

# Precision Xtra Plus

## Summary of an evaluation under the direction of SKUP Report SKUP/2006/49



### Background

The Precision-system is designed for glucose self-measurements by diabetics. Precision is produced and supplied by Abbott. The Precision Xtra Plus (G3c) is a third generation test strip with “True Measure Technology” from Abbott. In this evaluation the test strip is used with the Precision Xceed meter. The Precision Xtra Plus (G3c) test strip has not yet been launched onto the Norwegian market. The Precision Xceed meter was launched onto the Norwegian market in December 2004.

In order to give reimbursement for glucose test strips in Norway, The National Social Insurance Office (*Rikstrygdeverket*) instructs the companies to carry out an evaluation that includes a user-evaluation among diabetics. A user-evaluation of Precision Xtra Plus test strip was done under the direction of SKUP during the winter of 2005/2006. A supplementary user-evaluation was done during the summer of 2006.

### The aim of the user-evaluation

The aim of the user-evaluation of Precision Xtra Plus test strips at Precision Xceed was to

- reflect the analytical quality under standardised and optimal conditions (performed by biomedical laboratory scientists)
- reflect the analytical quality by the users
- compare the analytical quality among diabetics with and without training
- compare the analytical quality among diabetics before and after three weeks of practise
- check the variation between three lots of test strips
- examine if hematocrit interferes with the measurements
- evaluate Precision Xtra Plus/Precision Xceed regarding user-friendliness
- evaluate the Precision Xceed user-manual

### Materials and methods

The evaluation of Precision Xtra plus test strip has been performed twice and includes a first user-evaluation and a supplementary user-evaluation.

77 diabetics took part in the first evaluation; 40 of the participants had two consultations (the “training group”) and the rest had one consultation (the “mail group”). At the first consultation the diabetics in the training group were given a standardised instruction about the Precision-system before they did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also took samples from a finger capillary of the diabetics and measured twice with the system. In addition, two samples from a finger capillary were taken to a designated comparison method. The diabetics in the mail group received the Precision-system through the post and no training was given. Both groups of diabetics carried out a practice period of 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 finally answered

questionnaires about the user-friendliness of Precision Xtra Plus/Precision Xceed and the user-manual of Precision Xceed.

81 diabetics participated in the supplementary user-evaluation, 48 of these diabetics were recruited from the first user-evaluation and 33 diabetics were recruited through Sørlandet Hospital. The diabetics in the supplementary evaluation had only one consultation. The measuring procedure was similar to the procedure in the first user-evaluation.

## **Results**

The results from the first user-evaluation are presented in attachment 12.

The results from the supplementary user-evaluation:

- Under standardised and optimal measuring conditions, the repeatability of Precision Xtra Plus at Precision Xceed is approximately 6 %. The imprecision is a little higher for glucose concentrations below 7 mmol/L. When measured by the diabetics, the precision is acceptable with a CV of approximately 5 % for glucose concentrations above 7 mmol/L. As a whole the imprecision is not significantly more than 5 %.
- The Precision Xtra Plus gives slightly higher glucose results than the comparison method. The positive bias is approximately 4 to 5 % for glucose values < 10 mmol/L.
- Two of the three lots of test strips showed significantly higher values than the comparison method. The deviation was approximately 4 %.
- The quality goal set in the ISO 15197 is achieved under standardised and optimal measuring conditions. The results achieved by the diabetics also fulfil the goals set in ISO 15197.
- Glucose measurements at Precision Xtra Plus test strips at Precision Xceed do not seem to be affected by hematocrit values between 35 and 49 %.
- The diabetics summarise the Precision-device as easy to use. 26 (34 %) of the diabetics reported that they had technical problems with the meter during the testing period. For 16 of these diabetics the written comments indicated problems with the meter not turning on at all, or turning off too quickly. The diabetics that had used the user manual were satisfied with the manual.

## **Conclusion**

The imprecision of Precision Xtra Plus test strips at Precision Xceed under standardised and optimal measuring conditions and in use by the diabetics is just over 5 % as a whole. Glucose results at Precision Xtra Plus are approximately 4 to 5 % higher than at the comparison method for glucose values < 10 mmol/L. The quality goal set in the ISO-guide 15197 is achieved, both under standardised and optimal measuring conditions and by the measurements of the diabetics. The glucose measurements do not seem to be affected by hematocrit-values between 35 and 49 %. The users find the Precision-device simple to use.

## **Response from Abbott Diabetes Care**

Response from Abbott is found in attachment 19.

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