

FreeStyle Lite Glucose

Summary of an evaluation under the direction of SKUP Report SKUP/2007/64



Background

FreeStyle Lite blood glucose meter and FreeStyle Lite test strips are designed for glucose self-measurements performed by diabetes patients. The meter and the test strips are produced by Abbott Diabetes Care Inc. and are supplied in Scandinavia by Abbott. FreeStyle Lite blood glucose meter and FreeStyle Lite test strips was launched onto the Norwegian market the 1st of October 2007. 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 evaluation of FreeStyle Lite was done under the direction of SKUP from May to June 2007.

The aim of the evaluation

The aim of the evaluation of FreeStyle Lite is to

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

Materials and methods

82 diabetes patients took part in the evaluation. Half of the diabetes patients had two consultations (the “training group”) and the rest of them had one consultation (the “mail group”). The diabetes patients in the “training group” were given a standardised instruction about FreeStyle Lite 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 FreeStyle Lite. In addition, two capillary samples were taken for measurements with a designated comparison method. The diabetes patients in the “mail group” received FreeStyle Lite by mail and no training was given. Both groups of diabetes patients used the equipment for approximately three weeks at home, before they were called 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 FreeStyle Lite.

Results

- The precision of FreeStyle Lite was good. The repeatability CV was between 2 and 3 % under standardised and optimal measuring conditions and approximately 4 % when the measurements were performed by the diabetes patients.
- The trueness of FreeStyle Lite was acceptable. For glucose values < 7 mmol/L no significant bias between FreeStyle Lite and the comparison method was pointed out. For glucose values > 7 mmol/L there was a small, but statistically significant bias between FreeStyle Lite and the comparison method. FreeStyle Lite gave glucose values

approximately 0,3 mmol/L lower than the comparison method for glucose values 7 – 10 mmol/L and approximately 0,8 mmol/L lower than the comparison method for glucose values > 10 mmol/L.

- The agreement with a designated comparison method was good. The quality goal set in ISO 15197 was achieved under standardised and optimal measuring conditions. When handled by the diabetes patients, FreeStyle Lite also showed accurate results. These results were within the “adjusted ISO-goal” and also within the quality goal set in ISO 15197.
- Two of the three lots of test strips used in this evaluation gave significantly lower values than the comparison method. The third lot of test strips gave significantly higher values than the comparison method. The deviations are small, but statistically significant.
- Glucose measurements on FreeStyle Lite did not seem to be affected by hematocrit in this study. Hematocrit outside the range 31 – 48 % has not been tested.
- The diabetes patients summarised the FreeStyle Lite device as easy to use. Most of them were pleased with the device. Most of the diabetes patients that had used the user guide were satisfied with the guide.

Conclusion

The analytical quality of FreeStyle Lite was good. The precision of FreeStyle Lite was good. The results were accurate and within the quality goal for the total error set in the ISO-guide 15197. The glucose results did not seem to be affected by hematocrit in this study. The users found the FreeStyle Lite device easy to use and they were quite satisfied with the device.

Comments from Abbott

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

The complete report is found at www.skup.nu