

OneTouch GlucoTouch Glucose

Summary of an evaluation under the direction of SKUP Report SKUP/2005/40



Background

OneTouch GlucoTouch is a meter designed for glucose self-measurements by diabetic patients. The meter is produced and supplied in Scandinavia by LifeScan. OneTouch GlucoTouch was launched onto the Norwegian market in 1996.

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 diabetic patients. The evaluation of OneTouch GlucoTouch is done under the direction of SKUP during the spring of 2005.

The aim of the evaluation

The aim of the evaluation of OneTouch GlucoTouch is to

- reflect the analytical quality under standardised and optimal conditions (performed by two biomedical laboratory scientists)
- reflect the analytical quality by the users (diabetic patients)
- compare the analytical quality among diabetics with and without training and practise
- compare the analytical quality among diabetics before and after three weeks of practise
- check the variations between three lots of test strips
- examine if hematocrit interferes with the measurements
- evaluate OneTouch GlucoTouch regarding user-friendliness
- evaluate the OneTouch GlucoTouch user-manual

Materials and methods

82 diabetic patients took part in the evaluation. 43 participants had two consultations (the “training group”) and 39 participants had one consultation (the “postgroup”). At the first consultation the “training group” was given a standardised training about the OneTouch 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 diabetic patients and measured twice at OneTouch GlucoTouch. In addition, two capillary samples were taken to a designated comparison method. The postgroup received OneTouch GlucoTouch 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 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 and the user-manual of OneTouch GlucoTouch.

Results

- OneTouch 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 diabetic patients.
- 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 diabetic patients, OneTouch GlucoTouch also shows good results. 99 % of these results are within the quality goals set in ISO 15197 and 100 % are within the “adjusted ISO-goal”.

- Two of the three lots of test strips that were used showed significantly higher values than the comparison method, and one lot shows significant lower values than the comparison method. All the lots are within the ISO-limits.
- Glucose measurements on OneTouch GlucoTouch seem to be affected by the hematocrit values between 32 – 55 %. Hematocrit outside this range has not been tested.
- The diabetic patients summarise the OneTouch GlucoTouch device as easy to use. As a whole they were pleased with the device. The patients that had used the user manual were satisfied with the manual.

Conclusion

Glucose measurements on OneTouch GlucoTouch 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 diabetic patients are also within the ISO-goal. The glucose results in this evaluation are affected by hematocrit as described in the package insert. The users say that the OneTouch GlucoTouch device is easy to use and they are 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