

Background

The Ascensia BREEZE2 blood glucose meter and the Ascensia BREEZE2 test strips are designed for glucose self-measurements by diabetics. The meter and the test strips are produced by Bayer HealthCare and are supplied in Scandinavia by Bayer. Ascensia BREEZE2 and Ascensia BREEZE2 test strips have not yet been launched onto the Norwegian market. In order to give reimbursement for glucose test strips, the Norwegian Labour and Welfare Organisation (NAV) instructs the companies in Norway to carry out an evaluation that includes a user-evaluation among diabetics. The evaluation of Ascensia BREEZE2 and Ascensia BREEZE2 test strips was done under the direction of SKUP from October to December 2006.

The aim of the evaluation

The aim of the evaluation of Ascensia BREEZE2 is to

- reflect the analytical quality under standardised and optimal conditions (performed by biomedical laboratory scientists)
- reflect the analytical quality by the users (78 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 Ascensia BREEZE2 regarding user-friendliness
- evaluate the Ascensia BREEZE2 user guide

Materials and methods

78 diabetics took part in the evaluation. 38 participants had two consultations (the “training group”) and the rest had one consultation (the “mail group”). The diabetics in the “training group” were given a standardised instruction about the Ascensia BREEZE2 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 on Ascensia BREEZE2. In addition, two capillary samples were taken to a designated comparison method. The diabetics in the “mail group” received the Ascensia BREEZE2 by mail 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 answered questionnaires about the user-friendliness and the user guide of Ascensia BREEZE2.

Results

- Ascensia BREEZE2 shows good precision. The CV is approximately 3 % under standardised and optimal measuring conditions and between 3 and 5 % when the measurements are performed by the diabetics.
- The trueness of Ascensia BREEZE2 was good. For glucose values <10 mmol/L no significant bias between Ascensia BREEZE2 and the comparison method was pointed

out. For glucose values >10 mmol/L there was a small, but statistically significant bias between Ascensia BREEZE2 and the comparison method. Ascensia BREEZE2 gave glucose values approximately 0,3 mmol/L lower than the comparison method at this glucose level. In spite of this deviation the results still fulfil the quality goal.

- The agreement with a designated comparison method is good. The quality goal set in ISO 15197 is achieved under standardised and optimal measuring conditions. When handled by the diabetics, Ascensia BREEZE2 also shows accurate results. These results are within the “adjusted ISO-goal” and also within the quality goal set in ISO 15197.
- The three lots of test strips used in this evaluation gave glucose results in agreement with the comparison method. No significant difference was pointed out.
- Glucose measurements on Ascensia BREEZE2 seem to be affected by hematocrit. Hematocrit outside the range 33 – 50 % has not been tested.
- The diabetics summarise the Ascensia BREEZE2 device as easy to use. Most of them were pleased with the device. The diabetics that had used the user guide were satisfied with the guide.

Conclusion

The analytical quality of Ascensia BREEZE2 is good. The results are within the quality goal for the total error set in the ISO-guide 15197. The precision of Ascensia BREEZE2 is also good. The glucose results seem to be affected by hematocrit. The users find the Ascensia BREEZE2 device easy to use and they are quite satisfied with the device.

Comments from Bayer

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

The complete report is found at www.skup.nu