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## Introduction

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Thank you for choosing JS100 series Blood Glucose Monitoring System to monitor your blood glucose level. It is designed to be accurate, easy to use, and quick in response time. This User Manual contains all information needed to operate and maintain JS100 series Blood Glucose Monitoring System. Please read carefully before use.

JS100 series Blood Glucose Meter can be used with:

- JS100 Blood Glucose Test Strip

JS100 series Blood Glucose Monitoring System is for quantitatively measuring glucose (sugar) in whole blood obtained from the fingertip, palm, and forearm; or venous whole blood. It is **Only for use outside the body (For in vitro diagnostic use)** and intended for self-testings at homes and under professional settings to monitor blood glucose levels.

JS100 series Blood Glucose Monitoring System is comprised of JS100, JS100-B, JS200 and JS200-B meter and JS100 Blood Glucose Test Strip. The functions vary by individual model.

# Important Safety Instructions

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## For Home Use

All parts of JS100 series Blood Glucose Monitoring System should be considered potentially infectious and are capable of transmitting blood-borne pathogens. To assure that you are not placing yourself at risk, always remember:

- The meter and lancing device is for single person use. Do NOT share them with anyone including other family members! Do not use on multiple people!
- All parts of the kit are considered to be bio-hazardous and can potentially transmit infectious diseases even after cleaning and disinfection have been performed.

### Reference:

- "CDC: Safe Injection Practices and Your Health" <https://www.cdc.gov/injection-safety/about/index.html>
- "CDC: Considerations for Blood Glucose Monitoring and Insulin Administration" <https://www.cdc.gov/injection-safety/hcp/infection-control/index.html>

## For Professional Use

- Users need to adhere to Standard Precautions when handling or using this device. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting bloodborne pathogens between patients and healthcare professionals. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007", <http://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>
- The meter should be disinfected after use on each patient. This Blood Glucose Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer's disinfection procedures are followed.
- Only auto-disabling, single use lancing devices may be used with this device.
- Cleaning Solution and Disinfecting Solution: Clorox Bleach Germicidal Wipes (Clorox Professional Products Company. EPA Reg. No. 67619-12). Contact Clorox Company at 1-800-537-1415.

## About JS100 series Blood Glucose Monitoring System

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### ***The complete kit contains:***

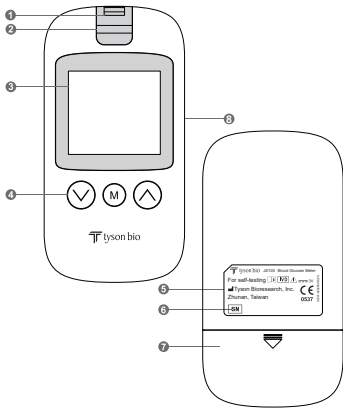
- One JS100 series Blood Glucose Meter (JS100 or JS100-B or JS200 or JS200-B)
- One JS100 Blood Glucose Test Strip vial
- One bottle of JS100 Control Solution
- One lancing device
- Sterile Lancets
- One JS100 series Blood Glucose Monitoring System User Manual
- One JS100 series Blood Glucose Monitoring System Quick Reference Guide
- One JS100 Blood Glucose Test Strip Package Insert
- One JS100 Control Solution Package Insert
- One Lancing Device Package Insert
- One Log Book
- One carrying case




### ***Note:***

***1. 25-strips & 50-strips can be purchased separately.***

***2. The actual composition is marked on the kit box. Some of the listed items above may not be included.***

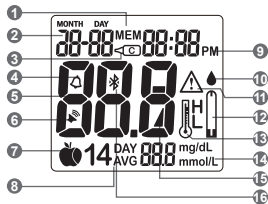
## About JS100 series Blood Glucose Meter



- 1. Test Port** Insert test strip here
- 2. Strip Ejector** Push to eject the test strip
- 3. Display** To display measuring results and information in numbers and icons
- 4.    Button** For the operation of the meter. See more in the further chapter
- 5. Meter Label** Manufacturer information
- 6. Serial Numbers** The meter manufacturer serials
- 7. Battery Cover** To slide open and replace battery
- 8. Data Port**  
*(Only for JS200, JS200-B)* To connect interface cable for data transferring

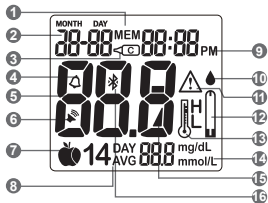
## About JS100 series Blood Glucose Meter Display

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- 1. Memory Icon**  
Appears during memory mode
- 2. Year/Date**  
To display year/date
- 3. Control Solution Icon**  
Appears during a Control Solution test and indicates its result as a Control Solution test result
- 4. Alarm Icon**  
Appears when an alarm is set
- 5. Test Result**  
To display test results
- 6. Buzzer Icon**  
Appears while sound setting
- 7. Meal Flag Icon**  
Pre-meal and post-meal
- 8. 14 day Average**  
The average glucose result calculated from all 14 day test results





### 9. Time

To display time.

### 10. Blood Drop Icon

Flashes when it's ready to perform a test and collect a blood sample.

### 11. Warning Icon

Appears when a result is out of range.

### 12. Test Strip Icon

Appears when the meter is ready for a test.

### 13. Temperature Icon

Appears when the meter exceeds the range of operating temperature.

### 14. Measurement Units

To identify test result units (mg/dL or mmol/L)

### 15. Battery Icon

Appears when battery power is low.

### 16. Bluetooth (only JS100-B, JS200-B)

Bluetooth connection.

## About JS100 Blood Glucose Test Strip

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JS100 Blood Glucose Test Strip is for blood glucose tests in conjunction with JS100 series Blood Glucose Meter.

Each strip can be used ONCE ONLY!

A test strip consists of the following parts

**1. Target Area**

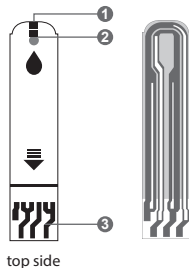
Where a blood drop or control solution is touched

**2. Confirmation Window**

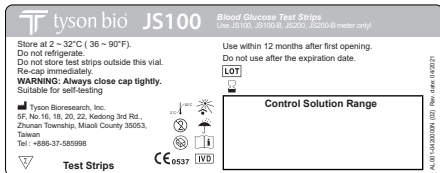
To confirm if sufficient blood drop or control solution has been applied to Target Area

**3. Contact Bar**

The end of the test strip is to be inserted into the test port (top side facing up)



# About JS100 Blood Glucose Test Strip Label



**tyson bio JS100** Blood Glucose Test Strips  
Use JS100, JS100-B, JS200, JS200-B meter only!

Store at 2 ~ 32°C ( 36 ~ 90°F).  
Do not refrigerate.  
Do not store test strips outside this vial.  
Re-cap immediately.  
**WARNING: Always close cap tightly.**  
Suitable for self-testing

Use within 12 months after first opening.  
Do not use after the expiration date.

LOT

Control Solution Range

Tyson Bioresearch, Inc.  
5F, No.16, 18, 20, 22, Kedong 3rd Rd.,  
Zhunan Township, Miaoli County 35053,  
Taiwan  
Tel : +886-37-585998

CE 0537 IVD

AL001-042000FN (02) Rev. date: 04/2021

Test Strips

Test Strip Vial Label



**tyson bio JS100**

Store at 2 ~ 32°C ( 36 ~ 90°F).  
Do not refrigerate.  
Do not store test strips outside this vial.  
Re-cap immediately.  
**WARNING: Always close cap tightly.**  
Suitable for self-testing

Tyson Bioresearch, Inc.  
5F, No.16, 18, 20, 22, Kedong 3rd Rd.,  
Zhunan Township, Miaoli County 35053,  
Taiwan  
Tel : +886-37-585998

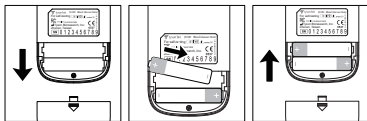
Test Strips

Test Strip Vial

# Setting the JS100 series Blood Glucose Meter

## Installing/Replacing Batteries (Fig.1)

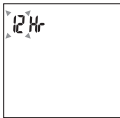
1. From the back of the meter, gently slide and remove the battery cover.
2. Install batteries with the + and – ends matching indication marks on the battery compartment. The meter requires 2 AAA batteries.
3. Slide battery cover back into place.



(Fig.1)

## Setting Date/Time

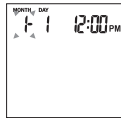
1. When the meter is off, press and hold  $\text{M}$  button for 4 seconds to enter this setting mode.
2. Press  $\text{V}$  or  $\text{A}$  to select "24hr" or "12hr". Press  $\text{M}$  to confirm (Fig.2).
3. The numbers of "year" will appear and flash. Press  $\text{V}$  or  $\text{A}$  to adjust and Press  $\text{M}$  to confirm (Fig.3).
4. The number of "month" will appear and flash. Press  $\text{V}$  or  $\text{A}$  to adjust and press  $\text{M}$  to confirm (Fig.4).



(Fig.2)



(Fig.3)



(Fig.4)

5. The numbers of "day " will appear and flash. Press  $\downarrow$  or  $\uparrow$  to adjust and press  $\text{M}$  to confirm (Fig.5).
6. The numbers of "hour" will appear and flash. Press  $\downarrow$  or  $\uparrow$  to adjust and press  $\text{M}$  to confirm (Fig.6).
7. The numbers of "minute" will appear and flash. Press  $\downarrow$  or  $\uparrow$  to adjust and press  $\text{M}$  to confirm (Fig.7).  
The set date and time will now display on the LCD screen (Fig.8, Fig.9).
8. Press  $\text{M}$  to turn off the meter. The meter date/time setting is complete.



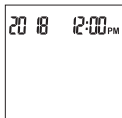
(Fig.5)



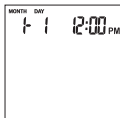
(Fig.6)



(Fig.7)



(Fig.8)



(Fig.9)

## Setting the Reminder Alarms

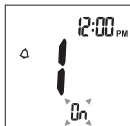
JS100 series Blood Glucose Meter provides 4 reminder alarms.

All reminder alarms are OFF as default. Please follow these steps to setup reminder alarms.

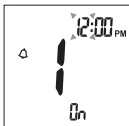
1. When the meter is OFF, press and hold  $\Delta$  button for 4 seconds or longer to enter setting.
2. The first reminder alarm will appear on the display (Fig.10).
3. Press  $\nabla$  or  $\Delta$  to select "ON" or "OFF". If "OFF" is chosen and  $\text{M}$  pressed, the meter will proceed to the next reminder alarm setting. If "ON" is chosen (Fig.11) and  $\text{M}$  pressed, the number of "hour" will start flashing (Fig.12).
4. Press  $\nabla$  or  $\Delta$  to adjust and press  $\text{M}$  to confirm.
5. The numbers of "minutes" will flash (Fig.13). Press  $\nabla$  or  $\Delta$  to adjust and press  $\text{M}$  to confirm. The meter will go to the next reminder alarm setting.
6. Repeat steps 3 to 5 to set the rest of reminder alarms.



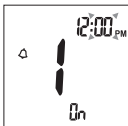
(Fig.10)



(Fig.11)



(Fig.12)

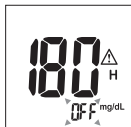


(Fig.13)

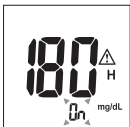
## Setting the HI/LO Alarms

**JS100 series Blood Glucose Meter provides HI/LO alarm.**

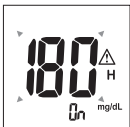
1. After completing the reminder alarm setting, press  $\text{M}$  to enter the setting begin with HI alarm setting.
2. Press  $\text{V}$  or  $\text{A}$  to change the setting to "ON", press  $\text{M}$  to confirm. If "OFF" is chosen, the meter will skip this setting.
3. The HI/LO alarms setting begins with no meal flag and proceed the setting of pre-meal and post-meal.
4. To change the HI alarm setting of no meal flag, press  $\text{V}$  or  $\text{A}$  until you reach your desired value and then press  $\text{M}$  to confirm (Fig.16).
5. To change the LO alarm setting of no meal flag, press  $\text{V}$  or  $\text{A}$  until you reach your desired value and then press  $\text{M}$  to confirm (Fig.19).
6. Repeat steps 4. and 5. to complete HI/LO setting of pre-meal (Fig.20 ~ 25) and post-meal (Fig.26 ~ 31).
7. When the LO alarm setting of post-meal is completed and  $\text{M}$  is pressed, the meter will be turned off.



(Fig.14)



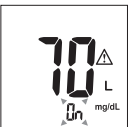
(Fig.15)



(Fig.16)



(Fig.17)



(Fig.18)

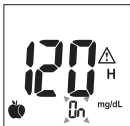


(Fig.19)

**(No meal HI/LO alarm setting)**



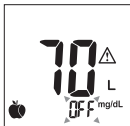
(Fig.20)



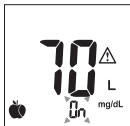
(Fig.21)



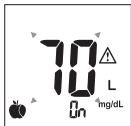
(Fig.22)



(Fig.23)



(Fig.24)



(Fig.25)

**(Pre-meal HI/LO alarm setting)**



(Fig.26)



(Fig.27)



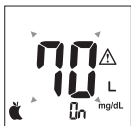
(Fig.28)



(Fig.29)



(Fig.30)



(Fig.31)

**(Post-meal HI/LO alarm setting)**



## ***Meal flag***

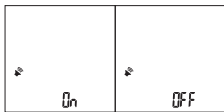
- No meal flag as default
  - HI alarm default value: 180mg/dL (10.0mmol/L)
  - LO alarm default value: 70mg/dL (4.0mmol/L)
- Pre-meal 🍏
  - HI alarm default value: 120mg/dL (6.7mmol/L)
  - LO alarm default value: 70mg/dL (4.0mmol/L)
- Post-meal 🍏
  - HI alarm default value: 180mg/dL (10.0mmol/L)
  - LO alarm default value: 70mg/dL (4.0mmol/L)

***HI alarm setting range: 100 ~ 350mg/dL (5.5 ~ 20.0mmol/L)***

***LO alarm setting range: 40 ~ 90mg/dL (2.0 ~ 5.0mmol/L)***

## Setting the Buzzer and Bluetooth (Bluetooth only for JS100-B, JS200-B)

1. When the meter is turned off, press and hold ⏴ for 4 seconds to enter the setting mode.
2. Buzzer feature is "ON" by default, press ⏴ or ⏵ to change the setting (Fig.32). Press Ⓜ to confirm buzzer setting, if the meter does not have bluetooth function, meter will be turned off. For meter that has bluetooth function, continue to set up bluetooth.
3. Bluetooth feature is "ON" by default, press ⏴ or ⏵ to change the setting (Fig.33). Press Ⓜ to confirm and the meter will be turned off.



(Fig.32)



(Fig.33)

## Important Information

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### ***Before Testing***

- Always keep test strips in the original vial. Tightly close the vial cap immediately after removing a test strip.
- Use each strip immediately after removing it from the vial. Each test strip should be used **ONCE ONLY**.
- Do not use test strips or Control Solution beyond the expiration date printed on the package since this may cause inaccurate results.
- Store your test strips and the meter in a cool, dry place between 2°C and 32°C (36°F and 90°F). Temperatures beyond this range, as well as humidity, can damage test strips and lead to inaccurate results.
- Any change of medications based on the JS100 series Blood Glucose Monitoring System results without advices of a doctor is **NOT RECOMMENDED**.
- The lancing device is intended only for single user and should **NOT** be shared.
- Only JS100 Blood Glucose Test Strips and Control Solution can be used with the JS100 series Blood Glucose Meter.
- For accurate results, testing must be done within the operating temperature range (4 - 40°C/ 39 - 104°F). If the meter is moved to an area appropriate conditions from where is out of operating temperature range, place the meter for 30 minutes before conducting the testing.

### ***Test Principle***

On each test strip there is a test area containing reaction chemicals. When blood is applied to this area, a chemical reaction takes place, then a transient electrical current is formed. The blood glucose concentration is calculated based on the electrical current detected by the meter, then the result is showed on the display. The test measures glucose from 10 mg/dL (0.56mmol/L) to 630 mg/dL (35.0mmol/L). The JS100 Test Strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

## Control Solution

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The Control Solution is to ensure that JS100 series Blood Glucose Meter is working properly and the user is performing a test correctly.

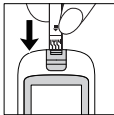
### ***When to Perform a Control Solution Test***

1. You get your meter for the first time before testing your blood test.
2. You open a new vial of test strips.
3. You want to check the meter and strips.
4. You suspect that the meter or test strips are not working properly.
5. Your blood glucose test results are not consistent with how you feel.
6. You think your test result does not accurate.
7. You dropped your meter.
8. Whenever your healthcare professional recommends it.

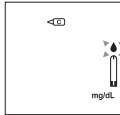
***Note: For more information regarding the Control Solution, please read the Control Solution package insert.***

## Performing a Control Solution Test

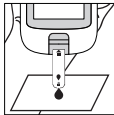
1. Prepare a vial of JS100 Blood Glucose Test Strip within the expired date and a JS100 series Blood Glucose Meter.
2. Be sure of the JS100 series Blood Glucose Meter, JS100 Blood Glucose Test Strip and Control Solution are at room temperature between 4°C ~ 40°C (39°F ~ 104°F) before testing.
3. Insert a JS100 Blood Glucose Test Strip, into the test port. The meter will be automatically turned ON (Fig.34).
4. When test strip is inserted, a beep will sound if the buzzer is turned on and the system checking will appear followed by a flashing "▲" icon (Fig.35).
5. Press and hold (M) button for 2 seconds to change to the Control Solution test mode. "◀C" will appear on the display. If (M) button is pressed again for 2 seconds, the meter will switch back to the normal testing mode.
6. Shake the Control Solution gently. Discard the first drop of the Control Solution and squeeze a small drop on a clean nonabsorbent surface such as a clean piece of wax paper (Fig.36). Do not apply the Control Solution to the test strip directly from the bottle, as contamination may occur.
7. Introduce the tip of the test strip to the droplet of the Control Solution. The Control Solution is automatically drawn into the strip. Hold until the meter beeps. The meter will now start to count down and the Control Solution test result will appear on the LCD screen (Fig.37).



(Fig.34)



(Fig.35)



(Fig.36)



(Fig.37)

**Caution: If your room temperature is not between 4°C ~ 40°C (39°F ~ 104°F), the Control Solution Test Result will be incorrect.**

## **Control Solution Results**

The JS100 series Blood Glucose Meter is functioning correctly only if the Control Solution test result is within the specified range printed on the test strip vial. If the test result is out of range, please repeat the test.

Out of range result may be caused by:

- Incorrect steps taken in performing the test
- The Control Solution temperature is lower than 4°C(39°F) or higher than 40°C(104°F)
- Expired or contaminated Control Solution
- Expired or contaminated test strips
- Meter malfunction

### **Note:**





- ***The result will not be included in day average calculation when the JS100 series Blood Glucose Meter is set in the Control Solution test mode.***
- ***DO NOT use JS100 series Blood Glucose Meter if the problem persists. Please contact customer service immediately.***

## Preparing Test Strip

### **Before testing, you need the following items:**

- JS100 series Blood Glucose Meter
- JS100 Blood Glucose Test Strip
- Lancing device and sterile lancet

### **Preparing the Test Strip**

1. Wash hands using soap and warm water. Rinse and dry thoroughly (Fig.38).
2. Please remove protective wrap completely before opening the vial.
3. Check the use by date on the test strip vial, use only test strips which are within the use by date.  
Take a test strip from the vial and re-cap the vial immediately (Fig.39).
4. Insert the test strip, top side facing up into the test port. The meter will automatically turn on (Fig.40).
5. System checking will appear (Fig.41).
6. A beep will sound, you can press  or  to select the meal flag for marking the test as Pre-meal test  , post-meal test  , or no meal flag (default) (Fig.42) .
7. A blood sample can now be obtained (refer to P.22).



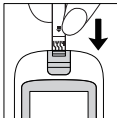
(Fig.38)



(Fig.39)



(Fig.40)



(Fig.41)

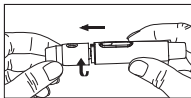


(Fig.42)

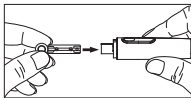
## Preparing the Lancing Device and Obtaining a Blood Sample

---

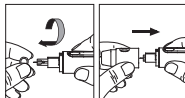
1. Hold the depth adjustable cap in one hand and hold hub in the other hand, twist off the depth adjustable cap (Fig.43).
2. Insert a new disposable lancet firmly into the lancet holder (Fig.44).
3. Twist off and set aside the protective cover of the disposable lancet (Fig.45).
4. Replace the depth adjustable cap (Fig.45).
5. Select a depth of penetration by rotating the top portion of the depth adjustable cap until the number matched to the window (Fig.46).



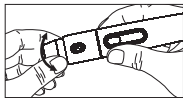
(Fig.43)



(Fig.44)



(Fig.45)

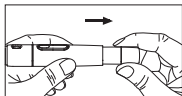


(Fig.46)

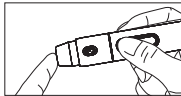


6. Hold the hub in one hand and pull on the plunger in the other hand. The device will be cocked. Release the plunger; it will go back to its original position near the hub (Fig.47).
7. Place the lancing device against the soft side into fingertip, press the release button. The better puncture sites are on the middle or ring fingers (Fig.48).
8. Squeeze a small drop of whole blood to apply (Fig.49).

For further instructions please see the insert provided with the lancing device.



(Fig.47)



(Fig.48)



(Fig.49)


**CAUTION:**

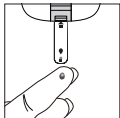
**To reduce chances of infection:**

- **Lancets are for single usage only.**
- **Wash hands thoroughly with soap and water before and after handling the meter, lancing device, and test strips.**
- **Please refer to section "Cleaning and Disinfection Procedure" (refer to P.37) for detail instructions of meter maintenance.**

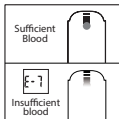
## Applying a Blood Sample to the Test Strip to perform a test

### SAMPLE MAY BE OBTAINED FROM FINGER, PALM OR FOREARM

1. Introduce the tip of the test strip to the drop of blood. Blood sample will be automatically drawn into the test strip (Fig.50). Discard the first drop of blood sample to prevent contamination.
2. Hold the tip of the test strip touching the blood drop until the meter beeps.
3. If applying insufficient blood sample, the error code (E-7) will appear on the display (Fig.51).
4. The meter will start to countdown as soon as the blood has completely filled the confirmation window of the test strip. The test result will appear on the display in 5 seconds (Fig.52). The result will be showed and stored into the meter memory automatically (Fig.53).
5. After the test strip is ejected, the meter will automatically turn off after 1 minute or the meter can be turned off immediately when  is pressed.
6. If the test strip is not ejected after test, the meter will automatically turn off after 2 minutes.



(Fig.50)



(Fig.51)



(Fig.52)

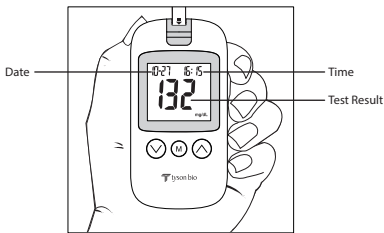


(Fig.53)

## Test Results

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1. The JS100 series Blood Glucose Meter displays the test result.
2. The LCD of the meter shows the measuring result, the date and the time (Fig.54)



(Fig.54)

### **Normal Glucose Values**

The glycemic recommendations for nonpregnant adults with diabetes:  
Preprandial capillary plasma glucose: 80 ~130 mg/dL (4.4 ~ 7.2 mmol/L)  
Peak postprandial capillary plasma glucose: 180 mg/dL (10.0 mmol/L)  
Diabetic patients may have blood glucose values that are moderately elevated.

## Ejecting the used Test Strip and Disposing of the Used Lancet

---

### Ejecting the used Test Strip

1. After completing the test, push the strip ejector (Fig.55) or use a tissue paper to remove the test strip.

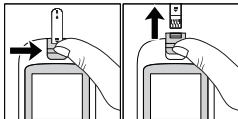
### To unload the lancing device

1. After sampling, carefully remove the cap containing the used lancet (Fig.56).

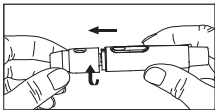
2. Push the exposed tip of the lancet into its Protective Cap (Fig.57).

3. Hold the hub with one hand and push the plunger by thumb to eject the used disposable lancet in appropriate container (Fig.58).

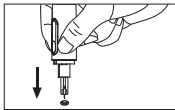
For further instructions please see the insert provided with the lancing device.



(Fig.55)



(Fig.56)



(Fig.57)



(Fig.58)

### Warning:

- **DO NOT point the test strip at anyone when ejecting.**
- **Used lancets and test strips are considered bio-hazardous. Dispose of used lancets and test strips in a clinical waste container**

## About Blood Lancets

---

### Intended Use:

The Blood lancets is intended for capillary blood sampling in order to obtain a small blood sample for various tests. It is designed for use by both healthcare professionals and lay users, providing a safe and convenient method for blood specimen collection in clinical and home healthcare settings.

### Contraindication:

Use with caution in individuals with coagulation mechanism disorders.

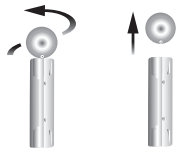
### Product main structure:

The Blood Lancets primarily consists of lancet body, needle and cap.

### Instructions for use:

1. Wash hands with soap and warm water. Dry thoroughly.
2. Insert a new blood lancet into the lancet holder of lancing device.
3. Remove lancet cover (steps 1 & 2).
4. Consult the instructions for use of your lancing device.
5. Select a fingertip site, and proceed to puncture the skin.
6. After use, discard the used lancet in appropriate container.
7. Wash hands with soap and warm water again.

**Wear gloves if use in healthcare facilities.**



1. Twist Cap

2. Pull Cap

**Precautions and cautions:**

- Please read the instructions before use.
- Check the package before use. Do not use it if the package is damaged.
- Do not reuse lancets.
- Do not store in Lancing Devices.
- For use only on a single patient.
- It is forbidden to use after the expiration date
- Discard the entire device to biohazard container after use.
- Used Lancets should be treated as sharps waste and/or medical waste and disposed of properly following

**Warning:**

- ***Not intended for more than one use. Do not use on more than one patient.***
- ***Improper use of blood lancets can increase the risk of inadvertent transmission of blood borne pathogens, particularly in settings where multiple patients are tested.***
- ***The expiration time is 5 years. Using the product beyond the expiration date is strictly prohibited.***
- ***For single use only. Do not use more than one patient. The device is deactivated after a single use, cannot be used more than once.***
- ***The product has no therapeutic or diagnostic function.***
- ***If the lancet's protective cap is damaged or lost, please do not use it.***
- ***Use with caution for those with coagulation mechanism disorders.***
- ***For obese users or individuals who require larger blood volumes, it is recommended to choose products with a smaller "G" value or large puncture depth for blood collection.***

**Shelf life:** Valid period of product is 5 years.

**Storage and Transportation:**

1. The device shall be stored at an environment where the temperature is between -20 ° C and 40 ° C and the relative humidity of less than 80%. The storage environment shall be free of corrosive gases, dry, away from sunlight, well-ventilated, and clean.

2. The device shall be handled with care during transportation and handling.

**Clinical benefit:**

Help medical staff and patients complete capillary blood sampling in order to obtain a small blood sample for various tests.

**Adverse events:**

We searched for adverse events and state of the art literature on equivalent and similar devices in the market, and found no adverse events for equivalent and similar products. The products comply with the current technical standard. The product has been sold in the market and no adverse events have been found so far. Therefore, product safety and efficacy have not been affected. If any adverse events occur during the use of the product, please contact us and we will resolve the relevant issues as soon as possible.

## HI and LO Readings

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JS100 series Blood Glucose Meter is designed to display test results between 10 ~ 630 mg/dL (0.56 ~ 35.0mmol/L). If a "HI" (Fig.59) or a "LO" (Fig.60) message appears on the display, it indicates that the meter has detected a blood glucose level is higher than 630 mg/dL (35.0 mmol/L) or lower than 10 mg/dL (0.56 mmol/L). It is suggested the testing procedure should be reviewed and the test should be repeated using a new test strip to confirm the result again.



(Fig.59)

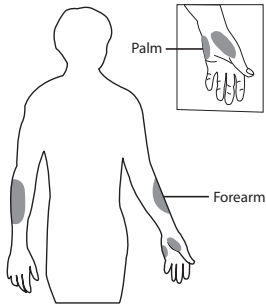


(Fig.60)



## Available Alternate Sites Testing

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There are limitations for doing AST. Please consult your healthcare professional before you do AST.

### **Palm and Forearm**

JS100 series Blood Glucose Monitoring System provides you alternate sites testing (AST). This system provides you to test on the palm and the forearm with the equivalent results to fingertip testing.

#### **Caution:**

***Physiological differences in the circulation between the finger and other test sites like the forearm and palm may result in differences in blood glucose measurements from the other test sites and your fingertips. Changes in blood glucose may be observed in finger blood samples sooner than blood samples from the forearm and other alternate sites. Rub the alternate test sites about 20 seconds before lancing. If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingertips.***

***Talk to your doctor to see if alternate site testing is right for you. With a little bit of education, you can give your fingertips a rest and maybe test more often than you do now. For people with diabetes, more frequent testing is a good thing. Just remember: any time you want to be sure of an accurate, up-to-date blood glucose reading, test on your fingertip. We strongly recommend you do.***

AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

DO NOT use AST if:

- You think your blood glucose is low.
- You are unaware of hypoglycemia.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.
- You are pregnant.

## Memory Features

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How to view glucose and control solution results stored in the memory

1. When the meter is off, press **M** button to turn on the meter. The Date and Time are displayed on the top of the screen. Year and Month-Day appear alternately.
2. Press **⏪** to view previous results. "MEM" icon will be displayed on the top center area (Fig.61). When "**👁**" is appearing under "MEM", this result stands for control solution test (Fig.62). Initially, the "year" will be display on the top left corner (Fig.63). After 1 second "month-day" will then be displayed on the top left corner and "time" will be displayed on the top right corner (Fig.64). The most recent memory results will be displayed first.
3. You can press **⏩** or **⏪** to scroll forwards and backwards through the results.
4. Press **M** button to exit the stored test results or the meter will be shut off automatically after 2 minutes without any action.



(Fig.61)



(Fig.62)



(Fig.63)



(Fig.64)

How to view "the latest" control solution test result in the memory

1. When the meter is off, press (M) button to turn on the meter.
2. Press (M) button again, and the latest control solution test result will be displayed (Fig.65).
3. Press (M) button to turn off the meter or the meter will be shut off automatically after 2 minutes without any action.



(Fig.65)

**Note:**

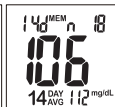
1. A result with  $\text{H}$  or  $\text{L}$  symbol indicates that the reading was taken out of the meter's specified operating temperature range and may not be accurate. This value is excluded from the average glucose result calculated from 7/14/30 day test results.

## View Time Period Results

1. Press  $\text{M}$  to turn the meter on, then Press  $\text{A}$  button to view time period results.
2. 7/14/30 day average glucose results marked with a no meal  $\text{A}$  / post-meal  $\text{B}$  and will be displayed on screen in sequence when is  $\text{A}$  pressed (Fig.66 ~ 74).
3. When the meter displays 7 days with no meal status assigned, press  $\text{B}$  button and the meter will then change to view stored test results in memory.
4. Press  $\text{M}$  button to turn off the meter or the meter will be shut off automatically after 2 minutes without any action.



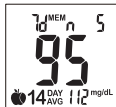
(Fig.66)



(Fig.67)



(Fig.68)



(Fig.69)



(Fig.70)



(Fig.71)



(Fig.72)



(Fig.73)



(Fig.74)



1. Time period
2. Meal flag (no meal / pre-meal 🍏 / post-meal 🍏)
3. The number of glucose results used in calculation
4. The average calculated based on day average (upper left), number of results (upper right), meal flag (lower left).
5. The average glucose result calculated from all 14 day test results

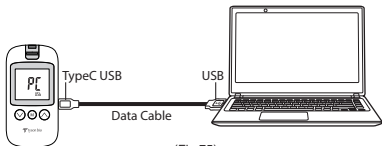
**Note:**

**1. The consecutive 7/14/30 day average glucose result is calculated from the test results obtained during the last consecutive 7/14/30 day periods.**

## Transfer Test Results to a Computer (Only JS200, JS200-B)

You can use software "Tyson Bio PC Link" to transfer test results to your personal computer. Obtain the required software and data cable separately. For order information please call Customer Service or visit website of [www.tysonbio.com](http://www.tysonbio.com)

1. Tyson Bio PC Link can be downloaded from [www.tysonbio.com](http://www.tysonbio.com)
2. Follow the instructions provided with software to install the software into your personal computer.
3. Connect the data cable to a data port on your computer while the meter is off(Fig.75).
4. Connect the other end of data cable to the data port of the meter(Fig.75).
5. The word "PC" will appear on the display indicates that the meter is now in the communication mode (Fig.76).



(Fig.75)



(Fig.76)

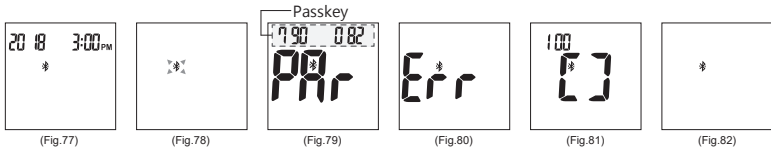
## Bluetooth Data Transfer (Only JS100-B, JS200-B)

### To Transfer Memory Data

1. Press **M** to turn on the meter (Fig.77).
2. Hold **M** for 4 seconds to enter Bluetooth mode. **✳** will flash when meter is not connected with a mobile device (Fig.78).
3. Turn on Bluetooth, and BLE tool APP (with Blood Glucose Test) on your mobile device.
4. Select the device shown (ex.Tysonbio-M23ZG000001; note: 23 stands for year 2023) in APP list and click "Connect", **✳** stops blinking when the meter and mobile device is connected. Meter will be paired with the device that is connected first time.

The passkey will be shown on the meter (Fig.79), please enter passkey on your device. If the passkey is not entered correctly, error code (Err) will appear on the display (Fig.80).

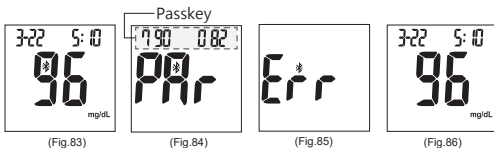
5. Press the button on APP to transfer data. The frame will display while data are being transferred (Fig.81).  
When data are completely transmitted to device, the frame will disappear (Fig.82).





## To Transfer Single Test Data

1. Refer to strip test process (p.21) to proceed the test (Fig.83).
2. Turn on BLE tool APP (with Blood Glucose Test) and Bluetooth on your mobile device after test is completed.
3. Select the device shown (ex.Tysonbio-M23ZG000001; note: 23 stands for year 2023) in APP list and click connect, \* stops blinking when the meter and mobile device is connected. Meter will be paired with the device that is connected first time. The passkey will be shown on the meter (Fig.84), enter passkey on your device. If the passkey is not entered correctly, error code (Err) will appear on the display (Fig.85).
4. Test result will automatically transmit to the APP, \* will disappear (Fig.86).



### Note:

1. If bluetooth setting is switched off before single test data is transmitted, press **(M)** for 4 seconds to turn the bluetooth on, \* will appear. After data is transmitted, bluetooth setting will turn to "OFF" as it was.
2. If it is not the first time your mobile device to connect with the meter, then the pair process is not required. Your device will connect with bluetooth meter directly.

## Cleaning and Disinfection Procedure

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### ***General Cleaning***

- Switch the meter off.
- Use a soft cloth moistened with water or a mild detergent, gently wipe the meter surface.
- Please avoid using alcohol or organic solvents in cleaning.
- Do not immerse the meter in water when cleaning. Do not allow water or cleaning fluids into the meter, test port, and data port.

### ***Professional Disinfection***

- Switch the meter off.
- The following product has been approved for cleaning and disinfecting the meter: Clorox Bleach Germicidal Wipes ( Clorox Professional Products Company. EPA Reg. No. 67619-12 ).
- Personal Protection: Sanitize hands, then put on gloves before removing a germicidal wipe from the canister. When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings.
- Thoroughly wipe the exterior of the meter, allow the surface to stay wet for 1 minute then allow to air dry.
- Disposal of Infectious Materials: Use disposable gloves. Never reuse or re-wet a disposable wipe. Disposing infectious waste according to local regulations.
- Please refer to the Clorox Bleach Germicidal Wipes detailed usage instructions.

## Meter Care

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Please handle the meter with care. Dropping the meter may result in damage.

The meter should be stored in a dry and clean area. **DO NOT STORE IN DIRECT SUNLIGHT OR AREAS WITH HIGH HUMIDITY AND/OR DUST.**






It is advised that you store all parts of JS100 series Blood Glucose Monitoring System in the carrying case provided.

## Meter Transportation and Storage

---

- Transport and store at temperature  $-20^{\circ}\text{C} \sim 50^{\circ}\text{C}$  ( $-4^{\circ}\text{F} \sim 122^{\circ}\text{F}$ ), Less than 90% RH
- Precision instrument, do not crash when being transported.

## Display Messages

<i>Display</i>	<i>Description</i>	<i>Action</i>
	 appears when the result is HIGHER than the "HI" alert setting.	The default setting is 180 mg/dL (10.0 mmol/L) and it can be changed according to 《Setting the HI/LO Alarms》
	 appears when the result is LOWER than the "LO" alert setting.	The default setting is 70 mg/dL (4.0 mmol/L) and it can be changed according to 《Setting the HI/LO Alarms》
	Test result is HIGHER than 630 mg/dL (35.0 mmol/L).	Repeat the test by using a new test strip. If the same message displays again, the result is confirmed to be higher than the meter operating range. Please consult your healthcare professional immediately for further advice.

## Display

## Description

## Action



Test result is LOWER than 10 mg/dL (0.56 mmol/L).

Repeat the test by using a new test strip. If the same message displays again, the result is confirmed to be lower than the meter operating range. Please consult your healthcare professional immediately for further advice.



Temperature exceeds the maximum operating temperature. (40°C/104°F)

Large variation may occur between results due to high or low temperature. Move to an environment (4°C ~ 40°C or 40°F ~ 104°F) and wait for 30 minutes before re-testing.



Temperature is under the minimum operating temperature. (4°C/39°F)

Large variation may occur between results due to high or low temperature. Move to an environment (4°C ~ 40°C or 40°F ~ 104°F) and wait for 30 minutes before re-testing.



The preset alarm is ringing to remind the user that it is time to perform a blood glucose test.

Please press any button to turn off the alarm or wait for the alarm to be turned off automatically in 30 seconds.

### ***Display***

### ***Description***

### ***Action***






1. Battery power is low, icon flashes for 10 seconds. Meter can work normally but will only provide approximately 10 more measurements.
2. Battery is depleted, icon flashes continuously with 3 short beeps. Meter will be shutdown in 10 seconds.

Replace with 2 AAA batteries.

## Error Messages

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<i>Display</i>	<i>Description</i>	<i>Action</i>
	Temperature is TOO HIGH to perform a test.	Move to an environment (4°C ~ 40°C or 39°F ~ 104°F) and wait for 30 minutes before re-testing.
	Temperature is TOO LOW to perform a test.	Move to an environment (4°C ~ 40°C or 39°F ~ 104°F) and wait for 30 minutes before re-testing.
	An error message indicates a problem with the test strip.	Please review the instructions and try again with a new test strip. If the problem persists, please contact customer service.

### ***Display***

### ***Description***

### ***Action***



An error message indicates a problem with the test strip or meter.

Please review the instructions and try again with a new test strip. If the problem persists, please contact customer service.



An error message indicates a problem with the meter.

Please remove batteries and wait for 1 minute, reinstall batteries to see if meter is working properly. If the problem persists, please contact customer service.



An error message indicates a problem with the test strip.

Please review the instructions and try again with a new test strip. If the problem persists, please contact customer service.



An error message indicates a problem with the meter.

Please remove batteries and wait for 1 minute, reinstall batteries to see if meter is working properly. If the problem persists, please contact customer service.



**Display****Description****Action**

An error message indicates a problem with the test strip.

Please review the instructions and try again with a new test strip. If the problem persists, please contact customer service.



An error message indicates insufficient volume of blood sample for the test.

Review the instructions and try again with a new test strip, then applying a sufficient blood sample to the test strip. Please contact customer service if the problem persists.



An error message indicates a problem with the meter.

Please remove batteries and wait for 1 minute, reinstall batteries to see if meter is working properly. If the problem persists, please contact customer service.

**For JS100-B, JS200-B only**

1. Incorrect bluetooth pairing passkey.
2. No passkey is entered in 30 seconds.

Please check passkey shown on the meter and enter it on your device.

## Trouble Shooting

---

### *Other problems which may occur*

### *Action*

A test strip has not been inserted into the meter properly.

Review the instructions and re-insert a test strip correctly.

Defective test strip.

Replace with a new test strip.

A test strip remains in the test port for more than 2 minutes before testing.

Review the instructions and re-insert a test strip correctly.

LCD display on the meter is blank when trying to perform a test.

Please contact customer services for assistance.

The meter does not function after new batteries are installed.

Please remove batteries and wait for 1 minute, reinstall batteries to see if meter is working properly.

## Specifications

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Operation Temperature	4°C ~ 40°C (39°F ~ 104°F)
Operation Humidity	10 ~ 90% RH
Hematocrit	0 ~ 70%
Test Sample	Venous and Capillary Whole Blood (fingertip, palm, forearm)
Sample Volume	0.5 µL
Measuring Unit	mg/dL or mmol/L
Measuring Range	10 ~ 630 mg/dL (0.56 ~ 35.0 mmol/L)
Test Time	5 seconds countdown
Memory Capacity	500 most recent results

External Output	TypeC USB (only JS200, JS200-B) Bluetooth (only JS100-B, JS200-B)
Average	7/14/30 days average glucose results
Power supply	2 AAA batteries
Battery Life	Approximately 1000 tests
Dimension	108L x 55W x 17H mm
Weight	60 g without batteries

***Note: Please refer to the Test Strip Insert for the performance of system accuracy and precision.***

Electromagnetic Compatibility








This Meter meets the electromagnetic compatibility requirements as per EN 61326-1 and EN 61326-2-6.

***Caution: Strong electromagnetic fields may interfere with the proper operation of the meter.  
Do not use the meter close to sources of strong electromagnetic radiation.***

## Tolerance summary of interference substance

Interfering substance	The max toleration concentration in the evaluation	Interfering substance	The max toleration concentration in the evaluation
Acetaminophen	4.25 mg/dL	Methyldopa	3.0 mg/dL
Ascorbate (Ascorbic acid)	3.0 mg/dL	Pralidoxime iodide (PAM)	5.0 mg/dL
Bilirubin	25.0 mg/dL	Salicylate	500.0 µg/mL
Cholesterol	1200.0 mg/dL	Tetracycline	5.0 mg/dL
Creatinine	10.0 mg/dL	Tolbutamide	100 mg/dL
Dopamine	2.0 mg/dL	Tolazamide	6.0 mg/dL
EDTA	200.0 mg/dL	Triglycerides	1525.0 mg/dL
Galactose	500.0 mg/dL	Urate(Uric acid)	8.0 mg/dL
Gentisic acid	2.5 mg/dL	Xylose	5.0 mg/dL
Glutathione	100.0 µmol/L	Sodium Carbonate	37.5 mEq/L
Haemoglobin-HUMAN	3.0 g/dL	Mannitol	0.09 mg/dL
Heparin	5.0 IU/mL	Sorbitol	0.09 mg/dL
Ibuprofen	500.0 µg/mL	Xylitol	0.09 mg/dL
Icodextrin	750.0 mg/dL	Isomalt	0.09 mg/dL
L-DOPA(L-3,4-dihydroxyphenylalanine)	5.0 µg/mL	Lactitol	0.09 mg/dL
Maltose	2575 mg/dL	Maltitol	0.09 mg/dL
		Hydrogenated starch hydrolysates (HSH)	0.09 mg/dL

## Icon Description

 Authorised Representative in the European Community	 Single sterile barrier system
 Do not use if package is damaged	 Manufacturer
 Temperature limitation	 In vitro diagnostic medical device
 Batch code	 Consult instructions for use
 Use by	 Sufficient for
 Keep dry	 Catalogue number
 Do not reuse	 Keep away from sunlight
 Serial Number	 Control
 Manufacturing Date	 Caution
	 Sterile
	 Unique device identifier
	 Non-pyrogenic
	 Sterilized using irradiation
	 Humidity limitation
	 The CE marking
	 Medical device
	 Importer

## Limitations of the Procedure

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### Caution:

- JS100 series Blood Glucose Monitoring System is designed for *in vitro* diagnostic use only and is not intended to test on neonate.
- Any change or administer of medication based on the JS100 series blood glucose test results without the consent advice of a physician or healthcare professional is not recommended.
- The JS100 Blood Glucose Test Strip are designed for use with fresh venous whole blood or capillary whole blood samples obtained from the fingertip, palm and forearm. DO NOT use samples other than venous whole blood or capillary whole blood.
- False results may occur when performing the test while severely dehydrated, severely hypotensive, in shock or in a hyperglycemic-hyperosmolar state. If you believe you are suffering from any of the above symptoms, consult a healthcare professional immediately.
- Please refer to JS100 Blood Glucose Test Strip Package Insert to access further information on strip limitations.

## Service and Warranty

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### **IMPORTANT**

- The JS100 series Blood Glucose Meter, JS100 Blood Glucose Test Strip and Control Solution are in conformity with the IVDD 98/79/EC.
- JS100 series Blood Glucose Monitoring System manufacturer warranty is valid only when used properly within the guidelines of this User Manual provided.
- The Lancing device and Lancets are in conformity with the MDR (EU) 2017/745.


### **Manufacturer Warranty**

- Tyson Bioresearch Inc. offers 3 years guarantee on this product. Our company shall repair or replace any JS100 series Blood Glucose Monitoring System found defective with a new one.
- This warranty does not apply to the performance of a JS100 series Blood Glucose Monitoring System that has been accidentally damaged, altered, misused, tampered with or abused in anyway. In no event shall our company be liable to the purchaser or any other person for any incidental, consequential, or punitive damages arising from or in anyway connected with the purchase or operation of JS100 series Blood Glucose Monitoring System.
- For manufacturer warranty services, purchaser must contact Tyson Bioresearch Inc. for help.



### ***Manufacturer of Blood Glucose Meter, Test Strip and Control Solution***

 Tyson Bioresearch, Inc.  
 5F., No. 16, 18, 20, 22, Kedong 3rd Rd., Zhunan Township, Miaoli County 35053, Taiwan  
 +886-37-585998  www.tysonbio.com

Customer Service  
 +886-37-585998 (GMT+8, 8:30 ~ 17:30, Monday ~ Friday)


  Medical Device Safety Service GmbH Schiffgraben 41, 30175 Hannover, Germany

When you call our customer service, please have your JS100 series Blood Glucose Meter, JS100 Blood Glucose Test Strips and all other system supplies available. This will allow us to answer your questions with speed and efficiency.

### ***Manufacturer of Lancet and Lancing Device***

 Shandong Lianfa Medical Plastic Products Co., Ltd.  
 No.1 Shuangshan Sanjian Road 250200 Zhangqiu City, Jinan, Shandong PEOPLE'S REPUBLIC OF CHINA

  Linkfar Healthcare GmbH Niederrheinstraße 71, 40474 Düsseldorf, Germany

 SteriLance Medical (Suzhou) Inc.  
 No.168 PuTuoShan Road, New District, 215153 Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

  Emergo Europe B.V. Westervoortsedijk 60, 6827 AT Arnhem, THE NETHERLANDS

 MEDIFUN CORPORATION  
 4F-1, 4F-9, 4F-10, No. 99, Jingke S. Rd., Nantun Dist. Taichung City 408, TAIWAN (R.O.C)

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