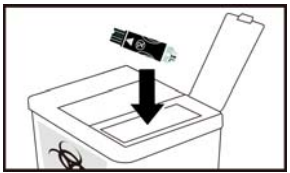
5. Remove the control solution bottle cap and wipe the tip of the bottle with a tissue.

6. Squeeze the bottle until a tiny drop forms at the tip of the bottle.

7. Touch the drop to the blood collection area at the tip of the test strip. When you hear beeps, you have enough control solution in the test strip.

8. The meter starts to count down from 5 seconds, the display shows “Ok”, and then shows the test result.

9. Do not remove the test strip yet. Check if the reading falls within the range printed on the test strip bottle.



10. 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 this range. 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 your test results.

Troubleshooting Checks	***Action***
✓ Was the test strip exposed to open air for a long period of time?	Repeat the control test with properly stored strips.
✓ Was the test strip bottle capped tightly?	This will humidify strips inside. Replace the test strips.
✓ Was the meter functioning well?	You can use control solution to verify the meter's functions. (Chapter 2)
✓ Is the control solution expired or contaminated?	Replace with new control solution to check the performance of SMBG system.
✓ Were test strips and control solutions stored in cool, dry places?	Repeat the control test with properly stored strips or control solutions.
✓ Did you follow the testing steps properly?	Read Chapter 2 "Control Solution Testing" and test again. if you still have problems, please contact your healthcare professional.

Chapter 3: Testing Your Blood Glucose

Using The Built-in Lancing Device

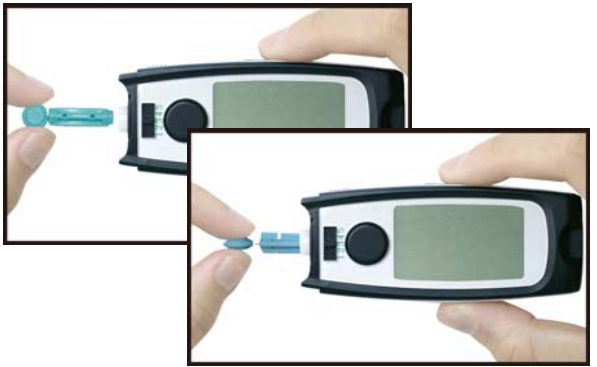
- The best depth setting is the lowest number that draws enough blood for a test. Try different settings to find the one that's right for you.
- Please do not share your lancing device with anyone. And always use a new, sterile lancet. Lancets are for one time use only.

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. The users may discuss methods for disposing of used test strips and lancets with their doctor.

Inserting A Lancet Into The Built-in Lancing Device

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

1. Unscrew the Cap.



2. Insert a new disposable lancet firmly into the carrier and then twist off the protective cover.

3. Recap the front cap.

4. Select the desired penetration depth.

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

5. Pull on the cocking button 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.

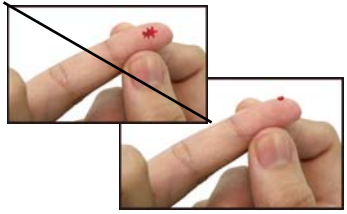
Running A Blood Glucose Test With Blood From Your Fingertip

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

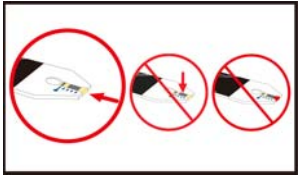
2. Put a test strip into the meter in the direction of the arrow. The meter beeps and turns on automatically.

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 release 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 blood 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.

Discarding Used Lancets

1. Unscrew and remove the cap. Without touching the used lancet, stick the lancet tip into its protective cover. Grip the lancet carrier firmly and pull the lancet safely out.

2. Discard the used disposable lancet into an appropriate sharps or biohazard container.

Understanding Your Test Results

The **DCD 2IN1** Blood Glucose test strips are plasma referenced and calibrated for easier comparison to lab results. The normal fasting blood glucose range for an adult without diabetes is 70-110 mg/dL. Two hours after meals, the blood glucose range for an adult without diabetes is less than 120 mg/dL. For people with diabetes: please consult your doctor for the blood glucose range appropriate for you.

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 doctor immediately.

1. **Extremely high humidity may affect the test results. A relative humidity greater than 90% may cause inaccurate results.**
2. **A red blood cell count (Hematocrit) that is either very high (above 55%) or very low (below 30%) may not provide accurate 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

What It Means:
The test result is higher than reference normal range. (70-110mg/dL)

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 and you have symptoms of high blood glucose, contact your healthcare professional immediately.
- If the result does not match how you feel, follow the steps under "Unusual Test Results."

Below 60 mg/dL

What It Means:
The test result is lower than reference normal range. (70-110mg/dL)

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 and you have symptoms of low blood glucose, contact your healthcare professional immediately.
- 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 DCD 2IN1 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.

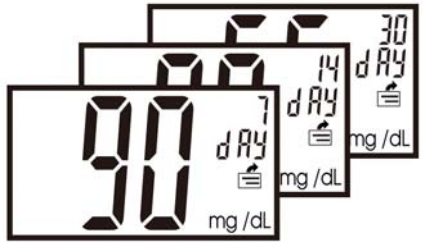
Chapter 4: Meter Memory, Setup

Memory, Storing Test Results

Your meter stores a maximum of 360 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 360 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



1. Press ↺ to turn the meter on.
2. Press ⟳ to view averages for 7/14/30 days.

3. Continue to press ⟳ to view the test result from latest to oldest.

4. To delete a test result, press for 3 seconds. When display shows "dEL", press to confirm the deletion.

Or press 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.

6. Press for 3 seconds to turn off the meter, or the meter turns off automatically in 120 seconds.

Chapter 5: Maintenance and Troubleshooting

Installing 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. Install 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 installed. 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 x 1 battery are 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 **DCD 2IN1** 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.

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 “ ↺ ” 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.

Cleaning Your Lancing Device

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

Screen Messages And Troubleshooting

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

	What it means ?	***What to do ?***
	System err.	Please replace the batteries first. If Err appears again, please contact your healthcare professional immediately.
	Humidified or used strip.	Please replace with a new strip.

	What it means ?	*What to do ?*
	Memory err.	Please replace the batteries first. If Err appears again, please contact your healthcare professional immediately.
	Low power.	Please replace with a new battery.

	What it means ?	*What to do ?*
	You may have a very high blood glucose level(severe hypoglycemia), over 600 mg/dL.	Please test again and if you get the same result, please contact your healthcare professional immediately.
	You may have a very low blood glucose level(severe hypoglycemia), lower than 20 mg/dL.	Please test again and if you get the same result, please contact your healthcare professional immediately.

	What it means ?	*What to do ?*
	Temperature is too high, outside the required range of 10°C - 40°C (50°F - 104°F). This alerts users that an incorrect result may occur if the test continues.	Relocate the meter to a location with temperature between 10°C - 40°C (50°F - 104°F).
	Temperature is too low, outside the required range of 10°C - 40°C (50°F - 104°F). This alerts users that an incorrect result may occur if the test continues.	Relocate the meter to a location with temperature between 10°C - 40°C (50°F - 104°F).

Chapter 6: Technical Information

Memory capacity	360 results
Test specimen	Capillary whole blood
Sample volume	0.6ul
Testing time	5 seconds
HCT range	30~55%
Measuring range	20~630 mg/dL
Operating range	10°C - 40°C (50°F - 104°F), R.H. ≦90%
AST	N/A
LCD dimension	37.5 x 21.5 mm
Meter dimension	94 x 34 x 14 mm
Weight	32 g
Battery life	Over 1,000 times
Power supply	CR2032 Lithium battery x 1
Auto shut-off	2 minutes
Data transferring	USB card reader

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. Hematocrit: The hematocrits between 30% and 55% will not significantly affect the results. Hematocrit below 30% may cause higher results. Hematocrit above 55% may cause lower results. If you do not know your hematocrit level, please consult with your healthcare professional.
6. Altitude up to 10000 feet 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)
9. 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 **DCD 2IN1** Blood 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

DCD 2IN1 SMBG System,
DCD 2IN1 Blood Glucose Test Strips,
DCD 2IN1 Blood Glucose Meter,
DCD 2IN1 Normal Control Solution,
DCD 2IN1 High Control Solution.

CE **0537**

Reference:

＊ American Diabetes Association: Standards of Medical Care for Patients with Diabetes Mellitus, Diabetes Care, 25(2002), p.S37

Manufacturer:
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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.

Lancet
Meets the requirements of MDD 93/42/EEC

Manufacturer:
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700-113 PUB GOT-DONG, IL SAN-GU, GOYANG-CITY, KYUNGGI-DO, KOREA
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