DANA DiabeCare®IISG

A glucose meter integrated in an insulin pump manufactured by SOOIL Development co. Ltd

Report from an evaluation organised by

SKUP

The evaluation of the glucose meter and test strips was ordered by Medical Home Tech AS

SKUP in Norway, NOKLUS, Box 6165, NO-5892 Bergen. Phone +47 55 97 95 02. www.SKUP.nu

SKUP/2008/66

The organisation of SKUP

Scandinavian evaluation of laboratory equipment for primary health care, *SKUP*, is a co-operative commitment of NOKLUS [1] in Norway, "Afdeling BFG"[2] in Odense, 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. A detailed list of previous SKUP evaluations is included in this report.

[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] "Afdeling for Biokemi, Farmakologi og Genetik" (Afdeling BFG) is the Department for Clinical Chemistry at the University Hospital in Odense, Denmark. Afdeling BFG in Odense and the national "Fagligt Udvalg vedrørende Almen Praksis" (Professional Committee for General Practice) have through an agreement created "the SKUP-division in Denmark". "Fagligt Udvalg vedrørende Almen Praksis" is a joint committee for "PLO", "Praktiserende Lægers Organisation" (General Practioners Organisation) and "Sygesikringens Forhandlingsudvalg" (Committee for Negotiations within the General Health Insurance System).

[3] EQUALIS AB (External quality assurance in laboratory medicine in Sweden) is a limited company in Uppsala, Sweden, owned by "Sveriges Kommuner och Landsting" (Swedish Association of Local Authorities and Regions), "Svenska Läkaresällskapet" (Swedish Society of Medicine) and IBL (Swedish Institute of Biomedical Laboratory Science).

To make contact with SKUP

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

SKUP in Denmark
Esther Jensen
Per Grinsted
Afdeling BFG
Odense Universitetshospital
DK-5000 Odense C
+45 6541 2865
skup@skup.dk
lko-bfg@ouh.regionsyddanmark.dk

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

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

www.SKUP.nu

Table of contents

Attachments with raw data are included only in the copy to Medical Home Tech AS.

1. Summary

Background
DANA DiabeCare IISG (DANA) blood glucose meter is designed for glucose self-measurements performed by diabetes patients who use an insulin pump. The meter and the test strips are produced by SOOIL Development co. Ltd. and are supplied in Scandinavia by Medical Home Tech. DANA blood glucose meter is integrated in an insulin pump. The DANA insulin pump has been in the Norwegian market for some years but the product integrated with a glucose meter is not launched yet. In order to give reimbursement for the test strips in Norway, the Norwegian Labour and Welfare Organisation (NAV) requires from the companies to carry out an evaluation that includes a user-evaluation among diabetes patients. The evaluation of DANA blood glucose meter was done under the direction of SKUP from February to June 2008.

The aim of the evaluation
The aim of the evaluation of DANA is to

- reflect the analytical quality under standardised and optimal conditions, performed by biomedical laboratory scientists in a hospital environment
- reflect the analytical quality by the intended users
- check the variation between three lots of test strips
- examine if hematocrit interferes with the measurements
- evaluate DANA regarding user-friendliness
- evaluate the DANA user guide

Materials and methods
87 diabetes patients took part in the evaluation. All the diabetes patients had two consultations. The diabetes patients were given a standardised instruction about DANA and did a few finger pricks to get to know the instrument. The diabetes patients used the equipment for approximately two weeks at home, before they attended for a final consultation. At this consultation the diabetes patients did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also collected capillary samples from the diabetes patients and measured twice on DANA. In addition, two capillary samples were taken for measurements with a designated comparison method. In addition a sample for hematocrit was taken. Three different lots of test strips were used in the evaluation. All the participants answered questionnaires about the user-friendliness and the user guide of DANA.

Results

- The precision of DANA was good. The repeatability CV was approximately 3% under standardised and optimal measuring conditions and between 3 and 6% when the measurements were performed by the diabetes patients.
- The trueness of DANA was acceptable. For glucose values <7 mmol/L there was a slight, positive bias (0,1 mmol/L) between DANA and the comparison method. For glucose values between 7 and 10 mmol/L DANA gave results in agreement with the comparison method. For glucose values ≥10 mmol/L a negative bias was pointed out, with a mean deviation from the comparison method of -0,6 mmol/L.
- As a whole, the accuracy of DANA was good. The quality goal set in ISO 15197 was achieved under standardised and optimal measuring conditions. When handled by the

diabetes patients, DANA also showed accurate results. These results were within the "adjusted ISO-goal" and also within the quality goal set in ISO 15197.

- One of the three lots of test strips (DN 24GA02C) used in this evaluation gave significantly lower values than the comparison method. The mean deviation from the comparison method for this lot was -0,44 mmol/L.
- Glucose measurements on DANA seemed to be slightly affected by hematocrit in this study. Hematocrit outside the range 30 – 47% has not been tested.
- The diabetes patients summarised the DANA device as quite easy to operate. Approximately half of them reported various difficulties regarding the test strips, especially when it came to inserting the strip. Quite a few diabetes patients commented the placing of the protection cap. Most of the diabetes patients that had used the user guide were satisfied with the guide.

Conclusion

The analytical quality of DANA was good. The precision was good and the results were accurate and within the quality goal for the total error set in the ISO-guide 15197. The glucose results seemed to be slightly affected by hematocrit. The users where quite pleased with the DANA device, but reported some difficulties regarding insertion of the test strip.

Comments from Medical Home Tech

For comments and additional information from Medical Home Tech, please see attachment 13.

2. Analytical quality specifications

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. DANA is designed for monitoring blood glucose, and the quality goals must be set according to this.

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

Accuracy
According to ADA the total error for meters designed for self monitoring and point of care testing of glucose should not exceed 10% in the range 1,67 – 22,2 mmol/L. The quality goal from ADA must be seen as an optimal goal for the analytical quality of these meters.

The quality goal for the total error of DANA is based on ISO 15197, *In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus* [4]. The ISO-guide is an international accepted protocol for evaluating meters designed for glucose monitoring.

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

This is a quality goal for measurements made by trained laboratory staff. Ideally, the same quality requirements should apply to measurements performed by the diabetes patients. Previous investigations under the direction of the NOKLUS-project "Diabetes-Self-measurements" in 1997 [3,5] showed that few of the self-monitoring glucose meters tested at the time met the ISO-requirements. Subsequent SKUP-evaluations confirmed these findings. As a consequence, the results achieved by the diabetes patients have been discussed towards a *modified* goal suggested by NOKLUS, with a total error of ± 25%. This modified goal has wide, and not ideal, limits. The intention was to tighten up the modified requirements for the diabetes patients over time, as the meters would hopefully improve due to technological development. More recent evaluations performed by SKUP [6] clearly show that the quality goals set by ISO 15197 now can be achieved also by the diabetes patients. But for the time being, the quality demands adjusted to the diabetes patients' self-measurements, still apply.

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

3. Materials and methods

3.1. DANA DiabeCare

DANA DiabeCare (DANA) is a blood glucose monitoring system based on electrochemical biosensor technology. The system consists of a meter, DANA DiabeCare, and dry reagent test strips, DANA Blood Glucose Strip. The system is designed for capillary blood glucose testing performed by persons with diabetes or by health care professionals. DANA is calibrated to report plasma glucose values. The system requires manual calibration, i.e. the user has to set a code number in the meter display identical to the code number printed on the test strip vial. The test principle of DANA is as follows: Glucose oxidase converts glucose to gluconic acid. Glucose is oxidised to gluconic acid by the catalytic action of glucose oxidase while the active site, FAD (Flavin adenine dinucleotide), of the glucose oxidase is reduced to FADH2 (Flavin adenine dinucleotide reduced form), which transfers its electron, in turn, to the electron transfer mediator while being returned to the oxidized form, FAD. The mediator is Hexaaminеruthenium(III)chloride.

$$\text{Glucose} + \text{MediatorOxidized} \xrightarrow{\text{Glucose Oxidase}} \text{Gluconic Acid} + \text{MediatorReduced}$$

The test strips are packed in a plastic bottle with a cap with desiccant. The system requires a blood volume of 0,5 µL. The blood is automatically drawn into the test strip. The result is shown after five seconds. According to the user guide alternative site testing is possible with DANA. The meter has the capacity of storing 500 results in the memory. Technical data from the manufacturer is shown in table 1.

3.1.1. Product information, *DANA DiabeCare IISG*

DANA DiabeCare IISG blood glucose meter integrated in an insulin pump

The insulin pump with meter is manufactured by:
SOOIL Development Co., Ltd.
196-1, Dogok-Dong, Kangnam-Gu
Seoul, Korea 135-270

DANA Blood Glucose Strip manufactured by:
I-Sense ILd.
465-14 Wolhye4-dong
Nowo-Gu, Seoul, Korea

Table 1. Technical data from the manufacturer

Technical data for DANA DiabeCare IISG	
Optimal operating temperature	10 — 40 °C
Sample volume	0,5 µL
Measuring time	5 seconds
Measuring range	1,1 — 33,3 mmol/L
Hematocrit	Not affected by hematocrit values from 20 to 60%
Memory	500 test results
Power source	One 3,6-volt lithium battery (DAC-006-00 size ½ AA)
Operating time	2-3 months
Humidity	10 — 90%
Dimensions	75 mm x 45 mm x 19
Weight	51 g (not including the battery)

24 DANA DiabeCare IISG blood glucose meters were used in this evaluation. Serial no. AHB00033FF (called meter A) and serial no. AHH00018FF (called meter B) were used by the biomedical laboratory scientists. Attachment 1 gives serial numbers for the 22 meters used by the diabetes patients.

DANA DiabeCare IISG test strips:
Lot DN24GA02C (code 27) Expiry 2008-06
Lot EY05GA03B (code 28) Expiry 2008-12
Lot EY05GA03A (code 28) Expiry 2008-12

Care Sense Control:
Used for group 1 (22 first diabetics):

Control Low	Lot CSDJ11BN	Expiry 2007-08
Control High	Lot CSDJ11BM	Expiry 2007-08

Used for group 2, 3 and 4

Control Low	Lot CSDD07AN	Expiry 2008-07
Control High	Lot CSDD07AM	Expiry 2008-07

Suppliers of DANA DiabeCare IISG in Norway:
Medical Home Tech AS
Jan P. Solbø
Sykehusveien 23
Postboks 6449
9294 Tromsø
Tlf. +47 77 28 28 60
Faks. +47 77 28 28 61
Cell phone +47 41 43 01 70
E-post: jan-p.solbo@medhometech.no
www.medhometech.no

3.2. The designated comparison method

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

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

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

Verifying of trueness
The comparison method has to show traceability equivalent to that of an internationally accepted reference solution, such as the standards supplied by the National Institute of Standards & Technology, NIST. The NIST-standard SRM 965a [7] consists of ampoules with human serum with certified concentrations of glucose (and their given uncertainties) at four levels. The uncertainty is defined as an interval estimated to have a level of confidence of at least 95%. The SRM 965a materials cover a glucose concentration range from 1,9 to 16,2 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 on a Reference laboratory in Belgium; Laboratory for Analytical Chemistry, University of Gent, Belgium [8]. The controls are included in NOKLUS's External Quality Assessment program. The results are summarized in chapter 5.1.2.

Internal quality assurance of the comparison method during the evaluation period
The Autonorm Human Liquid Control Solutions at two levels from Sero AS were included in all the measuring series in this evaluation. The controls were measured as the first and the last samples in all the series. The results are summarised in table 5.

3.2.1. Product information, the comparison method

Designated comparison method

Instrument
Architect ci8200. Manufactured by Abbott Laboratories. Serial no. C800890

Reagents
Glucose Reagent Kit, Ref. 3L82-20 and 3L82-40
Lot 54071HWOO Expiry 2008-05-31
Lot 61052HWOO Expiry 2008-11-30

Calibrator
Multiconstituent Calibrator, List No. 1E65
Lot 52631M100 Expiry 2008-07-31 Reference value, cal 1 = 5,44 mmol/L
Reference value, cal 2 = 24,70 mmol/L

Internal quality controls
Autonorm Human Liquid 1 and 2, Sero AS
Liquid 1: Value = 3,37 ±0,24 mmol/L Lot 609470 Expiry: 2008.11.30
Liquid 2: Value = 16,59 ±0,83 mmol/L Lot 611674 Expiry: 2009.01.31

External Quality controls, SERO AS
Reference value from Laboratory for Analytical Chemistry, University of Gent, Belgium; ID-GCMS method
TM Gluc L-1: Value = 7,43 ±0,06 mmol/L lot 0606357
TM Gluc L-2: Value = 10,40 ±0,08 mmol/Llot 0606358

NIST standards
Standard Reference Material® 965a, National Institute of Standards & Technology
Level 1: Value = 1,918 ±0,020 mmol/L
Level 2: Value = 4,357 ±0,048 mmol/L
Level 3: Value = 6,777 ±0,073 mmol/L
Level 4: Value = 16,24 ±0,19 mmol/L

Blood sampling device
Accu-Chek Softclix Pro, Ref: 3307522001, Lancets Lot: WIT 162, Expiry: 2011.12

Tubes used for sampling for the designated comparison method
Microvette CB 300 LH (lithium-heparin) manufactured by Sarstedt AS
Lot 7737201 Expiry: 2010.11

Centrifuge used for samples for the designated comparison method
Eppendorf Centrifuge 5418 Serial no. 008384

Pipette
Finnpipette Thermo Scientific DH91595 4500, 20 — 200µl

3.3. Planning of the evaluation

DANA DiabeCare IISG integrated in an insulin pump is produced by SOOIL Development Co., Ltd. and is supplied in Norway by Medical Home Tech AS. Medical Home Tech AS contacted SKUP in April 2007, and SKUP received written information about the product. In July Medical Home Tech confirmed that they wanted to perform an evaluation. The protocol had to be specially adjusted for DANA, and the suggested changes had to be approved by the Norwegian "Fagrådet", on behalf of the Norwegian Labour and Welfare Organisation, NAV. The protocol for the evaluation was accepted in November 2007. The biomedical laboratory scientists at NOKLUS received practical training in December, and the first group of diabetes patients met for personal training in February 2008. The Laboratory at Haraldsplass Diaconal Hospital (HDH) accepted to carry out the analytical part of the evaluation dealing with the samples for the comparison method. SKUP carried out the user-evaluation of DANA from February to June 2008.

SKUP evaluations are based upon the guidelines in the book "*Evaluation of analytical instruments. A guide particularly designed for evaluations of instruments in primary health care*" [9]. 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 by the NOKLUS-project "*Diabetes-Self-measurements*" [10]. This model is basis for the quality specifications used when NAV decides whether or not to give reimbursement for glucose test strips [11].

The evaluation of DANA glucose meter and test strips comprised the following studies:

- An examination of the analytical quality under standardised and optimal conditions, performed by biomedical laboratory scientists in a hospital environment
- An examination of the analytical quality among approximately 80 diabetes patients
- An examination of the agreement between DANA and a designated comparison method
- 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 DANA
- An evaluation of the user guide of DANA

After the evaluation, the diabetes patients returned the DANA devices to the project.

3.3.1. Evaluation sites and persons involved

The blood sampling of the diabetes patients and the measurements on DANA under standardised and optimal conditions, were done by Ann Kristin Fagerbakke, Camilla Eide Jacobsen and Grete Monsen, biomedical laboratory scientists, SKUP/NOKLUS. Two biomedical laboratory scientists, Grethe Kalleklev and Henriette Mohn Soldal, were given the responsibility for the practical work with the comparison method in the Laboratory at HDH. The statistical calculations and the report writing are done by Ann Kristin Fagerbakke, SKUP/NOKLUS in Bergen.

3.4. The evaluation procedure

3.4.1. The model for the evaluation

The practical work with the evaluation was carried out during 15 weeks from February until June 2008 at NOKLUS in Bergen, Norway.

The evaluation consisted of two parallel parts. One part of the evaluation was done under standardised and optimal conditions in a hospital laboratory. This part of the evaluation was done by laboratory educated personnel, in exact accordance with the protocol and the user guide 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 good analytical quality. The other part of the evaluation was done by diabetes patients. In order to determine the analytical quality of DANA by the users, 87 diabetes patients tested their blood glucose using DANA. Because the DANA glucose meter is integrated in an insulin pump, and diabetes patients using an insulin pump always get training before they can take such device in use, all the diabetes patients in this evaluation received personal training in how to use the DANA blood glucose meter. Training the whole group of participants instead of only half the group, makes a difference in the evaluation model compared to previous user-evaluations.
The model for the evaluation is shown in figure 1.

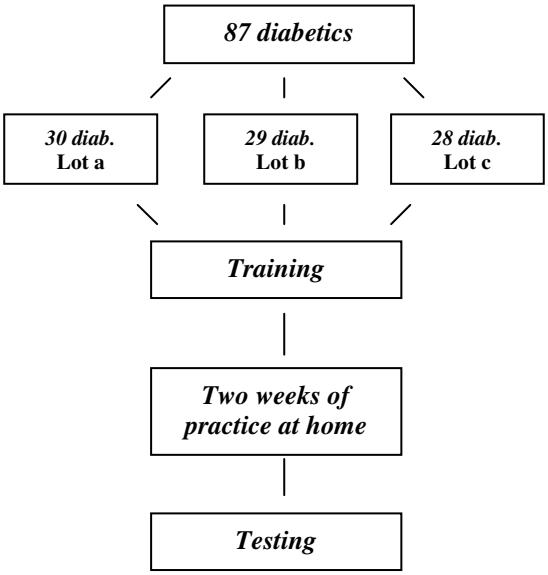


Figure 1. Model for the evaluation

3.4.2. Recruitment of the diabetes patients

A SKUP evaluation should always be carried out among the users the equipment is designed for. DANA glucose meter is integrated in an insulin pump, and the target group for the Dana device is persons with Type 1 diabetes using an insulin pump. It was not practical or possible to recruit only pump-users for the evaluation of DANA. Diabetes patients with Type 1 diabetes and insulin pump-users were especially encouraged to enrol for the evaluation, and where preferred in the selection of participants.

DANA glucose meter was tested in use by 87 diabetes patients. The diabetes patients were recruited through a brochure, by mail inquiry sent to members of the local branch of the Norwegian Diabetes Association and by an invitation to diabetes patients who had participated in a previous SKUP-evaluation. The group of diabetes patients was representative for diabetes patients who carry out self-monitoring of blood glucose (SMBG), except for the number of insulin- and insulin pump-users, which on purpose was higher than in previous user-evaluation. The group included diabetes patients from across a range of self-monitoring frequencies, i.e. diabetes patients who perform self-monitoring often (once or more a day) 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 (n=87)

Property		Number of diabetes patients
Total		87
Age	Median in years	58
	Range in years	18 — 77
Sex	Men	49
	Women	38
Diabetes	Type 1	35
	Type 2	51
	Missing	1
Treatment	Insulin	48
	Insulin and tablets	4
	Tablets	16
	Diet	8
	Missing	11
Insulin pump	Insulin pump	21
	No pump	66
Frequency of SMBG	Less than weekly	2
	1 — 3 per week	4
	4 — 6 per week	7
	7 — 10 per week	18
	>10 per week	48
	Missing	8

The SMBG-devices that the diabetes patients used regularly were:
Accu-Chek (model not specified) (4), Accu-Chek Aviva (6), Accu-Chek Compact/Compact Plus (12), Accu-Chek Sensor (1), Ascencia Dex/Dex 2 (2), Ascensia Breeze/Breeze 2 (7), Ascensia Contour (16), FreeStyle Mini (5), FreeStyle (2), FreeStyle Freedom (2), FreeStyle Lite (9), Glucometer Elite (1), GlucoTouch (1), One Touch (model not specified) (1), OneTouch Ultra/Ultra 2 (4), One Touch Ultra Easy (3), One Touch Ultra Smart (3), Precision Xceed/Xtra (6) and unregistered (2).

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

3.4.3. The training at the first consultation

Only 22 DANA instruments were available for the evaluation, and therefore the diabetics where divided in four main groups. All the diabetes patients in the evaluation participated in the training programme. They were divided in training groups with approximately eight patients in each group. They received the DANA along with test strips, lancet pen, lancets, user guide (in Norwegian), and an information letter with explanations regarding what to do with the DANA device during the period at home. The information letter is attached to the report (in Norwegian), see attachment 2. The responsibility for the training programme was undertaken by SKUP. Ann Kristin Fagerbakke, Camilla Eide Jacobsen and Grete Monsen were responsible for the training of the diabetes patients, after having been trained thoroughly themselves by a representative from Medical Home Tech.

The training programme
The training programme covered a simple demonstration of how to use DANA, with an explanation of the display and error messages, insertion of the test strips, blood sampling and drawing of the blood into the test strip, as well as precautions for storage etc. The training programme was standardised to make sure that all the diabetes patients received the same instruction.

3.4.5. Use of DANA by the diabetes patients at home

The diabetes patients used DANA at home for two weeks. During the practice period the diabetes patients used DANA in addition to their own glucose meter and they continued to carry out self-measurements with their own meter as normal.

The first week
The diabetes patients familiarised themselves with the new device during the first week. Each diabetes patient used approximately 20 test strips to measure his/her blood glucose with DANA. They could choose when to do the measurements themselves. Fasting was not necessary. If more convenient to them, they could perform the measurements at the same time as they performed measurements with their own meter.

The second week
During the second week the diabetes patients performed duplicate measurements on DANA 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 it was not necessary to be fasting. They could choose whether to use the lancets provided for the evaluation, or the lancets they use ordinarily.

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 solutions on DANA in the evaluation. To document correct functioning of the DANA 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 solutions when the diabetes patients met at the consultations.

3.4.6. The second consultation

Blood sampling
After the two-week practice period at home the 87 diabetes patients met at NOKLUS, one by one, for a consultation. Each diabetes patient brought their assigned DANA and the remaining test strips to the consultation. Before the samples were collected, the DANA 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. These results were registered for the evaluation. The biomedical laboratory scientist collected samples for the evaluation under standardised and optimal conditions. Finally, a venous sample for hematocrit was taken.

Evaluation of the user-friendliness and the user guide
Before the blood samples were collected and the measurements on DANA were done, the diabetes patients filled in questionnaires. The first questionnaire deals with the user-friendliness of DANA; the second covers the user guide. The questionnaires (in Norwegian) are attached to the report.

3.4.7. Evaluation under standardised and optimal conditions

The biomedical laboratory scientists used two DANA blood glucose meters for the evaluation (meter A and B). On meter A one lot of test strips were used for all the measurements. Meter B was used for the same three lots as distributed among the diabetes patients. The agreement of the three lots to the comparison method, was assessed. 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 (n) for each lot of strips measured under standardised and optimal conditions

DANA	Lot DN24GA02C (n)	Lot EY05GA03B (n)	Lot EY05GA03A (n)
Meter A	87 x 2		
Meter B	30 x 2	29 x 2	28 x 2
Total	117 x 2	29 x 2	28 x 2

Blood sampling
Meter A and B were checked by means of the manufacturer's control solutions every day they were used. The biomedical laboratory scientists measured one of the two internal quality controls on the diabetes patient's meter at the second consultation.

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

The blood sampling and analysis were done 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

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 in the evaluation is supervised. A more detailed explanation of the matter is found in the paragraph "*Analysing the samples for the comparison method*" and in section 5.1.3.

The order of 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. The biomedical laboratory scientist registered whether the diabetes patients used correct cleaning, drying, and skin puncture procedures, applied the blood sample correctly to the test strip, and otherwise followed manufacturer's instructions for performing a blood glucose test. A venous sample for hematocrit determination was taken. Hematocrit may influence on blood glucose readings, especially in meters designed for self-monitoring. The product insert of DANA test strips and the user guide states that measurements on DANA are not affected by hematocrit values from 20 to 65%.

Handling of the samples for the comparison method
The capillary samples for the comparison method were taken from a finger using Microvette Li-heparin tubes from Sarstedt. The samples were centrifuged immediately for three minutes at 10000g, and plasma was separated into sample vials. The plasma samples were frozen directly and stored at minus 80°C until the analysis took place [7].

Analysing the samples for the comparison method
The samples were analysed on an Architect instrument. Recommended minimum volume for analysis of glucose on Architect in this evaluation was 120 µL plasma. The samples were thawed at NOKLUS just before they were analysed. For each sampling sequence two samples for the comparison method were collected. The first and the second sample for the comparison method, 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 gave agreeable glucose concentrations on the comparison method, the mean of the two results was looked upon as the estimate of the true value of the sample. Basically, the difference between the first and the second comparative reading must not be more than 4% or 0,22 mmol/L (per ISO 15197 Section 7.3.2.). If the difference between any paired results exceeded these limits, the samples were re-analysed. If the results from the re-run confirmed the difference, the difference was looked upon as a real difference in the glucose concentration in the two samples. Deviations >10% were regarded as not acceptable and such results were excluded. As a consequence of this, the matching DANA results were excluded before assessment of accuracy and calculation of trueness. Differences between 4 and 10% are discussed and included in the calculations (see chapter 5.1.3.). If the deviation between the two results was not confirmed by the re-run, the result from the re-run was used as the accepted result. All the samples for the comparison method were analysed between April and June 2008.

Evaluation of the user-friendliness and the user guide
The biomedical laboratory scientists evaluated the user-friendliness of DANA and the user guide. The biomedical laboratory scientists provided a description in the form of key words and looked for any defects and deficiencies or whether there was anything with the system that did not function optimally.

3.4.8. Evaluation of analytical quality

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

1. Results from 87 measurements in duplicate under standardised and optimal conditions
2. Results from 87 measurements in duplicate from the comparison method
3. Results from 87 measurements in duplicate performed by the diabetes patients

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.

The three lots of test strips were distributed evenly between the diabetes patients (random distribution). Each lot was used by approximately 30 diabetes patients in each group (see figure 1).

4. Statistical expressions and calculations

4.1. Statistical terms and expressions

The definitions in this section come from the International Vocabulary of Metrology, VIM [12].

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 descriptive in general terms (good, acceptable, poor e.g.) and measured as imprecision. 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 and CV is usually reported in percent.

The frequently used terms within-series imprecision and between-series imprecision are often misinterpreted. Especially the terms between-series and between-day imprecision are often not precisely defined. To be able to interpret an assessment of precision, the precision conditions must be defined. The "specified conditions" can be, for example, repeatability, intermediate precision or reproducibility conditions of measurement.

Repeatability is the agreement between the results of consecutive measurements of the same component carried out under identical measuring conditions (within the measuring series). Reproducibility is the agreement between the results of discontinuous measurements of the same component carried out under changing measuring conditions over time. The reproducibility includes the repeatability.
The precision conditions in this evaluation are close to the defined *repeatability* and *reproducibility* conditions, and the imprecision is expressed as repeatability CV and reproducibility CV. The imprecision is summarised in tables.

4.1.2. Accuracy

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

Inaccuracy is a measure of the deviation of a single measurement from the true value, and implies a combination of random and systematic error (analytical imprecision and bias). Inaccuracy, as defined by a single measurement, is not sufficient to distinguish between random and systematic errors in the measuring system. Inaccuracy can be expressed as total error. The inaccuracy is illustrated by difference-plots with quality goals for the total error shown as deviation limits in percent.

4.1.3. 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 (systematic errors). Trueness is descriptive in general terms (good, poor), whereas bias is the estimate, reported in the same unit as the analytical result or in %. The bias at different glucose concentration levels is summarised in tables.

4.2. Statistical calculations

4.2.1. Number of samples

87 diabetes patients participated in the evaluation. The blood samples were taken at a consultation after two weeks of training. The total number of samples is: 87 x 2 (duplicates) x 4 (meter A, meter B, diabetes patient's meter, comparison method) = 696 samples.

4.2.2. Statistical outliers

The criterion promoted by Burnett [13] was 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 often set to 5%, so also in this evaluation. The segregation of outliers was made with repeated truncations. All the results were checked. Where the results are classified according to different glucose concentration levels, the outlier-testing is done at each level separately. Statistical outliers are excluded from the calculations. Possible outliers will be commented on under each table.

4.2.3. Missing or excluded results

Besides the statistical outliers, some results are missing or excluded for other reasons. They are summarized and explained here:

- ID 85 was not able to complete the evaluation and is missing from the final consultation as well as from the home measurements.
- ID 6, ID 11, ID 73 and ID 84 had a difference >10% between the paired results on the comparison method. The difference was confirmed by a rerun. As a consequence, these results are excluded when DANA is compared with the comparison method (accuracy and trueness) and from the calculation regarding the influence of hematocrit. The results are included in the calculations of the imprecision of DANA because each set of duplicate measurements on DANA is completed in less than a minute.
- Hematocrit is missing for ID 5, 8, 27, 30, 32, 43, 55, 61, 62, 73 and 79. The blood sampling for this parameter was voluntary.

4.2.4. Calculations of imprecision based on duplicate results

Two capillary samples were taken of each diabetes patient for meter A, meter B, the diabetes patient's meter and for the comparison method at each consultation. The imprecision was calculated by use of paired measurements [14, 15], based on the following formula:

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

Even if this formula is based on the differences between the two parallel measurements of every duplicate, the calculated standard deviation is still a measure of the imprecision of single values, and completely comparable with the more commonly used calculation based on repeated measurements of only one sample. The assumption for using this formula is that no systematic difference between the 1st and the 2nd measurement of the duplicate is acceptable. Table 4 shows that in five of the six t-tests no systematic difference was pointed out. The difference for glucose concentrations <7 mmol/L on meter A is significant, but may have appeared by chance. For the total set of data the conclusion is that there is no systematic difference between the paired measurements. This conclusion is also supported by corresponding results in all previous user-evaluations carried out by SKUP.

Table 4. Comparison of the 1st and the 2nd measurement. T-test for paired values

		Glucose level mmol/L	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	n
DANA	Meter A	<7	5,47	5,57	0,10	0,02 — 0,18	26
		7 — 10	8,52	8,58	0,06	-0,07 — 0,20	32
		>10	13,49	13,47	-0,02	-0,23 — 0,19	29
	Meter B	<7	5,61	5,66	0,05	-0,07 — 0,16	25
		7 — 10	8,46	8,48	0,02	-0,08 — 0,12	30
		>10	13,10	13,04	-0,06	-0,23 — 0,11	32

4.2.5. Calculation of trueness

To assess the trueness of the results on DANA, the average bias at three glucose concentration levels is calculated based on the results obtained under standardised and 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 on DANA meter A. The mean difference is shown with a 95% confidence interval.

4.2.6. Calculation of accuracy

To evaluate the accuracy of the results on DANA, the agreement between DANA and the comparison method is illustrated in difference-plots. In the plots 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 DANA with three lots and the mean value of the duplicate results on the comparison method.

5. Results and discussion

5.1. Analytical quality of the designated comparison method

5.1.1. The precision of the comparison method

The best estimate of the repeatability of a method is achieved by using patient samples. By doing so, the matrix effects in artificially produced materials are avoided. In this evaluation, though, the diabetes patient samples for the comparison method can not be used for this purpose. The blood sampling for the comparison method was certainly done in duplicate, but with small blood volumes and a time gap between the first and the second sample for each diabetes patient. Because of the small blood volumes each sample was analysed only once. Because of the time gap, the paired measurements reflect the stability of the glucose concentration during the sampling time, and not the precision of the method (see 5.1.3). To get a good estimate of the repeatability of the comparison method, the results from the documentation of trueness were used. The NIST-standards and the external quality controls are genuine patient materials with no additives, and the standards and the controls have been analysed repeatedly.

The repeatability of the comparison method is shown in table 6 and table 7. The results are obtained with the NIST-standards SRM 965a and freshly frozen, human serum controls produced by Sero.

The reproducibility of the comparison method is shown in table 5. The results are obtained with internal quality control solution at two levels of glucose concentrations. The controls were analysed in the beginning and at the end of each series of samples, except for the second serie where the controls only were analysed at the end of the serie. All the results were inside the limits of the target values for the controls.

The raw data from the internal quality control, Autonorm, analysed at the comparison method is shown in attachment 3.

Table 5. The comparison method – Reproducibility (results with internal quality control solutions)

Control Solution	Target value glucose (mmol/L)	Mean value glucose (mmol/L)	n	Outliers	CV% (95% CI)
Autonorm 1	3,4 ± 0,20	3,3	7	0	0,6 (0,4 — 1,2)
Autonorm 2	16,6 ± 0,83	16,2	7	0	0,7 (0,5 — 1,6)

Discussion

The precision of the comparison method is good. The reproducibility CV with internal quality control solutions is below 1,0%, and the repeatability CV with reference materials is also 1,0% or below (see table 6 and 7).

5.1.2. The trueness of the comparison method

In order to demonstrate the trueness of the comparison method, the SRM 965a 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 6.

Table 6. The comparison method – Standard Reference Material (SRM 965a) measured on the comparison method

SRM 965a	Date	Certified glucose concentration mmol/L (uncertainty)	Mean value glucose (mmol/L)	n	Combined CV% (95% CI)	% deviation from target value
Level 1	08.04.08	**1,918** (1,898 — 1,938)	1,93	5	1,0 (0,8 — 1,7)	+0,4
	08.05.08		1,93	5		+0,6
	26.06.08*		1,92	5		+0,1
	Total		**1,93**	**15**		
Level 2	08.04.08	**4,357** (4,309 — 4,405)	4,45	5	0,8 (0,6 — 1,2)	+2,1
	08.05.08		4,46	5		+2,4
	26.06.08*		4,40	5		+1,0
	Total		**4,44**	**15**		
Level 3	08.04.08	**6,777** (6,704 — 6,850)	6,89	5	0,7 (0,5 — 1,1)	+1,7
	08.05.08		6,88	5		+1,5
	26.06.08*		6,90	5		+1,9
	Total		**6,89**	**15**		
Level 4	08.04.08	**16,24** (16,05 — 16,43)	16,83	5	0,1 (0,0 — 0,1)	+3,7
	08.05.08		16,64	5		+2,4
	26.06.08*		16,60	5		+2,2
	Total		**16,69**	**15**		

* The last measurements were performed with a new lot of glucose reagent for Architect ci8200

Table 6 shows that the glucose results of the NIST-standards analysed at Architect ci8200 were slightly higher than the certified target values. For Level 2, 3 and 4 the achieved results were just outside the uncertainty limits. The results analysed at Architect are therefore adjusted according to the certified NIST-target values. The adjustment was done by means of the following regression equation: **y = 0,97x + 0,06** (R^2 = 1,0)
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) with glucose concentrations at two levels were analysed. The agreement with target values from the Reference laboratory in Belgium is shown in table 7.

Table 7. The comparison method – Control samples from NOKLUS's External Quality Assessment program, measured on the comparison method during the evaluation period

Control solution	Date	Target value glucose (mmol/L)	Mean value glucose (mmol/L)	n	Outliers	CV% (95% CI)	% deviation from target value
TM Gluc L-1	07.06.08	7,43	7,35	10	0	0,7 (0,5 — 1,3)	-1,1
TM Gluc L-2	07.06.08	10,40	10,23	10	0	0,6 (0,4 — 1,1)	-1,7

Discussion
The trueness of the comparison method is good.

5.1.3. Stability of the glucose concentration during the sampling time

The first and the second sample for the comparison method, taken at the start and at the end of each blood sampling sequence, reflect the stability of the glucose concentration during the sampling time (see chapter 3.4.7, *Analysing the samples for the comparison method*). In this evaluation, deviations >10% were regarded as not acceptable and such results were excluded without further discussion. This applies to ID 6, 11, 73 and 84. For further explanation, see chapter 4.2.3. 22 of 87 paired results on the comparison method gave deviations between 4 and 10%. For 18 of the 22 samples the deviation was less than 6%.

After a general evaluation of all the results, the paired measurements with differences between 4 and 10% are included in the calculations in this evaluation. The summing up in table 13 has been done with and without these 22 results. The percentage number of results that falls within the quality limits is not dependent on keeping or excluding these results.

5.2. Analytical quality of DANA

5.2.1. The precision of DANA

The DANA blood glucose meters in the user evaluation were checked with the manufacturer's control solutions by the biomedical laboratory scientists. All the results were inside the limits of the controls.

All results from the calculation of the precision are discussed at the end of this chapter.

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 raw data is shown in attachment 4.

Table 8. DANA – Repeatability. Results with blood samples from the diabetes patients, measured under standardised and optimal conditions

DANA	Glucose level (mmol/L)	Mean value glucose (mmol/L)	n	Outliers	CV% (95% CI)
Meter A	<7	5,5	26	0	2,8 (2,2 — 3,8)
Meter B	<7	5,6	25	0	3,4 (2,7 — 4,8)
Meter A	7 — 10	8,6	32	0	3,0 (2,4 — 4,0)
Meter B	7 — 10	8,5	30	0	2,1 (1,7 — 2,9)
Meter A	≥10	13,5	29	0	2,8 (2,2 — 3,8)
Meter B	≥10	13,1	32	0	2,6 (2,1 — 3,4)

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 performed by the diabetes patients.

The results obtained at home have a higher degree of uncertainty since it is impossible to check what has actually been 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 on the basis of these results.

The raw data from the diabetes patients' measurements at NOKLUS is shown in attachment 5.
The raw data from the diabetes patients' measurements at home is shown in attachment 6.

Table 9. DANA – Repeatability. Diabetes patients' self-measurements

DANA	Glucose level (mmol/L)	Mean value glucose (mmol/L)	n	Outliers	CV% (95% CI)
At NOKLUS	<7	5,7	24	0	3,1 (2,4 — 4,4)
	7 — 10	8,6	31	0	6,0 (4,8 — 8,0)
	≥10	13,5	32	0	3,9 (3,1 — 5,2)

Comment
The CV for the glucose level 7—10 mmol/L is higher than the CV in the lower and upper range of glucose concentrations. The higher CV is mainly caused by five measurements with obvious larger deviations than the rest of the measurements in this group. The differences are not recognized as statistical outliers according to Burnett. No obvious mistakes have been detected and no error codes occurred in connection with these measurements. The deviations are therefore inexplicable. The calculated CV is 3,3 mmol/L without these results, and more comparable with the CV in the lower and upper range.

Reproducibility with Internal Quality Control Solutions
The reproducibility is assessed with Care Sense Control Low and Care Sense Control High. The measurements are carried out on meter A and meter B during the whole evaluation period. Artificially produced control materials have other matrix effects than whole blood, and may therefore give other results than achieved with blood. The reproducibility of DANA on meter A and meter B is shown in table 10. The measurements at the 22 first consultations were performed with an expired Care Sense Control and are excluded.

Table 10. DANA – Reproducibility (results with Care Sense Control Low and Control High) measured by the biomedical laboratory scientists on meter A and meter B

DANA	QC	Target area (mmol/L)	Mean value glucose (mmol/L)	n	Outliers	CV% (95% CI)
Meter A	Low	4,9 — 8,1	6,4	16	0	4,8 (3,6 — 7,5)
	High	8,9 — 14,7	11,8	15	0	4,0 (2,9 — 6,3)
Meter B	Low	4,9 — 8,1	6,7	30	0	7,1 (5,6 — 9,5)
	High	8,9 — 14,7	11,9	30	0	7,3 (5,8 — 9,8)

Internal Quality Control on the diabetes patients' meters
The control measurements on the diabetes patients' meters were performed with Care Sense Control Low. All the control measurements are performed by the biomedical laboratory scientists 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 through out the evaluation period. The reproducibility on the meters of the diabetes patients is shown in table 11.

The raw data from the measurements with the internal quality control is shown in attachment 7.

Table 11. DANA – Reproducibility (results with Care Sense Control Low) measured by the biomedical laboratory scientists on the diabetes patients' meters

DANA	QC	Target area (mmol/L)	Mean value glucose (mmol/L)	n	Outliers	CV% (95% CI)
The diabetes patients' meters	Low	4,9 — 8,1	6,7	65	0	9,5 (8,1 — 11,5)

Comment
The relative high CV is hardly a representative estimate of the reproducibility of the test results, but more an expression of the keeping of the quality of the control material. The purpose of analysing the control material is to check if the test strips is working properly. All the measurements were within the target area of the control.

Discussion of the precision
The overall precision of DANA was good. The repeatability CV obtained under standardised and optimal conditions was between 2,0 and 3,5%, and significantly <5%. The repeatability CV obtained at NOKLUS when the measurements were performed by the diabetes patients for glucose level <7 mmol/L and >10 mmol/L was between 3 and 4%. CV% for glucose level 7-10 mmol/L was approximately 6%.

5.2.2. The trueness of DANA

The trueness of DANA is calculated from the results achieved by the biomedical laboratory scientists at the final consultation. The calculations are based on measurements on meter A and are shown in table 12. All the measurements on meter A are performed with lot DN24GA02C.

The raw data from the comparison method is shown in attachment 8.

Table 12. Bias. DANA results under standardised and optimal conditions from the final consultation

	<7 mmol/L		**7 —10 mmol/L**		**≥10 mmol/L**	
	The comparison method	**Meter A**	**The comparison method**	**Meter A**	**The comparison method**	**Meter A**
Mean glucose, mmol/L	5,6	5,7	8,5	8,5	13,7	13,1
Mean deviation from the comparison method, mmol/L (95% CI)	0,14 (0,02 — 0,26)		0,03 ((-0,08) — 0,14)		-0,57 ((-0,77) — (-0,38))	
n	25		29		28	
Outliers	0		0		1*	

* One outlier (ID 78) according to Burnett

Discussion

Table 12 shows that glucose concentrations <7 mmol/L on DANA were slightly higher than the measurements on the comparison method. The bias was approximately 0,1 mmol/L. The positive bias was small but statistically significant.

Glucose values from 7—10 mmol/L on DANA were in agreement with the comparison method. For glucose concentrations >10 mmol/L the glucose measurements on DANA were systematic lower than the measurements on the comparison method. The bias was approximately 0,6 mmol/L.

5.2.3. The accuracy of DANA

To evaluate the accuracy of the results with DANA, the agreement between DANA and the comparison method is illustrated in two difference-plots. The plots show the deviation of single measurement results on DANA from the true value, and give a picture of both random and systematic errors, reflecting the total error on DANA. 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 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, DANA meter B, under standardised and optimal measuring conditions, at the final consultation is shown in figure 2. The accuracy, DANA, as measured by the diabetes patients at the final consultation is shown in figure 3. The accuracy is summarised in table 13 and discussed afterwards.

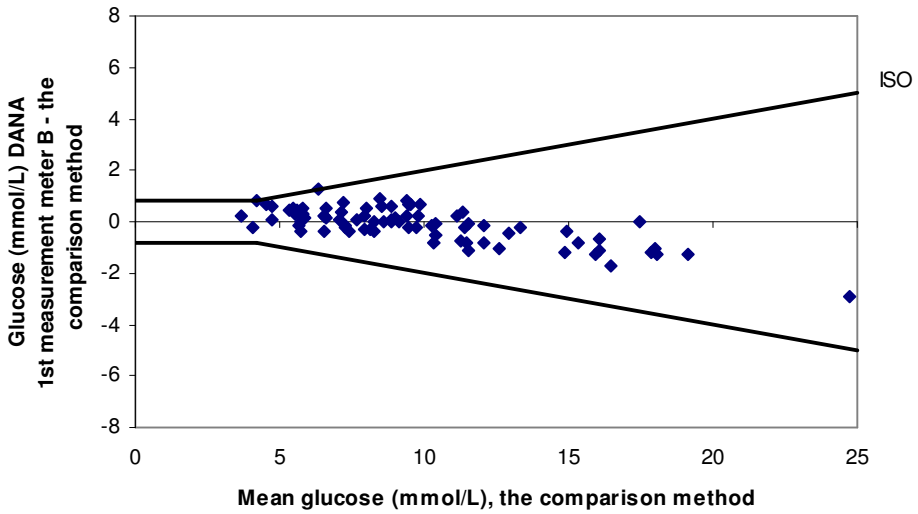


Figure 2. Accuracy. DANA meter B (three lots of test strips) under standardised and optimal measuring conditions at the final consultation. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on DANA and the mean value of the duplicate results on the comparison method, n = 83

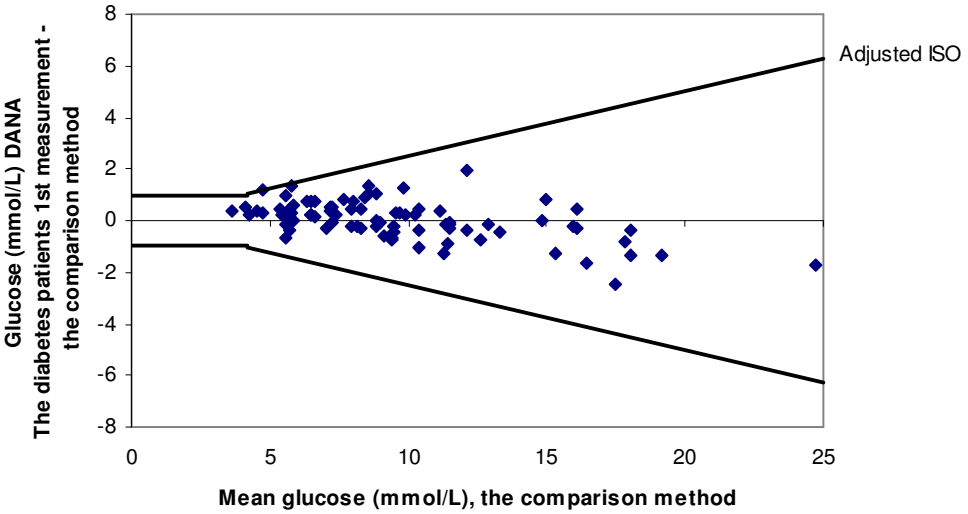


Figure 3. Accuracy. The diabetes patients' self-measurements. Three lots of test strips. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on DANA and the mean value of the duplicate results on the comparison method, n = 83

Table 13. Total error of DANA results compared to the comparison method. Percentage DANA results within the limits

Measurements performed by	Meter	n	Number of results within the limits (%)			Figure
			ADA <±10%	**ISO** ±20% at conc. ≥4,2 ±0,83 mmol/L at conc. <4,2	**"adjusted ISO"** ±25% at conc. ≥4,2 ±1,0 mmol/L at conc. <4,2	
Biomedical laboratory scientists	A 1st meas.	83	94	100		
	B 1st meas.	83	89	100		2
Diabetes patients at NOKLUS		83	76	98	100	3

Discussion
Figure 2 and 3 shows that the DANA results were lower than results from the comparison method for glucose concentrations above approximately 10 mmol/L.

Figure 2 shows that all the results obtained under standardised and optimal measuring conditions at the consultation are within the ISO limits. The summing up in table 13 also shows that all the measurements on meter A as well as meter B are within the ISO limits.

Figure 3 and the summing up in table 13 shows that all the diabetes patients´ measurements are within the "adjusted ISO goal". 98% of the measurements are also within the ISO goal.

Assessment of accuracy
The DANA IISG device fulfils the quality goal based on ISO 15197 when used under standardised and optimal conditions. The "adjusted ISO goal" as well as the ISO goal is also met by the measurements of the diabetes patients.

5.3. 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 distributed and used randomly among the patients. Only test strips from one lot was used per patient. The deviation from the comparison method for each of the three lots was calculated (paired t-test), as an indirect measure of the lot variation. Obviously, the mean glucose concentration in different groups of diabetes patients is not identical, and therefore the results achieved with the three different lots can not be used directly as a measure of the inter-lot-variation. The results are shown in table 14.

Table 14. Variation between three lots of test strips. T-test for paired values between three lots on meter B and the comparison method under standardised and optimal conditions at the final consultation

	The comparison method	**Meter B Lot DN 24GA02C**	**The comparison method**	**Meter B Lot EY 05GA03B**	**The comparison method**	**Meter B Lot EY 05GA03A**
Mean glucose, mmol/L	10,6	10,1	8,9	9,1	8,6	8,7
Mean deviation from the comparison method, mmol/L (95% CI)	-0,44 ((-0,66) — (-0,21))		+0,15 ((-0,02) —0,31)		+0,10 ((-0,12) — 0,33)	
n	28		28		26	
Outliers	1*		0		0	

* One outlier (ID 78) according to Burnett

Discussion
Lot DN24GA02C gave lower values than the comparison method.
The deviation is small, but statistically significant.

5.4. Effect of hematocrit

The product insert of DANA test strips states that the measurements are not affected by hematocrit values from 20 to 60%. To measure the effect of hematocrit on DANA, a hematocrit sample was taken of the diabetes patients.

The investigation of the effect of hematocrit is based on the measurements on DANA (meter A with one lot of test strips) under standardised and optimal measuring conditions. The glucose concentration range in the samples was 3,6 – 24,7 mmol/L. The hematocrit range was 30 – 47%.

The effect of hematocrit is shown in figure 4. The x-axis in the plot shows the hematocrit value in percentage and the y-axis shows the difference in glucose concentration between DANA and the comparison method (DANA – the comparison method) in mmol/L. The trend-line is shown in the figure. The raw data is shown in attachment 9.

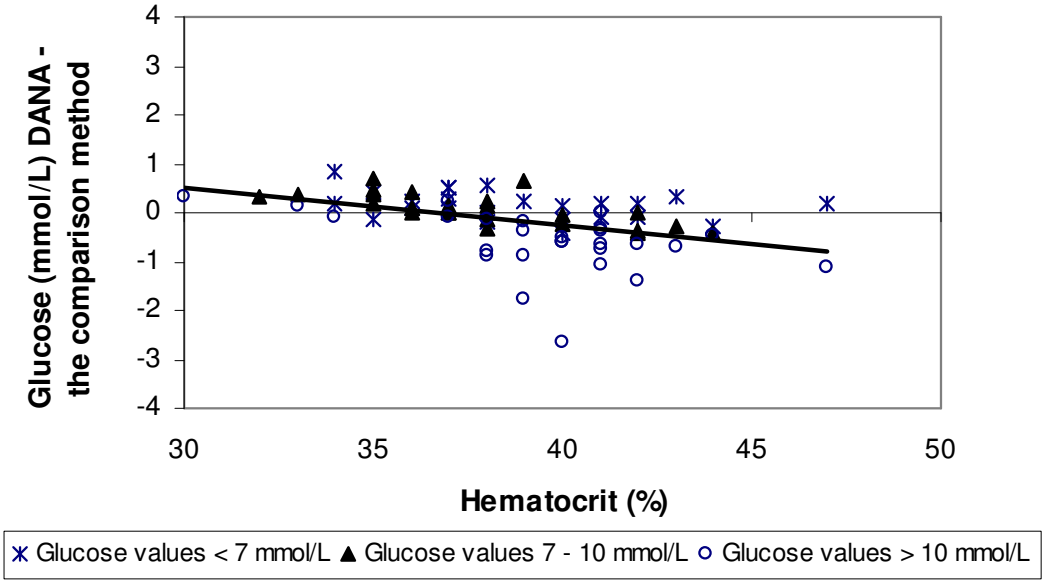


Figure 4. The effect of hematocrit on glucose measurements on DANA measured under standardised and optimal conditions. The x-axis shows the hematocrit value in %. The y-axis shows the difference in glucose concentration between DANA and the comparison method (DANA – the comparison method) in mmol/L, n= 76

Discussion

Glucose measurements on DANA seem to be affected by the hematocrit values of the samples. The trend line in figure 4 shows that the glucose measurements in DANA are overestimated when hematocrit is in the lower part of the reference range, and underestimated when hematocrit is in the upper part of the reference range. The effect of hematocrit does not seem to be related with the glucose concentration. Hematocrit outside the range 30 – 47% has not been tested.

5.5. Practical points of view

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

Questionnaires

Each diabetes patient filled in a questionnaire about the user-friendliness and a questionnaire about the user guide of DANA when they attended the final consultation (n = 87). The biomedical laboratory scientists were available to explain the questions, and there was room for free comments.

The questionnaires (in Norwegian) about the user-friendliness and about the user guide are attached to the report, see attachment 10 and 11.

5.5.1. Evaluation of the user-friendliness of DANA

The questionnaire about the user-friendliness was made up of nine questions concerning DANA. Table 15 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 is 3,9, 5,4 and 5,1 on the questions about inserting a strip into the meter, filling the strip with blood and removing the strip from the meter, respectively. This indicates that the diabetes patients seemed satisfied with the filling and removing of the strip, but that some of them thought it was difficult to insert the strip into the meter. The mean score is 5,4 on the question about reading the figures in the display. Most of the diabetes patients seemed satisfied with operating the meter, all in all The mean score is 4,5. Regarding the lancet pen the mean score is 4,9, which indicates that some of the diabetes patients found it a bit difficult to use the lancet pen.
The scores are slightly better for the patients in the target group for the glucose meter who use an insulin pump.

Table 15. DANA - Questions about the meter

How will you rank the following questions on a scale from 1 to 6, where 1 is difficult and 6 is simple

Questions about DANA		Total number	Not answered (% of total)	Range	Mean score
To insert a strip into the meter	All diabetes patients	87	0	1 - 6	3,9
	Diabetes patients using insulin pump	21	0		4,1
To fill the strip with blood	All diabetes patients	87	0	1 – 6	5,4
	Diabetes patients using insulin pump	21	0		5,6
To remove the strip from the meter	All diabetes patients	87	0	1 – 6	5,1
	Diabetes patients using insulin pump	21	0		5,4
To read the figures in the display	All diabetes patients	87	0	1 – 6	5,4
	Diabetes patients using insulin pump	21	0		5,7
All in all, to operate the meter	All diabetes patients	87	0	1 – 6	4,5
	Diabetes patients using insulin pump	21	0		4,8
To operate lancet pen	All diabetes patients	87	14	1 - 6	4,9
	Diabetes patients using insulin pump	21	19		5,1

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

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

1. The meter is integrated in an insulin pump (18) (14 of these use insulin pump)
2. The meter has short measuring time (14)
3. Easy to use (10)
4. The meter/strip requires a small blood sample volume (7)
5. Small, light and convenient meter (6)
6. The display is easy to read display (4)

The comments from the diabetes patients who use an insulin pump are in agreement with the comments from all the diabetes patients. Comment about the size of the meter (comment no. 6) is from diabetes patients who use insulin pump.

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

1. Different problems with the test strips (43); for instance the test strips are difficult to insert (21), too short (11), the lid on the test box is difficult to open (7), too weak (to easy to bend by mistake) (4), difficult to insert without removing the etui (3), not in a disc (2), difficult to remove (2), not singly packed (1)
2. The protection cap was placed in a way that made the insertion of the test strip difficult. The protection cap should have been placed beneath the insertion opening instead of above, where it hides the opening (16)
3. Different problems with the pen (11); for instance it is too easy to release (5), it is too slender (2), it pricks to weak, it is poor (1), it is difficult to change the lancet (1))
4. Difficult to read the display (7) (this was not commented of the diabetes patients who uses an insulin pump)

Two diabetes patients commented that they would like to have an etui with room for test strips and pen.

Table 16 shows the answers to the last question about DANA. 7% of the diabetes patients answered that they had technical problems with the meter during the testing period. One of them wrote that the meter sometimes didn't store all of the measurements. Written comments from the others indicate that their problems were not technical ones after all; four of them wrote that they had experienced error messages, and one had changed battery.

Table 16. DANA – Questions about the meter

Question about DANA	Total number	Yes (%)	No (%)	No answer (%)
Did you have any technical problems with the meter during the testing period?	87	7	92	1

5.5.2. Evaluation of the DANA user guide

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

Table 17 shows that 60% of the diabetes patients had used the guide. Only one of the diabetes patients who had used the guide answered that he/she was not satisfied with the description of how to perform a blood glucose measurement with the meter, but he/she didn't write what was missing. One of the diabetes patients thought the guide had essential shortcomings; he/she wrote that the guide was difficult to understand. 55 of 56 diabetes patients were satisfied with the user guide taken as a whole.

Table 17. DANA – Questions about the user guide

Questions about the user guide	Yes (%)	No (%)	Not answered (%)	Number
Have you been reading in the user guide?	69	28	3	87
Are you satisfied with the description of how to perform a blood glucose measurement with the meter?	98	2	0	56
Do you think the user guide has essential shortcomings?	2	98	0	55
All in all, are you satisfied with the user guide?	98	2	0	56

5.5.3. The biomedical laboratory scientists' evaluation

Positive comments:

The meter is integrated in an insulin pump and the meter has short measuring time. It was easy to fill the test strip.

Negative comments:

It was a bit difficult to search for previous measurements. The protection cap was placed in a way that made the insertion of the test strip difficult. The protection cap should have been placed beneath the insertion opening instead of above, where it hides the opening, or maybe the protection cap could be removed? Is it necessary to have a protection cap in front of the test strip gap? The test strip is short and too pliable.

Comments about the user guide

The user guide should be more comprehensive, for instance contain a section about how to program the standby time to more than one minute. The package insert (in Norwegian), that follows the test strips, was corrected by SKUP regarding linguistic errors and translations errors.

6. References

1. Stöckl D, Baadenhuijsen H, Fraser CG, Libeer JC, Petersen PH, Ricos C, "Desirable Routine Analytical Goals for Quantities Assayed in serum". Eur J Clin Biochem 1995; **33** (3): 157 – 169.
2. American Diabetes Association. Self-monitoring of blood glucose. Diabetes Care 1996; **19** (suppl 1): 62 – 66.
3. Skeie S, Thue G, Sandberg S, "Patient-derived Quality Specifications for Instruments Used in Self-Monitoring of Blood Glucose". Clinical Chemistry 2001; **47** (1): 67 – 73.
4. In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self- testing in managing diabetes mellitus, ed. ISO. 2003.
5. Kristensen, G.B., et al., Standardized evaluation of instruments for self-monitoring of blood glucose by patients and a technologist. Clin Chem, 2004. **50**(6): p. 1068-71.
6. www.skup.nu: Reports and summaries from evaluations under the direction of SKUP.
7. National Institute of Standards and Technology, Certificate of Analysis, Standard Reference Material® 965a, Glucose in Frozen Human Serum
8. Thienpont, L.M., et al., Determination of reference method values by isotope dilution-gas chromatography/mass spectrometry: a five years' experience of two European Reference Laboratories. Eur J Clin Chem Clin Biochem, 1996. **34**(10): p. 853-60.
9. Christensen, N.G, Monsen G, Sandberg S, Utprøving av analyseinstrumenter. 1997: Alma Mater Forlag.
10. Skeie, S., et al., Instruments for self-monitoring of blood glucose: comparisons of testing quality achieved by patients and a technician. Clin Chem, 2002. **48**(7): p. 994-1003.
11. Quality specifications for glucose test strips reimbursement from NAV http://www.uib.no/isf/noklus/diabetes/kravspes.pdf.
12. International vocabulary of metrology – Basic and general concepts and associated terms, VIM, 3rd edition, JCGM 200:2008.
13. Burnett RW, "Accurate Estimation of Standard Deviations for Quantitative Methods Used in Clinical Chemistry". Clinical Chemistry 1975; **21** (13): 1935 – 1938.
14. Saunders, E. Tietz textbook of clinical chemistry and molecular diagnostics. 2006. Chapter 14, Linnet, K., Boyd, J. "Selection and analytical evaluation of methods – with statistical techniques", ISBN 0-7216-0189-8.
15. Fraser, C.G. Biological variation: From principles to practice. 2006. Chapter 1 "The Nature of Biological Variation". AACC Press. ISBN 1-890883-49-2.

Attachments

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

Attachments with raw data are included only in the report to Medical Home Tech AS.

Attachment 1

Serial numbers, DANA DiabeCare IISG blood glucose meters used by the diabetes patients

ID	Serial number
1	AHH00009FF
2	AHH00002FF
3	AHH00007FF
4	AHH00002FF
5	AHK00013FF
6	AHH00014FF
7	AHK00007FF
8	AHK00014FF
9	AHH00010FF
10	AHH00007FF
11	AHH00016FF
12	AHH00014FF
13	AHH00012FF
14	AHK00012FF
15	AHK00006FF
16	AHH00009FF
17	AHH00015FF
18	AHH00013FF
19	AHH00008FF
20	AHH00001FF
21	AHH00002FF
22	AHH00015FF
23	AHB00034FF
24	AHK00008FF
25	AHH00003FF
26	AHH00019FF
27	AHH00008FF
28	AHH00014FF
29	AHK00011FF
30	AHK00007FF
31	AHK00014FF
32	AHH00006FF
33	AHH00006FF
34	AHH00006FF
35	AHH00007FF
36	AHK00011FF
37	AHH00001FF
38	AHK00011FF
39	AHH00010FF
40	AHH00016FF
41	AHH00019FF
42	AHH00012FF
43	AHK00013FF
44	AHH00012FF

ID	Serial number
45	AHH00015FF
46	AHH00013FF
47	AHK00006FF
48	AHK00008FF
49	AHB00034FF
50	AHK00012FF
51	AHH00001FF
52	AHH00019FF
53	AHK00007FF
54	AHB00034FF
55	AHH00009FF
56	AHK00012FF
57	AHH00007FF
58	AHK00008FF
59	AHK00006FF
60	AHK00013FF
61	AHH00009FF
62	AHK00008FF
63	AHK00013FF
64	AHH00012FF
65	AHH00003FF
66	AHH00003FF
67	AHH00013FF
68	AHK00007FF
69	AHH00016FF
70	AHH00002FF
71	AHK00011FF
72	AHH00019FF
73	AHK00014FF
74	AHH00008FF
75	AHH00016FF
76	AHB00034FF
77	AHK00006FF
78	AHH00014FF
79	AHH00010FF
80	AHK00014FF
81	AHK00012FF
82	AHH00010FF
83	AHH00015FF
84	AHH00008FF
86	AHH00001FF
87	AHH00006FF
88	AHH00013FF

NORSK KVALITETSFORBEDRING AV
LABORATORIEVIRKSOMHET UTENFOR SYKEHUS

NOKLUS

Mars 2008

Utprøving av blodsukkerapparat

Du har fått utlevert en pose med:

- 1 DANA Diabecare IISG insulinpumpe med integrert blodsukkermåler
- Apparatveske
- 1 batteri og 1 batterinøkkel
- 1 eske DANA blodglukose teststrimler (2x25 stk.)
- 1 prøvetakingspenn
- 25 lansetter
- Brukerveiledning

Du skal bruke utprøvingsapparatet hjemme i en periode på ca. to uker. I denne prøveperioden skal du bruke dette apparatet **i tillegg** til ditt eget apparat. Det betyr at du skal utføre blodsukkermålingene 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:

Uke 1:
Den første uken skal benyttes til å bli kjent med apparatet. I løpet av denne uken skal du bruke ca. 20 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 prøvetakingspennen som følger med apparatet.

Uke 2:
Etter at du har brukt de 20 første strimlene, skal du i løpet av den andre uken måle blodsukkeret med utprøvingsapparatet på fem forskjellige dager. Du kan selv velge når på dagen du vil gjøre disse målingene (du trenger ikke være fastende). Hver av disse fem dagene skal du: Stikke deg i fingeren og **måle blodsukkeret med utprøvingsapparatet to ganger rett etter hverandre.** Du skal helst benytte blod fra samme stikk til de to målingene, men 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.

NOKLUS
Boks 6165
5892 Bergen
Tlf: 55979500
Fax: 55979510
noklus@noklus.no
www.noklus.no
Seksjon for allmennmedisin, UiB
Haraldsplass Diakonale Sykehus
Bergen Diakonissehjem
org. nr. 984 027 737
Ulriksdal 8, 5009 Bergen

Dato	**DANA blodsukkermåler Svar 1** (mmol/L)	**DANA blodsukkermåler 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 utlevert prøvetakingspenn til prøvetakingen? ❑ Ja ❑ Nei ❑ Noen ganger

Av de 50 strimlene du fikk sammen med apparatet, skal du nå ha ca. 20 strimler igjen. Du må spare ca. ti av strimlene til målingene du skal gjøre når du kommer hit til NOKLUS, Haraldsplass Diakonale Sykehus for den avsluttende utprøvingen. Til den avsluttende utprøvingen skal du ta med dette skjemaet, DANA blodsukkermåler, resten av strimlene, prøvetakingspenn med lansetter og annet tilleggsutstyr du har fått utlevert. Den dagen du kommer til den avsluttende konsultasjonen, må du bære apparatet kroppsnært, dvs. festet i belte eller i lommen, helt til du kommer til NOKLUS. Der skal du 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 45 minutter.

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

Ann Kristin Fagerbakke tlf. 55 97 95 21 Hverdager mellom kl. 9:00 – 15:00
Camilla Eide Jacobsen tlf. 55 97 95 15 Hverdager mellom kl. 9:00 – 15:00

Lykke til!

Med vennlig hilsen

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

Grete Monsen (sign.)
Seksjonsleder

Ann Kristin Fagerbakke (sign.)
Avdelingsingeniør

Camilla Eide Jacobsen (sign.)
Avdelingsingeniør

Attachment 3

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

Date	Res. Autonorm 1 glucose, mmol/L	Res. Autonorm 2 glucose, mmol/L
08.04.2008	3,42	16,22
08.04.2008	3,40	16,28
08.04.2008	3,45	16,19
10.04.2008	3,40	16,28
10.04.2008	3,45	16,19
03.06.2008	3,36	16,30
03.06.2008	3,40	16,12
06.06.2008	3,40	15,97
06.06.2008	3,38	16,19

Attachment 7

Raw data glucose, internal quality control, Care Sense Control

	Care Sense Control	Lot-no	Expiry	Glucose level mmol/L
Used for group 1	Control Low	CSDJ11BN	2007-08	**4,9-8,1**
	Control High	CSDJ11BM	2007-08	**8,9-14,7**
Used for group 2, 3 and 4 (From 07.04.08)	Control Low	CSDD07AN	2008-07	**4,9-8,1**
	Control High	CSDD07AM	2008-07	**8,9-14,7**

Care Sense Control analysed on the biomedical laboratory scientists' meter A and B

	Meter A		Meter B			
Date Meter A (lot A)	Control Low glucose, mmol/L	Control High glucose, mmol/L	Date Meter B	Lot	Control Low glucose, mmol/L	Control High glucose, mmol/L
06.03.2008 *	5,33	11,5	06.03.2008 *	DN24GA02C	5,22	11,72
10.03.2008 *	5,66	11,94	06.03.2008 *	EY05GA03B	6,05	12,33
11.03.2008 *	5,61	11,61	06.03.2008 *	EY05GA03A	5,83	12,33
12.03.2008 *	5,83	11,94	10.03.2008 *	DN24GA02C	5,55	11,94
14.03.2008 *	5,66	11,5	10.03.2008 *	EY05GA03B	5,94	13
07.04.2008	6,16	10,94	10.03.2008 *	EY05GA03A	6,05	12,94
08.04.2008	6,16	11,22	11.03.2008 *	DN24GA02C	5,5	10,33
09.04.2008	6,83	11,83	11.03.2008 *	EY05GA03B	6,05	12,05
10.04.2008	7,11	12,27	11.03.2008 *	EY05GA03A	5,88	12,05
11.04.2008	6,66	11,5	12.03.2008 *	DN24GA02C	5,83	11,5
14.04.2008	6,44	12,1	14.03.2008 *	DN24GA02C	5,61	11,66
17.04.2008	6,27	12,55	07.04.2008	DN24GA02C	6,11	10,71
05.05.2008	6	11,66	07.04.2008	EY05GA03B	6,66	11,83
06.05.2008	6,33	11,61	08.04.2008	DN24GA02C	6,22	11,61
07.05.2008	6,27	11,77	08.04.2008	EY05GA03B	6,66	12,16
08.05.2008	6,5	12,55	09.04.2008	DN24GA02C	6,94	11,55
09.05.2009	6,05	11,33	09.04.2008	EY05GA03B	7,11	13,61
13.05.2008	5,94	12,22	10.04.2008	EY05GA03B	8,11	12,77
19.05.2008	6,33		10.04.2008	DN24GA02C	6,94	11,66
02.06.2008	6,33	11,94	11.04.2008	DN24GA02C	6,16	10,66
04.06.2008	6,33	11,55	11.04.2008	EY05GA03B	6,38	12,61
06.03.2008 *	5,22	11,72	14.04.2008	DN24GA02C	6,16	11,61
06.03.2008 *	6,05	12,33	14.04.2008	EY05GA03B	6,55	12,94
06.03.2008 *	5,83	12,33	17.04.2008	DN24GA02C	6,61	11,61
10.03.2008 *	5,55	11,94	17.04.2008	EY05GA03B	6,83	11,94
10.03.2008 *	5,94	13	05.05.2008	DN24GA02C	6,27	11,77
10.03.2008 *	6,05	12,94	05.05.2008	EY05GA03B	7	11,83
11.03.2008 *	5,5	10,33	05.05.2008	EY05GA03A	6,5	11,55
11.03.2008 *	6,05	12,05	06.05.2008	DN24GA02C	6,94	10,38
11.03.2008 *	5,88	12,05	06.05.2008	EY05GA03A	6,83	10,16
12.03.2008 *	5,83	11,5	07.05.2008	DN24GA02C	6,5	11,91
14.03.2008 *	5,61	11,66	07.05.2008	EY05GA03A	6,72	12,27
			08.05.2008	EY05GA03A	7,11	13
			09.05.2008	EY05GA03A	7,11	12,27
			13.05.2008	DN24GA02C	6,16	12,22
			13.05.2008	EY05GA03A		14,11
			19.05.2008	EY05GA03A	7,44	
			02.06.2008	DN24GA02C	6	11,44
			02.06.2008	EY05GA03B	6,73	12,11
			04.06.2008	DN24GA02C	6,16	11,27
			04.06.2008	EY05GA03B	7,16	12,33
			09.05.2009	DN24GA02C	6,11	11,27

Care Sense Control analysed on the diabetes patients' meters

ID	Data analyzed	Lot-no test strips	Control Low glucose, mmol/L
1	08.04.2008	EY05GA03B	6,50
2	07.04.2008	EY05GA03A	5,94
3	03.06.2008	DN24GA02C	6,27
4	05.05.2008	DN24GA02C	5,50
5	10.03.2008 *	EY05GA03A	6,0
6	09.05.2008	EY05GA03B	6,83
7	10.03.2008 *	EY05GA03B	6,33
8	12.03.2008 *	EY05GA03A	6,22
9	10.03.2008 *	DN24GA02C	5,0
10	12.03.2008 *	EY05GA03B	6,66
11	06.03.2008 *	EY05GA03A	7,27
12	12.03.2008 *	DN24GA02C	5,27
13	11.03.2008 *	EY05GA03B	5,50
14	10.03.2008 *	EY05GA03A	6,55
15	10.03.2008 *	DN24GA02C	5,44
16	14.03.2008 *	EY05GA03B	6,33
17	07.04.2008	EY05GA03B	6,72
18	11.03.2008 *	EY05GA03A	6,55
19	10.03.2008 *	DN24GA02C	6,00
20	12.03.2008 *	EY05GA03B	
21	11.03.2008 *	EY05GA03A	6,33
22	11.03.2008 *	DN24GA02C	
23	10.03.2008 *	EY05GA03B	6,72
24	11.03.2008 *	EY05GA03A	5,11
25	14.03.2008 *	DN24GA02C	5,22
26	10.03.2008 *	EY05GA03B	6,16
27	10.04.2008	EY05GA03A	7,61
28	17.04.2008	DN24GA02C	6,27
29	11.03.2008 *	DN24GA02C	4,94
30	08.04.2008	EY05GA03B	6,77
31	08.04.2008	EY05GA03A	7,55
32	08.04.2008	DN24GA02C	7,27
33	14.03.2008 *	DN24GA02C	5,55
34	04.06.2008	EY05GA03B	6,50
35	07.04.2008	EY05GA03B	7,11
36	07.04.2008	EY05GA03A	7,61
37	08.04.2008	DN24GA02C	5,94
38	13.05.2008	EY05GA03A	7,00
39	07.04.2008	EY05GA03A	6,88
40	10.04.2008	DN24GA02C	7,72
41	09.04.2008	EY05GA03B	7,61
42	09.04.2008	EY05GA03A	7,00
43	11.04.2008	DN24GA02C	7,77
44	09.05.2008	DN24GA02C	5,83
45	02.06.2008	EY05GA03B	6,88
46	08.04.2008	DN24GA02C	6,00
47	11.04.2008	EY05GA03B	6,33
48	08.04.2008	EY05GA03A	6,27
49	08.04.2008	DN24GA02C	6,83
50	07.04.2008	EY05GA03B	7,44
51	04.06.2008	EY05GA03A	6,88
52	03.06.2008	DN24GA02C	5,77
53	02.06.2008	EY05GA03B	7,11
54	03.06.2008	EY05GA03A	6,66
55	02.06.2008	DN24GA02C	5,66
56	05.05.2008	EY05GA03B	5,61
57	05.05.2008	EY05GA03A	6,44
58	05.05.2008	DN24GA02C	6,77
59	06.05.2008	EY05GA03B	7,44
60	04.06.2008	EY05GA03B	7,00
61	06.05.2008	EY05GA03A	6,33
62	03.06.2008	EY05GA03A	6,50
63	05.05.2008	DN24GA02C	5,55
64	02.06.2008	DN24GA02C	6,11
65	07.05.2008	EY05GA03B	6,44
66	03.06.2008	EY05GA03B	6,50
67	02.06.2008	EY05GA03A	7,44
68	06.05.2008	EY05GA03A	7,50
69	02.06.2008	DN24GA02C	6,38
70	02.06.2008	EY05GA03B	5,83
71	04.06.2008	EY05GA03A	6,38
72	07.05.2008	EY05GA03B	6,27
73	06.05.2008	EY05GA03A	7,16
74	19.05.2008	DN24GA02C	6,50
75	07.05.2008	EY05GA03B	7,11
76	08.05.2008	DN24GA02C	6,83
77	03.06.2008	DN24GA02C	6,22
78	04.06.2008	EY05GA03B	6,83
79	02.06.2008	EY05GA03A	7,16
80	04.06.2008	DN24GA02C	5,27
81	03.06.2008	EY05GA03B	6,94
82	08.05.2008	EY05GA03A	6,22
83	07.05.2008	DN24GA02C	6,27
84	02.06.2008	EY05GA03A	6,00
86	09.05.2008	EY05GA03B	7,16
87	07.04.2008	EY05GA03A	7,33
88	08.05.2008	EY05GA03A	8,38

Two missing: ID 20: Care Sense Control High was analyzed, ID22 where out of test strips.
* The measurements at the 22 first consultations were performed with an expired Care Sense Control

ID-nummer (diabetiker):_____

DANA DiabeCare IISG integrert blodsukkermåler

Spørreskjema om blodsukkerapparatets brukervennlighet

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

1. Å sette i en teststrimmel

Vanskelig *Enkelt*

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

2. Å fylle strimmelen med blod

Vanskelig *Enkelt*

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

3. Å fjerne strimmelen fra apparatet

Vanskelig *Enkelt*

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

4. Å lese tallene i displayet

Vanskelig *Enkelt*

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

5. Å betjene apparatet, totalt sett

Vanskelig *Enkelt*

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

6. Å betjene prøvetakingspenn som følger med apparatet (skal kun besvares hvis denne prøvetakingspennen er benyttet i utprøvingen)

Vanskelig *Enkelt*

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

ID-nummer (diabetiker):_____

DANA Diabecare IISG integrert blodsukkermåler

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

Hvis ja, kan du beskrive problemet/ene:_____

_____

_____

8. Synes du det er noen fordeler ved DANA blodsukkermåler?

- _____
- _____
- _____

9. Synes du det er noen ulemper ved DANA blodsukkermåler?

- _____
- _____
- _____

Evt. andre kommentarer:_____

_____

_____

Kryss av for om du er insulinpumpebruker: ☐ **Ja** ☐ **Nei**

ID-nummer (diabetiker):_____

DANA DiabeCare IISG integrert blodsukkermåler

Spørreskjema om brukerveiledning til apparatet

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

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

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

DANA DiabeCare blodsukkerapparat integrert i insulinpumpe fra SOOIL Development. Sammendrag fra en utprøving i regi av SKUP

Konklusjon
Presisjonen på DANA er god. CV er ca. 3 % når målingene utføres av laboratorieutdannet personale og mellom 3 og 6 % når målingene utføres av diabetikere. Målingene i denne utprøvingen oppfyller internasjonale kvalitetskrav (ISO 15197) med et avvik på mindre enn ± 20 % fra en anerkjent glukosemetode. Dette gjelder både for målinger utført av laboratorieutdannet personale og for målinger utført av diabetikere. Prøvens hematokrit ser ut til å påvirke glukosemålinger på DANA.

DANA er beregnet til egenmåling av glukose for diabetikere som bruker insulinpumpe. Målesystemet består av insulinpumpen DANA DiabeCare IISG med integrert glukosemåler og DANA DiabeCare IISG teststrimler. Apparatet må kodes. Apparatet slås automatisk på når en teststimmel settes inn. Det kreves 0,5 µL blod til hver måling. Målingen tar ca 5 sekunder. DANA har minnekapasitet til å lagre 500 målinger med dato og klokkeslett.

Utprøvingen er utført under optimale betingelser av laboratorieutdannet personale og blant diabetikere. I utprøvingen deltok 87 diabetikere. Alle diabetikerne fikk opplæring i bruken av apparatet, og brukte deretter apparatet hjemme i to uker før de møtte til en konsultasjon der det ble utført målinger med apparatet.

Resultater
Presisjonen er god. CV er ca. 3 % når målingene er utført av laboratorieutdannet personale. Når målingene er utført av diabetikere, er upresisheten mellom 3 og 6 %. DANA gir nøyaktige resultater. Ved glukoseverdier høyere enn 10 mmol/L gir DANA ca 0,6 mmol/L for lave resultater. Den totale målefeil var innenfor kvalitetsmålet (ISO 15197), som tillater avvik opp til ± 20 % fra en anerkjent metode for måling av glukose, både når det gjelder målinger utført av laboratorieutdannet personale og målinger utført av diabetikere. Prøvens hematokrit ser ut til å påvirke glukosemålinger på DANA.

Brukervennlighet
Diabetikerne som deltok i utprøvingen syntes at DANA var relativt enkel å bruke, men ca halvparten av diabetikerne rapporterte en eller flere vanskeligheter med teststrimmelen, som er liten og bøyelig, spesielt når det gjelder å føre inn strimmelen. De fleste av diabetikerne som hadde lest i brukermanualen, var fornøyde med denne.

Tilleggsinformasjon
Den fullstendige rapporten fra utprøvingen av DANA, SKUP/2009/66, finnes på SKUPs nettside, www.skup.nu. Opplysninger om pris fåes ved å kontakte leverandør. Laboratoriekonsulentene kan gi nyttige råd om analysering av glukose på legekontor. De kan også orientere om det som finnes av alternative metoder/utstyr.

~ *Medisinsk tekniske produkter til hjemme- og sykehusbehandling* ~

SKUP. NOKLUS Senter
v/ Grete Monsen
Haraldsplass Diakonale Sykehus
Ulriksdal 8, SMU-bygget 6 etg
5009 Bergen

Deres ref.: *Vår ref.:* JPS *Dato* 18.09.08

Vi har mottatt og studert den preliminære rapporten for DANA, og jeg må si at det var en særdeles hyggelig lesning. Vi er videre imponert over den profesjonalitet og fagkunnskap som dere besitter, og som er lagt til grunn under arbeidet. Jeg har opplevd samarbeidet med dere som meget godt, der vi underveis har samarbeidet for å få tilpasset protokollen til våre produkter, samt fortløpende sammen har funnet løsninger på uklare momenter.

Jeg fikk i vinter melding om at dere erfarte problemer med lansettpennene våre. Jeg er nå glad for å opplyse om at produsenten har lansert en ny, forbedret lansettpenn, der problemene er eliminert.

Endringer, DANA Diabecare Insulinpumpe/ Blodsukkermåler

- Ny, forbedret lansettpenn er lansert. Disse vil følge alle apparater som blir sendt ut fra oss.

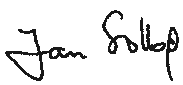
- Tidligere forpakning med en eske inneholdende 2 stk beholdere à 25 målestrimler, er nå endret til en eske inneholdende 1 stk. sylinderformet beholder à 50 målestrimler. Lokket på beholderen er også forbedret fra å være et lokk som må vris for å åpne til et lokk som vippes opp. Dette lokket er hengslet i bakkant av beholderen, noe som gjør at det er festet til beholderen. Boksen har også større omkrets, noe som gjør at det er letter å hente ut nye målestrimler.

- The manufacturer has now introduced a new, improved, easier to operate, Lancing Device. This new Lancing Device is included in all insulin pumps shipped from the manufacturer.

- The box containing two vials à 25 Blood Glucose Strips has been changed to one box containing one cylindrical shaped vial containing 50 pcs. of DANA Blood Glucose Strips. The opening of the vial cap is improved, and is now a “snap off” type in stead of the former “twist off” type cap. This new improved cap is hinged to the vial.The diameter of the vial is wider, and it is therefore easier to grip a new Blood Glucose Strip.

Vi vil til slutt takke for et hyggelig samarbeide, og håper at vi kan benytte oss av deres ekspertise igjen ved en senere anledning.

Jan P. Solbø



Daglig leder

MEDICAL HOME TECH AS Org. nr. 891 358 482
SYKEHUSVEIEN 23, FORSKNINGSPARKEN POSTBOKS 6449, 9294 TROMSØ
TLF.: 77 28 28 60 FAX.: 77 28 28 61 MOBIL: 41 43 01 70
E-mail: postmaster@medhometech.no WWW.MEDHOMETECH.NO

List of previous SKUP evaluations

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

Evaluations performed in 2004 – 2008

Evaluation no.	Component	Instrument/testkit	Producer
SKUP/2008/69*	Strep A	Diaquick Strep A test	Dialab GmbH
SKUP/2008/66	Glucose[1]	DANA DiabeCare IISG	SOOIL Developement co. Ltd
SKUP/2008/65	HbA1c	Afinion HbA1c	Axis-Shield PoC AS
SKUP/2007/64	Glucose[1]	FreeStyle Lite	Abbott Laboratories
SKUP/2007/63	Glucose[1]	*Confidential*	
SKUP/2007/62*	Strep A	QuikRead	Orion Diagnostica Oy
SKUP/2008/61	CRP	i-CHROMA	BodiTech Med. Inc.
SKUP/2007/60	Glucose[1]	*Confidential*	
SKUP/2007/59	Glucose[1]	Ascensia BREEZE2	Bayer HealthCare
SKUP/2006/58	HbA1c	*Confidential*	
SKUP/2007/57*	PT (INR)	Simple Simon PT	Zafena AB
SKUP/2007/56*	PT (INR)	*Confidential*	
SKUP/2007/55	PT (INR)	CoaguChek XS	Roche Diagnostics
SKUP/2007/54*	Mononucleosis	*Confidential*	
SKUP/2006/53*	Strep A	*Confidential*	
SKUP/2005/52*	Strep A	Clearview Exact Strep A Dipstick	Applied Biotech, Inc.
SKUP/2005/51*	Glucose[1]	FreeStyle	Abbott Laboratories
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

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

[1] Including a user-evaluation among diabetes patients

Evaluations performed in 1999 – 2004

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

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

[1] Including a user-evaluation among diabetes patients

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