



A.MENARINI
diagnostics

Letter for healthcare professionals

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Informative Safety Note

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

Dear Doctor,

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.

We therefore wish to emphasise the importance of following the instructions for the storage and use of the product and more specifically, users must:

1. 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;
2. Always store the test strips in their original vial;
3. Write the discard date on the vial label, counting 9 months after the date of first opening the vial itself.
4. Should users obtain anomalous values, they must repeat the test with a new test strip and if the results continue to be abnormal or not consistent with what they feel, they must contact their doctor before taking any other action.

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.

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Please inform all the staff concerned in your healthcare facility.

Your collaboration in informing patients of the appropriate storage and use conditions of the product is very important for obtaining accurate results, also thanks to the use of the attached document.

If you wish to receive further information or assistance please contact our representative in your area.

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

Attachment: Informative Safety Note for Users.