Contour blood glucose system

Summary of an evaluation under the direction of SKUP
Report SKUP/2009/75

Background
Contour blood glucose meter and Contour test strips are designed for glucose self-measurements performed by diabetes patients and measurements performed by health care professionals. The meter and the test strips are produced by Bayer Healthcare and supplied in the Nordic countries by Bayer. Contour was launched onto the Scandinavian market in 2006. Bayer turned to SKUP for an evaluation of Contour in order to get an assessment of the analytical quality of Contour according to a quality goal suggested by NOKLUS in 2008 for glucose instruments used in primary care centres and nursing homes. The quality goal allows a total error of 10%. The evaluation of Contour was carried out under the direction of SKUP from March to September 2009.

The aim of the evaluation
The aim of the evaluation of Contour was to

- assess the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
- assess the analytical quality by intended users in three primary care centres
- discuss achieved total measurement error according to a quality goal of 10%, suggested by NOKLUS as a quality goal for glucose device used in primary care and nursing homes
- examine the variation between three lots of test strips
- examine if hematocrit interferes with the measurements
- evaluate Contour regarding user-friendliness

Materials and methods
Capillary samples from 88 persons with diabetes and 10 healthy individuals were collected in a hospital laboratory. Two measurements on Contour were carried out for each person, and capillary samples were directly prepared for measurements with a designated comparison method. In addition a sample for hematocrit was taken. In three primary care centres a total of 119 capillary samples were measured in duplicate on Contour. Three different lots of test strips were used. The evaluators answered questionnaires about the user-friendliness of Contour.

Results

- The precision of Contour was good. The repeatability CV was approximately 4%, obtained under standardised and optimal conditions as well as when the measurements were performed in three primary care centres. The suggested quality goal for precision was obtained.
- For glucose concentrations <10 mmol/L Contour gave results in agreement with the comparison method. For glucose concentrations >10 mmolL the results on Contour were systematic lower than the results from the comparison method. The bias at this concentration level was -0,47 mmol/L (- 3,6%).
- The accuracy of Contour was good. The results fulfilled the quality goal proposed in ISO 15197. The total error of Contour was approximately 10%, coinciding with the suggested quality goal for use in Norwegian primary care centres and nursing homes.
- Two of the three lots of Contour test strips gave glucose results in agreement with the comparison method. The third lot gave lower results than the comparison method, with a systematic deviation of approximately -0,3 mmol/L.
- The glucose measurements on Contour did not seem to be affected by hematocrit values from 27 – 49%.
- The evaluators thought that the Contour device was user-friendly and easy to operate.

Conclusion
The precision of Contour was good, with a repeatability CV of approximately 4%. The accuracy of Contour was good. The calculated total error was approximately 10%. Suggested quality goals were obtained. Glucose measurements on Contour did not seem to be affected by hematocrit in this study. The users found the Contour device easy to use.

Comments from Bayer AS
A letter with comments from Bayer AS is attached to the report.