ONETOUCH® Verio™

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

Report from an evaluation
organised by

SKUP

The evaluation was ordered by LifeScan Norge

SKUP/2011/86

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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 LifeScan Norge.

1 Summary

Background
OneTouch Verio blood glucose meter and test strips are designed for glucose self-measurements performed by persons with diabetes as well as measurements performed by health care professionals. The OneTouch Verio system is produced by LifeScan Inc. and supplied in Scandinavia by LifeScan. The system has not been launched onto the Scandinavian market yet. In order to give reimbursement for the test strips in Norway, The Norwegian Health Economics Administration (HELFO) requires from the companies to carry out an evaluation that includes a user-evaluation among diabetes patients. In addition LifeScan wanted the test strip to be evaluated with focus on the analytical quality according to a quality goal suggested by NOKLUS in 2008 for glucose instruments used in Norwegian primary care centres and nursing homes. The evaluation of OneTouch Verio was carried out under the direction of SKUP from October to December 2010.

The aim of the evaluation
The aim of the evaluation of OneTouch Verio was to assess the analytical quality and the user-friendliness of OneTouch Verio:

- assess the analytical quality under standardised and optimal conditions, performed by two biomedical laboratory scientists in a hospital environment
- assess the analytical quality by the intended users
- compare the analytical quality among trained and un-trained diabetes patients
- compare the analytical quality among diabetes patients before and after three weeks of practice
- calculate a total measurement error (TE) based on the imprecision and bias of OneTouch Verio, and discuss the achieved TE according to a quality goal of 10%, suggested by NOKLUS as a quality goal for glucose device used in Norwegian primary care and nursing homes
- examine the variation between three lots of test strips
- examine if hematocrit interferes with the measurements
- evaluate OneTouch Verio regarding user-friendliness
- evaluate the OneTouch Verio owner's booklet

Materials and methods
The evaluation model is based on the guidelines in ISO 15197. A total of 91 diabetes patients took part in the evaluation. The participants in a "training group" had two consultations and the participants in a "mail group" had one consultation. The diabetes patients in the "training group" were given a standardised instruction about OneTouch Verio before they did a finger prick and performed two measurements on the meter. The biomedical laboratory scientists did a new finger prick and collected capillary samples from the diabetes patients for measurements on OneTouch Verio. In addition, two capillary samples were taken for measurements with a selected comparison method. The diabetes patients in the "mail group" received OneTouch Verio by mail and no training was given. Both groups of diabetes patients used the equipment for approximately three weeks at home, before they attended for a final consultation. The blood

glucose sampling and measurement procedures from the first consultation were repeated, and in addition a sample for hematocrit was taken. Three different lots of test strips were used in the evaluation. All participants answered questionnaires about the user-friendliness and the owner's booklet of OneTouch Verio.

Results

- The overall precision of OneTouch Verio was good. The repeatability CV obtained under standardised and optimal conditions was between 2,3 and 3,6%. The recommended quality goal for precision was obtained. The repeatability CV obtained by the diabetes patients was approximately 4,5%. Statistically, the CVs for the diabetes patients with and without training programme were not significantly different. The CVs for the diabetes patients after practise at home tend to be better than the results at the first consultation, but the precision improvement was not statistically significant.
- OneTouch Verio showed glucose results in agreement with the comparison method for glucose concentrations >10 mmol/L. For glucose concentrations <10 mmol/L OneTouch Verio showed higher glucose results than the comparison method. The deviation from the comparison method was between 0,2 and 0,3 mmol/L for glucose concentrations below 10 mmol/L. The deviation was small, but statistically significant.
- The accuracy of OneTouch Verio was good. The quality goal set in ISO 15197 was achieved under standardised and optimal measuring conditions and by the diabetes patients.
- The calculated total error of OneTouch Verio was between 6,9 and 8,3%, depending on the glucose concentration. The suggested quality goal for use in Norwegian primary care centres and nursing homes was obtained.
- The three lots of test strips used in this evaluation gave glucose results in agreement with the comparison method.
- Glucose measurements on OneTouch Verio in this study were not affected by hematocrit values within the range 30 – 49%.
- Most of the diabetes patients thought that the OneTouch Verio device was easy to operate. Most of the diabetes patients that had used the owner's booklet were satisfied with the booklet, but several commented that the size of the booklet was too large.

Conclusion

The analytical quality of OneTouch Verio was good. The precision of OneTouch Verio was good. The results were accurate and within the quality goal set in the ISO-guide 15197. The suggested quality goal for use in Norwegian primary care centres and nursing homes was obtained. The glucose results were not affected by hematocrit in this study. Most of the users found the OneTouch Verio device easy to use.

Comments from LifeScan

A letter with comments and additional information from the producer is 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. OneTouch Verio 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, 4].

Accuracy
The quality goal set in ISO 15197, *In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus* [5] applies for glucose self-measurements, and has been used as quality goal for previous user evaluation among diabetes patients organised by SKUP [6,7, 8]. The ISO-guide is an international protocol for evaluating meters designed for glucose monitoring, and gives the following minimum acceptable accuracy requirement:

ISO 15197 gives the following minimum acceptable accuracy requirement:
Ninety-five percent (95%) of the individual glucose results shall fall within ±0,83 mmol/L of the results of the comparison method at glucose concentrations <4,2 mmol/L and within ±20% at glucose concentrations ≥4,2 mmol/L.

This is a quality goal for measurements made by trained laboratory staff. Ideally, the same quality requirements should apply to measurements performed by the diabetes patients. Previous investigations under the direction of the NOKLUS-project "Diabetes-Self-measurements" in 1997 [3, 6] showed that few of the self-monitoring glucose meters tested at the time met the ISO-requirements. Subsequent SKUP-evaluations confirmed these findings. Consequently, the results achieved by the diabetes patients have been discussed towards a *modified* goal suggested by NOKLUS, with a total error of ±25%. This modified goal has wide, and not ideal, limits. The intention was to tighten up the modified requirements for the diabetes patients over time, as the meters would hopefully improve due to technological development. More recent evaluations performed by SKUP [7], clearly show that the diabetes patients also can achieve the quality goals set by ISO 15197. However, for the time being, the quality demands adjusted to the diabetes patients' self-measurements, still apply.

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

Total error
According to ADA the total error for meters designed for self monitoring of blood glucose should not exceed 10% in the range 1,67 – 22,2 mmol/L. The quality goal from ADA must be seen as an optimal goal for the analytical quality of these meters. In 2008 NOKLUS suggested a similar quality goal for glucose instruments for use in primary care centres and nursing homes in Norway [9].

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

In this evaluation the OneTouch Verio 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 Definition of P—Glucose

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”. In the database, the recommended name is given for the measurand and with which unit the result should be reported.

Name, code and unit for P—Glucose tests according to C-NPU:

NPU code	NPU22089
Full name of test	Plasma(capillary Blood)—Glucose; substance concentration = ?
Short name	P(cB)—Glucose
Unit	mmol/L

3.2 OneTouch Verio

OneTouch Verio is a blood glucose monitoring system based on amperiometric electrochemical biosensor technology. The system consists of the OneTouch Verio meter and dry reagent test strips. The system is designed for capillary blood glucose testing performed by persons with diabetes or by health care professionals. OneTouch Verio 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 0,4 µL. The blood is automatically drawn into the test strip. Blood can be applied to either side of the test strip. The result is shown in 5 seconds. According to the owner’s booklet, it is possible to use blood samples from fingertip, forearm or palm on OneTouch Verio. The meter has the capacity of storing 500 results in the memory. For more information about OneTouch Verio, see table 1 and attachment 1.

Test principle of OneTouch Verio

Glucose dehydrogenase converts glucose to gluconolactone. The cofactor in the reaction is flavin-adenine dinucleotide (FAD).

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

3.2.1 Product information, OneTouch Verio

OneTouch Verio is manufactured by LifeScan Inc. Technical data from the manufacturer is shown in table 1. For names of the suppliers in the Scandinavian countries and more details about OneTouch Verio, see attachment 1.

Table 1. Technical data from the manufacturer

Technical data for OneTouch Verio	
Optimal operating temperature	6 – 44° C
Humidity	10 – 90% (non-condensing)
Sample material	Capillary whole blood
Sample volume	0,4 µL
Measuring time	5 seconds
Measuring range	1,1 – 33,3 mmol/L
Hematocrit	Not affected by hematocrit values from 20 to 60%
Storage capacity	500 test results
Electrical power supply	Two 3-volt lithium battery (CR2032)
Operating time	Minimum six months at average of four tests per day
Dimensions	74,7 mm x 55,5 mm x 19,9 mm
Weight	52,6 g (including the batteries)

OneTouch Verio serial numbers
A total of 95 OneTouch Verio blood glucose meters were used in this evaluation. Four meters were used by the biomedical laboratory scientists under the standardised and optimal conditions. Serial no. BNBFJ021 (meter A) and no. BNBFB00J (meter B) in Arendal. Serial no.BNBDZ017 (meter A) and no. BNBFG046 (meter B) in Haugesund. Attachment 2 gives serial numbers for the 91 meters used by the diabetes patients.

OneTouch Verio test strips
The evaluation took place in advance of launching OneTouch Verio onto the market. A limited number of lots was available at the time. The three lots included in the evaluation have the same expire date, but come from separate production runs.

Lot 3051418, lot 3051422 and lot 3051424 Expiry 2011-09-30

OneTouch Verio Control Solution
The OneTouch Verio Control Solution is a blue aqueous glucose solution produced with glucose concentrations in a normal and high range. The Mid range control was used in this evaluation.

Control Mid	Lot 0Z3A04	Expiry 2011-09
	Lot 0Z3A03	Expiry 2011-06
	Target value:	5,7 – 7,7 mmol/L

Blood sampling device used by the diabetes patients
The diabetes patients could choose whether to use the OneTouch Mini Lancet Pen with OneTouch Ultra Soft lancets, or the lancet pen they usually use.

3.3 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.

3.3.1 The selected comparison method in this evaluation

In a SKUP evaluation the selected 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 selected 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 implemented 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 produced NADH absorbs light at 340 nm and is detected spectrophotometrically as an increased absorbance.

3.3.2 Verifying of the analytical quality of the comparison method

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 [10] consists of ampoules with human serum with certified concentrations of glucose at four levels, with given uncertainties. 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 [11]. The controls are included in NOKLUS's External Quality Assessment program. The results are summarized in chapter 5.2.3.

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

3.3.3 Product information, the comparison method

Comparison method on Architect ci8200
Architect *ci*8200 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

Quality controls produced by SERO AS
Reference values 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 concluded 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 used under standardised and optimal conditions (for single use only)
Medlance Plus Extra Lot P2V418C8 Expiry 2015-04
Safety-Lancet Lot P45U919B9 Expiry 2014-09

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

Centrifuges
Eppendorf 5415D Serial no. 0057100
Eppendorf MiniSpin Serial no. 0022772

3.4 Planning of the evaluation

Background for the evaluation
OneTouch Verio is a new blood glucose monitoring system designed for capillary blood testing performed by persons with diabetes as well as health care professionals. The OneTouch Verio system is produced by LifeScan Inc. and supplied in Scandinavia by LifeScan. The system has not been launched onto the Scandinavian market yet.

Inquiry about an evaluation
Sigbjørn Øvrebø, LifeScan Norge, applied to SKUP in March 2010 for an evaluation of OneTouch Verio glucose meter with OneTouch Verio test strips. SKUP accepted to carry out this evaluation on behalf of LifeScan.

Protocol, agreements and contract
The protocol for the evaluation was approved in July 2010. LifeScan Norge and SKUP signed a contract about the evaluation in July 2010. The laboratory at Haraldsplass Diaconale Hospital in Bergen agreed to carry out the analytical part of the evaluation centred around analysing the samples for the comparison method.

Preparations, training program, and practical work
SKUP started the preparations for the evaluation in May 2010. The biomedical laboratory scientists Anne Mouland Skaar and Bente Omenaas were hired to do the practical work with the evaluation. They were educated in the evaluation procedures by SKUP. In October 2010 Thorleif H. Skoge, LifeScan, demonstrated OneTouch Verio for the biomedical laboratory scientists, and a training session of approximately 30 minutes was completed.

Obviously all written information to diabetes patients participating in a SKUP-evaluation should be in their first language, which in this evaluation means Norwegian. The evaluation of OneTouch Verio was carried out for LifeScan in an early phase of getting prepared for launching in the Scandinavian marked. At the time, the OneTouch Verio owner's booklet unfortunately was not available in Norwegian, and Norwegian was not an option for the meter software. It was decided to use the English versions after all, with a short user guide in Norwegian as a supplement. In addition the matter was examined thoroughly when training the diabetes patients in the "training group". Possible misconceptions ascribed to linguistic problems will be taken into consideration when assessing the user-friendliness in the questionnaires.

The meters and test strips for the evaluation were received in September 2010. Shortly after the equipment were unpacked and prepared for distribution among the diabetes patient. The practical work with the evaluation was carried out from October to December 2010.

Blood sampling
The blood sample for the duplicate measurements was mainly collected from the same finger prick. Only if necessary two finger pricks were performed. Experiments carried out at NOKLUS (results not published) show no significant difference between duplicate measurements from blood drops from the same finger prick and duplicate measurements from two separate pricks. The diabetes patients performed finger pricks themselves for their measurements, while the biomedical laboratory scientists performed pricks for the measurements under standardised and

optimal conditions. The biomedical laboratory scientists wiped off the first drop of blood before the first measurement. Blood was also wiped off between the two sets of duplicates (meter A and B). The diabetes patients performed their measurements as they usually do. The biomedical laboratory scientists observed their measurements and noted if the diabetes patients did anything wrong during the measuring procedure. It was observed that not all the diabetes patients wiped off the first blood drop.

3.4.1 Evaluation sites and persons involved

The blood sampling of the diabetes patients and the measurements on OneTouch Verio under standardised and optimal conditions, were carried out by Anne Mouland Skaar, biomedical laboratory scientist, SKUP/NOKLUS at Sørlandet Hospital HF Arendal, and Bente Omenaas, biomedical laboratory scientist, SKUP/NOKLUS at Haugesund Hospital. Kjersti Østrem, biomedical laboratory scientist at the Laboratory at HDH, was given the responsibility for the practical work with the comparison method. Marianne Risa, SKUP/NOKLUS, did the statistical calculations and the report writing.

3.5 The evaluation procedure

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*" [12]. In principle, the 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 the model worked out by the NOKLUS-project "*Diabetes-Self-measurements*" [13]. This model has become basis for the quality specifications used when The Norwegian Health Economics Administration (HELFO) decides whether to give reimbursement for glucose test strips [14]. The evaluation model has been used by SKUP since 2002, and has been evaluated and discussed in an article from 2008 presenting the results from nine of the SKUP glucose evaluations [8].

The evaluation comprises the following studies:
- An examination of the analytical quality under standardised and optimal conditions, performed by two biomedical laboratory scientists in a hospital environment
- An examination of the analytical quality among approximately 90 diabetes patients
- The agreement between OneTouch Verio and a selected comparison method
- A calculation of total measurement error (TE) based on the imprecision and bias of OneTouch Verio, and discuss the achieved TE according to a quality goal of 10%, suggested by NOKLUS as a quality goal for glucose device used in Norwegian primary care and nursing homes
- A comparison of the analytical quality among diabetes patients with and without a training programme
- A comparison of the analytical quality among diabetes patients before and after practise at home
- An examination of the variation between three lots of test strips
- An examination to see if hematocrit interferes with the measurements
- An evaluation of the user-friendliness of OneTouch Verio
- An evaluation of the owner's booklet of OneTouch Verio

Recruitment of the diabetes patients
The diabetes patients were recruited in September and October, partly through advertisement in two local newspapers and by mail inquiry sent to the members of the local branch of The Norwegian Diabetes Association.

3.5.1 The model for the evaluation

The evaluation consisted of two parallel parts. One part of the evaluation was carried out under standardised and optimal conditions in a hospital laboratory. This part of the evaluation was performed by laboratory-educated personnel, in exact accordance with the protocol and the owner's booklet and after having received thorough training. All possibilities for disturbance of, and interference with the measurements were tried kept at a minimum. The evaluation under standardised and optimal conditions 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 OneTouch Verio by the users, 91 diabetes patients tested their blood glucose using the device. The diabetes patients were randomly divided into two groups. Half of the diabetes patients received personal training in how to use the blood glucose meter, hereafter called the "training group". The other group received the blood glucose meter and instructions by mail, hereafter called the "mail group". Dividing the diabetes patients into a "training group" and a "mail group" reflects the actual market situation regarding training when diabetes patients acquire blood glucose meters [13]. Three lots of test strips were distributed evenly between the diabetes patients in the "training group" and the "mail group" (random distribution in each group). The model for the evaluation is shown in figure 1.

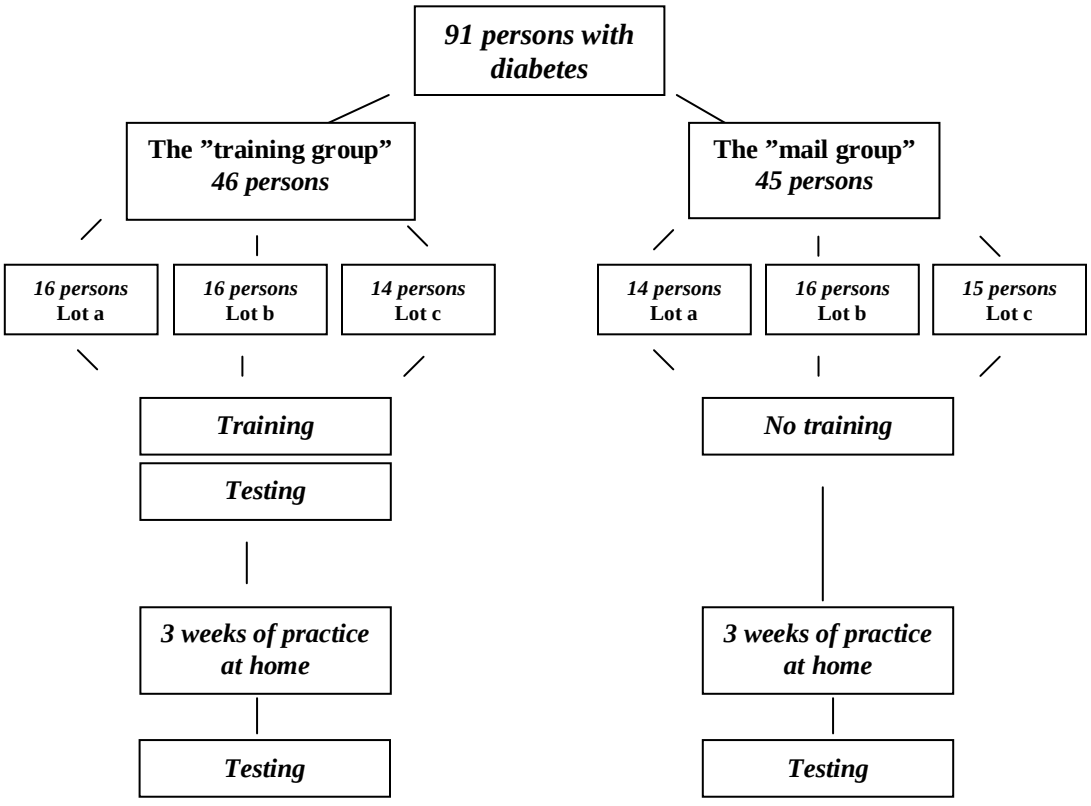

Figure 1. Model for the evaluation

3.5.2 Selection of diabetes patients

The OneTouch Verio glucose meter was tested in use by 91 diabetes patients. 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.
Characteristics of the diabetes patients are shown in table 2.

Table 2. Characteristics of the diabetes patients

		Number of diabetes patients
Total		91
Sex	Men	46
	Women	45
Age, median in years (range)		59 (19 – 81)
Diabetes	Type 1	30
	Type 2	58
	Impaired glucose tolerance (IGT)	1
	Don't know	2
Treatment	Insulin	33
	Insulin pump	7
	Insulin and tablets	10
	Tablets	33
	Diet	7
	Unspecified	1
Frequency of self-monitoring of blood glucose (SMBG)	Less than weekly	6
	1 – 3 per week	7
	4 – 6 per week	10
	7 – 10 per week	16
	>10 per week	50
	Not measuring	2*

*Two of the diabetes patients did not perform SMBG

The SMBG-devices the diabetes patients used regularly were: Accu-Chek (model not specified) (6), Accu-Chek Aviva/Aviva Nano (6), Accu-Chek Compact Plus (14), Accu-Chek Mobile (9), Ascensia Breeze/Breeze2 (2), Ascensia Contour/Contour (21), FreeStyle/FreeStyle Freedom/FreeStyle Mini/Mini+ (5), FreeStyle Lite/FreeStyle Freedom Lite (14), and OneTouch Ultra/Ultra2/Ultra Easy/Ultra Smart (9).

Some of the diabetes patients used more than one type of SMBG-device at home, but only one device is registered here.

3.5.3 The "training group" at the first consultation

The 46 diabetes patients who participated in the training programme were invited in pairs for training. They received the OneTouch Verio device along with test strips, lancet pen, OneTouch Ultra Soft lancets, owner's booklet (in English), and an information letter with explanations regarding what to do with the OneTouch Verio device when practising at home. The information letter is attached to the report (in Norwegian), see attachment 3. The responsibility for the training programme was undertaken by SKUP. Anne Mouland Skaar and Bente Omenaas were in charge of the training of the diabetes patients, after having been trained themselves by a representative from LifeScan.

The training programme

The training session shall correspond to ordinary training for new users.The training programme covered a simple demonstration of how to use OneTouch Verio. This includes an explanation of the display and error messages, insertion of the test strip, blood sampling and drawing of blood onto the test strip, as well as precautions for storage and the shelf life of test strips, etc. The training programme was standardised to make sure that all the diabetes patients received the same instruction. LifeScan approved the training programme.

Blood sampling

After being trained, the 46 diabetes patients made duplicate blood glucose tests on their assigned OneTouch Verio meter. Most of them used the OneTouch Mini Lancet Pen with OneTouch Ultra Soft lancets for the blood sampling. The results were registered for the evaluation. The biomedical laboratory scientists pricked another finger and collected samples for the evaluation under standardised and optimal conditions (see chapter 3.5.7.). Afterwards the diabetes patients brought the OneTouch Verio device home to use it over a three-week period. After this period they attended a final consultation (see chapter 3.5.6).

3.5.4 The "mail group"

The 45 diabetes patients in the "mail group" received the OneTouch Verio device by mail, along with test strips, lancet pen, OneTouch Ultra Soft lancets, owner's booklet (in English) and an information letter with explanations regarding what to do with the OneTouch Verio device during the period at home. No training was given. They used the meter over a three-week period at home. After this period, they attended a final consultation (see chapter 3.5.6).

3.5.5 Use of OneTouch Verio by the diabetes patients at home

All the diabetes patients used OneTouch Verio at home for three weeks. During the practice period, the diabetes patients used OneTouch Verio in addition to their own glucose meter, and they continued to carry out self-measurements with their own meter as usual.

The first and the second week

The diabetes patients familiarised themselves with the new device during the first two weeks. Each diabetes patient used approximately 25 test strips to measure his/her blood glucose with OneTouch Verio. They could choose when to do the measurements themselves. Fasting was not necessary. If more convenient, they could perform the measurements at the same time as they performed measurements with their own meter.

The third week
During the third week, the diabetes patients performed duplicate measurements on OneTouch Verio on five different days. The results were recorded on a provided form. They pricked a finger and made two consecutive measurements with blood from the same prick. If necessary, they pricked another finger for the second measurement. They were free to choose when to perform the measurements, and fasting was not necessary.

Internal quality control
The diabetes patients are not familiar with control solutions for glucose self-measurements. Therefore, they were not instructed to use the control solution on OneTouch Verio in the evaluation. To document correct functioning of the OneTouch Verio meters used by the diabetes patients during the test period, the biomedical laboratory scientists in charge of the practical work checked the meters with the control solution when the diabetes patients met at the consultations.

3.5.6 The final consultation

Blood sampling
After the three-week practice period at home, 89 of the 91 diabetes patients met, one by one, for a consultation. Two of the diabetes patients were not able to attend this consultation. The diabetes patient brought their assigned OneTouch Verio to the consultation. Before the samples were collected, the device was equilibrated to room temperature while the diabetes patients filled in the questionnaires. Then the diabetes patients made duplicate blood glucose tests on their assigned meter. Most of them used the OneTouch Mini Lancet Pen with OneTouch Ultra Soft lancets for the blood sampling. The measurements were performed with the test strips delivered to the diabetes patients for the evaluation. The results were registered for the evaluation. The biomedical laboratory scientists collected capillary samples for the evaluation under standardised and optimal conditions from a new finger prick. Finally, a venous sample for hematocrit was taken.

Evaluation of the user-friendliness and the owner's booklet
The diabetes patients filled in two questionnaires. The first questionnaire deals with the user-friendliness of OneTouch Verio; the second covers the owner's booklet. See section 5.6.

3.5.7 Evaluation under standardised and optimal conditions

The two biomedical laboratory scientists each used two OneTouch Verio blood glucose meters for the evaluation (one meter called meter A and one called meter B). 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. The test strips used under standardised and optimal conditions were kept at NOKLUS during the entire evaluation period. The number of samples for each lot of test strips measured under standardised and optimal conditions is shown in table 3.

Table 3. The number of samples for each lot of test strips measured under standardised and optimal conditions

OneTouch Verio		**Lot 3051418**	**Lot 3051422**	**Lot 3051424**
Meter A	First consultation	46 x 2		
	Final consultation	89 x 2		
Meter B	First consultation	15 x 2	18 x 2	13 x 2
	Final consultation	29 x 2	28 x 2	32 x 2
	Total	179 x 2	46 x 2	45 x 2

Blood sampling

Meter A and B were checked by means of the manufacturer's control solution every day they were used. The biomedical laboratory scientists measured the internal quality control (OneTouch Verio Control Mid) on the diabetes patient's meter at each consultation.

All samples for OneTouch Verio, as well as the samples for the comparison method, were collected from finger capillaries.

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

1. The biomedical laboratory scientist took a first sample for the comparison method
2. The biomedical laboratory scientist took samples and analysed on meter A, B, A and B
3. The diabetes patient took duplicate samples for his/her assigned meter
4. The biomedical laboratory scientist took a second sample for the comparison method

The pricking and sampling were carried out in turns by the biomedical laboratory scientist and the person with diabetes.

In order to reduce the possibility for a change in the glucose concentration during the sampling sequence, the sampling time ought not to exceed 10 minutes. The stability of the glucose concentration during the sampling was supervised. A more detailed explanation of the matter is found in the paragraph "*Stability of the glucose concentration during the sampling time*".

The order of the measurements on meter A and B was changed between each diabetes patient, but the blood samples for the comparison method were always taken at the start and in the end of each sampling sequence, in accordance with ISO 15197 [5]. The biomedical laboratory scientists registered whether the diabetes patients used correct cleaning, drying, and skin puncture procedures, if they applied the blood correctly to the test strip, and otherwise followed the manufacturer's instructions for performing a blood glucose test. At the final consultation, a

venous sample for hematocrit determination was taken. Hematocrit may influence on blood glucose measurements, especially in meters designed for self-monitoring. According to the technical specifications of OneTouch Verio, glucose measurements are not influenced by hematocrit values from 20 to 60%. The hematocrit results came from a Sysmex-system.

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 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 [10].

The samples were thawed at NOKLUS just before they were analysed on the comparison method. The samples were analysed during three following days in December.

Stability of the glucose concentration during the sampling time
For each sampling sequence, two samples for the comparison method were collected. These pairs of samples, taken at the start and at the end of each blood sampling sequence, reflect the stability of the glucose concentration during the sampling time. When the paired measurements give agreeable glucose concentrations on the comparison method, the mean of the two results is looked upon as the best estimate of the true value of the sample. To secure the decision regarding the stability of the glucose concentration, all the second samples were analysed in duplicate.

Assessment of the glucose concentration stability
To verify the glucose sample stability, the criteria suggested in ISO 15197 were used. The criteria are regarded as a starting point for decisions about sample exclusion. Samples with a change >4% between the first and second comparative result at glucose concentrations >5,5 mmol/L or >0,22 mmol/L for glucose concentrations ≤5,5 mmol/L should not be included in the data processing. Choice of criteria must be related to the precision capability of the measurement procedure. If criteria are too tight, samples will be discarded unnecessarily. If too loose, the apparent uncertainty will be inflated.

Evaluation of the user-friendliness and owner's booklet
The biomedical laboratory scientists evaluated the user-friendliness of OneTouch Verio and the owner's booklet. They looked for any defects and deficiencies or whether there was anything with the system that did not function optimally and they provided a description about the system and the booklet with key words.

3.5.8 Evaluation of analytical quality

The following sets of data give the basis for the evaluation of the analytical quality:

1. Results from 46 diabetes patients who had participated in the training programme, before using the blood glucose meter at home; the "training group"
2. Results from 44 diabetes patients in the "training group" after they had practiced using OneTouch Verio at home for three weeks
3. Results from 45 diabetes patients who had not participated in the training programme, but had practiced using OneTouch Verio at home for three weeks; the "mail group"
4. Results from 135 measurements in duplicate on OneTouch Verio under standardised and optimal conditions
5. Results from 135 measurements in duplicate from the comparison method

All the diabetes patients' measurements were evaluated against the results achieved under standardised and optimal conditions. All the measurements were compared with the results from the comparison method.

For missing or excluded results, see section 5.1.

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 [15].

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 [16] 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 and will be commented on under each table.

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 [17, 18]:

$SD = \sqrt{\frac{\sum d^2}{2n}}$, 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 first and the second 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 a combination of the analytical bias and imprecision, possible matrix effects left out of account, 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 [19] use 1,96 for a situation of no bias and 1,65 for the bias situation.

5 Results and discussion

5.1 Number of samples

5.1.1 Total number of samples

A total of 91 diabetes patients participated in the evaluation. 89 of them completed the evaluation. 44 of the 46 diabetes patients in the "training group" met at two consultations. Two were unable to attend the final consultation. The 45 diabetes patients in the "mail group" met at one consultation. Blood samples were taken at each consultation.
The total number of glucose samples is:
[(46 x 2 (duplicates)) + (44 x 2) + (45 x 2)] x 4 (meter A, meter B, diabetes patient's meter and the comparison method) = 1080 glucose samples.
Hematocrit samples were collected from 82 of the 89 diabetes patients.

5.1.2 The glucose concentration stability

Out of 124 paired results with glucose concentrations >5,5 mmol/L on the comparison method, 23 gave deviations between 4 and 10%. For 16 of these 23 samples the deviation was less than 7%. After a general evaluation of all the results, these 23 paired measurements were included in the calculations, as they did not affect the outcome of the assessment of accuracy or bias. The conclusions in this report are not dependent on keeping or excluding these results.
Changes >10% were regarded as unacceptable and the results were excluded. The matching meter results were removed before assessment of accuracy and hematocrit influence, and before calculation of trueness. This only applied to the samples from ID 18 at the first consultation.
Two of 10 paired results on the comparison method with glucose concentration <5,5 mmol/L, had deviations >0,22 mmol/L. These results are also excluded from the calculations. This applied to the samples from ID 16 and ID 20 at the final consultation.

5.1.3 Missing or excluded results

Besides the statistical outliers and the results excluded due to unstable glucose concentration, the following results are missing or excluded for other reasons:

- ID 19 and ID 137 were not able to attend the final consultation
- ID 103 at the first consultation was classified as an outlier according to Burnett in the calculation of repeatability on the comparison method. These results are excluded, and the matching meter results removed before assessment of accuracy and hematocrit influence, and before calculation of trueness
- ID 42 at the final consultation was classified as an outlier according to Burnett in the calculation of repeatability on meter A and is excluded from the calculation of trueness of OneTouch Verio
- ID 143 at the final consultation was classified as an outlier according to Burnett in the calculation of repeatability on meter B and is excluded from the calculation of lot variation. The result is included in the difference plot

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

The best estimate of the repeatability of a method is achieved by using patient samples. By doing so, matrix effects in artificially produced materials are avoided. In this evaluation, two capillary samples were taken of each individual for measurement on the comparison method. The blood sampling was carried out with a small time gap between the first and the second sample for each diabetes patient. The paired measurements reflect the stability of the glucose concentration during the sampling time, and not the precision of the method. To achieve a measure for the repeatability of the comparison method, the second sample was analysed in duplicate. The formula used for the calculation of the precision, and the assumption for using it, are shown in chapter 4. Subtle differences between the paired measurements on the comparison method were observed. The results are not shown. When using highly precise methods, an even negligible difference is easily pointed out as statistic significant. SKUP has gained experience with this glucose comparison method through many previous evaluations. Unquestionable the repeatability is good.

The repeatability of the comparison method is shown in table 4. The raw data is shown in attachment 4.

Table 4. Repeatability, the comparison method. Results achieved with capillary blood samples

Glucose level group	Comparison method (mmol/L)	n	Excluded results	Comparison method, mean (mmol/L)	CV% (95% confidence interval)
Low	<7	44	0	5,9	0,8 (0,6 – 1,0)
Medium	7 – 10	52	0	8,2	0,8 (0,7 – 1,1)
High	≥10	38	1*	13,5	0,9 (0,7 – 1,1)

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 103, first cons) according to Burnett's model

Discussion

The precision of the comparison method was good. The repeatability CV was approximately 1% and equivalent to results achieved in previous corresponding evaluations.

5.2.3 The trueness of the comparison method

In order to demonstrate the trueness of the comparison method calibration, 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 5.

Table 5. 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	20.12.10	1,836 (1,809 — 1,863)	5	1,82	
	22.12.10		5	1,85	
	Total		10	1,83	-0,2
Level 2	20.12.10	4,194 (4,135 - 4,253)	5	4,22	
	22.12.10		5	4,29	
	Total		10	4,25	+1,4
Level 3	20.12.10	6,575 (6,481 — 6,669)	5	6,63	
	22.12.10		5	6,66	
	Total		10	6,64	+1,0
Level 4	20.12.10	16,35 (16,15 — 16,55)	5	16,65	
	22.12.10		5	16,88	
	Total		10	16,77	+2,5

Comments

Table 5 shows that the glucose results of the NIST-standards at level 1, 2, and 3 on Architect were in agreement with the certified target values. The glucose results at level 4 on Architect were approximately 0,2 mmol/L above the upper uncertainty limit. All results from Architect are therefore adjusted according to the certified NIST-targets. The adjustment was carried out by means of inverse calibration [20, 21] by the following regression equation: $y = 0{,}9713x + 0{,}077$.

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

To verify the trueness of the comparison method, freshly frozen, human serum controls, produced by SERO AS, with glucose concentrations at two levels were analysed. The agreement between the comparison method and target values from the Reference laboratory in Belgium is shown in table 6.

Table 6. 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	20.12.10	4,78	5	4,73	
	22.12.10		5	4,76	
	Total		10	4,75	-0,7
TM Gluc L-2	20.12.10	11,80	5	11,73	
	22.12.10		5	11,86	
	Total		10	11,80	0,0

Discussion
The trueness of the comparison method was good.

5.3 Analytical quality of OneTouch Verio

5.3.1 Internal quality control

The OneTouch Verio meters in the user evaluation were checked with the manufacturer's control solutions by the biomedical laboratory scientists (see table 10 and 11). All results were within the control range printed on the control solution vial.

5.3.2 Comparison of the 1st and 2nd measurements

Two capillary samples were taken of each diabetes patient for measurements on meter A and meter B at each consultation. In addition, the diabetes patients took two capillary samples for measurements on their assigned meter at each consultation. All results have been checked to meet the assumption in 4.2.2. No systematic difference was pointed out between the paired measurements on meter A, meter B, and the diabetes patients' meter. This conclusion is also supported by observations in previous user-evaluations carried out by SKUP. Table 7 shows the results from the comparison of the first and second measurement on meter A and meter B. The results from the comparison of the first and second measurement on the diabetes patients' meter are not shown.

Table 7. Comparison of the 1st and 2nd measurement. T-test for paired values

OneTouch Verio	Glucose level (mmol/L)	n	Mean 1st measurement (mmol/L)	Mean 2nd measurement (mmol/L)	Mean difference 2nd – 1st measurement (mmol/L)	95% CI for the mean difference, (mmol/L)
Meter A	<7	40	5,9	5,9	0,04	-0,02 – +0,10
	7 – 10	56	8,2	8,2	0,00	-0,10 – +0,10
	≥10	39*	13,1	13,1	-0,06	-0,28 – +0,15
Meter B	<7	38	5,8	5,9	0,03	-0,06 – +0,12
	7 – 10	59**	8,1	8,2	0,03	-0,06 – +0,12
	≥10	38	13,2	13,2	0,03	-0,19 – +0,26

*One statistical outlier according to Burnett's model (ID 42, final consultation)
** One statistical outliers according to Burnett's model (ID 143, final consultation)

5.3.3 The precision of OneTouch Verio

Repeatability under standardised and optimal measuring conditions
The repeatability obtained under standardised and optimal conditions with capillary blood samples from the diabetes patients, is shown in table 8. The table gives the results from the biomedical laboratory scientists' measurements at the first and the final consultation together. The results are sorted and divided into three glucose levels according to the first measurement on OneTouch Verio.

The raw data is shown in attachment 5.

Table 8. Repeatability, OneTouch Verio. Results achieved by the biomedical laboratory scientists

OneTouch Verio	Glucose level (mmol/L)	n	Excluded results	Mean value glucose (mmol/L)	CV% (95% confidence interval)
Meter A	<7	40	0	5,9	2,3 (1,8 – 2,9)
Meter B	<7	38	0	5,9	3,2 (2,6 – 4,1)
Meter A	7 – 10	56	0	8,2	3,1 (2,6 – 3,7)
Meter B	7 – 10	59	1*	8,2	3,0 (2,5 – 3,7)
Meter A	>10	39	1**	13,1	3,5 (2,8 – 4,5)
Meter B	>10	38	0	13,2	3,6 (2,9 – 4,7)

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 143, final consultation) according to Burnett's model
**One statistical outlier (ID 42, final consultation) according to Burnett's model

Comments
Two results were segregated as statistical outliers according to Burnett. There were no error messages related to the two outliers. The repeatability CV was approximately 3%. The precision was good.

Repeatability obtained by the diabetes patients
The repeatability obtained by the diabetes patients with capillary blood samples is shown in table 9. The table gives the results from the measurements at the first and the final consultation for the "training group" and the results from the measurements at the consultation for the "mail group". All these measurements were carried out at NOKLUS and observed by the biomedical laboratory scientists.

The results obtained at home have a high degree of uncertainty since it is impossible to check what was actually done. The reporting of these home-values revealed that some of the diabetes patients did not quite understand the instruction on how to perform and report the five duplicate measurements they were supposed to carry out. The results obtained by the diabetes patients at home document their training efforts, but repeatability is not calculated based on these results.

The raw data from the diabetes patients' measurements at NOKLUS is shown in attachment 6.
The raw data from the diabetes patients' measurements at home is shown in attachment 7.

Table 9. Repeatability, OneTouch Verio. Results achieved by the diabetes patients

Consultation/ diabetic group	Glucose level (mmol/L)	n	Excluded results	OneTouch Verio mean value glucose(mmol/L)	CV% (95% confidence interval)
1st/training group	<7	12	0	5,6	5,9 (4,2 – 10,0)
2nd/training group	<7	15	0	6,1	5,1 (3,7 – 8,0)
The mail group	<7	8	0	6,1	4,0 (2,6 – 8,1)
1st/training group	7 – 10	23	0	8,2	5,8 (4,5 – 8,2)
2nd/training group	7 – 10	18	0	7,8	3,9 (2,9 – 5,9)
The mail group	7 – 10	22	0	8,4	6,2* (4,8 – 8,9)
1st/training group	≥10	11	0	13,4	5,2 (3,6 – 9,1)
2nd/training group	≥10	11	0	13,4	4,5 (3,1 – 7,9)
The mail group	≥10	15	0	14,3	4,7 (3,5 – 7,5)

*See comments below

Comments
The measuring procedures were carried out without any obvious or visible mistakes, and there were no error messages related to the measurements. The results achieved after three weeks of training tend to be better than at the first consultation, but the improvement is not statistical significant.

The CV for the glucose level 7 – 10 mmol/L in the mail group was 6,2%. This relative weak CV was mainly affected by the results of ID 108. The difference between the two measurements of ID 108 was 2,4 mmol/L. The difference is still not segregated as a statistical outlier according to Burnett. After visual inspection the result is clearly an atypical result. The actual CV was 4,7% without this result.

Reproducibility with Internal Quality Control Solution
The reproducibility is assessed with OneTouch Verio Control Mid. 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 meter A (one lot of test strips) and meter B (three different lots of test strips) during the whole evaluation period. The reproducibility of OneTouch Verio on meter A and meter B is shown in table 10.

Table 10. Reproducibility, OneTouch Verio. Results achieved with the control solution on meter A and meter B

OneTouch Verio	n	Excluded results	Target value (mmol/L)	Mean value glucose (mmol/L)	CV% (95% confidence interval)
Meter A	28	0	5,7 – 7,7	6,5	3,2 (2,5 – 4,3)
Meter B	32	0	5,7 – 7,7	6,6	2,4 (1,9 – 3,2)

Comments
The reproducibility CV achieved with the control solution on meter A and meter B was approximately 3%.

Internal Quality Control on the diabetes patients' meters
The control measurements on the diabetes patients' meters (91 meters) were performed with OneTouch Verio Control Mid. The biomedical laboratory scientists performed the control measurements with the test strips that were distributed to each diabetes patient (three different lots of test strips). The control solutions were kept according to the instructions in the product insert throughout the evaluation period. The control measurements on the diabetes patients' meters are shown in table 11.

The raw data from the measurements with the internal quality control is shown in attachment 8.

Table 11. Reproducibility, OneTouch Verio. Results achieved with the control solution on the diabetes patients' meters

OneTouch Verio Control Mid	**n**	**Excluded results**	**Target value (mmol/L)**	**Mean value glucose (mmol/L)**	**CV% (95% confidence interval)**
First consultations					
The diabetes patients' meters	46	0	5,7 – 7,7	6,5	2,4 (2,0 – 3,0)
Final consultations					
The diabetes patients' meters	89	0	5,7 – 7,7	6,8	3,5 (3,0 – 4,0)

Comments
The reproducibility CV achieved with the control solution on the diabetes patients' meters was approximately 3%. The mean value of the control was inside the target value limits. All control results were within the control range printed on the control solution vial.

Discussion, repeatability and reproducibility
The precision obtained under standardised and optimal conditions was good. The repeatability CV was between 2,3 and 3,6%. The recommended quality goal for precision was obtained. The repeatability CV obtained at NOKLUS when the measurements were performed by the diabetes patients was approximately 4,5%. The CVs for the diabetes patients with and without training (the "training group" and the "mail group") were not statistical significantly different. The CVs for the diabetes patients after practise at home tend to be better than the results at the first consultation, but the precision improvement was not statistical significant. This indicates that OneTouch Verio is a robust system, easy to use, and that training is not essential for a good result.

The reproducibility on OneTouch Verio under standardised and optimal conditions was good when measured with OneTouch Verio Control Mid. The CV was approximately 3%. The reproducibility CV obtained with OneTouch Verio Control Mid on the diabetes patients' meters was approximately 3%.

5.3.4 The trueness of OneTouch Verio

The trueness of OneTouch Verio is calculated from the results achieved by the biomedical laboratory scientists at the final consultation (the "training group" and the "mail group"). The measurements were performed with one lot of test strips on meter A. The results are sorted and divided into three glucose levels according to the mean measurements on the comparison method. The results are shown in table 12.

Table 12. Trueness of OneTouch Verio

Glucose level group Comparison method (mmol/L)		**n**	**Excluded results**	**Comparison method, mean (mmol/L)**	**OneTouch Verio, mean (mmol/L)**	**Mean deviation from the Comparison method, mmol/L (95% CI)**
Low	<7	28	0	6,0	6,2	+0,27 (+0,15 — +0,39)
Medium	7 - 10	32	0	8,0	8,2	+0,24 (+0,08 — +0,39)
High	>10	26	0	13,3	13,3	+0,01 (-0,25 — +0,27)

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

Discussion

OneTouch Verio showed glucose results in agreement with the comparison method for glucose concentrations >10 mmol/L. For glucose concentrations <10 mmol/L OneTouch Verio showed higher glucose results than the comparison method. The deviation from the comparison method was between 0,2 and 0,3 mmol/L for glucose concentrations below 10 mmol/L. The deviation was small, but statistical significant.

5.3.5 The accuracy of OneTouch Verio

To evaluate the accuracy of the results on OneTouch Verio, the agreement between OneTouch Verio and the comparison method is illustrated in two difference-plots. The plots show the deviation of single measurement results on OneTouch Verio from the true value, and give a picture of both random and systematic deviation, reflecting the total measuring error on OneTouch Verio. The total error is demonstrated for the first measurements of the paired results, only. On meter A, only one lot of test strips was used. On meter B, three different lots of test strips were used. The same three lots were randomly distributed between the diabetes patients. The limits in the plots are based upon the quality goals discussed in chapter 2 in this report. Under standardised and optimal measuring conditions, the ISO-goal at ±20% is used. For the diabetes patients' self-measurements, the "adjusted ISO-goal" at ±25% is used.

The accuracy, OneTouch Verio meter B, with three lots of test strips, under standardised and optimal measuring conditions, at the final consultation is shown in figure 2.

The accuracy, OneTouch Verio, as measured by all the diabetes patients at the final consultation (the "training group" and the "mail group") is shown in figure 3.

The accuracy is summarised in table 13 and discussed afterwards.

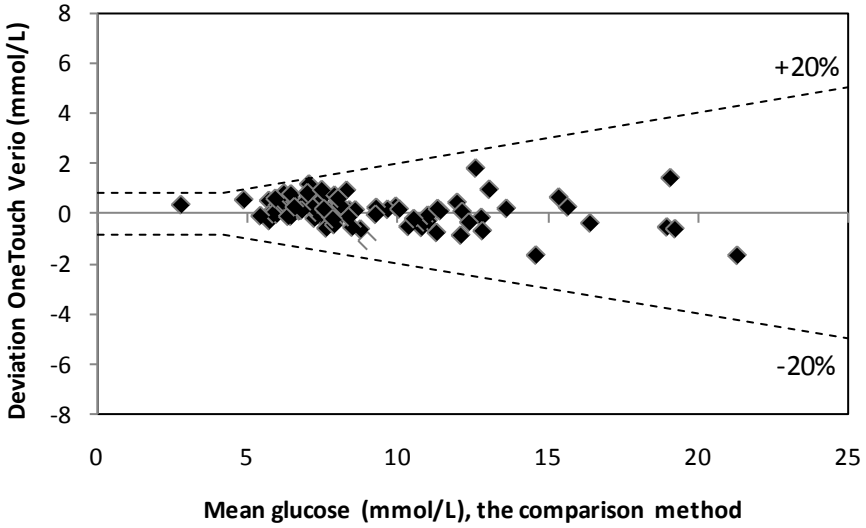

Figure 2. Accuracy. OneTouch Verio meter B (with three lots of test strips) under standardised and optimal measuring conditions at the final consultation. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on OneTouch Verio and the mean value of the duplicate results on the comparison method. Stippled lines represent limits suggested in ISO 15197 (±20%), n = 87. Open symbol represents ID 143, statistical outlier from the calculation of repeatability on meter B

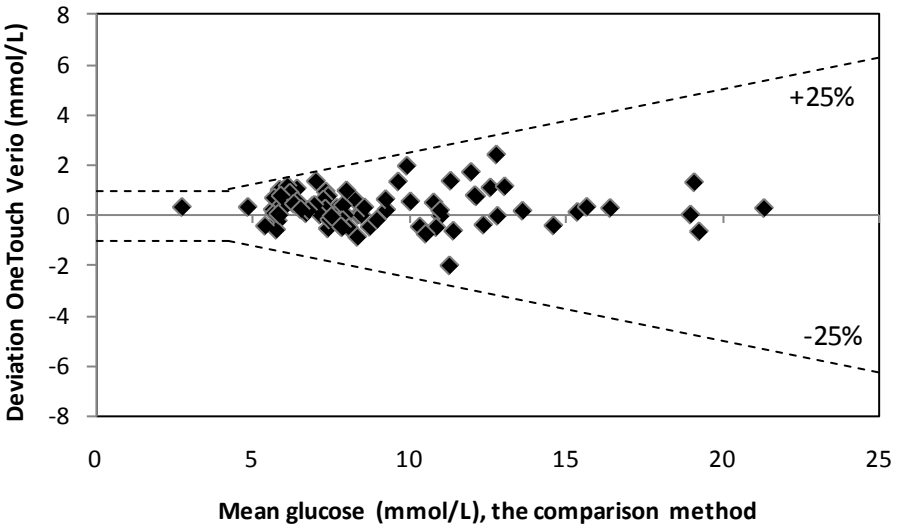

Figure 3. Accuracy. The diabetes patients' self-measurements at the final consultation. Three lots of test strips. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on OneTouch Verio and the mean value of the duplicate results on the comparison method. Stippled lines represent adjusted ISO limits suggested by NOKLUS (±25%), n = 87

Table 13. Accuracy of OneTouch Verio. Percentage OneTouch Verio results within the limits

Measure performed by	**Cons.**	**Meter**	**n**	**Number of results within the limits (%)**		**Shown in figure**
				ISO <±20% and <±0,83 mmol/L at conc. ≤4,2	**"Adjusted ISO" <± 25% and <±1,0 mmol/L at conc. ≤4,2**	
Biomedical laboratory scientists	First	A 1st measurement	44	100		
		B 1st measurement	44	100		
Biomedical laboratory scientists	Final	A 1st measurement	87	100		
		B 1st measurement	86	100		2
Diabetes patients at NOKLUS	First	1st measurement	44	100	100	
	Final	1st measurement	87	99	100	3

Discussion
Figure 2 shows that the results obtained under standardised and optimal measuring conditions at the final consultation are within the ISO-limits. The summing up in table 13 shows that 100% of the results achieved under optimal measuring conditions (meter A and meter B) at both the first and the final consultation, were within the quality limits proposed in ISO 15197. Figure 3 shows that all the diabetes patients' first self-measurements at the final consultation are within the "adjusted ISO-goal". The summing up in table 13 shows that all the diabetes patients' first self-measurements at the first and the final consultation are within the "adjusted ISO-goal".
100% of the first measurements at the first consultation and 99% of the first measurements at the final consultation are also within the ISO-goal. The accuracy was good and the quality goals were attained.

5.3.6 The calculated total error of OneTouch Verio

A total error based on the imprecision and bias of OneTouch Verio was calculated as described in section 4.2.5. Possible matrix effects are left out of account. The calculated total error of OneTouch Verio (meter A) is shown in table 14.

Table 14. The calculated total error of OneTouch Verio

Glucose	**<7 mmol/L**	**7 – 10 mmol/L**	**≥10 mmol/L**
CV%	2,3	3,1	3,5
Bias, mmol/L	0,27	0,24	0,01
Bias, %	4,5	2,9	0,1
TE (%) = |bias| + 1,65 · CV	**8,3**	**8,0**	5,9
TE = 1,96 · CV	4,5	6,1	**6,9**

Discussion
The calculated total error, based on the imprecision and bias of OneTouch Verio, was between 6,9 and 8,3%, depending on the glucose concentration. The suggested quality goal for use in Norwegian primary care centres and nursing homes was obtained.

5.4 Variation between three lots of test strips

The measurements on meter B 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 from the measurements on meter B at the final consultations were used. The results were sorted according to the lot of the 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 15.

Table 15. Variation between three lots of test strips

OneTouch Verio, lot number of test strips	**n**	**Excluded results**	**Comparison method, mean (mmol/L)**	**OneTouch Verio, mean (mmol/L)**	**Mean deviation from the Comparison method, mmol/L (95% CI)**
3051418	27	0	9,3	9,5	+0,21 (0,00 — +0,42)
3051422	28	0	8,9	9,0	+0,09 (-0,10 — +0,28)
3051424	31	1*	8,5	8,6	+0,11 (-0,03 — +0,26)

The given numbers of results (n) are counted before the exclusion of outliers
*One statistical outlier (ID 103) according to Burnett's model

Conclusion
The three lots of test strips used in this evaluation gave glucose results in agreement with the comparison method.

5.5 Effect of hematocrit

According to the technical specifications of OneTouch Verio glucose measurements are not influenced by hematocrit values from 20 to 60%. To measure the effect of hematocrit on OneTouch Verio, a hematocrit sample was taken of the diabetes patients at the final consultation. The investigation of the effect of hematocrit is based on the measurements on OneTouch Verio (meter A with one lot of test strips) under standardised and optimal measuring conditions. The glucose concentration range in the samples was 2,8 – 21,3 mmol/L. The hematocrit range was 30 – 49%.

The effect of hematocrit is shown in figure 4. The trend-line is shown in the figure.
The raw data is shown in attachment 9.

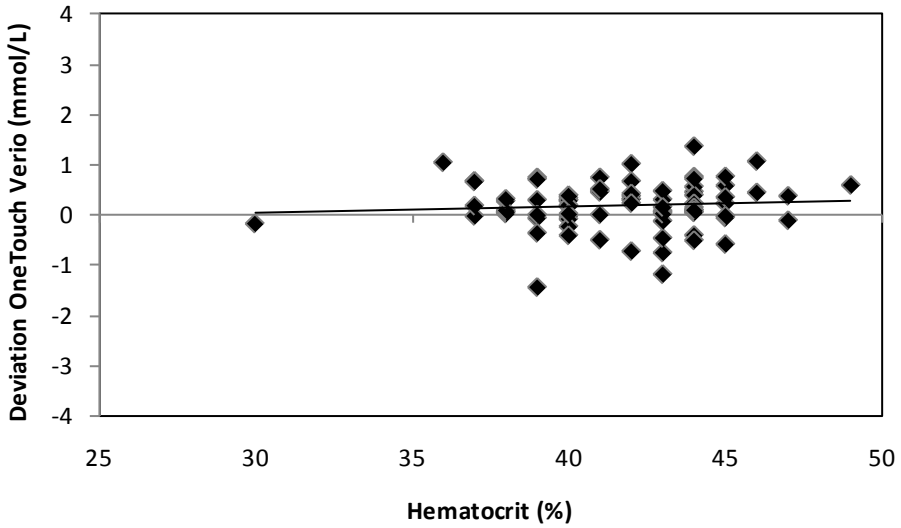

Figure 4. The effect of hematocrit on glucose measurements on OneTouch Verio measured under standardised and optimal conditions. The x-axis shows the hematocrit value in percent. The y-axis shows the difference in glucose concentration between OneTouch Verio and the comparison method (OneTouch Verio – the comparison method) in mmol/L, n= 82

Discussion
Glucose measurements on OneTouch Verio in this study were not affected by hematocrit values within the range 30 – 49%.

5.6 Practical points of view

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

Questionnaires
When attending the final consultation, 89 diabetes patients filled in a questionnaire about the user-friendliness and a questionnaire about the owner's booklet of OneTouch Verio. The biomedical laboratory scientists were available for clarifying questions, and there was room for free commenting. The questionnaires about the user-friendliness and owner's booklet are attached to the report (in Norwegian), see attachment 10 and 11.

5.6.1 Evaluation of the user-friendliness of OneTouch Verio

The questionnaire about the user-friendliness was made up of nine questions concerning OneTouch Verio. Table 16 summarizes six questions where the diabetes patients were asked to rank the answers on a scale from 1 to 6, where 1 is difficult and 6 is simple.

The mean score was 5,3 and 5,6 on questions about inserting a test strip into the meter and filling the test strip with blood respectively. This indicates that the diabetes patients seemed satisfied with the use of the test strips. The OneTouch Verio meters used by the diabetes patients in Haugesund had the sound signal turned off and they were therefore not asked about the sound signal. The mean score regarding the sound signal was 5,0 among the diabetes patients in Arendal. The mean score was 5,8 on the question about reading the figures in the display and 5,3 on the question about operating the meter, all in all. Regarding OneTouch Mini Lancet Pen the mean score was 5,3. This indicates that most of the diabetes patients that used the pen were satisfied with it.

Table 16. OneTouch Verio - Questions about the meter

Questions about OneTouch Verio		Total number	Range	Mean score	No answer (% of total)
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	89	2 - 6	5,3	1
	To fill the test strip with blood	89	3 - 6	5,6	0
	To hear the sound signal	89	1 - 6	5,0	52
	To read the figures in the display	89	3 - 6	5,8	0
	All in all, to operate the meter	89	2 - 6	5,3	0
	To operate the OneTouch Mini Lancet Pen	89	2 - 6	5,3	6

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

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

1. Easy to use (17)
2. The meter has short measuring time (16)
3. Readable display/large figures (12)
4. The meter/strip needs a small blood samples volume (11)
5. Good menu/software (9)
6. The test strip is easily filled (8)

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

1. Single test strips/not "all in one" (17)
2. Different problems with the test strips (11); the strips are small, slippery, stuck together, difficult to get out of the box, difficult to insert into the meter
3. The device is too big/unwieldy (9)
4. The carry case is too big (9)
5. The results seemed too high, variable results (6)

Table 17 shows the answers regarding technical problems with OneTouch Verio. Ten of the diabetes patients (11%) answered that they had technical problems with the meter during the testing period. Written comments indicate that the problems were not technical ones after all, but were problems related to error codes.

Table 17. OneTouch Verio – Questions about the meter

Question about OneTouch Verio	Total number	Yes (%)	No (%)	No answer (%)
Did you have any technical problems with the meter during the testing period?	89	11	78	11

5.6.2 Evaluation of the OneTouch Verio owner's booklet

In the questionnaire about the owner's booklet, each diabetes patient was first asked whether he/she had used the booklet. If the answer was no, they were to ignore the rest of the questionnaire.

Table 18 shows that 81% of the diabetes patients had used the booklet. Seven of the diabetes patients who had used the booklet answered that they were not satisfied with the description of how to perform a blood glucose measurement with the meter. Four of them thought the description was too complicated. Eight of the diabetes patients thought the booklet had essential shortcomings. Four of these missed information telling that the instrument starts automatically when you insert a test strip. Several of the diabetes patients commented that the size of the booklet was too large. 85% of the diabetes patients were satisfied with the owner's booklet.

Table 18. OneTouch Verio – Questions about the owner's booklet

Questions about the owner's booklet	Number	Yes (%)	No (%)	No answer (%)
Have you been reading in the owner's booklet?	89	81	17	2
If yes, did you read the entire owner's booklet?	74	43	46	11
And/or did you consult the owner's booklet when needed?	74	55	16	28
Are you satisfied with the description of how to perform a blood glucose measurement with the meter?	74	86	8	5
Do you think the owner's booklet has essential shortcomings?	74	11	78	11
All in all, are you satisfied with the owner's booklet?	74	85	9	5

5.6.3 The biomedical laboratory scientists' evaluation

Positive comments:

- The meter is small and easy to operate
- The text on the display is easy to read
- The test strip requires a small blood sample volume, and it is easily filled
- Short measuring time
- The starter guide was simple

Negative comments:

- The meter has a slippery surface. Easy to lose
- A bit difficult to insert the test strip into the meter
- The test strips easily stuck together
- The carry case was too big
- The size of the owner's booklet was too large

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Attachments

1. Facts about the instrument
2. Serial numbers, OneTouch Verio blood glucose meters used by the diabetes patients
3. Information letter to the diabetes patients (in Norwegian)
4. Raw data glucose, results from the comparison method
5. Raw data glucose, OneTouch Verio results under standardised and optimal conditions
6. Raw data glucose, OneTouch Verio results, the diabetes patients' measurements at NOKLUS
7. Raw data glucose, OneTouch Verio results, the diabetes patients' measurements at home
8. Raw data glucose, internal quality control, OneTouch Verio
9. Raw data hematocrit
10. Questionnaire, user-friendliness (in Norwegian)
11. Questionnaire, owner's booklet (in Norwegian)
12. "SKUP-info". Summary for primary health care (in Norwegian)
13. List of evaluations organised by SKUP
14. Comments from LifeScan

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

Facts about the instrument

Parts of this form are filled in by LifeScan.

a) Name of the instrument	***OneTouch Verio***

Physical dimensions	*74,7 mm x 55,5 mm x 19,9 mm*
Manufacturer (with address)	*LifeScan Europe* *Division of Cilag GmbH International* *6300 Zug* *Switzerland*
Distributor (with address)	*Denmark:* *Johnson & Johnson AB, LifeScan* *Bregnerødvej 133* *3460 Birkerød*
	Norway: *Johnson & Johnson AB, LifeScan* *Drammensveien 288* *0283 Oslo*
	Sweden: *Johnson & Johnson AB* *Staffansväg 2* *191 84 Sollentuna*

b) Analysis menu, sample materials and sample volume

Component	Sample materials	Sample volume
Glucose	*Fresh capillary whole blood (Venous in the hands of a professional)*	*0.4 µL*

c) Analysis principles (reference to the instruction manual)

Parameter	Principle
Glucose	*Amperometry, GDH-FAD*

d) Measuring range

Component	Measuring range	Unit
Glucose	*1.1-33.3*	*mmol/L*

e) Measuring time per component (precisely stated)

Component	Pre-analytic measuring time (with an explanation)	Measuring time
Glucose	*Measurement starts with application of sample/sample detection*	*5 seconds*

f) Calibration

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

g) Recommended maintenance

Maintenance	How often?
Battery replacement	*Within 100 tests after first display of the "Battery Low" Icon appearing.*
Meter Cleaning	*As required. Clean with a soft cloth dampened with water and mild detergent.*

h) Control materials

Is control material available (from the producer or other companies)?	*LifeScan supplied controls only.* *Verio Control Solution – Mid & High by request*

i) Marketing

In which country is the analyser marketed?	*Holland.* *Other countries will launch OneTouch ®VerioPro™*
When did the analyser first appear on the Scandinavian market?	*Not launched yet.* *OneTouch® VerioPro™ will be launched in Denmark, Norway, Sweden and Finland*
When did the analyser receive CE approval?	*November 6, 2009 OneTouch Verio* *October 20, 2010 One Touch VerioPro*

j) Language

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

k) Memory

What is the storage capacity of the analyser and what is stored?	*500 results.* *Meter reading, date, time,* ***If in use**: If the reading was: before meal or after meal.*
Is it possible to identify patients?	*No*
If yes, describe this:	

a) Name of the instrument	***OneTouch Verio***

l) Power supply

Electric network connection	*None*
Battery	*Yes*
If yes, which type and how many batteries	*Verio 2 x 3V Coin Cells, CR2032* *VerioPro 2 x AAA Cells*

m) Electronic communication

Can a printer be connected to the analyser?	*No*
Can a barcode reader be connected to the analyser?	*No*
Interface	*Verio – Serial* *VerioPro – mini USB-USB*
If yes, which port is required?	*Verio – Serial* *VerioPro –USB*
Communication method	*Verio – Proprietary Serial* *VerioPro – USB + LifeScan driver*
Transfer mode	*Verio – Proprietary* *VerioPro - Proprietary*
Transfer protocol	*Verio – Binary* *VerioPro – Virtual Comport*

n) Standards and controls

	Standard	Control
Name		*Verio Control Solution Mid & High*
Volume		*3 ml*
Shelf life unopened		*Per expiry date on label*
Shelf life opened		*6 months after first opening or labelled expiry date.*
Any comments:		

o) Reagents/Test strips/Test cassettes

Component	Time and temperature, unopened	Time and temperature, opened
OneTouch Verio test strips	*Below 30 deg C, do not refrigerate*	*6 months from first opening or labelled expiry date. Store below 30 deg C, do not refrigerate.*

p) Additional information

Serial numbers, OneTouch Verio blood glucose meters used by the diabetes patients

ID	Serial number
1	BNBFK00K
2	BNBFK00J
3	BNBFJ00T
4	BNBFH066
5	BNBFJ00D
6	BNBFJ00B
7	BNBFK03D
8	BNBFJ001
9	BNBFK03J
10	BNBFJ006
11	BNBFJ00P
12	BNBFL024
13	BNBFL02H
14	BNBFJ00R
15	BNBFJ017
16	BNBFL026
17	BNBFL02F
18	BNBFL022
19	BNBFJ00N
20	BNBFL028
21	BNBFL027
22	BNBFK02N
23	BNBFJ00S
24	BNBFB00D
25	BNBFB00H
26	BNBFB00W
27	BNBFB00L
28	BNBFB008
29	BNBFB01B
31	BNBFB00V
32	BNBFB003
33	BNBFB007
34	BNBFB009
35	BNBFB00T
36	BNBFB002
37	BNBFB00K
38	BNBFB006
39	BNBFB01H
40	BNBFB00C
41	BNBFB00B
42	BNBFB00G
43	BNBFJ00G
44	BNBFJ00Q
45	BNBFJ003
46	BNBDZ01L
101	BNBDV019
102	BNBDV03X
103	BNBDV01F

ID	Serial number
104	BNBDB01K
105	BNBDZ008
107	BNBDV01Z
108	BNBDZ00Z
111	BNBDV03N
112	BNBDV040
113	BNBDV03J
114	BNBDV03H
115	BNBDV030
116	BNBDW00K
118	BNBFB017
119	BNBDV01G
120	BNBDZ00C
122	BNBDV01L
123	BNBDW039
124	BNBFB00N
126	BNBDV03R
127	BNBDW03B
128	BNBDW00S
129	BNBFB019
130	BNBDZ006
131	BNBDZ013
132	BNBDW036
134	BNBFB010
135	BNBDV045
136	BNBFK02R
137	BNBDV03T
138	BNBFM002
140	BNBFB00Z
142	BNBDW035
143	BNBDV047
144	BNBFK05J
145	BNBDV03V
146	BNBDW00G
147	BNBDV046
149	BNBFK05G
151	BNBFL02B
153	BNBFK038
154	BNBFJ01F
157	BNBDW00L
159	BNBDV04B
160	BNBDV039
161	BNBFK02Q

NORSK KVALITETSFORBEDRING AV
LABORATORIEVIRKSOMHET UTENFOR SYKEHUS

NOKLUS

NN

Utprøving av blodsukkerapparat

November 2010

Du har fått utlevert:

- 1 OneTouch Verio blodsukkerapparat i etui
- 1 pakke OneTouch Verio teststrimler for glukose (2 x 25 stk.)
- 1 OneTouch prøvetakingspenn
- 25 lansetter
- Brukerveiledning

Du skal bruke utprøvingsapparatet hjemme i en periode på ca. 3 uker. I denne prøveperioden skal du bruke dette apparatet **i tillegg** til ditt eget apparat. Det betyr at du skal utføre blodsukkermålinger med ditt vanlige apparat så ofte som du ellers ville ha gjort. **Når du skal vurdere ditt eget blodsukker, skal du bruke resultatene fra ditt vanlige apparat.** Utprøvingsapparatet skal du bruke slik det står beskrevet nedenfor:

1. og 2. uke:

De to første ukene skal benyttes til å bli kjent med apparatet. I løpet av disse to ukene skal du bruke ca. 25 strimler til å måle ditt eget blodsukker med utprøvingsapparatet. Du kan selv velge når på dagen du vil gjøre disse målingene (du trenger ikke være fastende). Passer det best slik, kan du utføre blodsukkermålingen med utprøvingsapparatet samtidig som du måler med ditt vanlige apparat. Dersom du ønsker det, kan du benytte ditt eget utstyr for prøvetaking i stedet for OneTouch prøvetakingspenn.

3. uke:

Etter at du har brukt de 25 første strimlene, skal du i løpet av den tredje uken måle blodsukkeret med utprøvingsapparatet på 5 forskjellige dager. Du kan selv velge når på dagen du vil gjøre disse målingene (du trenger ikke være fastende). Hver av disse 5 dagene skal du: Stikke deg i fingeren og **måle blodsukkeret to ganger rett etter hverandre** med blod fra samme stikk. Dersom du ikke får nok blod til å utføre begge målingene, kan du stikke deg på nytt til andre måling. Resultatene føres i skjemaet på baksiden.

”ID”
“Serienr apparat”
“Lotnr teststrimler”

Dato	OneTouch Verio Svar 1 (mmol/L)	OneTouch Verio Svar 2 (mmol/L)	Er målingene gjort med blod fra samme/forskjellige stikk? Stryk det som ikke passer.
Dag 1:			Samme / forskjellige
Dag 2:			Samme / forskjellige
Dag 3:			Samme / forskjellige
Dag 4:			Samme / forskjellige
Dag 5:			Samme / forskjellige

Har du brukt OneTouch prøvetakingspenn til prøvetakingen?

☐Ja ☐Nei ☐Noen ganger

Av de 50 strimlene du fikk sammen med apparatet, skal du nå ha ca. 15 strimler igjen. Du må spare fem av strimlene til målingene du skal gjøre når du kommer hit til Haugesund sjukehus for den avsluttende utprøvingen. Til den avsluttende utprøvingen skal du ta med dette skjemaet, OneTouch Verio, resten av strimlene og OneTouch prøvetakingspenn med lansetter. Du skal utføre egne målinger med utprøvingsapparatet. I tillegg vil bioingeniøren stikke deg to ganger i fingeren og til slutt ta en blodprøve fra armen. Du vil også bli bedt om å svare på noen spørsmål mht. apparatets brukervennlighet og om brukerveiledningen. Det hele vil ta ca ½ time.

Har du spørsmål, enten før du starter eller i løpet av prøveperioden, er det bare å ringe:

Bente Omenås Tlf: 52 732 222 / 95 492 960

Lykke til!

Med vennlig hilsen

Sverre Sandberg (sign.)
Leder i NOKLUS/prof.dr.med.

Bente Omenås (sign.)
Laboratoriekonsulent / Bioingeniør

Raw data glucose, internal quality control, OneTouch Verio

OneTouch Verio Control Mid	Lot-no	Expiry	Glucose level mmol/L
Control Mid	0Z3A04	2011-09	5,7 – 7,7
Control Mid	0Z3A03	2011-06	5,7 – 7,7

OneTouch Verio Control analysed on the biomedical laboratory scientists' meter A and B

Date	OneTouch Verio Control Mid Glucose (mmol/L)	
	Meter A	Meter B
28.Oct.2010	6,6	6,7
29.Oct.2010	6,4	6,7
04.Nov.2010	6,6	6,5
05.Nov.2010	6,3	6,6
08.Nov.2010	6,5	6,4
09.Nov.2010	6,8	6,3
11.Nov.2010	6,3	6,3
12.Nov.2010	6,3	6,6
15.Nov.2010	6,4	6,4
16.Nov.2010	6,7	6,7
16.Nov.2010	6,7	6,3
17.Nov.2010	6,5	6,7
18.Nov.2010	6,5	6,5
19.Nov.2010	6,7	6,4
23.Nov.2010	6,5	6,6
24.Nov.2010	6,5	6,7

Date	OneTouch Verio Control Mid Glucose (mmol/L)	
	Meter A	Meter B
25.Nov.2010	6,4	6,6
25.Nov.2010	6,2	6,4
26.Nov.2010	6,4	6,5
26.Nov.2010	7,0	6,5
26.Nov.2010		6,4
29.Nov.2010	6,3	6,6
02.Dec.2010	6,4	6,5
02.Dec.2010		6,9
06.Dec.2010	6,5	6,3
06.Dec.2010	6,5	6,6
07.Dec.2010	6,9	6,8
08.Dec.2010	6,9	6,8
08.Dec.2010		6,5
09.Dec.2010	6,6	6,6
10.Dec.2010	6,8	6,5
10.Dec.2010		6,6

OneTouch Verio Control Mid analysed on the diabetes patients' meters

Training group

ID	Lot-no test strips	OneTouch Verio Control Mid Glucose (mmol/L)	
		1'st consultation	Final consultation
1	3051418	6,6	7,0
2	3051418	6,3	6,6
3	3051418	6,5	6,9
4	3051418	6,7	6,7
5	3051418	6,7	6,8
6	3051418	6,8	6,4
7	3051418	6,5	7,2
8	3051418	6,7	6,3
9	3051422	6,5	6,5
10	3051422	6,4	6,5
11	3051422	6,8	6,7
12	3051422	6,6	6,6
13	3051422	6,3	6,7
14	3051422	6,5	6,6
15	3051422	6,5	6,6
16	3051422	6,7	6,5
17	3051424	6,4	6,8
18	3051424	6,5	6,9
19	3051424	6,7	Unable to meet
20	3051424	6,5	7,0
21	3051424	6,4	6,7
22	3051424	6,6	6,9
23	3051424	6,6	7,1
101	3051418	6,5	7,2
103	3051418	6,1	6,8
107	3051418	6,8	7,0
111	3051418	6,4	6,9
114	3051418	6,7	6,8
115	3051418	6,7	6,9
119	3051418	6,5	7,1
122	3051418	6,6	6,7
123	3051422	6,5	7,0
126	3051422	6,6	6,9
127	3051422	6,2	6,9
128	3051422	6,5	7,0
132	3051422	6,3	6,2
135	3051422	6,6	6,7
137	3051422	6,4	Unable to meet
142	3051422	6,6	6,8
143	3051424	6,3	6,9
145	3051424	6,5	6,9
146	3051424	6,4	6,7
147	3051424	6,4	6,5
157	3051424	6,5	7,0
159	3051424	6,4	7,0
160	3051424	6,5	6,7

Mail group

ID	Lot-no test strips	OneTouch Verio Control Mid Glucose (mmol/L) Final consultation
24	3051418	6,9
25	3051418	6,7
26	3051418	6,7
27	3051418	7,0
28	3051418	6,7
29	3051418	6,4
31	3051422	6,6
32	3051422	6,7
33	3051422	6,6
34	3051422	6,6
35	3051422	6,9
36	3051422	6,8
37	3051422	6,8
38	3051422	6,7
39	3051424	6,7
40	3051424	6,8
41	3051424	6,5
42	3051424	6,7
43	3051424	6,6
44	3051424	6,8
45	3051424	6,4
46	3051424	6,4
102	3051418	6,9
104	3051418	7,2
105	3051418	6,3
108	3051418	6,8
112	3051418	7,3
113	3051418	7,0
116	3051418	6,7
118	3051422	6,6
120	3051422	6,5
124	3051422	7,2
129	3051422	6,5
130	3051422	7,3
131	3051422	6,5
134	3051422	6,7
136	3051422	6,7
138	3051424	6,8
140	3051418	6,4
144	3051424	6,7
149	3051424	6,7
151	3051424	6,8
153	3051424	6,7
154	3051424	6,4
161	3051424	6,5

ID-nummer (deltaker):_____

OneTouch Verio

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 strimmel 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 lese tallene i displayet

Vanskelig *Enkelt*

1	2	3	4	5	6
☐	☐	☐	☐	☐	☐

4. Å betjene apparatet, totalt sett

Vanskelig *Enkelt*

1	2	3	4	5	6
☐	☐	☐	☐	☐	☐

5. Å betjene OneTouch Verio lansettpenn (skal kun besvares hvis OneTouch Verio lansettpenn er benyttet i utprøvingen)

Vanskelig *Enkelt*

1	2	3	4	5	6
☐	☐	☐	☐	☐	☐

Snu arket

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 OneTouch Verio?**

- _____
- _____
- _____

8. **Synes du det er noen ulemper med OneTouch Verio?**

- _____
- _____
- _____

Evt. andre kommentarer:_____

_____

_____

_____

ID-nummer (deltaker):_____

OneTouch Verio

Spørreskjema om brukerveiledning 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

OneTouch Verio blodsukkerapparat fra LifeScan
Sammendrag fra en utprøving i regi av SKUP

SKUP
www.skup.nu
SKUP/2011/86

Konklusjon
Presisjonen på OneTouch Verio var god. CV var ca. 3 % når målingene ble utført av laboratorieutdannet personale, og ca. 4,5 % når målingene ble utført av personer med diabetes (brukerne). For glukosekonsentrasjoner under 10 mmol/L var resultatene systematisk høyere (< 0,3 mmol/L) enn resultatene på sammenligningsmetoden. Målingene i denne utprøvingen oppfylte internasjonale kvalitetskrav (ISO 15197) med et avvik på mindre enn ± 20 % fra en anerkjent glukosemetode. Den totale målefeil var under 10 %. Hematokrit så ikke ut til å påvirke glukosemålingene på OneTouch Verio.

OneTouch Verio er beregnet til måling av blodsukker, både av personer med diabetes og av helsepersonell. Målesystemet består av apparatet OneTouch Verio og OneTouch Verio teststrimler. Apparatet trenger ikke kodes. Det kreves 0,4 µL blod til hver måling, og blodet kan suges inn på begge sidekantene av teststrimmelen. Målingen tar 5 sekunder. OneTouch Verio har minnekapasitet til å lagre 500 målinger med dato og klokkeslett.

Utprøvingen ble utført under optimale betingelser av laboratorieutdannet personale og blant de brukere apparatet er beregnet for. I utprøvingen deltok 91 personer med diabetes. Deltakerne i "opplæringsgruppen" fikk opplæring i bruken av OneTouch Verio før det ble utført målinger med apparatet. Deltakerne i "postgruppen" fikk apparat og instruksjon tilsendt pr. post og fikk ingen opplæring. Alle deltakerne brukte OneTouch Verio hjemme i tre uker og møtte deretter til en avsluttende konsultasjon.

Resultater
Presisjonen var god. CV var ca. 3 % når målingene ble utført av laboratorieutdannet personale. Når målingene ble utført av personer med diabetes, var upresisheten ca. 4,5 %. Ved glukoseverdier under 10 mmol/L gav OneTouch Verio for høye verdier i forhold til resultatene på sammenligningsmetoden. Forskjellen var mindre enn 0,3 mmol/L. Ved glukoseverdier over 10 mmol/L samsvarte resultatene på OneTouch Verio med resultatene på sammenligningsmetoden. Målingene på OneTouch Verio gav nøyaktige resultater. Kvalitetsmålet fra ISO 15197, som tillater avvik opp til ± 20 % fra en anerkjent metode for måling av glukose, ble oppfylt. Den totale målefeil var under 10 %. Hematokrit i området 30 – 49 %, så ikke ut til å påvirke glukosemålinger på OneTouch Verio.

Brukervennlighet
De fleste brukerne som deltok i utprøvingen syntes at OneTouch Verio var enkel å bruke, og de var fornøyde med apparatet. De fleste brukerne som hadde lest i brukermanualen, var fornøyde med denne.

Tilleggsinformasjon
Den fullstendige rapporten fra utprøvingen av OneTouch Verio, SKUP/2011/86, 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/2010/88	HbA1c	*Confidential*	
SKUP/2011/86	Glucose[1]	OneTouch Verio	LifeScan, Johnson & Johnson
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/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.
SKUP/2005/51*	Glucose[1]	FreeStyle	Abbott Laboratories

*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

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

SKUP evaluations from number 1 — 50

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

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

Comments to the report from Skup

LifeScan wishes to thank SKUP for performing a technical laboratory and at-home evaluation of the OneTouch® Verio™ Blood Glucose Monitoring System. This extensive evaluation has concluded that the systems meet both the Quality goals for the Norwegian primary care centres and nursing homes and is within the performance guidelines defined in ISO 15197. The OneTouch® Verio™ technology is designed to exceed these specifications and we are pleased that your evaluation has confirmed these design goals.

The OneTouch® Verio™ system is the first strip and meter that uses the OneTouch® Verio™ Technology and we plan to launch a series of products based on this technology platform. The current enhanced product OneTouch® VerioPro™ incorporates the OneTouch® Verio™ technology and will provide enhanced meter based features with the equivalent performance of the OneTouch® Verio™ used in this evaluation.

The **OneTouch® VerioPro™** will come with an Owners Booklet in a different format than the one used in the SKUP test of **OneTouch® Verio™.** The format used in the SKUP test was a fold out format, and the **OneTouch® VerioPro™** will come with the Owners Booklet in a book format.

Below you will see a picture of the **OneTouch® VerioPro™** meter that will be launched in Norway.

LifeScan would like to take this opportunity to thank the SKUP organization for their positive and professional behavior throughout the process. It has been a pleasure to work with the SKUP team during this evaluation of the **OneTouch® Verio™ System.**

Best regards

Sigbjørn Øvrebø
Business Unit Manager
LifeScan Norway