

## OneTouch Verio

### Summary of an evaluation under the direction of SKUP Report SKUP/2011/86

#### Background

OneTouch Verio blood glucose meter and test strips are designed for glucose self-measurements performed by persons with diabetes as well as measurements performed by health care professionals. The OneTouch Verio system is produced by LifeScan Inc. and supplied in Scandinavia by LifeScan. The system has not been launched onto the Scandinavian market yet. In order to give reimbursement for the test strips in Norway, The Norwegian Health Economics Administration (HELFO) requires from the companies to carry out an evaluation that includes a user-evaluation among diabetes patients. In addition LifeScan wanted the test strip to be evaluated with focus on the analytical quality according to a quality goal suggested by NOKLUS in 2008 for glucose instruments used in Norwegian primary care centres and nursing homes. The evaluation of OneTouch Verio was carried out under the direction of SKUP from October to December 2010.

#### The aim of the evaluation

The aim of the evaluation of OneTouch Verio was to assess the analytical quality and the user-friendliness of OneTouch Verio:

- assess the analytical quality under standardised and optimal conditions, performed by two biomedical laboratory scientists in a hospital environment
- assess the analytical quality by the intended users
- compare the analytical quality among trained and un-trained diabetes patients
- compare the analytical quality among diabetes patients before and after three weeks of practice
- calculate a total measurement error (TE) based on the imprecision and bias of OneTouch Verio, and discuss the achieved TE according to a quality goal of 10%, suggested by NOKLUS as a quality goal for glucose device used in Norwegian primary care and nursing homes
- examine the variation between three lots of test strips
- examine if hematocrit interferes with the measurements
- evaluate OneTouch Verio regarding user-friendliness
- evaluate the OneTouch Verio owner's booklet

#### Materials and methods

The evaluation model is based on the guidelines in ISO 15197. A total of 91 diabetes patients took part in the evaluation. The participants in a "training group" had two consultations and the participants in a "mail group" had one consultation. The diabetes patients in the "training group" were given a standardised instruction about OneTouch Verio before they did a finger prick and performed two measurements on the meter. The biomedical laboratory scientists did a new finger prick and collected capillary samples from the diabetes patients for measurements on OneTouch Verio. In addition, two capillary samples were taken for measurements with a selected comparison method. The diabetes patients in the "mail group" received OneTouch Verio by mail and no training was given. Both groups of diabetes patients used the equipment for approximately three weeks at home, before they attended for a final consultation. The blood glucose sampling and measurement

procedures from 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 participants answered questionnaires about the user-friendliness and the owner's booklet of OneTouch Verio.

## **Results**

- The overall precision of OneTouch Verio was good. The repeatability CV obtained under standardised and optimal conditions was between 2,3 and 3,6%. The recommended quality goal for precision was obtained. The repeatability CV obtained by the diabetes patients was approximately 4,5%. Statistically, the CVs for the diabetes patients with and without training programme were not significantly different. The CVs for the diabetes patients after practise at home tend to be better than the results at the first consultation, but the precision improvement was not statistically significant.
- OneTouch Verio showed glucose results in agreement with the comparison method for glucose concentrations >10 mmol/L. For glucose concentrations <10 mmol/L OneTouch Verio showed higher glucose results than the comparison method. The deviation from the comparison method was between 0,2 and 0,3 mmol/L for glucose concentrations below 10 mmol/L. The deviation was small, but statistically significant.
- The accuracy of OneTouch Verio was good. The quality goal set in ISO 15197 was achieved under standardised and optimal measuring conditions and by the diabetes patients.
- The calculated total error of OneTouch Verio was between 6,9 and 8,3%, depending on the glucose concentration. The suggested quality goal for use in Norwegian primary care centres and nursing homes was obtained.
- The three lots of test strips used in this evaluation gave glucose results in agreement with the comparison method.
- Glucose measurements on OneTouch Verio in this study were not affected by hematocrit values within the range 30 – 49%.
- Most of the diabetes patients thought that the OneTouch Verio device was easy to operate. Most of the diabetes patients that had used the owner's booklet were satisfied with the booklet, but several commented that the size of the booklet was too large.

## **Conclusion**

The analytical quality of OneTouch Verio was good. The precision of OneTouch Verio was good. The results were accurate and within the quality goal set in the ISO-guide 15197. The suggested quality goal for use in Norwegian primary care centres and nursing homes was obtained. The glucose results were not affected by hematocrit in this study. Most of the users found the OneTouch Verio device easy to use.

## **Comments from LifeScan**

A letter with comments and additional information from the producer is attached to the report.