

## Limitations

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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

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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

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- 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

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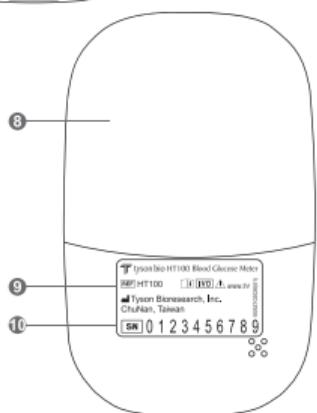
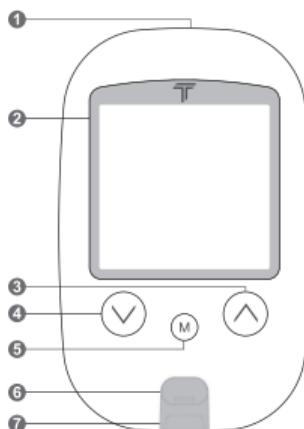
### ***The complete kit contains:***

- HT100-B Blood Glucose Meter
- HT100-B Blood Glucose Test Strip (10 strips)
- HT100-B Control Solution Level 2
- Adjustable Automatic Lancing Device
- 10 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

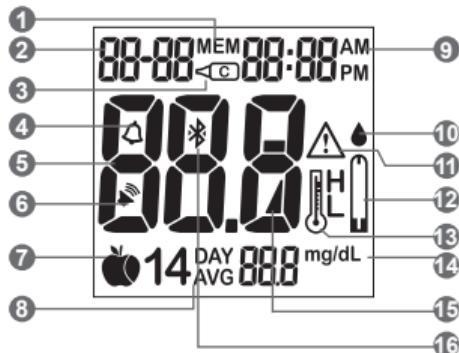
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1. **Data Port** To connect interface cable for data transferring
2. **Display** To display results in numbers and icons
3. **Ⓐ Button** Press and hold to enter reminder alarm and HI/LO alarm setup
4. **Ⓑ Button** To adjust numbers and to toggle settings
5. **Ⓒ Button** To browse test results and averages in memory
6. **Ⓓ Button** Press and hold to enter buzzer setup
7. **Ⓔ Button** To adjust numbers & to toggle settings
8. **Ⓕ Button** To browse test results and averages in memory
9. **Ⓖ Button** Press and hold to enter the year/date/time setting
10. **Ⓗ Button** To browse Control Solution test results
11. **Ⓘ Button** To turn the meter ON/OFF
12. **\_STRIP EJECTOR** Push to eject the test strip
13. **\_STRIP PORT** The test strip is inserted here
14. **BATTERY COVER** To slide open and close
15. **METER LABEL** Manufacturer information
16.  **SERIAL NUMBERS** The meter manufacturer serials

# About Tyson Bio HT100-B Blood Glucose Meter Display

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## 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

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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**

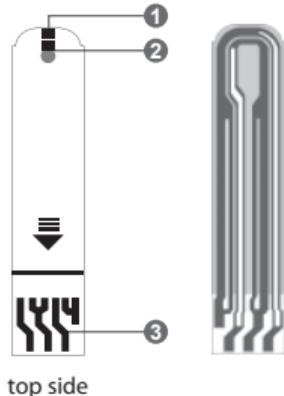
Where a blood drop or control solution to be applied

**2. Confirmation Window**

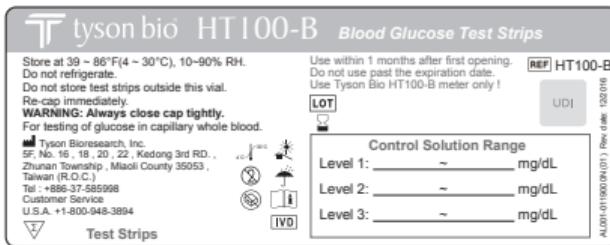
To confirm sufficient blood sample and control solution

**3. Contact Bar**

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



# Tyson Bio HT100-B Blood Glucose Test Strip



Test Strip Vial Label



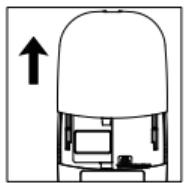
Test Strip Vial

# Setting Up Tyson Bio HT100-B Blood Glucose Meter

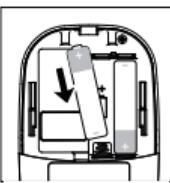
- Make sure the batteries are properly installed
- The default is set to January 1st, 0:00
- Please follow instructions to properly setup the meter

## Installing/Replacing Batteries

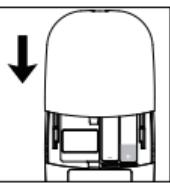
1. Slide and remove the battery cover (Fig.1).
2. Install batteries with the + and – ends matching indication marks on the battery compartment (Fig.2).
3. Slide battery cover back into place (Fig.3).



(Fig.1)



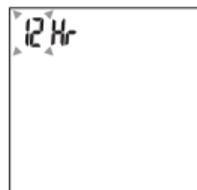
(Fig.2)



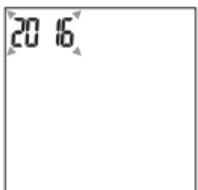
(Fig.3)

## Date/Time Setup

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



(Fig.4)



(Fig.5)



(Fig.6)

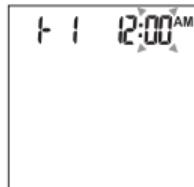


(Fig.7)

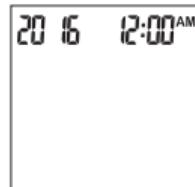


(Fig.8)

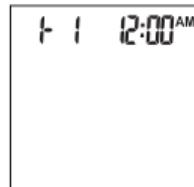
8. The numbers of "minute" will appear and flash. Press  $\odot$  or  $\oslash$  to adjust. Press  $\textcircled{M}$  to confirm (Fig.9).
9. The set date and time will now be displayed on screen (Fig.10, Fig.11). Press  $\textcircled{W}$  to turn off the meter.
10. The meter date/time setting is complete.



(Fig.9)



(Fig.10)

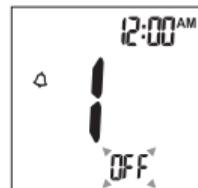


(Fig.11)

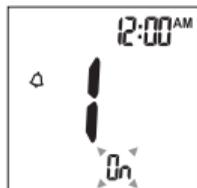
## Reminder Alarms Setup

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  $\odot$  for 4 seconds or longer to enter setting.
2. The first reminder alarm will appear on the display (Fig.12).
3. Press  $\odot$  or  $\oslash$  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  $\odot$  or  $\oslash$  to adjust and press  $\textcircled{M}$  to confirm.
5. The numbers of "minutes" will flash (Fig.15). Press  $\odot$  or  $\oslash$  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)



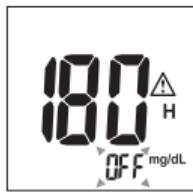
(Fig.14)



(Fig.15)

## HI/LO Alarms Setup

1. Press  $\textcircled{M}$  to enter the HI alarm setting after completing the reminder alarm setup.
2. Press  $\textcircled{V}$  or  $\textcircled{A}$  to set "ON" and press  $\textcircled{M}$  to confirm. If "OFF" is chosen, the meter will skip this setting (Fig. 16, 17).
3. To change the alarm setting, press  $\textcircled{V}$  or  $\textcircled{A}$  until you reach your desired HI setting and then press  $\textcircled{M}$  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  $\textcircled{M}$  to finish setting and the meter will be turned off.



(Fig.16)



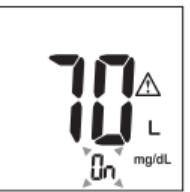
(Fig.17)



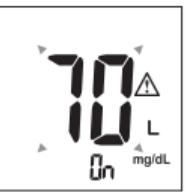
(Fig.18)



(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.***

# Important Information

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## ***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 Test Strip and Control Solution can be used with the Tyson Bio HT100-B Blood Glucose Meter.

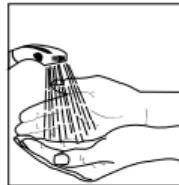
# Using Tyson Bio HT100 Blood Glucose Test Strip

## You need the following items to test

- Tyson Bio HT100-B Blood Glucose Meter
- Tyson Bio HT100-B Blood Glucose Test Strip
- Adjustable automatic 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.13).



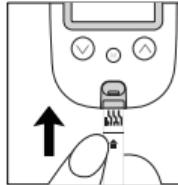
(Fig.22)



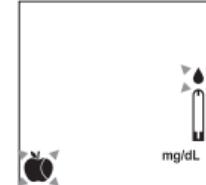
(Fig.23)



(Fig.24)



(Fig.25)



(Fig.26)

# Obtaining a Blood Sample

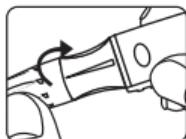
1. Unscrew the lancing device cap (Fig.27).
2. Place a lancet into the lancing device (Fig.28).
3. Twist and pull to remove the protective lancet cover to expose the sterile needle. Save the cap for later use (Fig.29).
4. Screw the lancing device cap back on. Select the skin penetration depth preferred (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).

## ***To unload the lancing device***

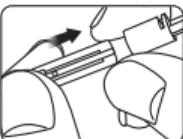
1. After sampling, carefully remove the cap containing the used lancet.
2. Push the exposed tip of the lancet into its Protective Cap (Fig.33).

Slide the Lancet Ejector forward and dispose the used lancet in an appropriate container.

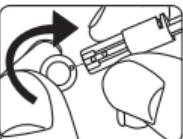
For further instructions please see the insert provided with the lancing device.



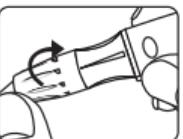
(Fig.27)



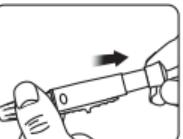
(Fig.28)



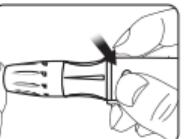
(Fig.29)



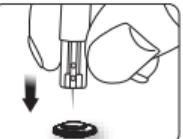
(Fig.30)



(Fig.31)



(Fig.32)



(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.25) for detail instructions of meter maintenance.***

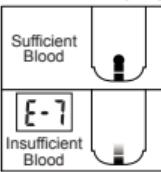
# Applying a Blood Sample

## 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)



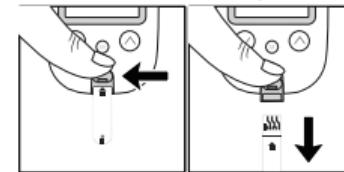
(Fig.35)



(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

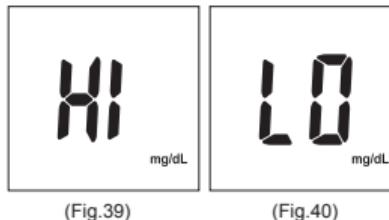
2 h after a meal: < 140mg/dL.

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

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- Tyson Bio HT100-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 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.

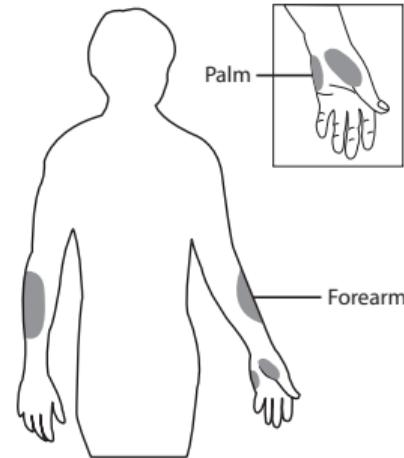
Physiological differences in the circulation between the finger and other test sites may result in differences in blood glucose measurements. Changes in blood glucose may be observed in finger blood samples sooner than blood samples from the alternate sites. If you are testing for hypoglycemia (low blood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

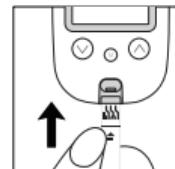
***Note: Please read the Control Solution package insert for more detail information.***

## ***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 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 "点滴" icon (Fig.42).



(Fig.41)

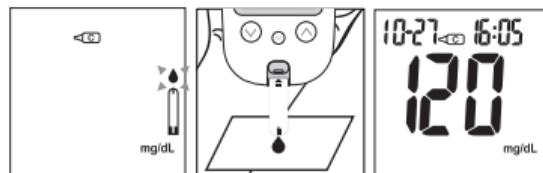


(Fig.42)

4. Press and hold  for 2 seconds to change to the Control Solution test mode. "" will appear on the display (Fig.43). Press  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.***



## Control Solution Results

(Fig.43)

(Fig.44)

(Fig.45)

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:**

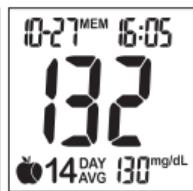
- ***The result will not be included in any day average calculation when the Tyson Bio HT100-B Blood Glucose meter is set in the Control Solution test mode.***
- ***DO NOT use Tyson Bio HT100-B Blood Glucose meter if the problem persists. Please contact customer service immediately.***

## Memory Features

1. Press  $\textcircled{M}$  to turn on the meter when the meter is off.
2. Press  $\textcircled{\text{V}}$  to view previous results.
  - "MEM" icon will be displayed on the top center area.
  - "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.
  - "Time" will be displayed on the top right corner (Fig.47).
  - The most recent memory results will be displayed first.
3. You can press  $\textcircled{\text{V}}$  or  $\textcircled{\text{A}}$  to scroll forwards and backwards.
4. Press  $\textcircled{M}$  to exit and view the Control Solution test result (Fig.48).
5. When the meter displays the last stored test result, press  $\textcircled{\text{A}}$  so the meter will display day average results (Fig.49).



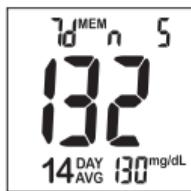
(Fig.46)



(Fig.47)



(Fig.48)



(Fig.49)

### Note:

- **The meter stores 500 results in the memory.**
- **When the memory is full, the oldest result will be replaced by the most recent result.**

## **View Day Average Results**

1. Press **M** to turn on the meter.
2. Press **Ⓐ** 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 pressed (Fig.50~ 57).
4. When the meter displays 7 days with no meal status assigned, press **ⓧ** button and the meter will change to view results in memory.



(Fig.50)



(Fig.51)



(Fig.52)



(Fig.53)



(Fig.54)



(Fig.55)



(Fig.56)



(Fig.57)

### **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.

## Exiting the Memory Mode

1. When the meter displays a Control Solution test result, press  $\textcircled{M}$  will turn the meter off.
2. The meter will also be turned off automatically after 2 minutes following the last key pressed.

## ***To Record Your Results***

We provide a log book for you to record. Please refer to the log book for details.

## Transfer Test Results to a Computer

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

1. Follow the instructions provided with software to install the software into your personal computer.
2. Connect the interface cable to a serial port on your computer while the meter is off.
3. Connect the other end of interface cable to the data port located on the side of the meter.
4. The word "PC" will appear on the display indicates that the meter is now in the communication mode (Fig.58)



(Fig.58)

## Bluetooth Data Transfer (HT100-B Only)

### Bluetooth Setup

- Press  $\textcircled{M}$  to turn on the meter.  $\textcircled{*}$  will appear when HT100-B has been detected (Fig. 59)
- Bluetooth is OFF by default.
- Please proceed the following steps.

### To Transfer Memory Data

1. When the meter is switched ON, hold  $\textcircled{M}$  for 4 seconds to enter Bluetooth mode.  $\textcircled{*}$  will appear and flash on the meter when meter is not connected with a mobile device (Fig. 60).
2. Turn on BLE tool APP (with Blood Glucose Test) and Bluetooth on your mobile device.
3. Click "Connect" and select the device shown (ex.  $\textcircled{B}$  TBMTXXXXXXX) in APP list.  $\textcircled{*}$  stops blinking when the meter & mobile device is connected.
4. Press the button on APP to transfer data. The meter will display while data are being transferred (Fig. 61)



(Fig.59)



(Fig.60)



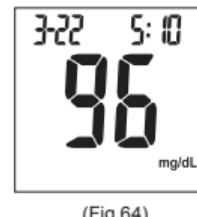
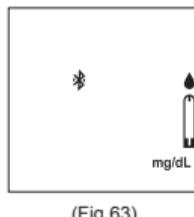
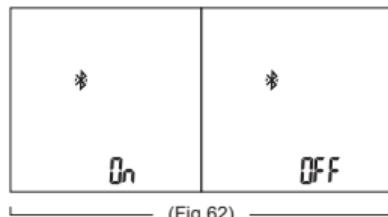
(Fig.61)

## To Connect via Bluetooth before a Blood Glucose Testing

1. When the meter is switched off, press and hold  button for 4 seconds to enter setting.
2. Press  to confirm Buzzer setting and enter Bluetooth function setting menu.
3. Press  or  to select Bluetooth "ON" or "OFF" (Fig. 62).
4. Select "ON" and press  to confirm and meter will be turned off.
5. Insert a test strip to turn ON the meter (Fig. 63).  will blink when the meter is NOT connected with a mobile device.
6. Turn on BLE tool APP (with Blood Glucose Test) and Bluetooth on your mobile device.

***Note: Please skip Step 1~4 if Bluetooth feature is already "ON".***

7. Click "Connect" and select the device shown (ex.  TBMTXXXXXXXX) in APP list.  stops blinking when the meter & mobile device is connected.
8. Perform your blood glucose test. After testing your blood glucose, the test result will automatically transmit to the APP.  will disappear (Fig. 64).

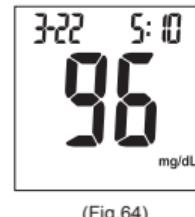
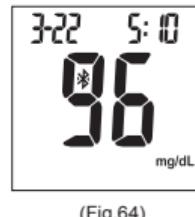
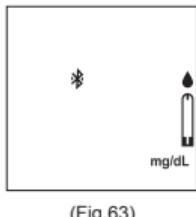
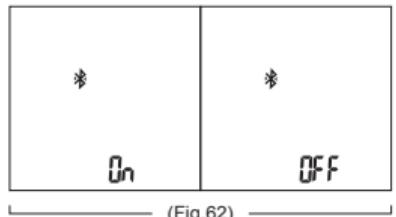


## To Connect via Bluetooth after a Blood Glucose Testing

1. When the meter is switched off, press and hold  button for 4 seconds to enter setting.
2. Press  to confirm Buzzer setting and enter Bluetooth function setting menu.
3. Press  or  to select Bluetooth "ON" or "OFF" (Fig. 65).
4. Select "ON" and press  to confirm and meter will be turned off.
5. Insert a test strip to turn ON the meter (Fig. 66).  will blink when the meter is NOT connected with a mobile device.
6. After testing your blood glucose, the test result is shown (Fig. 67). Bluetooth icon is still blinking.

***Note: Please skip Step 1~4 if Bluetooth feature is already "ON".***

7. Turn on BLE tool APP (with Blood Glucose Test) and Bluetooth on your mobile device
8. Click "Connect" and select the device shown (ex.  TBMTXXXXXXXX) in APP list.  stops blinking when the meter & mobile device is connected.
9. The test result will automatically transmit to the APP.  will disappear (Fig. 68).



# **Cleaning and Disinfection Procedure**

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## ***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

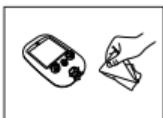
## **Note:**

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

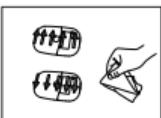
# Cleaning and Disinfection Procedure



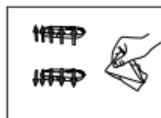
(Step 1)



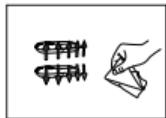
(Step 2)



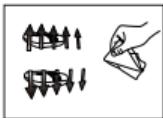
(Step 3)



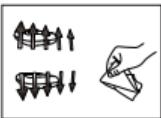
(Step 4)



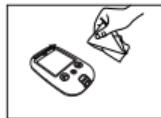
(Step 5)



(Step 6)



(Step 7)



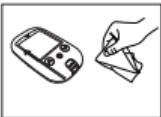
(Step 8)



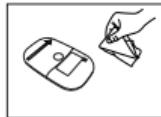
(Step 9)



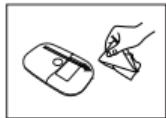
(Step 10)



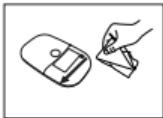
(Step 11)



(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.

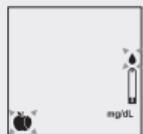
## **Care and Storage**

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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.
	$\triangle_H$ 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》
	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.

<b>Display</b>	<b>Description</b>	<b>Action</b>
	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.
	Battery power is LOW. Meter will only provide approximately 10 more measurements.	Replace with 2 AAA batteries.
	An error message indicates that the hematocrit of 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

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<b>Display</b>	<b>Description</b>	<b>Action</b>
	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 further usage.	Replace with 2 AAA batteries immediately
	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.

<b>Display</b>	<b>Description</b>	<b>Action</b>
<b>E-3</b>	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.
<b>E-4</b>	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.
<b>E-5</b>	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.
<b>E-6</b>	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.
<b>E-7</b>	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.
<b>E-9</b>	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

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<b><i>Other problems which may occur</i></b>	<b><i>Action</i></b>
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

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Operation Temperature	50°F ~ 104°F (10°C ~ 40°C)
Operation Humidity	10 ~ 90% RH
Hematocrit	10 ~ 65%
Test Sample	Capillary Whole Blood <small>(fingertip, palm, and forearm)</small>
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	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

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- 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

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	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		

## Service and Warranty

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### ***IMPORTANT***

- Tyson Bio HT100-B Blood Glucose Glucose Meter, Tyson Bio HT100-B 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.

**Notice**

**Federal Communications Commission (FCC) Statement**

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

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.

***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 of the device.

***FCC RF Radiation Exposure Statement:***

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

### ***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](http://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.

### ***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