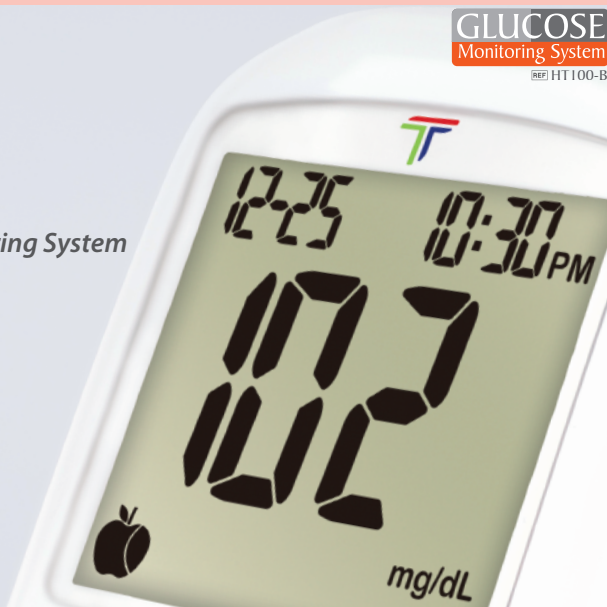


HT100-B Blood Glucose Monitoring System

User Manual

For in vitro diagnostic use only



Limitations

The Tyson Bio HT100-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.

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Introduction

Thank you for choosing Tyson Bio HT100-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 HT100-B Blood Glucose Monitoring System. Please read carefully before use.

Tyson Bio HT100-B Blood Glucose meter can be used with:

- Tyson Bio HT100-B Blood Glucose Test Strip

Intended Use Statement

The Tyson Bio HT100-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. Alternative 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 HT100-B Blood Glucose Monitoring System is comprised of the Tyson Bio HT100-B Blood Glucose Meter and Tyson Bio HT100-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) <https://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>

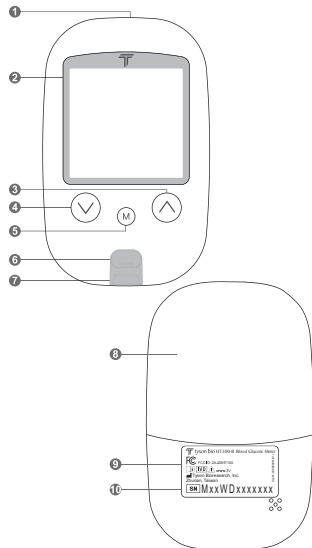
About Tyson Bio HT100-B Blood Glucose Monitoring System

The complete kit contains:

- HT100-B Blood Glucose Meter
- HT100-B Blood Glucose Test Strip (10 strips)
- HT100-B Control Solution Level 2
- Adjustable Automatic Lancing Device
- Sterile Lancets
- User Manual
- Quick Reference Guide
- Test Strip Package Insert
- Control Solution Package Insert
- Log Book
- Carrying case

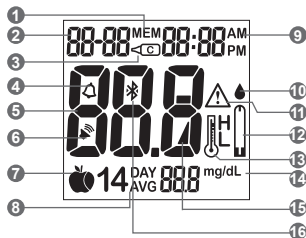
Note: 25-strips & 50-strips are sold separately.

About Tyson Bio HT100-B Blood Glucose Meter



- | | |
|---------------------------|--|
| 1. Data Port | To connect interface cable for data transferring |
| 2. Display | To display results in numbers and icons |
| 3. ⬆ Button | Press and hold to enter reminder alarm and HI/LO alarm setup |
| | To adjust numbers and to toggle settings |
| 4. ✓ Button | To browse test results and averages in memory |
| | Press and hold to enter buzzer setup |
| | To adjust numbers & to toggle settings |
| 5. M Button | To browse test results and averages in memory |
| | Press and hold to enter the year/date/time setting |
| | To browse Control Solution test results |
| | To turn the meter ON/OFF |
| 6. Strip Ejector | Push to eject the test strip |
| 7. Test Port | The test strip is inserted here |
| 8. Battery Cover | To slide open and close |
| 9. Meter Label | Manufacturer information |
| 10. Serial Numbers | The meter manufacturer serials |

About Tyson Bio HT100-B Blood Glucose Meter Display



1. Memory Icon

Memory mode

2. Year/Date

Display year/date

3. Control Solution Icon

Control Solution test mode and Control Solution test result

4. Alarm Icon

Reminder alarm

5. Test Result

Result display

6. Buzzer Icon

When buzzer is ON

7. Meal Indicator Icon

Pre-meal and post-meal

8. 14 day Average

14 day average result

9. Time

Time display

10. Blood Drop Icon

Flashes when the meter is ready to accept your blood sample to test

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 normal operating temperatures

14. Measurement Units

To identify test result units (mg/dL)

15. Battery Icon

Appears when battery power is low

16. Bluetooth icon

When Bluetooth is on

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 HT100-B Blood Glucose Test Strip

Tyson Bio HT100-B Blood Glucose Test Strip is only for Tyson Bio HT100-B Blood Glucose Meter.

Use each strip **ONCE ONLY!**

A test strip consists of the following parts:

1. Target Area

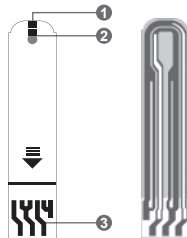
Where a blood drop or control solution to be applied

2. Confirmation Window

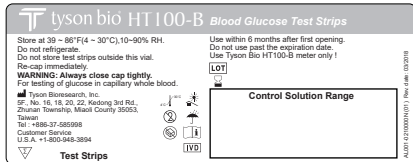
To confirm sufficient blood sample and control solution

3. Contact Bar

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



top side



Test Strip Vial Label



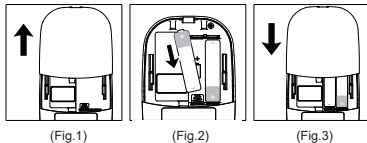
Test Strip Vial

Setting Up Tyson Bio HT100-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

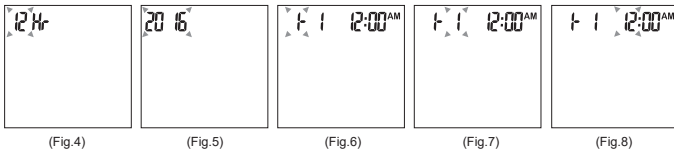
Installing/Replacing Batteries

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).



Setting Date/Time

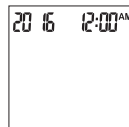
1. When the meter is off, press and hold M for 4 seconds to enter this setting mode.
2. Press V or A to select "24hr" or "12hr".
3. Press M to confirm (Fig.4).
4. The numbers of "year" will appear and flash. Press V or A to adjust and Press M to confirm (Fig.5).
5. The number of "month" will appear and flash. Press V or A to adjust and press M to confirm (Fig.6).
6. The numbers of "date" will appear and flash. Press V or A to adjust and press M to confirm (Fig.7).
7. The numbers of "hour" will appear and flash. Press V or A to adjust and press M to confirm (Fig.8).



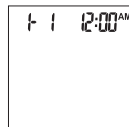
8. The numbers of "minute" will appear and flash. Press $\odot$ or $\triangle$ to adjust. Press M to confirm (Fig.9).
9. The set date and time will now be displayed on screen (Fig.10, Fig.11). Press M to turn off the meter.
10. The meter date/time setting is complete.



(Fig.9)



(Fig.10)

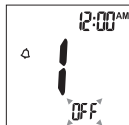


(Fig.11)

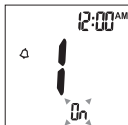
Setting Up Reminder Alarms

Tyson Bio HT100-B meter provides 4 reminder alarms. All reminder alarms are OFF as default. Please follow these steps to setup reminder alarms.

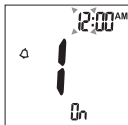
1. When the meter is OFF, press and hold $\triangle$ for 4 seconds or longer to enter setting.
2. The first reminder alarm will appear on the display (Fig.12).
3. Press $\odot$ or $\triangle$ to select "ON" or "OFF".
4. If "OFF" is chosen and M pressed, the meter will proceed to the next reminder alarm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



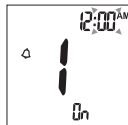
(Fig.12)



(Fig.13)



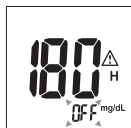
(Fig.14)



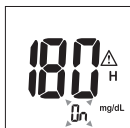
(Fig.15)

Setting Up HI/LO Alarms

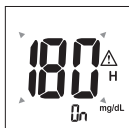
1. Press M to enter the HI alarm setting after completing the reminder alarm setup.
2. Press $\checkmark$ or $\wedge$ to set "ON" and press M to confirm. If "OFF" is chosen, the meter will skip this setting (Fig. 16, 17).
3. To change the alarm setting, press $\checkmark$ or $\wedge$ until you reach 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.



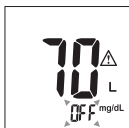
(Fig.16)



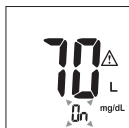
(Fig.17)



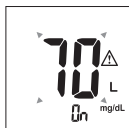
(Fig.18)



(Fig.19)



(Fig.20)



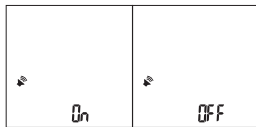
(Fig.21)

NOTE:

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

Setting Up Buzzer and Bluetooth

1. When the meter is turned off, press and hold ⏻ for 4 seconds to enter the setting mode of buzzer.
2. Buzzer feature is "ON" by default, press ⏻ or ⏶ to change the setting (Fig.22). Press ⏹ to confirm and the meter will enter to the setting mode of Bluetooth.
3. Bluetooth feature is "ON" by default, press ⏻ or ⏶ to change the setting (Fig.23). Press ⏹ to confirm and the meter will be turned off.



(Fig.22)



(Fig.23)

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 HT100-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 handling the meter, lancing device, or test strips.
- Only Tyson Bio HT100-B Blood Glucose Test Strip and Control Solution can be used with the Tyson Bio HT100-B Blood Glucose Meter.

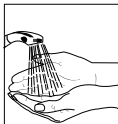
Preparing the Test Strip

You need the following items to test

- Tyson Bio HT100-B Blood Glucose Meter
- Tyson Bio HT100-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.24).
2. Please remove protective wrap completely before opening the vial.
3. Take a test strip from the vial and re-cap immediately (Fig.25).
4. Insert the test strip top side up into the test port (Fig.26). The meter will be automatically turned on.
5. System checking will appear (Fig.27).
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.28):
 - Pre-Meal Test 🍏
 - Post-Meal Test 🍎
 - No marker as default
7. A blood sample can now be obtained (refer to P.14).



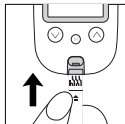
(Fig.24)



(Fig.25)



(Fig.26)



(Fig.27)

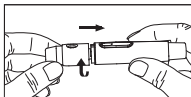


(Fig.28)

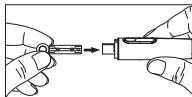
Preparing the Lancing Device and Obtaining a Blood Sample

1. Hold the depth adjustable cap in one hand and hold hub in the other hand, twist off the depth adjustable cap (Fig.29).
2. Insert a new disposable lancet firmly into the lancet holder (Fig.30).
3. Twist off and set aside the protective cover of the disposable lancet (Fig.31).
4. Replace the depth adjustable cap (Fig.31).
5. Select a depth of penetration by rotating the top portion of the depth adjustable cap until the number matched to the window (Fig.32).
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.33).
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.34).
8. Squeeze a small drop of whole blood to apply (Fig.35).

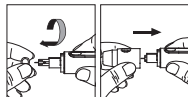
For further instructions please see the insert provided with the lancing device.



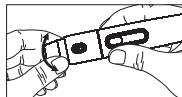
(Fig.29)



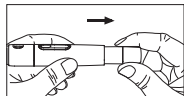
(Fig.30)



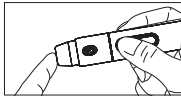
(Fig.31)



(Fig.32)



(Fig.33)



(Fig.34)

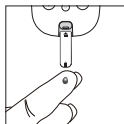


(Fig.35)

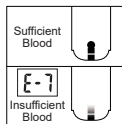
Applying a Blood Sample to the Test Strip

SAMPLE MAY BE OBTAINED FROM FINGER, PALM, OR FOREARM

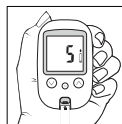
1. Introduce the tip of the test strip to the drop of blood. Blood sample will be automatically drawn into the test strip (Fig.36). Discard the first drop of blood sample to prevent contamination.
2. Hold the tip of the test strip touching the blood drop until the meter beeps.
3. If applying insufficient blood sample, the error code (E-7) will appear on the display (Fig.37).
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.38). The result will be showed and stored into the meter memory automatically (Fig.39).
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 $\textcircled{M}$ is pressed.
6. If the test strip is not ejected after test, the meter will automatically turn off after 2 minutes.



(Fig.36)



(Fig.37)



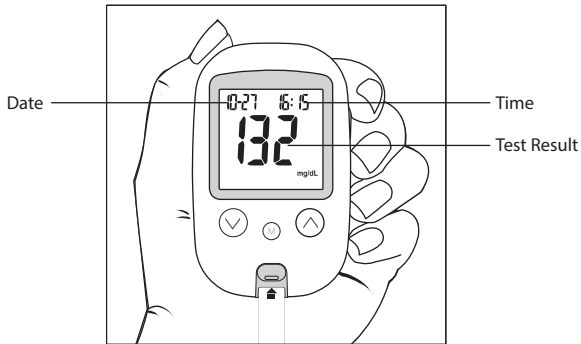
(Fig.38)



(Fig.39)

Test Results

1. The Tyson Bio HT100-B Blood Glucose Meter displays the test result.
2. The LCD of the meter shows the measuring result, the date and the time (Fig.40)



(Fig.40)

Normal Glucose Values

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

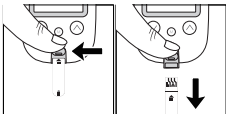
2 h after a meal: < 140mg/dL.

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

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.41) or use a tissue paper to remove the test strip.

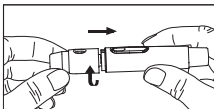


(Fig.41)

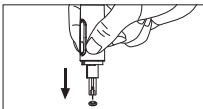
To unload the lancing device

1. After sampling, carefully remove the cap containing the used lancet (Fig.42).
2. Push the exposed tip of the lancet into its Protective Cap (Fig.43).
3. Hold the hub with one hand and push the plunger by thumb to eject the used disposable lancet in appropriate container (Fig.44).

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



(Fig.42)



(Fig.43)



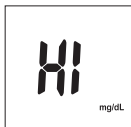
(Fig.44)

Warning:

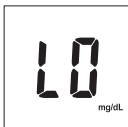
- **DO NOT** point the test strip at anyone when ejecting.
- **Used lancets and test strips are considered bio-hazardous. Dispose of used lancets and test strips in a clinical waste container**

HI and LO Readings

- Tyson Bio HT100-B Blood Glucose Meter is designed to display test results between 20 ~ 600 mg/dL.
- If "HI" (Fig.45) appears on the display, it indicates the reading is higher than 600 mg/dL.
- If "LO" (Fig.46) appears on the display, it indicates the reading is lower than 20 mg/dL.



(Fig.45)



(Fig.46)

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 HT100-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.

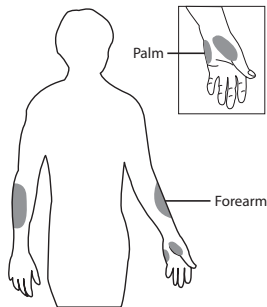
Physiological differences in the circulation between the finger and other test sites may result in differences in blood glucose measurements. Changes in blood glucose may be observed in finger blood samples sooner than blood samples from the alternate sites. If you are testing for hypoglycemia (low blood 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 HT100-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.
2. You use a new vial of test strips.
3. You suspect that the meter or test strips are not working properly.
4. Your test results are not consistent with how you feel.
5. You think your test result is not accurate.
6. You damage your meter.
7. An advice from your healthcare professional.

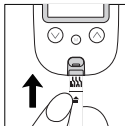
Note: Please read the Control Solution package insert for more detail information.

Performing a Control Solution Test

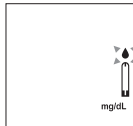
1. Be sure of the Control Solution is at a room temperature between 59°F ~ 95°F (15°C ~ 35°C) before testing.

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

2. Insert a Tyson Bio HT100-B Blood Glucose Test Strip, top side up, contact bar end first, into the test port. The meter will be automatically turned ON (Fig.47).
3. A beep will sound and the system checking will appear followed by a flashing “” icon (Fig.48).



(Fig.47)

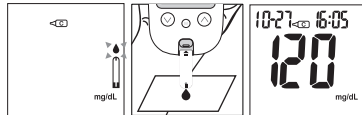


(Fig.48)

- Press and hold  for 2 seconds to change to the Control Solution test mode. " " will appear on the display (Fig.49). Press  again for 2 seconds and the meter will switch back to the normal testing mode.
- 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.50)
- 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.51).

Caution:

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



(Fig.49)

(Fig.50)

(Fig.51)

Control Solution Results

The Tyson Bio HT100-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 HT100-B Blood Glucose Meter is set in the Control Solution test mode.***
- ***DO NOT use Tyson Bio HT100-B Blood Glucose meter if the problem persists. Please contact customer service immediately.***

Memory Features

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

1. When the meter is off, press  button to turn on the meter. The Date 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  to view previous results. "MEM" icon will be displayed on the top center area (Fig.52). When " " is appearing under "MEM", this result stands for control solution test (Fig.53). Initially, the "year" will be display on the top left corner (Fig.54). 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.55). The most recent memory results will be displayed first.
3. You can press  or  to scroll forwards and backwards through the results.
4. Press  button to exit the stored test results or the meter will be shut off automatically after 2 minutes without any action.



(Fig.52)



(Fig.53)



(Fig.54)



(Fig.55)



(Fig.56)

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

1. When the meter is off, press  button to turn on the meter.
2. Press  button again, and the latest control solution test result will be displayed. (Fig.56).
3. Press  button to turn off the meter or the meter will be shut off automatically after 2 minutes without any action.

Note:

- 1. A result with  or  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 Day Average Results

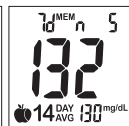
1. Press $\odot$ to turn on the meter.
2. Press $\triangle$ button to view day average results.
3. 7/14/30 day average results marked with a no meal/ pre-meal 🍏 / post-meal 🍎 and will be displayed on screen in sequence when is $\triangle$ pressed (Fig.57~ 64).
4. When the meter displays 7 days with no meal status assigned, press $\odot$ button and the meter will change to view results in memory.



(Fig.57)



(Fig.58)



(Fig.59)



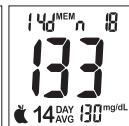
(Fig.60)



(Fig.61)



(Fig.62)



(Fig.63)



(Fig.64)

Note:

1. The 7/14/30 day average is calculated from the test results obtained during the last consecutive 7/14/30 day periods.
2. A result with a temperature warning symbol will NOT be calculated in 7/14/30 day average.
3. "LO" under 20 mg/dL and "HI" over 600 mg/dL readings will NOT be stored in the memory.

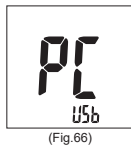
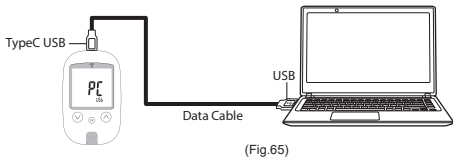
To Record Your Results

We have provided a log book for your recording convenience. To learn more about how to record your results, please refer to the log book for further instructions.

Transfer Test Results to a Computer

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

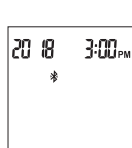
1. Tyson Bio PC Link can be downloaded from www.tysonbio.com
2. Follow the instructions provided with software to install the software into your personal computer.
3. Connect the data cable to a data port on your computer while the meter is off (Fig.65).
4. Connect the other end of data cable to the data port of the meter (Fig.65).
5. The word "PC" will appear on the display indicates that the meter is now in the communication mode (Fig.66).



Bluetooth Data Transfer

To Transfer Memory Data

1. Press  to turn on the meter (Fig.67).
2. Hold  for 4 seconds to enter Bluetooth mode.  will flash when meter is not connected with a mobile device (Fig.68).
3. Turn on Bluetooth, and BLE tool APP (with Blood Glucose Test) on your mobile device.
4. Select the device shown (ex.Tysonbio-BGM) 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.69), please enter passkey on your device. If the passkey is not entered correctly, error code (Err) will appear on the display (Fig.70).
5. Press the button on APP to transfer data. The frame will display while data are being transferred (Fig.71).
When data are completely transmitted to device, the frame will disappear (Fig.72).



(Fig.67)



(Fig.68)



(Fig.69)



(Fig.70)



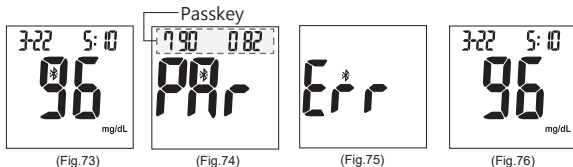
(Fig.71)



(Fig.72)

To Transfer Single Test Data

1. Refer to strip test process (p.14) to proceed the test (Fig.73).
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. TBMTXXXXXXXX) 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.74), enter passkey on your device. If the passkey is not entered correctly, error code (Err) will appear on the display (Fig.75).
4. Test result will automatically transmit to the APP,  will disappear (Fig.76).



Note:

1. If bluetooth setting is switched off before single test data is transmitted, press  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

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.

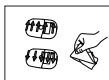
Cleaning and Disinfection Procedure



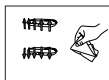
(Step 1)



(Step 2)



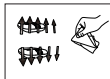
(Step 3)



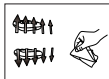
(Step 4)



(Step 5)



(Step 6)



(Step 7)



(Step 8)



(Step 9)



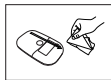
(Step 10)



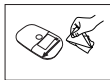
(Step 11)



(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.

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 HT100-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.
	 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》
	 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》
	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.

Display	Description	Action
	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.
	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.
	1. Battery power is low, icon flashes for 2 seconds. Meter can work normally but will only provide approximately 10 more measurements. 2. Battery is depleted, icon flashes continuously. Meter will be shutdown in 5 seconds.	Replace with 2 AAA batteries.
	An error message indicates that the hematocrit of the blood sample is too high for HT100-B system to perform a test.	Follow the instructions and try again with a new test strip. Please contact customer service if the problem persists.
	1. An error message indicates that the hematocrit of the blood sample is too low for HT100-B system to perform a test. 2. Use control solution to check the meter and test strips.	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.
	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.

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 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.
	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.

Remove batteries and wait for 1 minute. Reinstall batteries to see if meter is working properly.

Bluetooth does not work

1. Make sure the meter and your mobile device are within 10 Meters (32.8 feet) to each other.
2. Make sure the mobile device is ON and fully charged.
3. Restart the meter.
4. Reconnect your meter & mobile device.
5. Make sure that your mobile devices are installed with iOS 8.0 and Android 5.0 or above.
6. On your mobile device, go to Bluetooth setting and make sure that Bluetooth is available.

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
External Output	TypeC USB interface and Bluetooth
Power supply	2 AAA batteries
Battery Life	Approximately 1000 tests
Dimension	106L x 66W x 20H mm
Weight	65 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
 Bluetooth logo	 Manufacturing Date

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.

Service and Warranty

IMPORTANT

- Tyson Bio HT100-B Blood Glucose Glucose Meter, Tyson Bio HT100-B Blood Glucose Test Strip and Tyson Bio HT100-B Control Solution are in conformity with the CFR, Title 21 and IVDD 98/79/EC.
- Tyson Bio HT100-B Blood Glucose Monitoring System manufacturer warranty is valid only when used properly with in 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 HT100-B Blood Glucose Monitoring System found defective with a new one.
- This warranty does not apply to the performance of a Tyson Bio HT100-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 HT100-B 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

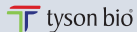
 +886-37-585998  www.tysonbio.com

Customer Service

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

 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.



 Tyson Bioresearch, Inc.

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Zhunan Township, Miaoli County 35053, Taiwan

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AF004-0050000N (05) Rev. date: 03/2023