# **Control Solution Package Insert**

#### Intended Use

The Control Solution is a desired aqueous glucose solution with small amounts of non-reactive ingredients and food coloring for verifying the accuracy of the entire Rossmax HS200 Blood Glucose Monitoring System. The control solutions are used to check the performance of the Rossmax HS200 meter, test strips, and your testing technique.

#### When To Perform a Control Solution Test

- 1. You get your meter for the first time before testing your blood test.
- 2. You open a new vial of test strips.
- 3. You want to check the meter and strips.
- You suspect that the meter or test strips are not working properly.
- 5. Your blood glucose test results are not consistent with how you feel.
- You think your test result does not accurate.
- 7. You dropped your meter.
- 8. Whenever your healthcare professional recommends it.

#### **Control Solution Contents**

Each Control Solution is provided as a buffered, stabilized, aqueous solution of desired D(+)-glucose containing a preservative and other non-reactive ingredients. The solutions are formulated to react equivalently to a whole blood sample containing approximate 50, 130 or 350 mg/dL glucose concentrations. Actual lot-specific ranges are printed on the Test Strip bottle label.

Control Solution	mg/dL	mmol/L
Level 1	50	2.8
Level 2	130	7.2
Level 3	350	19.4

Caution: Control Solution is for *in vitro* use only. It is not to be swallowed or injected. The use of the Control Solution is recommended to verify proper system performance and should not be considered as a substitution of actual capillary whole blood testing for blood glucose level.

## **Materials Required**

- 1. Glucose Meter
- 2. Test Strip
- 3. Control Solution

Note: Please make sure you are using the same model of Control Solution, Test Strip and Glucose Meter.

## **Test Procedure**

Note: Make sure the solution is at room temperature15°C to 35°C (59°F to 95°F) prior to testing.

### Preparation

Make sure that you have set the Glucose Meter in the Control Solution test "<© " mode, so the result will be stored in the memory and not be incorporated into the average. Please read the User Manual of your Rossmax HS200 Blood Glucose Monitoring System.

## Testing

 Insert a Rossmax HS200 Blood Glucose Test Strip into the test port. The meter will be automatically turned ON. When test strip is inserted, a beep will sound if the buzzer is turned on and the system checking will appear followed by a flashing " • " icon.

- 3. Shake the Control Solution gently. Discard the first drop of the Control Solution and squeeze a small drop on a clean nonabsorbent surface such as a clean piece of wax paper. Do not apply the Control Solution to the test strip directly from the bottle, as contamination may occur.
- 4. Introduce the tip of the test strip to the droplet of the Control Solution. The Control Solution is automatically drawn into the strip. Hold until the meter beeps. The meter will now start to count down and the Control Solution test result will appear on the LCD screen.
- 5. Compare the results with the Control Solution range printed on the Test Strip vial. The results should fall within the specified range listed on the Test Strip vial. If the test result is out of the range, repeat the test.

## Caution:

- Use the same model of Control Solution, Test Strip and Glucose Meter.
- DO NOT apply Control Solution to the Test Strip directly from the bottle, such operation could be leaded to contaminate and decrease the concentration of Control Solution. You MUST place a drop of Control Solution on a clean nonabsorbent surface first.
- Only for use outside the body (For in vitro diagnostic use).

## Result is out of range may be caused by:

- Incorrect steps taken in performing the test.
- The Control Solution temperature is not within 15°C(59°F)- 35°C(95°F) prior to testing.
- The Control Solution may be expired or contaminated or has been opened over 3 months.
- Expired or contaminated Test Strips.
- · Meter malfunction.

If the problem persists, the system may not be working properly. DO NOT continue to use the system to test your blood glucose level. If you continue to get results that fall outside the specified range, please return the device to your local distributor or service center.

#### Storage and Stability

For best results, store Control Solution at room temperature; do not refrigerate. Refer to the expiration date for stability. The solution should NOT be used after the expiration date or 3 months after opening.

## **Explanations of Symbols**

Authorised Representative in the European Community

Batch code

REF Catalogue number

Consult instructions for use

CONTROL Control

Do not use if package is damaged

In vitro diagnostic medical device
Keep away from sunlight
Manufacturer
Temperature limitation
Use by

Rossmax Swiss GmbH, 9435 Heerbrugg, Switzerland www.rossmax.com

Tyson Bioresearch, Inc.

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