mylife™ Unio™

Meter and test strips
designed for glucose self-measurement
Manufactured by Bionime Corporation

Report from the evaluation SKUP/2013/100

organised by SKUP at the request of Ypsomed Nordics

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The report was written by SKUP, October 2013. For more details about SKUP, see attachment 1. Main author was Marianne Risa, SKUP in Norway.

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Attachment 6, 8 and 9 are included only in the copy to Ypsomed.

1. Summary

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 ≤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: <±0,83 mmol/L at glucose conc. <4,2 mmol/L or <±20% at glucose conc. ≥4,2 mmol/L
** ISO 15197:2013: <±0,83 mmol/L at glucose conc. <5,55 mmol/L or <±15% at glucose conc. ≥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 ≤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 (≤2%).

Comments from Ypsomed

Ypsomed gratefully accepted the report and had no additional comments.

2. Abbreviations

ADA	American Diabetes Association
BLS	Biomedical Laboratory Scientist
CI	Confidence Interval
C-NPU	Committee on Nomenclature, Properties and Units
CV	Coefficient of Variation
DAK-E	Danish Quality Unit of General Practice
DEKS	Danish Institute of External Quality Assurance for Laboratories in Health Care
EQA	External Quality Assessment
Equalis	External quality assurance in laboratory medicine in Sweden
FAD	Flavin-Adenine Dinucleotide
HDH	Haraldsplass Diaconal Hospital
HELFO	the Norwegian Health Economics Administration
ISO	International Organization for Standardization
NIST	National Institute of Standards & Technology
Noklus	Norwegian Quality Improvement of Primary Care Laboratories
SKUP	Scandinavian evaluation of laboratory equipment for primary health care
SRM	Standard Reference Material

3. Quality goals

3.1. Analytical quality goals

Mylife Unio is designed for monitoring blood glucose, and the quality goals are set according to this.

Precision

According to the American Diabetes Association (ADA) the imprecision (CV) of new glucose devices must be less than 5% [1]. Other authors also recommend an imprecision of 5% or less [2-4].

Accuracy

The International Organization for Standardization (ISO)-standard 15197:2003 [5], is an international protocol for evaluating meters designed for glucose monitoring, and gives the following minimum acceptable accuracy requirement:
Ninety-five percent (95%) of the individual glucose results shall fall within ±0,83 mmol/L of the results of the comparison method at glucose concentrations <4,2 mmol/L and within ±20% at glucose concentrations ≥4,2 mmol/L.

This quality goal is set for measurements made by trained laboratory staff. The same requirement should be applicable for measurements performed by persons with diabetes. Evaluations performed by SKUP [6,7], show that the quality goal can be achieved by the end-user.

In 2013 a new version of the ISO-standard, ISO 15197:2013 [8], was approved. ISO 15197:2013 gives the following minimum acceptable accuracy requirement for measurements made by trained laboratory staff as well as measurements performed by persons with diabetes:
Ninety-five percent (95%) of the individual glucose results shall fall within ±0,83 mmol/L of the results of the comparison method at glucose concentrations <5,55 mmol/L and within ±15% at glucose concentrations ≥5,55 mmol/L.

Other analytical quality goals

In Norway: In the Norwegian Health Economics Administration's (HELFO) standard protocol [9] requirements with a total error of ±25% for measurements performed by persons with diabetes is given.
In Denmark: The analytical quality goals for point of care glucose measurement systems are CV <4% and bias <3% [3,4].

Other analytical quality limits

The number of results within fixed limits of ±25% (for the end-user's measurements) and of ±10% (for the biomedical laboratory scientists' measurements) will be reported, but not further assessed in this report.

Variation between lots

The agreement between three lots of test strips will be assessed. No specific quality goal for lot variation is set.

Technical errors
SKUP recommends that the percentage of "tests wasted" caused by technical errors should not exceed 2%. The evaluating persons register the number of error codes and technical errors during the evaluation.

3.2. Evaluation of user-friendliness

The evaluation of user-friendliness is carried out by asking the participants (the intended users) to fill in a questionnaire about the user guide and the user-friendliness of mylife Unio. Tables concerning assessment of time factors and assessment of quality control possibilities are filled in by SKUP. See section 5.5.

3.3. Principles for the assessments

3.3.1. Assessment of the analytical quality

The analytical results are assessed according to the quality goals set for the evaluation.

Precision
The decision whether the achieved coefficient of variation (CV) fulfils the quality goal or not is made on a 5% significance level. The distinction between the ratings, and the assessment of precision according to the quality goal, are shown in table 1.

Table 1. The rating of precision

Distinction between the ratings	Assessment according to the quality goal
The CV is lower than the quality goal (statistically significant)	The quality goal is fulfilled
The CV is lower than the quality goal (not statistically significant)	Most likely the quality goal is fulfilled
The CV is higher than the quality goal (not statistically significant)	Most likely the quality goal is not fulfilled
The CV is higher than the quality goal (statistically significant)	The quality goal is not fulfilled

Accuracy
The accuracy is illustrated in difference-plots with limits for the allowable deviation according to the quality goal. The percentage of results within the limits is calculated.
The accuracy is judged as either fulfilling the quality goal or not fulfilling the quality goal.

3.4. SKUP´s quality goals in this evaluation

The results from the evaluation of mylife Unio were assessed against the following quality goals:

Repeatability CV ……. ≤5%
Allowable deviation in the individual result from the comparison method result
(according to ISO 15197:2003)
for glucose concentration <4,2 mmol/L ……..…….≤0,83 mmol/L
for glucose concentration ≥4,2 mmol/L ……...≤±20%
Allowable deviation in the individual result from the comparison method result
(according to ISO 15197:2013)
for glucose concentration <5,55 mmol/L ……..……≤0,83 mmol/L
for glucose concentration ≥5,55 mmol/L …….≤±15%
Required percentage of individual results within the allowable deviation ……..≥95%
Percentage of technical errors …… ≤2%
User-friendliness …… Satisfactory

4. Materials and methods

4.1. Definition of the measurand

The Committee on Nomenclature, Properties and Units (C-NPU) describes clinical laboratory tests in a database [10]. In the NPU-database the specifications for the measurand in this evaluation are as shown in table 2.

Table 2.NPU-specifications

NPU code	Name of test according to NPU	Unit
NPU22089	Plasma(capillary Blood) — Glucose; substance concentration = ?	mmol/L

Another variable measured in the evaluation is haematocrit.

4.2. The evaluated measurement system; mylife Unio

The mylife Unio system is designed for blood glucose self-monitoring. The system consists of a mylife Unio meter (figure 1) and dry reagent test strips. The glucose measurement is based on biosensor technology with the enzyme glucosedehydrogenase and cofactor flavin-adenine dinucleotide (FAD). The system is automatically calibrated and switched on when a test strip is inserted. The measurement starts when a sufficient amount of blood is drawn into the test strip. According to the manufacturer, it is possible to use blood samples from alternative sites on mylife Unio. Mylife Unio reports plasma glucose values.

Figure 1. mylife Unio meter and test strip

A summary of technical data from the manufacturer is given in table 3. For the name of the manufacturer, the suppliers in the Scandinavian countries and more technical data about mylife Unio, see attachment 2 and 3. For product information, see attachment 4.

Table 3. Technical data from the manufacturer

Technical data for mylife Unio	
Sample material	Capillary blood
Sample volume	At least 0,7 µL
Measuring time	5 seconds
Measuring range	0,6 — 33,3 mmol/L
Tolerated haematocrit range	10 — 70%
Memory capacity	1000 results
Electrical power supply	Two CR 2032 coin cell batteries

4.3. The selected comparison method

A selected comparison method is a fully specified method which, in the absence of a Reference method, serves as a common basis for the comparison of a field method.

4.3.1. The selected comparison method in this evaluation

The selected comparison method in this evaluation is the routine method for quantitative determination of glucose in human serum and plasma in the laboratory at Haraldsplass Diaconal Hospital (HDH) in Bergen. The method is a photometric glucose hexokinase method and is implemented on Cobas 6000 System from Roche Diagnostics. The glucose method on HDH is accredited according to NS-EN ISO 15189 (2007) by Norwegian Accreditation. The laboratory can document good analytical quality of the method through participation in an external analytical quality assessment program. The laboratory guaranties a reproducibility CV ≤3% and shows a reproducibility CV between 1,0 and 2,5% in daily use.

4.3.2. Verification of the analytical quality of the comparison method

Precision

The repeatability of the comparison method was estimated from duplicate measurements of capillary patient samples.

Trueness

To document the trueness of the comparison method, the standard reference material (SRM 965b) from National Institute of Standards & Technology, NIST, was used [11]. SRM 965b consists of ampoules with human serum with certified concentrations of glucose at four levels with given uncertainties.

Internal quality control

Autonorm Human Liquid Control Solutions at two levels from SERO AS were included in the measuring series in this evaluation.

External quality control

Human serum controls, produced by Norwegian Quality Improvement of Primary Care Laboratories (Noklus), with glucose concentrations at two levels were analysed. These controls have target values determined with an isotope-dilution gas chromatography/mass spectrometry method in a Reference laboratory in Belgium [12]. The target value is given with an "expanded uncertainty" of 1,5 - 2% (k=2). The controls are used in Noklus' External Quality Assessment (EQA) program.

4.4. The evaluation

4.4.1. Planning of the evaluation

Background for the evaluation
Mylife Unio is a new blood glucose meter produced by Bionime Corporation. The mylife Unio glucose monitoring system has not been launched onto the Scandinavian market yet.

Inquiry about an evaluation
Gjermund Hansen, Ypsomed, applied to SKUP in January 2013 for an evaluation of mylife Unio meter with mylife Unio test strips.

Protocol, contract and agreement
In March 2013, the protocol for the evaluation was approved, and Ypsomed and SKUP signed a contract for the evaluation. The laboratory at HDH agreed to analyse the samples for the comparison method.

Preparations and training program
SKUP started the preparations for the evaluation in January 2013. Marianne Risa, Camilla Eide Jacobsen and Grete Monsen, biomedical laboratory scientists (BLSs), are familiar with several blood glucose measurement systems, also with earlier versions of the meters from Bionime. Further training from Ypsomed was not necessary. The meters and test strips for the evaluation were received in May 2013. The equipment was immediately prepared for distribution among the diabetes patients. The practical work with the evaluation was carried out in May and June 2013.

4.4.2. Evaluation sites and persons involved

Persons responsible for the evaluation are shown in table 4.

Table 4. Persons responsible for various parts of the evaluation

Name	Title	Place	Responsibility
Gjermund Hansen	General Manager, Nordic Region	Ypsomed	Ordered the evaluation Contact person
Grete Monsen	BLS SKUP Organisation Secretary	SKUP/Noklus	Responsible for the evaluation Practical work with the evaluation
Marianne Risa	BLS	SKUP/Noklus	Preparations for the evaluation Practical work with the evaluation Statistical calculations Author of the report
Camilla Eide Jacobsen	BLS Master of Science	SKUP/Noklus	Practical work with the evaluation
Henriette Mohn Soldal and Tom Atle Jermstad	BLS	Laboratory at HDH	Practical work with the comparison method

4.4.3. The evaluation model

The SKUP evaluation

SKUP evaluations are based upon the fundamental guidelines in the book "*Utprøving av analyseinstrumenter*" [13]. SKUP's model for glucose user-evaluation is based on a standard model used by HELFO for test strip reimbursement in Norway [9].

The model for the evaluation of mylife Unio

The evaluation consisted of two parallel parts. One part of the evaluation was carried out under standardised and optimal conditions by laboratory educated personnel in a hospital laboratory. This part documents the quality of the system under conditions as favourable as possible for achieving good analytical quality.

Diabetes patients performed the other part of the evaluation in order to determine the analytical quality of mylife Unio by the users. The diabetes patients received the device and instructions by mail. Three lots of test strips from separate productions were distributed evenly between the participants (random distribution). The model for the evaluation among diabetes patients is shown in figure 2.

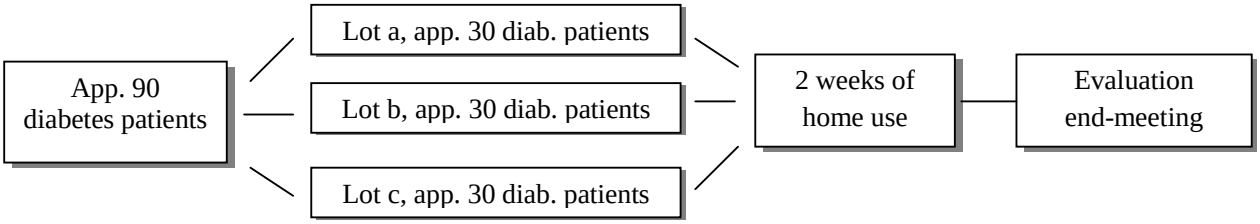

Figure 2. The model for the evaluation among the intended users

The aim of the evaluation

The evaluation of mylife Unio comprises the following studies:

- An examination of the analytical quality under standardised and optimal conditions, performed by BLSs in a hospital environment
    - Precision
    - Accuracy according to the quality goal given in ISO 15197:2003
    - Accuracy according to the quality goal given in ISO 15197:2013
- An examination of the analytical quality among approximately 90 diabetes patients
- An examination of the variation between three lots of test strips
- An examination to see if haematocrit interferes with the glucose measurements
- An evaluation of the user-friendliness of mylife Unio and the user guide

4.4.4. Recruitment, selection and characteristics of the diabetes patients

Recruitment

The diabetes patients were recruited in March and April 2013 by a brochure and by mail inquiry sent to the members of the local branch of The Norwegian Diabetes Association.

Selection

The participants were selected at random, but with the criterion to get variety in the group according to sex, diabetes type, age and how often the participants performed blood glucose measurements.

Characteristics of the diabetes patients that completed the evaluation

The mylife Unio glucose meter was tested in use by 49 men and 36 women with diabetes. The average age was 56 years (range 19 – 74). A total of 37 participants had Type1 diabetes, 46 had Type2 diabetes, one had Lada and one participant did not specify the type of diabetes. The group included diabetes patients from a range of self-monitoring frequencies, i.e. diabetes patients who perform self-monitoring often and those who perform self-monitoring less frequently.

4.4.5. The evaluation procedure under standardised and optimal conditions

The BLS used three mylife Unio blood glucose meters for the evaluation. For all the diabetes patients two measurements were performed with each of the three meters (totally six measurements for each diabetes patient). On meter A, lot 1133073 (called lot a) was used, on meter B, lot 1133181 (called lot b) was used, and on meter C, lot 1133258 (called lot c) was used for all the measurements. All possibilities for disturbance of, and interference with, the measurements were tried to be kept at a minimum.

Internal analytical quality control

Meter A, B and C were checked with the manufacturer's control solutions every day they were used.

Blood sampling

All samples for mylife Unio, as well as the glucose samples for the comparison method, were collected from finger capillaries. The blood sample for the duplicate measurements on mylife Unio was collected from the same finger prick. The BLS wiped off the first drop of blood before the first measurement and between the two sets of duplicates (meter A, B and C). In order to reduce the possible change in the glucose concentration during the sampling sequence, the sampling time ought not to exceed 10 minutes.

The blood sampling and analysis were carried out in the following order:

1. The BLS took a first sample for the comparison method
2. The BLS took samples and analysed on meter A, B, C, A, B and C (the order of the measurements on meter A, B and C was changed between each diabetes patient)
3. The diabetes patient took duplicate samples for his/her assigned meter
4. The BLS took a second sample for the comparison method
5. The BLS took a venous sample for haematocrit

Handling of the samples for the comparison method

The samples for the comparison method were taken from a finger capillary using Microvette Li-heparin tubes (300 µL) from Sarstedt. The samples were centrifuged immediately for three

minutes at 10 000 g, and plasma was separated into suitable sample vials. The plasma samples were frozen directly and stored at minus 80°C at Noklus until the analysis took place (according to the storing procedure for the standard reference material from NIST [11]).
The samples were analysed during one day in June and one day in July 2013.

Comparison method results
Two capillary samples were collected of each diabetes patient for measurement on the comparison method. The second sample was analysed in duplicate. The duplicate results were used for calculations of imprecision. The mean value of the first sample result and the two results of the second sample is referred to as the mean result of the comparison method. The mean result of the comparison method is an estimate of the true glucose value in the samples, and is used for the assessment of trueness and accuracy of mylife Unio, and for the assessment of bias with three lots of mylife Unio test strips and for the effect of haematocrit.

Stability of the glucose concentration during the sampling time
The stability of the glucose concentration during sampling was supervised. A capillary sample for the comparison method was taken at the start and in the end of each sampling sequence. Based on experience from several previous glucose user-evaluations, a stability criteria with a change <10% between the first and second comparative result is regarded as reasonable.

Measurement of haematocrit
Haematocrit may influence on blood glucose measurements. A venous sample was collected from each diabetes patient (voluntarily) and the haemotocrit was measured within six hours with Advia2120i or Cell-Dyn Sapphire at the laboratory at HDH.

Recording of results
All results were registered in a form provided by SKUP and signed by the evaluator. If one of the meters showed an error code while analyzing a sample, a new measurement was made. Error codes were recorded.

Evaluation of the user-friendliness
The BLSs looked for any defects and deficiencies or whether there was anything with the system that did not function optimally. They provided a description in keywords about the system and the user guide.

4.4.6. Evaluation among the intended users

The diabetes patients received the mylife Unio meter by mail, along with test strips, lancet pen, lancets, user manual and an information letter with explanations regarding what to do with the mylife Unio device during the period at home.

Use of mylife Unio at home
The diabetes patients used mylife Unio at home for approximately two weeks. They used mylife Unio in addition to their own glucose meter, and they continued to carry out self-measurements with their own meter as usual. During the first week the diabetes patients familiarised themselves with the new device. Each diabetes patient had approximately 25 test strips disposal to measure his/her blood glucose with mylife Unio this first week. If they preferred, they could perform the measurements at the same time as they performed measurements with their own meter. During the second week, the diabetes patients performed duplicate measurements on mylife Unio on five

different days. The results were recorded on a provided form for documentation of the training efforts.

Internal analytical quality control
To document correct functioning of the mylife Unio meters used by the diabetes patients, the BLS checked the meters with the control solution when the diabetes patients met at the evaluation end-meeting.

The evaluation end-meeting
After the two-week practice period at home, the diabetes patients met, one by one, for the evaluation end-meeting. The diabetes patients brought their assigned mylife Unio to the meeting. Before the samples were collected, the device was equilibrated to room temperature while the diabetes patients filled in the questionnaire regarding user-friendliness of mylife Unio and the user manual. The diabetes patients made duplicate blood glucose measurements on their assigned meter. For sampling procedure see section 4.4.5. Most of them used the distributed mylife AutoLance lancing device for the blood sampling. The measurements were performed with the test strips delivered to the diabetes patients for the evaluation. The results were registered. Error codes were recorded.

5. Results and discussion

Statistical expressions and calculations used by SKUP are shown in attachment 5.

5.1. Number of samples

A total of 90 diabetes patients signed up for the evaluation and 85 of them completed the evaluation. In total five participants withdrew from the evaluation for various reasons.
A venous sample for haematocrit was collected from 82 of the 85 participants.

5.1.1. The glucose concentration stability during sampling

Out of 85 pairs of results measured with the comparison method, three showed a difference >10% which means that these three participants had unstable glucose concentration during the sampling sequence time. This applied to ID 15, ID 54 and ID 82.

5.1.2. Excluded or missing results

The following results are missing or excluded:

- ID 15, ID 54 and ID 82 had a deviation of >10% between the first and second sample for the comparison method. All results from ID 15, ID 54 and ID 82 were removed before the assessment of accuracy and haematocrit influence, and before the calculation of bias.
- ID 129 was excluded as an outlier according to Burnett's model [14] in the calculation of repeatability of the comparison method. The results for ID 129 were removed before the assessment of accuracy and haematocrit influence, and before the calculation of bias.
- ID 15, ID 105 and ID 129 had no hematocrit result.

5.1.3. Failed measurements

The BLSs performed 703 measurements (6 measurements x 85 patients + 193 quality control measurements) on mylife Unio. None of these measurements failed because of technical errors.
The diabetes patients performed 170 measurements (2 measurements x 85 patients). One of these measurements failed with error code "Error 3 Signal failure".
Total percentage of technical errors was: (1 / 873) x 100 = 0,1%

A total of 37 error codes was reported in the evaluation. The most common error was Error 5 "Code error / Check strip" (n=26). See comment in section 5.5.2.

Other error codes reported:
Error 1 "Used strip / Insert new strip" (n=2)
Error 4 "Low blood quantity / Insert new strip" (n=5)
Error 8 "Sampling error / Insert new strip" (n=4)

Discussion
The percentage of technical errors was 0,1% and the goal (≤2%) was fulfilled.

5.2. Analytical quality of the selected comparison method

5.2.1. Internal quality control

In daily operation of the comparison method, the analytical quality of the method is monitored with internal quality control solutions at two levels of glucose concentrations. All control results from the evaluation period (two days) were within the limits the laboratory has set for the controls. The results are not shown.

5.2.2. Comparison of the 1st and 2nd measurement

To achieve a measure for the repeatability of the comparison method, one capillary sample collected of each diabetes patient was analysed in duplicate. The formula used for the calculation of repeatability (formula 1) is shown in attachment 5. The results have been checked to meet the imposed condition for using the formula (data not shown).

5.2.3. The precision of the comparison method

Repeatability

The repeatability of the comparison method with a 90% confidence interval (CI) is shown in table 5. The raw data is shown in attachment 6 (only available for the producer).

Table 5. Repeatability of the comparison method with capillary blood samples in the hospital laboratory

Glucose interval, mmol/L	n	Excluded results	Mean value glucose, mmol/L	CV (90% CI), %
<7	28	1*	5,8	1,1 (0,9 — 1,4)
7 – 10	31	0	8,3	0,8 (0,6 — 1,0)
>10	26	0	12,5	1,0 (0,8 — 1,4)

The given numbers of results (n) are counted before exclusion of outliers. Mean and CV are calculated after exclusion of outliers.

* One statistical outlier (ID 129) according to Burnett's model.

Discussion

The repeatability CV for the comparison method was approximately 1%.

5.2.4. The trueness of the comparison method

In order to demonstrate the trueness of the comparison method, the SRM 965b standards purchased from NIST, were analysed. The agreement between the comparison method and the NIST-standards is shown in table 6.

Table 6. Standard Reference Material (SRM 965b) measured on the comparison method

SRM 965b	Date	Certified glucose concentration, (uncertainty) mmol/L	n	Mean value glucose, mmol/L	Deviation from target value, %
Level 1	20.06.13	**1,836** (1,809 — 1,863)	5	1,89	+3,2
	02.07.13		5	1,89	+2,9
	Total		**10**	**1,89**	**+3,1**
Level 2	20.06.13	**4,194** (4,135 — 4,253)	5	4,35	+3,8
	02.07.13		5	4,27	+1,9
	Total		**10**	**4,31**	**+2,8**
Level 3	20.06.13	**6,575** (6,481 — 6,669)	5	6,75	+2,6
	02.07.13		5	6,70	+1,9
	Total		**10**	**6,73**	**+2,3**
Level 4	20.06.13	**16,35** (16,15 — 16,55)	5	16,60	+1,5
	02.07.13		5	16,74	+2,4
	Total		**10**	**16,67**	**+2,0**

Comments

Table 6 shows that the glucose results of the NIST-standards were just above the upper uncertainty limits. All results from the comparison method were therefore adjusted according to the certified NIST-targets. The adjustment was carried out by means of inverse calibration [15,16] by the following regression equation: $\mathbf{y = 0{,}9823x - 0{,}0308}$.

Further on in the report, whenever any result from the comparison method is presented, the result has already been adjusted according to this equation.

To verify the trueness of the adjusted comparison method results, human serum controls produced by Noklus, were analysed. The agreement between the comparison method and target values from the Reference laboratory in Belgium is shown in table 7.

Table 7. Trueness of the comparison method

Control	Date	Target value glucose, ("expanded uncertainty") mmol/L	n	Mean value glucose, mmol/L	Deviation from target value, %
Noklus 1	20.06.13	**5,71** (5,62 — 5,80)	5	5,79	1,3
	02.07.13		5	5,77	1,0
	Total		**10**	**5,78**	**1,2**
Noklus 2	20.06.13	**11,94** (11,70 — 12,18)	5	11,95	0,0
	02.07.13		5	12,01	0,6
	Total		**10**	**11,98**	**0,3**

Discussion

Table 7 documents that the comparison method produced true glucose values in the evaluation period.

5.3. Analytical quality of mylife Unio

5.3.1. Internal quality control

The mylife Unio meters used by the diabetes patients, were checked with the manufacturer's control solution (Control Normal) by the BLS at the end-meeting. All results were within the control range. The reproducibility CV was approximately 3,5% (n=85). The three mylife Unio meters used by the BLSs, were checked with control solutions every day they were used. All results were within the control range. The reproducibility CV was approximately 2,3% for Control Normal (n=54) and approximately 3,9% for Control High (n=54). Raw data is shown in attachment 7.

5.3.2. Comparison of the 1st and 2nd measurement

Two capillary samples were collected of each diabetes patient for measurements on meter A, meter B and meter C at the end-meeting. In addition, the diabetes patients took two capillary samples for measurements on their assigned meter at the end-meeting. For the calculation of imprecision, all results have been checked to meet the assumption for using formula 1 in attachment 5. For the total set of data the conclusion is that there is no systematic difference between the paired measurements (data not shown). This conclusion is also supported by observations in previous evaluations carried out by SKUP.

5.3.3. The precision of mylife Unio

Repeatability under standardised and optimal conditions in a hospital environment

The repeatability obtained by the BLSs with capillary blood samples is shown in table 8. The results are sorted and divided into three glucose levels according to the first measurement on mylife Unio. Raw data is shown in attachment 8.

Table 8. Repeatability, mylife Unio. Results achieved by the BLSs

mylife Unio	Glucose interval, mmol/L	n	Excluded results	Mean value glucose, mmol/L	CV (90% CI), %
Meter A	<7	31	0	5,9	2,1 (1,7 — 2,7)
Meter B	<7	28	0	6,1	2,2 (1,8 — 3,0)
Meter C	<7	28	0	5,9	2,5 (2,0 — 3,4)
Meter A	7 — 10	31	0	8,2	2,7 (2,2 — 3,4)
Meter B	7 — 10	32	0	8,4	1,9 (1,6 — 2,4)
Meter C	7 — 10	31	0	8,2	2,2 (1,8 — 2,8)
Meter A	>10	23	0	12,2	3,2 (2,6 — 4,3)
Meter B	>10	25	0	12,3	2,7 (2,2 — 3,6)
Meter C	>10	26	0	12,2	2,3 (1,9 — 3,0)

Repeatability obtained by the diabetes patients
The repeatability obtained by the diabetes patients with capillary blood samples is shown in table 9. The results are sorted and divided into three glucose levels according to the first measurement on mylife Unio. Raw data is shown in attachment 9.

Table 9. Repeatability, mylife Unio. Results achieved by the diabetes patients

Glucose interval, mmol/L	**n**	**Excluded results**	**Mean value glucose, mmol/L**	**CV (90% CI), %**
<7	28	0	6,0	4,5 (3,7 — 5,9)
7 — 10	31	0	8,4	4,3 (3,6 — 5,5)
>10	26	0	12,5	3,5 (2,8 — 4,6)

Discussion, repeatability
The repeatability CV obtained under standardised and optimal conditions was between 1,9 and 3,2%, and the quality goal of a CV ≤5% was fulfilled. The repeatability CV obtained at Noklus when the measurements were performed by the diabetes patients was between 3,5 and 4,5%. For glucose level ≤10 mmol/L the upper CI values are >5%. Most likely the quality goal is fulfilled. For glucose level >10 mmol/L the repeatability CV was 3,5%, and the quality goal was fulfilled.

Measurements at home
The results the diabetes patients obtained at home document the diabetes patients training efforts. Repeatability was not calculated based on these results.

5.3.4. The trueness of mylife Unio

The mean deviation of mylife Unio results from the comparison method results (bias) was calculated from the results achieved by the BLSs. The results are sorted and divided into three glucose levels according to the mean results on the comparison method. The bias of mylife Unio with three lots of test strips is shown in table 10.

Table 10. Bias of mylife Unio

mylife Unio, lot number of test strips	Glucose interval Comparison method, mmol/L	n	Excluded results	Comparison method, mean glucose, mmol/L	mylife Unio mean glucose, mmol/L	Bias (95% CI), mmol/L
1133073 (lot a)	<7	29	0	5,8	5,9	+0,08 ((+0,00) — (+0,15))
	7 – 10	28	0	8,3	8,1	−0,20 ((−0,29) — (−0,12))
	>10	24	0	12,3	12,0	−0,22 ((−0,40) — (−0,05))
1133181 (lot b)	<7	29	0	5,8	6,2	+0,39 ((+0,31) — (+0,48))
	7 – 10	28	0	8,3	8,5	+0,18 ((+0,10) — (+0,25))
	>10	24	0	12,3	12,3	+0,07 ((−0,13) — (+0,27))
1133258 (lot c)	<7	29	0	5,8	6,1	+0,24 ((+0,18) — (+0,31))
	7 – 10	28	0	8,3	8,4	+0,08 ((+0,00) — (+0,15))
	>10	24	0	12,3	12,3	+0,08 ((−0,08) — (+0,25))

Discussion

Only small deviations from the comparison method were shown. Still some of the deviations were statistically significant. Assessed as a whole, the glucose measurements on mylife Unio were in agreement with the comparison method. An assessment of the three lots of test strips is given in section 5.3.6.

5.3.5. The accuracy of mylife Unio

To evaluate the accuracy of the results on mylife Unio, the agreement between mylife Unio and the comparison method is illustrated in two accuracy plots. The plots show the deviation of single measurement results on mylife Unio from the true value, and give a picture of both random and systematic errors, reflecting the total measuring error on mylife Unio. The accuracy is demonstrated for the first measurements of the paired results, only.

The accuracy of mylife Unio meter A/lot a, meter B/lot b and meter C/lot c, under standardised and optimal measuring conditions is shown in figure 3. The accuracy of mylife Unio, as measured by all the diabetes patients is shown in figure 4. The accuracy is summarised in table 11.

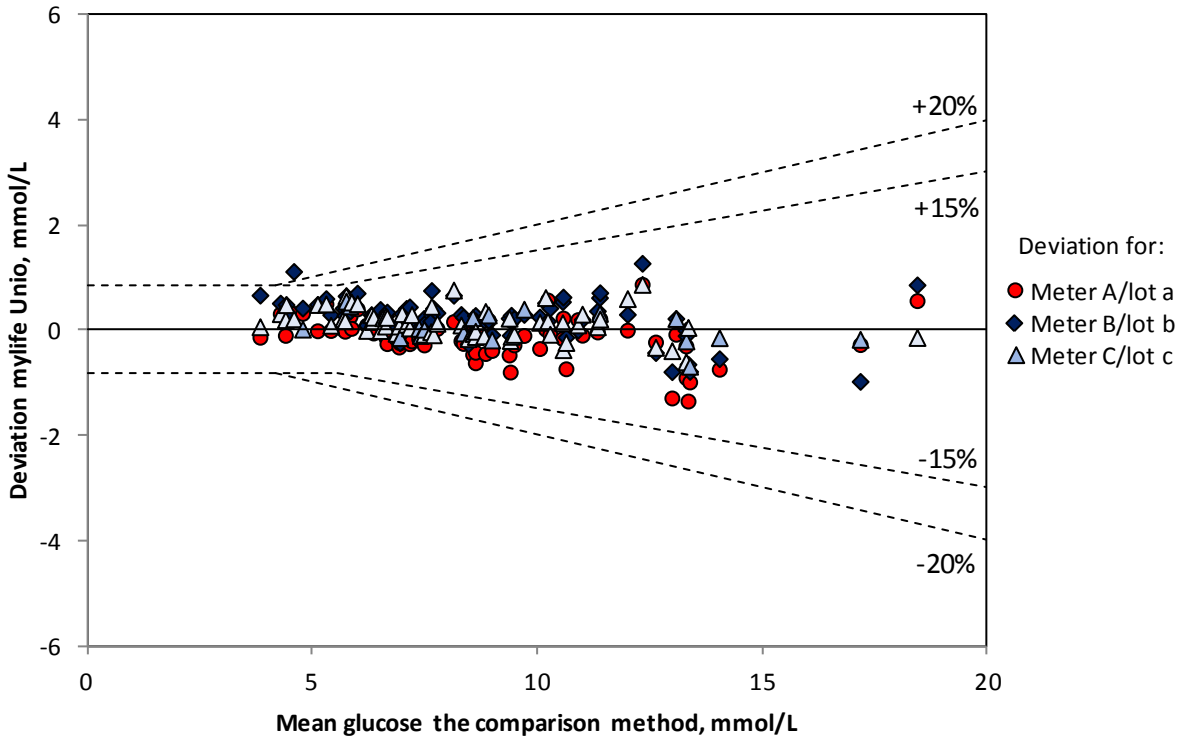

Figure 3. Accuracy. Mylife Unio meter A/lot a (marked with symbol ●), meter B/lot b (marked with symbol ♦) and meter C/lot c (marked with symbol Δ) under standardised and optimal measuring conditions. The x-axis represents the mean result on the comparison method. The y-axis shows the difference between the first measurement on mylife Unio and the mean result of the comparison method. Stippled lines represent quality goal limits set in ISO 15197:2003 (within ±0,83 mmol/L for glucose concentrations <4,2 mmol/L and within ±20% for glucose concentrations ≥4,2 mmol/L) and quality goal limits set in ISO 15197:2013 (within ±0,83 mmol/L for glucose concentrations <5,55 mmol/L and within ±15% for glucose concentrations ≥5,55 mmol/L).
Number of results (n) = 81.

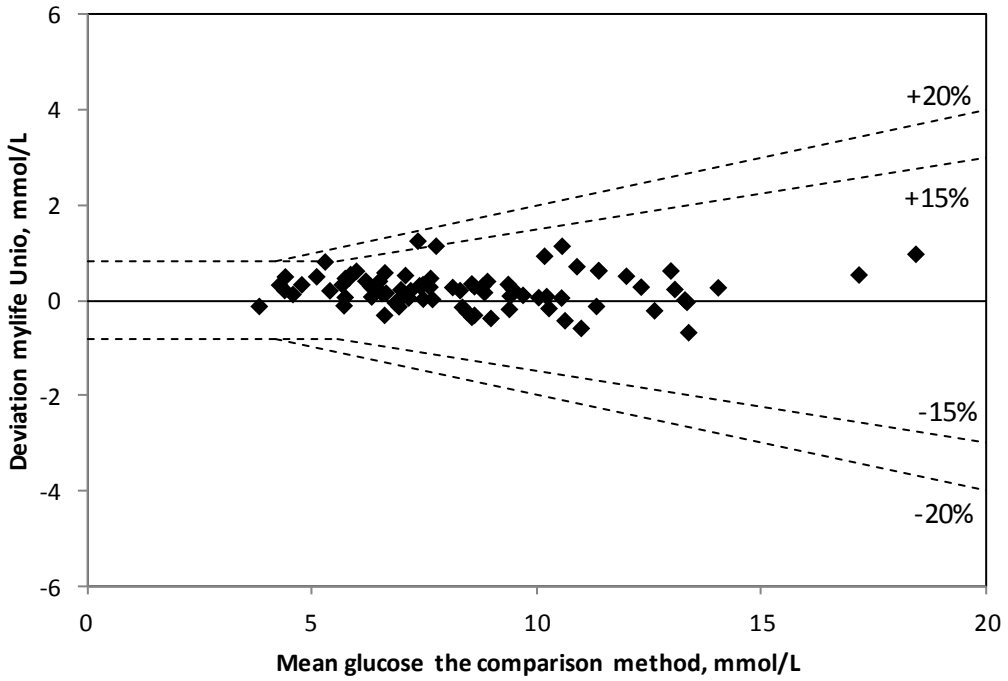

Figure 4. Accuracy. The diabetes patients' self-measurements on mylife Unio (three lots of test strips). The x-axis represents the mean result of the comparison method. The y-axis shows the difference between the first measurement on mylife Unio and the mean result of the comparison method. Stippled lines represent quality goal limits set in ISO 15197:2003 (within ±0,83 mmol/L for glucose concentrations <4,2 mmol/L and within ±20% for glucose concentrations ≥4,2 mmol/L) and quality goal limits set in ISO 15197:2013 (within ±0,83 mmol/L for glucose concentrations <5,55 mmol/L and within ±15% for glucose concentrations ≥5,55 mmol/L).
Number of results (n) = 81.

Table 11. Accuracy of mylife Unio, n = 81

Measurement performed by	Lot	n	Percentage of results within given limits, %			
			"Adjusted ISO"*	**ISO 15197:2003****	**ISO 15197:2013*****	**Fixed limit ±10%**
BLS	a	81		100	100	99
	b	81		99	99	90
	c	81		100	100	98
Diabetes patients at Noklus	a, b, c	81	100	100	99	93

*"Adjusted ISO": <±1,0 mmol/L at conc. <4,2 mmol/L or <±25% at conc. ≥4,2 mmol/L
** ISO 15197:2003: <±0,83 mmol/L at conc. <4,2 mmol/L or <±20% at conc. ≥4,2 mmol/L
*** ISO 15197:2013: <±0,83 mmol/L at conc. <5,55 mmol/L or <±15% at conc. ≥5,55 mmol/L

Discussion
Figure 3 and 4 show mylife Unio results in agreement with the comparison method. The summing up in table 11 shows that 100% of the results obtained by the BLSs 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 as well as within the accuracy quality limits specified 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. Table 11 also shows the number of results within fixed limit of ±10%. These results are for information only.

5.3.6. Bias with three lots of test strips

In figure 3 only small deviations between the three lots of test strips appear. Lot a tends to give slightly lower glucose results than the comparison method. Lot b tends to give slightly higher glucose results than the comparison method. Calculated bias for the three lots of test strips shown in table 10 indicates the same tendency.

5.4. Effect of haematocrit

According to the technical specifications, glucose measurements on mylife Unio are not influenced by haematocrit values from 10 to 70%. To measure the effect of haematocrit on mylife Unio, a venous sample for haematocrit was collected of the diabetes patients at the evaluation end-meeting. The investigation of the effect is based on the measurements on mylife Unio meter A (lot a) under standardised and optimal measuring conditions. The glucose concentration range was 3,8 – 18,4 mmol/L. The haematocrit range was 32 – 52%. The effect of haematocrit is shown with a trend-line and a regression equation in figure 5. The raw data is shown in attachment 10.

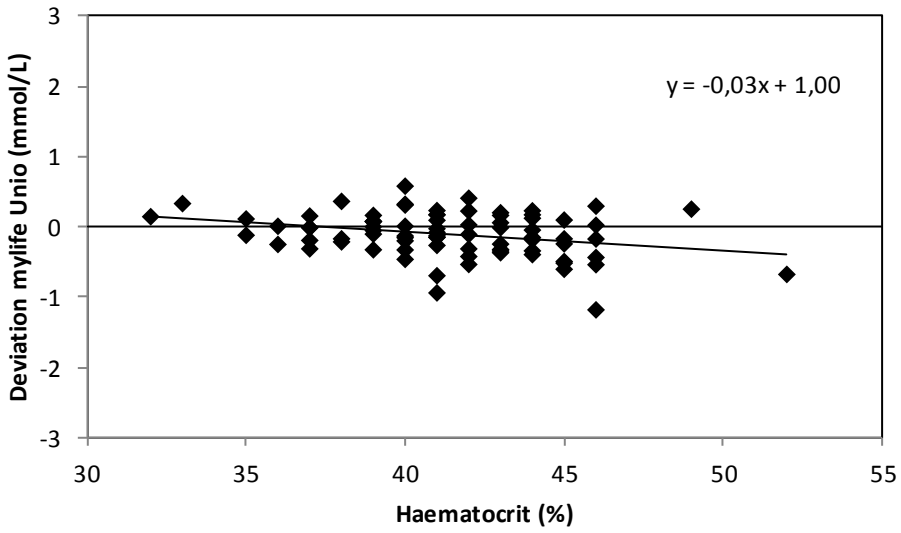

Figure 5. The effect of haematocrit on glucose measurements on mylife Unio meter A (lot a) measured under standardised and optimal conditions. The x-axis shows the haematocrit value in percent. The y-axis shows the difference in glucose concentration between mylife Unio and the mean result of the comparison method in mmol/L. Number of results (n) = 80.

Discussion

The slope of the trend-line is approximately (−0,03), with a 95% CI from (−0,046) to (−0,008). The slope is statistically significant different from zero. Glucose measurements on mylife Unio in the evaluation were slightly affected by haematocrit values within the range 32 — 52%. The glucose results fulfil the accuracy quality goal set by ISO.

5.5. Evaluation of user-friendliness

The most important response regarding user-friendliness comes from the users themselves. The end-users often emphasize other aspects than those pointed out by more extensively trained laboratory personnel.

Questionnaire

When attending the evaluation end-meeting, the diabetes patients filled in a questionnaire about the user-friendliness of the manual and the operation facilities of the meter. The BLS was available for clarifying questions, and there was free space for commenting. Each diabetes patient was first asked whether he/she had used the user manual. If the answer was no, they were to ignore the questions regarding the user manual.

The questionnaire and the expressed opinions are presented in table A and B. The first column shows what is up for consideration. The second to fifth column show the rating options as well as the number and percentage of diabetes patients who chose this alternative. The overall ratings from all the diabetes patients are marked in coloured, bold and underlined text. The last row in each table summarises the total rating in the table. The total rating is an overall assessment by SKUP of the described property, and not necessarily the arithmetic mean of the rating in the rows. Consequently, a single poor rating can justify an overall poor rating, if this property seriously influences on the user-friendliness of the system.

White areas in table A and B:	The topic is answered by the diabetes patients.
Grey areas in table A and B:	The topic is answered by SKUP. The diabetes patients were not presented for the issue.

Assessment of time factors and of quality control possibilities are shown in table C and D. These questions are answered by SKUP.

Principles of assessment in this evaluation

The assessment of user friendliness is based on the results in the tables filled in by the participants, the tables filled in by SKUP and the BLSs' evaluation. Viewpoints emphasised by approximately 1/3 of the participants or more are marked in coloured, bold and underlined text also when their assessments lead to different ratings.

Table A. Rating of the information in the manual

Information in the manual	**Rating** **Number of responses (Response in %)**			
General impression (68/71 responses)	Unsatisfactory 1 (1%)	Intermediate 9 (13%)	**Satisfactory** 58 (85%)	No opinion 0 (0%)
Description/illustration regarding specimen collection (70/71 responses)	Unsatisfactory 1 (1%)	Intermediate 7 (10%)	**Satisfactory** 62 (89%)	No opinion 0 (0%)
Description of how to perform a blood glucose measurement with the meter (70/71 responses)	Unsatisfactory 0 (0%)	Intermediate 7 (10%)	**Satisfactory** 63 (90%)	No opinion 0 (0%)
Description of how to insert a test strip* (69/71 responses)	Unsatisfactory 2 (3%)	Intermediate 16 (23%)	**Satisfactory** 51 (74%)	No opinion 0 (0%)
Description of how to change the lancet** (69/71 responses)	Unsatisfactory 0 (0%)	Intermediate 15 (22%)	**Satisfactory** 53 (77%)	No opinion 1 (1%)
Explanation of error sources (67/71 responses)	Unsatisfactory 0 (0%)	Intermediate 8 (12%)	**Satisfactory** 34 (51%)	No opinion 25 (37%)
Fault-tracing / Troubleshooting (66/71 responses)	Unsatisfactory 2 (3%)	Intermediate 8 (12%)	**Satisfactory** 30 (45%)	No opinion 26 (39%)
Readability / Clarity of presentation*** (69/71 responses)	Unsatisfactory 2 (3%)	Intermediate 14 (20%)	**Satisfactory** 53 (77%)	No opinion 0 (0%)
All in all, how satisfied are you with the user manual (67/71 responses)	Unsatisfied 0 (0%)	Intermediate 8 (12%)	**Satisfied** 57 (85%)	No opinion 2 (3%)
Table of contents	Unsatisfactory	Intermediate	**Satisfactory**	
Preparations / Pre-analytic procedures	Unsatisfactory	Intermediate	**Satisfactory**	
Measurement principle	Unsatisfactory	**Intermediate**	Satisfactory	
Keyword index	Unsatisfactory	**Intermediate**	Satisfactory	
Available in Danish, Norwegian and Swedish	Unsatisfactory	Intermediate	**Satisfactory**	
Total rating by SKUP	**Satisfactory**			

*Not good enough description in the manual, for instance how to remove the test strip (5 comments)
**The use of the lancing device is not good enough described (3 comments)
***Too small illustrations, too small letters, too many dark areas (9 comments)

Positive comments: The manual is simple and easy to follow (7 comments)

Comment
A total of 71 diabetes patients had used the user manual.

Table B. Rating of operation facilities

Operation facilities	**Rating** **Number of responses (Response in %)**			
All in all, to operate the meter (82/85 responses)	Difficult 4 (5%)	Intermediate 18 (22%)	**Easy** 60 (73%)	No opinion 0 (0%)
To perform a blood glucose measurement with the meter (84/85 responses)	Difficult 1 (1%)	Intermediate 12 (14%)	**Easy** 71 (85%)	No opinion 0 (0%)
To insert a test strip* (83/85 responses)	Difficult 10 (12%)	**Intermediate** 36 (43%)	**Easy** 37 (45%)	No opinion 0 (0%)
To fill the test strip with blood (84/85 responses)	Difficult 0 (0%)	Intermediate 15 (18%)	**Easy** 69 (82%)	No opinion 0 (0%)
To read the figures in the display** (84/85 responses)	Difficult 0 (0%)	Intermediate 3 (4%)	**Easy** 81 (96%)	No opinion 0 (0%)
To insert/change a lancet*** (74/85 responses)	Difficult 4 (5%)	Intermediate 21 (28%)	**Easy** 44 (59%)	No opinion 5 (7%)
The device, design and handling (82/85 responses)	Unsatisfactory 5 (6%)	Intermediate 17 (21%)	**Satisfactory** 60 (73%)	No opinion 0 (0%)
Sources of errors, error codes (81/85 responses)	Unsatisfactory 1 (1%)	Intermediate 10 (12%)	**Satisfactory** 48 (59%)	No opinion 22 (27%)
Cleaning / Maintenance; scale and time (83/85 responses)	Unsatisfactory 0 (0%)	Intermediate 6 (7%)	**Satisfactory** 48 (58%)	No opinion 29 (35%)
Hygiene, when using the test (83/85 responses)	Unsatisfactory 2 (2%)	Intermediate 9 (11%)	**Satisfactory** 70 (84%)	No opinion 2 (2%)
Size and weight of package (81/85 responses)	Unsatisfactory 1 (1%)	Intermediate 13 (16%)	**Satisfactory** 67 (83%)	No opinion 0 (0%)
To prepare the test/instrument (83/85 responses)	Unsatisfactory 1 (1%)	Intermediate 21 (25%)	**Satisfactory** 59 (71%)	No opinion 2 (2%)
Specimen volume**** (81/85 responses)	Unsatisfactory 4 (5%)	Intermediate 16 (20%)	**Satisfactory** 60 (74%)	No opinion 1 (1%)
Number of procedure steps (84/85 responses)	Unsatisfactory 2 (2%)	Intermediate 18 (21%)	**Satisfactory** 64 (76%)	No opinion 0 (0%)
Instrument/test design (82/85 responses)	Unsatisfactory 3 (4%)	Intermediate 7 (9%)	**Satisfactory** 71 (87%)	No opinion 1 (1%)
Storage conditions for tests, unopened package	–20°C	+2 to +8°C	**+15 to +30°C**	
Storage conditions for tests, opened package	–20°C	+2 to +8°C	**+15 to +30°C**	
Environmental aspects: waste handling	Special precautions	**Sorted waste**	No precautions	
Intended users	BLS	Laboratory experienced	**GP personnel or patients**	
Total rating by SKUP			**Satisfactory**	

* Different negative comments about the test strips (difficult to insert and remove, too big, difficult to get just one strip out of the test strip box if the box is full, single strips) (45 comments)
**Difficult to read black figures on a grey screen (2 comments)
***Different negative comments about the lancing device (difficult to use, did not work, single lancets) (15 comments)
****A large amount of blood is needed for measurements (9 comments)

Positive comments: The meter is small and light (20 comments)
The meter is easy to use (19 comments)
The lancing device is good (6 comments)
The meter etui is good, steady (5 comments)

Negative comments: The meter etui is too small (3 comments)

Table C. Rating of time factors (filled in by SKUP)

Time factors	**Rating**		
Duration of preparations / Pre-analytical time	>10 min.	6 to 10 min.	**≤6 min.**
Duration of analysis	>20 min.	10 to 20 min.	**≤10 min.**
Required training time	>8 hours	2 to 8 hours	**≤2 hours**
Stability of test, unopened package	<3 months	3 to 5 months	**>5 months**
Stability of test, opened package	<14 days	14 to 30 days	**>30 days**
Total rating by SKUP			**Satisfactory**

Table D. Rating of quality control (filled in by SKUP)

Quality Control	**Rating**		
Internal quality control	Unsatisfactory	Intermediate	**Satisfactory**
External quality control	Unsatisfactory	Intermediate	**Satisfactory**
Stability of quality control material, unopened	<3 months	3 to 5 months	**>5 months**
Stability of quality control material, opened	≤1 days	2 to 6 days	**>6 days or disposable**
Storage conditions for control material, unopened	–20°C	+2 to +8°C	**+15 to +30°C**
Storage conditions for control material, opened	–20°C	+2 to +8°C	**+15 to +30°C**
Usefulness of the Quality Control	Unsatisfactory	Intermediate	**Satisfactory**
Total rating by SKUP			**Satisfactory**

5.5.1. The biomedical laboratory scientists' evaluation

The BLSs' evaluation of mylife Unio is shown in table E.

Table E. The BLSs' evaluation of mylife Unio

	Positive comments	Negative comments
Control solution	– Stable even if it had been opened several times – Positive with controls in different concentrations levels	– Not commutable
To operate the meter	– Solid test strips – Short measuring time – Small blood volume – Nice design	– The test strip sometimes was difficult to insert and remove from the meter because of the two "sticks" in the test port – Could be difficult to get one test strip out of the test strip box when the box was full
The user manual	– Simple and easy to understand – Simple illustrations	– The illustrations would have been clearer in colours – Small letters – The names of the menus written in the text is not always similar to the names of the menus in the illustrations

5.5.2. Assessment of the user-friendliness

The overall feed-back from the participants in this evaluation was positive.

As seen in table A most of the users were satisfied with the information given in the manual.

Table B shows that the users were mostly satisfied with the operation facilities except for the insertion of test strip. Totally 45% of the participants thought it was easy to insert a test strip, 12% thought it was difficult and the opinion of the rest was "in between". Error code 5 "Code error / Check strip" occurred in approximately 3% of the efforts, and the test strip had to be reinserted.

Time factors and quality control possibilities are assessed as satisfactory (table C and D).

The BLSs found the device easy to use, but one of them commented that the test strips could be difficult to insert and remove from the meter.

Conclusion

Based on the assessments from the diabetes patients and SKUP, the user-friendliness of mylife Unio is rated as satisfactory.

6. References

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Attachments

1. The organisation of SKUP
2. Facts about mylife Unio
3. Information about manufacturer, retailers and marketing
4. Product information, mylife Unio
5. Statistical expressions and calculations
6. Raw data glucose, results from the comparison method
7. Raw data glucose, internal quality control, mylife Unio
8. Raw data glucose, mylife Unio results under standardised and optimal conditions
9. Raw data glucose, mylife Unio results from the diabetes patients' measurements at Noklus
10. Raw data haematocrit
11. "SKUP-info". Summary for primary health care (in Norwegian)
12. List of previous SKUP evaluations

Attachment 6, 8 and 9 are included only in the copy to Ypsomed.

The organisation of SKUP

Scandinavian evaluation of laboratory equipment for primary health care, *SKUP*, is a co-operative commitment of Noklus[1] in Norway, DAK-E[2] in Denmark, and Equalis[3] in Sweden. SKUP was established in 1997 at the initiative of laboratory medicine professionals in the three countries. SKUP is led by a Scandinavian *steering committee* and the secretariat is located at Noklus in Bergen, Norway.

The purpose of SKUP is to improve the quality of near patient testing in Scandinavia by providing objective and supplier-independent information on analytical quality and user-friendliness of laboratory equipment. This information is generated by organising SKUP *evaluations*.

SKUP offers manufacturers and suppliers evaluations of equipment for primary health care and also of devices for self-monitoring. Provided the equipment is not launched onto the Scandinavian market, it is possible to have a confidential pre-marketing evaluation. The company requesting the evaluation pays the actual testing costs and receives in return an impartial evaluation.

There are *general guidelines* for all SKUP evaluations and for each evaluation a specific *SKUP protocol* is worked out in co-operation with the manufacturer or their representatives. SKUP signs *contracts* with the requesting company and the evaluating laboratories. A *complete evaluation* requires one part performed by experienced laboratory personnel as well as one part performed by the intended users.

Each evaluation is presented in a *SKUP report* to which a unique *report code* is assigned. The code is composed of the acronym SKUP, the year and a serial number. A report code, followed by an asterisk (*), indicates a special evaluation, not complete according to the guidelines, e.g. the part performed by the intended users was not included in the protocol. If suppliers use the SKUP name in marketing, they have to refer to www.skup.nu and to the report code in question. For this purpose the company can use a logotype available from SKUP containing the report code.

SKUP reports are published at www.skup.nu.

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[1] Noklus (Norwegian Quality Improvement of Primary Care Laboratories) is an organisation founded by Kvalitetsforbedringsfond III (Quality Improvement Fund III), which is established by The Norwegian Medical Association and the Norwegian Government. Noklus is professionally linked to "Seksjon for Allmennmedisin" (Section for General Practice) at the University of Bergen, Norway.

[2] SKUP in Denmark is placed in Nordsjællands Hospital. SKUP in Denmark reports to DAK-E (Danish Quality Unit of General Practice), an organisation that is supported by KIF (Foundation for Quality and Informatics) and Faglig udvalg (Professional Committee), which both are supported by DR (The Danish Regions) and PLO (The Organisation of General Practitioners in Denmark).

[3] Equalis AB (External quality assurance in laboratory medicine in Sweden) is a limited company in Uppsala, Sweden, owned by "Sveriges Kommuner och Landsting" (Swedish Association of Local Authorities and Regions), "Svenska Läkaresällskapet" (Swedish Society of Medicine) and IBL (Swedish Institute of Biomedical Laboratory Science).

Facts about mylife Unio

This form is filled in by Ypsomed.

Table 1. Basic facts

Name of the measurement system:	mylife™ Unio™
Dimensions and weight:	Width: 39 mm Depth: 14 mm Height: 71 mm Weight: 50 g
Components of the measurement system:	mylife™ Unio™ meter, mylife™ Unio™ AutoLance lancing device, mylife™ Lancets, mylife™ Unio™ test strips, mylife™ Unio™ SoftCase
Measurand:	Glucose
Sample material:	Capillary, venous and arterial whole blood
Sample volume:	0,7 µL
Measuring principle:	Electrochemical. GDH-FAD
Traceability:	Plasma calibration, hexokinase method
Calibration:	Autocoding
Measuring range:	0,6 – 33,3 mmol/L
Linearity:	0,6 – 33,3 mmol/L
Measurement duration:	5 seconds
Operating conditions:	6 – 44° C and < 90 % RH (Relative Humidity)
Electrical power supply:	Two CR2032 coin cell batteries
Recommended regular maintenance:	No regular maintenance necessary when using it according to instruction for use
Package contents:	1 meter, 1 lancing device, 10 lancets, 10 test strips, 1 soft case, 1 instruction for use (4 languages), 1 handling card
Necessary equipment not included in the package:	All necessary equipment are included

Table 2. Post analytical traceability

Is input of patient identification possible?	No
Is input of operator identification possible?	No
Can the instrument be connected to a bar-code reader?	No
Can the instrument be connected to a printer?	No, but data can be printed in connection with a computer and a software

What can be printed?	Measurement values, date, time and markers
Can the instrument be connected to a PC?	Yes
Can the instrument communicate with LIS (Laboratory Information System)? If yes, is the communication bidirectional?	No
What is the storage capacity of the instrument and what is stored in the instrument?	1000 test results with date, time and markers
Is it possible to trace/search for measurement results?	Yes

Table 3. Facts about the reagent/test strips/test cassettes

Name of the reagent/test strips/test cassettes:	mylife™ Unio™ blood glucose test strips
Stability in unopened sealed vial:	24 months
Stability in opened vial:	3 months
Package contents:	2 x 25 test strips and package insert

Table 4. Quality control

Electronic self check:	Yes
Recommended control materials and volume:	mylife™ Unio™ ControlGDH control solution (normal / high)
Stability in unopened sealed vial:	24 months
Stability in opened vial:	3 months
Package contents:	mylife™ Unio™ ControlGDH control solution and package insert

Information about manufacturer, retailers and marketing

Table 1. Marketing information

Manufacturer:	BIONIME CORPORATION No. 100, Sec. 2, Daqing St., South Dist., Taichung City 40242, Taiwan (R.O.C.) Tel: +886 4 2369 2388 Fax: +886 4 2261 7586
Retailers in Scandinavia:	Denmark: Ypsomed Danmark c/o Postboks 421 Ulrikkenborg Plads 1 DK-2800 Kongens Lyngby Tel: +45 4824 0045 E-Mail: info@ypsomed.dk www.mylife-diabetescare.dk Norway: Ypsomed Papirbredden Grønland 58 NO – 3045 Drammen Phone: +47 22 20 93 00 E-Mail: info@ypsomed.no www.mylife-diabetescare.no Sweden: Ypsomed AB Adolfsbergsvägen 31 SE – 168 66 Bromma Phone: + 46 8 601 25 50 info@ypsomed.se www.mylife-diabetescare.se Finland: Ypsomed AB Eteläinen Salmitie 1 FI – 02430 Masala Puh.: +358 9 2501 350 E-Mail: info@ypsomed.fi www.mylife-diabetescare.fi
In which countries is the system marketed:	Globally ☒ Scandinavia ☐ Europe ☐
Date for start of marketing the system in Scandinavia:	February 2014
Date for CE-marking:	Oct. 31, 2012 (renewed Oct. 31, 2013)
In which Scandinavian languages is the manual available:	Norwegian/Swedish/ Danish/Finnish

Product information, mylife Unio

mylife Unio serial numbers
A total of 88 mylife Unio blood glucose meters were used in this evaluation.
Three meters (serial no. 1720LJA0940 (meter A), 1720LJA0938 (meter B) and 1720LJA0969 (meter C)) were used by the biomedical laboratory scientists under the standardised and optimal conditions.

mylife Unio test strips
Lot 1133073 Expiry 2015-02
Lot 1133181 Expiry 2015-02
Lot 1133258 Expiry 2015-03

mylife Control Solutions
mylife Control GDH Normal Lot Y700LK08B Expiry 2014-10
Target value lot 1133073: 4,9 – 6,6 mmol/L
Target value lot 1133181: 5,0 – 6,7 mmol/L
Target value lot 1133258: 5,0 – 6,7 mmol/L

mylife Control GDH High Lot Y700LH20A Expiry 2014-08
Target value lot 1133073: 13,8 – 18,7 mmol/L
Target value lot 1133181: 13,3 – 18,0 mmol/L
Target value lot 1133258: 14,2 – 19,2 mmol/L

Blood sampling device used by the biomedical laboratory scientists (single use only)
Accu-Chek Softclix Pro
Accu-Chek Softclix Pro Lancets

Blood sampling device used by the diabetes patients
The diabetes patients could choose whether to use the distributed mylife AutoLance lancing device (with mylife Pura lancets), or the lancet device they usually use.

mylife Pura lancets
Lot 01-100204 Expiry 2015-01
Lot 01-100317 Expiry 2015-02
Lot 01-121238 Expiry 2017-11

Statistical expressions and calculations

This chapter with standardised text deals with the statistical expressions and calculations used by SKUP. The chapter is a short extract of the comprehensive SKUP-document "Statistics in SKUP reports", presented at www.skup.nu**,** under the option "The SKUP evaluation". The statistical calculations will change according to the type of evaluation. The descriptions in section 4.2 are valid for evaluations of quantitative methods with results on the ratio scale.

Statistical terms and expressions

The definitions in this section come from the ISO/IEC Guide 99; International Vocabulary of Metrology, VIM [a].

Precision

Definition: Precision is the closeness of agreement between measured quantity values obtained by replicate measurements on the same or similar objects under stated specified conditions.

Precision is measured as *imprecision*. Precision is descriptive in general terms (good, poor e.g.), whereas the imprecision is expressed by means of the standard deviation (SD) or coefficient of variation (CV). SD is reported in the same unit as the analytical result. CV is usually reported in percent.

To be able to interpret an assessment of precision, the precision conditions must be defined.
Repeatability is the precision of consecutive measurements of the same component carried out under identical measuring conditions (within the measuring series).
Reproducibility is the precision of discontinuous measurements of the same component carried out under changing measuring conditions over time.

Trueness

Definition: Trueness is the closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value.

Trueness is inversely related to systematic measurement error. Trueness is measured as *bias*. Trueness is descriptive in general terms (good, poor e.g.), whereas the bias is reported in the same unit as the analytical result or in percent.

Accuracy

Definition: Accuracy is the closeness of agreement between a measured quantity value and the true quantity value of a measurand.

Accuracy is not a quantity and cannot be expressed numerically. A measurement is said to be more accurate when it offers a smaller measurement error. Accuracy can be illustrated in a difference-plot. Accuracy is descriptive in general terms (good, poor e.g.).

a. ISO/IEC Guide 99:2007, International vocabulary of metrology – Basic and general concepts and associated terms, VIM, 3rd edition, JCGM 200:2008

Statistical calculations

Statistical outliers

The criterion promoted by Burnett [b] is used for the detection of outliers. The model takes into consideration the number of observations together with the statistical significance level for the test. The significance level is set to 5%. The segregation of outliers is made with repeated truncations, and all results are checked. Where the results are classified according to different concentration levels, the outlier-testing is carried out at each level separately. Statistical outliers are excluded from the calculations.

Calculation of imprecision

The precision of the field method is assessed by use of paired measurements of genuine patient sample material. The results are divided into three concentration levels, and the estimate of imprecision is calculated for each level separately, using the following formula [c,d]:

$$SD = \sqrt{\frac{\sum d^2}{2n}}$$

d = difference between two paired measurements (formula 1)
n = number of differences

This formula is used when the standard deviation can be assumed reasonable constant across the concentration interval. If the coefficient of variation is more constant across the concentration interval, the following formula is preferred:

$$CV = \sqrt{\frac{\sum (d/m)^2}{2n}}$$

m = mean of paired measurements (formula 2)

The two formulas are based on the differences between paired measurements. The calculated standard deviation or CV is still a measure of the imprecision of single values. The imposed condition for using the formulas is that there is no systematic difference between the 1st and the 2nd measurement of the pairs. The CV is given with a 90% confidence interval.

Calculation of bias

The mean deviation (bias) at different concentration levels is calculated based on results achieved under optimal measuring conditions. A paired t-test is used with the mean values of the duplicate results on the comparison method and the mean values of the duplicate results on the field method. The mean difference is shown with a 95% confidence interval.

Assessment of accuracy

The agreement between the field method and the comparison method is illustrated in a difference-plot. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on the field method and the mean value of the duplicate results on the comparison method. The number of results within the quality goal limits is counted and assessed.

b. Burnett RW, "*Accurate Estimation of Standard Deviations for Quantitative Methods Used in Clinical Chemistry*". Clinical Chemistry 1975; **21** (13): 1935 – 1938

c. Saunders, E. Tietz textbook of clinical chemistry and molecular diagnostics. 2006. Chapter 14, Linnet, K., Boyd, J. "*Selection and analytical evaluation of methods – with statistical techniques*", ISBN 0-7216-0189-8

d. Fraser, C.G, Biological variation: *From principles to practice*. 2006. Chapter 1 "*The Nature of Biological Variation*". AACC Press. ISBN 1-890883-49-2

Raw data glucose, internal quality control, mylife Unio

mylife Control Solution	Lot-no	Expiry	Lot-no mylife Unio test strips	Target value Glucose (mmol/L)
Control GDH Normal	Y700LK08B	2014-10	1133073	4,9 – 6,6
			1133181	5,0 – 6,7
			1133258	5,0 – 6,7
Control GDH High	Y700LH20A	2014-08	1133073	13,8 – 18,7
			1133181	13,3 – 18,0
			1133258	14,2 – 19,2

mylife Control GDH Normal and mylife Control GDH High analysed on the biomedical laboratory scientists' meters A, B and C

Date	Meter	mylife Control GDH Normal Glucose (mmol/L)	mylife Control GDH High Glucose (mmol/L)
28.05.2013	A	5,7	17,4
28.05.2013	B	5,8	16,2
28.05.2013	C	5,6	17,8
29.05.2013	A	6,0	16,6
29.05.2013	B	5,8	15,9
29.05.2013	C	5,8	16,0
30.05.2013	A	5,6	15,8
30.05.2013	B	5,8	16,1
30.05.2013	C	5,6	16,6
31.05.2013	A	5,9	15,7
31.05.2013	A	5,7	16,1
31.05.2013	B	5,9	16,3
31.05.2013	B	5,9	15,9
31.05.2013	C	5,9	16,6
31.05.2013	C	5,8	17,2
05.06.2013	A	5,9	16,3
05.06.2013	B	5,8	15,7
05.06.2013	C	5,7	16,2
06.06.2013	A	5,7	16,4
06.06.2013	A	5,9	16,3
06.06.2013	B	5,7	16,7
06.06.2013	B	5,7	16,3
06.06.2013	C	5,7	16,4
06.06.2013	C	5,8	16,8
07.06.2013	A	5,9	16,5
07.06.2013	B	5,9	16,1
07.06.2013	C	5,9	15,7

Date	Meter	mylife Control GDH Normal Glucose (mmol/L)	mylife Control GDH High Glucose (mmol/L)
10.06.2013	A	5,9	15,9
10.06.2013	B	6,1	16,2
10.06.2013	C	5,7	16,2
11.06.2013	A	5,9	17,3
11.06.2013	B	5,8	16,9
11.06.2013	C	5,7	17,6
12.06.2013	A	5,8	17,4
12.06.2013	A	5,7	17,4
12.06.2013	B	5,8	16,9
12.06.2013	B	5,9	17,4
12.06.2013	C	5,7	17,8
12.06.2013	C	5,6	18,0
13.06.2013	A	5,7	16,4
13.06.2013	B	5,7	16,1
13.06.2013	C	5,7	16,6
14.06.2013	A	5,9	17,2
14.06.2013	B	6,2	16,6
14.06.2013	C	5,7	17,8
17.06.2013	A	6,1	15,8
17.06.2013	B	5,8	15,9
17.06.2013	C	5,8	16,4
18.06.2013	A	5,9	17,6
18.06.2013	B	5,8	16,3
18.06.2013	C	5,7	16,7
19.06.2013	A	6,0	17,2
19.06.2013	B	5,5	17,5
19.06.2013	C	5,9	17,6

Measurements on meter A are performed with lot 1133073.
Measurements on meter B are performed with lot 1133181.
Measurements on meter C are performed with lot 1133258.

mylife Control GDH Normal analysed on the diabetes patients' meters

ID	Lot-no mylife Unio test strips	mylife Control GDH Normal Glucose (mmol/L)
1	a	6,1
2	a	6,1
3	a	5,8
4	a	5,7
6	a	5,4
12	a	5,8
13	a	6,0
15	b	5,8
16	b	5,9
18	a	5,5
19	c	5,8
20	a	5,9
22	a	5,7
23	a	5,5
26	a	5,6
27	c	5,7
28	a	5,3
33	b	5,6
34	b	5,7
37	b	5,6
43	a	5,5
44	a	6,3
47	b	6,1
48	b	5,6
50	a	5,9
53	c	5,5
54	c	6,3
55	b	5,9
56	b	5,9
58	b	5,6
60	b	5,3
62	b	5,9
63	b	5,6
68	a	5,8
69	c	5,9
72	c	5,7
74	c	5,6
75	c	5,6
76	a	6,1
78	a	5,9
80	c	5,6
81	c	5,9
82	c	5,9
84	c	5,8
85	c	5,4

ID	Lot-no mylife Unio test strips	mylife Control GDH Normal Glucose (mmol/L)
86	c	5,7
87	c	5,9
88	a	5,7
92	b	5,5
93	a	5,7
94	c	5,7
96	b	5,7
97	b	5,8
98	b	6,0
99	b	5,6
100	b	5,8
103	b	5,9
105	b	5,9
106	b	5,8
108	b	6,1
109	c	5,8
110	c	6,0
116	c	5,6
117	a	5,7
120	c	5,7
121	c	5,8
122	c	5,6
123	c	5,9
124	c	5,8
126	c	6,0
127	c	5,9
129	c	5,9
133	a	5,6
134	a	5,7
135	c	5,8
137	a	5,7
138	b	5,9
139	b	6,2
141	a	5,9
142	a	6,0
143	a	5,5
145	b	5,7
147	b	5,8
156	b	5,9
157	b	5,8

Lot a: **1133073**
Lot b: **1133181**
Lot c: **1133258**

Raw data haematocrit

ID	Haematocrit
1	0,39
2	0,46
3	0,42
4	0,38
6	0,40
12	0,45
13	0,43
15	No result
16	0,43
18	0,41
19	0,41
20	0,42
22	0,44
23	0,52
26	0,42
27	0,46
28	0,41
33	0,32
34	0,40
37	0,41
43	0,44
44	0,46
47	0,45
48	0,43
50	0,44
53	0,36
54	0,36
55	0,45
56	0,40
58	0,41
60	0,43
62	0,40
63	0,42
68	0,38
69	0,33
72	0,44
74	0,45
75	0,40
76	0,39
78	0,41
80	0,35
81	0,45
82	0,39

ID	Haematocrit
84	0,37
85	0,37
86	0,40
87	0,37
88	0,43
92	0,39
93	0,46
94	0,49
96	0,42
97	0,41
98	0,43
99	0,37
100	0,44
103	0,39
105	No result
106	0,39
108	0,38
109	0,43
110	0,41
116	0,44
117	0,42
120	0,36
121	0,39
122	0,46
123	0,42
124	0,44
126	0,44
127	0,39
129	No result
133	0,45
134	0,40
135	0,41
137	0,35
138	0,41
139	0,41
141	0,40
142	0,39
143	0,43
145	0,37
147	0,46
156	0,40
157	0,41

SKUP-info

mylife Unio blodsukkerapparat fra Bionime Corporation
Sammendrag fra en utprøving i regi av SKUP

Konklusjon
Presisjonen og nøyaktigheten på mylife Unio var god. Variasjonen (CV) var mellom 1,9 og 3,2 % når målingene ble utført av laboratorieutdannet personale, og mellom 3,5 og 4,5 % når målingene ble utført av personer med diabetes. Resultatene fra mylife Unio samsvarte med resultatene fra en anerkjent sykehusmetode. Kvalitetsmålet fra ISO 15197:2013, som tillater avvik opp til ± 15 % fra en anerkjent metode for måling av glukose, ble oppnådd både for målinger utført av laboratorieutdannet personale og for målinger utført av deltakerne. Hematokrit, i området 32 – 52 %, påvirket glukosemålingene på mylife Unio kun i liten grad. De fleste brukerne var fornøyde med apparatet og med brukermanualen.

mylife Unio er beregnet til egenmåling av blodsukker. Systemet er produsert av Bionime Corporation, og består av mylife Unio blodsukkerapparat og mylife Unio teststrimler. Apparatet kalibreres automatisk når man setter inn en teststrimmel. Det kreves 0,7 µL blod til hver måling. Målingen tar 5 sekunder. mylife Unio kan lagre 1000 resultat.

Utprøvingen ble utført under optimale betingelser av laboratorieutdannet personale og blant 85 personer med diabetes. Alle deltakerne fikk apparat og instruksjon tilsendt pr. post. Deltakerne brukte mylife Unio hjemme i to uker og møtte deretter til et avslutningsmøte. Glukoseresultatene fra mylife Unio ble sammenlignet med resultatene fra en anerkjent sykehusmetode. Tre lot av teststrimler ble benyttet.

Resultater

Presisjonen var god. Variasjonen (CV) var mellom 1,9 og 3,2 % når målingene ble utført av laboratorieutdannet personale og mellom 3,5 og 4,5 % når målingene ble utført av deltakerne. Resultatene fra mylife Unio samsvarte med resultatene fra en anerkjent sykehusmetode. Kvalitetsmålet fra ISO 15197:2013, som tillater avvik opp til ± 15 % fra en anerkjent metode for måling av glukose, ble oppnådd både for målinger utført av laboratorieutdannet personale og for målinger utført av deltakerne. Hematokrit, i området 32 – 52 %, påvirket glukosemålingene på mylife Unio kun i liten grad.

Brukervennlighet

De fleste deltakerne syntes mylife Unio var enkel å bruke, og de var fornøyde med apparatet. Noen av deltakerne hadde problemer med å sette strimmelen på plass i strimmelporten. Dette resulterte i en feilmelding. De fleste deltakerne som hadde lest i brukermanualen, var fornøyde med denne.

Tilleggsinformasjon

Den fullstendige rapporten fra utprøvingen av mylife Unio, SKUP/2013/100, finnes på SKUPs nettside www.skup.nu. Opplysninger om pris fås ved å kontakte leverandør.
Laboratoriekonsulentene i Noklus kan gi nyttige råd om analysering av glukose på legekontor. De kan også orientere om det som finnes av alternative metoder/utstyr.

List of previous SKUP evaluations

Summaries and complete reports from the evaluations are found at www.skup.nu. In addition, SKUP reports are published at www.skup.dk, where they are rated according to the national Danish quality demands for near patient instruments used in primary health care. SKUP summaries are translated into Italian by Centre for Metrological Traceability in Laboratory Medicine (CIRME), and published at http://users.unimi.it/cirme. SKUP as an organisation has no responsibility for publications of SKUP results on these two web-sites.

The 30 latest SKUP evaluations

Evaluation no.	Component	Instrument/testkit	Producer
SKUP/2013/100	Glucose[1]	mylife Unio	Bionime Corporation
SKUP/2013/97	NT-proBNP	Cobas h 232 POC system	Roche Diagnostics GmbH
SKUP/2013/92	CRP	Eurolyser smart 700/340	Eurolyser Diagnostica GmbH
SKUP/2013/99*	Glucose	Accu-Chek Mobile	Roche Diagnostics
SKUP/2013/98*	Glucose	Accu-Chek Aviva	Roche Diagnostics
SKUP/2013/85	Glucose, β-Ketone	Nova StatStrip	Nova Biomedical Corporation, USA
SKUP/2013/96	Hemoglobin	DiaSpect Hemoglobin T	DiaSpect Medical GmbH
SKUP/2013/68	Allergens	ImmunoCap Rapid	Phadia AB Marknadsbolag Sverige
SKUP/2012/95	Glucose[1]	Mendor Discreet	Mendor Oy
SKUP/2012/94	Glucose[1]	Contour XT	Bayer Healthcare
SKUP/2012/91	HbA1c	Quo-Test A1c	Quoient Diagnostics Ltd
SKUP/2011/93*	Glucose	Accu-Chek Performa	Roche Diagnostics
SKUP/2011/90	CRP	*i*-Chroma	BodiTech Med. Inc.
SKUP/2011/84*	PT-INR	Simple Simon PT and MixxoCap	Zafena AB
SKUP/2011/86	Glucose[1]	OneTouch Verio	LifeScan, Johnson & Johnson
SKUP/2011/77	CRP	*Confidential*	
SKUP/2011/70*	CRP	smartCRP system	Eurolyser Diagnostica GmbH
SKUP/2010/83*	Glucose	*Confidential*	
SKUP/2010/78	HbA1c	In2it	Bio-Rad
SKUP/2010/80	PT (INR)	INRatio2	Alere Inc.
SKUP/2010/89*	Glucose	FreeStyle Lite	Abbott Laboratories
SKUP/2010/88*	HbA1c	*Confidential*	
SKUP/2010/82*	Glucose, protein, blood, leukocytes, nitrite	Medi-Test URYXXON Stick 10 urine test strip and URYXXON Relax urine analyser	Macherey-Nagel GmBH & Co. KG
SKUP/2010/81*	Glucose	mylife PURA	Bionime Corporation
SKUP/2010/67	Allergens	*Confidential*	
SKUP/2010/79*	Glucose, protein, blood, leukocytes, nitrite	CombiScreen 5SYS Plus urine test strip and CombiScan 100 urine analyser	Analyticon Biotechnologies AG
SKUP/2010/73	Leukocytes	HemoCue WBC	HemoCue AB
SKUP/2009/71	Glucose[1]	GlucoMen LX	A. Menarini Diagnostics
SKUP/2009/76*	HbA1c	*Confidential*	
SKUP/2009/75	Glucose	Contour	Bayer HealthCare

*A report code followed by an asterisk indicates that the evaluation is not complete according to SKUP guidelines, since the part performed by the intended users was not included in the protocol, or the evaluation is a follow-up of a previous evaluation, or the evaluation is a special request from the supplier.

[1] Including a user-evaluation among diabetes patients