Thank you for choosing Tyson Bio HT100 Blood Glucose Monitoring System to monitor your blood glucose level. It is designed to be accurate, easy to use, and quick in response time. This User Manual contains all information needed to operate and maintain Tyson Bio HT100 Blood Glucose Monitoring System. Please read carefully before use.

- Tyson Bio HT100 Blood Glucose meter can be used with:
- Tyson Bio HT100 Code-Calibration Blood Glucose Test Strip
- Tyson Bio HT100 Auto-Calibration Blood Glucose Test Strip
- Tyson Bio Auxiliary Kit
- MT-A Voice Guidance MT-B
  Bluetooth
- MT-C Voice Guidance & Bluetooth

Tyson Bio HT100 Blood Glucose Monitoring System is for quantitatively measuring glucose (sugar) in whole blood obtained from the fingertip, palm, and forearm; or venous whole blood. It is Only for use outside the body (For in vitro diagnostic use) and intended for self-testings at homes and under professional settings to monitor blood glucose levels.

Interchangeable Tyson Bio MT-B and MT-C Auxiliary Kit enable Bluetooth connectivity on your meter to communicate with other mobile devices. They can be purchased separately.

Voice Guidance feature of Tyson Bio MT-A and Tyson Bio MT-C Auxiliary Kit are not intended for the visually impaired.

For Home Use

All parts of Tyson Bio MT100 Blood Glucose Monitoring System should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. To assure that you are not placing yourself at risk, always remember:

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

Reference:
"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)
 http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

 "CDC: Infection Prevention during Blood Glucose Monitoring and Insulin Administration"
 (2010) http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html
Users need to adhere to Standard Precautions when handling or using this device. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting bloodborne pathogens between patients and healthcare professionals. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007" http://www. cdc.gov/hicpac/2007ip/2007isolationprecau tions.html.
The meter should be disinfected after use on each patient. This Blood Glucose Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer's disinfection procedures are followed.
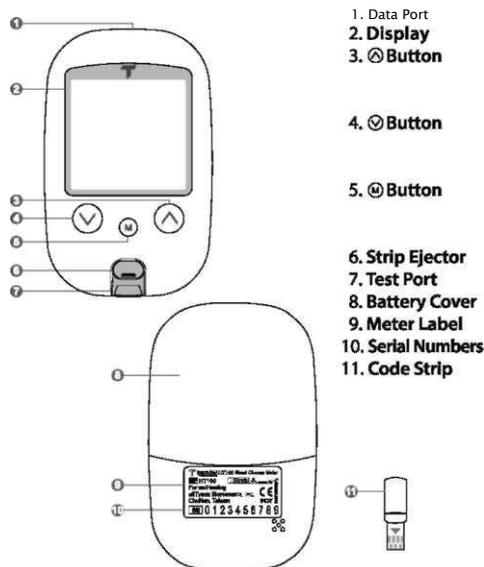Only auto-disabling, single use lancing devices may be used with this device.

Cleaning Solution and Disinfecting Solution: Clorox Bleach Germicidal Wipes (Clorox Professional Products Company. EPA Reg. No. 67619-12). Contact Clorox Company at 1 -800-537-1415.

About Tyson Bio HT100 Blood Glucose Monitoring System

The complete kit contains:

- One HT100 Blood Glucose Meter • One HT100 Blood Glucose Monitoring System User Manual
- One HT100 Blood Glucose * One HT100 Blood Glucose Monitoring System Quick Reference
  Guide Test Strip vial (10 strips) • One HT100 Blood Glucose Test Strip Package Insert
- One Code Strip • One HT100 Control Solution Package Insert (included
  with code-calibration test strip) • One Lancing Device Package Insert
- One bottle of Tyson Bio HT100 Control Solution • One Log Book
- One lancing device • One carrying case
- Ten lancets
- To connect interface cable for data transferring
- To display results in numbers and icons
- Press and hold to enter reminder alarm and HI/LO alarm setting
- To adjust numbers and to toggle settings
- To browse test results and averages in memory
- Press and hold to enter buzzer setting
- To adjust numbers & to toggle settings
- 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

1. Data Port
2. **Display**
3. ⊘ **Button**

4. ⊘ **Button**

5. ⓜ **Button**

6. **Strip Ejector**
7. **Test Port**
8. **Battery Cover**
9. **Meter Label**
10. **Serial Numbers**
11. **Code Strip**

Push to eject the test strip
Compatible test strips and Code Strip are inserted here To slide open and close Manufacturer information The meter manufacturer serials
For Code-Calibration type blood glucose test strip using only [Included in Code-Calibration type blood glucose test strip)
Memory Icon
Appears during memory mode
Year/Date
To display year/date
Control Solution Icon
Appears during a Control Solution test and indicates its result as a Control Solution test result
- 4. Alarm Icon

・Appears when an alarm is set

・5.　　Test Result

　・To display test results

・6.　　Buzzer Icon

　・Appears when buzzer is ON

　・7. Meal Indicator Icon

　　・Pre-meal and post-meal 8.**14** day Average

　　・14 day average result 9. Bluetooth icon

　　・Appears when Bluetooth is on

・10.　　Time

　　・To display time.

・11.　　Code

　　・Appears when a code is displayed.

・12.　　Blood Drop Icon

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

・13.　　Warning Icon

　　・Appears when a result is out of range.

・14.　　Test Strip Icon

　　・Appears when the meter is ready for a test.

・15.　　Temperature Icon

　　・Appears when the meter exceeds normal operating temperatures.

・16.　　Measurement Units

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

・17.　　Battery Icon

　　・Appears when battery power is low.

・**Setting Up Tyson Bio HT100 Blood Glucose Meter**

・Be sure the batteries are properly installed, the default is set to January 1 st, 0:00. Please follow instructions to properly setup the meter.

・**Installing/Replacing Batteries**

・1. From the back of the meter, gently slide and

・Install batteries with the + and - ends matching indication marks on the battery compartment. The meter requires 2 AAA batteries.

・Slide battery cover back into place.

Setting Date/Time

1.When the meter is off, press and hold ® button for 4 seconds to enter this setting mode.

2.Press ®or® to select"24hr"or"12hr". Press®toconfirm (Fig.2).

3.The numbers of "year" will appear and flash. Press ® or ® to adjust and Press ®to confirm (Fig.3). 4. The number of "month" will appear and flash. Press ® or ® to adjust and press ® to confirm (Fig.4). S.The numbers of "date" will appear and flash. Press® or® to adjust and press® to confirm (Fig.5). 6. The numbers of "hour" will appear and flash. Press ® or® to adjust and press ® to confirm (Fig.6). The numbers of "minute"will appear and flash. Press ® or ® to adjust　　**j. | g.(jjAM bQ g jff̈jjpl　(- j jf̈jjjj*''** and press ® to confirm (Fig.7).The set date and time will now display on the LCD screen (Fig.8, Fig.9). Press ® to turn off the meter. The meter date/time setting is complete.

(Fig.7)　　(Fig.8)　　(Fig.9)

Setting Up Reminder Alarms

Tyson Bio HT100 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 ® button for 4 seconds or longer to enter setting.

2.The first reminder alarm will appear on the display (Fig.10).

3. Press ® or® to select "ON" or"OFF". If "OFF" is chosen and ® pressed, the meter will proceed to the next reminder alarm setting. If "ON" is chosen (Fig.11) and ® pressed, the number of "hour" will start flashing (Fig.12).

4. Press ® or ® to adjust and press to confirm.

5. The numbers of "minutes" will flash (Fig.13). Press ®or® to adjust and press ®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.

Setting Up HI/LO Alarms

Tyson Bio HT100 meter provides HI/LO alarm.

1. After completing the reminder alarm setting, press ® to enter the HI alarm setting.

2. Press ® or ® to set "ON", press ® to confirm. If "OFF" is chosen, the meter will skip this setting (Fig. 14,15).

3. To change the alarm setting, press ® or ® until you reach your desired HI setting and then press ® to confirm. (Fig.16) The HI alarm value range is 100 ~ 400mg/dL (5.5 ~ 22.0mmol/L) and the default value is 180mg/dL (9.5mmol/L).

4. Continue to the LO alarm setting (Fig.17), repeat Step 2 and 3 (Fig.18,19) to confirm or to change LO alarm setting. Press ® to turn off the meter. The LO alarm value range is 40 ~ 90mg/dL (2.0 ~ 5.0mmol/L) and
  the default value is 70mg/dL (3.2mmol/L).

5.   Press ® to finish setting and the meter will be turned off.

Important Information

Important Information

Before Testing

' Always keep test strips in the original vial. Tightly close the vial cap immediately after removing a test strip.

·Replace the Code Strip every time you begin using a new vial of test strips.
  (For Code-Calibration type blood glucose test strip using only)

·Use each strip immediately after removing it from the vial. Each test strip should be used ONCE ONLY.

·Do not use test strips or Control Solution beyond the expiration date printed on the package since this may cause inaccurate results.

·Store your test strips and the meter in a cool, dry place between 4°C and 30°C (39°F and 86°F). Temperatures beyond this range, as well as humidity, can damage test strips and lead to inaccurate results.

·Any change of medications based on the Tyson Bio HT100 Blood Glucose Monitoring System results without advices of a doctor is NOT RECOMMENDED.

·The lancing device is intended only for single user and should NOT be shared.

·Only Tyson Bio HT100 test strips and Control Solution can be used with the Tyson Bio HT100 meter.

Before testing, you need the following items

·Tyson Bio HT100 Blood Glucose Meter

·Tyson Bio HT100 Blood Glucose Test Strip

■Code Strip (included with Code-Calibration test strip)

■Adjustable automatic lancing device and sterile lancet.

**Coding Tyson Bio HT100 Blood Glucose Meter Using a Code Strip**

For code-calibration test strip only

1.Please insert Code Strip to start the procedure (Fig.20). The meter
  will turn on automatically when Code Strip is inserted.
2.The screen will display a code, make sure the code is exactly the same
  as printings on the test strip vial label (Fig.21).
3.Remove the Code Strip to turn off the meter

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.Таке a
test strip from the vial and re-cap the vial immediately (Fig. 23).

4.Insert the test strip, top side facing up into the test port (Fig. 20). The meter will be automatically
turned on.
5.A code number will appear. Make sure the code is exactly the same as printings on the test strip vial
label (Fig.21).
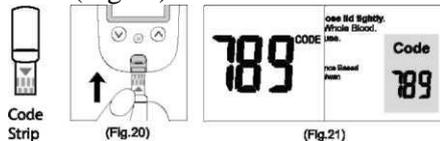
Note:
*If you are using Code-Calibration type blood glucose test strip for the first time without coding the
meter, a "OOO" will appear on the screen (Flg.24) and turn off automatically after 2 minutes. You
may not proceed to do any testing unless the meter Is coded.*

Reminder:
*Make sure that the code number on the display matches the code number displayed on the test strip
vial. It the numbers do not match, please code the meter by using anew Code Strip supplied with the
test strip vial. Insert Code Strip Into the meter until a new code appears on the screen. This should
match the code on the test strip vial label (Flg.21).*

6.A beep will sound, and a code number will appear and follow by a flashing " »" icon. You can press ®
  or ® to select the meal indicator for marking the test as Pre-meal test #, post-meal test C , or no marker
  (default) (Fig.25).
7.A blood sample can now be obtained (refer to P.I 5).

Obtaining a Blood Sample
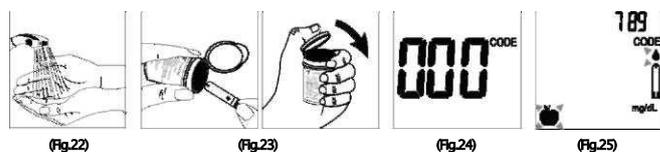
1.Unscrew the lancing device cap (Fig.31).
2.Place a lancet into the lancing device (Fig.32).

3. Twist and pull to remove the protective lancet cover to expose the sterile needle, save the cap for later use (Fig.33).

4. Screw the lancing device cap back on. Select the skin penetration depth preferred (Fig.34).

5. Pull the barrel back until you hear a 'click' sound (Fig.35).

6. Place the lancing device softly against the finger, palm, or forearm, and press the trigger to obtain a blood sample (Fig36).

7. Unscrew the lancing device cap (Fig.31).

8. Place a lancet into the lancing device (Fig.32).

9. Twist and pull to remove the protective lancet cover to expose the sterile needle, save the cap for later use (Fig.33).

10. Screw the lancing device cap back on. Select the skin penetration depth preferred (Fig.34).

11. Pull the barrel back until you hear a 'click' sound (Fig.35).

12. Place the lancing device softly against the finger, palm, or forearm, and press the trigger to obtain a blood sample (Fig36).

To unload the lancing device

1. After sampling, remove the cap containing the used lancet carefully.

2. Push the exposed tip of the lancet into its Protective Cap (Fig.37). Slide the Lancet Ejector forward and disposing the used lancet in an approved container.

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

To reduce chances of infection:

· *Always use a new and sterile lancet. 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 PJ5) for detail instructions of meter maintenance.*

· **Applying a Blood Sample**

SAMPLE MAY BE OBTAINED FROM FINGER, PLAM OR FOREARM

1. After obtaining a blood sample, discard the first drop to prevent contamination. Introduce the tip of the test strip to the drop of blood. Blood sample will be automatically drawn into the test strip (Fig.38).

2. Hold the tip of the test strip touching the blood drop until the meter beeps.

3. As soon as the blood has completely filled the confirmation window of the test strip, the meter will start a countdown. The test result will appear on the display after 5 seconds and will be automatically stored into the meter memory (Fig.39).

4. After the test result appears and if there is no further test, the meter will automatically turn off after 2 minutes. After completing the test, remove the used test strip by pushing the strip ejector or use a tissue paper to dispose (Fig.40). Please discard the test strip in the clinical waste container after use. If applying a blood sample of reduced volume,the error code (E-7) will appear on the diaplay (Error code informatioms are describe clearly in "Error Messages" section).
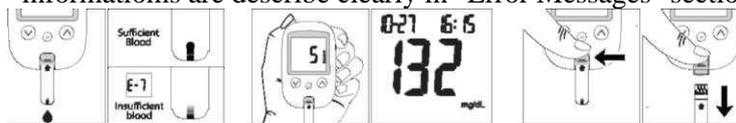
Warning: Please DO NOT point the test strip at people and animals when ejecting.
Used lancets and test strips are considered bio-hazardous. Dispose of used lancets and test strips in a clinical waste container.

Normal Glucose Values
The glycemic recommendations for nonpregnant adults with diabetes:
Preprandial capillary plasma glucose: 80-130 mg/dL (4.4-7.2 mmol/L) Peak

postprandial capillary plasma glucose: 180 mg/dL (10.0 mmol/LJ Diabetic patients may have blood glucose values that are moderately elevated.

HI and LO Readings

Tyson Bio HT100 meter is designed to display test results between 20 ~ 600 mg/dL (1.1- 33.3 mmol/L). If a "HI" (Fig.41) or a "LO"(Fig.42) message appears on the display, it indicates that the meter has detected a blood glucose level is higher than 600 mg/dL (33.3 mmol/L) or lower than 20 mg/dL (1.1 mmol/L). It is suggested the testing procedure should be reviewed and the test should be repeated using a new test strip to confirm the result again.

Available Alternate Sites Testing

Palm and Forearm

Tyson Bio HT100 Blood Glucose Monitoring System provides you alternate sites testing (AST). This system provides you to test on the palm and the forearm with the equivalent results to fingertip testing.

Caution:

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

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

AST ONLY in the following intervals:

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

•   Two hours or more after exercise.

DO NOT use AST if:

■You think your blood glucose is low.

■You are unaware of hypoglycemia.

■Your AST results do not match the way you feel.

■You are testing for hyperglycemia.

■Your routine glucose results are often fluctuating.

■You are pregnant.

■Control Solution

The Control Solution is to ensure that Tyson Bio HT100 meter is working properly and the user is performing a test correctly. ***When to Perform a Control Solution Test***

1.You get your meter for the first time before testing your blood test,

2.You open a new vial of test strips,

3.You want to check the meter and strips,

4.You suspect that the meter or test strips are not working properly,

5.Your blood glucose test results are not consistent with how you feel,

6.You think your test result does not accurate,

7.You dropped your meter, or

8.An advice from your healthcare professional.

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

Performing a Control Solution Test

1.If you purchase strip is Tyson Bio HT100 Code-Calibration Blood Glucose Test Strip, please make sure yourTyson Bio HT100 Meter is coded correct (refer to page 12 {Coding Tyson Bio HT100 Meter Using Code Strip))

2. If you purchase strip is Tyson Bio HT100 auto-calibration type blood glucose test strip, please go to step 3.

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

Caution: If your room temperature is not between 15°C~35°C (S9°F ~ 95°F), Hie Control Solution Test Result will incorrect.

4. Insert a Tyson Bio HT100 test strip, top side facing up, contact bar end first, into the test port. The meter will be automatically turned ON (Fig.43).

5. For Code-Calibration Type, all segments of the LCD display will appear, a beep will sound, and a code number will appear followed by a flashing "a" icon. Be sure the code number on the display matches the code number on the test strip vial label (Fig.44). For Auto-Calibration Type, a beep will sound and the system checking will appear followed by a flashing"»" icon (Fig.45).

6. Press and hold ® button for 2 seconds to change to the Control Solution test mode." O" will appear on the display (Fig.44). If ® button is pressed again for 2 seconds, the meter will switch back to the normal

(Fig.43)   (Fig.44)   (Fig.45)   (Fig.46)   (Fig.47)
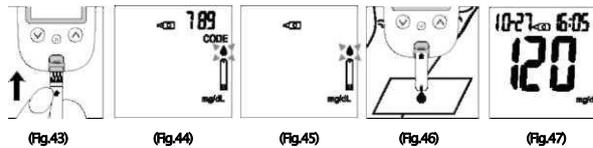
Caution: Follow the above instructions when performing a Control Solution test in order to prevent contamination.

testing mode.

7. Discard the first drop of the Control Solution and squeeze a small drop on a dean nonabsorbent surface such as a clean piece of wax paper. Do not apply the Control Solution to the test strip directly from the bottle, as contamination may occur (Fig.46).

8. Introduce the tip of the test strip to the droplet of the Control Solution.The Control Solution is automatically drawn into the strip. Hold until the meter beeps.The meter will now start to count down and the Control Solution test result will appear on the LCD screen (Fig.47).

9. **Control Solution Results**

The Tyson Bio HT100 meter is functioning correctly only if the Control Solution test result is within the specified range printed on the test strip vial. If the test result is out of range, please repeat the test.

Out of range result may be caused by:
- Incorrect steps taken in performing the test
- The Control Solution temperature is lower than 15°C(59°F) or higher than 35°C(95°F)
- Expired or contaminated Control Solution
- Expired or contaminated test strips
- Improper coding of the Meter
- Meter malfunction

Note:
'The result will not be included in day average calculation when the Tyson Bio HT100 meter Is set in the Control Solution test mode.
' DO NOT use Tyson Bio HT100 meter If the problem persists. Please contact customer service immediately.

Memory Features

How to view results stored in the memory

1. When the meter is off, press ©button to turn on the meter. The Data and Time will be shown on (At the left-upper corner. Firstly the year is shown for 1 second, and then Month-Day will be shown on in the same area).

2. Press ® to view previous results. "MEM" icon will be displayed on the top center area. Initially, the"year" will be display on the top left corner (Fig.48). After 1 second "month-day" will then be displayed on the top left corner and "time" will be displayed on the top right comer (Fig.49). 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 and view the Control Solution test result (Fig.50).

5. When the meter displays the last stored test result, press® button so the meter will display day average results (Fig.51).

Note:

The mater stores 500 results in the memory.

When the memory is full, the oldest result will be removed and replaced by the most recent result.

Exiting the Memory Mode

1. When the meter displays a Control Solution test result, press ® 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 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 your meter with Tyson Bio Link Health Management Software to transfer test results to your personal computer.

1. Obtain the required software and cable to be ordered separately. For order information
   please call Customer Service or visit website of www.tysonbio.com
2. Install the software on a computer Follow the instructions provided with
   software to install the software.
3. Get ready to transfer test results With meter turned off, connect the interface cable to a serial
   port on your computer, then connect the other end of interface cable to the data port located
   on the side of the meter. The word "PC" will appear on the display, indicating that the meter is
   in the communication mode (Fig.60).
4. Get ready to transfer test results With meter turned off, connect the interface cable to a serial
   port on your computer, then connect the other end of interface cable to the data port located
   on the side of the meter. The word "PC" will appear on the display, indicating that the meter is
   in the communication mode.
5. **Cleaning and Disinfection Procedure**

General Cleaning

· Switch the meter OFF.

· Use a soft cloth moistened with water or a mild detergent, gently wipe the meter surface.

■ Please avoid using alcohol or organic solvents in cleaning.
■ Do not immerse the meter in water when cleaning. Do not allow water or cleaning fluids into the meter, test port and data port *Professional Disinfection*

Applicable for people who use the blood glucose meter

■ Cleaning solution and disinfecting solution: Clorox Bleach Germicidal Wipes (Clorox Professional Products Company. EPA Reg. No. 67619-12). Contact Clorox Company at 1 -800-537-1415.

■ Personal Protection: Sanitize hands, then put on gloves before removing a germicidal wipe from the canister. When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings.

• Meter: turn it off

■ Wipe: Clorox Bleach Germicidal Wipes by thoroughly wetting the exterior of the meter, allow the surface to stay wet for 1 minute then allow to air dry.

■Disposal of Infectious Materials: Use disposable gloves. Never reuse or re-wet a disposable wipe. Dispose of according to local regulations for infectious waste disposal.

■Please refer to the Clorox Bleach Germicidal Wipes detailed usage instructions.

Care and Storage

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

1.   Do not expose the meter, test strips, and the Control Solution to extreme conditions such as high humidity, heat,
   freezing cold, or dust.
2.   The meter should be stored at room temperature in a dry and clean area. DO NOT STORE IN DIRECT SUNLIGHT OR
   AREAS WITH HIGH HUMIDITY AND/OR DUST.

It is advised that you store all parts of Tyson Bio HT100 Blood Glucose Monitoring System in the carrying case provided.

Caution:

• Tyson Bio HT100 Blood Glucose Monitoring System is designed for *in vitro* diagnostic use only and is not intended to test on neonate. Any change or administer of medication based on the Tyson Bio HT100 blood glucose test results without the consent advice of a physician or healthcare professional is not recommended.

• The Tyson Bio HT100 test strips are designed for use with fresh venous whole blood or capillary whole blood samples obtained from the fingertip, palm and forearm. DO NOT use samples other than venous whole blood or capillary whole blood. False results may occur when performing the test while severely dehydrated, severely hypotensive, in shock or in a hyperglycemic-hyperosmolar state. If you believe you are suffering from any of the above symptoms, consult a healthcare professional immediately.

• Please refer to Tyson Bio HT100 Test Strip Insert to access further information on strip Limitations.