Chapter 1 EUKARE Blood glucose monitor system

1.1 Introduction

Thank you for purchasing EUKARE blood glucose monitor system, this system can be used in both home and medical places, it is a delicate and precise blood glucose meter that helps diabetes patients detecting the glucose concentration in their blood.

Advanced bio electrode sensor technology is used in this system, only small amount of blood is needed to precisely calculate your blood glucose value and have it displayed on the display screen within 15 seconds. No need to count the time or wipe, it's just that simple to use. Please read this manual carefully before you use the blood glucose monitor system, detailed drawings and descriptions are described 80 In the manual, you can easily get the information you need.

Applications: EUKARE blood glucose monitor system must be used together with Ultra-speed blood glucose test specimen when blood glucose concentration is examined in full blood. This equipment is suitable for diabetes patients to detect the blood glucose concentration in their own home by themselves; it can also be used in hospital or clinic as a tool to detect the glucose concentrations of the patients.



Warning: Please read this manual carefully and perform some practice before you use this blood glucose monitor system to measure blood glucose concentration. This system can only be used for blood glucose test reference; it should not be used as a medical diagnosis tool.

1.2Package content_

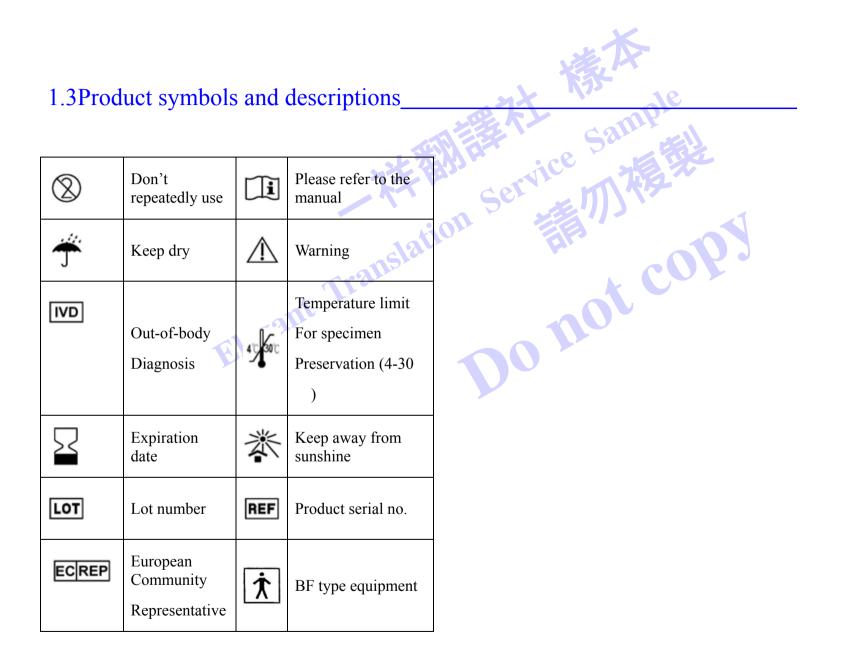
When you open this product's package, please check if all the followings items are in there, if any one of them is missing, please contact the distributor or change the product at the store you purchased it.

 	Se une produce de dire porte your particularity	
Items	Product name [Product serial number]	Quantity
1	EUKARE blood glucose meter [PM000301]	1
2	10 EUSURE blood glucose specimens, can-packaged [PS001001]	1
3	Setup and inspection card for EUSURE blood glucose meter	
	[PA001201]	
4	Blood picking tool XD [PA000403]	1
5	Blood picking needle 28 G XD [PA000301]	10
6	Li battery 3V[PA000101]	1
7	Medium level QC liquid [PA000601]	1
8	Nylon travel pack [PA000703]	1
9	EUKARE operational manual Chinese version (traditional	1
	Chinese)[PA001801]	
10	EUKARE fast operational guide Chinese version (traditional	1
	Chinese)[PA001901]	
11	EUSURE specimen manual Chinese version (traditional Chinese)	1
	[PA001102]	

Optional (Not included in the package of this product, you can purchase them in the store you purchased this product if you need them)

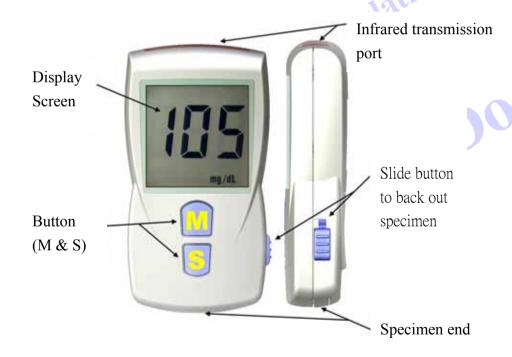
- 50 EUSURE test specimen, box-packaged, Chinese version (traditional Chinese)[PS001206]
- High level QC liquid [PA000603]
- Low level QC liquid [PA000604]

- EUKARE transmission line [PA000202] •
- EUKARE wireless receiver [PA002001]
- EUKARE blood glucose management software [PA002101]
- Lesant EUKARE blood glucose management software operational manual [PA002201] • ara va ta va



1.4 Product parts illustrations and descriptions

Blood glucose meter Front and side view)



Display screen: Display measured value and all operational messages.

Specimen opening:

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Place for plugging in specimen, specimen code and transmission line.

Button (M and S):

Press the button gently can execute two functions such as "re-read the recorded value" and "system reset".

Slide button to back out specimen:

Slide downward to back out the accessory inserted into the specimen opening.

Infrared transmission port:

Use infrared to transmit recorded values to the personal computer.



Blood glucose specimen (Front side)

Test body suck-in end:

The suck-in end of blood or QC liquid. Whenever the test body touches the suck-in end,

specimen will suck in the blood or QC liquid automatically .

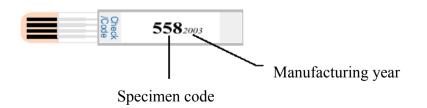
Specimen leads:

The place where the specimen is inserted into the equipment, the equipment will start automatically once the specimen is inserted. **Reaction zone:**

The zone where bio-electrode reacted, when blood or QC liquid is sucked in, please makes sure the blood or QC liquid covers the whole reaction zone .



Set up checking card (Front side)



Chapter 2 The installation and setup of blood glucose meter

2.1Installation /change of battery

Descriptions:

Your blood glucose monitor system contains one 3-volt lithium battery (model number CR2032); when the replacement is uncertain, please do not change arbitrarily batteries of different model no. Or spec. So that it won't damage the circuit of the equipment.



Operations:

- 1. Use one hand to fix blood glucose meter, use the thumb of another hand to press the battery cover and push it downward to open it (as shown in figure 1).
- 2. Direct the positive electrode "+" of the battery upward, press the transparent plastic piece on the battery base, then insert into the battery base (as shown in figure 2).
- 3. Push upward the battery cover back (as shown in figure 3).
- 4. After battery is installed, blood glucose meter will "beep" once, a horizontal line will show up on the screen to indicate the completion of installation.

Notices:

- 1. This equipment is equipped with automatic electricity-saving design, it will enter electricity-saving mode automatically when it is not used for a period of time, it should be re-started when the equipment needs to be re-operated.
- 2. Blood glucose meter will consume power for performing any function once it is started, when the lower power indication lights up after it is

turned on, please change the battery immediately, otherwise, it will affect the precision of the blood glucose meter.

3. During the change of battery, please pull upward the transparent plastic piece between the battery and battery base to take out old battery, then insert the new battery according to the above-mentioned actions .

- 4. During the installation of the battery, please do not let the transparent plastic piece between the battery and battery base cover the spring piece of the battery base, because this will cause bad contact between the battery and the battery base.
- 5. After the change of battery, please follow 2.2 the setup of blood glucose meter unit of this Chapter "The installation and setup of blood glucose meter" to set up blood glucose meter again, please also verify the precision of blood glucose meter according to 2.3 the setup of specimen code unit.
- 6. The action of change of battery won't affect the recorded value of blood glucose meter, but it will affect the correctness of time setup, please follow section 2.2 to set up the time again.

Warning:

1. Please avoid children from swallowing the batteries.

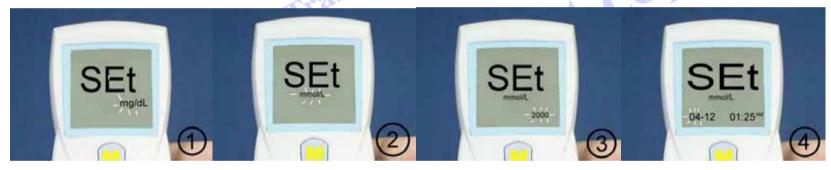
2. Li battery is toxic; when it is swallowed in mistake, please send the patient to the hospital immediately.

3. Please do not discard the battery after use, please process it according to the local environmental law.

2.2 The setup of blood glucose meter

EUKARE blood glucose meter is a perfect multiple functions blood glucose meter, it can set up blood glucose unit according to the user's favor, it can also record the time when blood glucose is measured, it also calculate the average blood glucose value for days and 14 days. For the correct execution of these functions, when the following conditions are met, please complete correct blood glucose meter setup according to the following operating procedures.

- 1. When use blood glucose meter for the first time.
- 2. After changing a new CR2032 Lithium battery.



Operations:

- 1. Press S button for 3 seconds to start, the screen will then display SET (Setup) and flash unit picture (as shown in figure 1).
- 2. Please press S button to change unit setup, each time it is pressed, the setup unit will change once (as shown in figure 2).
- 3. To continue the setup of year, please press **M** button to flash the picture of year on the screen, each time **S** button is pressed, it will add one to the year, if the **S** button is pressed for a long time, then the year will be added automatically until the button is released. (as shown in figure 3)
- 4. To continue the setup of date and time, please press **M** button, the pictures of, month, day, hour and minute will flash respectively (as shown in figure 4).
- 5. Set up month, day, hour and minute in the same way setting the year.

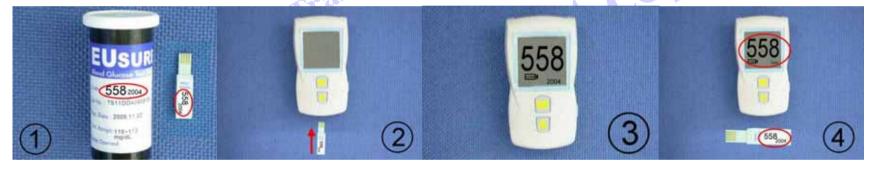
6. Press **M** button for 3 seconds after the setup is completed to turn off the equipment and to finish the setup of blood glucose meter. **Notices:**

- 1. Anytime in the setup process, you can press **M** button for 3 seconds to finish the setup action.
- 2. Please do not remove Lithium battery during the setup process, otherwise it could cause setup error.
- 3. Change the unit and time will not affect the recorded value of the blood glucose meter, but it will affect the average value calculation of 7 days and 14 days.
- 4. If the user does not set up the time, the system will use the default value 2000.01.01 as a standard for time calculation automatically after power is supplied by the Lithium battery.

2.3 The setup of specimen code_

Each box of blood glucose specimen has been strictly quality-controlled and inspected before it is delivered out from the factory, a specimen code is added to the label on the specimen bottle. Each time when blood glucose specimen is used, the specimen code displayed on the blood glucose meter should be compared with the specimen code on the label of the specimen bottle to see if they are the same. Under the following conditions, please perform specimen code setup to ensure the test accuracy.

- 1. When use the blood glucose meter for the first time.
- 2. When the specimen code on the specimen to be used is different than that on the blood glucose meter.





Operations:

1. Ensure the specimen code on the checking card is the same as that on the specimen bottle (as shown in figure 1).

- 2. Please insert the setup checking card into the specimen insertion end of the blood glucose meter (as shown in figure 2).
- 3. Wait until the specimen code appears on the screen (as shown in figure 3).
- 4. Ensure the specimen code on the blood glucose meter is the same as that on the setup checking card (as shown in figure 4).
- 5. Pull out the setup checking card, the blood glucose meter screen will show $\lceil PAS_{\perp} \rangle$, it means that the checking of blood glucose meter is complete(as shown in figure 5).

Notices:

If any of the following conditions are found, please contact the store you purchased this product :

- 1. Each box of blood glucose specimen is accompanied with a setup checking card, if the setup checking card in the specimen box is found missing.
- 2. If the screen does not appear specimen code after the setup checking card is inserted, or if the specimen code appeared is different than that designated on the label.
- 3. IF "Err" appears on the blood glucose meter screen after the setup checking card is pulled out.

Chapter 3 Blood glucose test

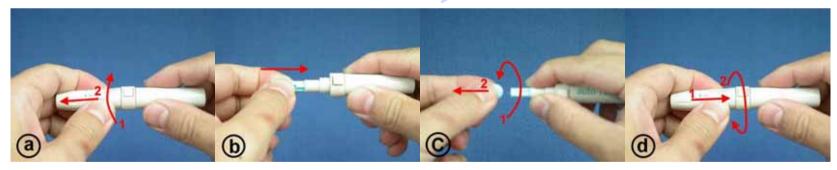
3.1 Preparation before use

Please be sure to prepare the following materials before the blood glucose measurement and follow all the procedures in this manual to ensure not cop the accuracy in the measurement processes and results.

Materials that need to be prepared include:

- 1. One EUKARE blood glucose meter.
- 2. One EUSURE blood glucose specimen.
- 3. One blood-picking tool and blood-picking needle.
- 4. Tissue paper or some cotton balls with alcohol concentration of 75%.

Operations:



- 1. Install the blood-picking tool.
 - 1a. Rotate to open the protection cover of the blood-picking tool as shown in figure a).
 - 1b. Insert blood-picking needle until it cannot be further pushed (as shown in figure b).
 - 1c. Grasp the bottom of the blood-picking needle; rotate carefully the protection cover of the blood-picking needle to remove the protection

cover (as shown in figure c).

1d. After the protection cover of the blood-picking tool is put on, adjust the scale on the protection cover to appropriate blood-picking depth (as shown in figure d).



- 2. Use soap, warm water to clean both hands and wipe them clean, massage gently on the location where blood is to be withdrawn to increase local blood output (as shown in figure 1).
- 3. Put on the cover immediately after the specimen is taken out to keep the specimens be stored in dry environments (as shown in figure 2).
- 4. Please insert the specimen leads into the specimen insertion end of the blood glucose meter (as shown in figure 3), the blood glucose meter will have a short "beep" and start.
- 5. After the equipment is started, specimen code will be displayed on the screen, check if it is the same as that labeled on the specimen bottle (as

shown in figure 4), if they are different, then pull out the specimen and follow section 2.3 to complete the specimen code setup and continue again from step 4.

- 6. Display the environmental temperature (as shown in figure 5), if the temperature exceeds the recommended specimen operating temperature, please move to a location of room temperature for 30 minutes and perform the measurement again.
- 7. Then the specimen and blood drop picture will flash, it means that the blood glucose meter is ready (as shown in figure 6).
- 8. Follow the manual of the blood-picking tool you use to withdraw blood on the fingertip for the blood glucose measurement.

Notices:

- 1. Please perform blood glucose measurement within 5 minutes after the specimen is taken out, if the measurement is not done within 5 minutes, please change to new blood glucose specimen for measurement.
- 2. Blood glucose specimen cannot be used repeatedly, if the used specimen is inserted, a "wrong specimen indication **X**" will appear in the blood glucose meter, please change to new specimen if this appears.
- 3. If the blood glucose specimen is inserted reversely, the blood glucose meter cannot be opened.
- 4. Press gently on the tissue at the peripherals of blood-picking hole to increase blood output, please perform measurement immediately on the full blood squeezed.

Warning: 🥖

- 1. Please do not re-use the blood-picking needle to prevent any infection.
- 2. For your health, please use qualified blood-picking needle.

3.2 Blood glucose measurement





Operations:

- 1. Pull out the blood-picking tool handle until a "click" sound can be heard and it cannot be further pulled out (as shown in figure 1).
- 2. Use blood-picking tool to withdraw appropriate amount of blood from the fingertip or side of finger end, squeeze gently to let the blood form a drop (as shown in figure 2 and figure 3).
- 3. Contact the suck-in end of the specimen to the blood test body, the blood will be automatically sucked into the reaction zone, there is no need to apply a coating (as shown in figure 4).
- 4. After a short "beep", the display screen will start to count down; finger can then be removed at this moment.
- 5. After the count down of 15 seconds, blood glucose meter will have a short beep to inform you that the measurement is completed, and the

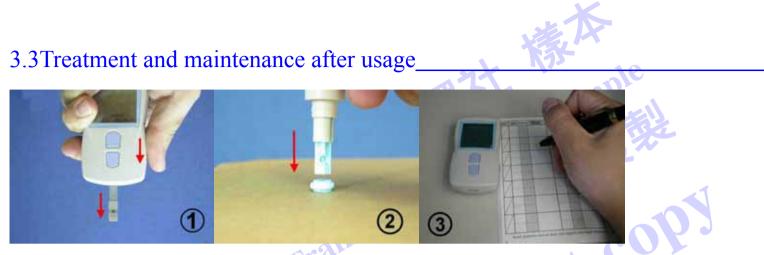
result will be displayed on the display screen (as shown in figure 5).

Notices:

- 1. Please take turns in changing the blood-picking locations on different fingertip or side of finger end, please avoid thick skin keratin layer, which will cause insufficient blood quantity.
- 2. If blood is dropped on the upper end of the reaction zone of the blood glucose specimen, the won't be able to be sucked into the reaction zone smoothly.
- 3. If the measurement is not performed within 5 minutes the blood glucose specimen is inserted, blood glucose meter will turn off automatically to save power consumption.

Warning:

When the display screen shows Lo, it means your blood glucose value could possibly be lower than 30mg/dL (1.6mmol/L), when it shows Hi, it means your blood glucose value could possibly be higher than 600mg/dL (33.3mmol/L), please follow the indications provided by the doctor.



Operations:

- 1. Align the specimen with reject collection box, push the slide button used to back out specimen at the side part of blood glucose meter to withdraw the specimen, the blood glucose meter stop automatically once the specimen is withdrawn. (as shown in figure 1)
- 2. Penetrate the blood-picking needle directly on the unfastened protection cover; discard the used blood-picking needle and the used specimen. (as shown in figure 2)
- 3. Please record the measurement date and time and the results on the record book. (as shown in figure 3)
- 4. If the blood glucose meter is in contact with blood test body in accident, please use clean-water-dipped tissue paper to clean it; please do not use any solvent or alcohol to clean.
- 5. Please put the blood glucose meter into travel pack at any time for protection when it is used and finished or when it is not in use.



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- 1. Used blood-picking needle and specimen could possibly cause personnel injury or contamination; please avoid its contact by other persons.
- 2. Please handle used blood glucose specimen and blood-picking needle according to local laws.
- 3. Please don't try to open the shell of the blood glucose meter to clean its inside.
- 4. Used blood glucose specimen, blood-picking needle and wiped disposals all have potential danger. If the user has contagious disease, the used

specimen could be a contagious source.

5. Even under clean conditions, all the products or objects in contact with blood could possibly cause contagious disease by the bacteria in it.

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Chapter 4 QC liquid test

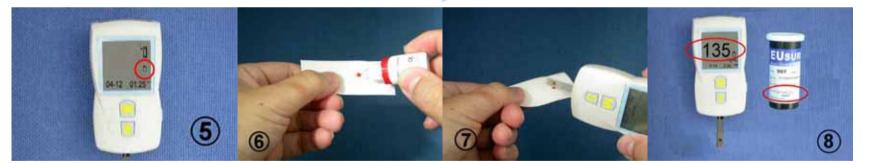
We recommend you perform the QC liquid test under the following conditions.

- 1. When you want to check the performance of blood glucose meter and blood glucose specimen.
- 2. When you are suspicious about blood glucose measurement results.
- 3. When it is recommended by professional person to use it.



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- 1. Please check the expiration date on the package of the blood glucose specimen (printed on the specimen bottle), please do not use expired specimen (as shown in figure 1).
- 2. Close the cover of the bottle immediately after specimen is taken out to keep the specimen stored in dry environment (as shown in figure 2).
- 3. Insert the specimen lead into the specimen insertion end of the blood glucose meter until the blood glucose meter starts (as shown in figure 3).

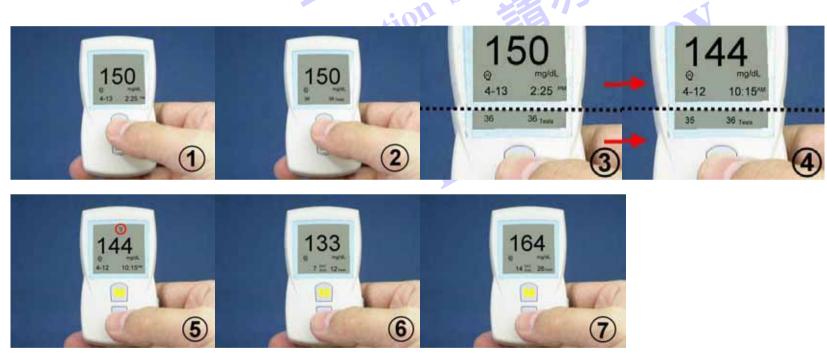
- 4. Ensure the specimen code displayed on the display screen is the same as that on the specimen bottle (as shown in figure 4).
- 5. When blood dropping hint appears, press **S** button to flash QC liquid picture, this is to indicate that this measured value is the measured result of QC liquid, it won't be included in the calculation of 7 days and 14 days average (as shown in figure 5).
- 6. Put a drop of QC liquid on the surface of clean and uncontaminated object (as shown in figure 6).
- 7. Use the suck-in end of the blood glucose specimen to contact QC liquid, the display screen will start to count down when the blood glucose meter "beep" once (as shown in figure 7).
- 8. After the count down, the display screen will show the measured value, then compare it to the QC range labeled on the body of the blood glucose specimen bottle (as shown in figure 8).

Notices:

- 1. Blood glucose specimen is a consumption material, it cannot be re-used.
- 2. Please write the opening date of the QC liquid on the label of the bottle body; please fasten the cover after use.
- 3. After the test of QC liquid is done, if the measured value is Hi or Lo, it means the QC range has been exceeded, please refer to chapter 8 for trouble shooting.

Chapter 5 Memory function

Blood glucose meter can store up to 150 tested results, blood glucose measured value and QC liquid test results will all be recorded, if it is labeled as QC liquid test before the measurement, the result will be recorded but not included in the calculation of 7 days and 14 days average .The following procedures describe how to search the measured results from the blood glucose meter.



Operations:

- 1. Press **M** button for 3 seconds, blood glucose meter will have one short "beep" and start, one measured value and measured date will appear (as shown in figure 1).
- 2. Date and the internal record location of memory are interconnected and can be automatically switched to each other; this is convenient for the

user to check the current recorded data amount and the current record number (as shown in figure 2).

- 3. Each time **M** button is pressed, it will jump to the last measured result, the date and memory location in the lower part will change accordingly (as shown in figure 3 and figure 4).
- 4. Press **S** button once to display trash can picture on the screen, this action means this measured result is going to be deleted, if the deletion is going to be cancelled, please press **S** button once more (as shown in figure 5).
- 5. Press **S** button for 3 seconds to display the average value of 7 days, the lower part of the screen will display all recorded data amount within 7 days (as shown in figure 6).
- 6. Press again **S** button to display the average value of 14 days, the lower part of the screen will display simultaneously all the recorded data amount within 14 days (as shown in figure 7).
- 7. Press again \mathbf{S} button for 3 seconds to go back to the recorded value display screen.

Notices:

- 1. If 150 data have been recorded already and one more measured result needs to be recorded, the earliest recorded value will be deleted automatically.
- 2. Please constantly connect your blood glucose meter to a personal computer or use hand writing for data transmission in order not to lose your invaluable data.
- 3. Under the memory read-back function menu, anytime the **M** button is pressed for 3 seconds can terminate this function to enter equipment stop mode.

Chapter 6 Communication transmission

The blood glucose meter has a very considerate design; you can select wire transmission or wireless transmission to suit different users' need .If you have transmission need, please purchase optional transmission cable or wireless transmission module set at the original store you purchased this equipment.

Please refer to the operational manual inside the transmission module set you purchased for detailed operational procedures.

Chapter 7 Maintenance and storage of specimen and blood glucose

meter

Since the reagent in the blood glucose specimen reaction zone is very sensitive to outer storage environment, any bad storage environment or wrong operations could possibly affect it, please follow related directions to store and use the blood glucose specimen and blood glucose meter you purchased.

Notices:

1.Blood glucose specimen, blood glucose meter, setup checking card and QC liquid, please have them stored at room temperature, damp, extremely hot and cold or direct sunshine environments or environment filled with too much dusts could affect them.

2. When dirt is adhered to the surface of blood glucose meter, please wipe clean carefully with wet cloth.

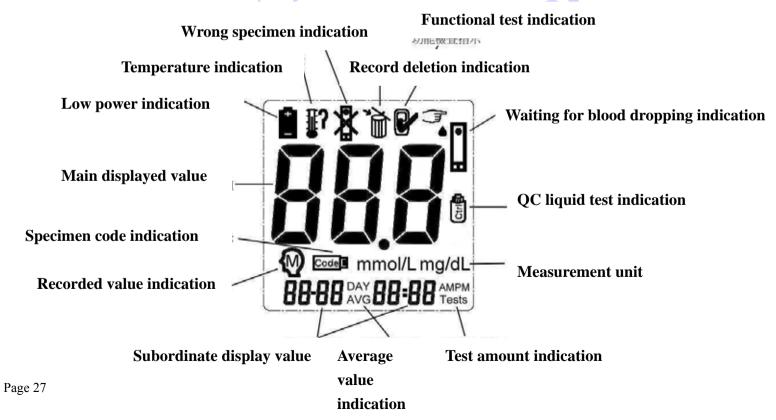
3. Please take out the battery if it is not used for a long time.

Chapter 8 Message descriptions and troubleshooting

8.1 Description of picture

Descriptions:

EUKARE blood glucose meter, in addition to being able to calculate the blood glucose value in the blood test body precisely, it is equipped with many considerate designs, it not only lets you use it conveniently, but also lets you understand the meaning through the picture displayed on the screen by the use of friendly user's interface.



Main displayed value : According to different usage statuses of blood glucose meter, it can display specimen code, environmental temperature value and the blood glucose test result.

Subordinate displayed value : Aid the main displayed value to display related test messages such as: test date, time and quantity.

Low power indication : When insufficient voltage is detected after blood glucose meter starts, this indication will lights up, please change the battery immediately.

Temperature indication : When performing blood glucose test, blood glucose meter will detect the environmental temperature automatically

when this function is executed, this indication will light up.

Wrong specimen indication : When used specimen is inserted, this indication will light up.

Record deletion indication : When user want to delete a recorded value, this indication will light up.

Functional check indication : When performing functional check, this indication will light up.

Indication of waiting for blood dropping: When blood glucose test is performed, when this indication lights up, it means that blood glucose meter is waiting for blood dropping test from the user.

QC liquid test indication : When the user set up the QC liquid test function, this indication will light up.

Measurement unit : Display the current setup blood glucose unit, it only displays one of them each time.

Test quantity indication : Accompanied with subordinate displayed value, this is used to display the recorded value data amount currently in the memory.

Average value indication: When entering into the averaging function of displaying 7 days or 14 days recorded value average, this indication will light up.

Recorded value indication: When entering into recorded value read-back function, this indication will light up.

Specimen code indication : When entering into specimen code setup function, this indication will light up.

8.2 Description of reminding sound

When you use specimen or button to start up blood glucose meter, later on, for any actions after startup action, the blood glucose meter will have reminding sound to remind your current usage status. Normal action reminding sound: One short "beep". Reminding sound for notices or malfunction: "beep, beep, beep, beep, beep", five short beeps. Equipment turnoff reminding sound: One long "beep ".

8.3 Troubleshooting

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Trouble	Possible cause	Recommendations
There is no display on the screen of blood glucose meter when EUKARE specimen is inserted or when button is pressed for 3 seconds.	 Specimen is not completely inserted. Specimen is inserted reversely. Battery is inserted reversely. Low battery power, low voltage. 	 Please insert until it cannot move forward. Please pull it out, reverse it and re-insert. Take out the battery and load it with positive electrode face upward. Change new Lithium battery (CR2032) , then press for 3 seconds again to start.
After the setup checking card is inserted, the screen shows a specimen code which is different than that of setup checking card.	The specimen code of setup checking card is wrong.	Please send back to the store you purchased the product.
After the insertion of blood glucose specimen, the specimen code displayed on the screen is different than that labeled on the specimen bottle.		Please pull out the specimen first, then Follow the procedures of "setup of specimen code "in section 2.3.
After setup checking card is pulled out, E-C will appear on blood glucose meter.	When setup checking card not compatible with EUKARE blood glucose meter is used.	Please change to correct setup checking card.

		* The
After setup checking card is pulled out, E-E appears on the blood glucose meter.	checking card is not complete ca before it is pulled out. 2. Pl	ease re-insert, pull out setup checking and until the specimen code appears. lease change to good setup checking and.
After setup checking card is pulled out, Err appears on the blood glucose meter.		e send back to the store you nased this product for assistance.
After blood glucose specimen sucks in test body, the count	in is not enough. of	ease re-operate by using larger amount f test body and new specimen.
down fails and test can't be performed.		lease send back to the store you urchased this product for assistance.
The blood glucose value is not displayed after countdown.	voltage too low. 2. Pl	hange to new Li battery (CR2032). lease send back to the store you urchased this product for assistance.

		1 th
The screen displays Lo after	1. Not enough test body is sucked	1. Please use enough test body quantity and
blood glucose measurement.	in by the blood glucose	new specimen to re-test.
	specimen, or the specimen is	2. Please check if the specimen code on the
	damp or suffers from quality	blood glucose meter the same as that on
	change.	the label of the specimen bottle.
	2. Specimen code is wrong.	3. Please follow the instruction provided by
	3. The blood glucose value at	doctor.
	this moment could possibly	APS 1
	lower than 30mg/dL	
	(1.7mmol/L).	
The screen displays Hi after	1.Not enough test body is sucked	1. Use enough test body quantity and new
blood glucose measurement.	in by the blood glucose	specimen to re-test.
	specimen, or the specimen is	2. Check if the specimen code on the blood
	damp or suffers from change of	glucose meter the same as that on the label
	quality.	of the specimen bottle.
	2. Specimen code is wrong.	3. Please follow the instruction provided by
	3. The blood glucose value at this	doctor.
	moment could possibly be	
	higher than 600mg/dL	
	(1.7mmol/L).	

		Le K
After the insertion of blood	The environmental temperature for	Please change measurement location to that
glucose specimen," beeps,	measurement is lower or higher	with appropriate environmental temperature,
beep, beep, beep, beep " five	than that can be taken by blood	wait for 30 minutes and re-operate until the
short beeps will be heard, the	glucose specimen.	whole blood glucose meter temperature
temperature indication P will	2 F Bross	balances the environment.
appear, the screen will display	no:	
Lo or Hi .	latio	ALL I
After the insertion of blood	The blood glucose specimen is	1 Ensure if the storage environment of the
glucose specimen," beeps,	damp or is used.	specimen is correct.
beep, beep, beep, beep " five	ant	2 The blood glucose specimen cannot be
short beeps will be heard, the	ega	re-used, please change an unused
wrong specimen indication		specimen and re-do the test.
≵ will appear.		
The whole screen has	The LCD display of blood glucose	Please send back to the original store you
incomplete display after the	meter is out of order.	purchased this product for assistance.
equipment is started.		
After equipment is started, and	The Lithium battery has voltage	Please change the battery as soon as possible.
indication of voltage too	too low.	
low .		

After equipment is started, and	The Lithium battery has voltage	Please change the battery as soon as possible.
indication of voltage too low	too low, blood glucose meter	14 11 - 1e
	system is waiting for Li battery	ELT Comp
and "E-b".	change.	Sar Hill
The measurement result of QC	1 Not enough test body is sucked	1 Please change to a new specimen, please
liquid is out of the QC limits.	in by the blood glucose	use enough test body to re-test.
	specimen.	2 Please change to non-expired or
	2 QC liquid expires or not well	unopened QC liquid.
	preserved after it is opened.	c Q Y ·

The **EUKARE** blood glucose meter and blood glucose specimen have been strictly quality-controlled; we recommend you read the manual carefully before you use it. Inappropriate preservation or impact will cause the reduction of the usage lifetime of blood glucose specimen and blood glucose meter, please follow the preservation and maintenance for specimen and blood glucose meter in Chapter 7.

Chapter 9 Specification

Chapter 9 S	pecification
Tost body '	Evil blood of blood conillant
	Full blood of blood capillary
Test body quantity :	3uL(at least)
Measurement time :	15 seconds
Measurement scope :	30~600 mg/dL (1.67~33.3 mmol/L)
Blood cell volume rati	35%~55%
o :	slate his Job
Memory capacity :	150 data
Battery type :	One 3V Lithium battery (CR2032)
Battery lifetime :	150 data One 3V Lithium battery (CR2032) About 1000 times $10 \sim 40 (55 \sim 104)$
Operating temperature :	$10 \sim 40 (55 \sim 104)$
Specimen storage	$4 \sim 30 (50 \sim 90)$
temperature :	
Operating relative	Smaller than 95%
humidity :	
Blood glucose meter	91 x 49 x 21 mm (3.58 x 1.93 x 0.83 in)
dimension :	
Blood glucose meter	About 50 grams
weight :	
System accuracy :	When blood glucose value is higher than 75 mg/dL $< +/-$ 15 %
	(use plasma biological value as standard of reference)
System accuracy :	When blood glucose value is higher than 75 mg/dL, $CV < 5 \%$

Chapter 10 Standards and specs

Blood glucose monitor system is in accordance with the medical equipment commands of European Community (98 /79 /EC). The followings are product design/manufacturing standards :

A A A

Items	Standard
Quality System	ISO 13485
Risk Analysis	ISO 14971
Radiation Test	EN 60601-1-2
Electromagnetic compatibility	IEC 61326
ESD, Mechanical Hazard	IEC 61010-1 : 2001
Precision, Accuracy, Repeatability, and Temperature Test	ISO / DIN 15197
Linearity	NCCLS EP6-P
Interference	NCCLS EP7-P
Labeling	EN 376 : 2002(E) / ISO 15223 : 2000
Lay Person Test	EN 376 : 2002(E)
Traceability	ISO 17511
Stability Test	prEN 13640

Chapter 11 Usage limits

- 1. This product is only for out-of-body use.
- the Sample 2. EUKARE blood glucose meter can only be used with blood glucose specimen certified by EUSURE and our company.
- 3. EUSRE blood glucose specimen could possibly be affected by oxygen content dissolved in the blood; test body taken at different body parts of the same tested person could have different test result.
- 4. If the finger for blood glucose measurement is dipped with sugar or beverage, it could possibly lead to wrong measurement results.
- 5. Some electrochemical active materials not listed in the usage limited materials could possibly affect measurement results due to unknown reason.
- 6. Self-blood glucose monitoring result could easily be affected by user's skill; new learners should get familiar with related operating procedures with the help of professional personnel to ensure measurement accuracy.
- 7. Medical personnel should periodically evaluate patient's operating methods and skills, in the clinic experiment; it should be compared with biological method.
- 8. Blood test body should not be preserved by Fluoride or Iodoacetic acid.
- 9. Test specimen is not suitable for blood glucose test of newborn baby.
- 10. Under normal blood glucose concentration (120 mg/dL or 6.67 mmol/L), blood test body with blood cell volume ratio in the range $35\% \sim 55\%$ won't affect the blood glucose test.
- 11. When cholesterol is lower than 500mg/dL (13.0mmol/L) or when triglyceride is lower than 3000mg/dL (33.9mmol/L), it won't affect blood glucose test.
- 12. Substances such as vitamin C and uric acid will not affect blood glucose value under normal blood glucose concentration.

Notices:

Use the blood of blood capillary as the test body of blood glucose test is not applicable to serious disease patients (such as terminal malignant tumor, acute respiratory failure, Generalized edema and serious life-threatening infection), serious dehydrated patient or patient under shock.

Chapter 12 Warranty card

Chapter 12 Warranty card			
Buyer		北魏初年中	Contact phone
Contact address		Arr Serv	E MAR
Email		dation	
	Equipment model	Trans	Seal of the distributor
Product information	Serial no.	III	100
	Purchasing date	mmddyy	

1. This product is warranted for one year after the purchasing date of it.

2. If defects are found in the new product, please bring the invoice with the complete original package to the store for change of product within seven days.

- 3. Free repair and maintenance is provided within warranty period, but material and repair and maintenance charge will be applied to the customer if any of the following situations occur.
- a. Malfunction or damage caused by operating the equipment without following the procedures in the manual.
- b. Damage caused by unauthorized disassembling and repairing.
- c. Damage caused by irresistible natural disaster or foreign force.
- 4. To be effective, the warranted card must be affixed with distributor's seal.