

## **GlucoMen LX blood glucose meter**

### **Summary of an evaluation under the direction of SKUP Report SKUP/2009/71**

#### **Background**

The GlucoMen LX blood glucose meter and the GlucoMen LX Sensor test strips are designed for glucose self-measurements performed by diabetes patients. The meter and the test strips are produced by A. Menarini Diagnostics and supplied in Scandinavia by A. Menarini Diagnostics. In Norway Med-Nett AS will distribute the system on license of A. Menarini Diagnostics. GlucoMen LX and GlucoMen LX Sensor test strips have not yet been launched onto the Norwegian market. In order to give reimbursement for the test strips in Norway, the Norwegian Labour and Welfare Organisation (NAV) requires from the companies to carry out an evaluation that includes a user-evaluation among diabetes patients.

The SKUP-evaluation of GlucoMen LX and GlucoMen LX Sensor test strip was carried out under the direction of SKUP from September to December 2008.

#### **The aim of the evaluation**

The aim of the evaluation of GlucoMen LX is to

- reflect the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
- reflect the analytical quality by the intended users
- compare the analytical quality among trained and un-trained diabetes patients
- examine the variation between three lots of test strips
- examine if hematocrit interferes with the measurements
- evaluate GlucoMen LX regarding user-friendliness
- evaluate the GlucoMen LX user guide

#### **Materials and methods**

84 diabetes patients took part in the evaluation. 43 participants had two consultations and the rest had one consultation. The diabetes patients in the “training group” were given a standardised instruction about GlucoMen LX before they did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also collected capillary samples from the diabetes patients and measured twice on GlucoMen LX. In addition, two capillary samples were taken for measurements with a designated comparison method. The diabetes patients in the “mail group” received GlucoMen LX by mail and no training was given. Both groups of diabetes patients used the equipment for approximately three weeks at home, before they attended for a final consultation. The blood glucose sampling and measurement procedures at the first consultation were repeated, and in addition a sample for hematocrit was taken. Three different lots of test strips were used in the evaluation. All the participants answered questionnaires about the user-friendliness and the user guide of GlucoMen LX.

## Results

- The overall precision of GlucoMen LX was acceptable. The repeatability CV obtained under standardised and optimal conditions was approximately 4,5%, and approximately 6% when the measurements were performed by the diabetes patients.
- For low glucose concentrations (<7 mmol/L) the results on GlucoMen LX were systematic higher than the results from the comparison method. The mean deviation from the comparison method at this concentration level was +0,45 mmol/L. For glucose concentrations between 7 and 10 mmol/L GlucoMen LX gave results in agreement with the comparison method. For high glucose concentrations ( $\geq 10$  mmol/L) GlucoMen LX gave lower results than the comparison method. The bias at this concentration level was -0,40 mmol/L.
- The accuracy of GlucoMen LX was good. The results fulfilled the quality goal proposed in ISO 15197. More than 95% of the results achieved under standardised and optimal conditions were within the limits described in ISO 15197. The “adjusted ISO-goal” was met by the measurements of the diabetes patients, and >95% of the results achieved by the diabetes patients also fulfilled the ISO-goal.
- There was no provable difference between the results achieved with three different lots of test strips.
- The glucose results on GlucoMen LX were not affected by hematocrit values from 30 – 49%.
- The diabetes patients thought that the GlucoMen LX device was easy to operate. Most of them were pleased with the device. The diabetes patients that had used the user guide were satisfied with the guide.

## Conclusion

The precision of GlucoMen LX was acceptable. The repeatability CV was between 4 and 7%. The accuracy of GlucoMen LX was good, and the results fulfilled the quality goal based on ISO 15197. Glucose measurements on GlucoMen LX were not affected by hematocrit in this study. Most of the users found the GlucoMen LX device easy to use.

## Comments from A. Menarini Diagnostics

There is no additional information from producer attached to the report.

The complete report is found at [www.skup.nu](http://www.skup.nu)