

Mendor Discreet SKUP/2012/95

Background

Mendor Discreet is a new blood glucose meter produced by Mendor Oy. The system is an “all-in-one” blood glucose meter with integrated lancing device and 25 test strips in a cartridge. The device is operated by pulling two covers up and down making access to the lancet and test strip. The evaluation was carried out at the request of Mendor Oy during the first months of 2012.

The aim of the evaluation was to

- assess the analytical quality under standardised and optimal conditions (hospital environment)
- assess the analytical quality by the intended users
- compare the analytical quality among diabetes patients with and without a training program
- examine the variation between three lots of test strips
- examine if haematocrit interferes with the measurements
- evaluate the user-friendliness of Mendor Discreet and the user guide

Materials and methods

A total of 108 diabetes patients took part in the evaluation; 85 completed. The participants were randomly divided into two groups. The “training group” received personal training in how to use the device, and the “mail group” received the device and instructions by mail. Both groups used the device for approximately two weeks at home, before they attended for an end-meeting.

Results

- The quality goal for imprecision ($CV < 5\%$) was fulfilled for all results except the high glucose results as achieved by the mail group. The repeatability CV was between 2,8 and 4,1% as obtained by the biomedical laboratory scientists and between 2,5 and 5,2% as achieved by the diabetes patients.
- The glucose measurements on Mendor Discreet gave slightly lower glucose results than the comparison method. The deviation from the comparison method was between (-0,1) and (-0,4) mmol/L. The deviation is small, but statistically significant.
- The accuracy quality goal in ISO 15197:2003 (deviation $< 20\%$) was fulfilled. 100% of the results obtained by the biomedical laboratory scientists and 99% of the results obtained by the diabetes patients were inside the limits.
- The three lots of test strips used in the evaluation gave corresponding glucose results.
- Glucose measurements on Mendor Discreet were marginally, but statistically significant, affected by haematocrit (range 31 – 48%).
- The response from the users about the user-friendliness was mixed. A great number of participants had some kind of difficulties with handling the device, reporting various types of problems. Approximately 2/3 of the participants did not find the meter easy to operate. The rest of the participants were principally positive to the device but their answers differed substantially. A total of 23 participants withdrew from the evaluation for various reasons.
- The fraction of technical errors was $< 2\%$, and the quality goal for this was fulfilled.

Conclusion

The precision and the accuracy were good. The accuracy quality goal set in ISO 15197:2003 was fulfilled. The response from the users about the user-friendliness was mixed.

Comments from Mendor Oy

A letter with comments from Mendor Oy is attached to the report.