EZ Smart-168

Blood Glucose Monitoring System

User's Manual

ID：B03B106257 (02)

for *in vitro* diagnostic use only

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Introduction

Congratulations on choosing the ***EZ Smart-168*** System, the latest advancement in biosensor technology. Adopted for its ease of use and quick response time, the ***EZ Smart-168*** has the ability to process accurate results utilizing only a small volume of blood for in vitro diagnostics. The ***EZ Smart-168*** System's intended use is to provide a convenient and safe monitoring system for diabetic individuals. This is an over the counter(OTC) product.

Technically, blood glucose is oxidized enzymatically when the electrical current generated by glucose oxidation is measured. The advantage of using the System comes from the ***EZ Smart-168*** Test Strips, which is specially designed to allow the monitoring of your blood glucose level quickly and easily. What makes the ***EZ Smart-168*** Test Strip so special is on how blood samples are drawn. Our unique design allows you to use a small amount of blood to produce results in only a short time.

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

About the Product

Your ***EZ Smart-168*** 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-168* System contains:

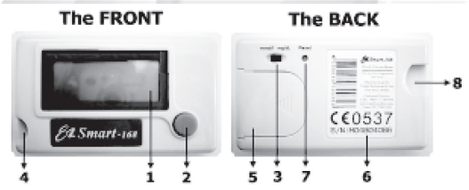
- ***EZ Smart-168*** Meter
- ***EZ Smart-168*** Test Strips (10 strips) *
- Lancing Device *
- Lancets *

*Option

- Carrying Case
- User's Manual
- Logbook *
- Quick Reference Guide *

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

About the EZ Smart-168 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.Button Press the button for memory mode. Display the average result and latest 28 test results.

3.Unit Switch Switch for mmol/l or mg/dL.

4.Test Port This is where you insert the Test Strip into the Meter.

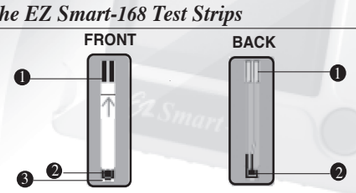
5.Battery Cover

6.Label

7.Reset Button Press this button to re-set the system.

8.Glucode Chip Insert the Glucode Chip for coding.

About the EZ Smart-168 Test Strips



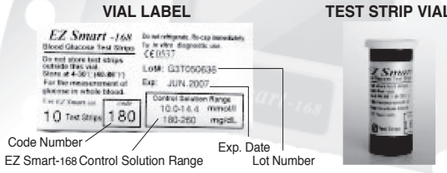
The ***EZ Smart-168*** Test Strip is used to perform the blood glucose test in conjunction with the ***EZ Smart-168*** Meter. Each strip can be used only once.
The ***EZ Smart-168*** Test Strip consists of the following parts:

1.Contact Bar This end of the ***EZ Smart-168*** Test Strip is inserted into the Test Port to activate the ***EZ Smart-168*** 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 ***EZ Smart-168*** Test Strip.

About the EZ Smart-168 Test Strip Vial



About the Glucode Chip

The Glucode Chip is used to ensure that your ***EZ Smart-168*** Meter provides you with accurate results. Before performing the blood glucose test or starting a new strip vial, please check your ***EZ Smart-168*** Meter with the Glucode Chip to ensure proper performance *(further instructions for use of the Glucode Chip is provided on page 8)*. After checking your Meter, the Glucode Chip is also used to code setting.

❖ Note: Always use the Glucode Chip to ensure your *EZ Smart-168* Meter is performing properly.

❖**DO NOT** misplace your Glucode Chip.

Installing/Replacing the battery

The *EZ Smart-168* 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-168* 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 pull the plastic tab out from the battery chamber, then press the reset button located at the back of the Meter and proceed with the following instructions.

Code Setting and Unit Selection

1. Select unit, mg/dL or mmol/l on the back.
2. Plug the Glucode Chip into the slot for strip coding.

Coding your EZ Smart-168 Meter

Each batch of ***EZ Smart-168*** Test Strip is encoded with a number that must match one of the code numbers stored in the ***EZ Smart-168*** Meter. In order to ensure an accurate result, the code number on the display must also match the code number found on the ***EZ Smart-168*** Test Strip vial.

1. Insert the ***EZ Smart-168*** Glucode Chip, Conductive Bar's end first, into the slot. The ***EZ Smart-168*** Meter will automatically be encoded.

Note: Code the ***EZ Smart-168*** Meter whenever you start a new Test Strip vial.

2. All segments of the LCD display will appear indicating that the ***EZ Smart-168*** Meter is functioning properly. Then a beep will sound, followed by the code number. If you are using the ***EZ Smart-168*** Meter for the first time, a "0" will appear on the screen.

3. Match the code number on the ***EZ Smart-168*** Meter display with the code number on the ***EZ Smart-168*** Test Strip vial. If the code matches, you may begin to test.

Testing your Blood Glucose Level

Before testing blood glucose, you need the following items:

1. ***EZ Smart-168*** Meter
2. ***EZ Smart-168*** Test Strips in vial
3. Adjustable Automatic Lancing Device
4. Sterile Lancet
5. Glucode Chip

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-168*** 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.

2. Pull out an ***EZ Smart-168*** Test Strip from the vial and re-cap the vial immediately.

3. Insert the Test Strip, white side face up, into the test port.

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.

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 Glucode Chip, accordingly.(*See page 8*)

Obtaining a Blood Sample

SAMPLE MAY BE OBTAINED FROM FINGER

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

1. Remove the endcap of the lancing device by gently pulling straight out.
2. Insert the lancet into the lancet holder.
3. Twist and remove the protective lancet cover to expose the sterile needle tip.
4. Recapping 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-168 Test Strip

1. After obtaining a blood sample, place the drop onto the test well of the ***EZ Smart-168*** Test Strip.

2. Blood is automatically drawn into the ***EZ Smart-168*** Test Strip.

3. As soon as enough blood has filled the Confirmation Window *(see picture)* of the Test Strip, the ***EZ Smart-168*** Meter will beep and begin counting down from **8** to **1**.

Confirmation Window

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-168*** results range between 20 to 600 mg/dL (1.1 to 33.3 mmol/l). If a **"HI"** message appears on your display, your ***EZ Smart-168*** 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 ***EZ Smart-168*** 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 ***EZ Smart-168*** 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 ***EZ Smart-168*** Test Strip to confirm the result. **If the same result occurs, consult your healthcare professional immediately.**

If no further tests are performed, the ***EZ Smart-168*** Meter will automatically shut off after 4 minutes.

After finishing the test, we recommend using a tissue paper to remove ***EZ Smart-168*** Test Strip from the ***EZ Smart-168*** Meter for proper disposal.

Memory Features

The ***EZ Smart-168*** Meter automatically stores the 28 most recent blood glucose results. It also provides you with an average of your blood glucose test results.

1. Press the button to turn on the ***EZ Smart-168 Meter.***

3. The 28 set data average will automatically appear, and flash for few seconds.

2. All segments of the LCD display will appear.

4. The most recent test result (1 st set) wil automatically appear. Press the button, the Meter displays the data order release the botton shows its reading, accordingly. When the 28 memories are full, the oldest result is removed and replaced with the newest result.

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.

Exiting the Memory Mode

1. Press and release the button to the end of the memory(000 will show). Press the button again to turn the meter off.
2. Meter will shut down automatically after 15 seconds with no further action.

Results marked as **"ctl"** (Control Solution) will not be averaged into the nor be stored into the memory.

Care and Storage

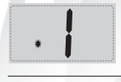
1. Handle the ***EZ Smart-168*** Meter with care. Dropping or throwing the Meter may cause damage to the device.
2. Do not expose the Meter, Test Strips, and Control Solution to extreme conditions, such as high humidity, heat, freezing cold or dust.
3. Always wash hands with soap and water and rinse 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.

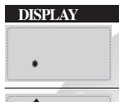
For healthcare professionals using this system on multiple patients, please be aware that all items that come in contact with human blood should be handled as potential biohazards. Users should follow the guidelines for prevention of blood-borne transmittable diseases in a healthcare setting for potentially 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 8)
	This is the current code number in use.	This code number should match the code number printed on your ***EZ Smart-168*** Test Strip vial.

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.
	EZ Smart-168 Meter detects blood glucose level is higher than 600 mg/dL(33.3 mmol/l).	Indicates high blood glucose level. Repeat test. If result still occurs, consult your physician immediately.
	The ***EZ Smart-168*** Meter detects blood glucose level is lower than 20 mg/dL (1.1 mmol/l).	Indicates low blood glucose level. Repeat test. If result still occurs, consult your physician immediately.

DISPLAY	WHAT IT MEANS	ACTION
	Temperature is too low to perform the test.	Repeat the test in a warmer setting (10 - 40ºC or 50 - 104ºF). Wait 15 minutes before re-testing.
	Temperature is too high to perform the test.	Repeat the test in a cooler setting (10 - 40ºC or 50 - 104ºF). Wait 15 minutes before re-testing.
	An error message indicating a problem with the ***EZ Smart-168*** Test Strip or Glucode Chip.	Review the instructions and try again with a new ***EZ Smart-168*** Test Strip or Glucode Chip.
	A error message indicating a problem with the ***EZ Smart-168*** Meter.	Check the meter again with the Glucode Chip. If the problem persists, contact Tyson Bioresearch, Inc. Customer Service for help.

DISPLAY	WHAT IT MEANS	ACTION
	Battery power is too low for further usage.	Replace with a new 3-Volt lithium battery (CR-2032).
	Battery power is low. Meter will provide approximately 50 more measurements.	Replace with a new 3-Volt lithium battery (CR-2032).
	All testing values recorded in the memory have been shown.	Press button or wait for 15 seconds to turn off the meter.
	An error message indicating a problem with the coding of ***EZ Smart-168*** Meter.	Check the meter again with the Glucode Chip. If the problem persists, contact Tyson Bioresearch, Inc. Customer Service for help.

Other problems that may occur	ACTION
The ***EZ Smart-168*** 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 ***EZ Smart-168*** Test Strip.	Replace with a new ***EZ Smart-168*** Test Strip.
Insufficient blood sample.	Repeat the test with new ***EZ Smart-168*** Test Strip.
Test Strip remains in the test port for more than 4 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
Sample Volume:	≥1.5 µl
Measuring Range:	20 - 600 mg/dL (1.1 - 33.3 mmol/l)
Test Time:	8sec
Memory Capacity:	28 most recent results
Average:	Calculates the consecutive results
Power supply:	3-Volt lithium battery (CR-2032)
Battery Life:	Approximately 1000 tests
Size:	76 x 47 x16 mm (3.0 x 1.8 x 0.6 in)
Weight:	44 g

❖The *EZ Smart-168* Meter and *EZ Smart-168* 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.
+886 37 585998

Authorized representative in the EU:
Medical Device Safety Service GmbH
Schiffgraben 4l, D-30175 Hannover, Germany
+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
+86-510-379-3149

Authorized Representative in the EU:
EMDAR BV
Ijsselburecht 3, Postbus 5486
6802 EL Arnhem, Netherlands
+31-263-653-375

❖The Lancing Device is being clasified as **MDD Class I.**

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

Authorized Representative in the EU:
EMDAR BV
Ijsselburecht 3, Postbus 5486
6802 EL Arnhem, Netherlands
+31-263-653-375

Limitations of the Procedure

Caution: The ***EZ Smart-168*** System is designed for *in vitro* use only and is not intended to test on newborns.

The ***EZ Smart-168*** Test Strips are designed for use with fresh capillary whole blood samples.

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-168*** Blood Glucose Monitoring System is designed for *in vitro* diagnostic use only. Tyson Bioresearch Inc. cannot endorse the performance of the ***EZ Smart-168*** System when used with Test Strips other than those designed for the *EZ Smart-168* Meter. The ***EZ Smart-168*** 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-168*** System and ***EZ Smart-168*** 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-168*** Meter found defective with a new ***EZ Smart-168*** Meter.

This warranty does not apply to the performance of a ***EZ Smart-168*** 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-168*** 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-168*** Meter, ***EZ Smart-168*** Test Strip and all other system supplies available. This will allow us to answer any of your questions with speed and efficiency.