



GLUCOSE
Monitoring System

HS100-B Blood Glucose Monitoring System

User Manual



Limitations

The Tyson Bio HS100-B Blood Glucose Test Strips give accurate results when the following limitations are observed.

- Use only capillary whole blood from finger, palm, and forearm.
- Do not use for testing neonatal blood.
- Altitude higher than 10745 feet may cause inaccurate results.
- Severe dehydration and excessive water loss may lead to inaccurate blood glucose test results.
Consult your physician immediately if you believe you are suffering from severe dehydration.
- For single-patient use only and should not be shared.
- Should not be used to test critically ill patients.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- For In vitro diagnostic only.
- For over the counter use.
- Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly).
- Alternative site measurements should never be used to calibrate continuous glucose monitors (CGMs).
- Alternative site measurements should never be used for insulin dosing calculations.

Warning

- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.
- Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Table of Content

Limitations

Introduction	01
Important Safety Instructions	02
About Tyson Bio HS100-B Blood Glucose Monitoring System	03
About Tyson Bio HS100-B Blood Glucose Meter	04
About Tyson Bio HS100-B Blood Glucose Meter Display	05
About Tyson Bio HS100-B Blood Glucose Test Strip	07
About Tyson Bio HS100-B Blood Glucose Test Strip Label	08
Setting Up Tyson Bio HS100-B Blood Glucose Meter	09
Installing/Replacing Batteries	09
Date/Time Setup	10
Reminder Alarms Setup	11
HI/LO Alarms Setup	12
Important Information	13
Using Tyson Bio HS100-B Blood Glucose Test Strip	14
Obtaining a Blood Sample	15
Applying a Blood Sample	17
HI and LO Readings	19

Table of Content

Available Alternate Sites Testing	20
Control Solution	21
Performing a Control Solution Test	21
Control Solution Results	23
Memory Features	24
View Day Average Results	26
Bluetooth Data Transfer	28
Cleaning and Disinfection Procedure	29
Care and Storage	32
Display Messages	33
Error Messages	36
Trouble Shooting	39
Specifications	40
Meter Storage	42
Icon Description	42
Service and Warranty	43
Federal Communications Commission Interference Statement	44
RF Exposure Warning	45

Introduction

Thank you for choosing Tyson Bio HS100-B Blood Glucose Monitoring System to monitor your blood glucose (sugar) level.

It is accurate, easy to use, and quick in response time. This User Manual contains all information needed to operate and maintain Tyson Bio HS100-B Blood Glucose Monitoring System. Please read carefully before use.

Tyson Bio HS100-B Blood Glucose meter can be used with:

- Tyson Bio HS100-B Blood Glucose Test Strip

Intended Use Statement

The Tyson Bio HS100-B Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternate site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use).

It is intended for self-testing by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis of or screening for diabetes or for neonatal use.

The Tyson Bio HS100-B Blood Glucose Monitoring System is comprised of the Tyson Bio HS100-B Blood Glucose Meter and Tyson Bio HS100-B Blood Glucose Test Strip.

Important Safety Instructions

- All parts of the system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals.
- **The meter and lancing device are for single person use. Do NOT share them with anyone including other family members!**
- **All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.**
- Cleaning Solution and Disinfecting Solution: Clorox Bleach Germicidal Wipes (Clorox Professional Products Company. EPA Reg. No. 67619-12).

Reference:

- "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm234889.htm>
- "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood-borne Pathogens" (2010) <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>
- "CDC: Infection Prevention during Blood Glucose Monitoring and Insulin Administration" (2010) <https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>

About Tyson Bio HS100-B Blood Glucose Monitoring System

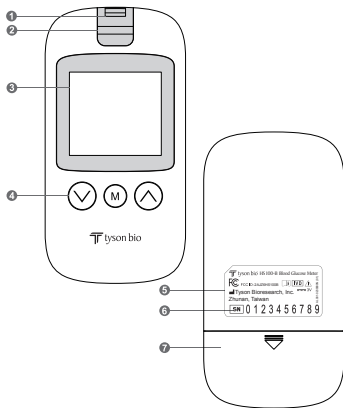
The complete kit contains:

- HS100-B Blood Glucose Meter
- HS100-B Blood Glucose Test Strip
- HS100-B Control Solution Level 2
- Adjustable Lancing Device
- Sterile Lancets
- User Manual
- Quick Reference Guide
- Test Strip Package Insert
- Control Solution Package Insert
- Log Book
- Carrying case

Note: 25-strips & 50-strips are sold separately.

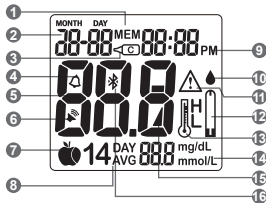
The actual composition is marked on the box. Some of items may not be included.

About Tyson Bio HS100-B 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 |

About Tyson Bio HS100-B Blood Glucose Meter Display



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

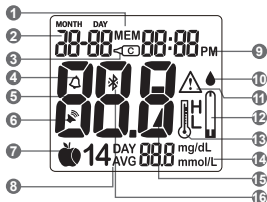
Appears while sound setting

7. Meal Indicator Icon

Pre-meal and post-meal

8. 14 day Average

14 day average result



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)

15. Battery Icon

Appears when battery power is low.

16. Bluetooth

Bluetooth connection.

Note:

The mg/dL is the standard unit in the United States. Meters used in the United States must be set to read in mg/dL.

About Tyson Bio HS100-B Blood Glucose Test Strip

Tyson Bio HS100-B Blood Glucose Test Strip is only for Tyson Bio HS100-B Blood Glucose Meter.

Use each strip **ONCE ONLY!**

A test strip consists of the following parts:

1. Target Area

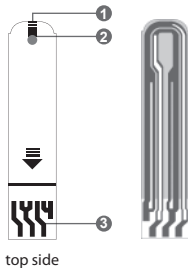
Where a blood drop or control solution to be applied

2. Confirmation Window


To confirm sufficient blood sample and control solution

3. Contact Bar


To be inserted into the test port and to activate the meter (top side up)










About Tyson Bio HS100-B Blood Glucose Test Strip Label


 tyson bio HS100-B *Blood Glucose Test Strips*

Store at 39 ~ 86°F (4 ~ 30°C), 10~90% RH.
Do not refrigerate.
Do not store test strips outside this vial.
Re-cap immediately.
WARNING: Always close cap tightly.
For testing of glucose in capillary whole blood.

 Tyson Bioresearch, Inc.
5F., No. 16, 18, 20, 22, Kedong 3rd Rd.,
Zhunan Township, Miaoli County 35053,
Taiwan
Tel: +886-37-585998
Customer Service
U.S.A. +1-800-948-3894


 **50 Test Strips**

Use within 6 months after first opening.
Do not use past the expiration date.
Use Tyson Bio HS100-B meter only !
LOT H8T121205
 **2018-12-25**


Control Solution Range	
	mg/dL
Level 1:	31 ~ 61
Level 2:	84 ~ 144
Level 3:	348 ~ 438


Date opened: _____
AL001-02370010N (01) Rev. date: 04/2018

Test Strip Vial Label

 tyson bio

Store at 39 ~ 86°F (4 ~ 30°C), 10~90% RH.
Do not refrigerate.
Do not store test strips outside this vial.
Re-cap immediately.
WARNING: Always close cap tightly.
For testing of glucose in capillary whole blood.

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

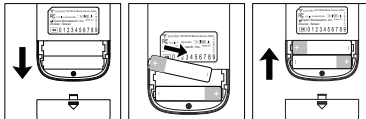
Test Strip Vial

Setting Up Tyson Bio HS100-B Blood Glucose Meter

- Make sure the batteries are properly installed
- The default is set to January 1st, 0:00
- Please follow instructions to properly setup the meter

Installing/Replacing Batteries

1. Slide and remove the battery cover (Fig.1).
2. Install batteries with the + and – ends matching indication marks on the battery compartment (Fig.2).
3. Slide battery cover back into place (Fig.3).



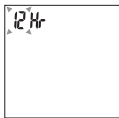
(Fig.1)

(Fig.2)

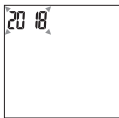
(Fig.3)

Date/Time Setup

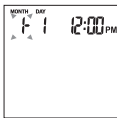
1. When the meter is off, press and hold (M) for 4 seconds to enter this setting mode.
2. Press (V) or (A) to select "24hr" or "12hr", and press (M) to confirm (Fig.4).
3. The numbers of "year" will appear and flash. Press (V) or (A) to adjust and Press (M) to confirm (Fig.5).
4. The number of "month" will appear and flash. Press (V) or (A) to adjust and press (M) to confirm (Fig.6).
5. The numbers of "day" will appear and flash. Press (V) or (A) to adjust and press (M) to confirm (Fig.7).
6. The numbers of "hour" will appear and flash. Press (V) or (A) to adjust and press (M) to confirm (Fig.8).
7. The numbers of "minute" will appear and flash. Press (V) or (A) to adjust, and press (M) to confirm (Fig.9).
8. The set date and time will now be displayed on screen (Fig.10, Fig.11).
Press (M) to turn off the meter.
9. The meter date/time setting is complete.



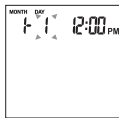
(Fig.4)



(Fig.5)



(Fig.6)



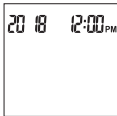
(Fig.7)



(Fig.8)



(Fig.9)



(Fig.10)

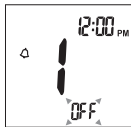


(Fig.11)

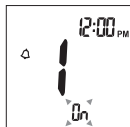
Reminder Alarms Setup

Tyson Bio HS100-B Blood Glucose Meter provides 4 reminder alarms. All reminder alarms are OFF as default. Please follow these steps to setup reminder alarms.

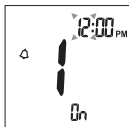
1. When the meter is OFF, press and hold \triangle for 4 seconds or longer to enter setting.
2. The first reminder alarm will appear on the display (Fig.12).
3. Press ∇ or \triangle to select "ON" or "OFF".
4. If "OFF" is chosen and \textcircled{M} pressed, the meter will proceed to the next reminder alarm setting. If "ON" is chosen (Fig.13) and \textcircled{M} pressed, the number of "hour" will start flashing (Fig.14). Press ∇ or \triangle to adjust and press \textcircled{M} to confirm.
5. The numbers of "minutes" will flash (Fig.15). Press ∇ or \triangle to adjust and press \textcircled{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.12)



(Fig.13)



(Fig.14)



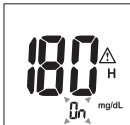
(Fig.15)

HI/LO Alarms Setup

1. Press M to enter the HI alarm setting after completing the reminder alarm setup.
2. Press V or A to set "ON" and press M to confirm. If "OFF" is chosen, the meter will skip this setting (Fig.16,17).
3. To change the alarm setting, press V or A until you reach your desired HI setting and then press M to confirm.
(Fig.18) The HI alarm value range is 100 ~ 400mg/dL and the default value is 180mg/dL.
4. Continue to the LO alarm setting (Fig.19), repeat Step 2 and 3 (Fig.20,21) to confirm or to change LO alarm setting.
The LO alarm value range is 40 ~ 90mg/dL and the default value is 70mg/dL.
5. Press M to finish setting and the meter will be turned off.



(Fig.16)



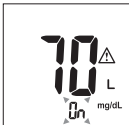
(Fig.17)



(Fig.18)



(Fig.19)



(Fig.20)



(Fig.21)

NOTE:

The hypoglycemic (LO) and hyperglycemic (HI) alarm glucose values should be selected in consultation with your health care provider.

Important Information

Before Testing

- Always keep test strips in the original vial. The vial contains drying agents to protect the test strips from moisture.
- Tightly close the vial cap immediately after removing a test strip.
- Use each strip immediately after removing it from the vial.
- Use each test strip **ONCE ONLY**.
- Do not use the test strips or Control Solution beyond the expiration date printed on the package. This may cause inaccurate results.
- Do not use the test strips or Control Solution if the package is damaged.
- Store your test strips and the Control Solutions between 39°F ~ 86°F (4°C ~ 30°C)
Temperature beyond this range can damage test strips and lead to inaccurate results.
- Any change of medications based on the Tyson Bio HS100-B 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.
- Users should wash hands thoroughly with soap and water after handing the meter, lancing device, or test strips.
- Only Tyson Bio HS100-B Blood Glucose Test Strip and Control Solution can be used with the Tyson Bio HS100-B Blood Glucose Meter.
- For accurate results, testing must be done within the operating temperature range (50°F ~ 104°F/10°C ~ 40°C).
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.

Using Tyson Bio HS100-B Blood Glucose Test Strip

You need the following items to test

- Tyson Bio HS100-B Blood Glucose Meter
- Tyson Bio HS100-B Blood Glucose Test Strip
- Adjustable lancing device and sterile lancet

Preparing the Test Strip

1. Wash hands using soap and warm water. Rinse and dry thoroughly (Fig.22).
2. Please remove protective wrap completely before opening the vial.
3. Take a test strip from the vial and re-cap immediately (Fig.23).
4. Insert the test strip top side up into the test port (Fig.24). The meter will be automatically turned on.
5. System checking will appear (Fig.25).
6. A beep will sound and following by a flashing "💧" icon. You can press ⏴ or ⏵ to select the meal indicator for marking the test as (Fig.26):
 - Pre-Meal Test 🍏
 - Post-Meal Test 🍎
 - No marker as default
7. A blood sample can now be obtained (refer to P.15).



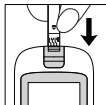
(Fig.22)



(Fig.23)



(Fig.24)



(Fig.25)

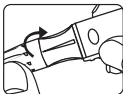


(Fig.26)

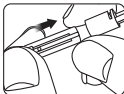


Obtaining a Blood Sample

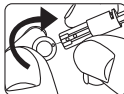
1. Unscrew the lancing device cap (Fig.27).
2. Place a lancet into the lancing device (Fig.28).
3. Twist and pull to remove the protective lancet cap to expose the sterile needle. Save the cap for later use (Fig.29).
4. Screw the lancing device cap back on. Select the skin penetration depth preferred (Fig.30).
5. Pull the barrel back until you hear a 'click' (Fig.31).
6. Place the lancing device against the finger, palm, or forearm. Press the trigger to obtain a blood sample (Fig.32).



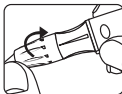
(Fig.27)



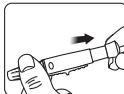
(Fig.28)



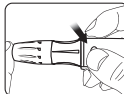
(Fig.29)



(Fig.30)



(Fig.31)

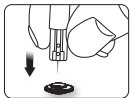


(Fig.32)

To unload the lancing device

1. After sampling, carefully remove the cap containing the used lancet.
2. Push the exposed tip of the lancet into its Protective Cap (Fig.33).
Slide the Lancet Ejector forward and dispose the used lancet in an appropriate container.

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



(Fig.33)

CAUTION:

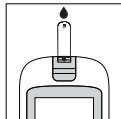
To reduce chances of infection:

- ***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.28) for detail instructions of meter maintenance.***

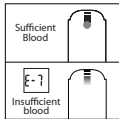
Applying a Blood Sample

SAMPLE MAY BE OBTAINED FROM FINGER, PLAM, 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.34). 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. The meter will start to countdown as soon as the blood has completely filled the confirmation window of the test strip
If applying an insufficient blood sample, the error code (E-7) will appear on the display (Fig.35).
4. The test result will appear on the display in 5 seconds (Fig.36). All results will be automatically stored into the meter memory (Fig.37).
5. The meter will automatically turn off after 2 minutes.
6. After completing the test, push the strip ejector (Fig.38) or use a tissue paper to remove the test strip.



(Fig.34)



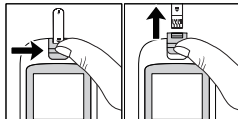
(Fig.35)



(Fig.36)



(Fig.37)



(Fig.38)

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***

Normal Glucose Values

Before a meal (fasting) : <100 mg/dL

2 h after a meal: < 140mg/dL.

These ranges were cited from the American Diabetes Association, Classification and Diagnosis of Diabetes, 2017.
Diabetes Care 40(Suppl. 1):S11–S24

HI and LO Readings

- Tyson Bio HS100-B Blood Glucose Meter is designed to display test results between 20 ~ 600 mg/dL.
- If "HI" (Fig.39) appears on the display, it indicates the reading is higher than 600 mg/dL.
- If "LO" (Fig.40) appears on the display, it indicates the reading is lower than 20 mg/dL.



(Fig.39)



(Fig.40)

We suggested the testing procedure should be reviewed and the test should be repeated using a new test strip to reconfirm the test result.

Available Alternate Sites Testing

Palm and Forearm

Tyson Bio HS100-B Blood Glucose Monitoring System provides you alternate sites testing (AST). This system allows you to test on the palm and the forearm with the equivalent results to fingertip testing.

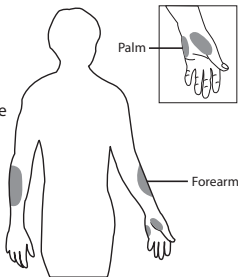
Physiological differences in the circulation between the finger and other test sites may result in differences in blood glucose measurements. Changes in blood glucose may be observed in finger blood samples sooner than blood samples from the alternate sites. If you are testing for hypoglycemia (low blood glucose), we recommend that you test on your fingertips.

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



There are limitations for doing AST.

Please consult your healthcare professional before you do AST. AST measurements should not be used to calibrate continuous glucose monitors (CGMs).

AST measurements should not be used for insulin dose calculations.

Control Solution

The Control Solution is to ensure that Tyson Bio HS100-B Blood Glucose Monitoring System is working properly and you are performing a test correctly.

When to Perform a Control Solution Test


- | | |
|--|--|
| 1. You use the meter for the first time. | 4. Your test results are not consistent with how you feel. |
| 2. You use a new vial of test strips. | 5. You think your test result is not accurate. |
| 3. You suspect that the meter or test strips are not working properly. | 6. You damage your meter. |
| | 7. An advice from your healthcare professional. |

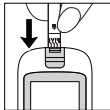
Note: Please read the Control Solution package insert for more detail information.

Performing a Control Solution Test

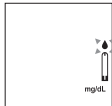
1. Be sure of the Control Solution is at a room temperature between 59°F ~ 95°F (15°C ~ 35°C) before testing.

Control solution that is not at room temperature when tested may cause out of range results.

2. Insert a Tyson Bio HS100-B Blood Glucose Test Strip, top side up, contact bar end first, into the test port. The meter will be automatically turned ON (Fig.41).
3. A beep will sound and the system checking will appear followed by a flashing “” icon (Fig.42).



(Fig.41)

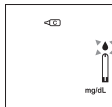


(Fig.42)

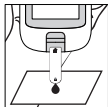
4. Press and hold **(M)** for 2 seconds to change to the Control Solution test mode. "**←C**" will appear on the display (Fig.43). Press **(M)** again for 2 seconds and the meter will switch back to the normal testing mode.
5. Discard the first drop of the Control Solution. Squeeze a small drop on a clean nonabsorbent surface e.g. wax paper. Do not apply the Control Solution to the test strip directly from the bottle because contamination may occur (Fig.44)
6. Introduce the tip of the test strip to the Control Solution drop. The Control Solution will be 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.45).

Caution:

Follow the above instructions when performing a Control Solution test in order to prevent contamination.



(Fig.43)



(Fig.44)



(Fig.45)

Control Solution Results

The Tyson Bio HS100-B Blood Glucose Monitoring System is working properly only if the Control Solution test result is within the specified range printed on the test strip vial. Please repeat the test when the test result is out of range.

Out of range result may be caused by:

- Incorrect steps while performing the test
- The Control Solution temperature is lower than 59°F (15°C) or higher than 95°F (35°C)
- Expired or contaminated Control Solution
- Expired or contaminated test strips
- Meter malfunction

Note:

- ***The result will not be included in any day average calculation when the Tyson Bio HS100-B Blood Glucose meter is set in the Control Solution test mode.***
- ***DO NOT use Tyson Bio HS100-B Blood Glucose meter if the problem persists. Please contact customer service immediately.***

Memory Features

How to view results stored in the memory

1. When the meter is off, press (M) button to turn on the meter. The Data and Time will be shown on (At the left-upper corner. Firstly the year is shown for 1 second, and then Month-Day will be shown on in the same area).
2. Press (V) to view previous results. "MEM" icon will be displayed on the top center area. Initially, the "year" will be display on the top left corner (Fig.46). 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.47). The most recent memory results will be displayed first.
3. You can press (V) or (A) 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.



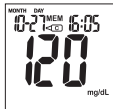
(Fig.46)



(Fig.47)

How to view the 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 lastest control solution test result will be displayed (Fig.48).
3. Press (M) button to turn off the meter or the meter will be shut off automatically after 2 minutes without any action.





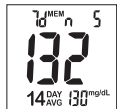
(Fig.48)

Note:

1. A result with H or 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 7/14/30 day average.

View Day Average Results

1. Press **(M)** to turn the meter on, then Press **(A)** button to view day average results.
2. 7/14/30 day average results marked with a no meal / pre-meal  / post-meal  and will be displayed on screen in sequence when is **(A)** pressed (Fig.49 ~ 57).
3. When the meter displays 7 days with no meal status assigned, press **(V)** button and the meter will then change to view stored test results in memory.
4. Press **(M)** button to turn off the meter or the meter will be shut off automatically after 2 minutes without any action.



(Fig.49)



(Fig.50)



(Fig.51)



(Fig.52)



(Fig.53)



(Fig.54)



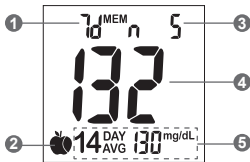
(Fig.55)



(Fig.56)



(Fig.57)





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

Note:

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

Bluetooth Data Transfer

Transfer Memory Data

1. Press (M) to turn on the meter (Fig.58).
2. When the meter is switched ON, hold (M) for 4 seconds to enter Bluetooth mode.  will appear and flash on the meter when meter is not connected with a mobile device (Fig.59).
3. Turn Bluetooth on your mobile device, and BLE tool APP (with Blood Glucose Test) on.
4. Select the device shown (ex.Tysonbio-BGM) in APP list and click "Connect" .  stops blinking when the meter & mobile device is connected.
5. Press the button on APP to transfer data. The meter will display while data are being transferred (Fig.60).



(Fig.58)



(Fig.59)



(Fig.60)

Cleaning and Disinfection Procedure

Cleaning

Cleaning removes visible soil, organic material, and most importantly, blood products. Always clean before disinfecting. The meter should be cleaned whenever it is visibly dirty.

Disinfection

Disinfection generally refers to the use of chemical and physical agents, such as chemicals, to destroy the potential inactivity of a material.

The meter should be disinfected periodically, such as twice per week.

Material

Clorox Bleach Germicidal Wipes (Clorox Professional Products Company. EPA Reg. No. 67619-12).

Signs of deterioration

- Performance: The control solution measurements are out of range which is listed on the test strip label.
- Physical: Polymer crazing (thin silver streaks appear), cracking, swelling, dissolving, softening, or becoming brittle, and the symbols are not clear in LCD display.

If these signs of deterioration are noted, users should stop using meter and contact customer service.

Customer Service

📞 U.S.A. +1-800-948-3894 24 hours a day, 7 days a week Taiwan

📞 Taiwan +886-37-585998 GMT+8, 8:30 ~ 17:30, Monday ~ Friday

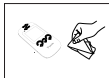
Note:

Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips should be included.

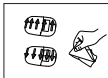
Cleaning and Disinfection Procedure



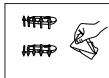
(Step 1)



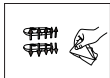
(Step 2)



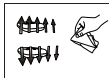
(Step 3)



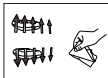
(Step 4)



(Step 5)



(Step 6)



(Step 7)



(Step 8)



(Step 9)



(Step 10)



(Step 11)



(Step 12)



(Step 13)



(Step 14)



(Step 15)

Cleaning:

- The meter should be cleaned prior to disinfection.
- Switch the meter OFF.
- Cleaning solution and disinfecting solution:
Clorox Bleach Germicidal Wipes
- Use a new cleaning wipe.
- The meter is cleaned follow by the illustrations (Step1~Step15).
- Wipe the entire surface of the meter to clean blood and other body fluids.
- Please avoid using alcohol or organic solvents in cleaning.
- Do not immerse the meter in water. Do not allow water or cleaning fluids into the meter, test port, and data port.

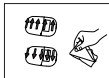
Cleaning and Disinfection Procedure



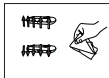
(Step 1)



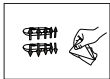
(Step 2)



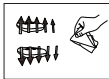
(Step 3)



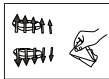
(Step 4)



(Step 5)



(Step 6)



(Step 7)



(Step 8)



(Step 9)



(Step 10)



(Step 11)



(Step 12)



(Step 13)



(Step 14)



(Step 15)

Disinfection:




- Cleaning solution and disinfecting solution: Clorox Bleach Germicidal Wipes
- Use a new disinfection wipe.
- The meter is cleaned follow by the illustrations (Step1~Step15).
- Wipe the entire surface of the meter to remove bloodborne pathogens.
- Dispose of the used wipe in a trash bin.
- Allow exteriors to remain wet for the 1 minute contact time.
- Wipe surface using a towel and allow to air dry.





Care and Storage





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

- Do not expose the meter, test strips, and the Control Solution to extreme conditions such as high humidity, heat, freezing cold, or dust.
- DO NOT STORE IN DIRECT SUNLIGHT OR AREAS WITH HIGH HUMIDITY AND/OR DUST.
- It is advised that you store all parts of Tyson Bio HS100-B Blood Glucose Monitoring System in the carrying case provided.





Display Messages

Display	Description	Action
	The system is ready to accept a blood sample.	Apply a blood sample.
	\triangle_H The result is HIGHER than the "HI" alert setting.	The default setting is 180 mg/dL and it can be changed according to 《HI/LO Alarms Setup》
	\triangle_L The result is LOWER than the "LO" alert setting.	The default setting is 70 mg/dL and it can be changed according to 《HI/LO Alarms Setup》

Display	Description	Action
	Test result is HIGHER than 600 mg/dL.	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 test range. Please consult your healthcare professional immediately for further advice.
	Test result is LOWER than 20 mg/dL.	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 test range. Please consult your healthcare professional immediately for further advice.
	Temperature is TOO HIGH during the test procedure.	Large variation may occur between results due to high or low temperature. Move to an environment (50°F ~ 104°F or 10°C ~ 40°C) and wait for 30 minutes before re-testing.
	Temperature is TOO LOW during the test procedure.	Large variation may occur between results due to high or low temperature. Move to an environment (50°F ~ 104°F or 10°C ~ 40°C) and wait for 30 minutes before re-testing.

Display	Description	Action
	The preset reminder alarm is ringing	Press any button to turn off the alarm or wait for the alarm to be turned off automatically in 30 seconds.
	Battery power is LOW. Meter will only provide proximately 10 more measurements.	Replace with 2 AAA batteries.
	An error message indicates that the hematocrit of the blood sample is too high for the system to perform a test.	Follow the instructions and try again with a new test strip. Please contact customer service if the problem persists.
	<ol style="list-style-type: none"> 1. An error message indicates that the hematocrit of the blood sample is too low for the system to perform a test. 2. Use control solution to check the meter and test strips. 	<ol style="list-style-type: none"> 1. Follow the instructions and try again with a new test strip. Please contact customer service if the problem persists. 2. Follow the instructions to enter control solution mode, and try again with a new test strip.

Error Messages

<i>Display</i>	<i>Description</i>	<i>Action</i>
	Temperature is TOO HIGH to perform a test.	Move to an environment between 50°F ~ 104°F or 10°C ~ 40°C and wait for 30 minutes before re-testing.
	Temperature is TOO LOW to perform a test.	Move to an environment between 50°F ~ 104°F or 10°C ~ 40°C and wait for 30 minutes before re-testing.
	Battery power is depleted for any further usage.	Replace with 2 AAA batteries immediately
	This message is displayed when your meter has NOT been coded.	Please contact customer services for assistance.

Display**Description****Action**

An error message indicates a problem with the test strip.

Review the instructions and try again with a new test strip. Please contact customer service if the problem persists.



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

Review the instructions and try again with a new test strip. Please contact customer service if the problem persists.







An error message indicates a problem with the meter.

Remove batteries and wait for 1 minute. Reinstall batteries to see if meter is working properly. Please contact customer service if the problem persists.



An error message indicates a problem with the test strip.

Review the instructions and try again with a new test strip. Please contact customer service if the problem persists.

<i>Display</i>	<i>Description</i>	<i>Action</i>
	An error message indicates a problem with the meter.	Remove batteries and wait for 1 minute. Reinstall batteries to see if meter is working properly. Please contact customer service if the problem persists.
	An error message indicates a problem with the test strip.	Review the instructions and try again with a new test strip. Please contact customer service if the problem persists.
	An error message indicates insufficient volume of blood sample for the test.	Follow 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.	Remove batteries and wait for 1 minute. Reinstall batteries to see if meter is working properly. Please contact customer service if the problem persists.

Trouble Shooting

<i>Other problems which may occur</i>	<i>Action</i>
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.	Remove batteries and wait for 1 minute. Reinstall batteries to see if meter is working properly.

Specifications

Operation Temperature	50°F ~ 104°F (10°C ~ 40°C)
Operation Humidity	10 ~ 90% RH
Hematocrit	10 ~ 65%
Test Sample	Capillary Whole Blood (fingertip, palm, and forearm)
Sample Volume	0.7 µL
Measuring Unit	mg/dL
Measuring Range	20 ~ 600 mg/dL
Test Time	5 seconds countdown
Memory Capacity	500 most recent results
Average	7/14/30 days average

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.

The Meter meets the electromagnetic compatibility requirements as per IEC 60601-1-2:2014 and EN 60601-1-2:2015.

Caution: Do not use the meter close to the electronic equipment which is a source of strong electromagnetic radiation, which may interfere with proper operation of meter.

Meter Storage

- Transport and store at temperature -4°F ~ 122 °F (-20°C ~ 50°C), less than 90% RH.
- Precision instrument, do not drop or crush when being transported.

Icon Description



Temperature limitation



Manufacturer



Batch code



In vitro diagnostic medical device



Use by



Consult instructions for use



Do not reuse



Sufficient for



Serial Number



Catalogue number



Caution



Control

Service and Warranty

IMPORTANT

- The Tyson Bio HS100-B Blood Glucose Meter, Tyson Bio HS100-B Blood Glucose Test Strip and Tyson Bio HS100-B Control Solution are in conformity with the CFR, Title 21 and IVDD 98/79/EC.
- Tyson Bio HS100-B 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 CFR, Title 21 and MDD 93/42/EEC.

Manufacturer Warranty

- Tyson Bioresearch Inc. offers 3 years guarantee on this product. Our company shall repair or replace any Tyson Bio HS100-B Blood Glucose Monitoring System found defective with a new one.
- This warranty does not apply to the performance of a Tyson Bio HS100-B 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 Tyson Bio HS100-B Blood Glucose Monitoring System.
- For manufacturer warranty services, purchaser must contact Tyson Bioresearch, Inc. for help.

Federal Communications Commission Interference Statement

15.105

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

15.21

Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

RF Exposure Warning

The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment.
The equipment must not be co-located or operating in conjunction with any other antenna or transmitter.


15.19

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

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

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 Taiwan +886-37-585998 GMT+8, 8:30 ~ 17:30, Monday ~ Friday

When you call our customer service, please have all components of the product 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

 SteriLance Medical (Suzhou) Inc.

 No.68 Litanghe Road,Xiangcheng Suzhou, Jiangsu 215133 P.R.China



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