mylife™ Pura™

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

Report from an evaluation
organised by

SKUP

The evaluation was ordered by Ypsomed AG, Norway

SKUP/2010/81*

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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 healthcare 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

[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 Hillerød 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).

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Attachments with raw data are included only in the copy to Ypsomed AG.

This report is written by
SKUP in Norway
May 2010

1. Summary

Background
Mylife Pura blood glucose meter and test strips are designed for glucose self-measurements performed by diabetes patients. The meter and test strips are produced by Bionime Corporation and supplied in the Nordic countries by Ypsomed AG. The mylife Pura system has not been launched onto the Scandinavian market yet. Mylife Pura is a new version of the previous system from Bionime; Bionime Rightest. SKUP organised a user evaluation of Rightest among diabetes patients in 2007. The results were good, but revealed a test strip that was calibrated to give whole blood glucose equivalent values. The required evaluation of mylife Pura was carried out in a hospital laboratory environment during February and March 2010.

The aim of the evaluation
The aim of the evaluation of mylife Pura was to

- assess the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
- assess the accuracy according to the quality goals set in ISO 15197
- discuss achieved total measurement error according to a quality goal of 10%, suggested by NOKLUS for glucose device used in primary care and nursing homes in Norway
- examine the variation between three lots of test strip

Materials and methods
Capillary samples from 82 persons with diabetes and 8 healthy individuals were collected. The sampling of the diabetes patients was carried out in a medical outpatient clinic at Haraldsplass Diaconal Hospital in Bergen. For each person two measurements on mylife Pura were performed, and a capillary sample was directly prepared for measurement with a designated comparison method. Three different lots of test strips were used.

Results

- The precision of mylife Pura was good. The repeatability CV was just above 2%. The suggested quality goal for precision was obtained.
- The glucose results on mylife Pura were systematic lower than the results from the designated comparison method. The mean deviation was -0,6 mmol/l (11%) for glucose concentrations below 7 mmol/L, -0,9 mmol/L (11%) for glucose concentrations between 7 and 10 mmol/L and -1,4 mmol/L (10%) for glucose concentrations above 10 mmol/L.
- The assessment of the accuracy confirmed the systematic deviation of the results. All results on mylife Pura were lower than the results from the comparison method. The results still fulfilled the quality goal proposed in ISO 15197.
- The total error of mylife Pura was between 13 and 15%. The suggested quality goal for use in Norwegian primary care centres and nursing homes was not obtained.
- The three lots of mylife Pura test strips gave corresponding results and lower than the results from the comparison method. The mean deviation was approximately -1,0 mmol/L for all three lots.

Conclusion
The precision of mylife Pura was good, with a repeatability CV just above 2%. The glucose results on mylife Pura were approximately 11% lower than the results from the comparison method. The suggested quality goal for use in Norwegian primary care centres and nursing homes with a total error <10% was not obtained. The results fulfilled the quality goal proposed in ISO 15197.

Comments from Ypsomed AG
A letter with comments from Ypsomed is attached to the report.

2. Analytical quality specifications

To qualify for an overall good assessment in a SKUP evaluation, the measuring system must show satisfactory analytical quality as well as satisfactory user-friendliness.

There are different criteria for setting quality specifications for analytical methods. Ideally the quality goals should be set according to the medical demands the method has to meet. For glucose it is natural that the quality specification is set according to whether the analysis is used for diagnostic purpose or for monitoring diabetes. Mylife Pura is designed for monitoring blood glucose, and it is reasonable to set the quality goals according to this.

Precision
For glucose meters designed for monitoring blood glucose one should point out the need of a method with good precision [1]. According to the American Diabetes Association (ADA) the imprecision (CV) of new glucose devices must be less than 5% [2]. Other authors also recommend an imprecision of 5% or less [3].

Accuracy
The quality goal set by ISO 15197, *In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus* [4] applies for glucose self-measurements, and has been used as quality goal for previous user evaluation among diabetes patients organised by SKUP [5,6]. The ISO-guide 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.

Total error
According to ADA the total error for meters designed for self monitoring and point of care testing of glucose should not exceed 10% in the range 1,67 – 22,2 mmol/L. The quality goal from ADA must be seen as an optimal goal for the analytical quality of these meters. In 2008 NOKLUS suggested a similar quality goal for glucose instruments for use in primary care centres and nursing homes in Norway [7].

When Ypsomed turned to SKUP for an evaluation of mylife Pura, the primary intention was to get an assessment of accuracy according to ISO 15197. In addition, they wanted to find out if mylife Pura could obtain the quality goal for the total error suggested by NOKLUS.

In this evaluation the mylife Pura results will be discussed according to the following analytical quality goals:

Precision, CV<5%
Accuracy according to ISO 15197
Total error <10%

3. Materials and methods

3.1. The mylife Pura device

Mylife Pura is a blood glucose monitoring system based on biosensor technology. The system consists of a mylife Pura meter and mylife Pura dry reagent test strips. The system is designed for capillary blood glucose testing performed by persons with diabetes. The system requires a blood volume of 1,0 µL. The result is displayed after five seconds. The measuring range is 0,6 – 33,3 mmol/L. The test strip is inserted transversely in the upper part of the instrument with a "click in" technique. The test strip has a large grip area, and can be removed without blood contact. The display is large with a bright background. Mylife Pura reports plasma glucose values. The meter is automatically coded. A three-button control system is available for the user's navigation.The memory can store 500 results. For more information about mylife Pura, see attachment 1.

Test principle of mylife Pura
The enzyme GOD oxidizes glucose to gluconic acid. Electrons from the glucose are transferred to the oxidized form of the mediator potassium ferricyanid, thereby converting the mediator to the reduced form. The mediator in turn delivers the electrons to the electrode. This step is measured as an electrical current by the meter. The current is directly proportional to the concentration of glucose in the sample.

$$Glucose + Mediator_{ox} \xrightarrow{GOD} Gluconic\ acid + Mediator_{red}$$

$$Mediator_{red} + electrical\ potecial \rightarrow Mediator_{ox} + e^{-}$$

3.1.1. Product information, mylife Pura

For information about the manufacturer of mylife Pura and suppliers in the Nordic countries, see attachment 1.

mylife Pura serial no
mylife Pura with serial number Z55IJA0042 was used throughout the evaluation.

mylife Pura test strips

Lot A, lot no 1191233	Expiry 2011-01
Lot B, lot no 1196167	Expiry 2011-05
Lot C, lot no 1194035	Expiry 2011-03

mylife Pura Control solution
The mylife Pura Control is a reddish aqueous glucose solution produced with glucose concentrations in low, normal and high range. The normal control was used in this evaluation.

Control Normal, lot no 11J20A Expiry 2011-09
Target values: Lot A: 3,9 – 5,4 mmol/L, lot B: 4,1 – 5,5 mmol/L, lot C: 4,2 – 5,5 mmol/L

3.2. The designated comparison method

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

The designated comparison method in this evaluation
In a SKUP evaluation the designated comparison method is usually a well established routine method in a hospital laboratory. The trueness of the comparison method is usually documented with reference materials and/or by comparison with external quality controls from an external quality assurance programme. A glucose comparison method should be a plasma method, hexokinase by preference.

In this evaluation, the routine method for quantitative determination of glucose in human serum and plasma (e.g. lithium heparin) on the Laboratory at Haraldsplass Diaconal Hospital (HDH) was used as the designated comparison method. The method will be called *the comparison method* in this report. The comparison method is a photometric enzymatic method, utilising hexokinase and glucose-6-phosphate dehydrogenase enzymes. The method is used on Architect *ci*8200 System from Abbott Laboratories, with reagents and calibrators from Abbott Laboratories. The measuring principle is as follows: Glucose is phosphorylated by hexokinase in the presence of ATP and magnesium ions. The glucose-6-phosphate that is formed is oxidised in the presence of glucose-6-phosphate dehydrogenase causing the reduction of NAD to NADH. The NADH produced absorbs light at 340 nm and can be detected spectrophotometrically as an increased absorbance.

Verifying of trueness
The comparison method has to show traceability equivalent to that of an internationally accepted reference solution, such as the standards supplied by the National Institute of Standards & Technology, NIST. The NIST-standard SRM 965b [8] consists of ampoules with human serum with certified concentrations of glucose (and their given uncertainties) at four levels. The uncertainty is defined as an interval estimated to have a level of confidence of at least 95%. The SRM 965b materials cover a glucose concentration range from 1,8 to 16,4 mmol/L, and were used in this evaluation to verify the trueness. In addition, freshly frozen, human serum controls, produced by SERO AS, 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; Laboratory for Analytical Chemistry, University of Gent, Belgium [9]. The controls are included in NOKLUS's External Quality Assessment program. The results are summarized in chapter 5.2.3.

Internal quality assurance of the comparison method during the evaluation period
The Autonorm Human Liquid Control Solutions at two levels from SERO AS were included in the measuring series in this evaluation. The results are shown in attachment 2.

3.2.1. Product information, the comparison method

Designated comparison method on Architect ci8200
Architect ci8200 is manufactured by Abbott Laboratories. Serial number C800890

Glucose reagent
Lot 78014HW00 Expiry 2010-04-30

Calibrator
Multiconstituent Calibrator
Lot 73223M200 Expiry 2010-06-30 Reference value, cal 1 = 5,27 mmol/L
Reference value, cal 2 = 24,03 mmol/L

Internal quality controls
Autonorm Human Liquid 1 and 2, SERO AS
Liquid 1: Value = 3,50 ±0,21 mmol/L Lot 0802102 Expiry 2010-04-30
Liquid 2: Value = 14,92 ±0,75 mmol/L Lot 0806267 Expiry 2010-08-31

External Quality controls, SERO AS
The quality control materials from SERO AS have reference values from an ID-GCMS method in the Laboratory for Analytical Chemistry, University of Gent, Belgium.
Serum TM Gluc L-1 Value = 4,78 ±0,09 mmol/L Lot 0809361 Expiry 2010-06
Serum TM Gluc L-2 Value = 11,80 ±0,16 mmol/L Lot 0809362 Expiry 2010-06

NIST standards
Standard Reference Material® 965b, National Institute of Standards & Technology
Expiry 2014-12-31
Level 1: Value = 1,836 ±0,027 mmol/L
Level 2: Value = 4,194 ±0,059 mmol/L
Level 3: Value = 6,575 ±0,094 mmol/L
Level 4: Value = 16,35 ±0,20 mmol/L

Blood sampling device
Accu-Chek Softclix Pro
Accu-Chek Softclix Pro lancets: Lot WIT 44 H 2 Expiry 2011-10

Tubes used for sampling for the designated comparison method
Microvette CB 300 LH (lithium-heparin) manufactured by Sarstedt AS
Lot 7737201 Expiry 2010-11

Centrifuge used for samples for the designated comparison method
Eppendorf MiniSpin Serial no. 0022772

3.3. Planning of the evaluation

Background for the evaluation
MyLife Pura is a blood glucose monitoring system designed for capillary blood testing performed by diabetes patients. The mylife Pura-system is produced by Bionime Corporation and supplied in Scandinavia by Ypsomed. The system has not been launched onto the Scandinavian market yet. Mylife Pura is a new version of the previous system from Bionime; Bionime Rightest. SKUP organised a user evaluation of Rightest among diabetes patients in 2007. The results were good, but revealed a test strip that was calibrated to give whole blood glucose equivalent values. For the results achieved by diabetes patients in the user evaluation of Bionime Rightest in 2007, please see attachment 3. Ypsomed needed a basic evaluation to get the accuracy of the mylife Pura test strip assessed in a hospital laboratory environment. In addition Ypsomed wanted an assessment of the analytical quality of mylife Pura according to the quality goal suggested by NOKLUS for glucose instruments used in primary care centres and nursing homes in Norway, allowing a total error of 10%.

Inquiry about an evaluation
Gjermund Hansen, Ypsomed, applied to SKUP in November 2009 for an evaluation of mylife Pura glucose meter with mylife Pura test strips. SKUP accepted to carry out this evaluation on behalf of Ypsomed.

Agreements, contract and protocol
The arrangement for an evaluation was agreed upon in December 2009. SKUP made a proposal for an evaluation protocol in December 2009. The protocol was approved in January 2010, and the evaluation contract was signed in February. The required evaluation of mylife Pura was carried out in a hospital laboratory environment during February and March 2010.

Evaluation sites and persons involved
The evaluation took place in a medical outpatient clinic at Haraldsplass Diaconal Hospital (HDH) in Bergen, Norway. Grete Monsen, SKUP/NOKLUS, was responsible for the practical work, and collected the capillary samples for the evaluation. The laboratory at HDH agreed to analyse the samples for the comparison method. The biomedical laboratory scientists Grethe Kalleklev and Kjersti Østrem were given the responsibility for the practical work in the laboratory. The statistical calculations were made by Grete Monsen, who also wrote the report.

Preparations and training program
The preparations for the evaluation started in January 2010. Gjermund Hansen visited NOKLUS to demonstrate the mylife Pura system, and brought at the same time the meters and test strips for the evaluation.

Sampling
Capillary samples from 82 persons with diabetes and 8 healthy individuals were collected. The sampling of the diabetes patients was carried out in a medical outpatient clinic at Haraldsplass Diaconal Hospital. Two measurements on mylife Pura were carried out for all the 90 persons, and a capillary sample was directly prepared for measurement with a designated comparison method. Three different lots of test strips were used.

3.4. The evaluation procedure

3.4.1. The model for the evaluation of mylife Pura

The SKUP evaluation

SKUP evaluations are based upon the fundamental guidelines in the book "*Evaluation of analytical instruments. A guide particularly designed for evaluations of instruments in primary health care*" [10].

The evaluation of mylife Pura comprises the following:

- assess the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
    - Precision
    - Accuracy according to ISO 15197
    - Total error
- examine the variation between three lots of test strips

Blood sampling

The samples for mylife Pura, as well as the samples for the comparison method, were collected from finger capillaries. The sampling sequence was started with duplicate measurements on mylife Pura, immediately followed by a sample for the comparison method. The mylife Pura meter was checked by means of the manufacturer's control solution every day it was used.

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 10.000g, and plasma was separated into sample vials. The plasma samples were frozen directly and stored at minus 80° C at NOKLUS until the analysis took place [8]. The samples were analysed on an Architect instrument in April 2010. The samples were thawed at NOKLUS just before they were analysed.

3.4.2. Number of samples

Capillary samples from 90 individuals were included in the evaluation.

The total number of samples was:

90 capillary samples x 2 (duplicate measurements on the biomedical scientist's meter)

90 capillary samples x 1 (for the comparison method), analysed in duplicate

3.4.3. Statistical outliers

Possible outliers will be commented on under each table.

4. Statistical expressions and calculations

This chapter deals with the statistical expressions and calculations used by SKUP. The statistical calculations will change according to the type of evaluation. The descriptions in section 4.2 are valid for evaluation of quantitative methods with results on the ratio scale.

4.1. Statistical terms and expressions

The definitions in this section come from the ISO/IEC Guide 99; International Vocabulary of Metrology, VIM [11].

4.1.1. 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, acceptable, 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.

4.1.2. 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 measured as *bias*. Trueness is descriptive in general terms (good, acceptable, poor e.g.), whereas the bias is reported in the same unit as the analytical result or in percent.

4.1.3. Accuracy

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

Accuracy is measured as *inaccuracy*. Accuracy is descriptive in general terms (good, acceptable, poor e.g.) and can be illustrated in a difference-plot. Inaccuracy is a combination of analytical imprecision and bias, and can be expressed as the total error of the measuring system.

4.2. Statistical calculations

4.2.1. Statistical outliers

The criterion promoted by Burnett [12] 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.

4.2.2. Calculation of imprecision

The precision of the field method is assessed by use of paired measurements of genuine patient sample material. The estimate of imprecision is calculated using the following formula [13, 14]:

$SD = \sqrt{\frac{\sum d^2}{2n}}$, d = difference between two paired measurements, n = number of differences

Even if this formula is based on the differences between paired measurements, the calculated standard deviation is a measure of the imprecision of single values. The assumption for using this formula is that no systematic difference between the 1st and the 2nd measurement is acceptable.

4.2.3. 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.

4.2.4. 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.

4.2.5. Calculation of total error

The total error is the combination of the analytical bias and imprecision according to the linear model:

Total error = $|bias| + z \cdot \sigma$

where z is the deviate according to a certain probability and σ is the imprecision. The z-value is 1,96 for a two-tailed probability of 0,05, and 1,65 for a corresponding one-tailed probability. Westgard et al [15] use 1,96 for a situation of no bias and 1,65 for the bias situation.

5. Results and discussions

5.1. Missing or excluded results

The following results are missing or excluded:

- Accuracy results for ID 70 and ID 81 are missing because of insufficient sample volume for analysing on the comparison method
- ID 35 was segregated as an outlier according to Burnett's model in the calculation of imprecision of the comparison method. This result is excluded from the calculation of imprecision on the comparison method and from the calculations where mylife Pura is compared with the comparison method
- ID 57 was segregated as an outlier according to Burnett's model in the calculation of imprecision on mylife Pura

5.2. Analytical quality of the designated 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. The control results from the evaluation period were inside the limits of the target values for the controls.
The internal quality control raw data is shown in attachment 2.

5.2.2. The precision of the comparison method

Repeatability
The best estimate of the repeatability of a method is achieved by using patient samples. By doing so, the matrix effects in artificially produced materials are avoided. The samples for the comparison method were analysed in duplicate, and the imprecision was calculated by means of the duplicate results.
The repeatability of the comparison method is shown in table 1.
The raw data is shown in attachment 4.

Table 1. Repeatability, the comparison method. Results achieved with capillary blood samples

Glucose level (mmol/L)	n*	Outliers	Mean glucose (mmol/L) the comparison method	CV% (95% confidence interval)
<7	21	0	5,8	0,9 (0,7 – 1,2)
7 – 10	24	1**	8,3	0,8 (0,6 – 1,1)
≥10	43	0	14,7	0,8 (0,6 – 1,0)

*The given numbers of results (n) are counted before exclusion of outliers. Mean and CV are calculated after exclusion of outliers.
**One outlier (ID 35) according to Burnett's model.

Discussion
The repeatability CV was just below 1,0%. The precision of the comparison method was good.

5.2.3. The trueness of the comparison method

In order to demonstrate the trueness of the comparison method, the SRM 965b standards supplied by the National Institute of Standards & Technology, NIST, were analysed. The agreement between the comparison method and the NIST-standards is shown in table 2.

Table 2. Standard Reference Material (SRM 965b) measured on the comparison method

SRM 965b	Date	Certified glucose concentration mmol/L (uncertainty)	n	Mean value glucose (mmol/L)	% deviation from target value
Level 1	26.04.10	**1,836**	5	1,83	
	27.04.10	(1,809 — 1,863)	5	1,85	
	Total		**10**	**1,84**	**0,3**
Level 2	26.04.10	**4,194**	5	4,26	
	27.04.10	(4,135 - 4,253)	5	4,27	
	Total		**10**	**4,26**	**+1,7**
Level 3	26.04.10	**6,575**	5	6,56	
	27.04.10	(6,481 — 6,669)	5	6,60	
	Total		**10**	**6,58**	**+0,1**
Level 4	26.04.10	**16,35**	5	16,71	
	27.04.10	(16,15 — 16,55)	5	16,73	
	Total		**10**	**16,72**	**+2,3**

Table 2 shows that the glucose results of the NIST-standards at level 2 and 4 on Architect ci8200 were slightly higher than the certified target values, and just outside the uncertainty limits. All results from Architect were therefore adjusted according to the certified NIST-targets. The adjustment was carried out by means of inverse calibration [16, 17] by the following regression equation: **y = 0,9745x + 0,0742**
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 comparison method, freshly frozen, human serum controls, produced by SERO AS, with glucose concentrations at two levels were analysed.
The agreement with target values from the Reference laboratory in Belgium is shown in table 3.

Table 3. Trueness of the comparison method

Control	Date	Target value glucose (mmol/L)	n	Mean glucose (mmol/L) The comparison method	% deviation from target value
TM Gluc L-1	26.04.10	4,78	5	4,75	
	27.04.10		5	4,78	
	Total		**10**	**4,76**	**-0,4**
TM Gluc L-2	26.04.10	11,80	5	11,74	
	27.04.10		5	11,87	
	Total		**10**	**11,80**	**0,0**

Discussion

The trueness of the comparison method is good.

5.3. Analytical quality of mylife Pura used in a hospital laboratory

5.3.1. Internal quality control

The mylife Pura meter was checked with the manufacturer's control solution every day it was in use. All results were within the control range given on the package insert in the test strip carton. The raw data from the measurements with the internal quality control is shown in attachment 5.

5.3.2. Comparison of the 1st and 2nd measurements

Two capillary samples were taken of each person for measurements on mylife Pura. The results are checked to meet the assumptions in 4.2.2. Table 4 shows that no systematic difference was pointed out between the paired measurements. This conclusion is also supported by observations in previous glucose evaluations carried out by SKUP.

Table 4. Comparison of the 1st and 2nd measurements on mylife Pura

Pura Glucose level (mmol/L)	n	Mean glucose 1st measurement (mmol/L)	Mean glucose 2nd measurement (mmol/L)	Mean difference 2nd – 1st measurement (mmol/L)	95% CI for the mean difference, (mmol/L)
<7	30	5,34	5,37	0,03	-0,04 - +0,10
7 – 10	30	8,36	8,39	0,03	-0,07 - +0,13
≥10	29	14,42	14,46	0,03	-0,10 - +0,16

5.3.3. The precision of mylife Pura

Repeatability under standardised and optimal measuring conditions in a hospital laboratory
The repeatability obtained with capillary blood samples is shown in table 5.
The raw data is shown in attachment 6.

Table 5. Repeatability. Results achieved with capillary blood samples measured under standardised and optimal conditions

Glucose level (mmol/L)	n*	Outliers	Mean glucose (mmol/L), Pura	CV% (95% confidence interval)
<7	30	0	5,4	2,4 (1,9 – 3,2)
7 – 10	30	0	8,4	2,2 (1,8 – 3,0)
≥10	30	1**	14,4	1,7 (1,3 – 2,3)

*The given number of results (n) is counted before exclusion of outliers. Mean and CV are calculated after exclusion of outliers.
** ID 57: Excluded as a statistical outlier. The results of the duplicate measurement were 18,6 and 16,6 mmol/L and appeared without error codes. No performance mistake was observed.

Reproducibility with Internal Quality Control Solution
The reproducibility was assessed with the mylife Pura Normal Control Solution. Artificially produced control materials have other matrix effects than whole blood, and may therefore give other results than results achieved with blood. The measurements are carried out on mylife Pura daily during the evaluation period. The reproducibility of mylife Pura is shown in table 6.

Table 6. Reproducibility. Results achieved with mylife Pura Control Normal

Pura Control N	**n***	**Outliers**	**Target value (mmol/L)**	**Mean value glucose (mmol/L)**	**CV% (95% confidence interval)**
Lot A	6	0	3,9 – 5,4	4,7	1,1 (0,7 – 2,7)
Lot B	8	0	4,1 – 5,5	4,9	2,2 (1,4 – 4,4)
Lot C	7	0	4,2 – 5,7	5,0	1,4 (0,9 – 3,0)

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

Discussion, repeatability and reproducibility
As argued for in chapter 2, the imprecision of glucose meters designed for monitoring blood glucose should be below 5%. The repeatability CV for mylife Pura shown in table 5 is just above 2%. The precision was good. The recommended quality goal for precision is obtained.
The reproducibility CV on mylife Pura was approximately 2% when measured with mylife Pura Control N (table 6).

5.3.4. The trueness of mylife Pura

The trueness of mylife Pura is calculated from the results achieved by the biomedical laboratory scientist in the hospital laboratory. The measurements on mylife Pura were performed with three lots of mylife Pura test strips.
The results are shown in table 7.

Table 7. Mean difference between mylife Pura and the comparison method

	Glucose <7 mmol/L		**Glucose 7 – 10 mmol/L**		**Glucose ≥10 mmol/L**	
	The comparison method	**Pura**	**The comparison method**	**Pura**	**The comparison method**	**Pura**
Mean glucose (mmol/L)	5,85	5,21	8,42	7,49	14,58	13,14
Mean deviation from the comparison method, mmol/L (95% CI)	-0,64 ((-0,75) — (-0,53))		-0,93 ((-1,08) — (-0,78))		-1,44 ((-1,65) — (-1,22))	
n*	23		23		41	
Outliers	0		0		0	

* The given numbers of results (n) are counted before exclusion of outliers

Discussion
The glucose results on mylife Pura were systematic lower than the results from the comparison method. The deviation was -0,6 mmol/L for glucose concentrations below 7 mmol/L, -0,9 mmol/L for glucose concentrations between 7 and 10 mmol/L and -1,4 mmol/L for glucose concentrations above 10 mmol/L.

5.3.5. The accuracy of mylife Pura

To evaluate the accuracy of the results on mylife Pura, the agreement between mylife Pura and the comparison method is illustrated in a difference-plot. The plot shows the deviation of single measurement results on mylife Pura from the true value, and gives a picture of both random and systematic deviation, reflecting the total measuring error on mylife Pura. Three different lots were used. The limits in the plot represent quality limits set in ISO 15197.
The accuracy of mylife Pura, with three lots of test strips is shown in figure 1.

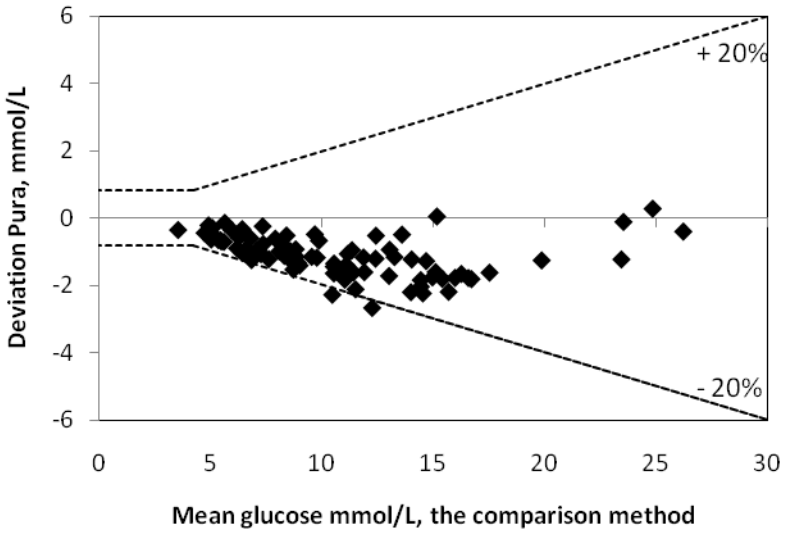

Figure 1. Accuracy. Mylife Pura with three lots of test strips under standardised and optimal measuring conditions. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on mylife Pura and the mean value of the duplicate results on the comparison method. Lines represent quality goal limits set in ISO 15197. n = 87

Discussion
Figure 1 illustrates that the glucose results on mylife Pura between 5 and 20 mmol/L were systematic lower than the results from the comparison method. Glucose results >20 mmol/L appear to agree better with the comparison method, but the low number of so high results makes a conclusion on this difficult. Two out of 87 results were outside the accuracy quality limits. The quality goal proposed in ISO 15197 was fulfilled.

5.3.6. The total error of mylife Pura

The total error of mylife Pura was calculated as described in section 4.2.5.
The total error of mylife Pura is shown in table 8.

Table 8. The total error of mylife Pura

Glucose	**<7 mmol/L**	**7 – 10 mmol/L**	**≥10 mmol/L**
CV%	2,4	2,2	1,7
Bias, mmol/L	-0,64	-0,93	-1,44
Bias, %	-10,9	-11,0	-9,8
TE (%) = |bias| + 1,65 · CV	**14,9**	**14,6**	**12,6**

Discussion
The total error of mylife Pura was between 12 and 15%, depending on the glucose concentration. Assessed as a whole, the total error was above 10%, and the suggested quality goal for use in Norwegian primary care centres and nursing homes was not obtained.

5.3.7. Variation between three lots of test strips

The measurements on mylife Pura were performed with three different lots of test strips. The three lots were not used for glucose measurement of the same diabetes patients. Obviously, the mean glucose concentration in the three groups of patients is not identical, and therefore the results achieved with the three different lots cannot be used directly as a measure of the inter-lot-variation. As an indirect measure of the lot variation, the deviation for each of the three lots from the comparison method was calculated (paired t-test). The results were sorted according to the lot of test strips. To get a sufficient number of results in each group, the deviation of each lot had to be calculated for the whole glucose concentration range together.
The results are shown in table 9.

Table 9. Variation between three lots of test strips

	The comparison method	**Pura Lot 1191233**	**The comparison method**	**Pura Lot 1196167**	**The comparison method**	**Pura Lot 1194035**
Mean glucose (mmol/L)	10,50	9,35	10,10	9,13	11,34	10,17
Mean deviation from the comparison method, mmol/L (95% CI)	-1,14 ((-1,36) — (-0,93))		-0,97 ((-1,22) — (-0,71))		-1,16 ((-1,39) — (-0,93))	
n*	29		29		29	
Outliers	0		0		0	

* The given numbers of results (n) are counted before exclusion of outliers

Discussion
The three lots of mylife Pura test strips gave significant lower results than the comparison method. The deviation was approximately -1,0 mmol/L for all three lots.

5.3.8. Effect of hematocrit

The effect of hematocrit on glucose results on mylife Pura was not checked in this evaluation. The hematocrit effect was documented for the previous system from Bionime; Bionime Rightest. The result from this test is shown in attachment 7.

5.4. Evaluation of user-friendliness

The user-friendliness of mylife Pura was not evaluated in this evaluation. The user-friendliness was documented for the previous system Bionime; Bionime Rightest. See attachment 8.

6. References

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17. Tellinghuisen, J, *Inverse vs. classical calibration for small data sets*. Fresenius J. Anal. Chem. (2000) 368:585-588.

Attachments

1. Facts about the instrument
2. Raw data glucose, internal quality control (Autonorm), the comparison method
3. Precision and accuracy of Bionime, from the evaluation of Bionime Rightest
4. Raw data glucose, results from the comparison method
5. Raw data glucose, internal quality control, mylife Pura
6. Raw data glucose, mylife Pura results under standardised and optimal conditions
7. The effect of hematocrit, from the evaluation of Bionime Rightest
8. User-friendliness, from the evaluation of Bionime Rightest
9. "SKUP-info". Summary for primary health care (in Norwegian)
10. List of evaluations organised by SKUP
11. Comments from Ypsomed AG

Attachments with raw data are included in the report to Ypsomed only.

Facts about the analyser

a) Name of the analyser	***Mylife Pura***

Physical dimensions	*90,6 mm x 46,0 mm x 16,5 mm (HxBxD)*
Manufacturer (with address)	*Bionime Corporation* *694, Renhua Road,* *Dali City,* *Taichung County, Taiwan 412*
Distributor (with address)	*Denmark:*
	Norway: *Ypsomed* *Papirbredden, Grønland 58* *3045 Drammen, Norge*
	Sweden:

b) Analysis menu, sample materials and volume of the analysis

Component	Sample materials	Volume of the analysis
Glucose	*Capillary whole blood*	*1,0 Microliter*

c) Analysis principles (reference to the instruction manual)

Parameter	Principle
Glucose	*Amperometric method, glucose is converted into electric current measured*

d) Measuring range

Component	Measuring range	Denomination
Glucose	*0,6 – 33,3*	*mmol/L*

e) Time for analysis per component (precisely stated)

Component	Pre-analysis time (with an explanation)	Analysis time
Glucose	*No pre analysis time, because system starts with insertion of strip*	*5 seconds*

f) Calibration

Is calibration possible?	*NO*
How often is calibration recommended?	..
Number of standards	..
Who should carry out calibration?	..

g) Recommended maintenance

Maintenance	How often?
Pura is maintenance-free	

h) Control materials

Is control material available (from the producer or other companies)?	***yes***

i) Marketing

In which country is the analyser marketed?	*Worldwide*
When did the analyser first appear on the Scandinavian market?	*August, 2010*
When did the analyser receive CE approval?	*2008*

j) Language

In which Scandinavian language is the manual?	*NO/SW/DK*

k) Memory

What is the storage capacity of the analyser and what is stored?	*500*
Is it possible to identify patients?	*No*
If yes, describe this:	

a) Name of the analyser	***Mylife™ Pura™***

l) Power supply

Electric network connection	*No*
Battery	*Yes*
If yes, which type and how many batteries	*2 x CR2032*

m) Electronic communication

Can a printer be connected to the analyser?	*No*
Can a barcode reader be connected to the analyser?	*No*
Interface	*USB to pc*
If yes, which port is required?	*Mini-usb*
Communication method	
Transfer mode	
Transfer protocol	*USB*

n) Standards and controls

	Standard	Control
Name		*Mylife Pura control solution*
Volume		*4 ml*
Shelf life unopened		*20 months*
Shelf life opened		*3 months*
Any comments:		*3 concentrations (low, high, normal)*

o) Reagents/Test strips/Test cassettes

Component	Shelf life unopened, storage temperature	Shelf life opened, storage temperature
mylife Pura teststrips	*Time?, 4 – 30 °C*	*3 months, 4 – 30 °C*

p) Additional information

Raw data glucose, internal quality control (Autonorm), the comparison method

Date	Res. Autonorm 1 glucose, mmol/L	Res. Autonorm 2 glucose, mmol/L
26.04.2010	3,48	14,87
26.04.2010	3,47	15,09
27.04.2010	3,51	14,89
27.04.2010	3,52	14,85

Precision and accuracy of BIONIME

The results in this attachment are from the evaluation of Bionime Rightest in SKUP 2007. The measurements are performed with test strips calibrated to give whole blood glucose values.

The precision of BIONIME

The BIONIME devices in the user evaluation were checked with the manufacturer's control solution by the biomedical laboratory scientists. All the results were inside the limits of the controls.

Repeatability obtained by the diabetes patients

The repeatability obtained by the diabetes patients with capillary blood samples is shown in table 1. The table gives the results from the measurements at the first and the second consultation for the "training group" and the results from the measurements at the consultation for the "mail group".

Table 1. BIONIME – Repeatability (with diabetic samples) measured by the "training group" and the "mail group"

BIONIME	Consultation/ diabetic group	Glucose level mmol/L	Mean value glucose mmol/L	n	Outliers	CV % (95 % CI)
At NOKLUS	1st/training group	< 7	4,7	14	0	2,8 (2,0 – 4,5)
	2nd/training group	< 7	6,3	9	0	2,8 (1,9 – 5,4)
	The mail group	< 7	5,5	11	0	3,6 (2,5 – 6,4)
At NOKLUS	1st/training group	7 – 10	8,7	11	0	3,1 (2,2 – 5,5)
	2nd/training group*	7 – 10	8,8	9	0	5,5 (3,7 – 10,5)
	The mail group	7 – 10	8,1	13	0	4,3 (3,1 – 7,1)
At NOKLUS	1st/training group	> 10	12,4	11	0	6,3 (4,4 – 11,0)
	2nd/training group	> 10	13,1	17	0	5,4 (4,0 – 8,2)
	The mail group	> 10	13,1	14	1**	6,5 (4,7 – 10,5)

* ID no. 140 had only one measurement on the assigned meter at the final consultation and is not included in the calculation

** ID no. 213 is a statistical outlier (according to Burnett)

Discussion

The repeatability obtained at NOKLUS when the measurements were performed by the diabetes patients, was acceptable with a CV between 3 % and 6 %. The CVs for the diabetes patients with and without training (the "training group" and the "mail group") were not significantly different. The CVs for the diabetes patients with and without practise at home (1st and 2nd training) were not significantly different either. This indicates that BIONIME is a robust system, easy to use, and that training is not essential for a good result.

The accuracy of BIONIME
To evaluate the accuracy of the results on BIONIME, the agreement between BIONIME and the comparison method is illustrated in two difference plots. The plots show the deviation of single measurement results on BIONIME from the true value, and give a picture of both random and systematic deviation and reflect the total measuring error on BIONIME. The total error is demonstrated for the first measurements of the paired results, only. On meter A one lot of test strips was used. On meter B three different lots were used. The same three lots were randomly distributed between the diabetes patients.

The limits in the plots are based upon quality goals derived from ISO 15197, *In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.* The ISO-guide is an international protocol for evaluating meters designed for glucose monitoring.

ISO 15197 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 is a quality goal for measurements made by trained laboratory staff. Ideally, the same quality requirements should apply to measurements performed by the diabetes patients. Previous investigations under the direction of the NOKLUS-project "Diabetes-Self-measurements" in 1997 showed that few of the self-monitoring glucose meters tested at the time met the ISO-requirements. Subsequent SKUP-evaluations confirmed these findings. As a consequence, the results achieved by the diabetes patients have been discussed towards a *modified* goal suggested by NOKLUS, with a total error of ± 25 %. This modified goal has wide, and not ideal, limits. The intention was to tighten up the modified requirements for the diabetes patients over time, as the meters would hopefully improve due to technological development. More recent evaluations performed by SKUP clearly show that the quality goals set by ISO 15197 now can be achieved also by the diabetes patients. But for the time being, the quality demands adjusted to the diabetes patients' self-measurements, still apply.

Quality demands, adjusted to the diabetes patients self-measurements:
Ninety-five percent (95 %) of the individual glucose results shall fall within ± 1,0 mmol/L of the results of the comparison method at glucose concentrations < 4,2 mmol/L and within ± 25 % at glucose concentrations ≥ 4,2 mmol/L.

Under standardised and optimal measuring conditions the ISO-goal at ±20 % is used. For the diabetes patients' self-measurements the "adjusted ISO-goal" at ±25 % is used.

The accuracy of BIONIME under standardised and optimal measuring conditions at the final consultation is shown in figure 1.

The accuracy of BIONIME achieved by the diabetes patients at the final consultation is shown in figure 2.

The accuracy is summarised in table 2 and discussed afterwards.

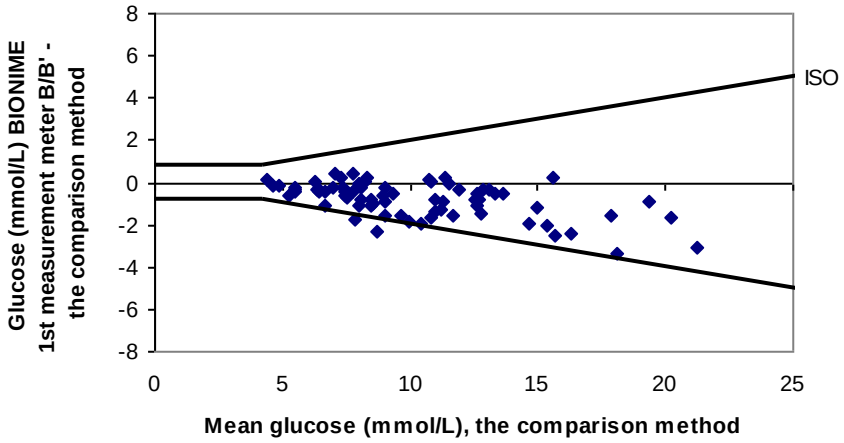

Figure 1. Accuracy. BIONIME (three lots of test strips) under standardised and optimal measuring conditions at the final consultation. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on BIONIME and the mean value of the duplicate results on the comparison method, n = 73

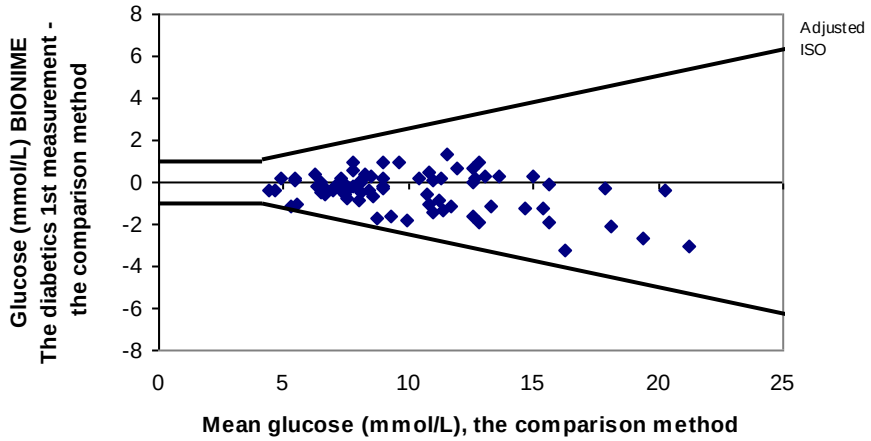

Figure 2. Accuracy. The diabetes patients' self-measurements at the final consultation. Three lots of test strips. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on BIONIME and the mean value of the duplicate results on the comparison method, n = 73

Table 2. Total error of BIONIME. Percentage BIONIME results within the limits

Measurements performed by	Consultation	Meter	n	Percentage of results		Shown in figure
				< ISO within ±20 % and within ±0,83 mmol/L at concentrations < 4,2 mmol/L	**< "adjusted ISO"** within ±25 % and within ±1,0 mmol/L at concentrations < 4,2 mmol/L	
Biomedical laboratory scientists	1st	A 1st measurement	36	97		
		B 1st measurement	36	94		
Biomedical laboratory scientists	2nd*	A 1st measurement	73	93		
		B 1st measurement	73	97		1
Diab. patients at NOKLUS	1st	1st measurement	36	94	97	
	2nd *	1st measurement	73	99	100	2

* ID no. 3 and 104 had a difference > 10 % between the paired results on the comparison method at the final consultations and are excluded from the calculations of accuracy

Discussion

Figure 1 shows that the results obtained under standardised and optimal measuring conditions for three lot of test strips (lot 1169062, 1169122 and 1169043) on BIONIME are systematic lower than the comparison method. Two results fall outside the lower ISO-limit. The summing up in table 2 shows that 94 % of the measurements at the first consultation are within the ISO-limits. At the final consultations the results fulfil the quality goal set in ISO 15197.

Figure 2 shows that the diabetes patients' measurements with three lots of test strips at the final consultation fulfil the "adjusted ISO-goal". The summing up in table 2 shows that these measurements also fulfil the quality goal set in ISO 15197. It seems as if the diabetes patients perform "better" than the biomedical laboratory scientists, but this must be explained by other factors than the measuring skills (for instance effect of ambient temperature).

Assessment of accuracy

The glucose results on BIONIME are systematic lower than the comparison method. If the results achieved under optimal measuring conditions on meter A and meter B at the first consultation are combined and assessed as a whole, the quality goal set in ISO 15197 is fulfilled. This also applies for the results achieved under optimal measuring conditions at the second consultation. The adjusted quality goal based on ISO 15197 is achieved when BIONIME is handled by the diabetes patients. These results are achieved with test strips calibrated to give whole blood glucose values. If converted theoretically to plasma values according to a factor of 1,11 (IFCC recommendation), or according to an equation recommended by the producer, all the results would be within the quality goal. The plasma calibrated test strips were not tested in this evaluation.

Attachment 5

Raw data glucose, internal quality control, mylife Pura

	mylife Pura Control Normal
Lot-no / Exp	11J20A / 2011-09
Glucose level:	
Lot A (1191233)	3,9 – 5,4 mmol/L
Lot B (1196167)	4,1 – 5,5 mmol/L
Lot C (1194035)	4,2 – 5,5 mmol/L

mylife Pura Control Normal, analysed on the biomedical laboratory scientist's meter

Date	**Lot 1191233, glucose mmol/L**	**Lot 1196167, glucose mmol/L**	**Lot 1194035, glucose mmol/L**
10.02.2010	4,7		
11.02.2010	4,7		
12.02.2010	4,7		
16.02.2010	4,7		
18.02.2010		5,0	
23.02.2010		5,0	
24.02.2010		4,9	
25.02.2010		4,8	
26.02.2010		4,8	5,0
02.03.2010			5,0
03.03.2010			5,1
04.03.2010			4,9
05.03.2010			5,0
09.03.2010			5,1
11.03.2010	4,8		5,0
16.03.2010	4,8	4,9	
19.03.2010		4,8	
23.03.2010		4,7	

Effect of hematocrit (from the evaluation of Bionime Rightest in SKUP 2007)

The product insert of BIONIME Rightest test strips states that hematocrit-values below 30 % may cause higher glucose results and hematocrit-values above 55 % may lower the glucose results. To measure the effect of hematocrit on BIONIME, a hematocrit sample was taken of the diabetes patients at the final consultation. For three of the diabetes patients there is no hematocrit result.

The investigation of the effect of hematocrit is based on the measurements on BIONIME under standardised and optimal measuring conditions. The glucose concentration range in the samples was 4,4 – 21,3 mmol/L. The hematocrit range was 34 – 50 %.

The effect of hematocrit is shown in figure 1. The x-axis in the plot shows the hematocrit value in percentage and the y-axis shows the difference in glucose concentration between BIONIME and the comparison method (BIONIME – the comparison method). Figure 1 shows the difference in mmol/L. The trend-line is shown in the figure.

The raw data is shown at the end of this attachment.

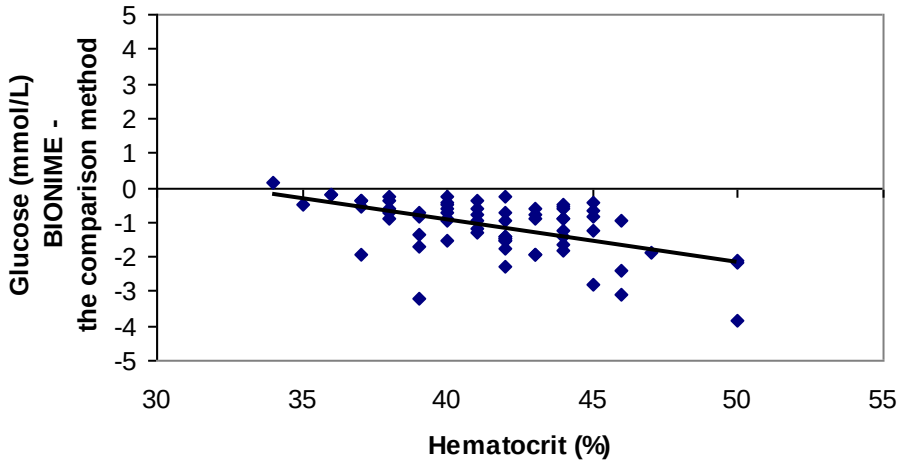

Figure 1. The effect of hematocrit at glucose measurements on BIONIME, measured under standardised and optimal conditions. The x-axis shows the hematocrit value in %. The y-axis shows the difference in glucose concentration between BIONIME and the comparison method (BIONIME – the comparison method) in mmol/L, n = 70.

Discussion

Figure 1 clearly demonstrates that the glucose results on BIONIME are systematic lower than the comparison method. The glucose measurements on BIONIME also seem to be affected by the hematocrit values of the samples. The trend-line in figure 1 shows that the glucose measurements on BIONIME are underestimated when the hematocrit is high.

Raw data hematocrit, from the evaluation of Bionime Rightest in SKUP 2007

ID	Hematocrit
3	0,41
5	0,50
6	
8	0,47
11	0,40
12	0,38
17	0,37
19	0,42
21	0,38
28	0,40
29	0,39
30	0,39
33	0,42
36	0,45
38	0,39
40	0,40
55	0,34
63	0,38
67	0,42
73	0,42
77	0,41
80	0,41
87	0,39
93	0,45
99	0,46
101	0,42
103	0,41
104	0,43
112	0,44
117	
120	0,46
129	0,44
130	0,41
133	0,42
136	0,43
140	
202	0,35
203	0,44
204	0,44
205	0,45
207	0,50

ID	Hematocrit
208	0,50
209	0,40
210	0,42
211	0,43
213	0,37
214	0,37
215	0,40
216	0,43
220	0,41
223	0,44
224	0,36
226	0,38
227	0,40
233	0,40
235	0,38
236	0,45
238	0,39
239	0,45
240	0,36
241	0,44
242	0,38
246	0,42
248	0,41
250	0,44
251	0,42
252	0,42
254	0,43
255	0,43
257	0,46
261	0,40
262	0,37
263	0,44
266	0,44
268	0,42

User-friendliness (from the evaluation of Bionime Rightest in SKUP 2007)

Questionnaires

Each diabetic filled in a questionnaire about the user-friendliness of BIONIME when they attended the final consultation (n = 74). The biomedical laboratory scientist was available for clarifying questions, and there was room for free comments.

The questionnaire about the user-friendliness (in Norwegian) is attached at the end of this attachment.

Evaluation of the user-friendliness of BIONIME Rightest

The questionnaire about the user-friendliness was made up of eleven questions concerning BIONIME. Table 1 summarizes eight questions where the diabetes patients were asked to rank the answers on a scale from 1 to 6, where 1 is difficult and 6 is simple. The mean score is between 5,5 and 5,8 on the questions about inserting a test strip into the meter, filling the strip with blood and removing the test strip. This indicates that the diabetes patients seemed satisfied with the use of the test strip. The diabetes patients also seemed satisfied with the meter. The mean score is between 5,2 and 6,0 on the questions about inserting the Code key, reading the figures in the display, recognizing the meters' sound signal and operating the meter, all in all. The Xinda lancet device gets a mean score of 5,0, which indicates that the diabetes patients were satisfied with the lancet pen too.

Table 1. BIONIME - Questions about the meter

Questions about BIONIME		Mean	Range	Not answered (% of total)	Total number
How will you rank the following questions on a scale from 1 to 6, where 1 is difficult and 6 is simple:	To insert the Code Key	5,7	3 - 6	3	74
	To insert a strip into the meter	5,6	3 - 6	0	74
	To fill the strip with blood	5,5	2 - 6	0	74
	To remove the strip from the meter	5,8	2 - 6	0	74
	To read the figures in the display	6,0	5 - 6	1	74
	To recognize the meters' sound signal	5,4	1 - 6	0	74
	All in all, to operate the meter	5,2	1 - 6	3	74
	To operate Xinda lancet device	5,0	2 - 6	10	74

The diabetes patients were asked if they had any positive and/or negative comments about BIONIME

Positive comments
58 diabetes patients reported one or more advantages with BIONIME. The most often reported advantages are distinctly grouped as follows:

1. The meter has short measuring time (25)
2. To read the figures in the display/good display with large digits (20)
3. Easy to use (13)
4. The test strip is robust and easy to handle (11)
5. The size of the meter (8)

Negative comments
43 diabetes patients reported one or more disadvantages with BIONIME. The most often reported disadvantages are distinctly grouped as follows:

1. Different comments about the test strips (for instance the test strip is too large, it is difficult to insert and remove the strip, the test strips has to be used singly) (18)
2. The meter turned on by accident or did not turn off automatically (10)
3. Not satisfied with the size of the meter, it is to large (11)

Table 2 shows the answers to the last question about BIONIME. 6,8 % of the diabetes patients answered that they had technical problems with the meter during the testing period. Two of the written comments indicate that meter did not turn off automatically and two comments indicated that the meter turned on by accident. One of the comments was not a technical one, but was an ordinary error-symbol.

Table 2. BIONIME – Questions about the meter.

Question about BIONIME	Yes	No	Not answered (%)	Total number
Did you have any technical problems with the meter during the testing period?	5	68	1	74

The biomedical laboratory scientists' evaluation
The biomedical laboratory scientists thought BIONIME was easy to use. Their positive comments were that the meter has a short measuring time and needs a small blood sample volume. It is easy to handle the test strips. The meters functioned without any technical problems during the evaluation period. It was pointed out that it was an advantage that you could check if the test strip was filled with enough blood.

BIONIME Rightest
Spørreskjema om blodsukkerapparatets brukervennlighet

Hvordan vil du rangere følgende på en skala fra 1 til 6, der 1 er *vanskelig* og 6 er *enkelt*:

1. Å sette i kodenøkkelen

Vanskelig *Enkelt*

1 **2** **3** **4** **5** **6**

☐ ☐ ☐ ☐ ☐ ☐

2. Å sette i en teststrimmel

Vanskelig *Enkelt*

1 **2** **3** **4** **5** **6**

☐ ☐ ☐ ☐ ☐ ☐

3. Å fylle strimmelen med blod

Vanskelig *Enkelt*

1 **2** **3** **4** **5** **6**

☐ ☐ ☐ ☐ ☐ ☐

4. Å fjerne strimmelen fra apparatet

Vanskelig *Enkelt*

1 **2** **3** **4** **5** **6**

☐ ☐ ☐ ☐ ☐ ☐

5. Å lese tallene i displayet

Vanskelig *Enkelt*

1 **2** **3** **4** **5** **6**

☐ ☐ ☐ ☐ ☐ ☐

6. Å oppfatte lydsignalet

Vanskelig *Enkelt*

1 **2** **3** **4** **5** **6**

☐ ☐ ☐ ☐ ☐ ☐

7. Å betjene apparatet, totalt sett

Vanskelig *Enkelt*

1 **2** **3** **4** **5** **6**

☐ ☐ ☐ ☐ ☐ ☐

8. Å betjene XINDA prøvetakingspenn (skal kun besvares hvis XINDA prøvetakingspenn er benyttet i utprøvingen)

Vanskelig *Enkelt*

1 **2** **3** **4** **5** **6**

☐ ☐ ☐ ☐ ☐ ☐

9. Var det tekniske problemer med apparatet i utprøvingsperioden? ☐ **Ja** ☐ **Nei**

Hvis ja, kan du beskrive problemet/ene:_____

_____

10. Synes du det er noen fordeler ved BIONIME?

- _____
- _____
- _____

11. Synes du det er noen ulemper ved BIONIME?

- _____
- _____
- _____

Evt. andre kommentarer:_____

_____

_____

SKUP-info

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

SKUP
www.skup.nu
SKUP/2010/81*

Konklusjon
Presisjonen på mylife Pura var god med en CV på ca. 2 %. Målingene oppfylte internasjonale kvalitetskrav (ISO 15197) med et avvik på mindre enn ± 20 % fra en anerkjent glukosemetode, til tross for at det ble påvist et systematisk avvik på ca. 11 % mellom mylife Pura og sammenligningsmetoden. Effekt av hematokrit og brukervennlighet ble vurdert i 2007 på forløperen til mylife Pura; Bionime Rightest. Deltakerne ved utprøvingen av Bionime Rightest, fant målesystemet enkelt å bruke, og de var fornøyd med apparatet. Hematokrit så ut til å påvirke målingene på Bionime Rightest.

mylife Pura er beregnet til egenmåling av glukose. Mylife Pura er en ny versjon av Bionimes tidligere produkt Bionime Rightest, som ble evaluert av SKUP i 2007. Målesystemet består av apparatet mylife Pura og mylife Pura blodsukkerteststrimler. Apparatet har automatisk koding. Det kreves 1,0 µL blod til hver måling. Målingen tar fem sekunder. mylife Pura har minnekapasitet til å lagre 500 målinger. Resultatene kan overføres til PC ved bruk av programvare fra produsenten.

Utprøvingen ble utført under optimale betingelser av laboratorieutdannet personale.
I utprøvingen ble det tatt prøver av 82 personer med diabetes samt av åtte friske personer.

Resultater
Presisjonen på mylife Pura var god med en CV på ca. 2 %. Glukoseresultatene på mylife Pura var systematisk ca. 11 % lavere enn resultatene på sammenligningsmetoden. Vurdering av nøyaktighet bekreftet det systematiske avviket mellom mylife Pura og sammenligningsmetoden. Den totale målefeil var likevel innenfor kvalitetsmålet (ISO 15197), som tillater avvik opp til ± 20 % fra en anerkjent metode for måling av glukose. Hematokrit så ut til å påvirke målingene på Bionime Rightest (evaluert av SKUP i 2007).

Brukervennlighet
Brukerne som deltok i utprøvingen av Bionime Rightest i 2007 syntes at systemet var enkelt å bruke, og de var fornøyde med apparatet. De av brukerne som hadde lest i brukermanualen, var fornøyde med denne.

Tilleggsinformasjon
Den fullstendige rapporten fra utprøvingen av mylife Pura, SKUP/2010/81*, finnes på SKUPs nettside, www.skup.nu. Et brev med kommentarer fra forhandler finnes som vedlegg til rapporten. Opplysninger om pris fås ved å kontakte leverandøren Ypsomed AG. 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

SKUP evaluations from number 51 and further

Evaluation no.	Component	Instrument/testkit	Producer
SKUP/2010/81*	Glucose	Mylife Pura	Bionime Corporation
SKUP/2010/79*	Glucose, protein, blood, leukocytes, nitrite	CombiScreen 5SYS Plus urine test strip and CombiScan 100 urine analyser	Analyticon Biotechnologies AG
SKUP/2009/75	Glucose	Contour	Bayer HealthCare
SKUP/2009/74	Glucose[1]	Accu-Chec Mobile	Roche Diagnostics
SKUP/2010/73	Leukocytes	HemoCue WBC	HemoCue AB
SKUP/2008/72	Glucose[1]	*Confidential*	
SKUP/2009/71	Glucose[1]	GlucoMen LX	A. Menarini Diagnostics
SKUP/2008/69*	Strep A	Diaquick Strep A test	Dialab GmbH
SKUP/2008/66	Glucose[1]	DANA DiabeCare IISG	SOOIL Developement co. Ltd
SKUP/2008/65	HbA1c	Afinion HbA1c	Axis-Shield PoC AS
SKUP/2007/64	Glucose[1]	FreeStyle Lite	Abbott Laboratories
SKUP/2007/63	Glucose[1]	*Confidential*	
SKUP/2007/62*	Strep A	QuikRead	Orion Diagnostica Oy
SKUP/2008/61	CRP	i-CHROMA	BodiTech Med. Inc.
SKUP/2007/60	Glucose[1]	*Confidential*	
SKUP/2007/59	Glucose[1]	Ascensia BREEZE2	Bayer HealthCare
SKUP/2006/58	HbA1c	*Confidential*	
SKUP/2007/57*	PT (INR)	Simple Simon PT	Zafena AB
SKUP/2007/56*	PT (INR)	*Confidential*	
SKUP/2007/55	PT (INR)	CoaguChek XS	Roche Diagnostics
SKUP/2007/54*	Mononucleosis	*Confidential*	
SKUP/2006/53*	Strep A	*Confidential*	
SKUP/2005/52*	Strep A	Clearview Exact Strep A Dipstick	Applied Biotech, Inc.
SKUP/2005/51*	Glucose[1]	FreeStyle	Abbott Laboratories

*A report code followed by an asterisk, indicates that the evaluation for instance is a pre-marketing evaluation, and thereby confidential. A pre-marketing evaluation can result in a decision by the supplier not to launch the instrument onto the Scandinavian marked. If so, the evaluation remains confidential. The asterisk can also mark evaluations at special request from the supplier or evaluations that are not complete according to SKUP guidelines, e.g. the part performed by the intended users was not included in the protocol.

[1] Including a user-evaluation among diabetes patients

Grey area – The instrument is not in the Scandinavian market any more

SKUP evaluations from number 1 — 50

Evaluation no.	Component	Instrument/test kit	Producer
SKUP/2006/50	Glucose[1]	Glucocard X-Meter	Arkray, Inc.
SKUP/2006/49	Glucose[1]	Precision Xtra Plus	Abbott Laboratories
SKUP/2006/48	Glucose[1]	Accu-Chek Sensor	Roche Diagnostic
SKUP/2006/47	Haematology	Chempaq XBC	Chempaq
SKUP/2005/46*	PT (INR)	*Confidential*	
SKUP/2006/45	Glucose[1]	HemoCue Monitor	HemoCue AB
SKUP/2005/44	Glucose[1]	Accu-Chek Aviva	Roche Diagnostics
SKUP/2005/43	Glucose[1]	Accu-Chek Compact Plus	Roche Diagnostics
SKUP/2005/42*	Strep A	Twister Quick-Check Strep A	ACON laboratories, Inc.
SKUP/2006/41*	HbA1c	*Confidential*	
SKUP/2005/40	Glucose[1]	OneTouch GlucoTouch	LifeScan, Johnson & Johnson
SKUP/2005/39	Glucose[1]	OneTouch Ultra	LifeScan, Johnson & Johnson
SKUP/2004/38*	Glucose	GlucoSure Plus	Apex Biotechnology Corp.
SKUP/2004/37*	u-hCG	Quick response u-hCG	Wondsfo Biotech
SKUP/2004/36*	Strep A	Dtec Strep A testcard	UltiMed
SKUP/2004/35*	u-hCG	RapidVue u-hCG	Quidel Corporation
SKUP/2004/34*	u-hCG	QuickVue u-hCG	Quidel Corporation
SKUP/2004/33	PT (INR)	Hemochron Jr. Signature	ITC International Technidyne Corp
SKUP/2004/32*	Strep A	QuickVue In-Line Strep A test	Quidel Corporation
SKUP/2004/31*	PT (INR)	*Confidential*	
SKUP/2004/30	Glucose[1]	Ascensia Contour	Bayer Healthcare
SKUP/2004/29	Haemoglobin	Hemo_Control	EKF-diagnostic
SKUP/2003/28*	Strep A	QuickVue In-Line Strep A test	Quidel Corporation
SKUP/2003/27*	Strep A	QuickVue Dipstick Strep A test	Quidel Corporation
SKUP/2003/26*	HbA1c	*Confidential*	
SKUP/2003/25*	HbA1c	*Confidential*	
SKUP/2003/24*	Strep A	OSOM Strep A test	GenZyme, General Diag.
SKUP/2002/23*	Haematology with CRP	ABX Micros CRP	ABX Diagnostics
SKUP/2002/22	Glucose[1]	GlucoMen Glycó	Menarini Diagnostics
SKUP/2002/21	Glucose[1]	FreeStyle	TheraSense Inc.
SKUP/2002/20	Glucose	HemoCue 201	HemoCue AB
SKUP/2002/19*	PT(INR)	Reagents and calibrators	
SKUP/2002/18	Urine–Albumin	HemoCue	HemoCue AB
SKUP/2001/17	Haemoglobin	Biotest Hb	Biotest Medizin-technik GmbH
SKUP/2001/16*	Urine test strip	Aution Sticks and PocketChem UA	Arkray Factory Inc.
SKUP/2001/15*	Glucose	GlucoSure	Apex Biotechnology Corp.
SKUP/2001/14	Glucose	Precision Xtra	Medisense
SKUP/2001/13	SR	Microsed SR-system	ELECTA-LAB
SKUP/2001/12	CRP	QuikRead CRP	Orion
SKUP/2000/11	PT(INR)	ProTime	ITC International Technidyne Corp
SKUP/2000/10	PT(INR)	AvoSure PT	Avocet Medical Inc.
SKUP/2000/9	PT(INR)	Rapidpoint Coag	
SKUP/2000/8*	PT(INR)	Thrombotest/Thrombotrack	Axis-Shield
SKUP/2000/7	PT(INR)	CoaguChek S	Roche Diagnostics
SKUP/2000/6	Haematology	Sysmex KX-21	Sysmex Medical Electronics Co
SKUP/2000/5	Glucose	Accu-Chek Plus	Roche Diagnostics
SKUP/1999/4	HbA1c	DCA 2000	Bayer
SKUP/1999/3	HbA1c	NycoCard HbA1c	Axis-Shield PoC AS
SKUP/1999/2*	Glucose	Precision QID/Precision Plus Electrode, whole blood calibration	Medisense
SKUP/1999/1	Glucose	Precision G/Precision Plus Electrode, plasma calibration	Medisense

For comments regarding the evaluations, please see the indications on the first page

YPSOMED
SELFCARE SOLUTIONS

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3045 Drammen
Tel: +47 483 000 05

SKUP
NOKLUS
Boks 6165
NO-5892 Bergen

Re: Report from evaluation of mylife Pura Blood Glucose Strips

Dear Grete Monsen,

We thank you for performing the evaluation test of Pura. We are very satisfied to note that the tests confirm that PURA is indeed a very precise blood glucose meter; 2,2 %, well within the goals proposed by SKUP. This is also in line with other studies that have been performed by us.
As to a certain bias in accuracy, Ypsomed believes this to be caused by variances in reference methods. Ypsomed will perform additional tests to verify data and will revert with additional comments to this once these have been performed

Drammen, 06. July 2010

Sincerely Yours,

Ypsomed

Gjermund Hansen
General Manager – Nordic Region