

CareSens Glucose Control Solution

PGA2E0300 REV6 07/2015

IMPORTANT

- Please read the following information and the User's Manual of your meter before using the CareSens Control Solution.
- Use the CareSens Control Solution only with the CareSens brand of meters and their corresponding strips.

INTENDED USE

The CareSens Control Solution, is red in color and is to be used to check that the CareSens brand of meters and the corresponding strips are working together properly and that you are performing the test correctly.

SUMMARY AND EXPLANATION

CareSens Control Solution is a solution containing a specific amount of glucose that is used to test meters and test strips in the CareSens brand. The CareSens Control Solution is for self-testing outside the body (*in vitro* diagnostic use). This solution may be used to check the performance of your meter and test strip or your testing technique. The test results you obtain should fall within the control solution range printed on the vial of test strips that you are using.

CAUTION

The control solution ranges printed on the test strip vial are for the CareSens Control Solution only. These ranges are used to check the meter and test strip performance.

These are not recommended ranges for your blood glucose level.

Use CareSens Glucose Control Solution when:

- You want to practice the test procedure, without using blood.
- You use your CareSens brand of meters for the first time.
- You begin using a new vial of test strips.
- You suspect that your meter or the strips are not working properly.
- You think your test results are inaccurate or do not reflect how you feel.
- You drop your meter.

STORAGE AND HANDLING

Store the CareSens Control Solution at temperatures between 8-30°C/46- 86°F, tightly capped in the bottle. It must be kept at room temperature (20- 25°C/68- 77°F) before testing to obtain correct results. Do not refrigerate or freeze the control solution. Use before the expiration date shown on the bottle and within 3 months (90 days) of opening.

WARNING AND PRECAUTIONS

- The CareSens Control Solution is for *in vitro* diagnostic use only.
- The CareSens Control Solution is intended to be used only for self diagnostic testing of CareSens brand of meters and their corresponding strips.
- Use CareSens Control Solution only with your CareSens brand of meters.
- Do not swallow or inject the control solution.
- Check the expiration date on the bottle. Do not use if expired.
- If the test results keep falling outside the specified range continually, do not use your system to test blood.
- Make sure your meter, test strips, and control solution are at room temperature before testing. Control solution tests must be done at room temperature (20-25°C/68-77°F).
- Shake the bottle well before use, discard the first drop of solution, and wipe the tip with a clean tissue before applying the solution to the test strip.
- This solution contains a dye that may stain clothes.

TEST PROCEDURE

Step 1

Insert the test strip into the strip port of your meter.

- If your meter is a coding meter, the meter turns on and displays the code number. If the code numbers on the display and test strip vial are not the same, see the coding meter to match test strips section of the User's Manual.
- If your meter is a no-coding meter, there is no need to match codes.

Step 2

Shake the control solution vial well before using.

Step 3

Discard the first drop of control solution you squeeze and wipe the dispenser tip clean.

Step 4

Dispense a drop of control solution onto a clean non-absorbent surface and apply the control solution to the narrow edge of the strip until the meter beeps.

Step 5

Test results appear after the meter counts down from 5 to 1.

Compare your control result with the appropriate control solution range printed on the test strip vial. If the result falls within the specified range, you are ready to use the meter and the test strips to test your blood.

Step 6

Remove the used test strip from the port. The meter will turn off automatically. Please read the CareSens brand of meter's User's Manual for further information before using the CareSens Control Solution.

INTERPRETATION OF OUT OF RANGE RESULTS

At room temperature, CareSens Control Solution test results should fall within the control solution range printed on the test strip vial about 95% of the time. Accurate results also depend upon the meter being properly coded to match the code number printed on each test strip vial (if your meter is a coding meter). If your control solution test results do not fall within the expected range printed on the test strip vial, repeat the test. Out-of-range results may be due to one or more of the following factors:

- An error in the way you are doing the test.
- Expired or contaminated control solution.
- Damaged or outdated test strips.
- A problem with the meter.
- Control solution that is too warm or too cold.
- Failure to shake the control solution vial vigorously and to wipe the vial tip clean.
- Code numbers of the meter and of the test strip bottle do not match. (if your meter is a coding meter)

IMPORTANT









If you continue to get control solution test results that fall outside the range printed on the test strip vial, the system may not be working properly. Do not use the system to test your blood. If you are unable to resolve the problem, contact your authorised i-SENS representative in your area.


CHEMICAL COMPOSITION

Each 4 mL vial of CareSens Control Solution contains:

- D-Glucose
- Preservative
- FD&C red dye
- Viscosity-adjusting agent

DESCRIPTION OF SYMBOL

	Consult instruction for use
	Temperature Limitations
	<i>In vitro</i> diagnostic medical device
	Manufacturer
	Authorised Representative
	CE Mark reg. IVDD 98/79/EC
	Batch code
	Use by

 **i-SENS, Inc.**
43, Banpo-daero 28-gil, Seocho-gu,
Seoul 06646, Korea
www.i-sens.com

© 2015 i-SENS, Inc. All Rights Reserved.

  0123