

E2Smart 608

Blood Glucose Monitoring System

CE 0537

User's Manual

For in vitro diagnostic use only



EZ Smart 608

User's Manual

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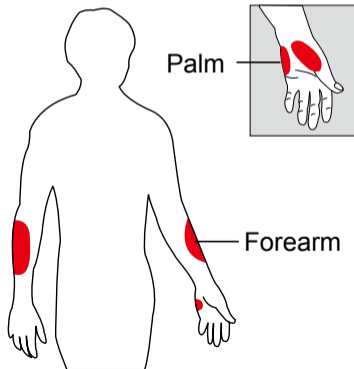
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Important Information

Available Alternative Sites Testing : Palm and Forearm

EZ Smart-608 Blood Glucose Monitoring System provides you alternative 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.

Alternative site results differ from fingertip results when glucose levels are changing rapidly such as after a meal, after taking insulin, during exercise, or when you are ill or under stress. Use blood from a fingertip rather than an alternative site if:

- you think your blood glucose is low,
 - you don't regularly have symptoms when your blood glucose is low, or
 - how you feel doesn't match the results from the alternative site.
 - When you have just taken insulin, or any time during or after exercise.
 - When there are unknown variables occurring in your day, such as illness.
 - Whenever you are about to drive.
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 alternative 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.

- 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.
- Any change or administer of medication based on the EZ Smart-608 blood glucose test results without the consent and advice of a physician or healthcare professional is not recommended.
- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.

Introduction

Thank you for choosing the EZ Smart-608 Blood Glucose Monitoring System, the latest advancement in biosensor technology. As you already know, self monitoring of blood glucose (SMBG) is a necessary part of the treatment plan of people with diabetes mellitus. The Diabetes Control and Complications Trial (DCCT) has confirmed the significant benefits from SMBG when practiced as part of a larger intensive strategy to tightly control blood glucose concentrations.

Adapted for its ease of use and quick response time, the EZ Smart-608 System has the ability to process accurate results utilizing only a small volume of blood for in vitro diagnostics. The EZ Smart-608 Blood Glucose Monitoring System is intended for use in the home and in professional settings to monitor whole blood glucose levels obtained from the fingertip, palm and forearm. This is an over the counter (OTC) product.

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

About the Product

Your EZ Smart-608 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.

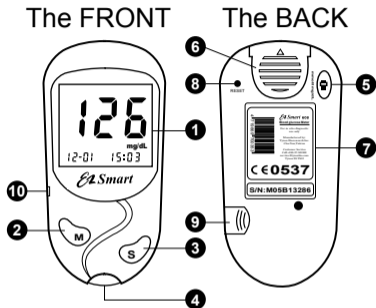
Your EZ Smart-608 System contains:

- EZ Smart-608 Meter
- One vial of EZ Smart-608 Test Strips (10 strips)
- One Glucose Chip(outside the strip vial)
- One Lancing Device (Optional)
- Ten Lancets (Optional)
- One carrying case
- User's Manual
- Log book (Optional)
- Quick Reference Guide
- One vial of Control solution(Optional)

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

About the EZ Smart-608 Meter

- 1. Display** Your test results are displayed here. The large, easy to read screen guides you through the test by using numbers and symbols.
- 2. M Button** The **M** (mode) button is used to set the year, month, day, time, enters the memory mode to show the consecutive 14-day average results and turns the Meter on and off.
- 3. S Button** The **S** (select/set) button is used to select the year, month, day, time, memory of results and control solution mode.
- 4. Test port** This is where you insert the Test Strip into the Meter.
- 5. Unit Switch** Switch for mmol/l or mg/dL.
- 6. Battery Cover**
- 7. Label**
- 8. Reset Button** Press this button to re-set the system.
- 9. Glucose Chip** Insert the Glucose Chip for coding.
- 10. Data port** Connect interface cable to transfer data.

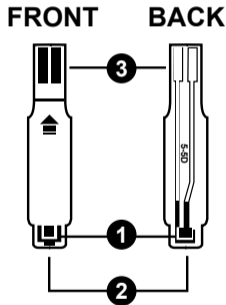


About the EZ Smart-608 Test Strip

The EZ Smart-608 Test Strip is used to perform the blood glucose test in conjunction with the EZ Smart-608 Meter. **Each strip can be used only once.**

The EZ Smart-608 Test Strip consists of the following parts:

- 1. Confirmation Window** This is where you can confirm that enough blood has been applied to the target area.
- 2. Target Area** This is where blood is drawn into the Test Strip.
- 3. Contact Bar** This end of the Test Strip is inserted into the meter Test Port to activate the Meter. (white side face up)



About the EZ Smart-608 Test Strip Vial

VIAL LABEL

EZ Smart 608
Blood Glucose Test Strips

Do not store test strips outside this vial.
Store at 4-30°C(39-86°F)
For the measurement of glucose in whole blood.

Use EZ Smart-608 only!

10 Test Strips

Do not refrigerate. Re-cap immediately.
For *in vitro* diagnostic use.

CE 0537

Lot#: G3T131036

Exp: May.2010

Control Solution Range

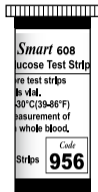
L: 31-61	mg/dL	1.7-3.4	mmol/l
N: 84-144	mg/dL	4.7-8.0	mmol/l
H: 348-438	mg/dL	19.3-24.3	mmol/l

Code
956

Lot Number
Expiration Date

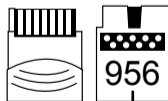
Code Number
Control Solution Range

TEST STRIP VIAL



About the Glucose Chip

The Glucose Chip is used to ensure that your EZ Smart-608 Meter provides you with accurate results. Before performing the blood glucose test or starting a new strip vial, please check your Meter with the Glucose Chip to ensure proper performance (further instructions for use of the Glucose Chip is provided on page 15). After checking your Meter, the Glucose Chip is also used to code setting.



CODE Number

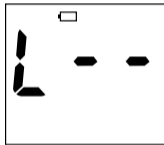
- **Note:** Always use the Glucose Chip to ensure your EZ Smart-608 Meter is performing properly.
- **DO NOT** misplace your Glucose Chip.

Installing/Replacing the battery

The EZ Smart-608 Meter uses one 3-Volt lithium battery (CR-2032).

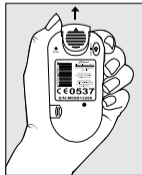
When to Replace the Battery

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 EZ smart-608 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 a 3-Volt lithium battery (CR-2032) with the “+” side facing up.
3. Slide battery cover back into place.

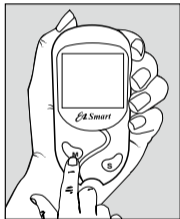


Setting Up the Meter

To turn the Meter on, first put the battery into the battery chamber, then press the reset button located at the back of the Meter and proceed with the following instructions.

Setting Up the Date, Time, Unit and Enter PC Link Mode

1. Press and hold the **M** button for 3 seconds. The Meter is now in the setting mode.
2. The Year setting will be the first to appear. Press and release the **S** button until the correct year appears. With the correct year on the display, press the **M** button and the month and date setting will appear.
3. Press and release the **S** button until the correct month appears. With the correct month on the display, press and release the **M** button and the day setting will flash.
4. Press and release the **S** button until the correct day appears. With the correct day on the display, press and release the **M** button to bring up the hour and minute display.

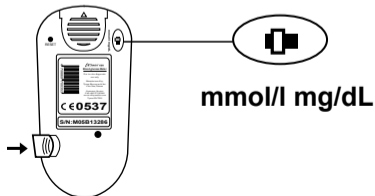


5. Press and release the **S** button until the correct hour appears. With the correct hour on the display, press the **M** button and the minute display will flash.
6. Press and release the **S** button until the correct minute appears. When the correct minute is on the display, press the **M** button to move on to PC link mode.
7. If you press **S** button (yes), it will appear “PC” link mode for transferring test data. Further instruction of transferring test data, see page.22. To finish setting, press **M** button (no) to turn off the meter. Your programmed settings will be shown on the display every time you use the Meter.



Code Setting and Unit Selection

1. Select unit, mg/dL or mmol/l on the back. (The mg/dL is the standard unit in the United State)
2. Plug the Glucose Chip into the Glucose Chip slot for strip coding.

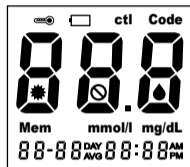


Checking the Performance of your EZ Smart-608 Meter

The Glucose Chip is used for checking and coding your EZ Smart-608 Meter.

To Check your Meter:

1. Insert the Glucose Chip into meter's Glucose Chip slot. All segments of the LCD display will appear indicating that the Meter is functioning properly.
2. If you are a first time user or start a new strip vial, please continue the coding procedure.



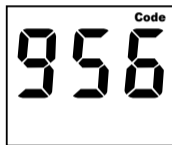
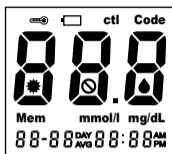
Coding your EZ Smart-608 Meter

Each batch of EZ Smart-608 Test Strip is encoded with a number that must match one of the code numbers stored in the EZ Smart-608 Meter. In order to ensure an accurate result, the code number on the display must also match the code number found on the Test Strip vial.

1. Insert the Glucose Chip into the Glucose Chip slot. The Meter will automatically be encoded.

Note: Code the Meter whenever you start a new test strip vial.

- All segments of the LCD display will appear indicating that the Meter is functioning properly. Then a beep will sound, followed by the code number.
- Match the code number on the Meter display with the code number on the Test Strip vial label. If the code matches, you may begin to test.
- If the meter code and vial code do not match, please ask the store/distributor to replace a new vial .



The Control Solution Test

The Control Solution is used to check and ensure that the EZ Smart-608 Meter and EZ Smart-608 Test Strip are working together properly and that you are performing the test correctly. For an accurate reading, check the system with the Control Solution on a routine basis (approximately once a week).

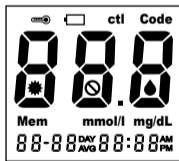
NOTE :

1. Control Solutions are required but not supplied.
2. There are three Control Solutions at different desired range of aqueous glucose (Low, Normal or High). For more information about the Control Solution, please read your Control Solution package insert. Two sets of control solution should be used, a high level and a low level control solution of your choice.

To perform a Control Solution Test:

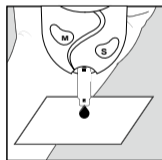
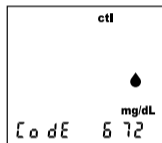
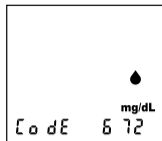


1. Insert the Test Strip, white side face up, Contact Bar's end first, into the test port. The Meter will automatically turn on.



2. All segments of the LCD display will appear, indicating that the Meter is functioning properly.

- A beep will sound and the code number will appear followed by a flashing “●” symbol. Be sure the code number on the display matches the code number on the Test Strip vial. If the code numbers do not match, code the Meter by using Glucose Chip, accordingly.
- After the “●” symbol appears, press the **S** button for 3 sec to switch “ctl” mode. The “ctl” symbol indicates that the Meter will mark your current test as a Control Solution test. Now you are ready to apply the Control Solution.
- 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 be counting down from 8 to 1 and the Control Solution test result will appear.



Caution: Please remember that in order to prevent contamination, follow the above instructions for performing the Control Solution test.

Comparing Control Solution Results

The EZ Smart-608 Meter 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
- 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 EZ Smart-608 Test Strips
- Improper coding of the EZ Smart-608 Meter
- EZ Smart-608 Meter malfunction

Note: The result will not be stored into the memory and will not be incorporated into the average in the “ctl” mode. DO NOT use the system if the problem persists. Please call Tyson Bioresearch, Inc., Customer Services at +886-37-585998 or website of www.tysonbio.com

Testing your Blood Glucose Level

Before testing blood glucose, you need the following items:

1. EZ Smart-608 Meter
2. EZ Smart-608 Test Strip
3. Glucose Chip
4. Adjustable Automatic Lancing Device
5. Sterile Lancet

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.
- **Always** use a new EZ smart-608 Test Strip. Test Strips are for single use only.
- **Do not** get lotion, oil, dirt or debris in or on the lancet and lancing device.

Preparing the Test Strip

1. Wash hands using soap and warm water. Rinse and dry thoroughly. (Fig.1)
2. Pull out the Test Strip from the vial and re-cap the vial immediately.(Fig.2)
3. Insert the Test Strip, white side face up, into the test port. (Fig.3)
4. A beep will sound and the code number will appear followed by a flashing “●” symbol. Now you are ready to obtain a blood sample. (Fig.4)

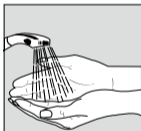


Fig.1



Fig.2

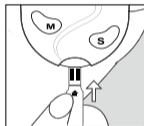


Fig.3

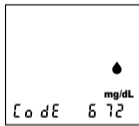


Fig.4

Reminder: Make sure that the code number on the display matches the code number displayed on the Test Strip vial. If the code number on the display does not match the code number on the Test Strip vial, code the Meter by using Glucose Chip, accordingly.(See page 15)

Obtaining a Blood Sample

SAMPLE MAY BE OBTAINED FROM FINGER, PALM or FOREARM

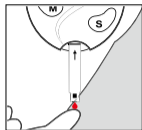
For further instructions please see the insert provided with lancing device.

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.

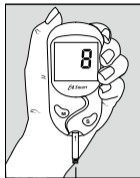
PERFORM THE TEST

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.

Applying Blood Sample to the EZ Smart-608 Test Strip

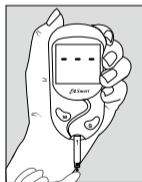


1. After obtaining a blood sample, place the drop onto the test well of the Test Strip.



3. As soon as enough blood has filled the Confirmation Window (see picture) of the Test Strip, the Meter will beep and begin counting down from 8 to 1.

Confirmation Window



2. Blood is automatically drawn into the Test Strip.



4. Your blood glucose result will appear on the LCD panel and will be stored into the Meter memory automatically.

Note: To ensure accurate results, make sure the Confirmation Window of the Test Strip is completely filled with your blood sample.

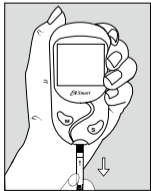




5. The EZ Smart-608 results range between 20 to 600 mg/dL (1.1 to 33.3 mmol/l). If a “HI” message appears on your display, your Meter has detected that your blood glucose level is higher than 600 mg/dL(33.3 mmol/l). It is suggested that you review your testing procedure and test again with a new Test Strip to confirm the result. **If the same result occurs, consult your healthcare professional immediately.**



6. If a “LO” message appears on your 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.**



If no further tests are performed, the Meter will automatically shut off after 4 minutes.

After finishing the test, we recommend using a tissue paper to remove the Test Strip from the Meter for proper disposal.

Caution: Any change or administer of medication based on the EZ smart-608 blood glucose test results without the consent advice of a physician or healthcare professional is not recommended.

Memory Features

The EZ Smart-608 Meter automatically stores the 300 most recent blood glucose results with date and time in its memory. It also provides you with a consecutive **14-day** average of your blood glucose test results.

1. Press the **M** button to turn on the Meter. All segments of the LCD display will appear.(Fig.1)
2. The date and time will appear first (Fig.2) followed by the Control Solution test result.* (Fig.3)
3. Wait a few seconds and the consecutive 14-day average will automatically appear, and a “**14 DAY/AVG**” symbol will flash.* (Fig.4)



Fig.1

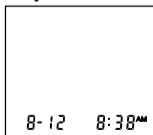


Fig.2



Fig.3



Fig.4



5. Wait a few seconds, and the most recent test result will automatically appear. Each time you press the **S** button, the Meter will recall the last 300 test results accordingly. When the memory is full, the oldest result is removed and replaced with the newest result.

Note: * If there is no test result during this stage, it will directly appear the most recent test result.

Exiting the Memory Mode

1. Press the **M** button to turn off the meter.
2. Meter will shut down automatically after 3 minutes with no further action.

Note: The consecutive **14-day** average is calculated from the blood glucose results obtained during the last consecutive **14-days**.

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.

PC Link Function

You can use your meter with TysonBio Link Diabetes Management Software to transfer test results to your personal computer.

1. Obtain the required software and cable For order information please call Tyson Bioresearch, Inc., Customer Service at +886-37-585998 or 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

Setting the meter to the PC link mode, see page 13. “PC” will appear on the display. 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.



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.

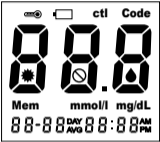
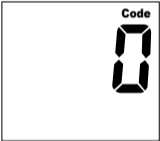

Care and Storage

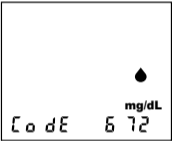
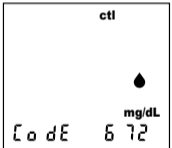

1. Handle the EZ Smart-608 Meter with care. Dropping or throwing the Meter may cause damage to the device.
2. Do not expose the Meter, Test Strips, and Control Solution to extreme conditions, such as high humidity, heat, freezing cold or dust.
3. Always wash hands with soap and water and rinse and dry completely before handling the Meter and Test Strips.
4. When cleaning the Meter, gently wipe the exterior surface using a damp soft cloth. **DO NOT USE ANY ORGANIC SOLVENT** for cleaning.
5. 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.


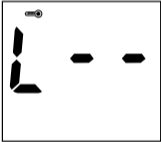
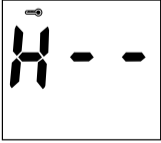
For healthcare professionals using this system on multiple patients, please be aware that all items that come in contact with human blood should be handled as potential biohazards. Users should follow the guidelines for prevention of blood-borne transmittable diseases in a healthcare setting for potentially infectious human blood specimens as recommended in the National Committee for Clinical Laboratory Standards, *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue: Approved Guideline*.

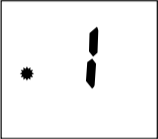

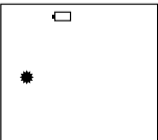
NCCLS document M29-A [ISBN 1-56238-339-6].

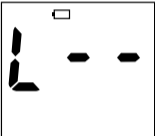

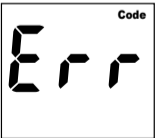
Display Messages

DISPLAY	WHAT IT MEANS	ACTION
	System check verifying that all segments of the Meter are functioning.	No Action Necessary
	This message appears immediately if your Meter has not been encoded.	Code Meter (see page 15)
	This is the current code number in use.	This code number should match the code number printed on your Test Strip vial.

DISPLAY	WHAT IT MEANS	ACTION
 <p>The display shows 'Co dE 6 72' on the left and 'mg/dL' on the right, with a small black drop icon above the text.</p>	<p>The system is ready to accept a blood sample.</p>	<p>You may now apply a blood sample.</p>
 <p>The display shows 'ctl' at the top, 'mg/dL' on the right, and 'Co dE 6 72' at the bottom, with a small black drop icon above the text.</p>	<p>The system is ready to accept a Control Solution sample.</p>	<p>You may now apply a drop of Control Solution sample.</p>
 <p>The display shows the letters 'HI' in a large, bold, black font.</p>	<p>The Meter detects blood glucose level is higher than 600 mg/dL (33.3 mmol/l).</p>	<p>Indicates high blood glucose level. Repeat test. If result still occurs, consult your physician immediately.</p>

DISPLAY	WHAT IT MEANS	ACTION
	<p>The Meter detects blood glucose level is lower than 20 mg/dL (1.1 mmol/l).</p>	<p>Indicates low blood glucose level. Repeat test. If result still occurs, consult your physician immediately.</p>
	<p>Temperature is too low to perform the test.</p>	<p>Repeat the test in a warmer setting (10 - 40°C or 50 - 104°F). Wait 15 minutes before re-testing.</p>
	<p>Temperature is too high to perform the test.</p>	<p>Repeat the test in a cooler setting (10 - 40°C or 50 - 104°F). Wait 15 minutes before re-testing.</p>

DISPLAY	WHAT IT MEANS	ACTION
	<p>An error message indicating a problem with the Test Strip.</p>	<p>Review the instructions and try again with a new Test Strip.</p>
	<p>An error message indicating a problem with the Meter.</p>	<p>Press the meter reset button and check the meter again with the Glucose Chip. If the problem persists, contact Tyson Bioresearch, Inc. Customer Service for help.</p>
	<p>Battery power is too low for further usage.</p>	<p>Replace with a new 3-Volt lithium battery (CR-2032).</p>

DISPLAY	WHAT IT MEANS	ACTION
	<p>Battery power is low. Meter will provide approximately 50 more measurements.</p>	<p>Replace with a new 3-Volt lithium battery (CR-2032).</p>
	<p>All testing values recorded in the memory have been shown.</p>	<p>Press M button or wait for 3 minutes to turn off the meter.</p>
	<p>An error message indicating a problem with the coding of the Meter.</p>	<p>Press the meter reset button and check the meter again with the Glucose Chip. If the problem persists, contact Tyson Bioresearch, Inc. Customer Service for help.</p>

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 a 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 Screen on the Meter is blank when trying to preform a test.	Contact Tyson Bioresearch, Inc. Customer Service for help.

Specifications

Meter Operating Conditions

Temperature:	10°C- 40°C (50°F - 104°F)
Relative Humidity:	10 - 90%
Hematocrit:	35 - 55%
Test Sample:	Capillary Whole Blood from Fingertip, Palm and Forearm
Sample Volume:	≥1.5 µl
Measuring Range:	20 - 600 mg/dL (1.1 - 33.3 mmol/l)
Test Time:	10 sec
Memory Capacity:	300 most recent results
Average:	14 days average results
Power supply:	3-Volt lithium battery (CR-2032)
Battery Life:	Approximately 1000 tests
Size:	102 x50 x15 mm (4.0 x 1.9 x 0.6 in)
Weight:	55 g

- The EZ Smart-608 Meter and EZ Smart-608 Test Strips 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 350,
Miao-Li County, Taiwan, R.O.C.
TEL: +886 37 585998

Authorized representative in the EU:

Medical Device Safety Service GmbH
Schiffgraben 41, D-30175 Hannover,
Germany
TEL: +49 511 62628630

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

Manufacturer:

Wuxi Xinda
Medical Device Co., Ltd.
No.42 Xixin Road, Zhangjing
Wuxi, Jiangsu, 214194, PRC
TEL: +86-510-379-3149

Authorized Representative in the EU:

EMDAR BV
Ijsselburecht 3, Postbus 5486
6802 EL Arnhem, Netherlands
TEL: +31-263-653-375

■ The Lancing Device is being classified as **MDD Class I**.

Manufacturer:

Wuxi Xinda
Medical Device Co., Ltd.
No.42 Xixin Road, Zhangjing
Wuxi, Jiangsu, 214194, PRC
TEL: +86-510-379-3149

Authorized Representative in the EU:

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6802 EL Arnhem, Netherlands
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Limitations of the Procedure

Caution: The EZ Smart-608 System is designed for in vitro use only and is not intended to test on newborns.

The EZ Smart-608 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: The EZ Smart-608 Blood Glucose Monitoring System is designed for *in vitro* diagnostic use only. Tyson Bioresearch Inc. cannot endorse the performance of the EZ Smart-608 System when used with Test Strips other than those designed for the EZ Smart-608 Meter. The EZ Smart-608 System manufacturer warranty is valid only when used properly within the guidelines of the provided User's Manual and is invalid when the EZ Smart-608 System and EZ Smart-608 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 EZ Smart-608 Meter found defective with a new EZ Smart-608 Meter.

This warranty does not apply to the performance of a EZ Smart-608 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 EZ Smart-608 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 and or its operation, or any attempt to correct a problem fails, please call our Customer Service Unit. Our trained specialists will be happy to assist you, train you, or even reaffirm your results.

**Customer Service Hotline:
+886-37-585998
our office hours are from
8:30am (GMT0030) - 5:30pm (GMT0930)
or E-Mail us at
service@tysonbio.com**

When you call our Customer Service Unit, please have your EZ Smart-608 Meter, EZ Smart-608 Test Strip and all other system supplies available. This will allow us to answer any of your questions with speed and efficiency.



Manufacturer:

Tyson Bioresearch, Inc.

5F, #22, Ke E. Road III

Science-Based Industrial Park,

Chu Nan, Taiwan

Tel : +886-37-585998 Fax : +886-37-585996

www.tysonbio.com Made in Taiwan

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