

DANA DiabeCare IISG blood glucose meter

Summary of an evaluation under the direction of SKUP Report SKUP/2008/66

Background

DANA DiabeCare IISG (DANA) blood glucose meter is designed for glucose self-measurements performed by diabetes patients who use an insulin pump. The meter and the test strips are produced by SOOIL Development co. Ltd. and are supplied in Scandinavia by Medical Home Tech. DANA blood glucose meter is integrated in an insulin pump. The DANA insulin pump has been in the Norwegian market for some years but the product integrated with a glucose meter is not launched yet. In order to give reimbursement for the test strips in Norway, the Norwegian Labour and Welfare Organisation (NAV) requires from the companies to carry out an evaluation that includes a user-evaluation among diabetes patients. The evaluation of DANA blood glucose meter was done under the direction of SKUP from February to June 2008.

The aim of the evaluation

The aim of the evaluation of DANA is to

- reflect the analytical quality under standardised and optimal conditions, performed by biomedical laboratory scientists in a hospital environment
- reflect the analytical quality by the intended users
- check the variation between three lots of test strips
- examine if hematocrit interferes with the measurements
- evaluate DANA regarding user-friendliness
- evaluate the DANA user guide

Materials and methods

87 diabetes patients took part in the evaluation. All the diabetes patients had two consultations. The diabetes patients were given a standardised instruction about DANA and did a few finger pricks to get to know the instrument. The diabetes patients used the equipment for approximately two weeks at home, before they attended for a final consultation. At this consultation the diabetes patients did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also collected capillary samples from the diabetes patients and measured twice on DANA. In addition, two capillary samples were taken for measurements with a designated comparison method. 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 DANA.

Results

- The precision of DANA was good. The repeatability CV was approximately 3% under standardised and optimal measuring conditions and between 3 and 6% when the measurements were performed by the diabetes patients.
- The trueness of DANA was acceptable. For glucose values <7 mmol/L there was a slight, positive bias (0,1 mmol/L) between DANA and the comparison method. For glucose values between 7 and 10 mmol/L DANA gave results in agreement with the comparison method. For glucose values ≥ 10 mmol/L a negative bias was pointed out, with a mean deviation from the comparison method of -0,6 mmol/L.

- As a whole, the accuracy of DANA was good. The quality goal set in ISO 15197 was achieved under standardised and optimal measuring conditions. When handled by the diabetes patients, DANA also showed accurate results. These results were within the “adjusted ISO-goal” and also within the quality goal set in ISO 15197.
- One of the three lots of test strips (DN 24GA02C) used in this evaluation gave significantly lower values than the comparison method. The mean deviation from the comparison method for this lot was -0,44 mmol/L.
- Glucose measurements on DANA seemed to be slightly affected by hematocrit in this study. Hematocrit outside the range 30 – 47% has not been tested.
- The diabetes patients summarised the DANA device as quite easy to operate. Approximately half of them reported various difficulties regarding the test strips, especially when it came to inserting the strip. Quite a few diabetes patients commented the placing of the protection cap. Most of the diabetes patients that had used the user guide were satisfied with the guide.

Conclusion

The analytical quality of DANA was good. The precision was good and the results were accurate and within the quality goal for the total error set in the ISO-guide 15197. The glucose results seemed to be slightly affected by hematocrit. The users where quite pleased with the DANA device, but reported some difficulties regarding insertion of the test strip.

Comments from Medical Home Tech

For comments and additional information from Medical Home Tech, please see attachment 13 in the report.

The complete report is found at www.skup.nu.