

# FreeStyle Glucose

## Summary of an evaluation under the direction of SKUP Report SKUP/2005/51\*



### Background

FreeStyle is a meter designed for glucose self-measurements by diabetic patients. The meter is produced and supplied by Abbott. FreeStyle was launched onto the Norwegian market in 2001. An evaluation of FreeStyle was done by SKUP in 2002 ([www.skup.nu](http://www.skup.nu), SKUP 2002/21).

In order to give reimbursement for the test strips, The National Social Insurance Office (*Rikstrygdeverket*) in Norway has instructed Abbott to carry out a supplementary evaluation that includes the quality of the system of finger measurements done by diabetics. The supplementary evaluation of FreeStyle is done under the direction of SKUP during the autumn of 2005.

### The aim of the evaluation

The aim of the evaluation of FreeStyle is to

- reflect the analytical quality of finger measurements done by the users (diabetic patients)
- reflect the analytical quality of finger measurements under standardised and optimal conditions (performed by biomedical laboratory scientist)

### Materials and methods

23 diabetic patients took part in the supplementary evaluation. All the diabetics participated in the evaluation of FreeStyle in 2002. In the evaluation in 2002 they were trained in how to use the meter. In this supplementary evaluation the diabetics received FreeStyle by post and no new training was given. After approximately one week they came for a consultation. The diabetics did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also took capillary samples of the diabetic patients and measured twice at FreeStyle. In addition, two capillary samples were taken to a designated comparison method. One lot of test strips was used in the evaluation.

### Results

- FreeStyle shows acceptable precision. The CV is  $\leq 5\%$  both under standardised and optimal measuring conditions and when the measurements are performed by diabetic patients.
- The agreement with a designated comparison method is good. Quality goals set in ISO 15197 are achieved when measurements are done in finger by diabetic patients. 100 % of these results are within the quality goals. The quality goals set in ISO 15197 are also achieved under standardised and optimal measuring conditions.

### Conclusion

Glucose measurements done in finger on FreeStyle have acceptable precision. The measurements performed by the diabetic patients and by a biomedical laboratory scientist are within the quality goals set in ISO-guide 15197.

### Comments from Abbott

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

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