

Informative Safety Note

Important information regarding the use and storage conditions of the product GlucoMen® LX Sensor – updated Instructions for Use (IFU)

Dear User,

We wish to inform you that as part of the ongoing quality monitoring of their products, A. Menarini Diagnostics has detected a few cases of inaccurate results obtained by some users of the GlucoMen® LX Sensor test strips for blood glucose self-monitoring, used with the glucometer GlucoMen® LX PLUS.

An in-depth analysis has enabled us to identify incorrect storage of the vial after first opening as the source of possible overestimated results.

In this regard, please note that we are taking steps to make the relevant sections of the instructions for use clearer (Storage and Handling; Limitations), by adding new instructions on the package and improving the legibility of the information indicated on the label.

For the correct monitoring of your blood glucose levels, we recommend you:

1. Follow the directions in the Instructions for Use included in the vial of test strips;
2. Pay special attention to the following safety information:
 - a) Close the vial immediately after each use: if the vial is left open to extremely high environmental humidity for a prolonged period of time, the test strips may overestimate the blood glucose value;
 - b) Always store the test strips in their original vial;
 - c) Write the discard date on the vial label, counting 9 months after the date of first opening the vial itself.
3. Should you obtain anomalous values, we invite you to repeat the test with a new test strip and if the results continue to be abnormal or not consistent with how you feel, please contact your doctor before taking any other action.



If you wish to receive further information or assistance please call the A. Menarini Diagnostics Customer Service at the freephone number 0800 243667, or contact your diabetes healthcare professional.

Confident that you will appreciate A. Menarini Diagnostics' constant effort in monitoring the quality and performance of their systems, we wish to thank you for your valuable collaboration.

With best regards

Richard King – Quality Manager