

TysonBio AC100 AC200

Blood Glucose Monitoring System

User's Manual

For *in vitro* diagnostic use only



Table of Contents

Introduction	2
Intended Use Statement	2
Important Safety Instructions	3
About the Product	4
About the Meter	4
About the Meter Display	6
About the Test Strip	7
About the Test Strip Vial	8
Installing/Replacing the Battery	8
Setting Up the Meter	9
Setting the the Date, Time	9
Setting the Reminder Alarm	10
Setting the HI / LO Alarm.....	11
Setting the Voice Guidance.....	12
Unit Selection.....	12
Important Information	13
Testing Your Blood Glucose Level	14
Preparing the Test Strip	14
Obtaining a Blood Sample	15
Applying Blood Sample to Test Strip	16
Available Alternate Sites Testing.....	18
Control Solution Test	20
Memory Features	23
Transfer Test Results to a Computer	25
Cleaning and Disinfection Procedure	26
Care and Storage	27
Display Messages	28
Specifications	32
Service and Warranty	34
Customer Service	36

Introduction

Thank you for choosing the TysonBio AC100 / AC200 Blood Glucose Monitoring System. As you already know, self monitoring of blood glucose (SMBG) is a necessary part of the treatment plan of people with diabetes mellitus. Adapted for its ease of use and quick response time, the TysonBio AC100 / AC200 System has the ability to process accurate results utilizing only a small volume of blood for in vitro diagnostics.

The TysonBio AC100 / AC200 System is been designed with auto coding feature. It means the meter will code itself automatically every time you insert a test strip. The voice guidance feature with TysonBio AC100 system provides a aid for user to get safe accurate test results every time.

Please read the entire User's Manual carefully before using this product.

Intended use statement

TysonBio AC100 / AC200 Blood Glucose Monitoring System is intended for use by lay users at home to monitor of blood glucose levels in the whole blood. TysonBio AC100 / AC200 System should only be used by a single person. The TysonBio AC100 / AC200 System allows the user an option to use the palm and forearm in addition to the fingertip (testing) to collect capillary blood for self monitoring of blood glucose within certain conditions as explained in product labeling. TysonBio AC100 / AC200 system is not intend for neonatal testing. The TysonBio AC100 / AC200 Test Strips are for testing outside the body (in vitro diagnostic use).

Important Safety Instructions

All parts of the 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 or other persons at risk, always remember:

- The meter and lancing device are for single person use. Do NOT share them with anyone including other family members! Do not use on multiple persons!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

Reference:

“FDA Public Health Notification: Use of Fingertick 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 Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010)

<http://www.cdc.gov/injectionsafety/Fingertick-DevicesBGM.html>

“CDC: Infection Prevention during Blood Glucose Monitoring and Insulin Administration” (2010)

<http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>

About the Product

Your TysonBio AC100 / AC200 System is made up of several components. This booklet is designed to guide you through the operation of the system with detailed directions and pictures. Your TysonBio AC100 / AC200 System contains:

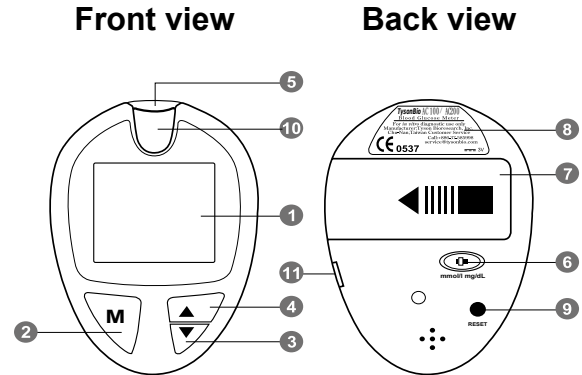
- TysonBio AC100 or AC200 Meter
- One vial Test Strips (10 strips)
- One Lancing Device (option)
- Ten Lancets (option)
- One Control Solution (Level 2)
- One carrying case
- User's Manual
- Log book (option)
- Quick Reference Guide

Note: 25, 50 test strips vial can be purchased individually.

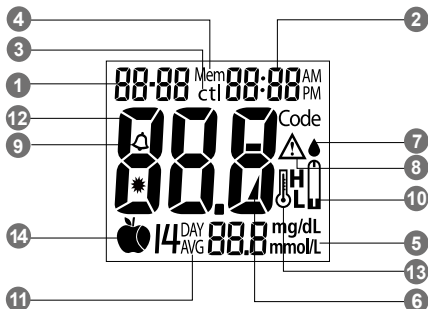
About the Meter

1. **Display** Shows blood glucose results and messages.
2. **M Button** Press this button to set the year/date/time; to view results and test average in memory or to turn the meter off.
3. **▼ Button** Press this button to set alarm; to enter control solution test mode or to decrease number/move forward in meter setting.

4. **▲ Button** Press this button to set voice guidance on/off and select languages or to increase number/move backward in meter setting.
5. **Test Port** Insert the test strip here.
6. **Unit Switch** Switch for mmol/l or mg/dL.
7. **Battery Cover** Slide cover to install and replace batteries.
8. **Label** Contains meter serial number and customer service phone number.
9. **Reset Button** Press this button to re-set the system.
10. **Strip Eject Button** Press this button to ejects the test strip.
11. **Data Port** Connect interface cable to transfer data.



About the Meter Display



- 1. Date**
- 2. Time**
- 3. Control Solution Test**

Appears when doing a control solution test and marking the result as a control solution test.
- 4. Memory Symbol**

Indicates in memory mode.
- 5. Units of Measurement**

Unit of mmol/l or mg/dL will appear with the test result.
- 6. Battery Symbol**

Appears when the battery is low or must be replaced.
- 7. Blood Drop Symbol**

Flashes when it is ready to apply sample to test strip.
- 8. Warning Symbol**

Appears when result is out of the range of your setting reference value.
- 9. Alarm Function Symbol**

Appears when the clock alarm is set.

10. Test Strip Symbol

Appears to tell you when the meter is ready for test.

11. Day Average Symbol

Shows the average value of test results.

12. Test Result Area

Display test results.

13. Temperature Message

Appears if your meter is out of operating temperature range.

14. Meal Indicator

Pre-meal 🍏 and post-meal 🍏

About the Test Strip

The TysonBio AC100 / AC200 test strip is used to perform the blood glucose test in conjunction with the TysonBio AC100 / AC200 meter.

Each strip can be used only once.

The test strip consists of the following parts:

1. Contact Bar

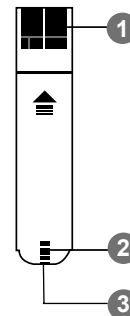
This end of the test strip is inserted into the test port to activate the meter. (white side face up).

2. Confirmation Window

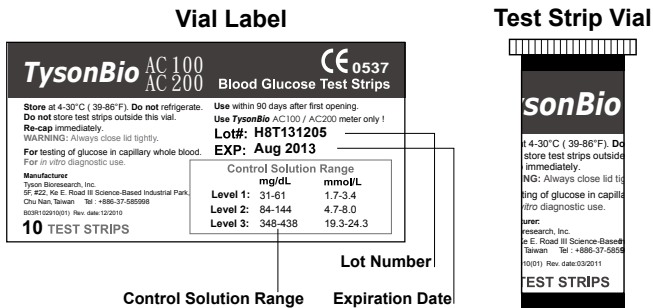
This is where you can confirm that enough blood has been applied to the target area.

3. Target Area

This is where blood is drawn into the test strip.

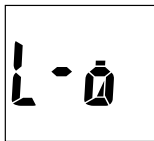


About the Test Strip Vial



Installing/Replacing the Battery

When the battery is low, the meter will show a warning signal. When this display appears, it is time to replace a new battery. When the low battery warning signal is shown, the meter will provide accurate results for approximately 50 more measurements.



How to Replace the Battery

1. From the back of the meter, gently slide and remove the battery cover.
2. Insert the batteries with the + and – ends matching the marks in the battery compartment.
3. Slide battery cover back into place.



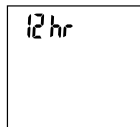
8

Setting Up the Meter

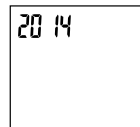
To turn the meter on, first install the batteries, then press the reset button located at the back of the meter and proceed with the following instructions.

Setting the Date, Time

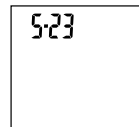
1. Press and hold **M** for 4 seconds with meter turn off to enter this mode.
(With the voice function on, you will hear "Please set date and time".)
2. Press **▲** or **▼** to select "24hr" or "12hr" setting. Press **M** to set.(Fig.1)
3. The year will now appear and flash. Press **▲** or **▼** to select the year. Press **M** to set.(Fig.2)
4. The number in the **month** position will now flash. Press **▲** or **▼** to select the month. Press **M** to set. (Fig.3)
5. The **date** will now flash. Press **▲** or **▼** to select the date. Press **M** to set.(Fig.3)
6. The number in the **hour** position will now flash. Press **▲** or **▼** to select the hour. Press **M** to set. (Fig.4)
7. The **minute** will now flash. Press **▲** or **▼** to select the minute. Press **M** to set and meter will turn off automatically. You have now completed the meter date/ time setting. (Fig.4)



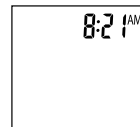
(Fig.1)



(Fig.2)



(Fig.3)



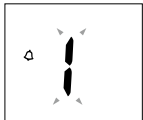
(Fig.4)

9

Setting the Reminder Alarm

TysonBio AC100 / AC200 meter provides four user setting reminder alarms for worry free testing. (Default is alarm off.)

1. Press and hold ▼ for 4 seconds with meter turn off to enter this mode.
(With the voice function on, you will hear "Please set reminder alarm".)
2. The first reminder alarm will appear on the display. (Fig.5). Press ▲ or ▼ to select which alarm you want to set (number 1 to 4). Press **M** to confirm.
3. Press ▲ or ▼ to select "yes" or "no". If "no" is chosen and **M** is pressed, the meter goes to next reminder alarm setting. If "yes" is chosen, press **M** to confirm and the time will appear. (Fig.6)
4. The number in the hour position will now flash. Press ▲ or ▼ to select hour. Press **M** to set. (Fig.7)
5. The minutes will now flash. Press ▲ or ▼ to select the minutes. Press **M** to set and meter will go to next reminder alarm setting. (For the fourth reminder alarm, press **M** will go to HI alarm setting.) (Fig.8)



(Fig.5)



(Fig.6)



(Fig.7)



(Fig.8)

6. Repeat steps 3 to 5 to set the next three reminder alarms. (if needed).
7. After finishing reminder alarm setting, keep pressing and releasing ▼ until HI alarm setting appear.

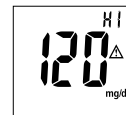
NOTE:

When the alarm is ringing, press any one button to turn off or the alarm will turn off automatically after 30 sec.

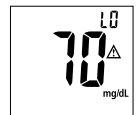
Setting the HI / LO Alarm

1. After finishing the reminder alarm setting, the HI alarm setting will appear. (Fig. 9) *(With the voice function on, you will hear "Please set Hyperglycemic value".)*
2. To change HI alarm setting, press ▲ or ▼ until you reach your desired HI setting and then press **M** to set. (The HI alarm value range is 100-400mg/dL / 6.0-21.0mmol/L, default is 180mg/dL / 10.0mmol/L.) (Fig. 9)
3. LO alarm setting will appear. (Fig.10) *(With the voice function on, you will hear "Please set Hypoglycemic value".)* To change this setting, press ▲ or ▼ until you reach your desired LO setting and then press **M** to set. Meter will turn off automatically, you have now completed the meter alarm setting. (The LO alarm value range is 30-90mg/dL / 2.4-5.8mmol/L, default is 70mg/dL / 4.0mmol/L.)

(Fig.9)



(Fig.10)



Setting the Voice Guidance (AC100 only)

1. Press and hold ▲ for 4 seconds with meter turn off to set voice function. *(With the voice function on, you will hear “Please set voice guidance”).*
2. The word “on” will appear on the display. Press **M** to turn on the voice function, or press ▼ to display “OFF” and then press **M** to turn off voice function. *(With the voice function on, you will hear “voice guidance on” or “voice guidance off”).*
3. After setting the voice guidance function “on”, “L1” will appear on the display. Press ▲ or ▼ to choose language L1 (English) or L2 (Spanish), and then press **M** to set. Meter will turn off automatically, you have now completed the voice guidance setting.

The image shows a rectangular LCD display with the word "ON" in a large, black, digital font.

The image shows a rectangular LCD display with the word "OFF" in a large, black, digital font.

The image shows a rectangular LCD display with the text "L1" in a large, black, digital font.

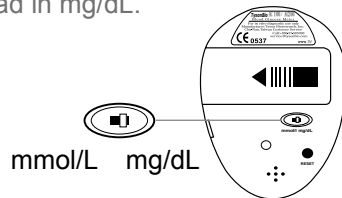
The image shows a rectangular LCD display with the text "L2" in a large, black, digital font.

Unit Selection

1. Select unit, mg/dL or mmol/L on the back.

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.



Important Information

You have to know before testing

- Always keep the test strips in the original vial only. Tightly close the vial immediately after removing a test strip.
- Use each strip immediately after removing it from the vial. Each test strip can be used once.
- Do not use test strips and control solutions beyond the expiration date printed on the package since this may cause inaccurate results.
- Store your test strips and meter in a cool, dry place between 4 °C and 30 °C (39 °F and 86 °F). Temperatures outside the required range, as well as moisture and humidity, can damage your test strips and lead to inaccurate results.
- **Any change or administer of medication based on the TysonBio AC100 / AC200 blood glucose test results without the consent and advice of a physician or healthcare professional is not recommended.**
- Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or if you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L) you should contact your healthcare professional and follow his or her treatment advice.
- The lancing device is intended only for single user and should **NOT** be shared.

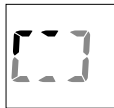
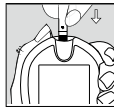
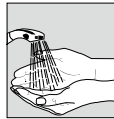
Testing Your Blood Glucose Level

Before testing blood glucose, you need the following items:

1. TysonBio AC100 / AC200 meter
2. TysonBio AC100 / AC200 test strip
3. Adjustable automatic lancing device
4. Sterile lancet

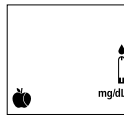
Preparing the Test Strip

1. Wash hands using soap and warm water. Rinse and dry thoroughly.
2. Pull out a test strip from the vial and re-cap the vial immediately.
3. Insert the test strip, white side face up, into the test port. The meter will automatically turn on.
4. A beep will sound, and a clockwise moving dotted lines will appear.



(With the voice function on, you will hear "system checking".)

5. After system checking ok, a flashing "●" symbol will appear. You can press ▲ or ▼ to select the meal indicator for marking the test as premeal 🍏 or postmeal test 🍏 (default premeal).
6. Now you are ready to obtain a blood sample.



(With the voice function on, you will hear "Please apply blood sample" "Premeal" or "Postmeal".)

Obtaining a Blood Sample

SAMPLE MAY BE OBTAINED FROM FINGER, PALM or FOREARM

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

1. Unscrew and remove the endcap of the lancing device.
2. Insert the lancet into the lancet holder.
3. Twist and remove the protective lancet cover to expose the sterile needle tip.
4. Recapping and screwing the endcap to the body of the lancing device.
5. Pull back on the cocking mechanism until it comes to a stop.
6. Place the lancing device firmly against the finger tip and press the release button.
7. After sampling, remove the endcap containing the used lancet carefully.
8. Remove the lancet from the lancing device. Discard the used lancet properly in accordance with local, state, and federal law.

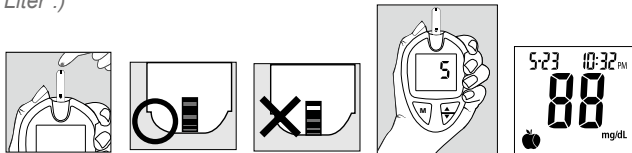
CAUTION: To reduce the chances of infection:

- **Never** share a lancing device and lancet with another person.
- **Always** use a new and sterile lancet. Lancets are for single use only.
- **Wash** hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
- **Refer** to section "Cleaning and disinfection procedure" (page.26) for how to clean / disinfect the meter and lancing device.

Applying Blood Sample to the test strip

1. After obtaining a blood sample, touch the tip of the test strip to the drop of blood. Blood is automatically drawn into the test strip. **Hold the tip of the test strip touching the blood drop until the meter beeps.**
2. As soon as enough blood has filled the confirmation window (see picture) of the test strip, the meter will start the countdown from 5 to 1. Your blood glucose result will appear on the display and will be stored into the meter memory automatically.

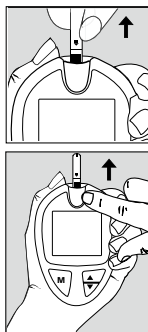
(With the voice function on, you will hear "Premeal/Postmeal blood glucose test result is (number) Milligram Per Deciliter/Millimole Per Liter".)



Reminder:

To ensure accurate results, make sure the confirmation window of the test strip is completely filled with your blood sample.

3. After the test result appears, if no further tests are performed, the meter will automatically shut off after 3 minutes. After finishing the test, you can push the strip eject button to remove the used strip or use a tissue to remove test strip from the meter for proper disposal.

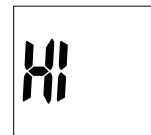


CAUTION:

Used lancets and test strips may be considered biohazardous waste in your area. Dispose of used lancets and test strips at the point of use in an approved sharps container. Be sure to follow your local regulations for proper disposal.

HI and LO Readings

1. TysonBio AC100 / AC200 meter is designed to display test results range between 20 to 600 mg/dL (1.1 to 33.3 mmol/L). If a "HI" message appears on the display, your meter has detected that your blood glucose level is higher than 600 mg/dL(33.3 mmol/L). It is suggested that you review your testing procedure and test again with a new test strip to confirm the result. **If the same result occurs, consult your healthcare professional immediately.** (Fig.11)
2. If a "LO" message appears on the display, your meter has detected that your blood glucose level is lower than 20 mg/dL (1.1 mmol/L). It is suggested that you review your testing procedure and test again with a new test strip to confirm the result. **If the same result occurs, consult your healthcare professional immediately.** (Fig.12)



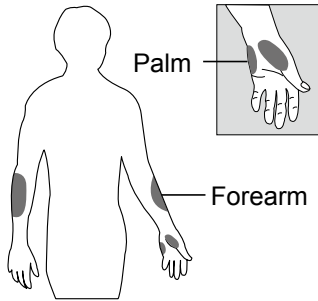
(Fig.11)



(Fig.12)

Available Alternate Sites Testing : Palm and Forearm

TysonBio AC100 / AC200 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.



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

CAUTION:

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

2. 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.

3. 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.
- If you are pregnant.

Control Solution Test

The control solution is used to check and ensure that the system is working properly and that you are performing the test correctly.

When to Perform a Control Solution Test

1. When you are using your TysonBio AC100 / AC200 system for the first time.
2. When you are using a new batch of test strips.
3. Anytime you question the performance of the system, or on a regular basis to ensure accuracy, e.g. once a week.
4. When you adjust your diabetic medication plans.
5. When your blood glucose test result is lower or higher than your normal level.

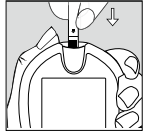
NOTE:

There are three control solutions at different desired range of aqueous glucose (Level 1, Level 2 or Level 3). For more information about the control solution, please read your control solution package insert. They are available and sold separately if not included in the kit. For order information, please contact customer service.

To Perform a Control Solution Test

1. Make sure the control solution is at room temperature (15°C to 28°C or 59°F to 82°F) prior to testing.

2. Insert a test strip, white side face up, contact bar's end first, into the test port. The meter will automatically turn on. *(With the voice function on, you will hear "meter power on music".)*



3. All segments of the LCD display will appear, a beep will sound, and a clockwise moving dotted lines will appear.

(With the voice function on, you will hear "system checking".)



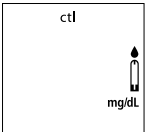
4. After system checking ok, a flashing "♦" symbol will appear.

(With the voice function on, you will hear "Please apply blood sample".)



5. Press and hold **M** for 4 sec to switch to control solution mode. The "ctl" will appear which indicates that the meter will mark your current test as a control solution test. Now you are ready to apply the control solution.

(With the voice function on, you will hear "Please apply control solution".)

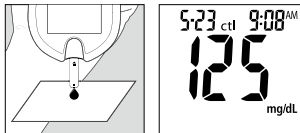


6. Discard the first drop of control solution and squeeze a small drop of control solution on a clean nonabsorbent surface (such as a clean piece of wax paper). **Do not apply control solution to the test strip directly from the bottle.**

- Bring the tip of the test strip to lightly touch the drop of Control Solution. Control Solution is automatically pulled into the strip through the tip. Hold until the meter beeps. The meter will now start the countdown from 5 to 1 and the control solution test result will appear. (Fig.6) *(With the voice function on, you will hear "Control solution test result is (number) Milligram Per Deciliter/Millimole Per Liter".)*

CAUTION:

Please remember that in order to prevent contamination, follow the above instructions properly when performing the control solution test.



Comparing Control Solution Results

The system is functioning properly if the result falls inside the specified range printed on the test strip vial. If the test result falls outside the specified range, repeat the test.

Results falling outside the specified range may be caused by

- Error in performing the test
- Control solution temperature is lower than 15°C(59°F) or higher than 28°C(82°F)
- Expired or contaminated control solution
- Expired or contaminated test strips
- Meter malfunction

NOTE: The result will not be included in calculating the average when the meter is set in the control solution test "ctl" mode. **DO NOT** use the system if the problem persists. Please contact customer service.

Memory Features

View results stored in the memory

- Press **M** to turn on the meter. The date and time will appear first.
- Press **▼** to review previous results. Results will be shown starting with the most recent. Each result will show the date and time the test was taken. If enough tests are performed and stored to calculate 14-day average result, the screen will also display the 14-day average result.

(With the voice function on, you will hear "Premeal/Postmeal blood glucose test result is (number) Milligram Per Deciliter/Millimole Per Liter".)

- You can press **▼** or **▲** to scroll forward or backward through the results. When "000" appears on the display, you have viewed all of the results in the memory. Press **▼** or **M** to turn off the meter.

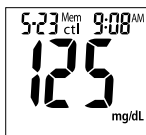
NOTE: The meter will hold 500 results in the memory. When the memory is full, the oldest result will be removed and replaced with the newest result.



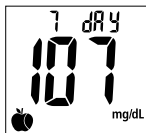
View control solution and day average result

- Press **M** to turn on the meter. The date and time will appear first. Press **M** again to view the memory.

- Continue to press and release ▼, the control solution result ^{*}, the consecutive 7/14/30-days pre-meal and post-meal average results ^{**} will be shown on display in order.



(With the voice function on, you will hear "Premeal/Postmeal (number) day average blood glucose test result is (number) Milligram Per Deciliter/Millimole Per Liter".)



- You can press ▼ or ▲ to scroll forward or backward through the results. When "000" appears on the display, you have viewed all of the results in the memory. Press ▼ or M to turn off the meter.



NOTE:

^{*} if no control solution test has been performed, pressing ▼ will directly display day average results.

^{**} The consecutive 7/14/30-day average is calculated from the blood glucose results obtained during the last consecutive 7/14/30-day. If there are not enough testing results for the calculation of 7, 14, 30 days premeal and postmeal average, pressing ▼ will directly reach the end of the memory.

Exiting the Memory Mode

- Press the M to turn off the meter at any time.
- Meter will shut down automatically after 3 minutes with no further action.

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 TysonBio Link Health Management Software to transfer test results to your personal computer.

1. Obtain the required software and cable

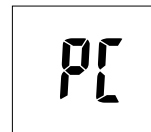
For order information please call Customer Service or visit website of www.tysonbio.com

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.



4. Transfer data

Follow the instructions provided in the software to download the results from the meter. After finishing the data transfer, press M button to turn off the meter.

NOTE:

While in the communication mode, you will be unable to perform a blood glucose test. If the meter is not in the PC link mode, it will not respond to computer commands.

Cleaning and Disinfection procedures

Definition of cleaning / disinfection:

- **Cleaning:** Cleaning generally refers to removal of soil and reduction in the number of microorganisms from a surface by a process such as washing in detergent without prior processing.
- **Disinfection:** Disinfection generally refers to the use of chemical and physical agents, such as chemicals, heat and radiation, to destroy the potential infectivity of a material. It does not imply the elimination of all viable micro-organisms but rather the reduction of the microbial population to a level which makes the disinfected object safe to handle.

When to clean / disinfect the meter and lancing device:

- The meter and lancing device should be cleaned whenever it is visibly dirty.
- The meter and lancing device should be disinfected periodically, such as once per week.
- If the meter is shared or being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person to avoid cross-contaminations.

How to clean / disinfect the meter and lancing device:

- **Cleaning Solution and Disinfecting Solution:** CaviCide Surface Disinfectant (Metrex Research Co., EPA Reg. No. 46781-6)
- **For Use as a Precleaning Decontaminant:** Spray CaviCide onto surface for 30 sec for precleaning process. Wipe surface using a towel and allow to air dry.

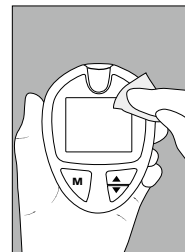
- **For Use as a Disinfectant:** Spray CaviCide directly onto precleaned surface, thoroughly wetting area to be treated. Allow surface to remain visibly wet for 2 minutes at room temperature (68°F/20°C).
- Wipe away residual moisture and fluids after disinfecting the area.
- Allow wiped areas to dry before performing a test.

NOTE:

- Cleaning and disinfecting solutions are readily available at medical distributor or drug store.

CAUTION:






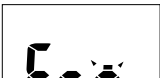

- **Ensure that the swab or cloth is only damp, not wet. Liquid entering the meter may cause meter malfunctions.**
 - **Wash hands thoroughly with soap and water after handling the meter , lancing device, or tet strips.**
- If you have any questions, please contact customer service.

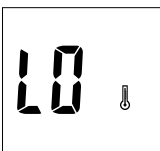
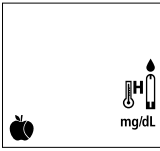
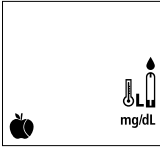





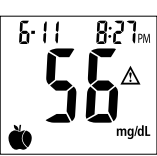
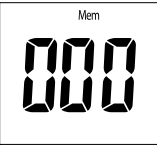

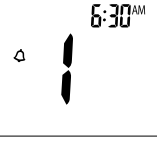
Care and Storage

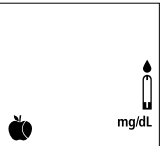
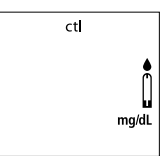
1. Handle the meter with care. Dropping or throwing the meter may cause damage to the device.
2. Do not expose the meter, test strips, and control solution to extreme conditions, such as high humidity, heat, freezing cold or dust.
3. The meter should be stored at room temperature in a dry and clean space. **DO NOT STORE IN DIRECT SUNLIGHT OR AREAS WITH HIGH HUMIDITY AND/OR DUST.** It is advised that you store the meter and its accessories into the provided carrying case.

Display Messages

DISPLAY	WHAT IT MEANS	ACTION
 	An error message indicating a problem with the test strip. <i>(Meter speaks "Strip error".)</i>	Review the instructions and try again with a new test strip.
 	An error message indicating a problem with the meter. <i>(Meter speaks "Meter error".)</i>	Press "reset" button and check the meter again with the test strip. If the problem persists, contact customer service for help.
	Battery power is low. Meter will provide approximately 50 more measurements.	Replace with two AAA batteries.
	Battery power is too low for further usage.	Replace with two AAA batteries immediately.
	Temperature is too high to perform the test. <i>(Meter speaks "Operating temperature error".)</i>	Repeat the test in a cooler setting (10 - 40°C or 50 - 104°F). Wait 15 minutes before re-testing.

DISPLAY	WHAT IT MEANS	ACTION
	Temperature is too low to perform the test. <i>(Meter speaks "Operating temperature error".)</i>	Repeat the test in a warmer setting (10 - 40°C or 50 - 104°F). Wait 15 minutes before re-testing.
	Temperature is high during the test procedure.	Large variation may occur between results due to high or low temperature. Move to the environment (10 - 40°C or 50 - 104°F) and wait 15 minutes before re-testing.
	Temperature is low during the test procedure.	Repeat the test in a warmer setting (10 - 40°C or 50 - 104°F) and wait 15 minutes before re-testing.
	Test result is higher than 600 mg/dL (33.3 mmol/L).	Repeat the test using a new test strip. If the result is still HI, consult your physician immediately.
	Test result is lower than 20 mg/dL (1.1 mmol/L).	Repeat the test using a new test strip. If the result is still Low, consult your physician immediately.

DISPLAY	WHAT IT MEANS	ACTION
	△ appears when the result is HIGHER than the “HI alarm setting” reference range.	For your reference, or you can change the default setting value 100 mg/dL according to page 10.
	△ appears when the result is LOWER than the “LO alarm setting” reference range.	For your reference, or you can change the default setting value 70 mg/dL according to page 10.
	All testing values recorded in the memory have been shown.	Press M or wait for 3 minutes to turn off the meter.
	The meter is in the PC communication mode.	Follow the instructions provided in the software to download the test results from the meter.
	The preset alarm is ringing to remind it is time to perform blood glucose test.	Press any button to shut off or the alarm will turn off automatically after 30 sec.

DISPLAY	WHAT IT MEANS	ACTION
	The system is ready to accept a blood sample.	You may now apply a blood sample.
	The system is ready to accept a control solution sample.	You may now apply a drop of control solution sample.

Other problems that may occur	Action
The test strip has not been inserted into the meter properly.	Review the instructions and re-insert the test strip correctly (white side face up).
Defective test strip.	Replace with a new test strip.
Insufficient blood sample.	Repeat the test with new test strip.
Test strip remains in the test port for more than 3 minutes prior to testing.	Meter will automatically turn-off. Re-insert the test strip to the test port.
LCD display on the meter is blank when trying to perform a test.	Contact Customer Service for help.

Specifications

Meter Operating Conditions

Temperature	10°C - 40°C(50°F - 104°F)
Humidity	10-90% RH
Hematocrit	35 - 55%
Test Sample	Capillary whole blood from fingertip, palm and forearm
Sample Volume	>0.5 µl
Measuring Unit	mg/dL or mmol/L
Measuring Range	20-600 mg/dL (1.1-33.3 mmol/L)
Test Time	5 sec
Memory Capacity	500 most recent results
Average	7/14/30 days average results
External Output	Standard RS232 PC interface
Power supply	two AAA batteries
Battery Life	Approximately 1000 tests
Dimension	94 x63 x25 mm
Weight	60 g without battery

- **The TysonBio AC100 / AC200 Meter, TysonBio AC100 / AC200 Test Strip and Control Solution are in conformity with the IVDD 98/79/EC.**

Manufacturer

Tyson Bioresearch, Inc.
5F. #22, Ke E. Road III, Science-Based Industrial Park
Chu-Nan, Miao-Li County, Taiwan, R.O.C.
TEL: +886-37-585998

EU authorized representative

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

- **The Lacing Device is in conformity with the MDD 93/42/EEC.**

Manufacturer

Beijing Ruicheng Medical Supplies Co. Ltd
Fengxiang Ave. Fengxiang Development Zone,
Yangsong Town, Huairou District,
Beijing 101400 P.R. China

EU authorized representative

Lotus Global Co., Ltd.
15 Alexandra Road, London
UK NW8 0DP

- **The Lancets are in conformity with the MDD 93/42/EEC.**

Manufacturer

SteriLance Medical (Suzhou) Inc.
No.68 Litanghe Road, Xiangcheng Suzhou,
Jiangsu 215133 P.R.China
TEL: +86-512-65799308

EU authorized representative

EMERGO EUROPE
Molenstraat 15, 2513 BH The Hague, Netherlands

Limitations of the Procedure

CAUTION:

The TysonBio AC100 / AC200 System is designed for in vitro diagnostic use only. It is not intended to test on newborns and not intended for the visually impaired. Any change or administer of medication based on the TysonBio AC100 / AC200 blood glucose test results without the consent advice of a physician or healthcare professional is not recommended.

The TysonBio AC100 / AC200 test strips are designed for use with fresh capillary whole blood samples obtained from the fingertip, palm and forearm. 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.

Service and Warranty

IMPORTANT:

Tyson Bioresearch Inc. cannot endorse the performance of the TysonBio AC100 / AC200 System when used with test strips other than those designed for the TysonBio AC100 / AC200 meter. The TysonBio AC100 / AC200 System manufacturer warranty is valid only when used properly within the guidelines of the provided user's manual and is invalid when the TysonBio AC100 / AC200 System and TysonBio AC100 / AC200 test strip are used improperly.

Manufacturer Warranty

Tyson Bioresearch, Inc. guarantees that this device will be free of defects in materials and workmanship for a period of three years from the date of original purchase. During the stated three-year period, our company shall repair or replace any TysonBio AC100 / AC200 meter found defective with a new TysonBio AC100 / AC200 meter.

This warranty does not apply to the performance of a TysonBio AC100 / AC200 meter that has been accidentally damaged, altered, misused, tampered with or abused in any way. 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 any way connected with the purchase or operation of the TysonBio AC100 / AC200 meter or its parts.

For manufacturer warranty services, purchaser must contact Tyson Bioresearch, Inc. for help.

Customer Service

If you have any questions or concerns regarding this product or its operation, or any attempt to correct a problem fails, please call our customer service. Our trained specialists will be happy to assist you, train you, or even reaffirm your results.

Customer Service Hotline

+886-37-585998

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

or E-Mail us at

service@tysonbio.com

website: www.tysonbio.com

When you call our customer service, please have your meter, test strip and all other system supplies available. This will allow us to answer any of your questions with speed and efficiency.

CE 0537

B03R106908 (02)
Rev. date:03/2014