

OneTouch Ultra Glucose

Summary of an evaluation under the direction of SKUP Report SKUP/2005/39



Background

OneTouch Ultra is a meter designed for glucose self-measurements by diabetics. The meter is produced by LifeScan, Johnson & Johnson, and is supplied in Scandinavia by LifeScan. OneTouch Ultra was launched onto the Norwegian market in the autumn 2002.

In order to give reimbursement for the test strips, The National Social Insurance Office (*Rikstrygdeverket*) in Norway instructs the companies to carry out an evaluation that includes a user-evaluation among diabetics. The evaluation of OneTouch Ultra is done under the direction of SKUP during the spring of 2005.

The aim of the evaluation

The aim of the evaluation of OneTouch Ultra is to

- reflect the analytical quality under standardised and optimal conditions (performed by a biomedical laboratory scientist)
- reflect the analytical quality by the users (77 diabetics)
- 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 OneTouch Ultra regarding user-friendliness
- evaluate the OneTouch Ultra user-manual

Materials and methods

77 diabetics took part in the evaluation. 39 participants had two consultations (the “training group”) and 38 participants had one consultation (the “post group”). At the first consultation the diabetics at the training group were given a standardised instruction about the OneTouch Ultra 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 OneTouch Ultra. In addition, two capillary samples were taken to a designated comparison method. The post group received the OneTouch Ultra by 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 second 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 and the user-manual of OneTouch Ultra.

Results

- 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 under standardised and optimal measuring conditions. When

handled by the diabetics, OneTouch Ultra also shows good results. 98,7 % of these results are within the “adjusted ISO-goal” and 97,4 % are also within the quality goals set in ISO 15197.

- The three lots of test strips that were used showed significantly lower values than the comparison method. The measured differences are between -0,3 and -0,9 mmol/L. In spite of these systematic deviations, the results attain the quality goal.
- Glucose measurements at OneTouch Ultra seem to be affected by the hematocrit values of the samples in 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. As a whole they were pleased with the device. The diabetics that had used the user manual were satisfied with the manual.

Conclusion

Glucose measurements on OneTouch Ultra have acceptable precision. The results obtained under optimal measuring conditions are within the quality goals set in the ISO-guide 15197. The measurements performed by the diabetics are within the “adjusted” quality goals set in the ISO-guide 15197 and also within the ISO-goal. The three lots used in this evaluation showed significantly lower values than the comparison method. The glucose results in this evaluation are affected by hematocrit in a higher degree than described in the package insert. In spite of the hematocrit effect, the glucose results still fulfil the quality goal set by ISO. The users find the OneTouch Ultra device easy to use and they are quite satisfied with the device.

Comments from LifeScan

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

The complete report is found at www.skup.nu