Wellion Calla Light

A system for measurement of plasma glucose
manufactured by Med Trust Handelsges.m.b.H in Austria

Report from the evaluation SKUP/2013/87

organised by SKUP at the request of Med Trust AB in Sweden

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The report was written by SKUP, autumn 2013. For more details about SKUP, see attachment 1. Main author was Elisabet Eriksson Boija, SKUP in Sweden.

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Attachments with raw data of the comparison method and Wellion Calla Light are included only in the copy to Med Trust.

1. Summary

Background
Wellion Calla Light is a blood glucose meter designed for glucose self-measurement by diabetes patients. The meter and test strips are manufactured and supplied by Med Trust Handelsges.m.b.H. The evaluation was carried out during 2012 and 2013 at the request of Med Trust AB in Sweden.

The aim of the evaluation
The aim of the evaluation was to determine the analytical quality and the user-friendliness of the Wellion Calla Light system. The evaluation was carried out by biomedical laboratory scientists under standardised and optimal conditions at a hospital laboratory and by the intended users, i.e., diabetes patients. In addition to the analytical quality, presented as repeatability, bias and accuracy, comparisons were made concerning variation between lots of test strips and interference by haematocrit.

Materials and methods
Out of 125 diabetes patients enrolled for the evaluation, 94 completed. The diabetes patients were randomly divided into a mail group, which received the meter and test strips by mail, and a training group, which got a brief lesson of the system before they received the meter and test strips. Of the diabetes patients completing the evaluation, 50 were in the mail group and 44 in the training group. Each diabetes patient got an individual meter and the biomedical laboratory scientists used two meters. Three lots of test strips were used. At the final meeting, the patients measured the glucose concentration on their individual meter and the biomedical laboratory scientists measured on their two meters. At the same occasion samples were obtained for the comparison method. The comparison method was a hexokinase method for measurement of plasma glucose concentrations. The analysis was done on a Modular instrument from Roche, which results are traceable to a reference method procedure. The quality goal for the repeatability was a CV of ≤5%. The quality goal for accuracy for the biomedical laboratory scientists' measurements was set according to ISO 15197:2003; at least 95% of the results should be within ±0,83 mmol/L at glucose concentrations <4,2 mmol/L, and within ±20% at glucose concentrations ≥4,2 mmol/L. The goal for the diabetes patients' measurements was that at least 95% of the results should be within ±1,00 mmol/L at glucose concentrations <4,2 mmol/L, and within ±25% at glucose concentrations ≥4,2 mmol/L. The trueness, determined as bias, was calculated but no quality goal was set. The quality goal of technical errors was ≤2%.

Results
The repeatability CV achieved by the biomedical laboratory scientists was 3,5−4,0% for one of the meters and one test strip lot and 4,3−5,1% for the other meter with three test strip lots (about one third of the results from each lot). The repeatability CV achieved by the diabetes patients was 5,7−6,0% with three test strip lots. The results of Wellion Calla Light were a little lower than the results of the comparison method. 98% of the results achieved by the biomedical laboratory scientists fulfilled the quality goal for accuracy. All the results achieved by the diabetes patients also fulfilled the quality goals for accuracy, as described in ISO 15197:2003 and thereby also the less restrictive goals set for users. There were no differences between the three lots of test strips. There was no difference in performance between the diabetes patients in the mail group and in the training group. A slight, but statistically significant, effect of haematocrit was shown in the range 35−49%. The percentage of technical errors was 0%. The user-friendliness was rated as satisfactory, although some possible improvements in the manual were pointed out.

Conclusion
The quality goal of a repeatability CV of ≤5%, when the biomedical laboratory scientists did the measurements, was fulfilled for one of the meters. The results achieved on the other meter most likely fulfilled the quality goal for two of the three concentration intervals, while the quality goal was most likely not fulfilled for one concentration interval. The quality goal for repeatability was most likely not fulfilled when the diabetes patients performed the measurements. The accuracy quality goals were fulfilled by all users. No differences were found between the results of three different lots of test strips. The quality goal for technical errors was fulfilled. The user-friendliness was satisfactory, which fulfils the quality goal.

A simplified summary in Swedish can be found in the end of this report (attachment 12).

Comments from Med Trust
Med Trust Handelsges.m.b.H is content with this report and has no further 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
GC-IDMS	Gas Chromatography-Isotope Dilution Mass Spectrometry
HELFO	The Norwegian Health Economics Administration
ISO	International Organization for Standardization
JCTLM	Joint Committee for Traceability in Laboratory Medicine
NIST	National Institute of Standards & Technology
Noklus	Norwegian Quality Improvement of Primary Care Laboratories
SD	Standard Deviation
SKUP	Scandinavian evaluation of laboratory equipment for primary health care
SRM	Standard Reference Material

3. Quality goals

3.1. Analytical quality

Wellion Calla Light is designed for monitoring of the concentration of glucose in plasma, and the quality goals are set according to this.

3.1.1. *Precision*

Glucose devices designed for monitoring blood glucose concentration, being calibrated to show concentration of glucose in plasma, need to have 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 [3-5].

3.1.2. *Accuracy*

The International Organization for Standardization (ISO)-standard 15197:2003 [6], 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 is a quality goal for measurements made by trained laboratory staff. In Norway the results achieved by the diabetes patients have been discussed towards a *modified* goal suggested by Norwegian Quality Improvement of Primary Care Laboratories (Noklus) [7, 8], which has been accepted as national quality goals in Sweden [9] and also implemented by SKUP:

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.

More recent evaluations performed by SKUP [10, 11], show that the diabetes patients also can achieve the quality goals set by ISO 15197:2003.

3.1.3. *Quality goals in Denmark*

The analytical quality goals for point of care glucose measurement systems in Denmark are CV <4% and bias <3% [4, 5].

3.1.4. *Lot variation*

Three different lots of test strips were used. An assessment of the lot-to-lot variation will be done, but no quality goal is set.

3.2. User-friendliness

The evaluation of user-friendliness is carried out by asking the diabetes patients to fill in a questionnaire, see section 5.5 and attachment 11. The biomedical laboratory scientists (BLSs) were also asked to evaluate the user-friendliness, see section 5.5.

SKUP recommends that the percentage of "tests wasted" caused by technical errors should not exceed 2%.

3.3. Principles for the assessments

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

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 a difference-plot with limits for the tolerated deviation according to the quality goal. The fraction of results within the limits is calculated.
The accuracy is judged as either fulfilling the quality goal or not fulfilling the quality goal.

3.3.2. *Assessment of the user-friendliness*

The user-friendliness is assessed according to the answers and comments given in the questionnaire (see section 5.5. and attachment 11). The response from the users is reviewed and summed up. To achieve quality goal satisfactory, the tested equipment and the manual must reach the total rating of "satisfactory".

The BLSs registers the fraction of error codes and technical errors during the evaluation.

3.4. SKUP´s quality goals in this evaluation

Based on the discussion about alternative quality goals above, it was agreed in the protocol to assess the results from the evaluation of Wellion Calla Light against the following quality goals:

Repeatability (CV) ..... ≤5%

Allowable deviation
in the individual result of BLSs from the comparison method result
for glucose concentrations <4,2 mmol/L ..... ≤±0,83 mmol/L
and for glucose concentrations ≥4,2 mmol/L ..... ≤±20%

in the individual result of diabetes patients from the comparison method result
for glucose concentrations <4,2 mmol/L ..... ≤±1,00 mmol/L
and for glucose concentrations ≥4,2 mmol/L ..... ≤±25%

Required percentage of individual results
within the allowable deviations ..... ≥95%

Fraction of technical errors ..... ≤2%

User-friendliness, total rating ..... 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 [12]. In the NPU-database the specifications for the measurand in this evaluation are as shown in table 2. In this evaluation the term glucose is used.

Table 2.NPU-specifications

NPU code	Name of test according to NPU	Unit
NPU22089	P(cB)—Glucose; subst.c.(proc.) = ? mmol/L	mmol/L

Another variable measured in the evaluation is haematocrit (raw data presented as fractions without unit, otherwise presented in %).

4.2. The evaluated measurement system Wellion Calla Light

Wellion Calla Light (figure 1) is designed for self-monitoring of blood glucose. The system uses test strips based on biosensor technology. Wellion Calla Light uses the enzyme glucose oxidase, no co-factor is needed. The enzyme reacts with glucose in blood and produces an electrical signal. This signal is measured by the Wellion Calla Light meter.Wellion Calla Light reports plasma glucose values. The meter needs no coding when changing test strip lot. It starts automatically when a test strip is inserted, and the measurement starts automatically when a sufficient amount of blood is drawn into the test strip.

Table 3 shows some technical data about Wellion Calla Light. For more technical data, and name of the manufacturer and the suppliers in the Scandinavian countries, see attachments 2 and 3. For product information, see attachment 4.

Table 3. Technical data from the manufacturer

Technical data for Wellion Calla Light	
Sample material	Capillary blood
Sample volume	0,65 µL
Measuring time	6 seconds
Measuring range	1,1 – 33,3 mmol/L
Haematocrit	30 – 55%
Storage capacity	500 results
Electrical power supply	2 alkaline AAA batteries

Figure 1. Wellion Calla Light meter

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 of Wellion Calla Light is the routine method for determination of the glucose concentration in plasma/serum at the Karolinska University Laboratory, Södersjukhuset in Stockholm, Sweden. The method is a photometric hexokinase method. The method is implemented on a Modular instrument from Roche, and reagents from Roche are used. The method is accredited and the laboratory can document good analytical quality of the method through indirect participation (master instrument at the Karolinska University Laboratory at Karolinska university hospital in Huddinge (Stockholm)) in an external quality assessment (EQA) program at External quality assurance in laboratory medicine in Sweden (Equalis). According to Roche the results are traceable to a reference method procedure [13]. The method is hereafter called the comparison method.

Haematocrit was measured on venous samples on Sysmex XE 5000.

4.3.2. *Verification of the analytical quality of the comparison method*

Precision

The second capillary sample from each diabetes patient was measured in duplicate.
The repeatability was estimated by using these results.

Trueness

To document the trueness of the comparison method, the method calibration was controlled by the international certified reference materials SRM 965b (glucose in frozen human serum) from National Institute of Standards & Technology (NIST) [14]. There are four materials with different levels of glucose. The concentrations are specified with uncertainties.

Internal quality control

For internal quality control glucose control BR1 and BR3 from Bio-Rad were used.

External quality control

Fresh frozen human serum (FHK0108), produced by Danish Institute of External Quality Assurance for Laboratories in Health Care (DEKS), was analysed. FHK0108 has a target value set by reference method measurements at three occasions during the years 2005 to 2011, with four measurements each time. The measurements were performed at a laboratory at Linköping University, Sweden, using gas chromatography-isotope dilution mass spectrometry (GC-IDMS). This method is approved as a reference method by the Joint Committee for Traceability in Laboratory Medicine (JCTLM). The laboratory at Linköping University was listed as a reference laboratory at JCTLM at that time, which means that the laboratory was approved by the Referenzinstitut fûr Bioanalytik, Germany, in EQA surveys for reference laboratories (Ringversuch).

4.4. The evaluation

4.4.1. *Planning of the evaluation*

Background for the evaluation

Wellion Calla Light is a blood glucose monitoring system designed for glucose self-measurements performed by persons with diabetes. Wellion Calla Light is produced by Med Trust Handelsges.m.b.H in Austria and will be supplied in Scandinavia by Med Trust AB in Sweden. Med Trust AB ordered this evaluation to get objective documentation of the analytical quality and the user-friendliness of Wellion Calla Light, as part of documentation required in the Swedish tender system.

Inquiry about an evaluation

Mikael Cederhag, former consultant at Med Trust AB in Sweden, applied to SKUP in March 2010 for an evaluation of Wellion Calla Light.

Protocol, arrangements and contract

The protocol for the evaluation was approved in October 2011. Med Trust Handelsges.m.b.H in Austria and SKUP signed a contract about the evaluation in November 2011. The Centre for Diabetes at Södersjukhuset in Stockholm, Sweden, agreed to be a part of recruitment of diabetes patients to the evaluation. The contract between SKUP and the centre was signed in January 2012. The department of Clinical Chemistry at the Karolinska University Laboratory at Södersjukhuset in Stockholm, Sweden agreed to perform the evaluation, including measurements with the comparison method. The contract between SKUP and the laboratory was signed in August 2012.

Preparations, training program and practical work

SKUP started the preparations for the evaluation in May 2011. An ethical approval was signed by the regional ethical review board in Stockholm in December 2011. Kristina Wikström, Christina Kullhammar, Eva Ytterfors and Farideh Rafiefard, biomedical laboratory scientists (BLSs), were trained in the handling of the Wellion Calla Light meter by Med Trust in March 2012. The meters and test strips for the evaluation were received in February 2012. The practical work with the evaluation was carried out in the period May 2012–October 2013. The practical work was gravely delayed due to difficulties with recruitment of diabetes patients and many drop-outs.

4.4.2. *Evaluation sites and persons involved*

Persons involved in the evaluation are presented in table 4.

Table 4. Persons responsible for various parts of the evaluation

Name	Title	Place	Responsibility
Sylvia Weißenbacher	Sales manager international, MSc	Med Trust Handelsges.m.b.H in Austria	Contact person at International Sales & Scientific Marketing
Mikael Cederhag		Former consultant to Med Trust AB in Sweden	Ordered the evaluation/ Former contact person
Lena Morgan	BLS	Former SKUP/Equalis	Preparation of the evaluation Author of the protocol Recruitment of diabetes patients
Elisabet Eriksson Boija	Biochemist, PhD	SKUP/Equalis	Responsible for the evaluation Recruitment of diabetes patients Statistical calculations Author of the report
Carina Ritzmo	Head of Department, BLS, MD	Clinical Chemistry, Karolinska University Laboratory, Södersjukhuset	Local organiser of the practical work with the evaluation and the comparison method Recruitment of diabetes patients
Kristina Wikström Christina Kullhammar Eva Ytterfors Farideh Rafiefard	BLSs	Clinical Chemistry, Karolinska University Laboratory, Södersjukhuset	Practical work with the evaluation and the comparison method
Ingela Åkesson Jacobsson	Diabetes nurse	Centre for Diabetes, Södersjukhuset	Recruitment of diabetes patients

4.4.3. *The evaluation model*

The SKUP evaluation

SKUP evaluations are based upon the fundamental guidelines in a book concerning evaluations of analytical instruments in primary health care [15]. SKUP's model for glucose user-evaluation is based on a standard model prescribed by The Norwegian Health Economics Administration (HELFO) for test strip reimbursement in Norway [16].

The evaluation of Wellion Calla Light

The evaluation consisted of two parallel parts. One part of the evaluation was carried out under standardised and optimal conditions by BLSs in a hospital laboratory. This part documents the quality of the system under conditions as favourable as possible for achieving good analytical quality. Precision, accuracy and trueness are evaluated, as is the user-friendliness. The samples used for this part of the evaluation are the samples taken by the BLSs at the final meeting with the diabetes patients (figure 2).

Diabetes patients performed the other part of the evaluation in order to determine the analytical quality and the user-friendliness of Wellion Calla Light when used by the intended users. The diabetes patients were randomly divided into two groups. One group received personal training in how to use the instrument, hereafter called the training group. The other group received the instrument and instructions by mail, hereafter called the mail group. Three lots of test strips were distributed evenly between the participants in the two groups (random distribution). The model for the evaluation among diabetes patients is shown in figure 2.

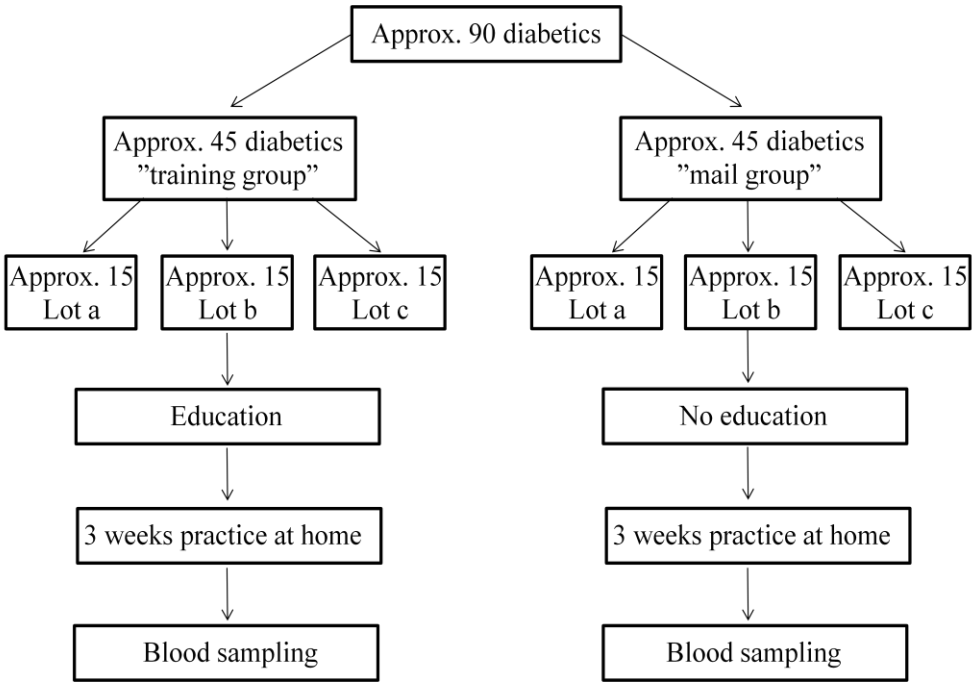

Figure 2. The model for the evaluation among the diabetes patients.

The aim of the evaluation

- To examine the analytical quality under standardised and optimal conditions, performed by a BLS in a hospital laboratory
- To examine the analytical quality among diabetes patients
- To compare the analytical quality among diabetes patients with and without a training program
- To examine the variation between three lots of test strips
- To examine if the haematocrit level interferes with the measurements
- To evaluate the user-friendliness of Wellion Calla Light and the manual

Blood sampling

All capillary samples for Wellion Calla Light and the comparison method were collected from finger-pricks. The blood sample for the duplicate measurements was mainly 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 and B). Three different lots of test strips for Wellion Calla Light measurements were used.

The blood sampling and analysis were carried out in the following order:
1. The BLS collected a first sample for the comparison method
2. The BLS collected samples and analysed on Meter A, B, A and B (for every second diabetes patient, the BLS started with Meter B)
3. The diabetes patient collected duplicate samples for his/her assigned meter
4. The BLS collected a second sample for the comparison method
5. The BLS collected a venous sample for haematocrit (voluntary)

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 difference between the first and the second result of the comparison method was not to exceed 4%, if it did the samples were reanalysed. If there still was a difference between 4 and 10%, the result will be commented on in this report. If the difference exceeded 10% all results, except for the calculations of the repeatability on Wellion Calla Light, of that diabetes patient were excluded.

Handling of samples for the comparison method
The capillary samples for the comparison method were taken from a finger-prick using two Microvette Li-heparin tubes (300 µL) from Sarstedt. Two samples (i.e., totally 4 tubes) were collected from separate finger-pricks as the first and the last in the series of samples, according to ISO 15197:2003 [6]. The samples were centrifuged immediately for three minutes at 10 000 g, and plasma was separated into two suitable sample tubes (first and last sample tubes). The plasma samples were frozen directly and stored at −80°C until the analysis took place (according to the storing procedure for the standard reference material from NIST [14]). The samples were analysed at two occasions.

Comparison method results
The second sample for the comparison method was analysed in duplicate. The duplicate results were used for calculations of imprecision. The mean value of the first sample result and the mean value of the two results of the second sample are referred to as the mean result of the comparison method, i.e.; mean result = (result 1+ (result 2+result 3)/2)/2. 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 Wellion Calla Light, for the assessment of bias with three lots of test strips, and for the examination of the interference from haematocrit.

Measurement of haematocrit
Haematocrit may have an influence on the measured blood glucose value. To check this, a venous sample was collected from each diabetes patient (voluntary) and the haematocrit was measured on Sysmex XE 5000.

4.4.4. *The evaluation procedure under standardised and optimal conditions*
The two BLSs each used two Wellion Calla Light blood glucose meters for the evaluation. On Meter A, one lot of test strips was used for all the measurements. Meter B was used for the same three lots as distributed among the diabetes patients. All possibilities for disturbance of, and interference with the measurements were tried to be kept at a minimum.

Internal analytical quality control
The Wellion Calla Light meters were checked by means of the manufacturer's control solution every day they were used.

Recruitment of diabetes patients
Some of the diabetes patients were informed about the evaluation by a letter from their diabetes nurse at the Centre of Diabetes, Södersjukhuset, but most of the diabetes patients were informed by two different announcements in a local newspaper. In the beginning the project leader at the hospital laboratory was notified of all interested diabetes patients by the Centre of Diabetes and SKUP in Sweden, and then recruited them by phone and e-mail. After the second announcement, the SKUP coordinator recruited the interested diabetes patients immediately when they called or e-mailed. The Wellion Calla Light meter was tested in use by 54 men and 40 women with diabetes. The average age was 58 years (range 28–82), and 50 were in the mail group and 44 in the training group. The group included diabetes patients with a range of self-monitoring frequencies, i.e., diabetes patients who perform self-monitoring often and those who perform self-monitoring less frequently.

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

Evaluation of user-friendliness
The BLSs evaluated the user-friendliness of Wellion Calla Light and its manual, see 5.5.

4.4.5. *Evaluation procedure among diabetes patients*

Internal analytical quality control
Many of the diabetes patients in the mail group were supplied with control solution from the manufacturer, but there were no instructions, nor requirement to use it. However, the BLS checked the diabetes patients' instruments with internal control at their final meeting.

Recruitment of diabetes patients
See 4.4.4.

Recording of results
See 4.4.4.

Evaluation of user-friendliness
A questionnaire for evaluating the user-friendliness and the manual of Wellion Calla Light was filled in by each diabetes patient at his/her final meeting at the hospital laboratory, right before the blood sampling (attachment 11 and section 5.5.).

5. Results and discussion

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

5.1. Number of samples

A total of 125 diabetes patients were enrolled, out of which 94 completed the evaluation. Various reasons or no reason at all were given by the 31 patients that dropped out. A venous sample for haematocrit was collected from 83 of the 94 diabetes patients.

5.1.1. *The glucose concentration stability during sampling*

Out of 94 paired results on the comparison method, 19 gave deviations >4%. For two (ID 50 and 113) of these 19 samples the deviation was >10%, which was regarded as unacceptable. All results were included at first in the repeatability calculations, where ID 50 was excluded as a statistical outlier according to Burnett [17]. ID 113 was not a statistical outlier, but giving the deviation of >10%, it was removed by the author before further processing of data.

5.1.2. *Excluded and missing results*

In addition to exclusions mentioned in 5.1.1, another statistical outlier (ID 75) was excluded from the results of the comparison method. Thus, in total three results were excluded from the comparison method. The matching results of Wellion Calla Light were removed before assessment of accuracy and haematocrit influence, and before calculation of trueness (bias), however, the matching results were included in the calculations of the repeatability of Wellion Calla Light.

Three statistical outliers (ID 19, 24 and 63) were excluded from the calculations of the repeatability of Wellion Calla Light achieved by BLSs. One statistical outlier (ID 2) was excluded from the calculations of the repeatability achieved by patients. ID 101 was excluded from the calculations of the repeatability achieved by diabetes patients since only the first measurement was reported.

One statistical outlier (ID 42) was excluded from the calculations of the trueness of Wellion Calla Light achieved by BLSs.

ID 4, 9, 11, 26, 37, 39, 59, 85, 90, 95 and 114 denied sampling for haematocrit measurements.

One statistical outlier (ID 61) was excluded from the calculations of the bias of Wellion Calla Light when comparing mail and training groups of the diabetes patients.

5.1.3. *Failed measurements*

No measurement failed and no technical errors were reported during the measurements at the final meeting. Thus, the total percentage of technical errors was 0%.

However, when filling out the user-friendliness questionnaire, 11 of the 94 diabetes patients stated they got error codes at one or more occasions during the three weeks period they used the meter at home. The error code E2; too little blood, was reported by seven users, one of them also reported error code E1; damaged, wet or already used test strip. Four users did not specify the error code.

5.2. Analytical quality of the selected comparison method

5.2.1. *Internal quality control*

For internal quality control glucose control BR1 and BR3 from Bio-Rad were used. From BR1 one lot was used, from BR3 two different lots were used, one on each of two occasions of analysis with the comparison method. All controls were within the limits set by the laboratory (data not shown).

5.2.2. *Comparison of the 1st and 2nd measurement*

To calculate the repeatability, the second sample from each diabetes patient was analysed in duplicate. The results are checked to meet the assumption for using formula 1 in attachment 5 for estimation of imprecision. There were no systematic differences pointed out between the paired measurements (data not shown).

5.2.3. *The precision of the comparison method*

Repeatability

The precision of the comparison method is presented as repeatability. The repeatability CV of the comparison method with a 90% CI is shown in table 5. The raw data are presented for the producer alone (attachment 6).

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	30	2*	5,5	2,8 (2,3 – 3,6)
7 – 10	32	0	8,8	2,5 (2,1 – 3,2)
>10	32	1*	14,9	1,6 (1,3 – 2,0)

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

*Two statistical outliers according to Burnett's model (ID 50 and 75) were excluded, and one result was excluded due to deviation >10% between first and second sample results of the comparison method (ID 113).

Discussion

The repeatability CV for the comparison method was between 1,6 and 2,8%.

5.2.4. *The trueness of the comparison method*

The trueness of the comparison method is shown (table 6) by analysis of the standard reference material SRM 965b purchased from NIST.

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

SRM965b	Date	Certified glucose concentration (uncertainty), mmol/L	n	Mean value glucose Comparison method, mmol/L	Deviation from target value, %
Level 1	2013-03-04	**1,836** (1,809 – 1,863)	8	1,97	+7,4
	2013-10-17		8	1,93	+4,9
	Total		**16**	**1,95**	**+6,2**
Level 2	2013-03-04	**4,194** (4,135 – 4,253)	8	4,52	+7,7
	2013-10-17		8	4,42	+5,3
	Total		**16**	**4,47**	**+6,5**
Level 3	2013-03-04	**6,575** (6,481 – 6,669)	8	6,95	+5,7
	2013-10-17		8	6,83	+3,8
	Total		**16**	**6,89**	**+4,8**
Level 4	2013-03-04	**16,35** (16,15 – 16,55)	8	17,28	+5,7
	2013-10-17		8	17,02	+4,1
	Total		**16**	**17,15**	**+4,9**

Comments

The glucose results of the NIST-standards were above the upper uncertainty limits (table 6). All results from the comparison method were therefore adjusted according to the certified NIST-targets. A curve was done with the certified glucose concentrations on the x-axis and the total mean glucose values on the y-axis (not shown). The curve resulted in the correction equation **x=0,95593y-0,03881**. This equation was used to adjust all results achieved by the comparison method. All results of the comparison method given further on in this report have been adjusted.

To verify the trueness of the adjusted comparison method results, a fresh frozen human serum control (FHK0108) produced by DEKS, was analysed (table 7). FHK0108 has a target value set by reference method measurements at three occasions with four measurements each time; the mean is presented in table 7.

Table 7. Verification of the trueness of the comparison method

Control	Date	Target value glucose (uncertainty, k=2), mmol/L	n	Mean value glucose Comparison method, mmol/L	Deviation from target value, %
FHK0108	2013-03-04	**8,21** (8,02–8,30)	5	8,27	+0,7
	2013-10-17		5	7,95	–3,2
	Total		**10**	**8,11**	–1,2

Discussion

The result from the second run was slightly below the uncertainty interval, but overall the results confirm the trueness of the comparison method.

5.3. Analytical quality of Wellion Calla Light in a hospital laboratory

5.3.1. *Internal quality control*

The two Wellion Calla Light meters used by the BLSs were checked with control solution Level 1 every day they were used. According to the BLSs all results were within the allowable control range (data not shown).

5.3.2. *Comparison of the 1st and 2nd measurement*

Two capillary samples were taken by a BLS from each diabetes patient for measurements on Wellion Calla Light Meter A and B. The results are checked to meet the assumption for using formula 1 in attachment 5 for estimation of imprecision. There were no systematic differences detected between the paired measurements (data not shown).

5.3.3. *The precision of Wellion Calla Light*

Repeatability under standardised and optimal conditions in a hospital laboratory

The precision of Wellion Calla Light is presented as repeatability. The repeatability CV of Wellion Calla Light under standardised and optimal conditions with a 90% CI is shown in table 8. The results are sorted and divided into three intervals according to the mean concentrations of the comparison method results. The calculations are made separately for Meter A (test strip lot a) and Meter B (test strip lot a, b or c). The raw data are presented for the producer alone (attachment 7).

Table 8. Repeatability, glucose Wellion Calla Light. Results achieved by BLSs.

Instrument Wellion Calla Light	Glucose interval Comparison method, mmol/L	n	Excluded results	Mean value glucose, mmol/L	CV (90% CI), %
A	<7	30	0	5,2	3,5 (2,8 – 4,4)
B	<7	30	1*	5,1	4,3 (3,6 – 5,5)
A	7 – 10	32	1*	8,0	4,0 (3,3 – 5,0)
B	7 – 10	32	0	8,1	5,1 (4,2 – 6,5)
A	>10	32	1*	13,6	3,5 (2,9 – 4,4)
B	>10	32	0	13,4	4,3 (3,6 – 5,5)

The given numbers of results (n) are counted before the exclusion of outliers. Mean and CV are calculated after the exclusion of outliers. Meter A used only test strip lot a, Meter B used any of the test strip lots (a, b or c).
*Three statistical outliers according to Burnett's model (ID 19, 24 and 63) were excluded.

Discussion

The repeatability CV achieved at standardised and optimal conditions by BLSs was between 3,5 and 5,1%. The repeatability achieved by the BLSs on Meter A (test strip lot a) fulfilled the quality goal of CV ≤5% at all concentration intervals. The repeatability achieved by the BLSs on Meter B (test strip lot a, b or c) most likely fulfils the quality goal at the low and high concentration intervals (CI above limit), but most likely the quality goal is not fulfilled at the intermediate concentration interval.

5.3.4. *The trueness of Wellion Calla Light*

The trueness of Wellion Calla Light is calculated as bias (systematic error) from the comparison method. The results are sorted and divided into three intervals according to the mean concentrations of the comparison method results. The calculations are made separately for Meter A (test strip lot a) and Meter B (test strip lot a, b or c). The bias of Wellion Calla Light is shown in table 9.

Table 9. Bias, glucose Wellion Calla Light. Results achieved by BLSs.

Instrument Wellion Calla Light	Glucose interval Comparison method, mmol/L	n	Excluded results	Mean value glucose Comparison method, mmol/L	Mean value glucose Wellion Calla Light, mmol/L	Bias (95% CI), mmol/L
A	<7	28	0	5,5	5,3	–0,24 (–0,38 – –0,11)
B	<7	28	0		5,3	–0,30 (–0,46 – –0,15)
A	7 – 10	32	0	8,8	8,1	–0,72 (–0,91 – –0,54)
B	7 – 10	32	0		8,1	–0,70 (–0,90 – –0,50)
A	>10	31	1*	14,8	13,4	–1,18 (–1,49 – –0,88)
B	>10	31	0		13,4	–1,45 (–1,79 – –1,11)

The given numbers of results (n) are counted before the exclusion of outliers. Mean and bias of Wellion Calla Light are calculated after the exclusion of outliers. Meter A used only test strip lot a, Meter B used any of the test strip lots (a, b or c).

* One statistical outlier according to Burnett's model (ID 42) was excluded.

Discussion

A negative bias was shown for all three concentration intervals. All deviations were statistically significant (differs from zero).

5.3.5. *The accuracy of Wellion Calla Light*

The deviation from the comparison method is used to evaluate the accuracy of Wellion Calla Light; the result is shown in an accuracy plot (figure 3). The plot shows the deviation of the first measurement on each meter (A and B) by BLSs from the mean value of the corresponding sample on the comparison method. The plot illustrates both random and systematic differences on Wellion Calla Light.

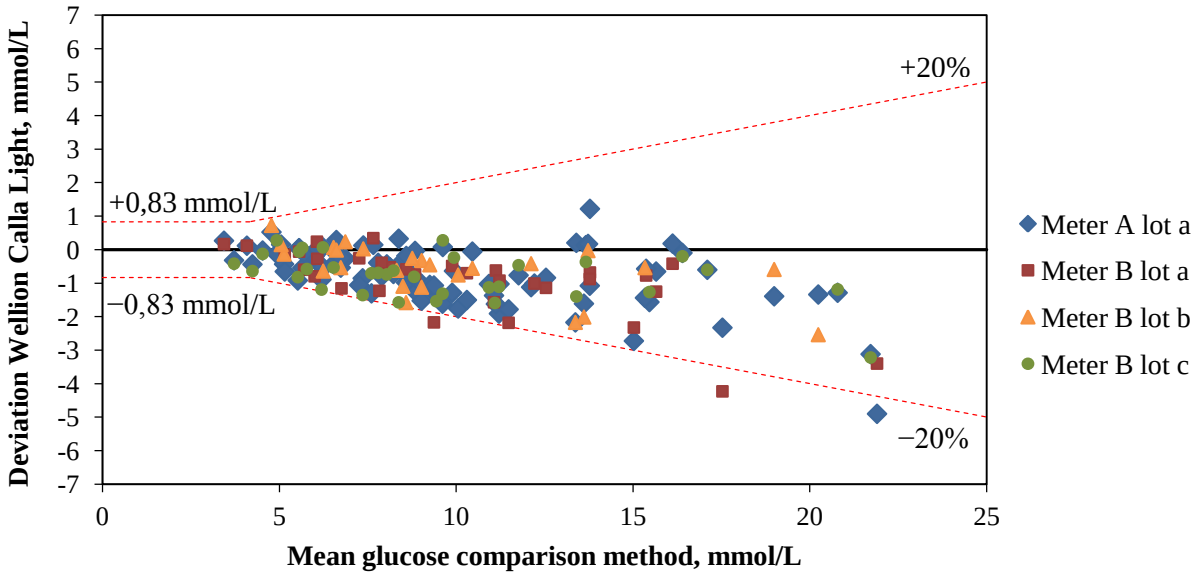

Figure 3. Accuracy of Wellion Calla Light Meter A/test strip lot a (♦) and Meter B/test strips lots a (■), b (▲) and c (●) under standardised and optimal measuring conditions. The x-axis represents the mean result on the comparison method. The y-axis represents the deviation of the first measurement on Wellion Calla Light from the mean result of the comparison method. The red stippled lines represent the quality goal according to ISO15197:2003. Number of results (n) = 91 for Meter A/lot a, and 91 for Meter B/ lot a, b and c.

Discussion

The quality limits given in ISO 15197:2003 refer to that at least 95% of the results must be within the limits, which are ±0,83 mmol/L at glucose concentrations <4,2 mmol/L, and ±20% at glucose concentrations ≥4,2 mmol/L. For the results achieved by BLSs on Meter A (test strip lot a) one out of the 91 results is outside the quality goal, thus 98,9% (90 of 91) of the results are within the limits, which fulfils the ISO 15197:2003 quality goal. For the results achieved by BLSs with the same patient samples on Meter B (test strip lot a, b or c) two out of the 91 results are outside the quality goal, thus 97,8% (89 of 91) of the results are within the limits, which fulfils the ISO 15197:2003 quality goal. Thus, the accuracy of Wellion Calla Light appears to be neither instrument nor test strip lot dependent.

5.3.6. *Bias with three lots of test strips*

All results with Wellion Calla Light Meter A were achieved using test strips lot a, the results of Meter B were achieved by using any of the three lots of test strips.

Discussion

As shown in figure 3, the results on Wellion Calla Light appeared similar with all three test strip lots. Due to this, the bias (table 9) needs not to be presented on a lot-level for Meter B.

5.3.7. *Effect of haematocrit*

According to the manufacturer, measurements on Wellion Calla Light are not to be influenced by haematocrit values in the range 30–55% (table 3). To evaluate the effect of haematocrit on Wellion Calla Light glucose measurements, venous samples were collected from the patients at their final meeting at the hospital. The sampling was voluntary. The effect of haematocrit is shown in figure 4. The Wellion Calla Light results shown are rendered from Meter A (test strip lot a), which was used by the BLSs under standardised and optimal conditions, and it comprise the glucose concentration range 3,4–19,5 mmol/L. The raw data is shown in attachment 8.

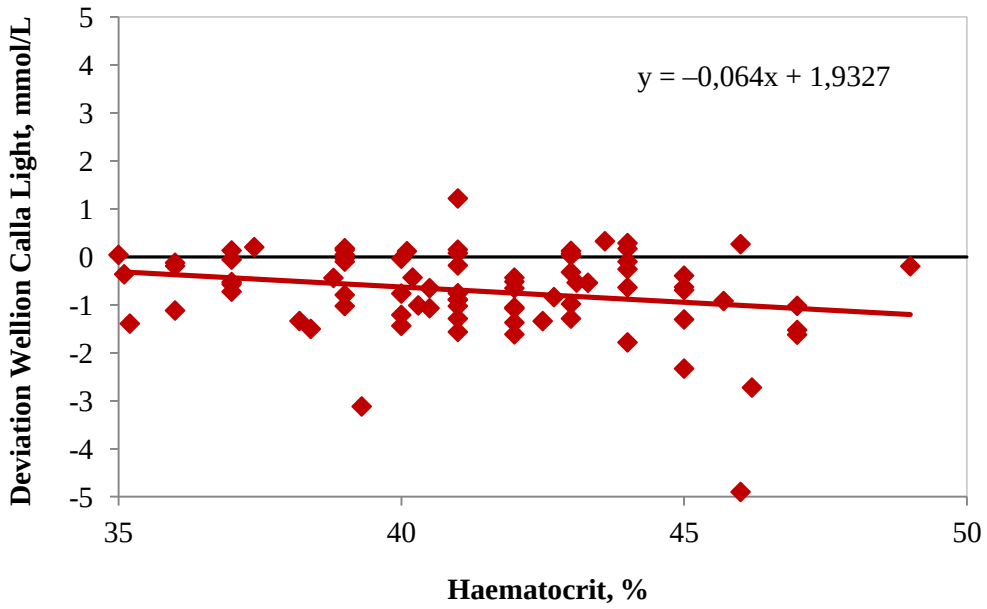

Figure 4. The effect of haematocrit on glucose measurements on Wellion Calla Light Meter A/test strip lot a under standardised and optimal measuring conditions. The x-axis represents the haematocrit values. The y-axis represents the deviation of the first measurement on Wellion Calla Light from the mean result of the comparison method. The thick red line represents the regression. Number of results (n) = 80.

Discussion

The slope of the trend-line is –0,064 with a 95% CI of –0,125 to –0,003. The slope is statistically significant (differs from zero). The glucose measurements on Wellion Calla Light in the evaluation were slightly affected by haematocrit within the range 35–49%. The deviation shown on the y-axis is the same as shown in the accuracy plot (figure 3).

5.4. Analytical quality of Wellion Calla Light among diabetes patients

5.4.1. *Internal quality control*

The diabetes patients were not obliged to use internal control. The BLS checked the diabetes patients' instruments and the test strips of the diabetes patients with internal control Level 1 at their final meeting. During the evaluation two lots of control solution were used and three lots of test strips. Out of 188 measurements (duplicate on 94 meters) 153 (81%) were within the allowable limits of the control assigned by the manufacturer. The reproducibility CV was 10,8%. The frequency of controls outside the allowable range was unexpectedly large. Calculations were done to see if the deviating results could be related to the test strip lot or its expiration date, or the control lot or its expiration date (specifications in attachment 4). The relation turned out to be dependent on the control lot, as most of the controls outside allowable range appeared when using lot TJC130701M (data not shown). Raw data is shown in attachment 9.

5.4.2. *Comparison of the 1st and 2nd measurement*

Two capillary samples were taken of each person for measurements on Wellion Calla Light. The results are checked to meet the assumption for using formula 1 in attachment 5 for estimation of imprecision. There were no systematic differences pointed out between the paired measurements (data not shown).

5.4.3. *The precision of Wellion Calla Light*

Repeatability achieved among diabetes patients

The precision of Wellion Calla Light is presented as repeatability. The repeatability CV of Wellion Calla Light achieved by the diabetes patients with a 90% CI is shown in table 10. The results are sorted and divided into three intervals according to the mean concentrations of the comparison method results. The raw data are presented for the producer alone (attachment 10).

Table 10. Repeatability, Wellion Calla Light. Results achieved by diabetes patients.

Glucose interval Comparison method, mmol/L	n	Excluded results	Mean value glucose, mmol/L	CV (90% CI), %
<7	30	1*	5,4	6,0 (4,9 – 7,6)
7 – 10	32	0	8,4	5,7 (4,7 – 7,2)
>10	31	0	14,1	5,7 (4,7 – 7,2)

The given numbers of results (n) are counted before the exclusion of outliers. Mean and CV are calculated after the exclusion of outliers. The diabetes patients used any of the three test strips lots (a, b or c).
*One statistical outlier according to Burnett's model (ID 2) was excluded.

Discussion

The repeatability CV achieved by the diabetes patients was between 5,7 and 6,0%. Most likely the quality goal of CV ≤5% is not fulfilled.

5.4.4. *The bias of Wellion Calla Light among diabetes patients*

The bias of Wellion Calla Light from the comparison method is shown in table 11. The results are sorted and divided into three intervals according to the mean concentrations of the comparison method results. The results are calculated for all patient results without differentiating between the test strip lots.

Table 11. Bias, glucose Wellion Calla Light. Results achieved by diabetes patients.

Glucose interval Comparison method, mmol/L	n	Excluded results	Mean value glucose Comparison method, mmol/L	Mean value glucose Wellion Calla Light, mmol/L	Bias (95% CI), mmol/L
<7	28	0	5,5	5,5	–0,04 (–0,23 – +0,15)
7 – 10	32	0	8,8	8,4	–0,43 (–0,62 – –0,23)
10	31	0	14,8	14,1	–0,74 (–1,14 – –0,35)

The diabetes patients used any of the three test strips lots (a, b or c).

Discussion

At the low glucose concentration interval, the results of Wellion Calla Light are in agreement with the comparison method. At higher glucose concentrations a negative bias is shown. The bias obtained by the diabetes patients are consistent with the bias obtained by the BLSs under standardised and optimal conditions

5.4.5. *The accuracy of Wellion Calla Light among diabetes patients*

The deviation from the comparison method is used to evaluate the accuracy of Wellion Calla Light; the result is shown in an accuracy plot (figure 5). The plot shows the deviation of the first measurement by every diabetes patient from the mean value of the corresponding sample on the comparison method. The plot illustrates both random and systematic differences on Wellion Calla Light.

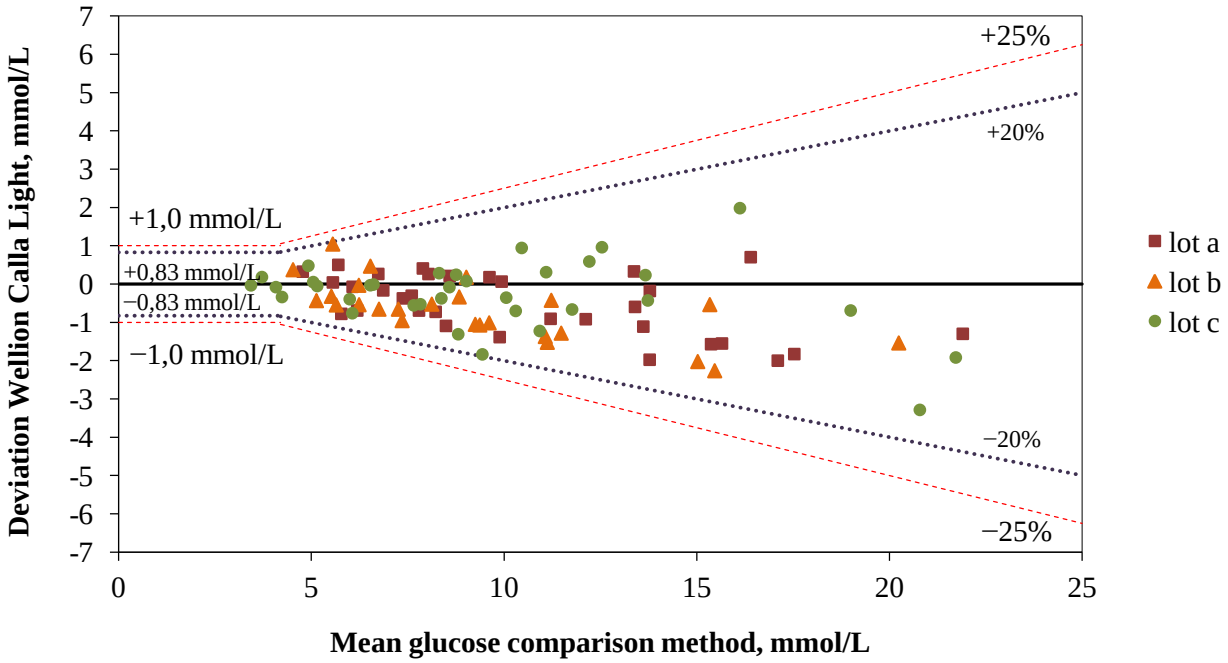

Figure 5. Accuracy of Wellion Calla Light meter when used by the diabetes patients. Three lots of test strips were used; lot a (■), b (▲) and c (●). The x-axis represents the mean result on the comparison method. The y-axis represents the deviation of the first measurement on Wellion Calla Light from the mean result of the comparison method. The red stippled lines represent the quality goal according to SKUP and the purple dotted lines the quality goal according to ISO 15197:2003. Number of results (n) = 91.

Discussion
All results, i.e., 100%, of Wellion Calla Light when used by diabetes patients are within the quality goal implemented by SKUP. Furthermore, all results, i.e., 100%, were also within the quality goal specified in ISO 15197:2003 (figure 5) (at least 95% of the results must be within the limits, which are ±0,83 mmol/L at glucose concentrations <4,2 mmol/L, and ±20% at glucose concentrations ≥4,2 mmol/L).

5.4.6. *Comparison mail and training groups*
To reveal possible differences between the patients who had received the Wellion Calla kit by mail and the patients who had been trained by the BLSs, the repeatability and the bias were calculated for these two groups separately (table 12).

Table 12. Repeatability and bias, glucose Wellion Calla Light. The results are divided into mail and training groups.

	Repeatability				**Bias**			
Patient group	**n**	**Excluded results**	**Mean value glucose, mmol/L**	**CV (90% CI), %**	**n**	**Excluded results**	**Mean value glucose, mmol/L**	**Bias (95% CI), mmol/L**
Mail	49	0	9,0	7,3 (6,2 – 8,7)	50	0	9,1	–0,25 (–0,47 – –0,04)
Training	41	0	9,8	5,2 (4,4 – 6,3)	41	1*	9,7	–0,54 (–0,76 – –0,32)

*One statistical outlier according to Burnett's model (ID 61) was excluded.

Discussion
The repeatability CV achieved by the diabetes patients was 7,3% for the mail group and 5,2% for the training group (all concentration levels). The training group most likely did not fulfil the quality goal of CV ≤5%, and the mail group did not fulfil the goal. However, since the CI overlaps, the difference between the groups is not statistically significant. The results from both groups showed a negative bias towards the comparison method. The bias was statistically significant (differs from zero). Since the CI from the groups overlaps, the groups' bias was not statistically significant from each other.

5.5. Evaluation of user-friendliness

5.5.1. *Questionnaire to the evaluators*

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.

At the end of the evaluation period, each user filled in a questionnaire about the user-friendliness of the instrument and the manual (table 13 and attachment 11). In addition the BLSs were asked for their opinion on the user-friendliness of the instrument and the manual. Finally, SKUP rated both time factors for the preparation and the measurement, and performance of internal and external quality controls (tables 14 and 15).

The total rating is an overall assessment by SKUP of the described property, and not necessarily the arithmetic mean of the rating. Consequently, a single poor rating can justify an overall poor rating, if this property seriously influences on the user-friendliness of the system.

All comments given by the diabetes patients are presented in attachment 11, a summary is presented below.

5.5.2. *Assessment of the user-friendliness*

5.5.2.1. *Assessment by the diabetes patients*

The manual was rated as mainly satisfactory by the diabetes patients. The users were satisfied with the description of how to collect samples and measure the glucose value. However, some of the diabetes patients complained that the language was difficult to read and understand (9/80) and that the text was too small and also difficult to read when the background was green (5/80).

Concerning the questions on how user-friendly Wellion Calla Light meter is the diabetes patients were satisfied. The patients gave high rating on how easy it was to insert the test strip, although this mean grade is somewhat lower than the others (further commented below). The patients gave high ratings on how easy it was to fill the test strip with blood and read the results. They also gave high rating on how easy the meter was to use in its entirety (table 13). There were many (75) positive comments (attachment 11). The dominant ones were the small amount of blood needed (24/75) and the big and easy readable display (22/75). Many (18/75) were satisfied of the short measuring time and several pointed out the user-friendliness (11/75).

Table 13. Grading of how the measurement system was to use.

Question **number that answered (total number)**	**Range of grades***	**Mean grade**
Grade how it was to insert the test strip into the instrument 93 (94)	1-6	4,8
Grade how it was to fill the test strip with blood 93 (94)	1-6	5,7
Grade how it was to read the test result on the display 93 (94)	2-6	5,7
Grade how it was to use the measurement system in its entirety 92 (94)	1-6	5,0

* Grade 1 through 6 could be chosen, where 1 was difficult and 6 was easy.

However, many comments (82) on disadvantages were given. The main concern was that Wellion Calla Light is big (mainly thick) and heavy (35/82). There were also many comments concerning the test strips, mainly that it was difficult to see what was front and back, up and down on the strips (13/82), and that it was difficult to get them out of the container and easy to contaminate them (14/82). Another common problem was the easiness to end up at setting menu when searching for historic results; some (9/82) had problems holding the button for exact right time in order to navigate in the menu.

5.5.2.2. *Assessment by the biomedical laboratory scientists*

The BLSs were satisfied with the explanations in the manual of how to collect samples, the measurement procedure, how to read the result, and the chapter on sources of error with troubleshooting. However, they were less satisfied with the table of content and the readability of the manual (how easy it was to read the manual including language and design (text size, background colour)).

The BLSs were satisfied with the instrument usage, giving satisfactory assessment on most issues, such as preparation of the instrument, preparation of the sample, application of the sample, the sample volume, number of proceeding steps, reading of the results, maintenance and hygiene. However, three of the four BLSs rated the design of Wellion Calla Light as intermediate (neither satisfactory nor unsatisfactory) or unsatisfactory with the explanation that it was too big and that it was difficult to work the menu button (difficult to end up in the intended place in the menu).

5.5.2.3. *Assessment by SKUP*

The manual has some disadvantages, according to SKUP-rating; there is no keyword index and of the Scandinavian languages it is only available in Swedish. These two aspects will be added to the overall rating of the manual.

SKUP has rated the time factors and the quality control (tables 14 and 15) as satisfactory. However, the user should be aware of the environmental aspects; the lancets should be sorted into sharp waste or put in plastic container and thrown in domestic waste. This is consistent with all glucose meters on the market.

5.5.2.4. *Conclusion of the user-friendliness*

The manual showed several short-comings such as difficult language and small text with green areas being difficult to read. In addition the table of content was not fully satisfactory and there was no keyword index in the manual. Furthermore, the manual is not available in Danish and Norwegian. However, most evaluators were satisfied with the content of the manual. The total rating is therefore satisfactory.

The user-friendliness of Wellion Calla Light was rated as satisfactory, with advantages as small amount of blood, and big easily read display. The main complaint was that the meter was too big.

Table 14. Rating of time factors (filled in by SKUP)

Topic	Assessment	Assessment	Assessment
Required training time	**<2 hours**	2 to 8 hours	>8 hours
Durations of preparations / Pre-analytical time	**<6 min.**	6 to 10 min.	>10 min
Duration of analysis	**<10 min.**	10 to 20 min.	>20 min
Storage conditions for test strips, unopened package	**+15 to +30°C**	+2 to +8°C	–20°C
Storage conditions for test strips, opened package	**+15 to +30°C**	+2 to +8°C	–20°C
Stability of test strips, unopened package	**>5 months**	3 to 5 months	<3 months
Stability of test strips, opened package	**>30 days**	14 to30 days	<14 days
Stability of quality control material, unopened	**>5 months**	3 to 5 months	<3 months
Stability of quality control material, opened	**>6 days or disposable**	2 to 6 days	≤1 day
Total rating by SKUP	**Satisfactory**		

Table 15. Rating of quality control (filled in by SKUP)

Topic	Assessment	Assessment	Assessment
Reading of the internal quality control	**Satisfactory**	Intermediate	Unsatisfactory
Usefulness of the internal quality control	Satisfactory	**Intermediate**[1]	Unsatisfactory
External quality control	**Satisfactory**	Intermediate	Unsatisfactory
Total rating by SKUP	**Satisfactory**		

The control material should always be stored at room temperature (+10 to +30°C), despite if the bottle is unopened or opened. This gives the rating of **satisfactory**.

[1]There were discrepancies in the information in the manual and in the insert of the control solution, which may confuse the user. The discrepancies concerned how to handle deviating results and where to find the allowable range.

6. References

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Attachments

1. The organisation of SKUP
2. Facts about Wellion Calla Light
3. Information about manufacturer, retailers and marketing
4. Product information, Wellion Calla Light
5. Statistical expressions and calculations
6. Raw data glucose, results from the comparison method
7. Raw data glucose, Wellion Calla Light results under standardised and optimal conditions
8. Raw data haematocrit
9. Raw data glucose, internal quality control, analysed on the diabetes patients' Wellion Calla Light meters
10. Raw data glucose, Wellion Calla Light results achieved by the diabetes patients
11. User-friendliness, Wellion Calla Light as evaluated by the diabetes patients
12. "SKUP-info". Summary for primary health care in Swedish
13. List of previous SKUP evaluations

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 Wellion Calla Light

This form was filled in by MED TRUST Handelsges.m.b.H.

Table 1. Basic facts

Name of the measurement system:	Wellion CALLA Light Blood Glucose Meter
Dimensions and weight:	Width: 69,6 mm Depth: 62,6 mm Height: 23 mm Weight: 68 g (including batteries)
Components of the measurement system:	Wellion CALLA Light Meter, Wellion CALLA Test strips
Measurand:	Glucose
Sample material:	Capillary whole blood
Sample volume:	0,65 µl
Measuring principle:	Amperometric
Traceability:	Plasma calibration, glucose oxidase method
Calibration:	Plasma
Measuring range:	20 – 600 mg/dl (1,1 – 33,3 mmol/l)
Linearity:	The test results of Wellion CALLA Light met the criteria of SD ≤4,5 mg/dl (0,25 mmol/l) at glucose concentration <75 mg/dl (4,2 mmol/l), and CV ≤6% at glucose concentration ≥6%. The blood measurement range between 1,1-33,3 mmol/l is validated. (data referring to Linearity study)
Measurement duration:	6 seconds
Operating conditions:	10 – 40°C
Electrical power supply:	2 AAA batteries
Recommended regular maintenance:	None
Package contents:	Meter, carrying case, lancing device, 10 lancets, user guide
Necessary equipment not included in the package:	None

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
What can be printed?	N/A
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?	500 blood glucose results with time and date
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:	Wellion CALLA test strips
Stability in unopened sealed vial:	24 months from production
Stability in opened vial:	6 months from first opening
Package contents:	10 or 50 test strips per vial

Table 4. Quality control

Electronic self check:	Yes, every time when test strip is inserted
Recommended control materials and volume:	Wellion CALLA control solution, 3 levels, 0,65 µl
Stability in unopened sealed vial:	12 months from production
Stability in opened vial:	3 months from first opening
Package contents:	1 vial of control solution

Information about manufacturer, retailers and marketing

This form was filled in by MED TRUST Handelsges.m.b.H.

Table 1. Marketing information

Manufacturer:	MED TRUST Handelsges.m.b.H
Retailers in Scandinavia:	Denmark: Norway: Sweden: MED TRUST AB Sweden
In which countries is the system marketed:	Globally ■ Scandinavia ☐ Europe ☐
Date for start of marketing the system in Scandinavia:	Not marketed until now
Date for CE-marking:	May 2nd, 2011
In which Scandinavian languages is the manual available:	Swedish

Product information, Wellion Calla Light

Wellion Calla Light meter serial numbers
Two meters (serial no. DG008217 (Meter A) and serial no. DF016428 (Meter B)) were used by the BLSs under standardised and optimal conditions. Each participating diabetes patients got a personal meter during the evaluation.

Wellion Calla Light test strips
Lot TJQ345 Expiry 2013-10 (“lot a”)
Lot TJQ344 Expiry 2013-10 (“lot b”)
Lot TJQ343 Expiry 2013-10 (“lot c”)

Wellion Calla Control Solutions
Wellion Calla Control solution Level 1
Lot TJC110801M Expiry 2013-01
Lot TJC130701M Expiry 2014-12

Target value, lot TJQ345: 5,1-7,7 mmol/L
Target value, lot TJQ344: 5,1-7,7 mmol/L
Target value, lot TJQ343: 5,2-7,8 mmol/L

Blood sampling device used by the biomedical laboratory scientists
Pro lancet (No 7594 green depth 1,8 mm) from HaeMedic

Blood sampling device used by the diabetes patients
The diabetes patients could choose whether to use the distributed Wellion lancing device with Wellion 28G lancets, or the lancet device they usually use.

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
n = number of differences

(formula 1)

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 assumption 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, results from the comparison method

Raw data from the comparison method measurements are shown only in the report to Med Trust.

Raw data glucose, Wellion Calla Light results under standardised and optimal conditions

Raw data from the Wellion Calla Light measurements are shown only in the report to Med Trust.

Raw data haematocrit

Patient ID	Haematocrit, no unit
1	0,47
2	0,39
3	0,43
4	---
5	0,47
6	0,38
7	0,43
8	0,39
9	---
10	0,35
11	---
12	0,38
14	0,41
18	0,41
19	0,41
20	0,42
21	0,46
22	0,39
23	0,36
24	0,41
25	0,43
26	---
27	0,40
30	0,37
31	0,41
34	0,40
35	0,41
36	0,46
37	---
39	---
42	0,46
43	0,37

Patient ID	Haematocrit, no unit
44	0,47
45	0,39
47	0,35
48	0,40
49	0,37
50	0,42
51	0,39
52	0,43
53	0,45
54	0,39
55	0,44
56	0,42
58	0,39
59	---
61	0,43
63	0,49
64	0,42
65	0,41
67	0,45
68	0,44
69	0,44
70	0,42
71	0,46
72	0,40
73	0,37
74	0,43
75	0,37
77	0,42
78	0,40
80	0,41
81	0,35
84	0,44

Patient ID	Haematocrit, no unit
85	---
87	0,42
88	0,40
90	---
92	0,41
93	0,43
94	0,36
95	---
96	0,44
97	0,39
98	0,44
101	0,40
102	0,41
103	0,42
105	0,44
108	0,43
109	0,45
110	0,42
111	0,37
112	0,37
113	0,40
114	----
115	0,43
118	0,36
120	0,39
121	0,45
122	0,39
123	0,40
124	0,40
125	0,45

Raw data glucose, internal quality control, analysed on the diabetes patients' Wellion Calla Light meters

Glucose concentration of the internal control in mmol/L. For allowable range, see attachment 4.

Patient ID	Lot test strip	QC sample 1	QC sample 2
1	TJQ343	6,0	6,3
2	TJQ344	6,8	6,7
3	TJQ344	6,8	6,8
4	TJQ344	7,4	6,6
5	TJQ344	7,5	7,7
6	TJQ343	7,6	6,7
7	TJQ343	7,3	7,3
8	TJQ343	7,4	7,1
9	TJQ344	6,6	7
10	TJQ343	8,3	8,1
11	TJQ343	7,8	7,2
12	TJQ343	7,3	7,1
14	TJQ343	7,2	7,3
18	TJQ345	7,3	7,5
19	TJQ345	7,9	7,3
20	TJQ344	7,2	7,5
21	TJQ344	7,9	7,8
22	TJQ344	6,8	6,6
23	TJQ345	7,0	6,9
24	TJQ343	6,4	6,5
25	TJQ343	8,3	7,8
26	TJQ345	8,5	7,8
27	TJQ343	5,6	5,6
30	TJQ345	7,4	7,1
31	TJQ345	6,4	6,5
34	TJQ343	7,8	7,3
35	TJQ343	6,7	6,8
36	TJQ344	7,6	7,3
37	TJQ345	6,2	6,7
39	TJQ345	7,5	7,6
42	TJQ345	7,8	7,3
43	TJQ343	7,5	6,5
44	TJQ344	7,2	7,1
45	TJQ343	7,1	7,1
47	TJQ343	6,7	7,0
48	TJQ343	6,7	6,1
49	TJQ344	6,6	6,3
50	TJQ344	7,6	7,1
51	TJQ343	7,7	7,3
52	TJQ345	7,3	6,6
53	TJQ345	6,7	7,1
54	TJQ344	6,2	6,5
55	TJQ343	6,8	6,7
56	TJQ345	6,6	6,5
58	TJQ344	8,1	7,6
59	TJQ345	7,1	7,2
61	TJQ343	7,0	6,7

Patient ID	Lot test strip	QC sample 1	QC sample 2
63	TJQ343	7,0	7,1
64	TJQ343	7,6	7,7
65	TJQ345	8,2	8,1
67	TJQ345	8,0	8,2
68	TJQ345	8,2	7,6
69	TJQ343	7,1	7,2
70	TJQ344	6,6	6,1
71	TJQ343	8,0	9,0
72	TJQ344	6,6	6,6
73	TJQ345	7,0	7,0
74	TJQ343	6,9	6,7
75	TJQ344	7,8	7,7
77	TJQ344	8,0	8,2
78	TJQ344	7,6	7,1
80	TJQ343	7,6	8,0
81	TJQ345	6,6	6,4
84	TJQ344	7,8	7,8
85	TJQ345	7,1	7,2
87	TJQ344	7,5	7,3
88	TJQ343	8,0	7,5
90	TJQ345	6,7	6,7
92	TJQ345	6,6	6,9
93	TJQ345	7,7	7,8
94	TJQ345	6,3	6,2
95	TJQ344	7,5	7,0
96	TJQ345	8,6	8,3
97	TJQ345	7,3	6,8
98	TJQ343	6,5	6,7
101	TJQ343	6,5	6,6
102	TJQ344	6,5	6,5
103	TJQ344	7,6	7,5
105	TJQ344	8,2	7,7
108	TJQ345	7,4	7,3
109	TJQ345	11,5	11,9
110	TJQ345	7,6	7,1
111	TJQ345	7,7	7,8
112	TJQ343	7,3	7,5
113	TJQ344	7,3	7,1
114	TJQ345	6,7	6,7
115	TJQ344	7,7	7,6
118	TJQ343	7,0	6,9
120	TJQ345	7,3	7,3
121	TJQ345	9,6	8,9
122	TJQ343	8,1	7,7
123	TJQ343	6,8	7,0
124	TJQ344	7,8	7,3
125	TJQ343	5,9	6,0

Raw data glucose, Wellion Calla Light results achieved by the diabetes patients

Raw data from the Wellion Calla Light measurements are shown only in the report to Med Trust.

User-friendliness, Wellion Calla Light as evaluated by the diabetes patients

The diabetes patients' user-friendliness questionnaire was written in Swedish, but has been translated below. In table 1 the diabetes patients have commented on advantages and disadvantages of Wellion Calla Light. In table 2 the diabetes patients have evaluated the Wellion Calla Light manual. The overall ratings are presented in Table 13, section 5.5.2.1. Error codes appearing during the evaluation period are presented in section 5.1.3.

Table 1. Comments about Wellion Calla Light.

Question number that answered	**Categories (explanation) (n)**
Do you think there are any advantages with Wellion Calla Light? 75	Small amount of blood needed (24) The display is large and easy to read (22) Fast (18) User-friendly / easy (11) The instrument is small and has low weight (4) Before / after meal choice (3) Alarm (3) Sound (2) Mean values (2) Big pack (50) with test strips (1) Good absorption to the test strip (1)
Do you think there are any disadvantages with Wellion Calla Light? 82	Big (mainly thickness) and heavy (35) Test strip container (difficult to take out a single strip) (14) Test strips (difficult to see back/front/up/down, long) (13) Difficult to get saved results; to easy to end up in settings (9) No case (8)* Bad lancets with unclear marks (6) Result variations (5) No light at insertion point for test strip (4) Display; colour and too small text (except for the result) (4) Display must be read at exact right angle (4) Many parts (4) Too many functions (4) Too few functions (computer connection requested) (3) Stand-up model; wobbly (3) Sound; difficult to set and beeps to often (3) Display; too weak light (2) Design; test strip away from user (2) Control solution difficult to handle (2) Does not work at temperatures below +10°C (2) Too many steps to set before or after meal, would be good if one could be set as default (2)

All answers were in free text. The author of the report has put the comments into categories to be able to draw conclusions.

*There is a case delivered with the Wellion Calla Light meter start kit; however it was not delivered for the SKUP evaluation. Thus, this disadvantage can be ignored, but still it shows the importance of a case.

Table 2. Evaluation of the user manual.

Question number that answered (total number)	**Yes, n**	**Yes Specifications (n)**	**No, n**	**No Specifications (n)**
Have you read the manual? 93 (94)	79	-	14*	-
Have you read the whole manual? 72 (80)	44	-	28	-
Have you only read when you needed? 61 (80)	42	-	19	-
Are you happy with the explanation how to perform glucose measurements with Wellion Calla Light? 80 (80)	67	-	13	No information which end of the test strip to insert (2) Difficult to find how to collect the sample (1) The control level was said to be given on the bottle, but it was on the container of the test strips (1) No info of how often the control solution should be used (1) You are advised to contact the healthcare system if you get the result Lo, but the alarm level is too low, at this point the diabetes patient is severely affected and might not be able to look for help (1)
Do you think anything is missing in the manual? 75 (80)	16	Quick guide (3) The lancet; how to assemble and how to tighten the spring (2) What the control level should be (2) More illustrations (1) More detailed table of content (1) No information that you have to set before / after meal every time (1) No information that it is easy to contaminate the test strip while taking it out of the container (1)	59	-
In total, are you satisfied with the manual? 78 (80)	63	-	15	Difficult language / bad flow / long-winded (9) Difficult to read due to small text and green areas (5) Misspellings (3) A lot of browsing to find what you need (3) Would like results in IFCC-standard (1)

Three of the questions allowed answers in free text. The author of the report has, when possible, put the comments into categories to be able to draw conclusions.

*The diabetes patients answering No to the first question did not fill out the rest of the questionnaire.

SKUP-info

Wellion Calla Light egenmätare för glukos
Sammanfattning av en utprövning i regi av SKUP

Slutsats
Wellion Calla Light uppnådde kvalitetsmålet för imprecision när den användes av biomedicinska analytiker, men inte när den användes av diabetespatienter.
Wellion Calla Light uppnådde kvalitetsmålet för noggrannhet med alla utprövare.
Wellion Calla Light bedömdes som användarvänlig.

Wellion Calla Light är en egenmätare för övervakning av glukoskoncentrationen hos diabetespatienter. Prov tas kapillärt genom ett stick i en fingertopp, alternativt annat ställe på kroppen. Resultaten visas som koncentrationen av plasmaglukos. Wellion Calla Light tillverkas av Med Trust Handelsges.m.b.H (Österrike) och säljs i Norden av Med Trust AB (Sverige). Systemet består av Wellion Calla Light mätare och Wellion Calla Light teststickor. Det behövs 0,65 µL blod till mätningen, som tar 6 sekunder. Wellion Calla Light kan lagra 500 resultat i minnet.

Utprövningen
Detta var en brukarutprövning, där diabetespatienter fick använda utrustningen hemma i ca tre veckor och sedan ta prover själva (reella förhållanden) på ett sjukhuslaboratorium. Vid samma tillfälle tog även biomedicinska analytiker (BMA) prover (standardiserade och optimala förhållanden). Diabetespatienterna disponerade varsitt instrument, BMA disponerade två instrument. Det användes tre olika lotnummer av teststickor i utprövningen. Det togs också prov till en välkontrollerad sjukhuslaboratoriemetod, kallad jämförelsemetoden, som man jämförde Wellion Calla Light-resultaten emot. Dessutom togs venprov för att mäta hematokrit (EVF), för att undersöka om denna inverkade på resultaten från Wellion Calla Light.

Resultat
Det var 94 diabetespatienter som deltog i och fullföljde utprövningen, knappt hälften av dem fick upplärning i hur man använder Wellion Calla Light medan resten fick lära sig själva. Alla fick öva hemma i tre veckor innan provtagningen.
Imprecisionen anger hur nära resultaten från upprepade mätningar på samma prov/patient ligger varandra och mäts i CV%. Beräkning av imprecisionen gjordes i tre koncentrationsintervaller. Wellion Calla Light gav imprecisionen 3,5–5,1 CV% för BMA och 5,7–6,0 CV% för diabetespatienterna. För att uppfylla kvalitetsmålet ska CV vara under 5 %, så målet uppnåddes endast av BMA. Resultaten från Wellion Calla Light var i genomsnitt något för låga både för BMA och för diabetespatienterna. Noggrannheten mäts genom att räkna andelen resultat med acceptabel avvikelse från jämförelsemetoden. Enligt kvalitetsmålet ska minst 95 % av resultaten avvika mindre än ±0,83 mmol/L (BMA) eller mindre än ±1,00 mmol/L (patienter) vid glukoskoncentrationer <4,2 mmol/L och mindre än ±20 % (BMA) eller mindre än ±25 % (patienter) vid glukoskoncentrationer ≥4,2 mmol/L. Respektive kvalitetsmål uppfylldes både när BMA och när diabetespatienter var användare. Wellion Calla Light kunde även uppnå BMA:s kvalitetsmål när patienter var användare. Resultaten påverkades inte av vilken av de tre teststickeloterna som användes. Hematokrit hade bara en liten påverkan på Wellion Calla Light-resultaten. Wellion Calla Light bedömdes som användarvänlig av alla utprövare, men många hade synpunkter på att instrumentet var stort och på manualens språk och layout.

Tilläggsinformation
En fullständig rapport om Wellion Calla Light, SKUP/2013/87, finns på SKUP:s hemsida, www.skup.nu.

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 25 latest SKUP evaluations

Evaluation no.	Component	Instrument/test kit	Producer
SKUP/2013/87	Glucose[1]	Wellion Calla Light	Med Trust Handelsges.m.b.H
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

*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