CONTOUR® NEXT and CONTOUR® XT

Test strips and meter designed for
self-monitoring of blood glucose

Report from the evaluation SKUP/2012/94

The evaluation was organised by SKUP

at the request of Bayer AS in Norway

SKUP in Norway, NOKLUS, Box 6165, 5892 Bergen, Phone +47 55 97 95 02, www.SKUP.nu

The report was written by SKUP, March 2012.
Main author was Camilla Eide Jacobsen, SKUP in Norway.

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Attachments with raw data are included only in the copy to Bayer AS.

1. Summary

Background
Contour XT is a new blood glucose meter produced by Bayer HealthCare.

The aim of the evaluation was to
- assess the analytical quality under standardised and optimal conditions (hospital environment)
- assess the analytical quality by the intended users
- compare the analytical quality among diabetes patients with and without a training program
- examine the variation between three lots of test strips
- examine if haematocrit interferes with the measurements
- evaluate the user-friendliness of Contour XT and the user guide

Materials and methods
A total of 83 diabetes patients took part in the evaluation. The participants were randomly divided into two groups. The "training group" received personal training in how to use the device, and the "mail group" received the device and instructions by mail. Both groups used the device for approximately two weeks at home, before they attended for an end-meeting.

Results
- The quality goal for imprecision was fulfilled. The repeatability CV obtained by the biomedical laboratory scientists was between 1,8 and 3,3%. The repeatability CV obtained by the diabetes patients was between 1,5 and 4,2%. The diabetes patients performed the measurements with approximately the same good precision, regardless of being trained or not
- Contour XT showed glucose results in agreement with the comparison method for glucose concentrations ≥10 mmol/L. For glucose concentrations <10 mmol/L Contour XT gave systematically higher results than the comparison method. The bias was small (approximately 0,25 mmol/L), but statistically significant
- The accuracy of Contour XT was good. 100% of the results obtained by the biomedical laboratory scientists as well as by the diabetes patients were inside the accuracy quality limits in ISO 15197 (2003)
- All three lots of test strips used in the evaluation gave significantly higher glucose results than the results achieved with the comparison method. The deviation was small, but statistically significant
- Glucose measurements on Contour XT were not affected by haematocrit (range 34 – 49%)
- The diabetes patients were satisfied with the meter, the test strips and the user guide
- The fraction of technical errors was <2%, and the quality goal was fulfilled

Conclusion
The precision and the accuracy were good. The accuracy quality goal set in ISO 15197 was fulfilled. The user-friendliness of Contour XT and the user guide were assessed as satisfactory.

Comments from Bayer
A letter with comments from Bayer AS is attached to the report.

2. Abbreviations

ADA	American Diabetes Association
BLS	Biomedical Laboratory Scientist
CI	Confidence Interval
C-NPU	Committee on Nomenclature, Properties and Units
CV	Coefficient of Variation
DAK-E	Danish Quality Unit of General Practice
DEKS	Danish Institute of External Quality Assurance for Laboratories in Health Care
EQA	External Quality Assessment
EQUALIS	External quality assurance in laboratory medicine in Sweden
FAD	Flavin-Adenine Dinucleotide
GDH	Glucose Dehydrogenase
HDH	Haraldsplass Diaconal Hospital
IFCC	The International Federation of Clinical Chemistry and Laboratory Medicine
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
NIST	National Institute of Standards & Technology
NOKLUS	Norwegian Quality Improvement of Primary Care Laboratories
SKUP	Scandinavian evaluation of laboratory equipment for primary health care
SRM	Standard Reference Material

3. Quality goals

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.

3.1. Analytical quality goals

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

Precision

According to the American Diabetes Association (ADA) the imprecision (CV) of new glucose devices must be less than 5% [1]. Other authors also recommend an imprecision of 5% or less [2,3].

Accuracy

The ISO-standard 15197:2003, In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus [4], 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 NOKLUS:

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.

Recent evaluations performed by SKUP [5,6], show that the diabetes patients also can achieve the quality goals set by ISO 15197.

Quality goals in Denmark

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

Other analytical quality limits

The number of results within fixed quality limits (without cut offs) of ±15% and ±10% will be registered under the summarising of the accuracy of Contour XT. These results are also of interest, but will not be further assessed in this report.

3.2. Evaluation of user-friendliness

The evaluation of user-friendliness is carried out by asking the diabetes patients (intended users) to fill in two questionnaires. The first questionnaire deals with the user-friendliness of Contour XT; the second covers the user guide. See section 5.5.

General practitioners in Denmark mean that the fraction of "tests wasted" caused by technical errors should not exceed 2%.

3.3. SKUP´s quality goals in this evaluation

SKUP has decided to assess the results from the evaluation of Contour XT against the following quality goals:

Repeatability CV	<5%
Accuracy according to ISO 15197	<±20%
Accuracy according to goal modified by NOKLUS.....	<±25%
Fraction of technical errors	<2%

3.4. Principles for the assessments

The rating of analytical quality in SKUPs evaluations:

Good	The achieved result is within the quality goal
Poor	The lower CI limit of the achieved result is outside the quality goal

The diabetes patients register the fraction of error codes and technical errors during the evaluation.

4. Materials and methods

4.1. Definition of the measurand

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and International Union of Pure and Applied Chemistry (IUPAC) work in a joint Committee on Nomenclature, Properties and Units (C-NPU). The descriptions of clinical laboratory tests are listed in the ”NPU database” [7]. In the database the recommended name is given for the measurand (Plasma (capillary Blood)—Glucose) together with which unit the result should be reported in (mmol/L). In this report the term glucose will be used for the measurand.

4.2. The evaluated measurement system; Contour XT

Contour XT is a blood glucose monitoring system based on biosensor technology and uses the enzyme Flavin-Adenine Dinucleotide Glucose Dehydogenase (FAD-GDH). The system consists of a Contour XT meter and Contour Next dry reagent test strips. The system is designed for glucose testing performed by persons with diabetes or by health care professionals. Contour XT reports plasma glucose values. The system is automatically calibrated when a test strip is inserted.

A summary of technical data from the manufacturer is shown in table 1. For name of the manufacturer, the suppliers in the Scandinavian countries and more technical data about Contour XT, see attachment 1. For product information, see attachment 2.

Table 1. Technical data from the manufacturer

Technical data for Contour XT	
Sample material	Capillary blood
Sample volume	0,6 µL
Measuring time	5 seconds
Measuring range	0,6 – 33,3 mmol/L
Tolerated haematocrit range	0 – 70%
Memory capacity	480 results
Electrical power supply	Two 3-volt lithium battery (DL2032 or CR2032)

4.3. The selected comparison method

The selected 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.

4.3.1. The selected comparison method in this evaluation

The selected comparison method in this evaluation was 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). The method is a photometric hexokinase method. The method is implemented on Architect *ci*8200 System from Abbott Laboratories. The Laboratory can document good analytical quality of the method through participation in an external analytical quality assessment program.

4.3.2. Verification of the analytical quality of the comparison method

Precision

The second capillary sample for the comparison method will be analysed in duplicate. The repeatability will be estimated with use of these results.

Trueness

To document the trueness of the comparison method, the standard reference material (SRM 965b) from National Institute of Standards & Technology, NIST, was used [8]. The SRM 965b consists of ampoules with human serum with certified concentrations of glucose at four levels, with given uncertainties.

Internal quality control

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

External quality control

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 [9]. The controls are used in NOKLUS's External Quality Assessment (EQA) program.

4.4. The evaluation

4.4.1. Planning of the evaluation

Background for the evaluation

The new glucose monitoring system from Bayer, Contour XT meter with Contour Next test strips, has not been launched onto the Scandinavian market yet. The Contour Next test strip has a new electron mediator and the meter has a new compensation algorithm for electronic noise.

Inquiry about an evaluation

Frank Young-Halvorsen, Bayer AS, applied to SKUP in June 2011 for an evaluation of Contour XT meter with Contour Next test strips. SKUP accepted to carry out this evaluation.

Protocol, arrangements and contract

The protocol for the evaluation was approved in November 2011. Simultaneously, Bayer AS and SKUP signed the contract. The laboratory at HDH in Bergen agreed to analyse the samples for the comparison method.

Preparations and training program

Preparations for the evaluation started in September 2011. The biomedical laboratory scientists (BLS) Karina Hill Bjerkestrand and Randi Rekkebo, NOKLUS, were hired to do the practical work with the evaluation. They were educated in the evaluation procedures by SKUP. In October 2011, Bjørn-Erik Bjerke, Bayer, demonstrated Contour XT for the BLS. Training for approximately three hours was given.

The meters and the test strips for the evaluation were received in October 2011. Shortly after, the equipment was prepared for distribution among the diabetes patients. The practical work with the evaluation was carried out between November 2011 and January 2012.

4.4.2. Evaluation sites and persons involved

Persons responsible for the evaluation are shown in table 2.

Table 2. Persons responsible for various parts of the evaluation

Name	Title	Place	Responsibility
Frank Young-Halvorsen	Country Manager Diabetes Care Norway	Bayer AS	Ordered the evaluation
Grete Monsen	BLS Organisation Secretary	SKUP/NOKLUS	Responsible for the evaluation
Camilla Eide Jacobsen	BLS Master of Science	SKUP/NOKLUS	Statistical calculations Author of the report
Marianne Risa	BLS	SKUP/NOKLUS	Preparations for the evaluation
Randi Rekkebo	BLS	NOKLUS, Levanger Hospital	Practical work with the evaluation
Karina H. Bjerkestrand	BLS	NOKLUS, St. Olavs Hospital	Practical work with the evaluation
Grete H. Solsvik	BLS	Laboratory at HDH	Practical work with the comparison method

4.4.3. The evaluation model

The SKUP evaluation

SKUP evaluations for quantitative methods 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]. In principle, an evaluation of a self-monitoring blood glucose device 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 a model worked out by the NOKLUS-project "*Diabetes-Self-measurements*" [11].

The model for the evaluation of Contour XT

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

Diabetes patients performed the other part of the evaluation in order to determine the analytical quality of Contour XT by the users. The diabetes patients were randomly divided into two groups. One group received personal training in how to use the device, hereafter called the "training group". The other group received the device 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 1.

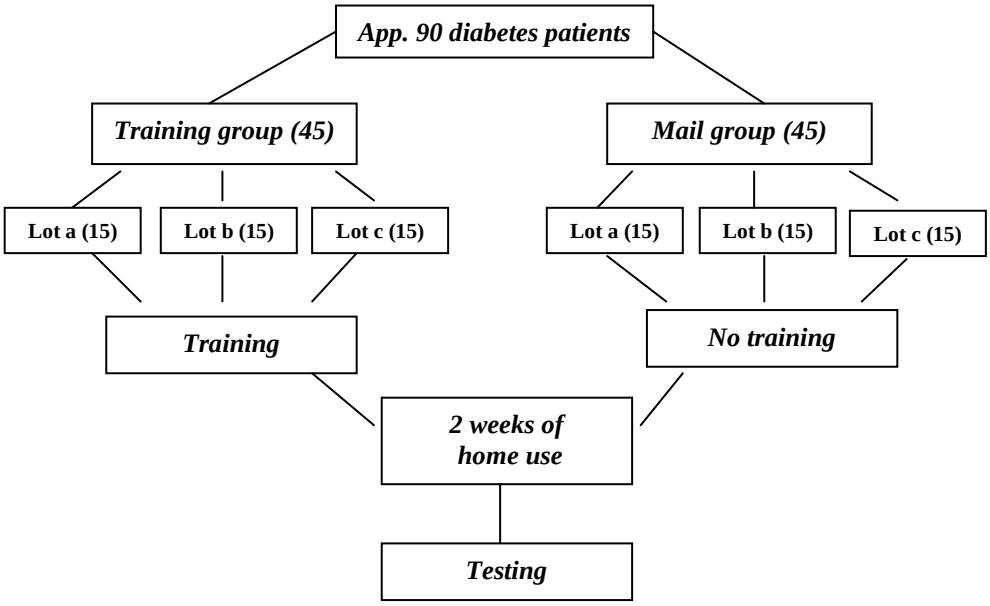

Figure 1. The model for the evaluation among the intended users

The aim of the evaluation
The evaluation of Contour XT comprises the following studies:
- An examination of the analytical quality under standardised and optimal conditions, performed by BLS in a hospital environment
- An examination of the analytical quality among approximately 90 diabetes patients
- A comparison of the analytical quality among diabetes patients with and without a training program
- An examination of the variation between three lots of test strips
- An examination to see if haematocrit interferes with the measurements
- An evaluation of the user-friendliness of Contour XT and the user guide

4.4.4. Recruitment and selection of the diabetes patients
Recruitment
The diabetes patients were recruited in October 2011, partly through advertisement in an online newspaper, and by mail inquiry sent to the members of the local branch of The Norwegian Diabetes Association.

Selection
The participants were selected at random. The Contour XT glucose meter was tested in use by 43 men and 40 women with diabetes. The average age was 58 years (range 25 – 75). A total of 23 participants had Type1 diabetes, 59 had Type2 diabetes and one didn't know. The group included diabetes patients from a range of self-monitoring frequencies, i.e. diabetes patients who perform self-monitoring often and those who perform self-monitoring less frequently.

4.4.5. The evaluation procedure under standardised and optimal conditions
The two BLS each used two Contour XT 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 kept at a minimum.

Internal analytical quality control
Meter A and B were checked by means of the manufacturer's control solution every day they were used.

Blood sampling
All samples for Contour XT, as well as the glucose samples for the comparison method, were collected from finger capillaries. 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).

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

In order to reduce the possible change in the glucose concentration during the sampling sequence, the sampling time ought not to exceed 10 minutes.

Handling of the samples for the comparison method
The samples for the comparison method were collected from a finger capillary using Microvette Li-heparin tubes from Sarstedt (300 µL). The samples were centrifuged immediately for three minutes at 10.000 x g, and plasma was separated into suitable sample vials. The plasma samples were frozen directly and stored at minus 80° C. The samples were transported under cold storage to NOKLUS in Bergen where they were kept at minus 80° C until the analysis took place [8].

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 two results of the second sample is referred to as the mean result of the comparison method. The mean result of the comparison method is an estimate of the true glucose value in the samples, and is used for the assessment of trueness and accuracy of Contour XT, and for the assessment of bias with three lots of Contour Next test strips and the effect of haematocrit.

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

Measurement of haematocrit
Haematocrit may influence on blood glucose measurements. A venous sample was collected from each diabetes patient (voluntarily) and the haemotocrit was measured within six hours with one of the routine methods; Sysmex XE 2100 at St. Olavs Hospital or CellDyn Sapphire at Levanger Hospital.

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

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

4.4.6. Evaluation among the intended users

The training group

The diabetes patients who participated in the training programme were invited in groups of approximately 10 participants. They received the Contour XT meter along with test strips, Microlet®2 lancing device, lancets, user guide and an information letter with explanations regarding what to do with the Contour XT device when practising at home. Karina H. Bjerkestrand and Randi Rekkebo, NOKLUS, were in charge of the training of the diabetes patients. The training programme covered a simple demonstration of how to use Contour XT. The training programme was standardised to make sure that all the diabetes patients received the same instruction. Bayer approved the programme.

The mail group

The diabetes patients in the "mail group" received the Contour XT meter by mail, along with test strips, Microlet 2 lancing device, lancets, user guide and an information letter with explanations regarding what to do with the Contour XT device during the period at home. No training was given.

Use of Contour XT at home

Both groups of diabetes patients used Contour XT at home for approximately two weeks. They used Contour XT in addition to their own glucose meter, and they continued to carry out self-measurements with their own meter as usual. During the first week the diabetes patients familiarised themselves with the new device. Each diabetes patient had approximately 25 test strips disposal to measure his/her blood glucose with Contour XT this first week. If they preferred, they could perform the measurements at the same time as they performed measurements with their own meter. During the second week, the diabetes patients performed duplicate measurements on Contour XT on five different days. The results were recorded on a provided form for documentation of the training efforts.

Internal analytical quality control

To document correct functioning of the Contour XT meters used by the diabetes patients, the BLS checked the meters with the control solution when the diabetes patients met at the evaluation end-meeting.

The evaluation end-meeting

After the two-week practise period at home, the diabetes patients met, one by one, for the evaluation end-meeting. The diabetes patient brought their assigned Contour XT to the meeting. Before the samples were collected, the device was equilibrated to room temperature while the diabetes patients filled in the questionnaires regarding user-friendliness of Contour XT and the user guide. The diabetes patients made duplicate blood glucose measurements on their assigned meter. For sampling procedure see section 4.4.5. Most of them used the Microlet 2 lancing device for the blood sampling. The measurements were performed with the test strips delivered to the diabetes patients for the evaluation. The results were registered. Any error codes were recorded. The BLS registered whether the diabetes patients followed the manufacturer's instructions for performing a blood glucose test.

5. Results and discussion

Statistical expressions and calculations used by SKUP are shown in attachment 3.

5.1. Number of samples

A total of 89 diabetes patients participated in the evaluation. 83 of them completed the evaluation; 38 diabetes patients in the "training group" and 45 in the "mail group".
A venous sample for haematocrit was collected from all the 83 participants.

5.1.1. The glucose concentration stability

Out of 83 pairs of results measured with the comparison method, four showed a difference >10%. ID 48, with a difference of approximately 20%, was excluded from all calculations regarding Contour XT. The other three samples had differences just above 10% and were included in the calculations to maintain a sufficient number of counting results. The conclusions in this report are not dependent on keeping or excluding these three samples.

5.1.2. Excluded or missing results

The following results are missing or excluded:

- ID 59 had only one measurement of the second sample for the comparison method. ID 59 is therefore missing in the calculation of repeatability of the comparison method, but is included in the calculation regarding Contour XT
- ID 48 had a deviation of approximately 20% between the first and second sample for the comparison method. All results from ID 48 were removed before the assessment of accuracy and haematocrit influence, and before the calculation of trueness and lot variation
- ID 6 (in the mail group) had only one measurement performed by the diabetes patient. ID 6 was therefore excluded from the calculation of repeatability
- ID 21 was classified as an outlier according to Burnett's model in the calculation of repeatability on meter B and was excluded from the calculation of lot variation. The result is showed with an open symbol in the accuracy plot, but excluded in the calculation of accuracy
- ID 85, meter B, was not registered with lot number and was therefore excluded from the calculation of lot variation

5.1.3. Failed measurements

The BLS performed 415 measurements (5 strips x 83 patients) on Contour XT. Four of these measurements failed with error codes E3. The diabetes patients performed 166 measurements (2 test strips x 83 patients), and three of these measurements failed; two error codes E3 and one error code E2.
Total fraction of technical errors was: (7 / 581) x 100 = 1,2%

Comments
Error code description from the user guide:
E2 The test strip has not filled enough for an accurate test. Insufficient blood drop
E3 The meter is sensing a used test strip or the wrong control solution was used

Discussion
The quality goal for fraction of technical errors <2% was fulfilled.

5.2. Analytical quality of the selected comparison method

5.2.1. Internal quality control

In daily operation of the comparison method, the analytical quality of the method is monitored with internal quality control solutions at two levels of glucose concentrations. All control results from the evaluation period were inside the limits of the target values for the controls. The results are not shown.

5.2.2. The precision of the comparison method

Repeatability

Two capillary samples were collected of each diabetes patient for measurement on the comparison method. To achieve a measure for the repeatability, the second sample was analysed in duplicate. The formula used for the calculation of repeatability (formula 1), and the assumption for using it, is shown in attachment 3. The repeatability of the comparison method is shown in table 3. Raw data is shown in attachment 4.

Table 3. Repeatability of the comparison method. Results achieved with capillary blood samples

Glucose level Comparison method (mmol/L)	n	Excluded results	Comparison method, mean (mmol/L)	CV% (95% CI)
<7	22	0	5,8	0,7 (0,5 – 1,0)
7 – 10	37	0	8,3	0,7 (0,5 – 0,8)
≥10	23	0	12,9	0,7 (0,5 – 1,0)

Discussion

The precision of the comparison method was good. The repeatability CV was less than 1%.

5.2.3. The trueness of the comparison method

In order to demonstrate the trueness of the comparison method calibration, the SRM 965b from NIST were analysed. The agreement between the comparison method and the NIST-standards is shown in table 4.

Table 4. 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	06.02.12	1,836 (1,809 — 1,863)	5	1,85	
	08.02.12		5	1,86	
	Total		10	1,86	+1,2
Level 2	06.02.12	4,194 (4,135 - 4,253)	5	4,37	
	08.02.12		5	4,32	
	Total		10	4,35	+3,6
Level 3	06.02.12	6,575 (6,481 — 6,669)	5	6,76	
	08.02.12		5	6,76	
	Total		10	6,76	+2,8
Level 4	06.02.12	16,35 (16,15 — 16,55)	5	17,28	
	08.02.12		5	17,18	
	Total		10	17,23	+5,4

Comments

Table 4 shows that the glucose results of the NIST-standards on level 2, 3 and 4 were above the upper uncertainty limits. All results from Architect were therefore adjusted according to the certified NIST-targets. The adjustment was carried out by means of inverse calibration [12, 13] by the following regression equation: **y = 0,943x + 0,120**.

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

To verify the trueness of the adjusted comparison method results, freshly frozen, human serum controls, produced by SERO AS, were analysed. The agreement between the comparison method and target values from the Reference laboratory in Belgium is shown in table 5.

Table 5. Trueness of the comparison method

Control	Date	Target value glucose (mmol/L)	n	Mean value glucose (mmol/L)	% deviation from target value
TM Gluc L-1	06.02.12	4,78	5	4,77	
	08.02.12		5	4,75	
	Total		10	4,76	-0,5
TM Gluc L-2	06.02.12	11,80	5	11,71	
	08.02.12		5	11,60	
	Total		10	11,66	-1,2

Discussion

The trueness of the comparison method was good.

5.3. Analytical quality of Contour XT

5.3.1. Internal quality control

The Contour XT meters used by the diabetes patients, were checked with the manufacturer's control solutions by the BLS at the end-meeting. The reproducibility CV was approximately 5% (n=82). All along, the control results were in the upper range of the given interval, and 29% of the results were higher than the upper limit. The results were presented for Bayer during the evaluation. Without thorough mixing of the control, a high biased result can occur. This was hardly the reason for the high control results in the evaluation. In agreement with Bayer, the QC results were taken note of, but not stressed further.
The four Contour XT meters used by the BLS, were checked with control solution every day they were used. The reproducibility CV was approximately 3% (n=40), and all results were within the control range. Raw data is shown in attachment 5.

5.3.2. Comparison of the 1st and 2nd measurement

Two capillary samples were collected of each diabetes patient for measurements on meter A and meter B at the end-meeting. In addition, the diabetes patients took two capillary samples for measurements on their assigned meter at the end-meeting. For the calculation of imprecision, all results have been checked to meet the assumption for using formula 1 in attachment 3. No systematic difference was pointed out between the paired measurements on meter A, meter B, or the diabetes patients' meter (data not shown).

5.3.3. The precision of Contour XT

Repeatability under standardised and optimal conditions
The repeatability obtained by the BLS 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 Contour XT. Raw data is shown in attachment 6.

Table 6. Repeatability, Contour XT. Results achieved by the BLS

Contour XT	Glucose level (mmol/L)	n	Excluded results	Mean value glucose (mmol/L)	CV% (95% CI)
Meter A	<7	24	0	5,9	3,3 (2,6 – 4,6)
Meter B	<7	24	1*	5,9	1,8 (1,4 – 2,5)
Meter A	7 – 10	38	0	8,4	2,1 (1,7 – 2,7)
Meter B	7 – 10	38	0	8,4	2,5 (2,1 – 3,3)
Meter A	≥10	21	0	12,6	2,5 (1,9 – 3,6)
Meter B	≥10	21	0	12,7	1,9 (1,5 – 2,8)

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

* One statistical outlier (ID 21) according to Burnett's model

Comments
There was no error message related to the outlier (ID 21) at glucose level <7 mmol/L, meter B.

Repeatability obtained by the diabetes patients
The repeatability obtained by the diabetes patients with capillary blood samples is shown in table 7. The results are sorted into "training group" and "mail group", and divided into three glucose levels according to the first measurement on Contour XT. Raw data is shown in attachment 7.

Table 7. Repeatability, Contour XT. Results achieved by the diabetes patients

Group	Glucose level (mmol/L)	n	Excluded results	Mean value glucose (mmol/L)	CV% (95% CI)
Training group	<7	10	0	6,0	1,7 (1,2 – 3,1)
Mail group	<7	14	0	6,0	2,7 (1,9 – 4,3)
Training group	7 – 10	15	0	8,4	2,8 (2,0 – 4,3)
Mail group	7 – 10	20	0	8,4	3,5 (2,6 – 5,1)
Training group	≥10	13	0	12,5	4,2 (3,0 – 6,9)
Mail group	≥10	10	0	12,3	1,5 (1,0 – 2,8)

Comments
The CV for the glucose level ≥10 mmol/L in the training group was 4,2%. This CV is affected by three duplicate measurement results with differences >1 mmol/L. There were no error messages related to these measurements. The actual CV is 2,8% without these three results.

Discussion, repeatability
The precision was good. The repeatability CV obtained under standardised and optimal conditions was between 1,8 and 3,3%. The repeatability CV obtained at NOKLUS when the measurements were performed by the diabetes patients was between 1,5 and 4,2%. The recommended quality goal for precision was fulfilled.

For glucose results ≥10 mmol/L the mail group achieved a statistic significant lower CV than the training group. The precision for the training group's high glucose measurements is affected by three results as commented on above, and cannot be explained more precisely. As a whole, all the diabetes patients performed the measurements with approximately the same good precision, regardless of being trained or not. This indicates that training is not essential for achieving a good result with Contour XT.

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

5.3.4. The trueness of Contour XT

The mean deviation of Contour XT from the comparison method (bias) was calculated from the results achieved by the BLS with one lot of test strips on meter A. The results are sorted and divided into three glucose levels according to the mean results on the comparison method. The trueness of Contour XT is shown in table 8.

Table 8. Trueness of Contour XT

Glucose level Comparison method (mmol/L)	n	Excluded results	Comparison method, mean (mmol/L)	Contour XT, mean (mmol/L)	Bias, mmol/L (95% CI)
<7	31	0	5,9	6,2	+0,27 ((+0,18) – (+0,35))
7 – 10	30	0	8,4	8,6	+0,24 ((+0,16) – (+0,32))
≥10	21	0	12,5	12,6	+0,10 ((-0,06) – (+0,25))

Discussion

Contour XT showed glucose results in agreement with the comparison method for glucose concentrations ≥10 mmol/L. For glucose concentrations <10 mmol/L Contour XT gave higher glucose results than the comparison method. The bias was between +0,2 and +0,3 mmol/L. The bias is small, but statistical significant.

5.3.5. The accuracy of Contour XT

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

The accuracy of Contour XT meter B, with three lots of test strips, under standardised and optimal measuring conditions is shown in figure 2. The accuracy of Contour XT, as measured by all the diabetes patients is shown in figure 3. The accuracy is summarised in table 9.

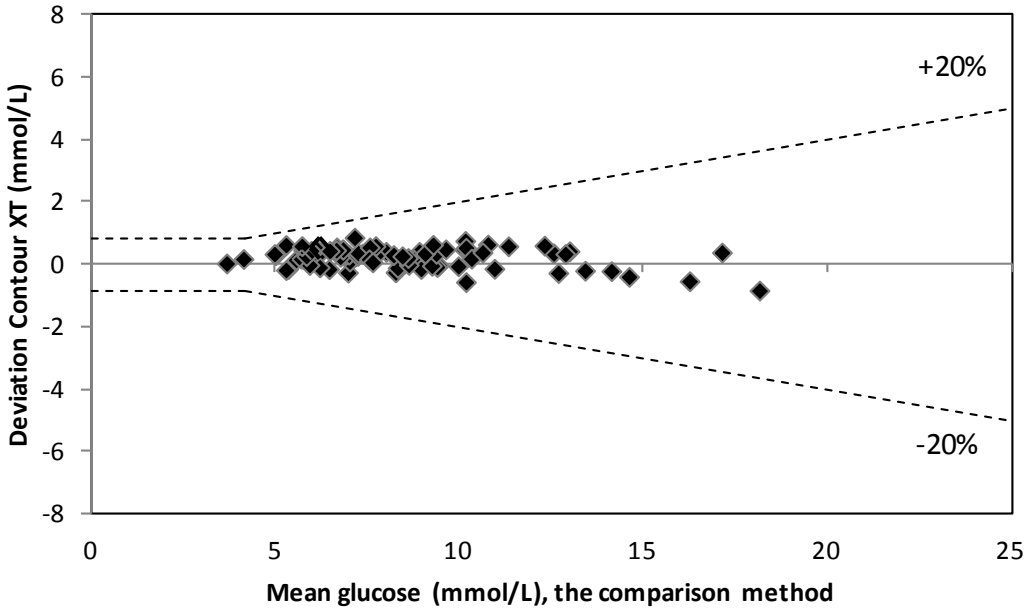

Figure 2. Accuracy. Contour XT meter B (three lots of test strips) under standardised and optimal measuring conditions. The x-axis represents the mean result on the comparison method. The y-axis shows the difference between the first measurement on Contour XT and the mean result of the comparison method. Stippled lines represent quality goal limits suggested in ISO 15197. ID 21, statistical outlier from the calculation of repeatability on meter B, is represented with an open symbol, but is hidden behind all other symbols at glucose concentration 6,2 mmol/L. n = 82

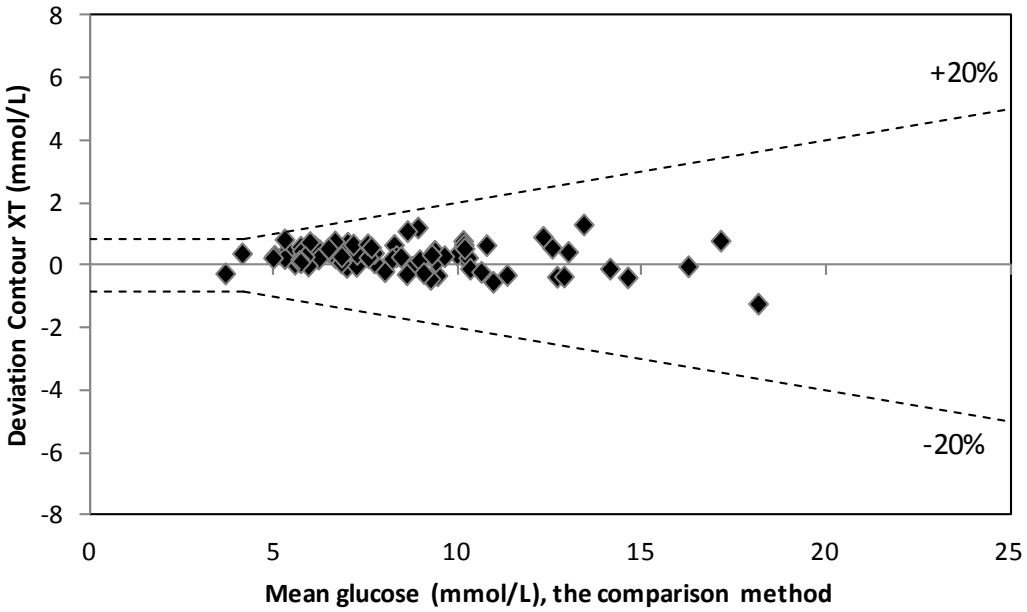

Figure 3. Accuracy. The diabetes patients' self-measurements on Contour XT (three lots of test strips). The x-axis represents the mean result of the comparison method. The y-axis shows the difference between the first measurement on Contour XT and the mean result of the comparison method. Stippled lines represent quality goal limits suggested in ISO 15197. n = 82

Table 9. Accuracy of Contour XT

Measure performed by	Meter, measurement	n	Number of results (%) within the limits			
			"Adjusted ISO" <± 25% and <±1,0 mmol/L at conc. ≤4,2	**ISO 15197 <±20% and <±0,83 mmol/L at conc. ≤4,2**	**Fixed limit without cut off**	
					±15%	**±10%**
BLS	A (one lot) 1st measurement	82		100	100	100
	B (three lots) 1st measurement	81		100	100	96
Diabetes patients at NOKLUS	1st measurement	82	100	100	99	91

Discussion

Figure 2 and 3 show Contour XT results in agreement with the comparison method. The summing up in table 9 shows that 100% of the results obtained by the BLS as well as by the diabetes patients were inside the accuracy quality limits proposed in ISO 15197. Table 9 also shows the number of results within fixed limits of ±15% and ±10%, but these results are for information only, and will not be further assessed.

5.3.6. Bias with three lots of test strips

The measurements on Contour XT meter B were performed with three different lots of test strips. The mean deviation for each of the three lots from the comparison method (bias) was calculated (paired t-test) as an indirect measure of the lot variation. To get a sufficient number of results in each group, the bias was calculated for the entire glucose concentration range. The bias with three lots of test strips is shown in table 10.

Table 10. Bias with three lots of test strips

Contour XT, lot number of test strips	**n**	**Excluded results**	**Comparison method, mean (mmol/L)**	**Contour XT, mean (mmol/L)**	**Bias, mmol/L (95% CI)**
TPP-43	29	0	8,4	8,7	+0,26 ((+0,16 – (+0,36))
TPP-44	27	0	8,8	9,1	+0,28 ((+0,16) – (+0,40))
TPP-46	24	0	8,2	8,3	+0,19 ((+0,05) – (+0,32))

Conclusion

Statistically, glucose results on Contour XT with all three lots of test strips used in the evaluation were significantly higher than the results achieved with the comparison method. The bias was between +0,2 and +0,3 mmol/L. The bias is small, but statistically significant.

5.4. Effect of haematocrit

According to the technical specifications, glucose measurements on Contour XT are not influenced by haematocrit values from 0 to 70%. To measure the effect of haematocrit on Contour XT, a venous sample for haematocrit was collected of the diabetes patients at the end-meeting in the evaluation. The investigation of the effect is based on the measurements on Contour XT meter A (one lot of test strips) under standardised and optimal measuring conditions. The glucose concentration range was 3,7 – 18,1 mmol/L. The haematocrit range was 34 – 49%. The effect of haematocrit with a trend-line and a regression equation is shown in figure 4. The raw data is shown in attachment 8.

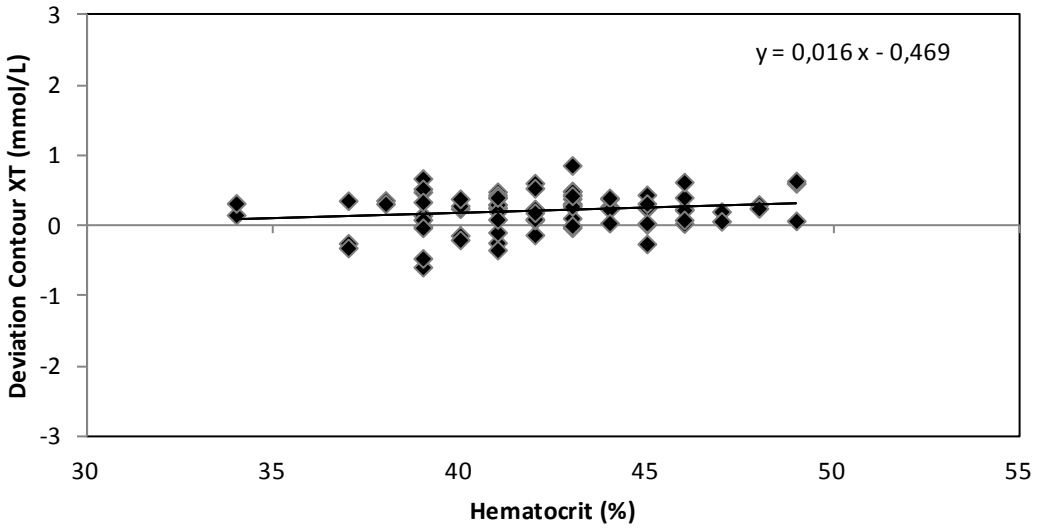

Figure 4. The effect of haematocrit on glucose measurements on Contour XT meter A measured under standardised and optimal conditions. The x-axis shows the haematocrit value in percent. The y-axis shows the difference in glucose concentration between Contour XT and the mean result of the comparison method in mmol/L, n= 82

Discussion

The slope of the trend-line is 0,016, with a 95% CI from (-0,002) to (+0,034). The slope is not statistically significant different from zero. Glucose measurements on Contour XT in the evaluation were not affected by haematocrit values within the range 34 – 49%.

5.5. Evaluation of user-friendliness

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

Questionnaires

When attending the evaluation end-meeting of the evaluation, the diabetes patients filled in a questionnaire about the user-friendliness of the meter and a questionnaire about the user-friendliness of the user guide. The BLS was available for clarifying questions, and there was free space for commenting. The questionnaires (in Norwegian) are shown in attachment 9.

5.5.1. Evaluation of the user-friendliness of Contour XT

Table 11 summarises the questions regarding user-friendliness of Contour XT. The diabetes patients were asked to rank the answers on a scale from 1 to 6, where 1 is difficult and 6 is simple. Table 12 shows the answers regarding technical problems with Contour XT.

Table 11. Contour XT - Questions about the meter

Questions about the Contour XT system		Total number	Range	Mean score	No answer
How will you rank the following questions on a scale from 1 to 6, where 1 is difficult and 6 is simple	To insert a test strip into the meter	83	1 – 6	5,3	0
	To fill the test strip with blood	83	1 – 6	5,7	0
	To hear the sound signal	83	1 – 6	5,7	3
	To read the figures in the display	83	1 – 6	5,8	0
	All in all, to operate the meter	83	1 – 6	5,4	1

Discussion

The mean score was between 5,4 and 5,8 on questions about the Contour XT system. This indicates that the diabetes patients in this evaluation were satisfied with the meter and the test strip.

Table 12. Contour XT – Questions about the meter

Question about Contour XT	Total number	Yes (%)	No (%)	No answer (%)
Did you have any technical problems with the meter during the testing period?	83	5	90	5

Comments

Four of the diabetes patients (5%) answered that they had technical problems with the meter during the evaluation period. Written comments indicate that the problems were not technical ones after all.

Positive comments
42 diabetes patients reported one or more advantages with Contour XT. The most often reported advantages are:

1. Easy to use (14)
2. The meter/strip needs a small blood sample volume (11)
3. The meter has a short measuring time (9)

Negative comments
39 diabetes patients reported one or more disadvantages with Contour XT. The most often reported disadvantages are:

1. Single test strips/not "all in one", old-fashioned, cumbersome (20)
2. The device is too big/unwieldy (7)

5.5.2. Evaluation of the user guide

In the questionnaire about the user guide of Contour XT, each diabetes patient was first asked whether he/she had used the user guide. If the answer was no, they were asked to ignore the rest of the questionnaire. Table 13 summarizes the questions about the user guide.

Table 13. Contour XT – Questions about the user guide

Questions about the user guide	Number	Yes (%)	No (%)	No answer (%)
Have you been reading in the user guide?	83	75	22	4
If yes, did you read the entire user guide?	65	43	38	18
And/or did you consult the user guide when needed?	65	52	14	34
Are you satisfied with the description of how to perform a blood glucose measurement with the meter?	65	92	3*	5
Do you think the user guide has essential shortcomings?	65	0	92	8
All in all, are you satisfied with the user guide?	65	91	0	9

*One of the participants was not able to refill the test strip according to the instruction in the user guide.

Comments
75% of the diabetes patients had used the user guide and they were satisfied with it.

5.5.3. The biomedical laboratory scientists' evaluation

Positive comments about the Contour XT device and the user guide

- Short measuring time
- Needs a small blood sample volume
- Easy to operate
- Reliable in operation, few error codes
- The user guide has a handy size, nice pictures, simple language

Negative comments about the Contour XT device

- Some participants had problems with inserting the test strip into the meter

6. References

1. American Diabetes Association. *Self-monitoring of blood glucose*. Diabetes Care 1996; **19** (suppl 1): 62 – 66.
2. Skeie S, Thue G, Sandberg S, "*Patient-derived Quality Specifications for Instruments Used in Self-Monitoring of Blood Glucose*". Clinical Chemistry 2001; **47** (1): 67 – 73.
3. Kvalitetssikring og kvalitetskrav til laboratoriemedicinske aktiviteter i almen praksis. Udarbejdet af Regionernes Lønnings- og Takstnævn (RTLN) og Praktiserende Lægers Organisation (PLO). 2010. http://skup.dk/flx/kvalitetsmaal/
4. *In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self- testing in managing diabetes mellitus*, ed. ISO 15197:2003.
5. *Reports and summaries from evaluations under the direction of SKUP*. www.skup.nu.
6. Kristensen G.B.B, Monsen G, Skeie S, Sandberg S, "*Standardized Evaluation of Nine Instruments for Self-Monitoring of Blood Glucose*". Diabetes Technology & Therapeutics, 2008; **10** (6), p. 467-77.
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8. National Institute of Standards and Technology, Certificate of Analysis, Standard Reference Material® 965b, Glucose in Frozen Human Serum.
9. Thienpont, L.M., et al., *Determination of reference method values by isotope dilution-gas chromatography/mass spectrometry: a five years' experience of two European Reference Laboratories.* Eur J Clin Chem Clin Biochem, 1996. **34** (10): p. 853-60.
10. Christensen, N.G, Monsen G, Sandberg S, *Utprøving av analyseinstrumenter*. 1997: Alma Mater Forlag.
11. Skeie, S, et al., *Instruments for self-monitoring of blood glucose: comparisons of testing quality achieved by patients and a technician.* Clin Chem, 2002. **48** (7): p. 994-1003.
12. Krutchkoff, R. G, *Classical and inverse Regression Methods of Calibration*. Technometrics, Vol. 9, No. 3: 425-439
13. Tellinghuisen, J, *Inverse vs. classical calibration for small data sets*. Fresenius J. Anal. Chem. (2000) 368:585-58

7. 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. 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 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).

To make contact with SKUP

SKUP secretariat
Grete Monsen
+47 55 97 95 02
grete.monsen@noklus.no

SKUP in Denmark
Esther Jensen
Stine B. Weber
Hillerød Hospital
Klinisk Biokemisk Afdeling
Dyrehavevej 29, indgang 16A
DK-3400 Hillerød
+45 48 29 41 76
sbwe@hih.regionh.dk
esj@hih.regionh.dk

SKUP in Norway
Grete Monsen
Camilla Eide Jacobsen
Marianne Risa
Sverre Sandberg
NOKLUS
Boks 6165
NO-5892 Bergen
+47 55 97 95 02
grete.monsen@noklus.no
camilla.jacobsen@noklus.no
marianne.risa@noklus.no
sverre.sandberg@isf.uib.no

SKUP in Sweden
Arne Mårtensson
Lena Morgan
Gunnar Nordin
EQUALIS
Box 977
SE-751 09 Uppsala
+46 18 69 31 64
arne.martensson@equalis.se
lena.morgan@equalis.se
gunnar.nordin@equalis.se

www.SKUP.nu

Attachments

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

Facts about Contour XT

This form is filled in by Bayer.

Table 1. Basic facts

Name of the measurement system:	Contour®XT
Dimensions and weight:	Width: 57 mm Depth: 19 mm Height: 77 mm Weight: 47,5 gram
Components of the measurement system:	Contour®XT and Contour®NEXT
Measurand:	Glucose
Sample material:	Venous or capillary blood sample
Sample volume:	0,6 µL
Measuring principle:	The Contour Next blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and the mediator. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation is required
Traceability:	-
Calibration:	No calibration is required, No coding technology
Measuring range:	0,6 – 33,3 mmol/L
Linearity:	-
Measurement duration:	5 seconds
Operating conditions:	5-45 ºC and 10-93% RH (Relative Humidity)
Electrical power supply:	Two 3-volt lithium batteries DL2032 or CR2032
Recommended regular maintenance:	No regular maintenance required. General care will do
Package contents:	Contour®XT, Contour®NEXT, Microlet®2 lancing device
Necessary equipment not included in the package:	All necessary equipment are included

Table 2. Post analytical traceability

Is input of patient identification possible?	No
Is input of operator identification possible?	No
Can the instrument be connected to a bar-code reader?	No
Can the instrument be connected to a printer?	yes
What can be printed?	Results that are saved in the memory (result, date, time)
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?	480 Blood glucose test results, date, time
Is it possible to trace/search for measurement results?	Yes, the meter has an internal memory

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

Name of the reagent/test strips/test cassettes:	Contour®NEXT
Stability in unopened sealed vial:	24 months
Stability in opened vial:	24 months
Package contents:	Contour®NEXT vial and package insert

Table 4. Quality control

Electronic self check:	Yes
Recommended control materials and volume:	Contour®NEXT control solution
Stability in unopened sealed vial:	24 months
Stability in opened vial:	6 months
Package contents:	Contour®NEXT control solution and package insert

Table 5. Marketing information

Manufacturer:	Bayer Healthcare
Retailers in Scandinavia:	Denmark: Bayer AS Diabetes Care Arne Jacobsens Allé 13 DK-2300 København S Norway: Bayer AS Diabetes Care Drammensveien 147 B Postboks 14 N-12 Oslo Sweden: Bayer AB Diabetes care Gustav III:s Boulevard 56 Box 606 S-169 26 Solna
In which countries is the system marketed:	Globally ✓ Scandinavia ☐ Europe ☐
Date for start of marketing the system in Scandinavia:	1.april 2012
Date for CE-marking:	19-09-2011
In which Scandinavian languages is the manual available:	Norwegian/Swedish/Danish/Finish

Product information, Contour XT
SKUP/2012/94

Contour XT serial numbers
A total of 93 Contour XT blood glucose meters were used in this evaluation.
Four meters (serial no. TW 40452, TW 40417, TW 40490 and TW 40413) were used by the biomedical laboratory scientists under the standardised and optimal conditions.

Contour next test strips (Tatsu sensors)

Lot TPP-43	Expiry 2012-10
Lot TPP-44	Expiry 2012-10
Lot TPP-46	Expiry 2012-10

Contour Control Solution

Control Normal	Lot 2057	Expiry 2012-02-31
Target value lot TPP-43:	6,4 – 8,0 mmol/L	
Target value lot TPP-44:	6,4 – 8,0 mmol/L	
Target value lot TPP-46:	6,5 – 8,1 mmol/L	

Blood sampling device used by the biomedical laboratory scientists (single use only)

Accu-Chek Safe-T-Pro Plus	Lot T152031	Expiry 2014-06
Medlance plus (2,4 mm)	Lot R23Z718G4	Expiry 2012-06

Blood sampling device used by the diabetes patients
The diabetes patients could choose whether to use the MicroLet 2 pen with MicroLet lancets from Bayer, or the lancet pen they usually use.

Statistical expressions and calculations

This standardised text deals with the statistical expressions and calculations used by SKUP. The text 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 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, intermediate, 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, intermediate, 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, intermediate, 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.

Calculation of bias

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

Assessment of accuracy

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

b. Burnett RW, "*Accurate Estimation of Standard Deviations for Quantitative Methods Used in Clinical Chemistry*". Clinical Chemistry 1975; **21** (13): 1935 – 1938
c. Saunders, E. Tietz textbook of clinical chemistry and molecular diagnostics. 2006. Chapter 14, Linnet, K., Boyd, J. "*Selection and analytical evaluation of methods – with statistical techniques*", ISBN 0-7216-0189-8
d. Fraser, C.G, Biological variation: *From principles to practice*. 2006. Chapter 1 "*The Nature of Biological Variation*". AACC Press. ISBN 1-890883-49-2

Raw data glucose, internal quality control, Contour XT

Contour Control Solution	Lot-no	Expiry	Lot-no Contour next test strip	Target value Glucose (mmol/L)
Control Normal	2057	2012-02-31	TPP-43	6,4 – 8,0
			TPP-44	6,4 – 8,0
			TPP-46	6,5 – 8,1

Contour Control Solution analysed on the biomedical laboratory scientists' meter A and B

Date	Contour Control Normal Glucose (mmol/L)		
	Value	Meter	Lot-no
22.11.2011	7,3	A	TPP-43
23.11.2011	7,2	A	TPP-43
24.11.2011	7,3	A	TPP-43
20.01.2012	7,1	A	TPP-43
24.01.2012	7,4	A	TPP-43
27.01.2012	7,4	A	TPP-43
22.11.2011	7,5	B	TPP-43
23.11.2011	7,2	B	TPP-43
24.11.2011	7,5	B	TPP-43
20.01.2012	7,4	B	TPP-43
24.01.2012	7,1	B	TPP-43
27.01.2012	7,3	B	TPP-43
22.11.2011	7,2	B	TPP-44
23.11.2011	7,1	B	TPP-44
24.11.2011	7,5	B	TPP-44
20.01.2012	7,7	B	TPP-44
24.01.2012	7,3	B	TPP-44
27.01.2012	7,4	B	TPP-44
22.11.2011	7,9	B	TPP-46
23.11.2011	7,7	B	TPP-46
24.11.2011	7,6	B	TPP-46
20.01.2012	7,7	B	TPP-46
24.01.2012	7,2	B	TPP-46
27.01.2012	7,6	B	TPP-46

Date	Contour Control Normal Glucose (mmol/L)		
	Value	Meter	Lot-no
25.11.2011	7,6	A	TPP-43
28.11.2011	7,4	A	TPP-43
01.12.2011	7,2	A	TPP-43
02.12.2011	7,1	A	TPP-43
25.11.2011	7,6	B	TPP-43
28.11.2011	7,3	B	TPP-43
01.12.2011	7,0	B	TPP-43
02.12.2011	7,0	B	TPP-43
25.11.2011	7,6	B	TPP-44
28.11.2011	7,5	B	TPP-44
01.12.2011	7,6	B	TPP-44
02.12.2011	7,1	B	TPP-44
25.11.2011	7,4	B	TPP-46
28.11.2011	7,6	B	TPP-46
01.12.2011	7,3	B	TPP-46
02.12.2011	7,1	B	TPP-46

Contour Control Solution analysed on the diabetes patients' meters

Training group

ID	Lot-no Contour next test strips	Contour Control Normal Glucose (mmol/L)
47	TPP-43	7,4
48	TPP-44	7,6
49	TPP-46	8,0
50	TPP-43	7,9
51	TPP-44	7,4
52	TPP-46	7,9
53	TPP-43	8,1
54	TPP-44	8,0
55	TPP-46	7,7
56	TPP-43	8,0
58	TPP-46	7,3
59	TPP-43	8,0
61	TPP-46	7,5
62	TPP-43	8,5
63	TPP-44	7,9
64	TPP-46	7,8
66	TPP-44	7,3
67	TPP-46	7,6
68	TPP-43	8,3
71	TPP-43	7,4
72	TPP-44	8,9
73	TPP-46	8,1
74	TPP-43	8,3
75	TPP-44	7,9
76	TPP-46	7,3
78	TPP-44	8,1
79	TPP-46	No data
81	TPP-44	9,1
82	TPP-46	8,3
83	TPP-43	7,4
84	TPP-44	7,1
85	TPP-46	8,4
86	TPP-43	8,3
87	TPP-44	7,8
88	TPP-46	8,1
89	TPP-43	8,3
91	TPP-46	7,4
92	TPP-44	7,7

Mail group

ID	Lot-no Contour next test strips	Contour Control Normal Glucose (mmol/L)
1	TPP-43	8,3
2	TPP-44	8,2
3	TPP-46	7,9
4	TPP-43	8,3
5	TPP-44	7,4
6	TPP-46	8,3
8	TPP-44	7,6
9	TPP-46	8,1
10	TPP-43	7,8
11	TPP-44	7,6
12	TPP-46	7,3
13	TPP-43	8,2
14	TPP-44	8,3
15	TPP-46	7,1
16	TPP-43	7,7
17	TPP-44	8,3
18	TPP-46	7,9
19	TPP-43	8,0
20	TPP-44	7,7
21	TPP-46	7,7
22	TPP-43	7,3
23	TPP-44	7,7
24	TPP-46	8,1
25	TPP-43	8,4
26	TPP-44	7,8
27	TPP-46	8,1
28	TPP-43	7,9
29	TPP-44	7,6
30	TPP-46	7,9
31	TPP-43	7,3
32	TPP-44	7,9
33	TPP-46	8,5
34	TPP-43	7,9
35	TPP-44	8,1
38	TPP-44	8,4
39	TPP-46	7,4
40	TPP-43	7,8
41	TPP-44	7,9
42	TPP-46	7,8
43	TPP-43	8,4
44	TPP-44	7,4
45	TPP-46	8,1
46	TPP-43	7,8
57	TPP-44	7,7
80	TPP-43	8,5

Raw data haematocrit

ID	Haematocrit
1	0,41
2	0,41
3	0,43
4	0,41
5	0,41
6	0,37
8	0,49
9	0,42
10	0,46
11	0,39
12	0,34
13	0,47
14	0,46
15	0,47
16	0,39
17	0,41
18	0,46
19	0,41
20	0,45
21	0,48
22	0,49
23	0,49
24	0,37
25	0,41
26	0,42
27	0,39
28	0,43
29	0,40
30	0,39
31	0,41
32	0,41
33	0,45
34	0,45
35	0,43
38	0,43
39	0,44
40	0,42
41	0,39
42	0,43
43	0,41
44	0,43
45	0,41
46	0,42
47	0,45
48	0,43

ID	Haematocrit
49	0,40
50	0,39
51	0,44
52	0,44
53	0,46
54	0,43
55	0,38
56	0,44
57	0,44
58	0,46
59	0,41
61	0,45
62	0,45
63	0,39
64	0,39
66	0,45
67	0,48
68	0,39
71	0,40
72	0,42
73	0,43
74	0,43
75	0,46
76	0,45
78	0,43
79	0,39
80	0,45
81	0,40
82	0,42
83	0,37
84	0,43
85	0,41
86	0,43
87	0,38
88	0,40
89	0,43
91	0,34
92	0,42

ID-nummer (diabetiker):_____

Contour XT

Spørreskjema om blodsukkerapparatets brukervennlighet

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

1. Å sette strimmelen inn i apparatet

Vanskelig *Enkelt*

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

☐ ☐ ☐ ☐ ☐ ☐

2. Å fylle strimmelen med blod

Vanskelig *Enkelt*

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

☐ ☐ ☐ ☐ ☐ ☐

3. Å oppfatte lydsignalet

Vanskelig *Enkelt*

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

☐ ☐ ☐ ☐ ☐ ☐

4. Å lese tallene i displayet

Vanskelig *Enkelt*

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

☐ ☐ ☐ ☐ ☐ ☐

5. Å betjene apparatet, totalt sett

Vanskelig *Enkelt*

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

☐ ☐ ☐ ☐ ☐ ☐

Contour XT

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

Hvis ja, kan du beskrive problemet/ene:_____

_____

_____

7. Synes du det er noen fordeler med Contour XT?

- _____
- _____
- _____

8. Synes du det er noen ulemper med Contour XT?

- _____
- _____
- _____

Evt. andre kommentarer:_____

_____

_____

_____

ID-nummer (diabetiker):_____

Contour XT

Spørreskjema om brukerveiledningen til apparatet

Har du lest i brukerveiledningen? ☐ **Ja** ☐ **Nei**

Hvis du svarer nei, skal du ikke svare på resten av spørsmålene på dette arket.

Hvis du svarer ja:

- har du lest gjennom hele brukerveiledningen? ☐ **Ja** ☐ **Nei**

- og/eller har du slått opp i den ved behov? ☐ **Ja** ☐ **Nei**

1. **Er du fornøyd med beskrivelsen av hvordan man skal utføre en blodsukkermåling med dette apparatet?** ☐ **Ja** ☐ **Nei**

   Hvis nei, kan du beskrive hva du ikke er fornøyd med: _____

   _____

   _____

2. **Mener du at det er vesentlige mangler i brukerveiledningen?** ☐ **Ja** ☐ **Nei**

   Hvis ja, kan du beskrive hva som mangler: _____

   _____

   _____

3. **Totalt sett, er du fornøyd med brukerveiledningen?** ☐ **Ja** ☐ **Nei**

   Hvis nei, kan du beskrive hva du ikke er fornøyd med: _____

   _____

   _____

   Evt. andre kommentarer:_____

   _____

   _____

   _____

SKUP-info

Contour XT blodsukkerapparat fra Bayer
Sammendrag fra en utprøving i regi av SKUP

SKUP
www.skup.nu
SKUP/2012/94

Konklusjon
Presisjonen og nøyaktigheten på Contour XT var god.
CV var mellom 1,8 og 3,3 % når målingene ble utført av laboratorieutdannet personale, og mellom 1,5 og 4,2 % når målingene ble utført av personer med diabetes. For glukosekonsentrasjoner under 10 mmol/L var resultatene fra Contour systematisk litt høyere (0,2 - 0,3 mmol/L) enn resultatene fra sammenligningsmetoden. Målingene i denne utprøvingen oppnådde internasjonalt kvalitetsmål (ISO 15197) med et avvik på mindre enn ± 20 % fra en anerkjent glukosemetode. Hematokrit, i området 34 – 49 %, påvirket ikke glukosemålingene på Contour XT. Brukervennligheten var tilfredsstillende.

Contour XT er beregnet til egenmåling av blodsukker. Målesystemet består av apparatet Contour XT og Contour next teststrimler. Apparatet trenger ikke kodes. Det kreves 0,6 µL blod til hver måling, og måletiden er 5 sekunder. Contour XT kan lagre 480 resultat.

Utprøvingen ble utført under optimale betingelser av laboratorieutdannet personale og blant 83 personer med diabetes. De 83 deltakerne ble delt inn i to grupper. Opplæringsgruppen fikk opplæring i bruk av Contour XT. Postgruppen fikk apparat og instruksjon tilsendt pr. post og fikk ingen opplæring. Alle deltakerne brukte Contour XT hjemme i to uker og møtte deretter til et avslutningsmøte.

Resultater
Presisjonen var god. CV var mellom 1,8 og 3,3 % når målingene ble utført av laboratorieutdannet personale. Når målingene ble utført av personer med diabetes, var CV mellom 1,5 og 4,2 %. Ved glukoseverdier over 10 mmol/L samsvarte resultatene fra Contour XT med resultatene fra sammenligningsmetoden. Ved glukoseverdier under 10 mmol/L var resultatene fra Contour XT systematisk litt høyere (0,2 – 0,3 mmol/L) enn resultatene fra sammenligningsmetoden. Målingene på Contour XT gav nøyaktige resultater. Kvalitetsmålet fra ISO 15197, som tillater avvik opp til ± 20 % fra en anerkjent metode for måling av glukose, ble oppnådd. Hematokrit, i området 34 – 49 %, påvirket ikke glukosemålinger på Contour XT.

Brukervennlighet
De fleste deltakerne i utprøvingen syntes at Contour XT var enkel å bruke. De var fornøyde med apparatet og brukermanualen.

Tilleggsinformasjon
Den fullstendige rapporten fra utprøvingen av Contour XT, SKUP/2012/94, finnes på SKUPs nettside www.skup.nu. Opplysninger om pris fås ved å kontakte leverandør.
Laboratoriekonsulentene i NOKLUS kan gi nyttige råd om analysering av glukose på legekontor. De kan også orientere om det som finnes av alternative metoder/utstyr.

List of previous SKUP evaluations

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

Recent SKUP evaluations

Evaluation no.	Component	Instrument/testkit	Producer
SKUP/2012/94	Glucose	Contour XT	Bayer HealthCare
SKUP/2011/93*	Glucose	Accu-Chek Performa	Roche Diagnostics
SKUP/2012/91	HbA1c	Quo-Test A1c	Quoient Diagnostics Ltd
SKUP/2011/90	CRP	*i*-Chroma	BodiTech Med. Inc.
SKUP/2010/89*	Glucose	FreeStyle Lite	Abbott Laboratories
SKUP/2010/88*	HbA1c	*Confidential*	
SKUP/2011/86	Glucose[1]	OneTouch Verio	LifeScan, Johnson & Johnson
SKUP/2011/84*	PT-INR	Simple Simon PT and MixxoCap	Zafena AB
SKUP/2010/83*	Glucose	*Confidential*	
SKUP/2010/82*	Glucose, protein, blood, leukocytes, nitrite	Medi-Test URYXXON Stick 10 urine test strip and URYXXON Relax urine analyser	Macherey-Nagel GmBH & Co. KG
SKUP/2010/81*	Glucose	mylife PURA	Bionime Corporation
SKUP/2010/80	PT (INR)	INRatio2	Alere Inc.
SKUP/2010/79*	Glucose, protein, blood, leukocytes, nitrite	CombiScreen 5SYS Plus urine test strip and CombiScan 100 urine analyser	Analyticon Biotechnologies AG
SKUP/2010/78	HbA1c	In2it	Bio-Rad
SKUP/2011/77	CRP	*Confidential*	
SKUP/2009/76*	HbA1c	*Confidential*	
SKUP/2009/75	Glucose	Contour	Bayer HealthCare
SKUP/2009/74	Glucose[1]	Accu-Chec Mobile	Roche Diagnostics
SKUP/2010/73	Leukocytes	HemoCue WBC	HemoCue AB
SKUP/2008/72	Glucose[1]	*Confidential*	
SKUP/2009/71	Glucose[1]	GlucoMen LX	A. Menarini Diagnostics
SKUP/2011/70*	CRP	smartCRP system	Eurolyser Diagnostica GmbH
SKUP/2008/69*	Strep A	Diaquick Strep A test	Dialab GmbH
SKUP/2010/67	Allergens	*Confidential*	
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.

*A report code followed by an asterisk indicates 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

Bayer HealthCare

Comments from Bayer to the SKUP Report/2012/94

Bayer AS would like to thank the SKUP organization for the full evaluation of the Bayer's CONTOUR™ XT meter with the new generation sensor, CONTOUR™ NEXT. Bayer is very pleased with the overall conclusions drawn from the evaluation, and feel it supports our own internal and external data presented at several international congresses.* We feel the CONTOUR XT/NEXT system while highly accurate and precise, also accomplishes a high level of Patient satisfaction as expressed in their mean scores provided in Table 11 *("CONTOUR XT – questions about the meter"*). Ease of use, combined with high satisfaction and performance should support good compliant testing and help patients and healthcare professionals to make better decisions based on the test results.

Best regards

Torstein Myhre
Managing Director Bayer AS

*Bailey T, Wallace J, Parkes JL, Pardo S, Schachner HC, Castro R, Simmons DA, Chu A. Performance of a new blood glucose test strip. Diabetes. 2011;60(suppl 1):A246.

Performance Evaluation of a Novel Blood Glucose Monitoring System, Lemke C, Petruschke T, Wallace J, Pardo S, Parkes J, Matthaei S, Poster presented at the Annual Meeting of the Diabetes Technology Society, October 27-29, 2011, San Francisco, CA