Wellion Calla Light Blood Glucose System

Summary of an evaluation under the direction of SKUP
Report SKUP/2013/87

Background
Wellion Calla Light is a blood glucose meter designed for glucose self-measurement by diabetes patients. The meter and test strips are manufactured and supplied by Med Trust Handelsges.m.b.H. The evaluation was carried out during 2012 and 2013 at the request of Med Trust AB in Sweden.

The aim of the evaluation
The aim of the evaluation was to determine the analytical quality and the user-friendliness of the Wellion Calla Light system. The evaluation was carried out by biomedical laboratory scientists under standardised and optimal conditions at a hospital laboratory and by the intended users, i.e., diabetes patients. In addition to the analytical quality, presented as repeatability, bias and accuracy, comparisons were made concerning variation between lots of test strips and interference by haematocrit.

Materials and methods
Out of 125 diabetes patients enrolled for the evaluation, 94 completed. The diabetes patients were randomly divided into a mail group, which received the meter and test strips by mail, and a training group, which got a brief lesson of the system before they received the meter and test strips. Of the diabetes patients completing the evaluation, 50 were in the mail group and 44 in the training group. Each diabetes patient got an individual meter and the biomedical laboratory scientists used two meters. Three lots of test strips were used. At the final meeting, the patients measured the glucose concentration on their individual meter and the biomedical laboratory scientists measured on their two meters. At the same occasion samples were obtained for the comparison method. The comparison method was a hexokinase method for measurement of plasma glucose concentrations. The analysis was done on a Modular instrument from Roche, which results are traceable to a reference method procedure. The quality goal for the repeatability was a CV of ≤5%. The quality goal for accuracy for the biomedical laboratory scientists' measurements was set according to ISO 15197:2003; at least 95% of the results should be within ±0,83 mmol/L at glucose concentrations <4,2 mmol/L, and within ±20% at glucose concentrations ≥4,2 mmol/L. The goal for the diabetes patients' measurements was that at least 95% of the results should be within ±1,00 mmol/L at glucose concentrations <4,2 mmol/L, and within ±25% at glucose concentrations ≥4,2 mmol/L. The trueness, determined as bias, was calculated but no quality goal was set. The quality goal of technical errors was ≤2%.

Results
The repeatability CV achieved by the biomedical laboratory scientists was 3,5−4,0% for one of the meters and one test strip lot and 4,3−5,1% for the other meter with three test strip lots (about one third of the results from each lot). The repeatability CV achieved by the diabetes patients was 5,7−6,0% with three test strip lots. The results of Wellion Calla Light were a little lower than the results of the comparison method. 98% of the results achieved by the biomedical laboratory scientists fulfilled the quality goal for accuracy. All the results achieved by the diabetes patients also fulfilled the quality goals for accuracy, as described in ISO 15197:2003 and thereby also the less restrictive goals set for users. There were no differences

between the three lots of test strips. There was no difference in performance between the diabetes patients in the mail group and in the training group. A slight, but statistically significant, effect of haematocrit was shown in the range 35−49%. The percentage of technical errors was 0%. The user-friendliness was rated as satisfactory, although some possible improvements in the manual were pointed out.

Conclusion
The quality goal of a repeatability CV of ≤5%, when the biomedical laboratory scientists did the measurements, was fulfilled for one of the meters. The results achieved on the other meter most likely fulfilled the quality goal for two of the three concentration intervals, while the quality goal was most likely not fulfilled for one concentration interval. The quality goal for repeatability was most likely not fulfilled when the diabetes patients performed the measurements. The accuracy quality goals were fulfilled by all users. No differences were found between the results of three different lots of test strips. The quality goal for technical errors was fulfilled. The user-friendliness was satisfactory, which fulfils the quality goal.

A simplified summary in Swedish can be found in the end of this report (attachment 12).

Comments from Med Trust
Med Trust Handelsges.m.b.H is content with this report and has no further comments.