

SuperCheck Plus

Blood Glucose Monitoring System



No Coding
Required

Model: 5228B

USER GUIDE

Explanation of symbols:

	Do not re-use
	Use-by date
	Batch code
	<i>In vitro</i> diagnostic medical device.
	Temperature limit
	Caution (refer to accompanying documents). Please refer to safety-related notes in the manual accompanying this instrument.
	Consult instructions for use.
	Keep away from sunlight.
	Authorised representative in the european community.
	Manufacturer

1. Contents

Section Topic	Page
1. Contents	1
2. Introduction	2-3
3. Appearance and Key Functions of the meter	4
4. Alternate Site Testing	5-8
5. Safety Information	9
6. Quick Testing Instructions	10

Preparing for Testing

7. Installing the Battery	11
8. Settings (Date/Time/Alarm/Measuring Unit/ Memory Deletion)	12-16
9. Running a Control Solution Test	17-18

Blood Testing

10. Running a Blood Glucose Test	19-21
11. Recalling the Memory and Viewing the Average	22-23
12. Expected Values	24
13. Transmitting Results	24

Maintenance

14. Maintenance of Your System	25
15. Troubleshooting	26-27
16. Customer Service	28
17. Limitations	29

Important Additional Information

18. Specifications	30
19. Ordering Supplies	31
20. Warranty Information	31

NOTE: For information about the name of the manufacturer of the lancing device and the lancets, please refer to the package inserts that came with your starter kits.

2. Introduction to the System

Intended Use / Indications for Use

The **SuperCheck Plus** Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the forearm and venous whole blood. It is intended for self-testing by people with diabetes mellitus at home and healthcare professionals as an aid in monitoring the effectiveness of a diabetes control program.

The **SuperCheck Plus** Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, nor for use with neonates.

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

Contents of the System

This User Guide has been prepared to describe the proper use of the **SuperCheck Plus** Blood Glucose Monitoring System.

Please read this User Guide and the package insert that comes with the **SuperCheck Plus** Glucose Test Strips before testing. The system is available either as a meter alone or as a kit. If you have a meter only, you can purchase the system supplies from your system provider.

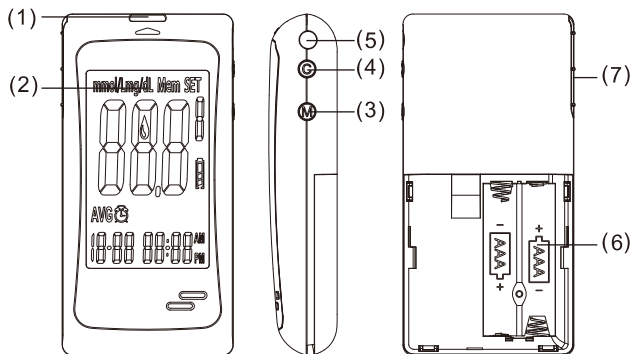
The starter kit of **SuperCheck Plus** Blood Glucose Monitoring System includes the following items:

1. **SuperCheck Plus** Glucose Meter with 2 AAA batteries
2. User Guide
3. Log Book
4. Carrying Case
5. **SuperCheck Plus** Glucose Test Strips
6. **SuperCheck Plus** Control Solution (Medium)
7. Sterile Lancets
8. Lancing Device
9. Package Inserts for Test Strips, Control Solution, and Lancets/Lancing Device

"A single level control solution (Medium) is provided in the "Starter Kit," and no control solution is included in the "Meter Kit". You may purchase any control solutions that you need from your system provider."

The **SuperCheck Plus** Glucose Meter uses **SuperCheck Plus** Glucose Test Strips. Neither the meter nor the test strips will work when used with any other brand of glucose products.

3. Appearance and Key functions of the meter



1. Test strip slot - When the strip is inserted into the slot, the meter will automatically turn on.
2. LCD Display - Guide you through the test using symbols and simple messages.
3. M Key - Power ON/OFF, also for memory recalling mode, please refer to manual for detailed function description.
4. C Key - Setting mode, please refer to manual for detailed function description.
5. RS232 port - Cable connection and data transmitting. The built-in Bluetooth also supports the data transmitting.
6. Battery Compartment - Where batteries are located.
7. Ejector - Remove used strip.

*If your meter has the backlight feature, it will be on in every operation to increase the readability in operation, hence help the user to operate the meter more smoothly.

The principle of the method

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 and based on the current measured.

4. Alternate Site Testing (AST)

What is AST?

AST is the sampling from anatomical sites (parts of the body) other than the fingertip (i.e. forearm) to check the blood glucose levels. This system allows you to test on the forearm with the equivalent results to fingertip testing.

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

What is the advantage ?

It is more painful feeling when taking blood sample from fingertips because fingertips have many nerve endings. Other body sites do not have as many nerve endings, so you will not feel as much pain as at the fingertip.

When to use AST ?

Medication, stress, illness, food and exercise can affect blood glucose levels. Capillary whole blood at the fingertip can reflect test changes faster than capillary blood at other sites of body. If you test your blood glucose level during or immediately after a meal, physical exercise or stressful events, take the blood sample from your fingertip instead of from other sites.

Use AST only:

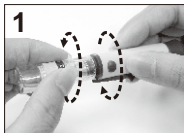
1. 2 hours or more after taking insulin;
2. 2 hours or more after a meal;
3. 2 hours or more after exercise.

Do not use AST if you are pregnant, or if you are aware that your glucose level is not as stable as usual, or if you think you have hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar).

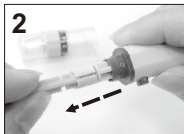
Do not use AST if you think your blood glucose is low and if your AST results do not match the way you feel.

Testing Procedure for AST

1. Please unscrew the lancing device by turning the end cap counter clockwise. A clear cap will come with the package of a meter kit or a lancing device. The clear cap on the lancing device will make it easy for you to get a drop of blood for AST.



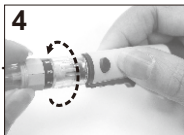
2. Insert a new lancet firmly into the lancet holder.



3. Twist off the protective top of the lancet.



4. Close the end cap of the lancing device and grasp the lancing device as shown. Slide into locking position. If necessary, please set the lancing device for a deeper puncture.



5. Select a soft, fleshy area on your forearm that is clean and dry, away from bone and free of visible veins and hair.



6. Massage the selected area gently to increase blood flow to the puncture site. Clean the test location with an alcohol wipe or with soap and water.



7. Open the test strip vial. Take one new test strip out of the vial and quickly recap the vial to keep air out.



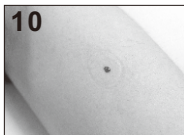
8. Insert the test strip into the meter while the meter is off. The meter will turn on automatically. A blinking blood icon will be displayed on the screen. If no action is taken in 2 minutes, the meter will turn off automatically.



9. Press and hold the loaded lancing device against the forearm for a few seconds, then press and release the button.



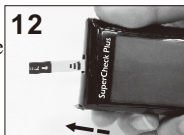
10. Wait for a few seconds until the blood drop forms. Make sure you have sufficient blood to fill the small window of the test strip. For individuals who experience difficulty in getting sufficient blood for a test, it may be helpful to rub the puncture site a little longer before using the lancing device.



11. Apply your blood to the front edge (the tip) of the test strip, and the meter will start counting down for 5 seconds then display the test results on the screen.



12. Remove the used strip by hand or by pushing the ejector button. The meter will turn off automatically.



5. Safety Information

Please use this device only for the intended use described in this user guide.

Before using this system to test your blood glucose please read instructions thoroughly and practice the test when you first use this system. Do a quality check on the system following the instructions and consult with your healthcare professionals for 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.

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

Please be cautious when removing the lancet. Take the lancet out carefully. Always place the protective cap back on the exposed tip or (if using a twist lancet) place the cap on a hard surface and push the exposed tip into the protective cap and discard properly.

Never try to disassemble the meter in any circumstance. If your meter is not working properly, or if you need the Technical Support, please contact your local distributor for help.

6. Quick Testing Instructions

(For detailed instructions start on page 17 for Control Solutions and page 19 for Blood Testing.)

1. Insert a new test strip into the meter while the meter is off. The meter will turn on automatically. A blinking blood icon will be displayed on the screen.



2. Lance the finger and let a blood drop form.



3. Apply the blood drop to the front edge of the test strip when the blood drop icon is still blinking on the meter. Wait for 5 seconds, and the meter will display the test result.



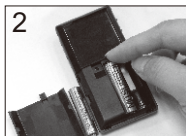
4. Remove the used strips by hand or by pushing the ejector and the meter will power off.



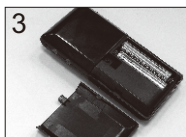
7. Installing the battery



1. Turn off the meter by pressing “M” button and hold for 2 seconds before replacing the batteries. Slide down the battery cover on the back of the meter by pushing the cover in the direction of the arrow and put the cover aside.



2. Remove the two used batteries.



3. Insert 2 new batteries with correct + / - direction.
(Battery : AAA 1.5V 2 Alkaline 24A LR03)



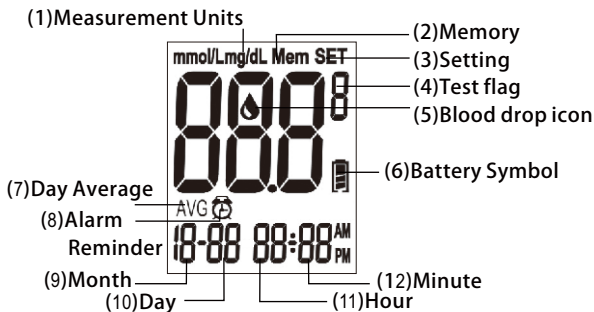
4. Put the battery cover back in place by pushing the cover in the opposite direction of the arrow to close the cover into position.

Note:

1. It is suggested that batteries need to be replaced when the battery icon appears empty. If you keep using the meter, the battery icon will start flashing and an error message E_3 will appear on the screen.
2. Note that replacing the battery will not reset the stored testing results.
3. You need to reset the time and date after the batteries are replaced.
4. If there is any unexpected symbol on the display, please follow the above procedure to replace the batteries again.
5. Please dispose of batteries according to your local ordinances.

8. Settings (Date / Time / Alarm / Measuring Unit / Memory Deletion)

The LCD screen will show as below:



1. Appears with the test result either in mg/dL or in mmol/L.
2. Appears when you recall the memory.
3. Appears when you are in setting mode.
4. Appears for control solution test flag (c).
5. Indicates the meter is ready to take the blood sample when it flashes.
6. Indicates the battery status.
7. Indicates current displayed result is an average.
8. Appears when alarm is on.
9. Month
10. Day
11. Hour
12. Minute

1. Set the Year - With the meter off, by pressing the M key and hold for 2 seconds, you will enter the setting modes, press C key to adjust the year until the desired year is displayed and then press the M key to confirm the year setting. When pressing the C key, the year will be adjusted in the range of 2009 to 2029. After the year setting is confirmed, you will see the month segment flashing on the screen.



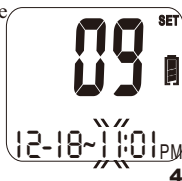
2. Set the Month - Press C key to adjust the month until the desired month is displayed and then press the M key to confirm the month setting. You will then see the day segment is flashing on the screen.



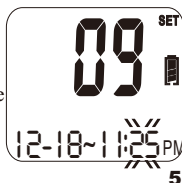
3. Set the Day - Press C key to adjust the day until the desired day appears and then press the M key to confirm the day setting. You will then see the hour segment is flashing on the LCD screen.



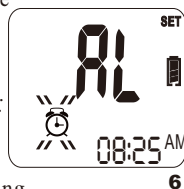
4. Set the Hour - Press C key to adjust the hour until the desired hour appears on the screen and then press the M key to confirm the setting. You will then see the minute segment is flashing on the screen.



5. Set the Minute - Press C key to adjust the minute until the desired minute appears on the screen and then press the M key to confirm the setting. You will then see an “AL” displayed on the screen center.



6. Set the Alarm Reminder - Press C key to toggle between the alarm reminder setting and no-setting mode. If you see the LCD display a small flashing icon of alarm clock in the lower left corner with a time segment display, it means that you are in the alarm setting mode. If you see only AL without the icon of the small alarm clock, it means that you are not in the alarm setting mode. Press M key to confirm the alarm setting mode. If you select the alarm setting mode, alarm clock icon will stop flashing and the hour of the time segment will start flashing. Press C key until the desired alarm hour appears and then press M key to confirm the hour setting. Then the minute segment will start flashing. Press C key until the desired minute appears on the screen and then press M key to confirm the minute setting. You will see the measuring unit flashing on the upper left corner of the LCD display.



7. Set the measurement unit - Press C key to toggle between mg/dL and mmol/L measurement units. Press M key to confirm the setting. You will see a “dEL” displayed in the center of the screen. The unit of measurement -mmol/L is the standard unit of measurement in the Europe. If the meter is to be sold in the Europe, the unit of measurement will be set to mmol/L by default.



7

8. Delete Memory - Press C key to toggle between a flashing “dEL” for memory deletion and a non-flashing “dEL”. If you want to delete all memory, press M key while the “dEL” is flashing. If you do not want to delete all memory, press M key when the “dEL” is not flashing.



8

Note: Your meter can show results either in “mg/dL” or “mmol/L” units. It is very important to use the correct unit of measurement to properly manage your diabetes. If you live in the Europe, you should use mmol/L; your results will always have a decimal point. The unit of measurement will be set to mmol/L by default. If you do not see a decimal point in your test results, it indicates the measuring unit is in mg/dL.

Note:

1. When you change the date and time backward, you will not change the test results in the meter memory.
2. You need to move through the year, month, day, hour, minutes, alarm, measurement unit, and dEL to save the meter settings and turn off the meter.
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.

9. Running a Control Solution Test

IMPORTANT:

Always make sure you press C key for Control Solution test, otherwise the control solution test result will be stored in the memory, and affect your $\bar{x}$ AVG $\bar{x}$ results.

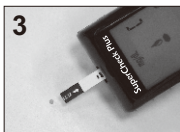
1. Insert a test strip into the meter while the meter is off. The meter will turn on automatically. A blinking blood icon will be displayed on the screen.



2. Press the C key, and the meter will display a letter “C” on the upper right corner of screen, indicating the control test mode. The test result will not be stored in the memory.



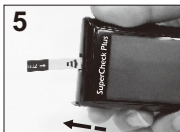
3. Squeeze a small amount of Control Solution on a flat surface and apply to the front edge of the test strip.



4. Wait for 5 seconds, and the meter will display the result.



5. Remove the used strips by hand or by pushing the ejector and the meter will power off.



IMPORTANT!!!

1. You must press the C key to distinguish the control solution test from the blood glucose test. Do not perform the blood test in Control Solution mode. (If you perform the blood test in Control Solution mode, the test result will not be stored in the memory.)
2. Use only **SuperCheck Plus** Control Solution with **SuperCheck Plus** Glucose Meter.
3. **SuperCheck Plus** Control Solutions are used to check that the meter and the test strips are working together as a system and that you are performing the test correctly.
4. **SuperCheck Plus** Control Solution contains a known amount of glucose that reacts with test strips. The Medium and High level Control Solution are intended to check the monitoring system in different measurement ranges.
5. Shake the vial, discard the first drop of control solution, and wipe off the dispenser tip to ensure a good sample and an accurate result.
6. Use only for 3 months after first opening. Record the open date on the Control Solution vial. Discard after 3 months.
7. Compare your Control Solution test results with the expected range printed on the test strip vial 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) You may not be doing the test correctly; repeat the test, by shaking the control solution vial well and carefully following instructions. Please make sure the test is done within the temperature range.
 - (2) The Control Solution is expired or contaminated.
 - (3) The test strips are damaged or outdated.
 - (4) You may have applied the Control Solution before the blood drop appears on the screen. This will cause incorrect glucose measurement.
 - (5) Meter malfunction.

10. Running a Blood Glucose Test

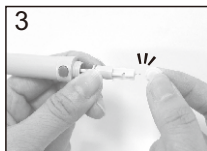
1. Please unscrew the lancing device by turning the end cap counter clockwise.



2. Insert a new lancet firmly into the lancet holder.



3. Twist off the protective tip of the lancet.



4. Close the end cap of the lancing device as shown. Slide into locking position.



5. Wash your hands in warm, soapy water. Be sure to rinse and dry well.



6. Open the test strip vial. Take one new test strip out of the vial and recap the vial quickly and firmly.



7. Insert the test strip into the meter while the meter is off. The meter will turn on automatically. A blinking blood icon will be displayed on the screen. If no action is taken in 2 minutes, the meter will turn off automatically.



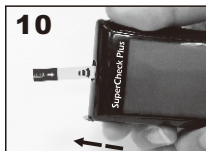
8. Use the adjustable lancing device or the disposable lancet to take a blood sample from the fingertip and let it form a small round blood drop. To avoid body fluid contamination, it is recommended that you do not use the first blood drop for glucose testing.



9. Apply a small blood drop to the front edge of the test strip, and the blood should be pulled into the confirmation window before the meter begins to count down. Do not push your finger against the test strip or try to apply a smeared blood sample.



10. The meter will start counting down for 5 seconds and your test result will be displayed on the screen. Remove the used test strip by hand or by pushing the ejector button. The meter will turn off and the test result is stored automatically.



Important:

1. Never reuse a test strip or a lancet. An "E_5" error message will be displayed in the center of screen if a used strip is inserted into the meter.
2. The used strip and lancet will contaminate, please discard them according to your local ordinances.
3. The used meter should be treated as contaminated that may carry a risk of infection during measurement. The battery in this used meter should be removed and the meter should be disposed in accordance with local ordinances.

11. Recalling the Memory and Viewing the Average

A. Using the Meter Memory

The test results for blood sample will be stored in the memory automatically. The meter can store up to 500 of the most recent test results. You can also view the average of test results for various periods of 7, 14, 28, 60 and 90 days. The control solution test results will not be stored in the memory.

(Note: Please make sure that you press C key when you run a Control Solution test, so that the control test result will not be added to the memory.)

B. Recalling the Test Results from the Meter Memory

1. With meter off, press M key to turn on the meter. After a brief full screen display, the meter will display the total number of test data stored in memory. Then the screen will display “001” as the sequential number of the most recent test result in memory. The memorized test data will be displayed next. If there is no memorized result in the meter, “---” is displayed. The meter will turn off after 60 seconds if no action is taken.
2. The screen will display each of the memorized test data in sequence. Press M and C key to review your test results in the memory forwards and backwards.
3. To turn off the meter, press M key for 2 seconds, or the meter will turn off automatically after 60 seconds if no activity.

C. Viewing the Average (AVG) of Test Data in Memory

1. To display the average (AVG) test result, please turn meter off. Press C and M keys at the same time and hold for about 2 seconds, wait for AVG displayed on the screen, then release the two buttons. The meter will be in the average mode with “AVG” font displayed.
2. When the “AVG” is flashing at the lower left corner of the screen, the number 7 will be displayed under AVG and the average of the last 7 days test results will be displayed in the center of the screen. The number of tests done in the last 7 days will be also displayed at the lower right corner of the screen. If you want to see the average of 14, 28, 60 and 90 days, keep pressing the M key to move the LCD display forward from 7 day average to 90 day average. The average display will move from 90 days backward to 7 days if you continue to press C key.
3. Press the M key and hold for only 2 seconds to exit the recall mode and turn off the meter, or the meter will automatically power off after 60 seconds.
4. When “---” is displayed, showing that there are no test results in the memory.

Calculations:

The 7 days average is the average of the last 7 day test results.
The 14 days average is the average of last 14 day test results.
The 28 days average is the average of last 28 day test results.
The 60 days average is the average of last 60 day test results.
The 90 days average is the average of last 90 day test results.

Note:

1. HI/LO results are not stored in the memory.
2. Do not insert the strip into the meter when you want to recall the test results.

12.Expected Values Reference¹

Blood glucose levels normally will vary from time to time depending on food intake, medication dosages, health, stress or exercise. Consult your physician or healthcare professional for the target glucose value appropriate for you.

Expected plasma blood glucose values for normal, nondiabetic adults are as follows.

Before eating	< 5.6 mmol/L (100mg/dL)
Two hours after meals	< 7.8 mmol/L (140mg/dL)

SuperCheck Plus meter gives plasma equivalent results.

13. Transmitting Results

Note:

SuperCheck Plus Glucose Meter allows you to transfer the test results stored in its memory to your personal computer. However, you will need to order software and a Data Download Cable separately from your distributor."

The software and its data download procedure will come as a CD in the download cable box. You can also check with your distributor for the software download option. The meter still keeps the results in the memory after transmitting.

1. With the meter off, hold the M and C keys down at the same time for 5 seconds until "PC" is displayed.
2. Press the C key to start transmitting. The meter will display a flashing "PC" during the transmission process. When the "PC" on the screen stops flashing, it indicates the transmission is completed. The meter will be power off if no action is taken in 60 seconds or M key is pressed for 2 seconds.
3. Built-in Bluetooth Function
To enable the Bluetooth data transmitting function, press the C button for 2 seconds when the meter is power off. You'll see "BLE" on the screen. Then you may work with your APP to choose either single data transmitting or total data transmitting.

If there has no response with 90 seconds, the Bluetooth function will be turned off automatically. For more information, please refer your APP service.

Note:

- 1.The meter will not be able to upload data when Bluetooth function is not turned on.
- 2.To prevent the accuracy or the interference, the Bluetooth function will not be able to use during the blood testing.
- 3.The meter can work with the below APP services:
-Health2sync
-Dr. Cloud

14. Maintenance of your system

Please, treat this meter with proper care, and keep it in good condition.

- 1.Store your meter in its case, in a clean dry place at 35.6~86°F(2~30°C).
- 2.Always clean your meter after use. Wipe and clean surface of the meter with a soft cloth that has been slightly dampened with alcohol.
- 3.Please handle with care and do not drop the meter.
- 4.If this meter is used by healthcare professional infection control policies should be strictly followed.
- 5.The meter has a shelf-life of 2 years.

We suggest you should periodically compare the test system to another test system which is well maintained and monitored by a healthcare provider .

15.Troubleshooting :

Following is a summary of all Error Messages. These messages help to 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 under Solution.

Error messages:

E_1: The temperature is too low.

E_2: The temperature is too high.

E_3: Battery Low.

E_4: Memory damaged.

E_5: The strip is wet or used.

E_6: Error in meter or strip.

E_7: The blood sample is not sufficient.

HI :The glucose level is too high.

LO:The glucose level is too low.

Problem	Possible Cause	Solution
(1) The meter displays an E_1 error message.	The meter is operating in an ambient temperature below 10 °C or 50°F which is the lowest range of operating temperature.	Repeat the test after the meter and strip are placed in a warmer environment and allow the meter to warm up for a while before retesting.
(2) The meter displays an E_2 error message.	The meter is operating in an ambient temperature above 40 °C or 104°F which is the cap of operating temperature.	Repeat the test after the meter and strip are placed in a cooler environment and allow the meter to cool down for a period before retesting.
(3) The meter displays an E_3 error message.	The battery is too low to operate the meter.	Please replace the two AAA batteries.
(4) The meter displays an E_4 error message.	The memory chip of the meter could be damaged or malfunctioning.	The meter can perform the glucose measuring without storing the test results into the meter's memory. Please write down the test results into the data logger before you call a customer service representative.
(5) The meter displays an E_5 error message.	1.If you apply the sample before blood drop icon appears on the screen. 2.The inserted test strip has been wet or used.	Please check the test strip to see if it is damaged or used. In either case, please discard the strip and repeat the test using a new strip.
(6) The meter displays an E_6 error message.	The meter is not working properly, either because of a defective meter or a defective strip.	Repeat the test with a new test strip. If E_6 continues to show up on screen, please call a customer service representative.
(7) The meter displays an E_7 error message.	The blood sample is not sufficient .	Please re-test by inserting a new test strip ensuring an adequate amount of blood comes into contact with the test strip.
(8) The meter displays HI on screen.	The test result is higher than the measuring range of 33.3 mmol/L (600 mg/dL).	Test again following the user guide for correct glucose measurement process. If you see HI again, please call your medical doctor for advice immediately.
(9) The meter displays LO on the screen.	The test result is lower than the measuring range of 1.1 mmol/L (20 mg/dL).	Test again following the user guide for correct glucose measurement process. If you see LO again, please call your medical doctor for advice immediately.

16.Customer Service

If you need assistance with your **SuperCheck Plus** Glucose Monitoring System, please contact:

Biotest Medical Corporation

No. 3-2 Chien-kuo Road, TEPZ Tantz, Taichung 427
Taiwan R.O.C.

TEL: 886-4-2532 6668

E-mail: info@mail.biotestsystems.com

For questions related to your health condition,
please call your doctor or healthcare professional.

17.Limitations

- 1.No Neonatal use
Do not use for neonatal blood glucose testing.
- 2.Hematocrit range
Hematocrit in the range of 20~60% has been shown not to affect the glucose results. If you do not know your hematocrit level, consult your healthcare professional.
- 3.Elevated Cholesterol and Triglycerides
Cholesterol levels up to 12.9 mmol/L (500 mg/dL) and Triglycerides up to 33.1 mmol/L(1000 mg/dL) has been shown not to affect glucose results.
- 4.Interference was observed for therapeutic levels of Glutathione.
- 5.Constraints
Certain substances occurring in the blood naturally, such as uric acid, or from normal therapeutic treatments (Ascorbic acid, L-Dopa, Tolazamide, and Gentisic acid) will not significantly affect results. However, higher concentrations in blood may cause incorrect results.
- 6.There are no significant interference in the presence of galactose, maltose, or fructose observed in blood glucose test.
- 7.Use only Heparin or EDTA for anticoagulation of fresh capillary or venous whole blood.
- 8.Xylose
Do not test blood glucose during or soon after xylose absorption test. Xylose in the blood can give falsely elevated results.
- 9.The test strips may be used at altitudes up to 10,744 feet (3,275 m) without an effect on test results.
- 10.Persons suffering from severe dehydration should not be tested using a capillary whole blood sample.
- 11.Test results below 3.9 mmol/L(70 mg/dL) indicate low blood glucose (hypoglycemia). Test results greater than 13.3 mmol/L (240 mg/dL) indicate high blood glucose (hyperglycemia). If you get results below 3.9 mmol/L(70 mg/dL)or above 13.3 mmol/L (240 mg/dL), repeat the test, and if the results are still below 3.9 mmol/L(70 mg/dL)or above 13.3 mmol/L(240 mg/dL), please consult your healthcare professional immediately².
- 12.Inaccurate 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.

18.Specifications

Test: Glucose

Sample: Whole Blood

Principle of the test method: Amperometric,
FAD- glucose dehydrogenase

Test sites: Fingertip, forearm

Measurement time: 5 seconds

Measurement Range: 1.1~33.3mmol/L (20~600 mg/dL).

Batteries: 2 x AAA 1.5 V Alkaline 24A LR03

Operating Condition: 10~40°C (50-104°F)
20~80% RH (non-condensing)

Storage/Transportation Condition:
2~30°C (35.6-86°F), below 80% RH

Width: 50 mm

Length: 100 mm

Thickness: 20 mm

Weight: ~72g

Memory: 500 measurement results with date and time

Auto power off after 2 minutes without action when a strip is inserted, or 60 seconds if there is no strip inserted.

Traceability of glucose monitoring system: The accuracy of **SuperCheck Plus** Blood Glucose Monitoring System was assessed by comparing blood results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, which is calibrated by YSI calibrator solution, refer to NIST SRM (standard reference material) # 917A Clinical Dextrose. The device has certified to meet the following standard: IVD 98/79/EC, EN 61010-1, EN 61010-2-101, EN 61326-1, EN 61326-2-6, ISO 15197

(P.S. Please refer to the package insert that came with your test strips, and you will also find information on how the system works and on the performance characteristic reference.)

Lancets and lancing device are medical devices under the Directive 93/42/EEC.



Manufacturer (Lancets) :
SteriLance Medical (Suzhou) Inc.
No. 68 Litanghe Road, Xiangcheng,
Suzhou 215133, China

Emergo Europe
Molenstraat 15
2513 BH The Hague 30
The Netherlands

19.Ordering Supplies

To order supplies, please contact the Manufacturer :
Biotest Medical Corporation

No.3-2, Chien-kuo Rd., TEPZ Tantz, Taichung 427,
Taiwan, R.O.C.

E-mail: info@mail.biotestsystems.com

20.Warranty Information

Your **SuperCheck Plus** Glucose Meter is warranted to be free of defects in materials and workmanship for one year from the date of the original purchase. This warranty does not cover device failure due to owner misuse or negligence, or normal wear and tear.

If you have a question about your **SuperCheck Plus** Glucose Meter or this warranty, please contact:

Biotest Medical Corporation

No.3-2, Chien-kuo Rd., TEPZ Tantz, Taichung 427,
Taiwan, R.O.C.

E-mail: info@mail.biotestsystems.com

Reference:

- 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>
<http://www.forecast.diabetes.org/diabetes-101/hypoglycemia>

Federal Communication Commission Interference Statement

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 radiate radio frequency energy and, if not installed 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 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.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT NOTE:

Radiation Exposure Statement:

The product comply with the US portable RF exposure limit set forth for an uncontrolled environment and are safe for intended operation as described in this manual. The further RF exposure reduction can be achieved if the product can be kept as far as possible from the user body or set the device to lower output power if such function is available.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Btm



BiotesT Medical Corporation

No. 3-2, Chien-kuo Road, TEPU Tantz, 427 Taichung, Taiwan ROC.

Tel : 886-4-25326668

Fax: 886-4-25326528



MEDNET GmbH

Borkstrasse 10,
48163 Münster
Germany

CE 0537