

CERA-CHEK™ 1070

User Manual

1 IMPORTANT SAFETY INSTRUCTIONS

- READ THIS BEFORE USE.
- The following basic safety precautions should always be taken:
- Close supervision is necessary when the device is used by or for children or disabled.
 - Use the device only for the intended use described in this manual.
 - Do not use with accessories which are not supplied by the manufacturer.
 - Do not let the device come into contact with hot surfaces.
 - Do not use the device where aerosols or sprays are being used.
 - Do not use the device if it is not working properly, or if it has suffered any damage.
 - Before using this product, read all instructions thoroughly.
 - Contact control solution test as directed in the manual.
 - Consult with a diabetes healthcare professional before usage.

NOTE
PLEASE KEEP THE USER'S MANUAL NEARBY THE GLUCOSE TEST METER.

2 TABLE OF CONTENTS

- | | |
|--|--|
| 1. IMPORTANT SAFETY INSTRUCTIONS | 9. TESTING YOUR BLOOD |
| 2. TABLE OF CONTENTS | 9-1. Getting a Drop of Blood |
| 3. INTRODUCTION | 9-2. Alternative Site Testing (AST) |
| 3-1. Intended Use | 10. MEMORY |
| 3-2. Principle of Measurement | 10-1. Reviewing Results from the memory |
| 4. IMPORTANT USE CONSIDERATIONS | 10-2. Clearing the memory |
| 5. CONTENTS OF THE SYSTEM | 10-3. Blood Glucose Monitoring Chart |
| 6. UNDERSTANDING THE CERA-CHEK™ 1070 BLOOD GLUCOSE MONITORING SYSTEM | 11. TRANSFERRING STORED DATA |
| 6-1. Appearance and Key Functions of the Test Meter | 12. CARING FOR YOUR TEST METER AND TEST STRIPS |
| 6-2. Explanation of the Test Meter Display | 12-1. Maintenance |
| 6-3. Test Strips Description | 12-2. Storage and Handling |
| 6-4. Code Key Description | 12-3. Error Message and Trouble-shooting |
| 7. PREPARATION BEFORE USE | 13. SPECIFICATIONS |
| 7-1. Changing the Battery | 14. PERFORMANCE CHARACTERISTICS |
| 8. BEFORE TESTING | 14-1. Accuracy |
| 8-1. Coding the Test Meter | 14-2. Precision |
| 8-2. Glucose Control Solution Test | 15. WARRANTY |
| | 16. SYMBOLS FOR PROPER USAGE |

3 INTRODUCTION

Thank you for choosing the CERA-CHEK™ 1070 Blood Glucose Monitoring System. The CERA-CHEK™ 1070 is superior in accuracy, reliability, and portability. Stored test results are easily retrievable so that you may compare them to laboratory results with your physician.

This allows for better management of your diabetes and periodic blood glucose testing. Please be sure to read this manual before using the CERA-CHEK™ 1070 Blood Glucose Monitoring System. If you have any questions, please contact your local healthcare professional.

3-1. Intended Use

The CERA-CHEK™ 1070 Blood Glucose Monitoring System is intended to help people manage their diabetes with measuring their glucose level with fresh capillary whole blood from the fingertip, the palm, the forearm, the upper arm, the thigh, the calf for self testing. It also provides professional healthcare personnel with the helpful information with measuring glucose concentration in fresh capillary whole blood as well as fresh venous blood. The CERA-CHEK™ 1070 Blood Glucose Monitoring System is intended for in vitro diagnostic use.

3-2. Principle of Measurement

The test is based on the measurement of an electrical current generated by the reaction of glucose with the reagent of the test strip.

The test meter measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

4 IMPORTANT INFORMATION

- Severe dehydration and excess water loss may cause false, low results.
- If you believe you are suffering from severe dehydration, please consult your healthcare professional immediately.
- Your blood glucose results are higher or lower than usual but you do not have any unusual symptoms, repeat the test once more for accuracy.
- If you have symptoms or continue to get results higher or lower than usual, follow the treatment advice of your healthcare professional.

- Only apply fresh whole blood sample to the absorbent hole. Applying other substances to the absorbent hole will cause inaccurate results.
- If you are experiencing symptoms that are not consistent with your blood glucose test results, and you have followed all instructions described in this manual, call your healthcare professional.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Abnormally low results may occur for patients experiencing a hypoglycemic or hyperglycemic state, with or without ketosis. Critically ill patients should not be tested with test meters.
- Please refer to the insert paper in your teststrip package for additional important information.

5 CONTENTS OF THE SYSTEM

Your test meter has been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only with the manufacturer's compatible test strip and glucose control solution with the test meter.

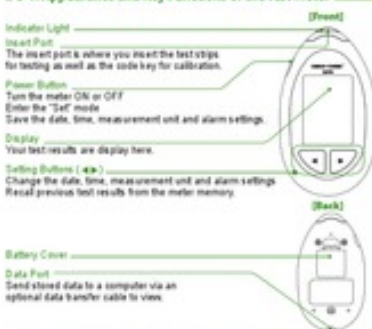
- Your system includes:
- 1 Test Meter
 - 1 Lancing Device
 - 1 3V Lithium Coin Battery
 - 1 User Manual
 - 1 Carrying Case
 - 1 Test Strips including Code Key (both optional)
 - 1 Glucose Control Solution (sold separately)
 - 1 Sterile Lancet (optional)



NOTE
CERA-CHEK™ 1070 Blood Glucose Test Strips (including code key) and Glucose Control Solution are sold separately.

6 UNDERSTANDING THE CERA-CHEK™ 1070 BLOOD GLUCOSE MONITORING SYSTEM

6-1. Appearance and Key Functions of the Test Meter



6-2. Explanation of the Test Meter Display



- Measurement Unit:** Appears with the test result either in mg/dL or in mmol/L.
- Temperature Symbol:** Appears when the temperature is abnormally high or low.
- Day Average:** Indicates a test result in average.
- Set:** Appears when in the setting mode.

6-3. Test Strip Description

Your test strip measures the concentration of glucose in whole blood. Blood is applied to the absorbent hole of the test strip and is automatically drawn into the reaction zone.

Contact Pad: Insert the end of the test strip into the test meter. Push it in firmly until it will go no further.

Drop: Hold the pad to insert or remove the test strip.

Confirmation Window: This is where you confirm if enough blood has been applied to the absorbent hole of the test strip.

Absorbent Hole: Apply a drop of blood here. The blood will automatically flow into the reaction zone.

6-4. Code Key Description

When using the CERA-CHEK™ 1070 Blood Glucose Monitoring System for the first time, or before using a new box of test strips, you will need to calibrate the test meter. There is a code key in every box of test strip. Calibration can be done by inserting the code key into the test meter. The code key will match the code number on the test strip and LCD display.

Please check the right direction to insert the code key into the test meter.

7 PREPARATION BEFORE USE

7-1. Changing the Battery

- NOTE**
- To save battery power, the test meter automatically turns off after 2 minutes of inactivity.
 - When the low battery symbol appears with other displayed data, it means the battery is running low but has enough power to run 20 tests. It is recommended that you should replace the battery as soon as possible. The battery symbol will only appear if the battery is low to perform any more blood glucose tests. The meter will not function until the battery is replaced.
 - Discard old battery as per local guidelines.



- Make sure the meter is off before removing the battery.
- Push the back on the battery cover and pull the cover forward.
- Remove the old battery and replace with a new 3V lithium battery (CR 2032). Make sure that the positive (+) side is facing up.
- Close the battery cover.

CAUTION

- Replacing the battery will not delete test meter settings unless you:
- Touch the metal wires inside the battery and with your fingers or with another metal.
 - Exceed 1 minute when replacing the battery.
 - Load the battery incorrectly.
 - Load a used or weak battery.

WARNING

- Keep away all batteries from children's reach.
- If a battery is swallowed, please consult a doctor immediately.

NOTE

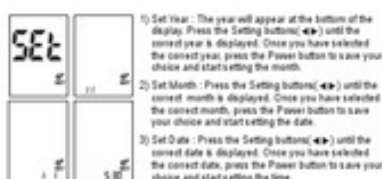
Recheck and reset the clock setting as necessary after battery replacement to ensure time is set correctly. To set the meter clock, see Test Meter Set up on the next page.

7-2. Test Meter Set-up

Set-up Mode: The meter will enter the set-up mode when replace the battery. With your meter turned on or off, press the Power button for 3 seconds to enter the set-up mode. To exit the set-up mode in any step of the setting, press the Power button for 3 seconds. The meter will save the settings and it will turn off.

IMPORTANT

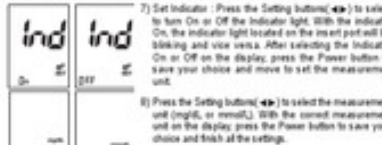
Please always set the date and time before using the CERA-CHEK™ 1070 Blood Glucose Monitoring System for the first time or after replacing the battery. Do not perform a blood glucose test until you have set-up the test meter.



NOTE
Pressing the Setting buttons (▲) continuously will pass the numbers quickly.



NOTE
Default alarm times are 6:30, 9:30, 12:30, 18:30 and 21:30. You can choose from these or set your own time.



IMPORTANT

Special caution is needed to choose the measurement unit since the test results can be different according to your choice of measurement unit. Please consult with your diabetes healthcare professional about the measurement unit.

NOTE

Your test meter displays 7, 14 and 30 days average which you can access from the test meter memory. These averages are calculated from results obtained during 7, 14, 30 days from the current date and time settings. When you set a new date and time, the 7, 14, 30 days averages may change. After 2 minutes of inactivity while the test meter is in the setting mode, it will shut down automatically.

8 BEFORE TESTING

8-1. Coding the Test Meter

Insert the code key completely into the code key port with the code number facing up and the code number will appear on the LCD display. Make sure the code numbers on the display match the code key and the test strip vial. If all of the numbers match, you may begin testing.



NOTE

If the code numbers displayed on the screen do not match the code key and the test strip vial, by calibrating again or contact your local distributor.

8-2. Glucose Control Solution Test

Checking the System with Glucose Control Solution: CERA-CHEK™ 1070 Glucose Control Solution contains glucose that reacts to the test strips. By comparing the result tested using the control with the expected range printed on the test strip vial label, it is able to check that the test meter and the test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get accurate results.

- Perform a Glucose Control Solution Test if:
- You would like to test your system without using a blood sample.
 - You are using the test meter for the first time.
 - You suspect the test meter or test strips may not be functioning properly.
 - Test results appear to be abnormally high, or low or are not consistent with the symptoms you are experiencing.
 - The test strip vial was left open.
 - You are using a new vial of test strips.
 - You changed the test meter.

NOTE

The results obtained from your Glucose Control Solution test do not indicate your personal glucose levels.

IMPORTANT

Use CERA-CHEK™ 1070 Blood Glucose Test Meter only with CERA-CHEK™ 1070 Test Strips, Glucose control solution is sold separately. Do not use the control solution after expiration date as printed on the vial. Use the control solution within 4 months after opened. It is recommended to record the discard date on the coming 4 months on the glucose control solution vial as a reminder when to dispose the opened control solution.

For example: You open the control solution on January 1st, Count forward four months to April 1st. This is your discard date. Record this date on the side of the control solution vial.

Always close the cap on the Glucose Control Solution immediately after use.

- Insert the test strip into the insert port of the test meter. The blood symbol will start blinking. The indicator will also blink if you have chosen "ON" for Indicator in the setting mode.
- Prepare the Glucose Control Solution. Shake the Glucose Control Solution vial thoroughly. Remove the cap, squeeze the vial, discard the first drop, and wipe off the dispenser tip to prevent contamination.
- Apply glucose control solution. Aim directly at the absorbent hole of the test strip.
- Squeeze the vial again to get another drop and the drop will be automatically drawn in the test strip. Make sure the confirmation window is completely filled. The test meter will count down from 5 seconds and then display the Glucose Control Solution test result.

If the test result is out of the range numbers printed on the test strip vial, repeat the test. If you continue to have out-of-range results, it means that the system may not be working properly. Do not use the product and please contact your local distributor for assistance.

9 TESTING YOUR BLOOD

9-1. Getting a Drop of Blood

Please wash and dry your hands prior to starting.

