

ONETOUCH Ultra Glucose ONETOUCH GlucoTouch Glucose

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Summary of two evaluations organised by SKUP Report SKUP/2005/39 and SKUP/2005/40

Background

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. The evaluation results must fulfil the quality goals set in ISO 15197.

OneTouch Ultra and OneTouch GlucoTouch are meters designed for glucose self-measurements by diabetics. The meters are produced by LifeScan, Johnson & Johnson, and are supplied in Scandinavia by LifeScan. OneTouch Ultra was launched onto the Norwegian market in the autumn 2002 and GlucoTouch was launched in 1996. The evaluations were done under the direction of SKUP during the spring of 2005.

The aim of the evaluation

The aim of the evaluation is to

- reflect the analytical quality under standardised and optimal conditions, performed by biomedical laboratory scientists
- reflect the analytical quality achieved by the users (160 diabetic patients participated in the two evaluations)
- 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 the user-friendliness of the device
- evaluate the user-manual

Materials and methods

Approximately 80 diabetics took part in each evaluation. One group of participants had two consultations (the "training group") and the other group had one consultation (the "post group"). At the first consultation the diabetics in the "training group" were given a standardised instruction about the OneTouch Ultra or the GlucoTouch device before they did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also took capillary samples of the diabetics and measured twice at the device. In addition, two capillary samples were taken to a designated comparison method. The "post group" received the device by post and no training was given. Both groups of diabetics carried out a practice period of three weeks at home, before they were called for a second consultation. The same blood glucose sampling and measurement procedures 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 and the user-manual.

Results, OneTouch Ultra

OneTouch Ultra shows acceptable precision. The CV is < 5 % under standardised and optimal measuring conditions and between 2 and 6 % when the measurements are performed by diabetics.

The agreement with a designated comparison method is good. Quality goals set in ISO 15197 are achieved, both under standardised and optimal measuring conditions and by the diabetic patients. The three lots of test strips showed significantly

lower values than the comparison method. The measured differences are between -0,3 and -0,9 mmol/L. Glucose measurements at OneTouch Ultra seem to be affected by the hematocrit values of the samples in a higher degree than described in the package insert. Glucose values are over-estimated when the hematocrit is below 30 %. With hematocrit values over approximately 40 % the glucose values are under-estimated.

The diabetics summarise the OneTouch Ultra device as easy to use. Most of them were pleased with the device. The diabetics that had used the user manual were satisfied with the manual.

Results, OneTouch GlucoTouch

GlucoTouch shows acceptable precision. The CV is < 5 % under standardised and optimal measuring conditions and between 3 and 7 % when the measurements are performed by the diabetic patients. The agreement with a designated comparison method is good. Quality goals set in ISO 15197 are achieved, both under standardised and optimal measuring condition and by the diabetics. Two of the three lots of test strips showed significantly higher values than the comparison method, and one lot shows significant lower values than the comparison method.

Glucose measurements on GlucoTouch seem to be affected by hematocrit values between 32 and 55 %. Hematocrit outside this range has not been tested. The diabetic patients summarise the GlucoTouch device as easy to use. Most of them were pleased with the device and satisfied with the user manual.

Conclusion

Glucose measurements with OneTouch Ultra and OneTouch GlucoTouch have acceptable precision. The accuracy is good. The results are within the quality goals set in ISO 15197. Glucose results at OneTouch Ultra seem to be affected by hematocrit in a higher degree than described in the package insert, while the glucose results at GlucoTouch seem to be affected as described in the package insert. The users find the device easy to use and are quite satisfied with the device and the user manual.

The complete evaluation reports are available at www.skup.nu