

GLUCOCARD™

Σ SIGMA

BLOOD GLUCOSE METER

arkray

Operating manual

SELF-TESTING IVD



83-04339

Thank you for choosing the GLUCOCARD™ Σ. We have designed this compact blood glucose meter for faster and easier testing of your blood glucose. We hope our product will help you manage your diabetes. This manual explains how to use your new meter. Before testing, carefully read through this manual and the package inserts that come with the GLUCOCARD™ Σ Test Strips and GLUCOCARD™ Σ Control Solution. Pay particular attention to listed warnings and cautions. Please keep this manual handy for future reference. If you have any questions, please contact our authorized distributor(s) at the end of this manual.

## Chapter 1 Introduction

### 1.1 Intended Use

The GLUCOCARD™ Σ and GLUCOCARD™ Σ Test Strips are for quantitatively measuring the glucose level in fresh capillary whole blood. They are intended for use outside of the body (*in vitro* diagnostic use) at home or in a clinical setting as an aid to monitor and control blood glucose levels. **Do not use them to diagnose diabetes.** Also, **do not** alter treatment based on the test results of this meter without instructions from your doctor or healthcare professional.

### 1.2 Measurement Principle

Glucose in the blood reacts with the reagent in the test strip and this produces a small electric current. The strength of this current is proportional to the concentration of glucose in the blood. The meter measures this current and calculates your glucose level.

### 1.3 What's Included

- GLUCOCARD™ Σ
- Carrying case
- Operating Manual (this manual)
- GLUCOCARD™ Σ Test Strips\*
- Multile™ (lancets)\*
- Multi-Lancet Device™ (lancing device)\*

Some kits do not include the above items with an asterisk (\*).

## Chapter 2 Before Tests

### 2.1 Important Health-Related Information

#### ⚠ WARNING

You may get test results higher than your actual glucose level if taking PAM (1-Methylpyridine-6-carbaldehyde oxime).

Taking unnecessary measures to lower your blood glucose level may induce severe low blood glucose symptoms such as coma.

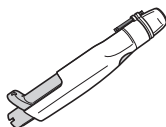
### 2.2 What You Need for Each Test



a. GLUCOCARD™ Σ (meter)



b. GLUCOCARD™ Σ Test Strips



c. Lancing device



d. Lancet

#### ⚠ WARNING

Keep the meter, test strips and other items away from young children. Small items are choking hazards.

### 2.3 Cautions on Using the Meter

#### ⚠ CAUTION

- For accurate test results, allow the meter to adjust to the surroundings:
  - Temperature: 10 to 40°C (50 to 104°F)
  - Humidity: 20 to 80% RH (Relative Humidity)
 for 30 minutes before testing your blood glucose.
- **Do not** store or use the meter where:
  - There are sharp temperature fluctuations.
  - Humidity is high enough to cause condensation (bathrooms, drying rooms, kitchen, etc.).
  - There is a strong electromagnetic field (microwave oven, cell phone, etc.).
- **Do not** use the meter after it has been dropped in liquid or liquids have entered inside, even if dried afterwards.
- Keep hands away from the test strip slot on the meter. A thermo sensor is housed inside the meter to minimize detection of errors.
- **Do not** connect the communication cable to the connection terminal during testing. The meter may be damaged, leading to inaccurate test results.
- **Do not** apply blood directly to the test strip slot on the meter.

### 2.4 Cautions on Using the Test Strips

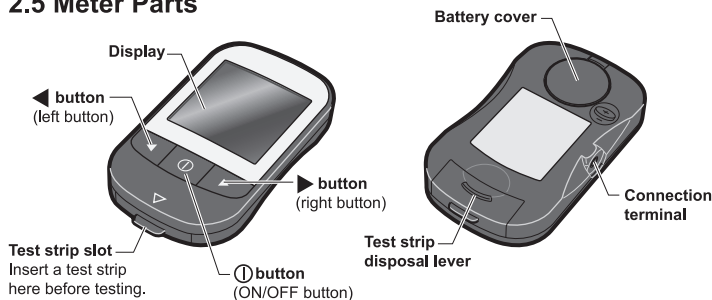
#### ⚠ CAUTION

- Use only the GLUCOCARD™ Σ Test Strips for testing with the GLUCOCARD™ Σ. **Do not** use other test strips as it causes inaccurate test results.
- **Do not** use test strips beyond their expiration date. The expiration date is written on the test strip bottle next to "Exp."
- For accurate test results, allow test strips to adjust to the surroundings:
  - Temperature: 10 to 40°C (50 to 104°F)
  - Humidity: 20 to 80% RH
 for 30 minutes before testing your blood glucose.
- **Do not** use the test strips if 6 months or more have passed since opening the bottle.
- The test strips are for single-use only. **Do not** use test strips that have already absorbed blood or control solution.

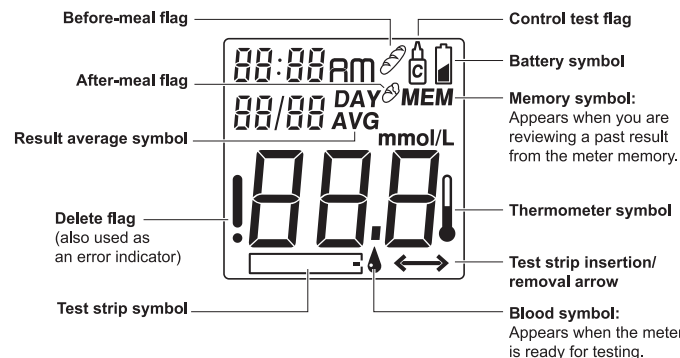
#### NOTE

Store test strips in their original bottle to maintain quality. **Do not** transfer them to other containers.

### 2.5 Meter Parts



### 2.6 Display



### 2.7 Inserting Test Strips into the Meter

Start with the following steps to test your blood glucose level.

1. With clean, dry hands, remove 1 test strip from the bottle.

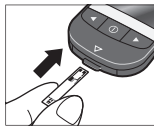
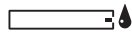
#### NOTE

- Tightly close the bottle immediately after taking out a test strip.
- **Do not** apply blood to the test strip before inserting it into the meter.

## 2. Insert the test strip fully into the test strip slot.

The meter turns on. Check that a full display appears as in chapter 2.6.

The test strip symbol and the flashing blood symbol appear on the screen.



If nothing appears on the screen, remove the test strip and insert it back into the test strip slot.

### NOTE

If the thermometer symbol appears on the screen, see chapter 9 "If a Message Appears".



### CAUTION

If you cannot test your blood glucose due to a problem with your meter or test strips, promptly contact your healthcare professional and distributor.

### Next ...

Go to chapter 3 "Blood Sampling". Draw blood and apply it to the test strip no more than 2 minutes after you insert the test strip into the meter. Otherwise, the meter turns itself off.

## Chapter 3 Blood Sampling

This chapter briefly explains how to get a blood sample using the Multi-Lancet Device™ and Multilet™. If using some other lancing device to sample blood, see the manual for that device.

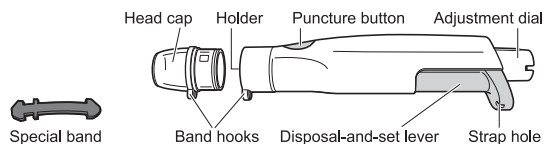
### 3.1 Lancing Device Parts

#### Multilet™ (lancet)



Protective cap

#### Multi-Lancet Device™ (lancing device)



### 3.2 Cautions on Using the Multi-Lancet Device™

Follow these cautions to reduce the risk of infection by pathogenic microorganisms.

### CAUTION

- Wash the puncture site with soap and water. Dry the site thoroughly before sampling blood.
- **Do not** share the same lancet or lancing device with anyone to avoid the risk of infection.
- Always use a new lancet. Lancets are for single-use only. **Do not** reuse a lancet that you have already used.

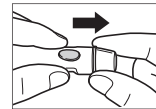
### 3.3 Selecting a Sampling Site

**Alternative site testing (AST):** This meter can test the glucose level of blood from your fingertip or palm. However, test results from the palm may differ from a fingertip measurement. Consult your doctor or healthcare professional before testing blood from the palm.

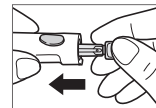
Use blood from:	If you are going to test:
Fingertip or palm	<ul style="list-style-type: none"> <li>■ Before meals</li> <li>■ Two hours or more after meals</li> <li>■ Two hours or more after exercise</li> </ul>
Fingertip	<ul style="list-style-type: none"> <li>■ When there is the possibility of blood glucose level changing rapidly (e.g. after meals or exercise)</li> <li>■ When experiencing symptoms of hypoglycemia such as perspiration, cold sweats, a floating sensation or trembling</li> <li>■ When immediate testing is needed for suspected hypoglycemia</li> <li>■ When in poor physical condition such as having a cold, etc.</li> </ul>

### 3.4 Sampling from Your Fingertip

1. Remove the head cap.



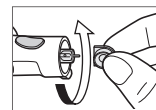
2. Insert a new lancet into the holder until it stops.



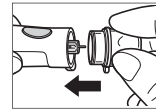
### NOTE

Use a lancet before its expiration date.

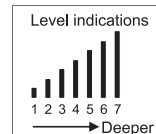
3. Twist off the protective cap on the lancet. Keep the protective cap for disposing of the lancet after the test.



4. Attach the head cap to the lancing device body.



5. If needed, adjust the lancing depth by turning the adjustment dial.



6. Wash the puncture site with soap and water. Dry thoroughly.

7. Press the head cap against your fingertip and press the puncture button lightly.



If you accidentally press the puncture button before reaching the puncture site, press the disposal-and-set lever until you hear a click. The device is then reset.



8. Obtain as much blood as that shown in "Actual size" on the right.



### Next ...

Go to chapter 4 "Testing Your Blood Glucose".

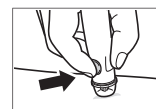
### 3.5 Sampling from Your Palm

1. See steps 1 to 5 in chapter 3.4.

2. Select a soft, fleshy area on the palm that is free of visible veins or moles and away from bone.

3. Massage the puncture site.

4. Wash the puncture site with soap and water. Dry thoroughly.

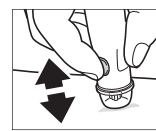


5. Press the head cap hard against the puncture site for about 10 seconds. Press the puncture button lightly.

If you accidentally press the puncture button before reaching the puncture site, press the disposal-and-set lever until you hear a click. The device is then reset.



6. Hold the head cap against the site. Add and reduce pressure to the site repeatedly, one cycle per second, to obtain as much blood as that shown in "Actual size" on the right.



If you obtained an insufficient amount of blood, rub or warm a new puncture site to increase blood flow. Then, make another puncture.

Actual size: ●

### Next ...

Go to chapter 4 "Testing Your Blood Glucose".

## Chapter 4 Testing Your Blood Glucose

### 1. Make sure that the blood symbol is flashing on the screen.

If nothing appears on the screen, remove the test strip and insert it back into the slot. Then, wait until the blood symbol starts flashing.

### 2. Touch the tip of the test strip to the drop of blood.

Let the test strip draw up blood until the dark-colored check window is filled with blood.

#### NOTE

Do not add any extra blood. It may cause inaccurate test results.

Accurate test results will not be obtained if you apply your blood to the check window directly.



When the countdown starts, remove the test strip from the blood. The meter counts down from 7 to 1 during the test.

#### NOTE

- For accurate test results, touch the test strip to your blood immediately after obtaining a sufficient size of blood drop. This is normally achieved within 10 seconds.
- Use only a round drop of blood. Wipe away smeared blood.
- Do not test blood that runs or spreads out from the puncture site.
- Do not smear blood on the test strip.
- Do not press the test strip into your puncture site with force.
- Keep your hands away from the test strip until the test result appears.

### 3. Read your test result.

The meter stores this test result with the test date and time in the memory.



#### WARNING

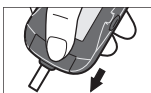
Test results are shown in mmol/L. You cannot change the unit of measure. If the results appear in mg/dL by any possibility, contact your distributor immediately. Using mg/dL may cause you to misread test results and lead to incorrect treatment.

#### CAUTION

- **If “Lo” or “Hi” appears on the screen:**  
Repeat the test. If “Lo” or “Hi” still appears, contact your doctor or healthcare professional. “Lo” appears if your test result is less than 0.6 mmol/L. “Hi” appears if your test result is more than 33.3 mmol/L.
- **If test results do not match how you feel:**  
Make sure you performed the test properly as explained in chapters 2 to 4. Then, do a control test to check there are no problems with the meter or test strips. If you tested blood from the palm, repeat the test with blood from a fingertip. If test results still do not match how you feel, contact your doctor or healthcare professional.
- **Do not ignore test results. Do not** alter your blood glucose management or treatment without consulting your doctor or healthcare professional. It is important to follow their instructions.

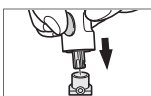
### 4. Point the test strip down. Slide the test strip disposal lever to eject the test strip.

The meter turns itself off.



### 5. Remove the used lancet from your lancing device.

Remove the head cap from the lancing device body. Stab the protective cap with the tip of the lancet.



Push the disposal-and-set lever in the direction of the arrow to remove the lancet.



#### Disposal of Biohazardous Waste

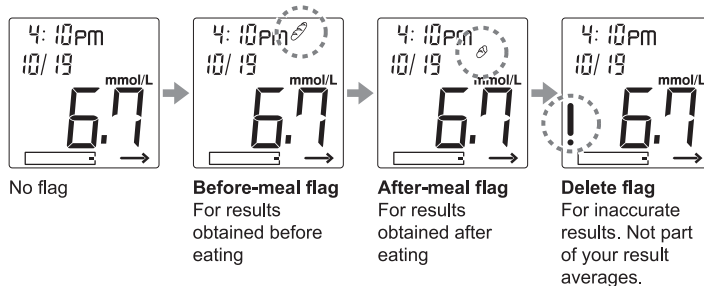
Test strips and lancets qualify as biohazardous waste once used to test blood glucose. After use, dispose of them according to your local regulations on biohazardous waste.

## Chapter 5 Managing Your Test Results

### 5.1 Flagging Test Results

Flags help you categorize and identify results.

1. Leave the test strip in the meter after the test result appears on the screen.
2. Press the ◀ button until the flag you want appears.



3. Point the test strip down. Slide the test strip disposal lever to eject the test strip. The meter turns itself off.

### 5.2 Reviewing Past Results

You can review past results stored in the memory. Your meter stores up to 250 test results. New results beyond the 250th overwrite previously stored results in the order of oldest first. You can also follow these steps when viewing result averages.

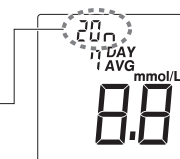
1. Make sure the meter is off.
2. Press Ⓚ button to turn on the meter.
3. Press ◀ button.  
The meter displays the most recent test result stored in the memory.

Three bars “—” appear when there is no past result.

4. To view the result averages, press ◀ button.

The result average changes in the order of 7-, 14- and 30-day each time ◀ button is pressed.

The number of tests included in the average calculation.



Three bars “—” appear when there is no past result to be included in the average calculation.

5. To view other test results, go to the 30-day average screen and press ◀ button.

To go to the next result, press ◀ button.  
To go back to the previous result, press ▶ button.  
To scroll through results, hold down ◀ or ▶ button.  
To show the latest result, press ◀ button while the oldest result is on. See step 3.

To turn off the meter, press Ⓚ button twice.

### 5.3 Deleting All Test Results from the Memory

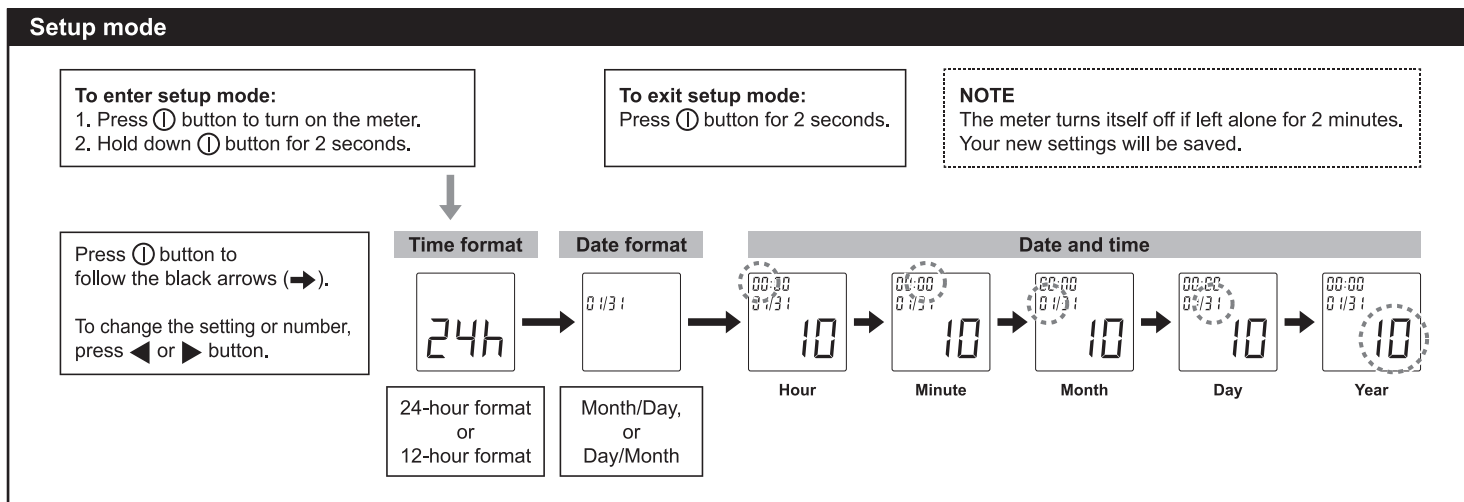
You can delete all test results from the memory. Remember that results cannot be retrieved once deleted.

1. See steps 1 and 3 in chapter 5.2.
2. Hold down both ◀ and ▶ buttons for 5 seconds. “ALL” and “dEL” will alternately flash on the screen.  
To cancel at this point, release the buttons and press ◀ button.
3. Hold down ▶ button for 2 seconds.  
To turn off the meter, press Ⓚ button twice.

## Chapter 6 Meter Setup

Your meter is set up as below at the time of purchase. To change the settings, see the setup mode flowchart.

- Date and time: Current local time



## Chapter 7 Control Test

This meter checks itself every time you insert a test strip. You do not need to run frequent control tests. Do a control test if:

- You suspect the meter or test strips are not working properly.
- You dropped the meter.
- You damaged the meter.
- Your test results do not match how you feel.
- You want to check performance of the meter and test strips before a blood glucose test.

### NOTE

Use only the GLUCOCARD™ Σ Control Solution to test your meter and test strips.

### CAUTION

- **Do not** use control solutions beyond their expiration date. The expiration date is written on the control solution bottles next to "Exp."
- Leave the meter and test strips at 10 to 40°C (50 to 104°F) and 20 to 80% RH, and the control solution at 15 to 30°C (59 to 86°F) for at least 30 minutes before running the control test.
- **Do not** drink control solution. It is not for human consumption.
- Keep control solution away from skin and eyes. Contact may cause inflammation.

1. See steps 1 and 2 in chapter 2.7.

2. Press button to attach the control test flag to the screen.

Without the control test flag, your control test result will be inaccurate and will be included in your result averages.



3. Make sure that the blood symbol is flashing on the screen.

4. Touch the tip of the test strip to a drop of control solution.



The test starts when the meter detects the control solution. The meter counts down from 7 to 1 during the test.

### NOTE

- Tightly close the control solution bottle.
- **Do not** touch the test strip until the test result appears.

5. Check your test result is within the acceptable range.

The acceptable range is shown on the label of test strip bottles. If within range, the meter and the test strip are working properly. If out of range, make sure the control test flag is on and test the control solution again.

### CAUTION

If you still have test results that are out of the acceptable range, stop using your meter, test strips and control solutions, and contact your distributor.

6. Point the test strip down. Slide the test strip disposal lever to eject the test strip.

The meter turns itself off.

## Chapter 8 Meter Care

### 8.1 Storing Your Meter

After use, tightly close the caps of the test strip bottle and control solution bottle to maintain their quality.

Store your meter, test strips, control solutions and manuals in your carrying case and store it in a dry location. The correct storage temperatures are 0 to 50°C (32 to 122°F) for the meter, 1 to 30°C (34 to 86°F) for test strips, and 2 to 30°C (36 to 86°F) for control solutions. **Do not** freeze. Avoid heat, humidity and direct sunlight.

### CAUTION

To obtain accurate test results:

- **Do not** use test strips or control solutions if their bottles are broken or have been left open.
- **Do not** use the test strips or control solutions beyond their expiration dates.

## 8.2 Cleaning Your Meter and Lancing Device

Your meter and lancing device do not need special cleaning. If your meter and lancing device get dirty, wipe them with a soft piece of cloth moistened with water. To disinfect these items after cleaning, wipe with a soft cloth moistened with 70% ethanol, 70% isopropanol or diluted household bleach (0.05% sodium hypochlorite solution).

## 8.3 Changing the Battery

When the battery symbol appears on the screen, the battery is getting low. Before using your meter, change the battery. Date and time settings will not be cancelled if you insert a new battery within 30 seconds. Past results remain in the memory even when the battery is changed.



### NOTE

Your meter uses one CR2032 3V lithium battery. This type of battery is available in many stores. Keep a spare battery handy at all times.

1. Make sure the meter is off.
2. Open the battery cover by lifting the tab with your finger or fingernail.



3. Remove the old battery.

If necessary, turn the meter over and tap it gently against your palm until the battery falls out.



### NOTE

Do not use sharp objects that may damage the meter.

4. Set the new battery into the meter with the "+" side facing upward.
5. Close the battery cover.



### NOTE

The error message "E00" may appear the next time when the meter is turned on. If "E00" appears, set the correct date and time. See the setup mode flowchart in chapter 6.

Dispose of old batteries according to your local environmental regulations.



## Chapter 9 If a Message Appears

If a problem occurs with the meter or test strips, a message appears on the screen. A message does not appear in all cases when a problem has occurred. No indication appears for improper use of the meter or test strips even though you may get inaccurate test results.

Error Message	What's the problem	What to do
E00	<ul style="list-style-type: none"> <li>■ The date and time have been reset.</li> </ul>	See chapter 6 "Meter Setup" to set the correct date and time.
E01	<ul style="list-style-type: none"> <li>■ The insertion portion (electrode) of the test strip is dirty.</li> <li>■ A used test strip is inserted into the meter.</li> </ul>	Repeat the test with a new test strip.
E04	<ul style="list-style-type: none"> <li>■ The battery is almost dead. Test results and changes made in the setup mode are not stored in the memory.</li> </ul>	Change the battery. See chapter 8.3.
E06	<ul style="list-style-type: none"> <li>■ The operating environment is not right for testing.</li> </ul>	Leave the meter and test strips somewhere where the temperature is 10 to 40°C (50 to 104°F) and humidity is 20 to 80% RH for at least 30 minutes. Remove the test strip and insert it back into the slot. Test your blood only after the error and the thermometer symbol disappear. If the error still appears on the screen, contact your distributor.
E07	<ul style="list-style-type: none"> <li>■ There was a sharp change in the surrounding temperature.</li> </ul>	
E08	<ul style="list-style-type: none"> <li>■ The meter could not read test strip information.</li> </ul>	Remove the test strip and insert it back into the test strip slot.
E11	<ul style="list-style-type: none"> <li>■ There is a problem with the inside of the meter.</li> </ul>	Contact your distributor.
E13	<ul style="list-style-type: none"> <li>■ A different type of test strip is inserted into the meter.</li> </ul>	Use a GLUCOCARD™ Σ Test Strip to repeat the test.
	<ul style="list-style-type: none"> <li>■ The test strip touched blood again after the test started.</li> <li>■ The test strip inside the meter moved during testing.</li> <li>■ The blood was not correctly drawn into the test strip.</li> <li>■ There was not enough amount of blood to perform the test.</li> </ul>	Repeat the test with a new test strip.
E21	<ul style="list-style-type: none"> <li>■ There is a problem with the inside of the meter.</li> </ul>	Contact your distributor.
E22	<ul style="list-style-type: none"> <li>■ There is a problem with the inside of the meter.</li> </ul>	Contact your distributor.
E23	<ul style="list-style-type: none"> <li>■ The meter could not detect the surrounding temperature correctly.</li> </ul>	See "What to do" for E06 / E07.

Symbol	What's the problem	What to do
	<ul style="list-style-type: none"> <li>■ The battery is getting low.</li> </ul>	Change the battery. See chapter 8.3.
	<ul style="list-style-type: none"> <li>■ The surrounding temperature is too low or too high.</li> <li>■ The meter has not adjusted to the surrounding temperature.</li> </ul>	Leave the meter and test strips somewhere where the temperature is 10 to 40°C (50 to 104°F) and humidity is 20 to 80% RH for at least 30 minutes. Remove the test strip and insert it back into the slot. Test your blood only after the thermometer symbol disappears. Your meter can test your blood even when the thermometer symbol is displayed, but this may produce inaccurate test results. These results are stored along with the thermometer symbol and cannot be part of your result averages.

# Chapter 10 Technical Information

## 10.1 Specifications

Product	GLUCOCARD™ Σ
Model	GT-1070
Test item	Blood glucose level
Sample	Fresh capillary whole blood*1
Sample size	0.5 µL
Test strips	GLUCOCARD™ Σ Test Strips
Unit of measure	mmol/L
Test range	0.6 to 33.3 mmol/L
Test time	7 seconds from blood detection
Temperature compensation	Automatic compensation using built-in thermo sensor
Battery	3 V lithium battery (CR2032) × 1
Battery life	Approx. 2,000 tests (Actual number of tests may be less under some conditions of use.)
Power consumption	0.02 W (Max.)
Memory capacity	250 test results
Clock accuracy	Within ±75 seconds/month
Operating environment	Temperature: 10 to 40°C (50 to 104°F) Humidity: 20 to 80% RH (No condensation)
Expected life	3 years (according to company data)
Dimensions	L83 × W47 × 15 mm (L3.3 × W1.9 × 0.6 inches)
Weight	Approx. 39 g (1.38 ounces)

\*1: Although whole blood samples are used for measurement, displayed results are equivalent to plasma glucose levels.

- Store the meter at 0 to 50°C (32 to 122°F).
- The meter is shipped with the battery loaded. So, you can start testing immediately. However, the battery may not satisfy the "Battery life".
- Product specifications and appearance are subject to change without notice.

## 10.2 Product Safety Information

### Electromagnetic Interference (EMI)

This meter complies with CISPR 11: 2003, Class B (Radiated Only). It emits low levels of energy that are not likely to interfere with nearby electronic equipment.

### Static Electricity and Radiated Magnetic Field Immunity

This meter clears immunity requirements for Level 3 electrostatic discharge set forth in IEC 61000-4-2. This meter clears immunity requirements for radio frequency interference in the 80 MHz to 2.5 GHz range (3 V/m) set forth in IEC 61000-4-3.

## 10.3 Disposing of Your Meter

The meter qualifies as biohazardous waste once used to test blood glucose. When no longer needed, remove the battery and dispose of the meter according to your local regulations on biohazardous waste. This meter is not subject to requirements of European Directive 2002/96/EC (Directive on Waste Electrical and Electronic Equipment (WEEE)).

## 10.4 Symbols

Symbol	Description	Symbol	Description
	Storage temperature limitation		GLUCOCARD™ Σ conforms to the Directive 98/79/EC
	In Vitro Diagnostic Medical Device		Multilet™ conforms to the Directive 93/42/EEC.
	Manufacturer		Multi-Lancet Device™ conforms to the Directive 93/42/EEC
	Biological risks		Suitable for self testing
	Caution, consult accompanying documents		Authorized Representative in the European Community
	Batch code		Serial number
	Use by		Consult instructions for use
			Catalogue number

## 10.5 Warranty

ARKRAY shall repair or replace the GLUCOCARD™ Σ free-of-charge in the event that there are defects in material and workmanship for a period of one year from the date of purchase. However, this warranty does not apply to the following:

1. Trouble or damage due to careless use.
2. Trouble or damage due to unforeseen circumstances such as natural disasters.
3. Trouble or damage due to unauthorized repairs or remodeling.
4. Trouble or damage for which ARKRAY is not responsible.

IVD Directive (98 / 79 / EC)  
0 1 2 3

**Manufacturer**  
**ARKRAY Factory, Inc.**  
1480 Koji, Konan-cho, Koka-shi,  
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