

# OKmeter CORE

## BLOOD GLUCOSE MONITORING SYSTEM

### USER GUIDE



IVD	For In vitro diagnostic use	Temperature limitation / Store at
i	Please consult instructions for use	Use by /Expiry date
Do not reuse		Manufacturer
LOT	Lot number	Caution, consult accompanying document
Keep dry		Keep away from sunlight
Humidity limitation	CE REP	EU representative.
CE 0123	This product fulfills the requirements of Directive 98/79/EC in vitro diagnostic medical device.	

Performance Characteristics:  
Accuracy: 95% of the measured glucose values shall fall within either  $\pm 15$  mg/dL ( $\pm 0.83$  mmol/L) of the average measured values of the reference measurement procedure at glucose concentrations  $< 100$  mg/dL ( $< 5.55$  mmol/L) or within  $\pm 15\%$  at glucose concentrations  $\geq 100$  mg/dL ( $\geq 5.55$  mmol/L).  
PRECISION: Standard deviation (SD) for each glucose concentration  $< 100$  mg/dL (5.55 mmol/L) and coefficient of variation (CV) for each glucose concentration  $\geq 100$  mg/dL (5.55 mmol/L) is  $< 5.0$  mg/dL (0.278 mmol/L) and  $< 5.0\%$ , respectively.

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SIDE A

## Before You Begin

### PLEASE READ THIS BEFORE USING.

The following basic safety precautions should always be taken.

- Close supervision is necessary when the device is used by, on, or near children, handicapped persons or invalids.
- Use the device only for the intended use described in this manual.
- Do not use test strips and control solutions which are not supplied by the manufacturer.
- Do not use the device if it is not working properly, or if it has suffered any damage.
- Before using any product to test your blood glucose, read all instructions thoroughly and practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional.
- KEEP THESE USER GUIDE WITH YOU.

### Intended Use

IVD The system is intended for use outside the body (in vitro diagnostic use only). It should be used only for testing blood glucose (blood sugar) and only with fresh capillary whole blood samples. The system is intended for self-testing at home and for clinical settings. It should not be used for the diagnosis of diabetes.

### Principle of Measurement

Blood glucose is measured by an electrical current that is produced when a blood sample mixes with the reagent (special chemicals) of the test strip. The electrical current changes with the amount of glucose in the blood sample. The OKmeter Core meter measures the strength of the electrical current, calculates your blood glucose level and then displays your result in either milligrams of glucose per deciliter (mg/dL) or millimoles of glucose per liter (mmol/L).

### Caution

- The user should not take any decision of medical relevance without first consulting his or her medical practitioner.
- Call your doctor immediately if you experience symptoms that are not consistent with your blood glucose test results.
- High altitudes above than 3,402 meter (11,161 ft) may affect the test results.
- Temperatures outside the range of 10°C to 40°C (50°F to 104°F) may affect the test results. Do not test beyond the temperature range.
- No modification of this equipment is allowed.
- If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.
- Do not use this meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

### IMPORTANT HEALTH-RELATED INFORMATION

- Apply only capillary whole blood sample to test your blood glucose. Applying other substances or plasma, serum will cause wrong results.
- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- Test results below 60 mg/dL (3.3 mmol/L)\*1 indicates low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L)\*2 indicates high blood glucose (hyperglycemia). If your results are below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), repeat the test, and if the results are still below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), consult your healthcare professional immediately.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-

hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.

- Abnormal red blood cell counts (hematocrit level below 20% or above 60%) may cause false results. Please consult your healthcare professional if you do not know your hematocrit level.
- Interference: Reducing substances occurring in the blood naturally (uric acid, bilirubin) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect the OKmeter Core test results. However, elevated concentrations of these substances may affect test results. The compounds listed in the tables were found to have no effect at the concentration indicated.

Compounds	Concentrations higher than the following values may cause inaccurate results	Compounds	Concentrations higher than the following values may cause inaccurate results
Acetaminophen	8.0 mg/dL (0.53 mmol/L)	Hydroxyurea	3.0 mg/dL (0.39 mmol/L)
Ascorbic Acid	5.0 mg/dL (0.28 mmol/L)	Ibuprofen	50 mg/dL (2.42 mmol/L)
Aspirin	60 mg/dL (3.33 mmol/L)	Inodextrin	13 mg/dL (0.01 mmol/L)
Bilirubin	90 mg/dL (1.54 mmol/L)	L-dopa	10 mg/dL (0.51 mmol/L)
Cholesterol	500 mg/dL (12.9 mmol/L)	Maltose	900 mg/dL (26.3 mmol/L)
Creatinine	5.0 mg/dL (0.44 mmol/L)	Methyldopa	3.0 mg/dL (0.13 mmol/L)
Dopamine	2.0 mg/dL (0.11 mmol/L)	Pralidoxime iodide	25 mg/dL (0.94 mmol/L)
EDTA	360 mg/dL (12.3 mmol/L)	Salicylate	60 mg/dL (4.34 mmol/L)
Galactose	900 mg/dL (50 mmol/L)	Tolazamide	100 mg/dL (3.21 mmol/L)
Gentisic Acid	5.0 mg/dL (0.32 mmol/L)	Tolbutamide	400 mg/dL (14.8 mmol/L)
Glutathione	53 mg/dL (1.72 mmol/L)	Triglycerides	2,000 mg/dL (22.6 mmol/L)
Haemoglobin	500 mg/dL (0.08 mmol/L)	Uric Acid	8.0 mg/dL (0.48 mmol/L)
Heparin	8,000 U/dL	Xylose	100 mg/dL (6.66 mmol/L)

REFERENCE:  
\*1: Kahn, R. and Weir, G.: Joslin Diabetes Mellitus, 13th Philadelphia: Lea and Febiger (1994), 489.  
\*2: Krall, L.P. and Beaser, R. S.: Joslin Diabetes Manual, Philadelphia: Lea and Febiger (1989), 261-263.

## 1. Getting To Know Your System

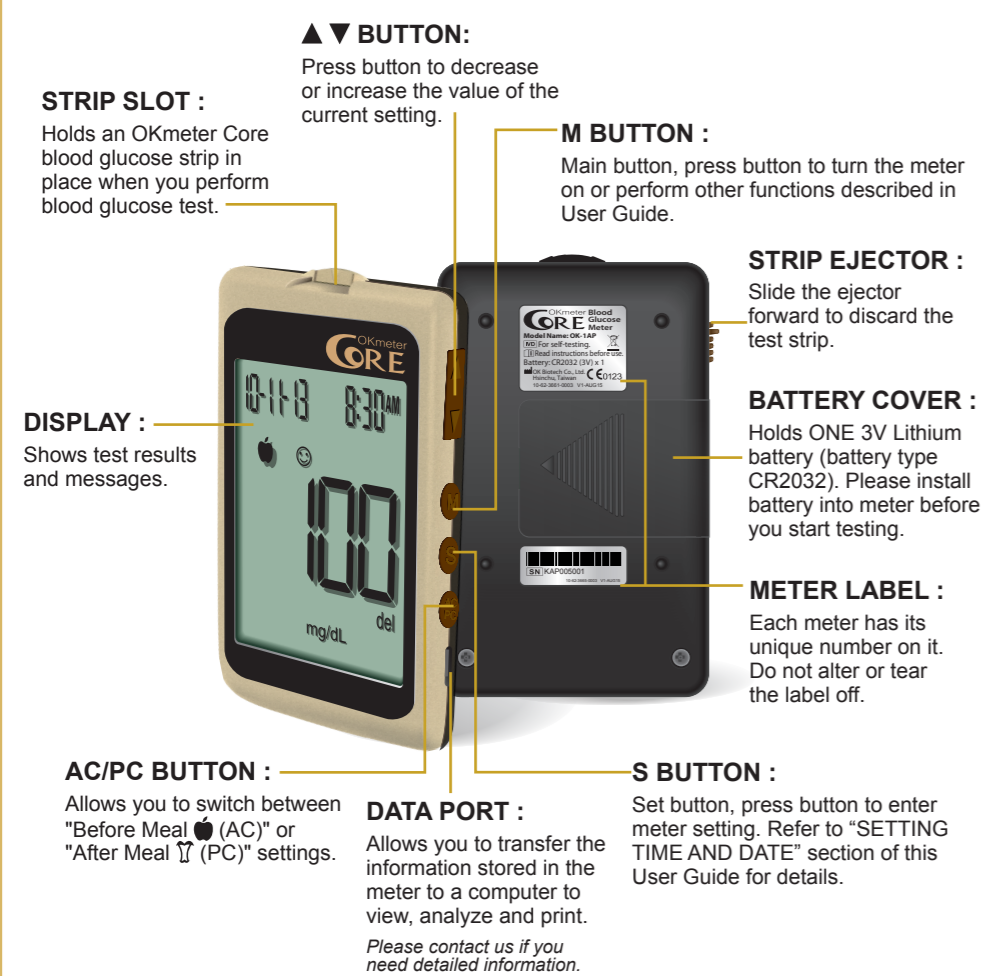
### The OKmeter Core Blood Glucose Monitoring System.

The OKmeter Core system uses the latest technology to provide you with easy and comfortable testing. The system requires only 0.7  $\mu$ L blood sample to complete the testing in only 5 seconds.

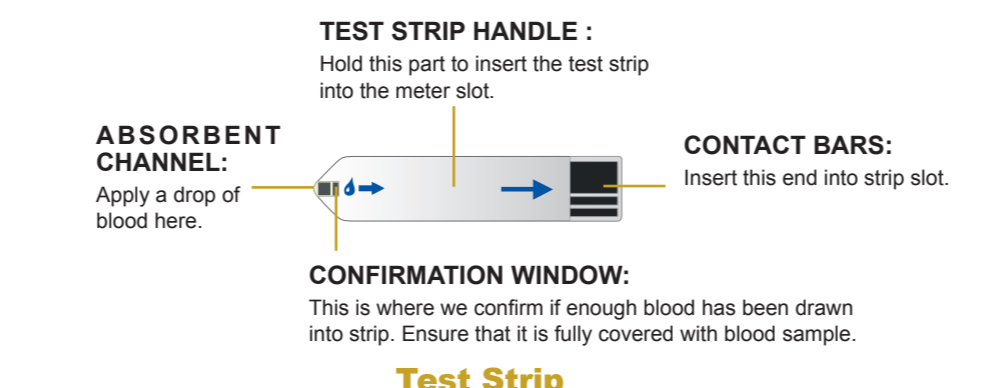
The OKmeter Core system consists of

- OKmeter Core Blood Glucose Meter
- OKmeter Core Blood Glucose Test Strips
- OKmeter Control Solution

**Important :** Use only OKmeter Core test strips and control solutions with this meter can produce inaccurate results.



Meter



### Test Strip

- DATE :** Displays date, month and year. (DD-MM-YY)
- AVERAGE :** Appears when the meter is in the memory mode while recalling 7/14/30/90 days average.
- TIME :** Displays time for either 12 or 24 hour period format according to your setting.
- CONTROL SYMBOL :** Appears when you preset the test as Control Solution Test and the test result will not be stored in meter memory.
- ALARM SYMBOL :** Appears when you are setting alarms.
- NEONATE TESTING MODE :** Appears when you preset the test as Neonate Test.
- TEST STRIP SYMBOL :** Appears when the meter is turned on and waiting for test strip to be inserted.
- DELETE SYMBOL :** when it flashes, press S BUTTON for 3 seconds to delete the selected test result.
- UNIT OF MEASURE :** Appears with the test result either in mg/dL or mmol/L.
- THERMOMETER SYMBOL :** Appears when ambient temperature is above or below the acceptable range needed for testing.
- BATTERY SYMBOL :** Appears when battery is weak.
- MEMORY SYMBOL :** Appears when in memory mode.
- ☺ :** Appears when test result is lower than 70 mg/dL (3.9 mmol/L) or higher than 180 mg/dL (10 mmol/L). ☹ : Appears when test result is within the range of 70 to 120 mg/dL (3.9 mmol/L) to 6.7 mmol/L).
- 🍷 :** BEFORE MEAL: Indicates that your test is a Before Meal test.
- 🍷 :** AFTER MEAL: Indicates that your test is an After Meal test.

### REPLACING THE BATTERY

The OKmeter Core meter comes with ONE Lithium batteries (battery type CR2032). Battery life will vary depending on usage, so always keep a spare battery on hand. The battery should last about 1000 tests or 12 months when testing 3 times a day. When the battery symbol appears on the meter display, battery is getting low. You will still be able to test with low battery, but you should replace it as soon as possible. When the battery symbol and E-b shows up in the meter display, the meter will no longer give results and you must replace the battery immediately. Please always have one spare battery with you to ensure that you can replace the battery anytime.

### How to replace the battery

- Make sure the meter is turned off. Let the front of the meter rest in the palm of your hand. Slide battery cover open.
- Press the semicircle tip of battery holder, and the battery leaps out of the compartment.
- Insert new battery (battery type CR2032), and be sure to align the plus (+) side up. You should hear a beep to indicate the battery installed correctly. If not, please reinsert the battery correctly.
- Close battery cover.

### NOTE:

- Replacing the battery does not affect the test result stored in memory. However the time and date may need to re-set.
- As with all small objects, the battery should be kept away from small children as a safety precaution. If the battery is swallowed, seek medical assistance immediately.
- Batteries might leak chemicals if not used for a long time. Remove the batteries if you are not going to use the device for extended (i.e., 3 months or more).
- Please discard the product or the batteries properly according to the regulations of your country.

### SETTING TIME AND DATE

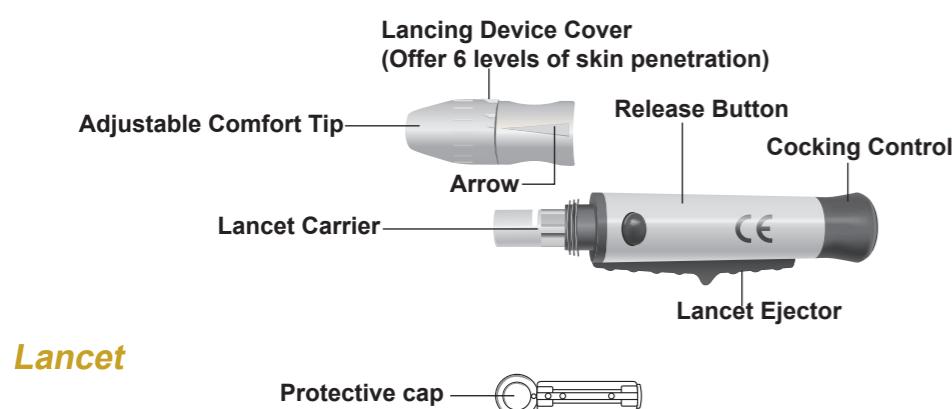
Your OKmeter Core meter comes with a new battery (Battery Type: CR2032). Please install battery first and set correct time and date before you begin to test.

- STEP 1. Enter Setting Mode**  
Press S BUTTON to turn on the meter.
- STEP 2. Set the Year, Month and Date (DD-MM-YY)**  
After the buzzer, you have entered the time setting mode. Press ▲ or ▼ BUTTON to obtain the desired Year and press "S" BUTTON to confirm and move to next Month and Date setting. Repeat to set the month and the date.
- STEP 3. Set the Hour**  
The hour appears with the number flashing. Press ▲ or ▼ BUTTON to obtain the desired hour. The meter preset the time in a 12-hour(AM/PM) format, if you want to change to 24-hour format, press and hold AC/PC BUTTON for 3 seconds to switch to 24-hour format. Press S BUTTON to confirm.
- STEP 4. Set the Minute**  
The minute appears with the number flashing. Press and release ▲ or ▼ BUTTON to obtain the desired minute. Press S BUTTON to confirm.
- STEP 5. Delete Memory**  
When the ☹ symbol and "del" appear on the display, you can choose to clear the memory. If you do not want to clear the memory, press the S BUTTON again to skip this step. If you want to clear ALL memory, press and hold M BUTTON for 3 seconds. "del" will flash 3 times, and then "----" and the ☹ symbol will appear on the LCD screen to indicate that all memory has been deleted.
- STEP 6. Complete Setting**  
After deleting the memory, the meter will display "OFF" before shut down. The meter setting is now completed.

## 2. Prepare For Blood Sampling

### Adjustable Lancing Device

Your lancing device and lancets are used for obtaining capillary blood samples from the puncture site.



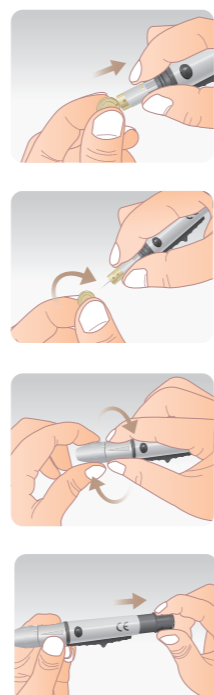
### Lancet

### Important Lancing Device and Lancets Information

- ☹Lancet is for single use only.
- Keep lancing device and lancets clean.
- Use caution when removing the used lancet from the device and when disposing the used lancet.

**IMPORTANT :** The meter and lancing device are for single patient use. Do NOT share them with anyone including other family members ! Do NOT use on multiple patients !

### Setting your Lancing Device



- Screw off the cap of lancing device. Insert a lancet into the lancet holder and push down until it is fully seated.
- Twist off the protective cap until it separates from the lancet.
- Replace the lancing device cap and set the puncture depth to the desired number. To select the best depth:  
  - ☹ For delicate skin
  - ☹☹ For normal skin
  - ☹☹☹ For thick or callused skin
- Pull back the cocking control until it makes a click, and then release. If it does not click, the device may have been cocked when the lancet was inserted.

## 3. Set the Alarm

- STEP 1. Enter Alarm Settings**  
Alarms can be set in setting mode. Press S BUTTON to turn on the meter. Press and release S BUTTON until the value of "minute" flashes, press and hold M BUTTON for 3 seconds to enter Alarm Settings.
- STEP 2. Set the Alarm**  
The meter allows you to set 4 different alarms with an order from AL 1 to AL 4. ☹ will be displayed during the alarm setting.  
  - Press ▲ or ▼ to turn the alarm ON (Fig.A) or OFF (Fig.B).
  - Press S BUTTON to move to hour setting for alarm. (Fig.C) Use ▲ or ▼ BUTTON to set your desired hour. Press S BUTTON again to set the minute. (Fig.D)
  - Press S BUTTON to set the next alarm.
  - Repeat (1) to (3) procedures to set the second, third and fourth alarms.
- STEP 3. Complete Setting**  
When the meter displays time and date, press S BUTTON for 6 times to skip the rest of the setting mode; the meter displays "OFF" and shut down.

