FreeStyle *Lite*

Meter and test strips
designed for glucose self-measurement
and measurements by health care professionals
Manufactured by Abbott Diabetes Care Inc.

Report from an evaluation
organised by

SKUP

The evaluation was ordered by Abbott Norge AS

SKUP/2010/89*

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The report was written by SKUP, December 2010.
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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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A detailed list of previous SKUP evaluations is attached to this report.
Attachments with raw data are included only in the copy to Abbott Norge AS.

1 Summary

Background
FreeStyle Lite blood glucose meter and FreeStyle Lite test strips are designed for glucose self-measurements performed by diabetes patients and measurements performed by health care professionals. The meter and the test strips are produced by Abbott Diabetes Care Inc. and supplied in Scandinavia by Abbott. FreeStyle Lite was evaluated by SKUP in 2007 and was launched onto the Norwegian market in 2007. The need of a verification of the evaluation from 2007 is due to change of the coenzyme in the test strips from pyrroloquinolone quinone (PQQ) to flavin-adenine dinucleotide (FAD). In addition Abbott wanted the FreeStyle Lite test strip to be evaluated with focus on the analytical quality according to a goal suggested by NOKLUS in 2008 for glucose instruments used in primary health care centres and nursing homes. The quality goal allows a total error of 10%. The new evaluation of FreeStyle Lite was first carried out in a hospital laboratory environment during February and March 2010. The accuracy results were discussed with Abbott in a meeting in May 2010. Following the evaluation, Abbott had centred the product factory calibration after having more clinical data available. Abbott therefore asked SKUP to repeat the evaluation of FreeStyle Lite. The evaluation was repeated during October and November 2010.

The aim of this evaluation
The aim of this evaluation of FreeStyle Lite was to

- assess the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
- discuss achieved total measurement error according to a quality goal of 10%, suggested by NOKLUS as a quality goal for glucose devices used in primary health care and nursing homes
- examine the variation between three lots of test strips

Materials and methods
Capillary samples from 80 persons with diabetes and 10 healthy individuals were collected. The sampling of the diabetes patients was carried out in a medical outpatient clinic at Haraldsplass Diaconal Hospital. For each person two measurements on FreeStyle Lite were carried out, 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 FreeStyle Lite was good. The repeatability CV was <3%. The suggested quality goal for precision was obtained.
- FreeStyle Lite showed glucose results in agreement with the comparison method for glucose concentrations <7 mmol/L. Statistically, FreeStyle Lite showed significantly lower glucose results than the comparison method for glucose concentrations >7 mmol/L. For glucose concentrations between 7 and 10 mmol/L the deviation was small but statistically significant. The deviation was approximately -1,0 mmol/L for glucose concentrations above 10 mmol/L.

- The assessment of the accuracy confirmed that FreeStyle Lite glucose results were in agreement with the comparison method for glucose concentrations <7 mmol/L. For glucose concentrations above approximately 7 mmol/L most of the results on FreeStyle Lite were lower than the results from the comparison method. The quality goal proposed in ISO 15197 was fulfilled.
- The total error of FreeStyle Lite was between 4,6 and 10,4%. Assessed as a whole, the total error was below 10%. The suggested quality goal for use in Norwegian primary health care centres and nursing homes was obtained.
- Glucose results on FreeStyle Lite with two of the three lots of test strips used in this evaluation were systematic lower than the results achieved with the comparison method. The deviation was -0,35 mmol/L for lot 1071713 and -0,65 mmol/L for lot 1071910. Lot 1071901 gave glucose results in agreement with the comparison method.

Conclusion

The precision of Free Style Lite was good, with a repeatability CV <3%. For glucose concentrations above approximately 7 mmol/L, the results on FreeStyle Lite were systematically lower than the results from the designated comparison method. The bias was from -0,2 mmol/L to -1,0 mmol/L. The results fulfilled the quality goal proposed in ISO 15197. The suggested quality goal for use in Norwegian primary health care centres and nursing homes was obtained.

Comments from Abbott

There are no comments or additional information from the producer attached to the report.

2 Analytical quality goals

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. FreeStyle Lite 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 a quality goal for previous user evaluations 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 health care centres and nursing homes in Norway [7].

When Abbott turned to SKUP for an evaluation of FreeStyle Lite, the primary intention was to get an assessment of accuracy according to ISO 15197. In addition, they wanted to know if FreeStyle Lite could obtain the quality goal for the total error suggested by NOKLUS.

In this evaluation the FreeStyle Lite results will be discussed according to the following analytical quality goals:

Precision, CV<5%
Accuracy requirement from ISO 15197
Total error <10%

3 Materials and methods

3.1 FreeStyle Lite

FreeStyle Lite is a blood glucose monitoring system based on coulometric electrochemical biosensor technology. The system consists of a meter, FreeStyle Lite, and dry reagent test strips, FreeStyle Lite. The system is designed for capillary blood glucose testing performed by persons with diabetes or by health care professionals. FreeStyle Lite reports plasma glucose values. The system does not require calibration by the user. The test strips are packed in a plastic bottle with flip-top closure and desiccant. The system requires a blood volume of 0,3 µL. The blood is automatically drawn into the test strip. If the amount of blood is insufficient, more blood can be applied within 60 seconds. The result is shown in approximately 5 seconds, dependent on the glucose concentration. According to the user guide alternative site testing is possible with FreeStyle Lite. The meter has the capacity of storing 400 results in the memory. For more information about FreeStyle Lite, see attachment 1.

Test principle of FreeStyle Lite
Glucose dehydrogenase converts glucose to gluconolactone. The coenzyme in the reaction is flavin-adenine dinucleotide (FAD).

$$\text{Glucose} + \text{Mediator}_{\text{Oxidized}} \xrightarrow{\text{FAD Glukose Dehydrogenase}} \text{Gluconolactone} + \text{Mediator}_{\text{Reduced}}$$

3.1.1 Product information, FreeStyle Lite

FreeStyle Lite is manufactured by Abbott Diabetes Care Inc. Technical data from the manufacturer is shown in table 1. For names of suppliers in the Scandinavian countries and more details about FreeStyle Lite, see attachment 1.

Table 1. Technical data from the manufacturer

TECHNICAL DATA FOR FREESTYLE LITE	
Optimal operating temperature	4 – 40 °C
Humidity	5 – 90%
Sample material	Capillary whole blood
Sample volume	0,3 µL
Measuring time	Approximately 5 seconds
Measuring range	1,1 – 27,8 mmol/L
Hematocrit	Not affected by hematocrit values from 15 to 65 %
Storage capacity	400 test results
Electrical power source	One 3-volt lithium battery (CR2032)
Operating time	Approximately 500 tests
Dimensions	40 mm x 74 mm x 17 mm
Weight	28,3 – 31,2 g (including the battery)

FreeStyle Lite serial no
FreeStyle Lite with serial number DCMP116-N5150 was used throughout the evaluation.

FreeStyle Lite test strips

Lot 1071713	Expiry 2012-02
Lot 1071901	Expiry 2012-02
Lot 1071910	Expiry 2012-02

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

Control High

Lot 0FN11	Expiry 2011-12	Target value: 13,8 – 20,6 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) in 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 with 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.

3.2.1 Product information, the comparison method

Designated comparison method on Architect ci8200
Architect ci8200 is manufactured by Abbott Laboratories. Serial no. C800890

Glucose reagent
Lot 38367UQ03 Expiry 2011-03-31

Calibrator
Multiconstituent Calibrator
Lot 77118M200 Expiry 2011-06-30 Reference value, cal 1 = 5,27 mmol/L
Reference value, cal 2 = 24,20 mmol/L

Internal quality controls
Autonorm Human Liquid 1 and 2, SERO AS
Liquid 1: Value = 3,34 ±0,20 mmol/L Lot 908395 Expiry 2011-10-30
Liquid 2: Value = 14,99 ±0,75 mmol/L Lot 903131 Expiry 2011-05-31

External Quality controls, SERO AS
Reference value from Laboratory for Analytical Chemistry, University of Gent, Belgium; ID-GCMS method
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*
* Internal testing at NOKLUS on the 27th of October 2010 documented that the controls are still stable

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 7074501 Expiry 2010-10

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

3.3 Planning of the evaluation

Background for the evaluation
FreeStyle Lite is a blood glucose monitoring system designed for capillary blood testing performed by diabetes patients or by health care professionals. The FreeStyle Lite-system is produced by Abbott Diabetes Care Inc. and supplied in Scandinavia by Abbott. FreeStyle Lite was evaluated by SKUP in 2007 and launched onto the Norwegian market in 2007. The need for a verification of the evaluation from 2007 is due to change of the coenzyme in the test strips from pyrroloquinolone quinone (PQQ) to flavin-adenine dinucleotide (FAD). In addition Abbott wanted the test strip to be evaluated with focus on the analytical quality of FreeStyle Lite according to a quality goal suggested by NOKLUS in 2008. This quality goal allows a total error up to 10%, and was suggested for glucose instruments used in primary health care centres and nursing homes [7]. During February and March 2010 SKUP performed an evaluation of the new test strip. The results fulfilled the quality goal proposed in ISO 15197 but did not meet the more narrow quality goal suggested by NOKLUS. The accuracy results were discussed with Abbott in a meeting in May 2010. Following the evaluation, Abbott had centred the product factory calibration after having more clinical data available. Abbott wanted SKUP to repeat the evaluation of FreeStyle Lite to bring up to date the documentation of the accuracy. The evaluation was repeated during October and November 2010. For the results from the evaluation in February-March 2010, see attachment 2.

Inquiry about an evaluation
Ingrid Stiff Aamlid, Abbott Norge AS, applied to SKUP in July 2010 for a repeated evaluation of FreeStyle Lite glucose meter with FreeStyle Lite test strips. SKUP accepted to carry out this evaluation on behalf of Abbott.

Agreements, contract, and protocol
The arrangement for the first evaluation was agreed upon in November 2009 and the evaluation contract was signed in February 2010. SKUP made a proposal for the evaluation protocol in December 2009. The protocol was approved in December 2009. In agreement with Abbott the same protocol was used for this new evaluation. The new evaluation of FreeStyle Lite was carried out in a hospital laboratory environment during October and November 2010.

Preparations and training program
The preparations for the evaluation started in August 2010. Ingrid S. Aamlid sent the meters and the new test strips for the evaluation to SKUP. Marianne Risa and Grete Monsen were familiar with the device from the previous evaluation.

Collections of samples
Capillary samples from 80 persons with diabetes and 10 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 FreeStyle Lite were carried out for all the 90 persons, and a capillary sample was directly prepared for measurement with the designated comparison method. Three different lots of test strips were used.

3.3.1 Evaluation sites and persons involved

The evaluation took place in a medical outpatient clinic at Haraldsplass Diaconal Hospital (HDH) in Bergen, Norway. Marianne Risa and Grete Monsen, SKUP/NOKLUS, was responsible for the practical work, and collected the capillary samples for the evaluation. The biomedical laboratory scientist Grethe Kalleklev was given the responsibility for the practical work with the comparison method. The statistical calculations and report writing were done by Marianne Risa, SKUP/NOKLUS.

3.4 The evaluation procedure

3.4.1 The model for the evaluation of FreeStyle Lite

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 a self-monitoring blood glucose device in principle follows the guidelines in the book, but the evaluation in primary health care is replaced by a user-evaluation conducted among diabetes patients, based on the model worked out by the NOKLUS-project "*Diabetes-Self-measurements*" [11]. This model has become basis for the quality specifications used when The Norwegian Labour and Welfare Organisation (NAV) decides whether or not to give reimbursement for glucose test strips [12]. The evaluation model has been used by SKUP since 2002, and has recently been evaluated and discussed in an article presenting the results from nine of the SKUP evaluations [13]. The original evaluation of FreeStyle Lite in 2007 included an assessment of the analytical quality achieved by the intended user, an evaluation of user-friendliness of FreeStyle Lite among diabetes patients and an examination of hematocrit interference. These aspects are therefore not included in this evaluation. For results from the evaluation in 2007, see the report at www.skup.nu (SKUP/07/64).

This evaluation of FreeStyle Lite 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

3.4.2 Evaluation procedure in the hospital laboratory (standardised and optimal conditions)

Blood sampling

The samples for FreeStyle Lite, as well as the samples for the comparison method, were collected from finger capillaries. The sampling sequence was started with duplicate measurements on FreeStyle Lite, immediately followed by a sample for the comparison method. The FreeStyle Lite 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 during two following days in November 2010. The samples were thawed at NOKLUS just before they were analysed.

3.4.3 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

3.4.4 Statistical outliers

Possible statistical 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 in this report 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 [14].

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 [15] 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 [16, 17]:

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

$$\text{Total error} = |\text{bias}| + z \cdot \sigma$$

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 [18] 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 result is excluded:

- ID 44 was segregated as a statistical outlier according to Burnett's model in the calculation of lot variation of FreeStyle Lite. The sample had a glucose value of approximately 25 mmol/L. After closer inspection of the duplicate results on FreeStyle Lite, the deviation is clearly not due to random errors because the two paired measurements for ID 44 agree. The deviating result is a systematic error, and consequently not a true outlier according to the definition

5.2 Analytical quality of the designated comparison method

5.2.1 Internal quality control

In the 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 in the evaluation period (two days) were inside the limits of the target values for the controls.

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 these duplicate results. The repeatability of the comparison method is shown in table 2.
The raw data is shown in attachment 3.

Table 2. 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	32	0	5,8	0,6 (0,5 – 0,8)
7 – 10	27	0	8,8	0,7 (0,5 – 0,9)
≥10	31	0	16,1	0,6 (0,5 – 0,8)

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

Discussion

The repeatability CV was 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 3.

Table 3. 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	08.11.10	**1,836**	5	1,81	
	09.11.10	(1,809 — 1,863)	5	1,81	
	Total		**10**	**1,81**	**-1,3**
Level 2	08.11.10	**4,194**	5	4,24	
	09.11.10	(4,135 — 4,253)	5	4,22	
	Total		**10**	**4,23**	**+0,8**
Level 3	08.11.10	**6,575**	5	6,58	
	09.11.10	(6,481 — 6,669)	5	6,54	
	Total		**10**	**6,56**	**-0,2**
Level 4	08.11.10	**16,35**	5	16,61	
	09.11.10	(16,15 — 16,55)	5	16,48	
	Total		**10**	**16,54**	**+1,2**

Discussion
Table 3 shows that the agreement between the comparison method and the NIST-standards was good.

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 4.

Table 4. 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	08.11.10	4,78	5	4,79	
	09.11.10		5	4,74	
	Total		**10**	**4,76**	**-0,4**
TM Gluc L-2	08.11.10	11,80	5	11,97	
	09.11.10		5	11,94	
	Total		**10**	**11,95**	**+1,3**

Discussion
The trueness of the comparison method was good.

5.3 Analytical quality of FreeStyle Lite used in a hospital laboratory

5.3.1 Internal quality control

The FreeStyle Lite meter was checked with the manufacturer's control solution every day it was in use. All the results were within the control range. The raw data from the measurements with the internal quality control is shown in attachment 4.

5.3.2 Comparison of the 1st and 2nd measurements

Two capillary samples were taken on each person for measurements on FreeStyle Lite. The results are checked to meet the assumption in 4.2.2. Table 5 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 5. Comparison of the 1st and 2nd measurements on FreeStyle Lite

FreeStyle Lite 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	5,7	5,7	0,03	-0,05 – (+0,10)
7 – 10	29	8,4	8,5	0,09	0,00 – (+0,18)
≥10	31	15,2	15,2	0,00	-0,22 – (+0,22)

5.3.3 The precision of FreeStyle Lite

Repeatability under standardised and optimal measuring conditions in a hospital laboratory
The repeatability obtained with capillary blood samples is shown in table 6. The results are sorted and divided into three glucose levels according to the first measurement on FreeStyle Lite. The raw data is shown in attachment 5.

Table 6. Repeatability. Results achieved with capillary blood samples measured under standardised and optimal conditions

Glucose level (mmol/L)	n*	Outliers	Mean glucose (mmol/L), FreeStyle Lite	CV% (95% confidence interval)
<7	30	0	5,7	2,5 (2,0 – 3,3)
7 – 10	29	0	8,5	2,1 (1,7 – 2,8)
≥10	31	0	15,2	2,7 (2,2 – 3,6)

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

Reproducibility with Internal Quality Control Solution
The reproducibility was assessed with FreeStyle Control High. 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 FreeStyle Lite during the whole evaluation period. The reproducibility of FreeStyle Lite is shown in table 7.

Table 7. Reproducibility. Results achieved with FreeStyle Control High

FreeStyle Control High	n*	Outliers	Target value glucose (mmol/L)	Mean value glucose (mmol/L)	CV% (95% confidence interval)
Stand. and opt. conditions	18	0	13,8 – 20,6	16,6	2,1 (1,6 – 3,2)

*The given numbers of results (n) are 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 results in table 6 were achieved under standardised and optimal conditions. No results were segregated as statistical outliers according to Burnett. The repeatability CV was <3%. The precision was good. The recommended quality goal for precision is obtained. The reproducibility CV on FreeStyle Lite was approximately 2% when measured with FreeStyle Control High (table 7).

5.3.4 The trueness of FreeStyle Lite

The trueness of FreeStyle Lite is calculated from the results achieved by the biomedical laboratory scientist in the hospital laboratory. The results are sorted and divided into three glucose levels according to the mean measurements on the comparison method. The measurements on FreeStyle Lite were performed with three lots of FreeStyle Lite test strips. The results are shown in table 8.

Table 8. Mean difference between FreeStyle Lite and the comparison method

	Glucose <7 mmol/L		**Glucose 7 – 10 mmol/L**		**Glucose ≥10 mmol/L**	
	The comparison method	**FreeStyle Lite**	**The comparison method**	**FreeStyle Lite**	**The comparison method**	**FreeStyle Lite**
Mean glucose (mmol/L)	5,80	5,77	8,71	8,50	16,14	15,19
Mean deviation from the comparison method, mmol/L (95% CI)	-0,03 ((-0,12) — (+0,06))		-0,20 ((-0,33) — (-0,08))		-0,95 ((-1,22) — (-0,68))	
n*	31		28		31	
Outliers	0		0		0	

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

Discussion

FreeStyle Lite showed glucose results in agreement with the comparison method for glucose concentrations <7 mmol/L. Statistically, FreeStyle Lite showed significantly lower glucose results than the comparison method for glucose concentrations >7 mmol/L. For glucose concentrations between 7 and 10 mmol/L the deviation was small but statistically significant. The deviation was approximately -1,0 mmol/L for glucose concentrations above 10 mmol/L.

5.3.5 The accuracy of FreeStyle Lite

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

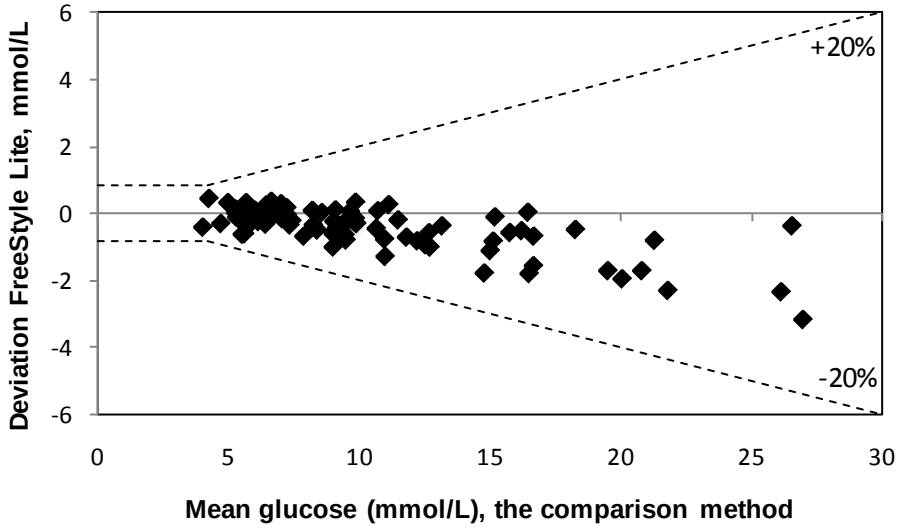

Figure 1. Accuracy. FreeStyle Lite with three lots of test strips under standardised and optimal measuring conditions. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on FreeStyle Lite and the mean value of the duplicate results on the comparison method. Lines represent quality goal limits set in ISO 15197 (±20%). n = 90

Discussion

Figure 1 confirms that FreeStyle Lite glucose results were in agreement with the comparison method for glucose concentrations below 7 mmol/L. For glucose concentrations above approximately 7 mmol/L most of the results on FreeStyle Lite were lower than the results from the comparison method. None of the 90 results were outside the accuracy quality limits. The quality goal proposed in ISO 15197 was fulfilled.

5.3.6 The total error of FreeStyle Lite

The total error of FreeStyle Lite was calculated as described in section 4.2.5.
The total error of FreeStyle Lite is shown in table 9.

Table 9. The total error of FreeStyle Lite

Glucose	**<7 mmol/L**	**7 – 10 mmol/L**	**≥10 mmol/L**
CV%	2,5	2,1	2,7
Bias, mmol/L	-0,03	-0,20	-0,95
Bias, %	-0,5	-2,3	-5,9
TE (%) = |bias| + 1,65 · CV	**4,6**	**5,8**	**10,4**

Discussion
The total error of FreeStyle Lite was between 4,6 and 10,4%, depending on the glucose concentration. Assessed as a whole, the total error was below 10%, and the suggested quality goal for use in Norwegian primary health care centres and nursing homes was obtained.

5.3.7 Variation between three lots of test strips

The measurements on FreeStyle Lite were performed with three different lots of test strips. The three lots were not used for glucose measurement on the same diabetes patients. Obviously, the mean glucose concentration in the three groups 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. The deviation for each of the three lots from the comparison method was calculated (paired t-test), as an indirect measure of the lot variation. 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 must be calculated for the entire glucose concentration range.
The results are shown in table 10.

Table 10. Variation between three lots of test strips

	The comparison method	**FreeStyle Lite Lot 1071713**	**The comparison method**	**FreeStyle Lite Lot 1071901**	**The comparison method**	**FreeStyle Lite Lot 1071910**
Mean glucose (mmol/L)	10,53	10,18	8,21	8,10	11,44	10,79
Mean deviation from the comparison method, mmol/L (95% CI)	-0,35 ((-0,55) — (-0,15))		-0,11 ((-0,27) — (+0,06))		-0,65 ((-0,88) — (-0,41))	
n*	30		30		30	
Outliers	0		1**		0	

* The given numbers of results (n) are counted before exclusion of outliers
** One outliers (ID 44) according to Burnett's model

Comment
ID 44 with lot 1071901 was pointed out as a statistical outlier according to Burnett's model. The sample had a glucose value of approximately 25 mmol/L. After closer inspection of the duplicate results on FreeStyle Lite, the deviation is clearly not due to random errors because the two paired measurements for ID 44 agree. The deviating result is a systematic error, and consequently not a true outlier according to the definition. The mean deviation for lot 1071901 with this result included is -0,20 mmol/L.

Discussion
Statistically, glucose results on FreeStyle Lite with two of the three lots of test strips used in this evaluation were significantly lower than the results achieved with the comparison method. The deviation was -0,35 mmol/L for lot 1071713 and -0,65 mmol/L for lot 1071910. Lot 1071901 gave glucose results in agreement with the comparison method.

5.3.8 Effect of hematocrit

The effect of hematocrit was evaluated by SKUP in 2007. See results at www.skup.nu, report SKUP/2007/64.

5.4 Evaluation of user-friendliness

The user-friendliness of FreeStyle Lite was evaluated by SKUP in 2007. See results at www.skup.nu, report SKUP/2007/64.

6 References

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Attachments

1. Facts about the instrument
2. Results from the evaluation in February-March 2010
3. Raw data glucose, results from the comparison method
4. Raw data glucose, internal quality control, FreeStyle Lite
5. Raw data glucose, FreeStyle Lite results under standardised and optimal conditions
6. "SKUP-info". Summary for primary health care (in Norwegian)
7. List of previous SKUP evaluations

Attachments with raw data are included only in the report to Abbott Norge AS.

Facts about the instrument

Parts of this form are filled in by Abbott.

a) Name of the instrument	***FreeStyle Lite***

Physical dimensions	*40 mm x 74 mm x 17 mm*
Manufacturer (with address)	*Abbott Diabetes Care Inc.* *1360 South Loop Road* *Alameda* *CA 94502 USA*
Distributor (with address)	*Denmark:* *Abbott Laboratories A/S* *Abbott Diabetes Care* *Emdrupvej 28 C* *2100 København Ø* *www.medisense.dk*
	Norway: *Abbott Norge AS* *Abbott Diabetes Care* *Pb 1, 1330 Fornebu* *www.abbottdiabetescare.no*
	Sweden: *Abbott Scandinavia AB* *Abbott Diabetes Care* *BOX 509* *169 29 Solna* *www.abbott-diabetes.se*

b) Analysis menu, sample materials and sample volume

Component	Sample materials	Sample volume
Glucose	*Whole blood*	*0,3 µL*

c) Analysis principles (reference to the instruction manual)

Parameter	Principle
Glucose	*Coulometri* *GDH/FAD*

d) Measuring range

Component	Measuring range	Unit
	1,1-27,8	*mmol/L*

e) Measuring time per component (precisely stated)

Component	Pre-analytic measuring time (with an explanation)	Measuring time
Glucose	*No pre-analysis time, because system starts with insertion of strip*	*About 5 second*

f) Calibration

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

g) Recommended maintenance

Maintenance	How often?
Battery	*When battery icon is shown in display*
Cleaning	*When needed*

h) Control materials

Is control material available (from the producer or other companies)?	*Yes, high and low*

i) Marketing

In which country is the analyser marketed?	*Nordics, Europe*
When did the analyser first appear on the Scandinavian market?	—
When did the analyser receive CE approval?	—

j) Language

In which Scandinavian language is the manual?	*Norwegian, Danish, Swedish, Finnish*

k) Memory

What is the storage capacity of the analyser and what is stored?	*Up to 400*
Is it possible to identify patients?	*No*
If yes, describe this:	

a) Name of the instrument	***FreeStyle Lite***

l) Power supply

Electric network connection	*No*
Battery	*Yes*
If yes, which type and how many batteries	*One 3-volt lithium battery (CR2032)*

m) Electronic communication

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

n) Standards and controls

	Standard	Control
Name		*FreeStyle Control high and low*
Volume		*3 mL*
Shelf life unopened		*Until Exp date*
Shelf life opened		*90 days*
Any comments:		

o) Reagents/Test strips/Test cassettes

Component	Time and temperature, unopened	Time and temperature, opened
FreeStyle Lite test strip	*4-30 degrees*	*Use immediately*

p) Additional information

Results from the evaluation in February-March 2010

All the results in this attachment are from the evaluation of FreeStyle Lite in February-March 2010.

The trueness of FreeStyle Lite

The trueness of FreeStyle Lite was calculated from the results achieved by the biomedical laboratory scientist in the hospital laboratory. The results are sorted and divided into three glucose levels according to the mean measurements on the comparison method. The measurements on FreeStyle Lite were performed with three lots of FreeStyle Lite test strips. The results are shown in table 1.

Table 1. Mean difference between FreeStyle Lite and the comparison method

	Glucose <7 mmol/L		**Glucose 7 – 10 mmol/L**		**Glucose ≥10 mmol/L**	
	The comparison method	**FreeStyle Lite**	**The comparison method**	**FreeStyle Lite**	**The comparison method**	**FreeStyle Lite**
Mean glucose (mmol/L)	5,85	5,46	8,42	7,86	14,02	12,58
Mean deviation from the comparison method, mmol/L (95% CI)	-0,39 ((-0,46) — (-0,32))		-0,56 ((-0,68) — (-0,44))		-1,44 ((-1,66) — (-1,22))	
n*	23		23		41	
Outliers	0		0		2**	

* The given numbers of results (n) are counted before exclusion of outliers
** Two outliers (ID 30 and ID 31) according to Burnett's model

Comments
ID 30 and ID 31 were pointed out as outliers according to Burnett's model at the glucose level ≥10 mmol/L. The samples were segregated in two truncations. Both samples had a glucose value >20 mmol/L. After closer inspection of the results, they are clearly not due to random errors. The two paired measurements for ID 30 and ID 31 agree. The two deviating results are systematic errors, and consequently not true outliers according to the definition. The mean deviation for the glucose level ≥10 mmol/L with these two samples included is -1,61 mmol/L.

Discussion
FreeStyle Lite showed significantly lower glucose values than the comparison method. The deviation was -0,4 mmol/L for glucose concentrations below 7 mmol/L, -0,6 mmol/L for glucose concentrations between 7 and 10 mmol/L and -1,4 mmol/L for glucose concentrations above 10 mmol/L.

The accuracy of FreeStyle Lite

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

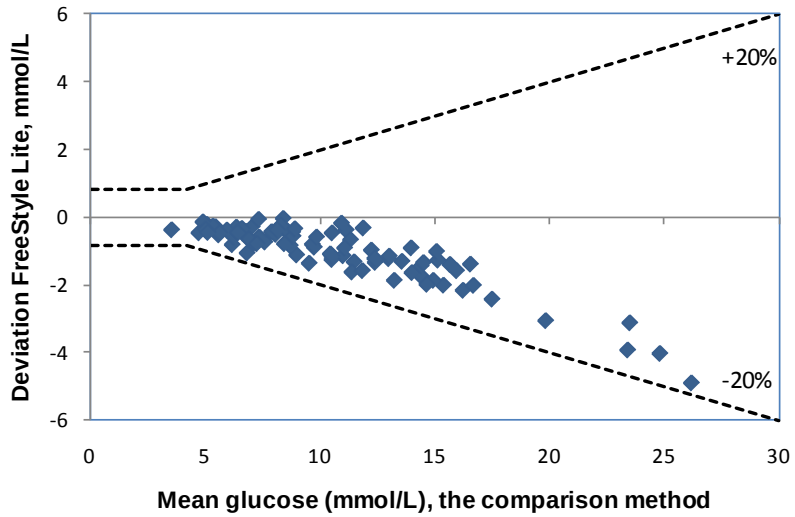

Figure 1. Accuracy. FreeStyle Lite with three lots of test strips under standardised and optimal measuring conditions. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on FreeStyle Lite and the mean value of the duplicate results on the comparison method. Lines represent quality goal limits set in ISO 15197 (±20%). n = 87

Discussion

Figure 1 illustrates that the glucose results on FreeStyle Lite were systematic lower than the results from the comparison method. None of the 87 results were outside the accuracy quality limits. The quality goal proposed in ISO 15197 was fulfilled.

The total error of FreeStyle Lite

The total error of FreeStyle Lite was calculated as described in section 4.2.5 in the report SKUP/2010/89*. The total error of FreeStyle Lite is shown in table 2.

Table 2. The total error of FreeStyle Lite

Glucose	**<7 mmol/L**	**7 – 10 mmol/L**	**≥10 mmol/L**
CV%	2,9	1,7	2,6
Bias, mmol/L	-0,39	-0,56	-1,44*
Bias, %	-6,7	-6,7	-10,3
TE (%) = |bias| + 1,65 · CV	**11,5**	**9,5**	**14,6**

* Two outliers (ID 30 and ID 31) according to Burnett's model

Comments
ID 30 and ID 31 were pointed out as outliers according to Burnett's model at the glucose level ≥10 mmol/L in the calculation of bias. The samples were segregated in two truncations. For further explanation, please see comments under table 1. TE (%) for glucose level ≥10 mmol/L with these two samples included is 15,3%.

Discussion
The total error of FreeStyle Lite was between 9,5 and 14,6%, 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.

Raw data glucose, internal quality control, FreeStyle Lite

FreeStyle Control	Lot-no	Expiry	Glucose level, mmol/L
High	0FN11	2011-12	13,8 – 20,6

FreeStyle Control High, analysed on the biomedical laboratory scientist's meter

Date	Lot 1071713 glucose, mmol/L	Lot 1071901 glucose, mmol/L	Lot 1071910 glucose, mmol/L
05.10.2010	17,0		
06.10.2010	16,5		
07.10.2010	16,2		
12.10.2010	16,0		
13.10.2010		16,9	
14.10.2010		17,1	
19.10.2010		17,2	
20.10.2010			16,7
21.10.2010			16,6
25.10.2010			16,6
26.10.2010			16,1
27.10.2010	16,8		
28.10.2010			16,4
01.11.2010			16,6
02.11.2010		16,2	
03.11.2010	16,4		
04.11.2010	16,2	16,6	

SKUP-info

FreeStyle Lite blodsukkerapparat fra Abbott Diabetes Care Inc.
Sammendrag fra en utprøving i regi av SKUP

Konklusjon
Presisjonen på FreeStyle Lite var god med en CV på < 3 %. Resultatene på FreeStyle Lite samsvarte med resultatene på sammenligningsmetoden for glukosekonsentrasjoner < 7 mmol/L. For glukosekonsentrasjoner > 7 mmol/L var resultatene på FreeStyle Lite systematisk lavere enn resultatene på sammenligningsmetoden. Internasjonale kvalitetskrav fra ISO 15197, med et avvik mindre enn ± 20 % fra en anerkjent glukosemetode, ble oppfylt. Den totale målefeil var mellom 4,6 og 10,4 %.

FreeStyle Lite er beregnet til måling av blodsukker i kapillærblod, både av personer med diabetes og av helsepersonell. Systemet er produsert av Abbott Diabetes Care Inc. og består av FreeStyle Lite apparat og FreeStyle Lite teststrimmel. Apparatet trenger ikke kodes. Apparatet slås automatisk på når en teststrimmel settes inn. Det kreves 0,3 µL blod til hver måling. Målingen tar ca. 5 sekunder avhengig av glukosekonsentrasjon. FreeStyle Lite har minnekapasitet til å lagre 400 resultat.

Utprøvingen
SKUP utførte en brukerutprøving av FreeStyle Lite i 2007. Denne utprøvingen måtte etterprøves i 2010 pga. endringer i reagenset. En ny utprøving ble utført under optimale betingelser av laboratorieutdannet personale og innbefattet ikke brukere. Det ble tatt prøver av 80 personer med diabetes og av 10 personer uten diabetes.

Resultater
Presisjonen på FreeStyle Lite var god med en CV på < 3 %. Resultatene på FreeStyle Lite samsvarte med resultatene på sammenligningsmetoden for glukosekonsentrasjoner < 7 mmol/L.For glukosekonsentrasjoner > 7 mmol/L var resultatene på FreeStyle Lite systematisk lavere enn resultatene på sammenligningsmetoden. Avviket var fra -0,2 mmol/L til -1,0 mmol/L. Kvalitetsmålet fra ISO 15197, som tillater avvik opp til ± 20 % fra en anerkjent metode for måling av glukose, ble oppfylt. Den totale målefeil var mellom 4,6 og 10,4 %.

Tilleggsinformasjon
En fullstendig rapport fra den nye utprøvingen av FreeStyle Lite, SKUP/2010/89*, og fra utprøvingen utført i 2007, SKUP/2007/64, finnes på SKUPs nettside, www.skup.nu. Opplysninger om pris fås ved å kontakte leverandør. Laboratoriekonsulentene i NOKLUS kan gi nyttige råd om analysering av glukose på legekontor. De kan også orientere om det som finnes av alternative metoder/utstyr.

List of previous SKUP evaluations

Summaries and complete reports from the evaluations are found at www.skup.nu

SKUP evaluations from number 51 and further

Evaluation no.	Component	Instrument/testkit	Producer
SKUP/2010/89*	Glucose	FreeStyle Lite	Abbott Laboratories
SKUP/2010/82*	Glucose, protein, blood, leukocytes, nitrite	Medi-Test URYXXON Stick 10 urine test strip and URYXXON Relax urine analyser	Macherey-Nagel GmBH & Co. KG
SKUP/2010/81*	Glucose	mylife Pura	Bionime Corporation
SKUP/2010/79*	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-Chek 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 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	QuickVue u-hCG	Quidel Corporation
SKUP/2004/34*	u-hCG	RapidVue 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.