

mylife Unio blood glucose system



Summary of an evaluation under the direction of SKUP Report SKUP/2013/100

Background

Mylife Unio is a blood glucose meter designed for glucose self-measurements performed by persons with diabetes. The meter and test strips are produced by Bionime Corporation and supplied by Ypsomed. The evaluation was carried out from May to June 2013 at the request of Ypsomed Nordics.

The aim of the evaluation was to

- estimate the imprecision of mylife Unio
- compare mylife Unio results achieved under standardised and optimal conditions (hospital environment) with results from an established hospital laboratory method for glucose
- compare mylife Unio results achieved by the intended users with results from an established hospital laboratory method for glucose
- examine the variation between three lots of test strips
- examine if haematocrit interferes with the measurements
- evaluate the user-friendliness of mylife Unio and the user guide

Materials and methods

A total of 90 persons with diabetes took part in the evaluation and 85 of them completed. All the participants received the device and instructions by mail. They used the device for approximately two weeks at home, before they attended for an end-meeting. Three lots of test strips were used.

The quality goal for imprecision was a repeatability CV $\leq 5\%$. The quality goal for accuracy was set according to ISO 15197:2003* and ISO 15197:2013**. These quality goals state that 95% of the individual glucose results shall fall within the accuracy limits.

* ISO 15197:2003: $\leq \pm 0,83$ mmol/L at glucose conc. $< 4,2$ mmol/L or $\leq \pm 20\%$ at glucose conc. $\geq 4,2$ mmol/L

** ISO 15197:2013: $\leq \pm 0,83$ mmol/L at glucose conc. $< 5,55$ mmol/L or $\leq \pm 15\%$ at glucose conc. $\geq 5,55$ mmol/L

Results

- The repeatability CV was between 1,9 and 3,2% as achieved by the biomedical laboratory scientists and between 3,5 and 4,5% as achieved by the diabetes patients.
- Assessed as a whole, the glucose measurements on mylife Unio were in agreement with the comparison method.
- All the results obtained by the biomedical laboratory scientists with meter A/lot a and meter C/lot c and 99% of the results obtained with meter B/lot b, were within the accuracy quality limits specified in ISO 15197:2003 and in ISO 15197:2013. All the results obtained by the diabetes patients were within the accuracy quality limits specified in ISO 15197:2003, and 99% of their results were within the accuracy quality limits specified in ISO 15197:2013.
- No pronounced difference between the three lots of test strips was found.
- Glucose measurements on mylife Unio were marginally, but statistically significant, affected by haematocrit (range 32 – 52%).
- The user-friendliness was rated as satisfactory.
- The percentage of technical errors was 0,1%. When inserting the test strip, an error code appeared in approximately 3% of the efforts, and the test strip had to be reinserted.

Conclusion

The quality goal of a CV $\leq 5\%$ was fulfilled as obtained by the biomedical laboratory scientists. For measurements performed by the diabetes patients, the quality goal for precision was fulfilled for the glucose level >10 mmol/L. For the glucose levels <7 mmol/L and $7 - 10$ mmol/L the upper confidence interval values for the CVs are $>5\%$. Most likely the quality goal for precision is fulfilled, also for glucose results ≤ 10 mmol/L.

Assessed as a whole, the glucose measurements on mylife Unio were in agreement with the comparison method, and only small deviations from the comparison method were found with the three lots of test strips. The results achieved by the biomedical laboratory scientists and the results achieved by the diabetes patients fulfilled the quality goal for accuracy specified in ISO 15197:2003 and in ISO 15197:2013. The user-friendliness was rated as satisfactory. The percentage of technical errors fulfilled the goal ($\leq 2\%$).

Comments from Ypsomed

Ypsomed gratefully accepted the report and had no additional comments.

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