GLUCOCARD™ X-METER
GLUCOCARD™ X-SENSOR

Meter and test strips designed for glucose self-measurement manufactured by Arkray, Inc.

Report from an evaluation organised by

SKUP

The evaluation was ordered by Tamro MedLab AS, Norway

SKUP in Norway, NOKLUS, Division of General Practice, University of Bergen, 5009 Bergen, www.SKUP.nu

SKUP/2006/50

Summary

Background
The Glucocard X-Meter blood glucose meter and the Glucocard X-Sensor test strips are designed for glucose self-measurements by diabetics. The meter and the test strips are produced by Arkray, Inc. and are supplied in Scandinavia by Tamro MedLab. Glucocard X-Meter and Glucocard X-Sensor have not yet been launched onto the Norwegian market.

In order to give reimbursement for the test strips, The National Social Insurance Office (*Rikstrygdeverket*) in Norway instructs the companies to carry out an evaluation that includes a user-evaluation among diabetics. The evaluation of Glucocard X-Meter/Glucocard X-Sensor is done under the direction of SKUP from October 2005 to January 2006. Further on in this report Glucocard X-Meter/Glucocard X-Sensor will be referred to as Glucocard X-Meter.

The aim of the evaluation
The aim of the evaluation of Glucocard X-Meter is to

- reflect the analytical quality under standardised and optimal conditions (performed by biomedical laboratory scientists)
- reflect the analytical quality by the users (83 diabetics)
- compare the analytical quality among diabetics with and without training
- compare the analytical quality among diabetics before and after three weeks of practise
- check the variation between three lots of test strips
- examine if hematocrit interferes with the measurements
- evaluate Glucocard X-Meter regarding user-friendliness
- evaluate the Glucocard X-Meter user-manual

Materials and methods
83 diabetics took part in the evaluation. 40 participants had two consultations (the "training group") and the rest had one consultation (the "post group"). At the first consultation the diabetics in the "training group" were given a standardised instruction about the Glucocard X-Meter before they did a finger prick and performed two measurements at the meter. The biomedical laboratory scientist also took capillary samples of the diabetics and measured twice at Glucocard X-Meter. In addition, two capillary samples were taken to a designated comparison method. The diabetics in the "post group" received the Glucocard X-Meter by post and no training was given. Both groups of diabetics carried out a practice period of approximately three weeks at home, before they were called for a final consultation. The blood glucose sampling and measurement procedures at the first consultation were repeated, and in addition a sample for hematocrit was taken. Three different lots of test strips were used in the evaluation. All the participants finally answered questionnaires about the user-friendliness and the user-manual of Glucocard X-Meter.

Results

- Glucocard X-Meter shows acceptable precision. The CV is approximately 5 % under standardised and optimal measuring conditions and slightly poorer when the measurements are performed by the diabetics with a CV of approximately 6 %.

- The trueness of Glucocard X-Meter is good. For glucose values > 10 mmol/L there is a significant bias between Glucocard X-Meter and the comparison method. Glucocard X-Meter gives glucose values approximately 0,6 mmol/L lower than the comparison method at this glucose level.
- The agreement with a designated comparison method is good. The quality goal set in ISO 15197 is achieved under standardised and optimal measuring conditions. When handled by the diabetics the results are within the "adjusted ISO-goal".
- Two of the three lots of test strips that were used showed significantly lower values than the comparison method. The results still attain the quality goal.
- Glucose measurements at Glucocard X-Meter seem to be affected by hematocrit values. Glucose concentration > 10 mmol/L are affected by hematocrit in a higher degree than samples with glucose concentration < 10 mmol/L, but the tendency is the same. High glucose values in combination with high hematocrit values give an under-estimated glucose result, while high glucose values in combination with low hematocrit values are over-estimated. Hematocrit outside the range 32 – 51 % has not been tested.
- The diabetics summarise the Glucocard X-Meter device as easy to use. Most of them were pleased with the device. The diabetics that had used the user manual were satisfied with the manual.

Conclusion

Glucose measurements at Glucocard X-Meter have acceptable precision. The results obtained under standardised and optimal measuring conditions are within the quality goal set in the ISO-guide 15197. The measurements performed by the diabetics are within the "adjusted ISO-goal". Two of the three lots of test strips that were used showed significantly lower values than the comparison method. The results still attain the quality goal. The glucose results seem to be affected by hematocrit. High glucose values in combination with high hematocrit values give an under-estimated glucose result, while high glucose values in combination with low hematocrit values are over-estimated. The users find the Glucocard X-Meter device easy to use and they are quite satisfied with the device.

Comments from Tamro MedLab

An information letter from Tamro MedLab is found in attachment 13.

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Attachments with raw data are included only in the copy to Tamro MedLab.

1. The organisation of SKUP

Scandinavian evaluation of laboratory equipment for primary health care, *SKUP*, is a co-operative commitment of NOKLUS[1] in Norway, the "Afdeling KKA"[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 Centre in Bergen, Norway.

The goal of SKUP is to produce reliable, objective and independent information about the analytical quality and user-friendliness of laboratory equipment for primary healthcare. 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 of blood glucose. As long as 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 in return, receives 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 representative. SKUP signs *contracts* both with the requesting company and with the evaluating laboratories. A *complete evaluation* requires both one part performed by experienced laboratory personnel and 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 a supplier uses 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 from SKUP containing the report code. SKUP reports are published at www.skup.nu and summaries are distributed to physicians' offices, councils for laboratory medicine, laboratory instructors and healthcare authorities. For a detailed list of previous SKUP evaluations, please look in the attachments of this report.

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[1] NOKLUS (Norwegian Quality Improvement of Primary Care Laboratories) is an organisation attached to "Seksjon for Allmennmedisin" (Section for General Medicine) at the University of Bergen.

[2] "The SKUP-division in Denmark" is an organisation created through an agreement between the national "Fagligt Udvalg vedrørende Almen Praksis" (Professional Committee for General Practice) and the "Afdeling KKA" (Department for Clinical Chemistry) at the University Hospital in Odense. "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 owned by "Sveriges Kommuner och Landsting" (Swedish Association of Local Authorities and Regions), "Svenska Läkarsällskapet" (Swedish Society of Medicine) and IBL (Swedish Institute of Biomedical Laboratory Science).

2. The planning of the evaluation

Tor Schye from Tamro MedLab AS applied to SKUP in the spring of 2005 for an evaluation of the glucose meter Glucocard X-Meter with Glucocard X-Sensor test strips. In August 2005 a preliminary suggestion regarding how to organise the evaluation of Glucocard X-Meter was sent to Tamro MedLab. The protocol for the evaluation was accepted in October 2005 and a contract was set up between Tamro MedLab and SKUP. 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.

The Glucocard X-Meter system is produced by Arkray, Inc. and supplied by Tamro MedLab. The system has not yet been launched onto the Norwegian market. SKUP carried out the user-evaluation of Glucocard X-Meter from October 2005 to January 2006.

SKUP evaluations are made according to guidelines in the book "*Evaluation of analytical instruments. A guide particularly designed for evaluations of instruments in primary health care*" (Christensen, Monsen et al. 1997) [1]. 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 diabetics, based on the model by the NOKLUS-project "*Diabetes-Self-measurements*" [2].

The evaluation comprises the following studies:

- An examination of analytical quality under standardised and optimal conditions done by biomedical laboratory scientists
- An examination of analytical quality among approximately 80 diabetics
- An examination of agreement between Glucocard X-Meter and a designated comparison method
- A comparison of analytical quality among diabetics with and without a training programme
- A comparison of analytical quality among diabetics before and after three weeks of practise
- An examination of variation between three lots of test strips
- An examination to see if hematocrit interferes with the measurements
- An evaluation of the user-friendliness of Glucocard X-Meter
- An evaluation of the user-manual of Glucocard X-Meter

The blood sampling of the diabetics and the measurements at Glucocard X-Meter under standardised and optimal conditions, were done by Bente Knudsen, Margarita Milan and Signe Røynås, biomedical laboratory scientists and laboratory consultants, SKUP/NOKLUS. Two biomedical laboratory scientists, Wenche Eilifsen Hauge and Kjersti Østrem, were given the responsibility for the practical work with the comparison method at the Laboratory at HDH. The statistical calculations and the report writing are done by Marianne Risa, SKUP/NOKLUS Centre in Bergen.

3. 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. Glucocard X-Meter 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 [3]. According to the American Diabetes Association (ADA) the imprecision of new glucose devices must be less than 5 % [4]. Other authors also recommend an imprecision of 5 % or less [5].

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 Glucocard X-Meter is found in ISO 15197, *In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus* [6]. The ISO-guide is an international protocol for evaluating meters designed for glucose monitoring systems.

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 done by the diabetics. Previous investigations under the direction of the NOKLUS-project "Diabetes-Self-measurements" in 1997 [5,7] 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 by the diabetics 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 diabetics over time, as the meters would hopefully improve due to technological development. More recent evaluations performed by SKUP [8] clearly show that the quality goals set by ISO 15197 now can be achieved also by the diabetics. But for the time being, the quality demands adjusted to the diabetics' self-measurements, still apply.

Quality demands, adjusted to the diabetics 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.

4. Materials and methods

4.1. Statistical terms and expressions

4.1.1. Precision

The common 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. In this report, the terms are replaced by the precisely defined terms *repeatability and reproducibility*. 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 two terms are measured as imprecision. Precision is descriptive in general terms as “good”, “acceptable” and “poor”, whereas 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 imprecision will be summarised in tables.

4.1.2. Accuracy

Accuracy is the closeness of agreement between the result of one measurement and the true value. Inaccuracy is a measure of a single measurements deviation from a 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 will be illustrated by difference plots with quality goals for the total error shown as deviation limits in percent.

4.1.3. Trueness

Trueness is the agreement between an average value obtained from a large number of measuring results and a true 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 will be summarised in tables.

4.2. Glucocard X-Meter

Glucocard X-Meter is a blood glucose monitoring system based on biosensor technology. The system consists of a meter, Glucocard X-Meter, and dry reagent test strips, Glucocard X-Sensor, designed for capillary blood glucose testing by people with diabetes or by health care professionals. Glucocard X-Meter reports plasma glucose values. The meter is turned on by insertion of a Glucocard X-Sensor test strip. The Glucocard X-Meter automatically makes calibration using necessary information from the inserted test strip. The user has to make sure that the code number displayed by the meter matches the code number printed on the test strip box. The test principle of Glucocard X-Meter is as follows: Glucose in the sample reacts with glucose dehydrogenase and hexaammineruthenium (III) chloride in the test strip, producing hexaammineruthenium (II) chloride. Oxidation of hexaammineruthenium (II) chloride produces a current which is measured. The current produced is in proportion to the glucose concentration.

The test strips are packed in a plastic bottle with flip-top closure. The system requires a blood volume of 0,3 µL. The finger to be lanced and the tip of the lancing device have to be disinfected before pricking the finger. The blood is automatically drawn into the test strip. If the amount of blood is insufficient, it may cause incorrect test results or prevent measurement. Adding any extra blood may cause incorrect test results. The result is provided within 5 seconds. It is possible to test with blood from the forearm, collected with a special lancing device. The meter has the capacity of storing 360 results in the memory. When analysing a Glucocard X-Meter Control Solution, the user has to enter the control mode by pressing an orange button under the button cover. Technical data from the manufacturer is shown in table 1.

Table 1. Technical data from the manufacturer.

TECHNICAL DATA FOR GLUCOCARD X-METER	
Ambient temperature	10 – 40 °C
Sample volume	0,3 µL
Measuring time	5 seconds
Measuring range	0,6 – 33,3 mmol/L
Hematocrit	Higher glucose concentration range: The result is lowered if the hematocrit is high and elevated by low hematocrit. Normal and low glucose concentration: Not effected of hematocrit.
Memory	360 tests (included control-results)
Power source	One 3-volt lithium battery (CR2032 or DL2032)
Operating time	Approximately 2000 tests
Dimensions	50 x 100 x 12 (mm)
Weight	Approximately 45 g (including the battery)

4.2.1. Product information, Glucocard X-Meter

Glucocard X-Meter blood glucose meter system
Manufactured by: Arkray, Inc.

Suppliers of Glucocard X-Meter in the Scandinavian countries:

Sweden:
Tamro MedLab AB
P.O. Box 49
SE-401 20 Göteborg
Sweden

Phone: +46 31 706 3065
www.tamromedlab.com

Norway:
Tamro MedLab AS
Postboks 413
N-1471 Skårer
Norway

Phone: +47 67 92 27 00
www.tamromedlab.no

Denmark:
Tamro MedLab A/S
Langebjerg 23
DK-4000 Roskilde
Denmark

Phone: +45 2127 8632
www.tamromedlab.com

Finland:
Tamro MedLab OY.
P.O. Box 11
FIN-01641 Vantaa
Finland

Phone: +358 020 445 4775
www.tamromedlab.com

87 Glucocard X-Meter blood glucose meters were used in this evaluation.
Serial no. J 517581 (called meter A), serial no. J 517547 (called meter B), serial no. J 400296 (called meter C) and serial no. J 517599 (called meter D) were used by the biomedical laboratory scientists under the standardised and optimal conditions. Attachment 1 gives serial numbers for the 83 meters used by the diabetics.

Glucocard X-Sensor Test Strips:

Lot-no. 05H2A16	Expiry 2007-02
Lot-no. 05H2A17	Expiry 2007-02
Lot-no. 05H2A18	Expiry 2007-02

Glucocard X-Meter Controls:

Control L, ref-no 78492	Lot-no GXLSAMP	Expiry 2006-06
Control N, ref-no 78493	Lot-no GXNSAMP	Expiry 2006-06
Control H, ref-no 78494	Lot-no GXHSAMP	Expiry 2006-06

4.3. 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.

Verifying of trueness
The results from self-monitoring blood glucose devices (SMBG-devices) must be compared with a recognized comparison method. The comparison method should be a plasma method, hexokinase by preference. The 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 with four levels of glucose concentrations was used in this evaluation. In addition, freshly frozen, human serum controls from NOKLUS with glucose concentrations at two levels were analysed. The NOKLUS-controls have target values determined with an isotope-dilution gas chromatography/mass spectrometry method at a Reference laboratory in Belgium; Laboratory for Analytical Chemistry, University of Gent, Belgium [9]. The results are summarized in chapter 6.1.2.

The designated comparison method in this evaluation
In this evaluation, the routine method for quantitative determination of glucose in human serum, plasma (e.g. lithium heparin), urine and cerebrospinal fluid (CSF) at the Laboratory at 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 at Architect *ci*8200 System from Abbott Laboratories, with reagents and calibrators from Abbott Laboratories. The measuring principle in the Architect *ci*8200 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 NADP to NADPH. The NADPH produced absorbs light at 340 nm and can be detected spectrophotometrically as an increased absorbance.

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

4.3.1. Product information, the comparison method

Designated comparison method Architect ci8200
Manufactured by: Abbott Laboratories
Serial no. C800890

Reagents
Glucose Reagent Kit, List No. 7D66
Lot-no. 32024HW00 Expiry 2006-06-23

Calibrator
Multiconstituent Calibrator. List No. 1E65
Lot-no. 19906M200 Expiry 2006-02-28 Reference value, cal 1 = 5,55 mmol/L
Reference value, cal 2 = 24,31 mmol/L

Internal controls
Seronorm Autonorm Human Liquid 1 and 2, Sero AS
Liquid 1: Value = 5,2 ± 0,36 mmol/L Lot-no. NO3588 Expiry 2006-01
Liquid 2: Value = 15,0 ± 1,05 mmol/L Lot-no. MI4298 Expiry 2006-07

NOKLUS controls
(ID-GCMS method; reference value from Laboratory for Analytical Chemistry, University of Gent, Belgium)
Level 1: Value = 3,20 ± 0,010 mmol/L
Level 2: Value = 7,78 ± 0,026 mmol/L

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: Lot-no. WIP 011
Accu-Chek Softclix Pro lancets: Lot-no. WIP 45 G 3 Expiry 2008-12-31
Accu-Chek Softclix Pro lancets: Lot-no. WIR 27 H 4 Expiry 2009-12-31

Tubes used for sampling for the designated comparison method
Microvette CB 300 LH (lithium-heparin) manufactured by Sarstedt AS
Lot-no. 5070201 Expiry 2008-01

Centrifuge used for samples for the designated comparison method
Eppendorf Centrifuge 5415D Serial no. 0057100
Sigma 203 Serial no. 30361

4.4. Evaluation procedure

4.4.1. Model for the evaluation

The practical work with the evaluation was carried out during 14 weeks from October 2005 to January 2006 at Sørlandet Hospital, Kristiansand, Norway. The practical work was done by the biomedical laboratory scientists Bente Knudsen, Margarita Milan and Signe Røynås.

The evaluation consisted of two parallel evaluations. One part of the evaluation was done by the biomedical laboratory scientists under standardised and optimal conditions. This part of the evaluation was done by laboratory educated personnel, completely according to the protocol and user manual after having received thoroughly 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 as good conditions as possible. The other part of the evaluation was done by diabetics. In order to determine the analytical quality of Glucocard X-Meter by the users, 83 diabetics tested their blood glucose using Glucocard X-Meter. The diabetics were divided into two groups (random distribution). 40 diabetics were called in and received personal training in how to use the blood glucose meter, here called the "training group". 43 diabetics received the blood glucose meter and instructions by post, here called the "post group".
The reason for dividing the diabetics into a "training group" and a "post group" is that this reflects the actual market situation regarding training when diabetics acquire blood glucose meters [2]. The model for the evaluation is shown in figure 1.

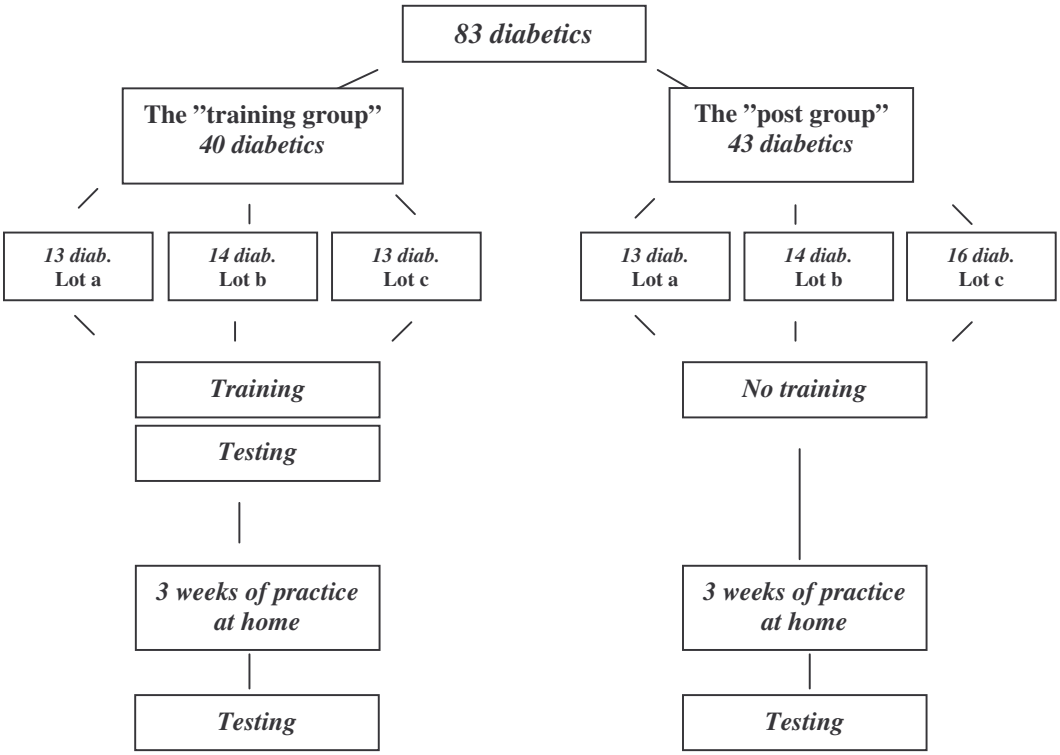

Figure 1. Model for the evaluation

All the diabetics could not participate in the user evaluation during the same weeks. The biomedical laboratory scientists had capacity to receive approximately 20 diabetics a week. The start-up was spread out over 4 weeks, and the final consultations consequently spread out correspondingly.

4.4.2. Recruiting of the diabetics

The Glucocard X-Meter glucose meter was tested in use by 83 diabetics. The evaluation started with 85 diabetics and 83 diabetics completed the evaluation. The diabetics were recruited through advertisement in the daily press, by promotion of the evaluation in the local radio station and by mail inquiry sent to members of the local branch of the Norwegian Diabetes Association. The group of diabetics was representative for diabetics who carry out self-monitoring of blood glucose (SMBG). The group included diabetics from across a range of self-monitoring frequencies, i.e. diabetics who performed self-monitoring often (one or more times a day) and those who performed self-monitoring less frequently (once a week). Characteristics of the diabetics are shown in table 2.

Table 2. Characteristics of the diabetics included (n=83).

		Number of diabetics
Total		83
Sex	Men	45
	Women	38
Age (years), mean and range		56 (18 – 75)
Diabetes	Type 1	25
	Type 2	55
	Mody III	1
	Don't know	2
Treatment	Insulin	43
	Insulin and tablets	4
	Tablets	27
	Diet	9
Frequency of SMBG	Less than weekly	4
	1 – 3 per week	13
	4 – 6 per week	6
	7 – 10 per week	18
	> 10 per week	40
	Do not measure	2

The SMBG-devices that the diabetics used regularly were:
Accu-Chek (model not specified) (6), Accu-Chek Compact (16), Accu-Chek Sensor/Accutrend (11), Ascensia Contour (4), Ascensia Elite/Elite XL (5), EuroFlash (1), FreeStyle Mini (3), GlucoMen (1), MediSense (model not specified) (4), MediSense Precision Xtra/Xceed (17), OneTouch (model not specified) (1), OneTouch Ultra/Ultra Smart (12). Some of the diabetics used more than one SMBG-device at home, but only one device is registered here.

4.4.3. The "training group" at the first consultation

The 40 diabetics that were selected to participate in a training programme were called in two at a time. They received the Glucocard X-Meter device along with test strips, lancet pen, lancets, user manual, and an instruction letter with explanations regarding what to do with the Glucocard X-Meter device during the period at home. The instruction letter is attached to the report (in Norwegian). See attachment 2. The responsibility for the training programme was undertaken by SKUP. Bente Knudsen, Margarita Milan and Signe Røynås were in charge of the training of the diabetics, after having been trained themselves by a representative from Tamro MedLab.

Training programme

The training programme covered a simple demonstration of how to use Glucocard X-Meter 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 and the shelf-life of test strips, etc. The training programme was standardised to make sure that all the diabetics received the same instruction.

Blood sampling

After having been trained, the 40 diabetics made duplicate blood glucose tests at Glucocard X-Meter. These results were registered for the evaluation. The biomedical laboratory scientist collected samples for the evaluation under standardised and optimal conditions (see chapter 4.4.7.). Afterwards the diabetics took the Glucocard X-Meter home to use it over a three-week period. After this period they attended a final consultation (see chapter 4.4.6).

4.4.4. The "post group"

The 43 diabetics in the "post group" received the Glucocard X-Meter device by post, along with test strips, lancet pen, lancets, user manual and an instruction letter with explanations regarding what to do with the Glucocard X-Meter device during the period at home. No training was given. They used the meter over a three-week period at home. After this period they attended a final consultation (see chapter 4.4.6).

4.4.5. Use of Glucocard X-Meter by the diabetics at home

The diabetics used Glucocard X-Meter at home for three weeks. The length of this practice period ought not to exceed three weeks by more than a few days. Most users read the user manual at once when they receive the meter. As the diabetics should evaluate the user manual at the final consultation, it would be unfortunate if the practice period at home was too long. During the practice period the diabetics used Glucocard X-Meter in addition to their own glucose meter and they continued to carry out self-measurements with their own meter as normal.

The first and the second week

The diabetics familiarised themselves with the new device during the first two weeks. Each diabetic used approximately 25 test strips to measure his/her blood glucose with Glucocard X-Meter. 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 measured the blood glucose with their own meter.

The third week
During the third week the diabetics performed duplicate measurements at Glucocard X-Meter 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 diabetics are not familiar with control solutions for self-measurements. Therefore they were not instructed to use control solution at Glucocard X-Meter in the evaluation. To document correct functioning of the Glucocard X-Meters used by the diabetics during the test period, the biomedical laboratory scientists in charge of the practical work checked the meters with the control solution when the diabetics were called for the consultations.

4.4.6. The final consultation

Blood sampling
After the three week practice period at home, the 83 diabetics were called for, one by one, to a consultation. Each diabetic brought their assigned Glucocard X-Meter and the remaining test strips to the consultation. They made duplicate blood glucose tests at their assigned Glucocard X-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.

The questionnaires
After all the blood samples were collected and the measurements at Glucocard X-Meter were done, the diabetics filled in two questionnaires. The first questionnaire was about the user-friendliness of Glucocard X-Meter, the second about the user-manual. The questionnaires (in Norwegian) are attached to the report. After the evaluation, the diabetics could choose whether to keep Glucocard X-Meter or return it to the project.

4.4.7. Evaluation under standardised and optimal conditions

The biomedical laboratory scientists used four Glucocard X-Meter blood glucose meters for the evaluation (meter A, B, C and D). Meter A and C were mainly used for one lot of test strips for all the measurements. Meter B and D were used for the same three lots as distributed among the diabetics. The variation between the three lots, or more precisely, the agreement of the three lots to the comparison method, will be assessed. The number of samples for each lot of 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.

Glucocard X-Meter		Lot 05H2A16 (n)	Lot 05H2A17 (n)	Lot 05H2A18 (n)
Meter A/C	1st consultation	38 x 2	2 x 2	
	2nd consultation	61 x 2	17 x 2	5 x 2
Meter B/D	1st consultation	14 x 2	25 x 2	1 x 2
	2nd consultation	22 x 2	28 x 2	33 x 2
Total		135 x 2	72 x 2	39 x 2

Blood sampling
Meter A/C and B/D were checked by means of the manufacturer's control solution every day they were used.
The blood sampling and analysis were done in the following order:

1. The biomedical laboratory scientist took a sample for the comparison method
2. The diabetic took duplicate samples for his/her assigned meter
3. The biomedical laboratory scientist took samples and analysed at meter A, B, A and B or meter C, D, C and D
4. The biomedical scientist took a second sample for the comparison method
5. The biomedical laboratory scientist measured an internal quality control at the diabetic's meter

In order to reduce the possibility for a change in the glucose concentration during sampling, the sampling time should not exceed 10 minutes.

The order of meter A and B or meter C and D was changed between each diabetic, but the blood samples for the comparison method were always taken first and last in accordance with ISO 15197. The biomedical laboratory scientists registered whether the diabetics 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. At the final consultation a venous sample for hematocrit determination was taken. Hematocrit may influence blood glucose readings, especially in meters designed for self-monitoring. This also applies to Glucocard X-Meter. The package insert of Glucocard X-Sensor test strips states that normal and low glucose concentrations are not affected by hematocrit values. In a higher glucose range, the glucose result is lowered as the percentage of hematocrit increases and elevated as the hematocrit percentage decreases.

Handling of the samples for the comparison method
The samples for the comparison method were capillary taken using Microvette Li-heparin tubes from Sarstedt. The samples were centrifuged immediately for three minutes at 10000 g (Eppendorf 5415D) or for ten minutes at 2000g (Sigma 203), and plasma was separated into sample vials. The plasma samples were frozen directly and stored at minus 80 °C (minus 81 to minus 85 °C). The samples were transported under cold storage (minus 18 to minus 24 °C) to NOKLUS Centre where they were kept at minus 80 °C until the analysis took place.

Analysing the samples for the comparison method
The samples were analysed at Architect. Recommended minimum volume for analysis of glucose at Architect in this evaluation was 120 µL plasma. The samples were thawed at NOKLUS Centre just before they were analysed. The first and the second sample for the comparison method, taken at the start and at the end of each blood sampling, reflect the stability of the glucose concentration during the sampling time. When the paired measurements give agreeable glucose concentrations at the comparison method, the mean of the two results is 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 Glucocard X-Meter results were excluded for accuracy and trueness calculations. Differences between 4 and 10 % are discussed and included in the calculations (see chapter 6.1.3.). 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.

The questionnaires
The biomedical laboratory scientists evaluated the user-friendliness of Glucocard X-Meter and the user-manual. 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 in the system that did not function optimally.

4.4.8. Evaluation of analytical quality

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

1. Results from 40 diabetics in the "training group" who had participated in the training programme, but not practised using the blood glucose meter at home
2. Results from the same diabetics after they had practised using Glucocard X-Meter at home for three weeks
3. Results from 43 diabetics in the "post group" who had not participated in the training programme, but who had practised using Glucocard X-Meter at home for three weeks
4. Results from 123 measurements under standardised and optimal conditions
5. Results from 123 measurements from the comparison method

The results from the diabetics with and without training were compared (item 2 and 3) and the results from the diabetics with and without practise at home (item 1 and 2) were also compared. All the diabetic 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 user-friendliness and the user-manual were evaluated by means of questionnaires.

The three lots of test strips were distributed evenly between the diabetics in the group with and without training (random distribution in each group). Each lot was used by approximately 13 diabetics in each group (see figure 1).

5. Statistical calculations

5.1. Number of samples

83 diabetics completed the evaluation. The 40 diabetics in the "training group" met at two consultations and the 43 diabetics in the "post group" met at one consultation. Blood samples were taken at each consultation. This means that the total number of samples is:
123 x 2 (duplicates) x 4 (meter A/C, B/D, diabetic's meter, comparison method) = 984 samples.

5.2. Statistical outliers

All the results are checked for outliers according to Burnett [10], with repeated truncations. 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. 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.

5.3. Missing or excluded results

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

- At the first consultation the second measurement of ID 177 at meter A/C got the result high. ID 177 is therefore missing in the comparison of the 1st and the 2nd measurement and in the calculation of repeatability based on the diabetics' samples measured under standardised and optimal conditions.
- ID 33 had forgotten to bring the assigned Glucocard X-Meter to the final consultation. ID 33 is therefore missing in the calculation regarding the repeatability (with diabetic samples) at the final consultation and the calculation regarding accuracy. ID 36 had only one measurement at assigned meter at the final consultation and is missing in the calculation regarding the repeatability (with diabetic samples) at the final consultation.
- In the calculation of repeatability based on the diabetics' measurements at home some measurements are missing. Some of the diabetics had not done five duplicate measurements and totally 24 results are missing from this calculation.
- ID 104 at the first consultation and ID 9, ID 33, ID 107 and ID 109 at the final consultation are missing QC-results and are therefore missing in the calculation of reproducibility based on control results. The control result for ID 241 at the first consultation was outside the limits of the control. For this reason the results of the measurements at this meter at the first consultation have been excluded from all calculations.
- ID 4 had no hematocrit result.

5.4. Calculations of imprecision based on duplicate results

Two capillary samples were taken of each diabetic to meter A or C, to meter B or D, to the diabetic's meter and to the comparison method at each consultation. The imprecision was calculated by use of paired measurements, 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 paired measurements, the SD 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 is acceptable. Table 4 shows that there is no systematic difference in glucose concentration between the paired measurements at Glucocard X-Meter in this evaluation.

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
Glucocard X-Meter	Meter A/C	< 7	5,9	5,9	0,05	-0,10 – 0,20	27
		7 – 10	8,6	8,7	0,15	-0,03 – 0,33	43
		> 10	13,7	13,7	0,01	-0,26 – 0,27	51*
	Meter B/D	< 7	5,7	5,8	0,06	-0,05 – 0,17	27
		7 – 10	8,5	8,6	0,18	-0,03 – 0,38	41
		> 10	14,1	14,1	0,02	-0,24 – 0,28	55

* ID 177 1st consultation is missing because the second measurement gave the result high. There is also one statistical outlier (according to Burnett) in this group.

5.5. Calculation of trueness

To measure the trueness of the results at Glucocard X-Meter, 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 at the comparison method and the mean values at Glucocard X-Meter A/C.

5.6. Calculation of accuracy

To evaluate the accuracy of the results at Glucocard X-Meter, the agreement between Glucocard X-Meter and the comparison method is illustrated in difference plots. In the plots the x-axis represents the mean value of the duplicate results at the comparison method. The y-axis shows the difference between the first measurement at Glucocard X-Meter B/D with three lots and the mean value of the duplicate results at the comparison method.

6. Results and discussion

6.1. Precision and trueness of the designated comparison method

6.1.1. 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 diabetic samples 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 with a time gap between the first and the second sample for each diabetic. 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 sampling, and not the precision of the method (see 6.1.3). To get a good estimate of the repeatability of the comparison method in this evaluation, the results from the documentation of the trueness were used. Both the NIST-standards and the NOKLUS controls are genuine patient materials with no additives, and the standards and 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 SRM 965a standards supplied by the National Institute of Standards & Technology, NIST, and freshly frozen, human serum controls from NOKLUS. The repeatability is calculated as a combined CV %.

The reproducibility of the comparison method is shown in table 5. The results are obtained with the internal control solution at two levels of glucose concentrations. The controls were analysed in duplicate in the beginning and at the end of each series of samples, giving a total number of more than 100 results. In table 5 only the first result in each series is included. All of the results were inside the limits of the target values for the controls. The results are shown in attachment 3.

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

Control Solution	Target value glucose (mmol/L)	Mean value glucose (mmol/L)	n	Outliers	CV % (95 % CI)
Autonorm 1	5,2 ± 0,36	5,0	52	0	1,5 (1,2 – 1,8)
Autonorm 2	15,0 ± 1,05	14,7	52	0	1,3 (1,1 – 1,7)

Discussion

The precision of the comparison method is good. The repeatability is approximately 1,0 CV% (see table 6 and 7) and the reproducibility is approximately 1,5 CV%.

6.1.2. 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 four times during the evaluation period. SRM 965a consists of ampoules with human serum with certified concentrations and uncertainties for glucose at four concentrations. The SRM 965a materials cover a glucose concentration range from 1,9 to 16,2 mmol/L.

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 at the comparison method during the evaluation period.

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	30.11.05	**1,918** (1,898 - 1,938)	1,9	5	0,0 *	0
	05.01.06		1,9	5		0
	25.01.06		1,9	5		0
	Total		**1,9**	**15**		**0**
Level 2	30.11.05	**4,357** (4,309 - 4,405)	4,38	5	0,8 (0,6 – 1,3)	0,5
	05.01.06		4,38	5		0,5
	25.01.06		4,40	5		1,0
	Total		**4,39**	**15**		**0,7**
Level 3	30.11.05	**6,777** (6,704 - 6,850)	6,82	5	0,5 (0,4 – 0,9)	0,6
	06.01.06		6,78	5		0,0
	25.01.06		6,80	5		0,3
	Total		**6,80**	**15**		**0,3**
Level 4	30.11.05	**16,24** (16,05 - 16,43)	16,24	5	0,5 (0,4 – 0,8)	0,0
	06.01.06		16,34	5		0,6
	25.01.06		16,26	5		0,1
	Total		**16,28**	**15**		**0,2**

* The comparison method gives values with only one decimal. All the measurements at level 1 gave the result 1,9 mmol/L, and thereby the CV at this level is 0,0 %.

To verify the trueness of the comparison method, freshly frozen, human serum controls from NOKLUS with glucose concentrations at two levels were analysed. The NOKLUS-controls have target values determined with an isotope-dilution gas chromatography/mass spectrometry method at a Reference laboratory in Belgium; Laboratory for Analytical Chemistry, University of Gent, Belgium [9]. 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 at the comparison method during the test period.

Control solution	Date	Target value from Reference lab. in Belgium (mmol/L)	Mean value glucose (mmol/L)	n	Outliers	Combined CV% (95% CI)	% deviation from target value
NOKLUS control 1	14.12.05	3,20	3,20	6		1,2 (0,9 – 2,1)	0,0
	11.01.06		3,15	6			-1,6
	Total		**3,18**	**12**	**0**		**-0,8**
NOKLUS control 2	14.12.05	7,78	7,73	6		0,8 (0,5 – 1,3)	-0,6
	11.01.06		7,80	6			+0,3
	Total		**7,77**	**12**	**0**		**-0,2**

Discussion
The trueness of the comparison method is very satisfactory.

6.1.3. Stability of the glucose concentration during sampling

The first and the second sample for the comparison method, taken at the start and at the end of each blood sampling, reflect the stability of the glucose concentration during the sampling time (see chapter 4.4.7). Deviations > 10 % are regarded as not acceptable in an evaluation like this and such results are excluded without further discussion. In this evaluation no samples had a deviation > 10 %. Two samples with a low glucose concentration (below 5,5 mmol/L) had a difference just over the limit at 0,22 mmol/L, but are still included in the calculations. 13 of 123 paired results at the comparison method gave deviations between 4 and 10 %. For 10 of these 13 samples the deviation was less than 7 %. 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 15 results. The percentage number of results that falls within the different quality limits is not dependent on keeping or excluding these results. In both cases, the results in the evaluation fulfil the quality goals set by ISO.

6.2. Precision, trueness and accuracy of Glucocard X-Meter

6.2.1. The precision of Glucocard X-Meter

The Glucocard X-Meters in the user evaluation were checked with the manufacturer's control solutions by the biomedical laboratory scientists. All the results except one (ID 241 at the first consultation) were inside the limits of the controls.

All the results from the calculations 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 diabetics, is shown in table 8. The table gives the results from the biomedical laboratory scientists' measurements at the first and the final consultation together. Raw data is shown in attachment 4.

Table 8. Glucocard X-Meter – Repeatability (results with blood samples from the diabetics) measured under standardised and optimal conditions.

Glucocard X-Meter	Glucose level (mmol/L)	Mean value glucose (mmol/L)	n	Outliers	CV % (95 % CI)
Meter A/C	< 7	5,9	27	0	4,5 (3,5 – 6,2)
Meter B/D	< 7	5,8	27	0	3,5 (2,7 – 4,7)
Meter A/C	7 – 10	8,7	43	0	4,8 (4,0 – 6,2)
Meter B/D	7 – 10	8,6	41	0	5,4 (4,5 – 6,9)
Meter A/C	> 10	13,7	51*	1**	4,8 (4,0 – 5,9)
Meter B/D	> 10	14,1	55	0	4,8 (4,0 – 5,9)

* ID 177 1st consultation is missing because the second measurement gave the result high.
** One statistical outlier (according to Burnett).

Repeatability obtained by the diabetics

The repeatability obtained by the diabetics with capillary blood samples is shown in table 9. The table gives the results from the measurements at the first and the second consultation for the "training group", the results from the measurements at the consultation for the "post group" and the results the diabetics obtained at home. The results obtained at home have, of course, a higher degree of uncertainty since it is impossible to check what has actually been done. The reporting of these home-values also reveals that some of the diabetics did not quite understand "the recipe" on how to perform and report the five duplicate measurements they were supposed to carry out according to the written instruction they had received.

Raw data from the diabetics' measurements at NOKLUS is shown in attachment 5.
Raw data from the diabetics' measurements at home is shown in attachment 6.

Table 9. Glucocard X-Meter – Repeatability (results with diabetic samples) measured by the "training group" and the "post group".

Glucocard X-Meter	Consultation/ diabetic group	Glucose level (mmol/L)	Mean value glucose (mmol/L)	n	Outliers	CV % (95 % CI)
At NOKLUS	1st/training group	< 7	6,2	8	0	6,2 (4,1 – 12,7)
	2nd/training group**	< 7	5,6	4	0	9,1 (5,1 – 33,8)
	The post group	< 7	5,9	11	0	5,9 (4,1 – 10,4)
At home*		< 7	5,6	121	1	7,1 (6,3 – 8,2)
At NOKLUS	1st/training group	7 – 10	8,4	12	0	6,1 (4,3 – 10,3)
	2nd/training group	7 – 10	9,0	10	0	5,5 (3,8 – 10,0)
	The post group	7 – 10	8,4	14	0	6,1 (4,4 – 9,8)
At home*		7 – 10	8,5	147	0	7,5 (6,8 – 8,6)
At NOKLUS	1st/training group	> 10	14,8	20	0	6,3 (4,8 – 9,2)
	2nd/training group	> 10	14,1	24	0	4,6 (3,6 – 6,5)
	The post group	> 10	13,9	18	0	6,8 (5,1 – 10,1)
At home*		> 10	13,6	120	2	6,8 (6,1 – 7,9)

* 24 home measurements are missing and 3 outliers among the home measurements are excluded.

** ID 33 had forgotten to bring the assigned Glucocard X-Meter to the final consultation and is missing.
ID 36 had only one measurement at assigned meter at the final consultation and is missing.

Reproducibility with Internal Quality Control

The results for reproducibility are obtained with the Glucocard X-Meter Control N and H. The measurements are carried out at meter A/C and meter B/D during the whole evaluation period. The reproducibility of Glucocard X-Meter at meter A/C and meter B/D is shown in table 10.

Internal Quality Control at the diabetics' meters

The control measurements at the diabetics' meters were done with the Glucocard X-Meter Control L, N and H. All the control measurements are done by the biomedical laboratory scientists with the test strips that were distributed to each diabetic. The control solutions were kept at NOKLUS during the evaluation period. The imprecision at the meters of the diabetics is shown in table 11.

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

Table 10. Glucocard X-Meter – Reproducibility (results with Glucocard X-Meter Control N and H) measured by the biomedical laboratory scientists at meter A/C and meter B/D.

Glucocard X-Meter	QC	Target value (mmol/L)	Mean value glucose (mmol/L)	n	Outliers	CV % (95 % CI)
Meter A/C	N	5,8 – 9,6	8,5	13	0	5,7 (4,1 – 9,3)
	H	15,0 – 25,0	21,1	18	0	3,0 (2,3 – 4,6)
Meter B/D	N	5,8 – 9,6	8,4	12	0	5,9 (4,1 – 9,9)
	H	15,0 – 25,0	21,2	18	0	4,0 (3,0 – 6,0)

Table 11. Glucocard X-Meter – Reproducibility (results with Glucocard X-Meter Control L, N and H) measured by the biomedical laboratory scientists at the diabetics' meters.

Glucocard X-Meter	QC	Target value (mmol/L)	Mean value glucose (mmol/L)	n	Outliers	CV % (95 % CI)
1st consultation**						
The diabetics' meters	N	5,8 – 9,6	7,8	23	1*	5,1 (3,9 – 7,2)
	H	15,0 – 25,0	20,9	15	0	5,5 (4,1 – 8,7)
2nd consultation***						
The diabetics' meters	L	1,9 – 3,5	3,0	7	0	4,9 (3,1 – 10,8)
	N	5,8 – 9,6	8,4	40	0	7,8 (6,4 – 10,1)
	H	15,0 – 25,0	20,7	32	0	4,2 (3,4 – 5,6)

* The control result for ID 241 was outside the limits of the control and is excluded.
** ID 104 is missing QC-result.
*** ID 9, ID 33, ID 107 and ID 109 are missing QC-results.

Discussion

The precision at Glucocard X-Meter is acceptable. The repeatability obtained under standardised and optimal conditions is approximately 5 %. The repeatability obtained at NOKLUS when the measurements are performed by the diabetics, is slightly poorer with a CV of approximately 6 %. The CVs for the diabetics with and without training programme (the "training group" and the "post group") are not significantly different. The CVs for the diabetics with and without practise at home (1st and 2nd training) are not significantly different either. This indicates that Glucocard X-Meter is a robust system, easy to use, and that training is not essential for a good result. The results at home show that the diabetics have been practising with the new system according to the instructions, but one should not make a point of the calculated CV values.

The reproducibility at Glucocard X-Meter was acceptable when measured with internal control solutions. The CV was approximately 5 %.

6.2.2. The trueness of Glucocard X-Meter

The trueness of Glucocard X-Meter is calculated from the results achieved by the biomedical laboratory scientists at the final consultation (the "training group" and the "post group"). The calculations are based on measurements at meter A/C and are shown in table 12. The measurements at meter A/C are mainly done with lot-no. 05H2A16.

Raw data from the samples analysed at the comparison method is shown in attachment 8.

Table 12. Mean difference between Glucocard X-Meter and the comparison method, based on the mean of each duplicate at both methods. Results achieved under standardised and optimal conditions at the final consultation.

	< 7 mmol/L		**7 – 10 mmol/L**		**> 10 mmol/L**	
	The comparison method	**Meter A/C**	**The comparison method**	**Meter A/C**	**The comparison method**	**Meter A/C**
Mean glucose, mmol/L	5,7	5,7	8,6	8,5	14,0	13,4
Mean deviation from the comparison method, mmol/L (95 % CI)	0,00 (-0,16 – 0,16)		-0,15 (-0,45 – 0,15)		-0,58 (-0,97 – (-0,20))	
n	19		23		41	
Outliers	0		0		0	

Discussion

The trueness of Glucocard X-Meter is good. Table 12 shows that no significant bias between Glucocard X-Meter and the comparison method for glucose values < 10 mmol/L was pointed out. For glucose values > 10 mmol/L there is a significant bias between Glucocard X-Meter and the comparison method. Glucocard X-Meter gives glucose values approximately 0,6 mmol/L lower than the comparison method at this glucose level.

6.2.3. The accuracy of Glucocard X-Meter

To evaluate the accuracy of the results at Glucocard X-Meter, the agreement between Glucocard X-Meter and the comparison method is illustrated in two difference plots. The plots show the deviation of single measurement results at Glucocard X-Meter from the true value, and give a picture of both random and systematic deviation and reflect the total measuring error at Glucocard X-Meter. The total error is demonstrated for the first measurements of the paired results, only. At meter A/C mainly one lot of test strips was used. At meter B/D three different lots were used. The same three lots were randomly distributed between the diabetics.
The limits in the plots are based upon the quality goals discussed in chapter 3 in this report. Under standardised and optimal measuring conditions the ISO-goal at ± 20 % is used. For the diabetics' self-measurements the "adjusted ISO-goal" at ± 25 % is used.

The accuracy, Glucocard X-Meter B/D, under standardised and optimal measuring conditions, at the final consultation is shown in figure 2.
The accuracy, Glucocard X-Meter, as measured by the diabetics at the final consultation is shown in figure 3.
The accuracy is summarised in table 13 and discussed afterwards.

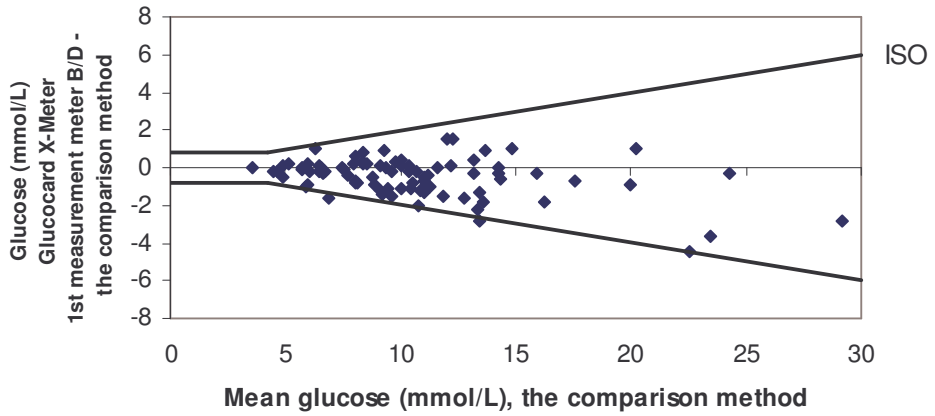

Figure 2. Accuracy. Glucocard X-Meter B/D (three lots of test strips) under standardised and optimal measuring conditions at the final consultation. The x-axis represents the mean value of the duplicate results at the comparison method. The y-axis shows the difference between the first measurement at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

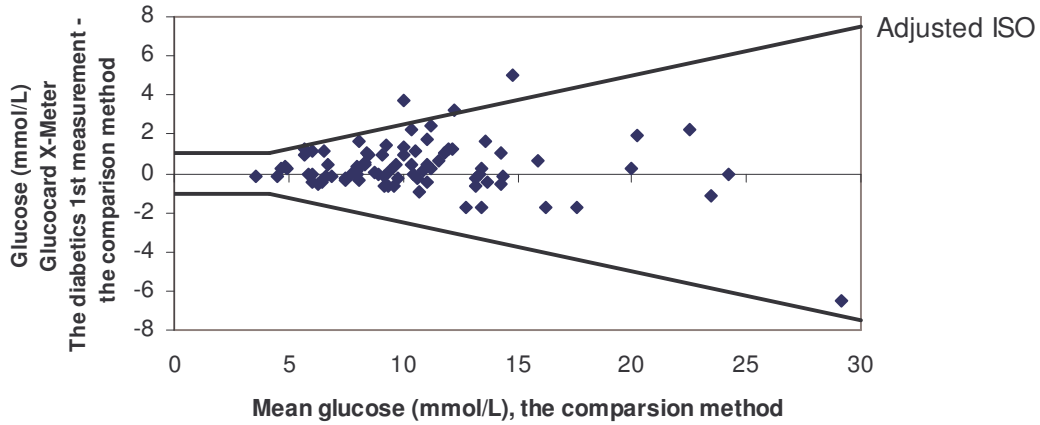

Figure 3. Accuracy. The diabetics' self-measurements at the final consultation. Three lots of test strips. The x-axis represents the mean value of the duplicate results at the comparison method. The y-axis shows the difference between the first measurement at Glucocard X-Meter and the mean value of the duplicate results at the comparison method, n = 82.

Table 13. Total error of Glucocard X-Meter. Percentage Glucocard X-Meter results within the limits.

Measurements done by	Consultation	Meter	n	Percentage of results			Shown in figure
				< ADA (< ± 10 %)	**< ISO** < ± 20 % and < ± 0,83 mmol/L at concentrations ≤ 4,2	**< "adjusted ISO"** < ± 25 % and < ± 1,0 mmol/L at concentrations ≤ 4,2	
Biomedical laboratory scientists	1st	A/C 1st measurement	40	75	98		
		B/D 1st measurement	40	73	98		
Biomedical laboratory scientists	2nd	A/C 1st measurement	83	69	100		
		B/D 1st measurement	83	69	98		2
Diabetics at NOKLUS	1st *	1st measurement	39	69	95	97	
	2nd **	1st measurement	82	73	91	96	3

* The control result for ID 241 at the first consultation was outside the limits of the control. The results of the measurements at this meter at the first consultation have been excluded.

** ID 33 had forgotten to bring the assigned Glucocard X-Meter to the final consultation and is missing.

Discussion

Figure 2 shows that most of the results obtained under standardised and optimal measuring conditions are within the ISO-limits. The summing up in table 13 shows that 98 % of the first measurements at the first consultation are within the ISO-limits. At the final consultation all the first measurements at meter A/C and 98 % of the first measurements at meter B/D are within the ISO-limits.

Figure 3 shows that most of the diabetics' first self-measurements at the final consultation are within the "adjusted ISO-goal". The summing up in table 13 shows that 97 % of the diabetics' first self-measurements at the first consultation are within the "adjusted ISO-goal". 96 % of the diabetics' first self-measurements at the final consultation are within the "adjusted ISO-goal".

Assessment of accuracy

The Glucocard X-Meter device fulfils the quality goal set in ISO 15197 when used under standardised and optimal conditions. The "adjusted ISO-goal" is met by the measurements of the diabetics.

6.3. Variation between three lots of test strips

The measurements at meter A/C were mainly performed with one lot of test strips. The measurements at meter B/D were performed with three different lots of test strips, in three different groups of diabetics. The three lots can not be compared with each other because the mean glucose concentrations in the three groups of diabetics are different. To measure the variation between the three lots, all the mean glucose results at Glucocard X-Meter obtained under standardised and optimal conditions at meter B/D were compared with the mean of the paired values from the comparison method (paired t-test). The results are shown in table 14.

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

	The comparison method	**Meter B/D Lot 05H2A16**	**The comparison method**	**Meter B/D Lot 05H2A17**	**The comparison method**	**Meter B/D Lot 05H2A18**
Mean glucose, mmol/L	9,4	9,3	11,1	10,5	10,6	10,2
Mean deviation from the comparison method, mmol/L (95 % CI)	-0,10 (-0,44 – 0,24)		-0,64 (-1,15 – (-0,13))		-0,40 (-0,66 – (-0,14))	
n	21		28		33	
Outliers	1		0		0	

Discussion

Lot 05H2A16 gives glucose results in agreement with the comparison method. Lot 05H2A17 and lot 05H2A18 give significantly lower values than the comparison method, but the results are still within the ISO-limits.

6.4. Effect of hematocrit

The package insert of Glucocard X-Sensor test strips states that normal and low glucose concentrations are not affected by hematocrit values. In a higher glucose range, the glucose result is lowered as the percentage of hematocrit increases and elevated as the hematocrit percentage decreases. To measure the effect of hematocrit at Glucocard X-Meter, a hematocrit sample was taken of the diabetics (voluntary) at the second consultation. Unfortunately there is no hematocrit result for one of the diabetics.

The investigation of the effect of hematocrit is based on the measurements at Glucocard X-Meter under standardised and optimal measuring conditions. The glucose concentration range in the samples was 4,5 – 29,2 mmol/L. The hematocrit range was 32 – 51 %.

The effect of hematocrit is shown in figure 4 and figure 5. The x-axis in the plots shows the hematocrit value in percentage and the y-axis shows the difference in glucose concentration between Glucocard X-Meter and the comparison method (Glucocard X-Meter – the comparison method) in mmol/L. Figure 4 shows samples with glucose concentration < 10 mmol/L, and figure 5 shows samples with glucose concentrations > 10 mmol/L. The trend-lines are shown in the figures. Raw data is shown in attachment 9.

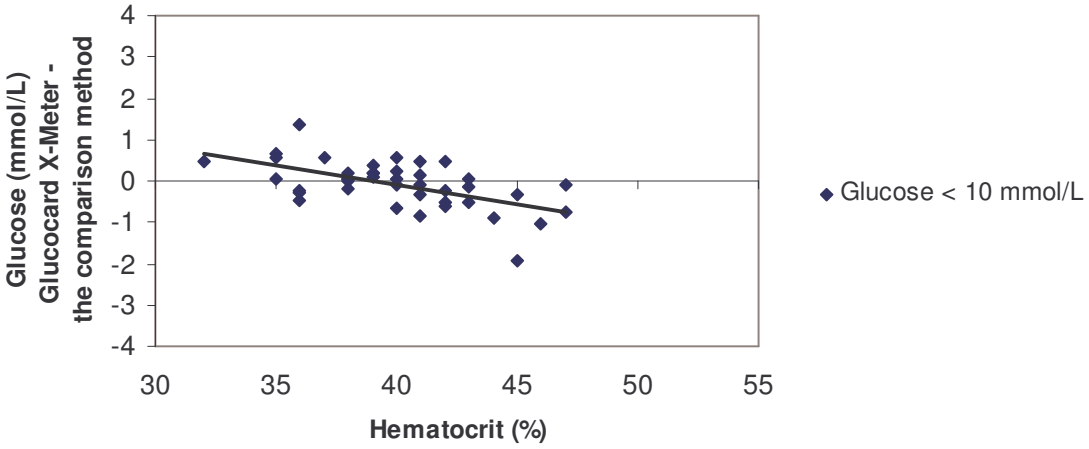

Figure 4. The effect of hematocrit at glucose measurements for glucose concentrations < 10 mmol/L at Glucocard X-Meter measured under standardised and optimal conditions. The x-axis shows the hematocrit value in %. The y-axis shows the difference in glucose concentration between Glucocard X-Meter and the comparison method (Glucocard X-Meter – the comparison method) in mmol/L, n= 41. ID 4 has no hematocrit result.

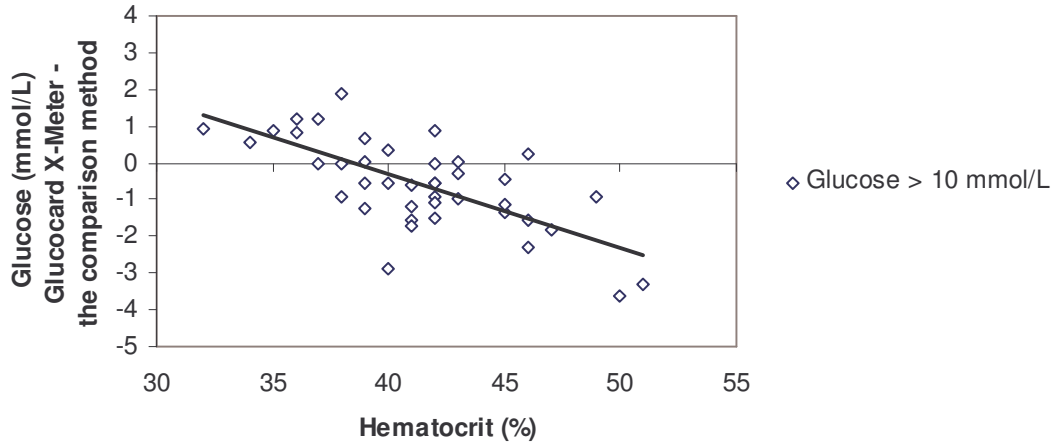

Figure 5. The effect of hematocrit at glucose measurements for glucose concentrations > 10 mmol/L at Glucocard X-Meter measured under standardised and optimal conditions. The x-axis shows the hematocrit value in %. The y-axis shows the difference in glucose concentration between Glucocard X-Meter and the comparison method (Glucocard X-Meter – the comparison method) in mmol/L, n=41

Discussion

The trend-line in figure 4 and in figure 5 shows that the glucose measurements at Glucocard X-Meter seem to be affected by hematocrit values. The two figures show that samples with glucose concentration > 10 mmol/L are affected by hematocrit in a higher degree than samples with glucose concentration < 10 mmol/L, but the tendency in the two figures is the same. High glucose values in combination with high hematocrit values give an under-estimated glucose result, while high glucose values in combination with low hematocrit values are over-estimated. Hematocrit outside the range 32 – 51 % has not been tested.

7. Practical points of view

Questionnaires

Each diabetic filled in a questionnaire about the user-friendliness and a questionnaire about the user manual of Glucocard X-Meter when they attended the final consultation (n = 83). Some diabetics needed assistance in filling in the questionnaires.

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

7.1. Evaluation of the user-friendliness of Glucocard X-Meter

The questionnaire about the user-friendliness had nine questions concerning Glucocard X-Meter. Table 15 summarizes six questions where the diabetics were asked to rank the answers on a scale from 1 to 6, where 1 is difficult and 6 is simple. The mean is 5,7 and 5,8 on the questions about inserting a strip into the meter and about filling the strip with blood, respectively. This indicates that the diabetics seemed satisfied with the use of the test strip. The diabetics also seemed satisfied with the use of the meter. The mean is between 5,4 and 5,9 on the questions about coding the meter, reading the figures in the display, recognizing the meters' sound signal and operating the meter, all in all.

Table 15. Glucocard X-Meter - Questions about the meter.

Questions about Glucocard X-Meter		Mean	Range	Not answered (% of total)	Total number
How will you rank the following questions on a scale from 1 to 6, where 1 is difficult and 6 is simple:	To code the meter	5,7	2 – 6	6	83
	To insert a strip into the meter	5,7	2 – 6	0	83
	To fill the strip with blood	5,8	3 – 6	0	83
	To read the figures in the display	5,9	3 – 6	0	83
	To recognize the meters' sound signal	5,6	1 – 6	0	83
	All in all, to operate the meter	5,4	2 - 6	0	83

The diabetics were asked if they had any positive and/or negative comments about Glucocard X-Meter.

Positive comments
63 diabetics reported one or more advantages with Glucocard X-Meter. The most often advantages reported are distinctly grouped as follows:

1. the meter has short measuring time (32)
2. the small size of the meter (21)
3. the meter/strip needs little blood sample volume (17)
4. easy to use (16)

Negative comments
34 diabetics reported one or more disadvantages with Glucocard X-Meter. The most often disadvantages reported are distinctly grouped as follows:

1. different comments about the test strips (for instance the test strips are too small, it is difficult to take them out from the box, the test strips has to be used singly) (17)
2. difficult to use/problems with the button cover and the buttons (10)
3. not satisfied with the memory function (4)

Table 16 shows the answers to the last question about Glucocard X-Meter. 7 % of the diabetics answered that they had technical problems with the meter during the testing period. Written comments indicate that these problems were not technical ones, but were ordinary error-symbols.

Table 16. Glucocard X-Meter – Questions about the meter.

Question about Glucocard X-Meter	Yes (%)	No (%)	Not answered (%)	Total number
Did you have any technical problems with the meter during the testing period?	7	89	4	83

7.2. Evaluation of the Glucocard X-Meter user manual

In the questionnaire about the user manual each diabetic was first asked whether he/she had used the manual. If not, they were to ignore the rest of the questions in the questionnaire.

Table 17 shows that 82 % of the diabetics had used the manual, i.e. 68 of the 83 diabetics that participated in the study. Most of them answered that they were satisfied with the description of how to perform a blood glucose measurement with the meter. Some of them thought the manual had essential shortcomings, but they did not mention what was missing. Most of the diabetics were quite satisfied with the user manual.

Table 17. Glucocard X-Meter – Questions about the user manual.

Questions about the user manual	Yes (%)	No (%)	Not answered (%)	Number
Have you been reading in the user manual?	82	17	1	83
If yes, did you read the entire user manual?	51	35	14	69
And/or did you consult the user manual when needed?	62	17	20	69
Are you satisfied with the description of how to perform a blood glucose measurement with the meter?	91	6	3	69
Do you think the user manual has essential shortcomings?	6	84	10	69
All in all, are you satisfied with the user manual?	93	4	3	69

7.3. The biomedical laboratory scientists' evaluation

The biomedical laboratory scientists thought Glucocard X-Meter was easy to use. Their positive comments were that the meter has a short measuring time, needs little blood sample volume and functioned without any technical problems during the evaluation period. They agreed with the diabetics that the buttons were too small and difficult to use and that the button cover fell off to easy. They also thought it was difficult to get only one test strip out of the box. One of the biomedical laboratory scientists commented that the meter ought not to give any answer if too little blood sample volume was applied. The biomedical laboratory scientists thought the user manual was too comprehensive and that the most essential information should be pointed out better.

8. References

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10. Burnett RW, "Accurate Estimation of Standard Deviations for Quantitive Methods Used in Clinical Chemistry". *Clinical Chemistry* 1975; **21** (13): 1935 – 1938.

9. Attachments

1. Serial numbers, Glucocard X-Meter blood glucose meters
2. Information letter to the diabetics (in Norwegian)
3. Raw data, internal quality control, Architect
4. Raw data, Glucocard X-Meter results under standardised and optimal conditions, meter A/C and meter B/D
5. Raw data, Glucocard X-Meter results, the diabetics measurements at NOKLUS
6. Raw data, Glucocard X-Meter results, the diabetics measurements at home
7. Raw data, internal quality control, Glucocard X-Meter
8. Raw data, Architect results, diabetic blood samples
9. Raw data, hematocrit
10. Questionnaire, user-friendliness (in Norwegian)
11. Questionnaire, user manual (in Norwegian)
12. SKUP evaluations
13. Information letter from Tamro MedLab

Attachments with raw data are included only in the report to Tamro MedLab.

Attachment 1

Serial numbers, Glucocard X-Meter instruments used by the diabetics

ID	Serial number
3	J 517583
4	J 517595
5	J 517542
9	J 517528
10	J 517503
17	J 517557
18	J 517523
32	J 517576
33	J 517561
36	J 517541
37	J 517537
43	J 517525
46	J 517506
51	J 517585
53	J 517509
55	J 517511
56	J 517534
57	J 517521
62	J 517516
63	J 517518
65	J 517535
72	J 517540
76	J 517563
79	J 517584
84	J 517505
86	J 517578
88	J 517519
89	J 517573
91	J 517565
95	J 517588
98	J 517554
103	J 517526
104	J 517545
105	J 517531
107	J 517510
109	J 517569
110	J 517529
111	J 517564
120	J 517507
122	J 517536
126	J 517532
127	J 517549

ID	Serial number
128	J 517538
129	J 517562
131	J 517596
132	J 517587
135	J 517552
137	J 517574
140	J 517575
146	J 517517
148	J 517566
149	J 517582
152	J 517512
153	J 517559
157	J 517555
161	J 517589
162	J 517553
169	J 517514
174	J 517572
177	J 517551
180	J 517533
194	J 517530
195	J 517544
196	J 517546
200	J 517579
201	J 517504
209	J 517598
214	J 517515
220	J 517508
221	J 517522
222	J 517571
223	J 517560
227	J 517524
231	J 517567
233	J 517556
234	J 517513
237	J 517586
241	J 517539
242	J 517568
245	J 517502
246	J 517501
247	J 517577
265	J 517597

NORSK KVALITETSFORBEDRING AV LABORATORIEVIRKSOMHET UTENFOR SYKEHUS

NOKLUS

«Navn» flettes inn
«Adresse» flettes inn
«Postadresse» flettes inn

«ID-nr.» flettes inn

Desember 2005

Utprøving av blodsukkerapparat

Du har fått utlevert en eske med:

- 1 Glucocard X-Meter blodsukkerapparat i etui
- 2 pakker Glucocard X-Sensor teststrimler for glukose (50 stk.)
- 1 Glucoject Plus 2 prøvetakingspenn
- 50 lansetter
- Brukerveiledning

Du skal bruke utprøvingsapparatet hjemme i en periode på ca. 3 uker. I denne prøveperioden skal du bruke dette apparatet **i tillegg** til ditt eget apparat. Det betyr at du skal utføre 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:

1. og 2. uke:

De to første ukene skal benyttes til å bli kjent med apparatet. I løpet av disse to ukene skal du bruke ca. 25 strimler til å måle ditt eget blodsukker med utprøvingsapparatet.

Du kan selv velge når på dagen du vil gjøre disse målingene (du trenger ikke å 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 Glucoject Plus 2 prøvetakingspenn.

3. uke:

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

«ID-nr.» flettes inn
«Lot-num. teststrimler» flettes inn
«Serie-nummer apparat» flettes inn

Dato	***Glucocard X-meter*** **Svar 1 (mmol/L)**	***Glucocard X-meter*** **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 Glucoject Plus 2 prøvetakingspenn til prøvetakingen?

☐Ja ☐Nei ☐Noen ganger

Av de 50 strimlene du fikk sammen med apparatet, skal du nå ha ca. 15 strimler igjen. Du må spare fem av strimlene til målingene du skal gjøre når du kommer hit til laboratoriet for den avsluttende utprøvingen. Til den **avsluttende utprøvingen skal du ta med Glucocard X-Meter, resten av strimlene og** Glucoject Plus 2 prøvetakingspenn med lansetter. Du skal utføre egne målinger med utprøvingsapparatet. I tillegg vil bioingeniøren stikke deg to ganger i fingeren og til slutt ta en blodprøve fra armen. Du vil også bli bedt om å svare på noen spørsmål mht. apparatets brukervennlighet og om brukerveiledningen. Det hele vil ta ca. ½ time.

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

Signe Røynås, Bente Knudsen eller Margarita Milán på tlf. 38073425 eller 99226232
mandag til fredag fra kl. 08-15.30

Lykke til!

Med vennlig hilsen

Sverre Sandberg
Prosjektansvarlig (sign.)

Bente Knudsen og Margarita Milán
Bioingeniør (sign.)

ID-nummer (diabetiker): _____

Glucocard X-Meter

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 kontrollere riktig kode (kalibrering) på apparatet

Vanskelig *Enkelt*

1	2	3	4	5	6
☐	☐	☐	☐	☐	☐

2. Å sette strimmel inn i apparatet

Vanskelig *Enkelt*

1	2	3	4	5	6
☐	☐	☐	☐	☐	☐

3. Å fylle blod i strimmelen

Vanskelig *Enkelt*

1	2	3	4	5	6
☐	☐	☐	☐	☐	☐

4. Å lese tallene i displayet

Vanskelig *Enkelt*

1	2	3	4	5	6
☐	☐	☐	☐	☐	☐

5. Å oppfatte lydsignal fra apparatet

Vanskelig *Enkelt*

1	2	3	4	5	6
☐	☐	☐	☐	☐	☐

6. Å betjene apparatet, totalt sett

Vanskelig *Enkelt*

1	2	3	4	5	6
☐	☐	☐	☐	☐	☐

Snu arket

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 Glucocard X-Meter?

- _____
- _____
- _____

9. Synes du det er noen ulemper ved Glucocard X-Meter?

- _____
- _____
- _____

Evt. andre kommentarer:_____

_____

_____

_____

ID-nummer (diabetiker):_____

Glucocard X-Meter

Spørreskjema om brukerveiledning til apparatet

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

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

Hvis du svarer ja:

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

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

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

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

   _____

   _____

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

   Hvis ja, kan du beskrive hva som mangler: _____

   _____

   _____

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

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

   _____

   _____

   Evt. andre kommentarer:_____

   _____

   _____

Evaluations under the direction of SKUP

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

Evaluations performed in 2004 - 2006

Evaluation no.	Component	Instrument/testkit	Producer
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/2006/48	Glucose[1]	Accu-Chek Sensor	Roche Diagnostic
SKUP/2006/47	Hematology	Chempaq XBC	Chempaq
SKUP/2005/46*	PT-INR		
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/2005/41*	HbA1c		
SKUP/2005/40	Glucose[1]	OneTouch GlucoTouch	LifeScan, Johnson & Johnson
SKUP/2005/39	Glucose[1]	OneTouch Ultra	LifeScan, Johnson & Johnson
SKUP/2004/38*	Glucose[1]	GlucoSure Plus	Apex Biotechnology Corp.
SKUP/2004/37*	u-hCG	Quick response u-hCG	Quidel Corporation
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		
SKUP/2004/30	Glucose[1]	Ascensia Contour	Bayer Healthcare
SKUP/2004/29	Hemoglobin	Hemo_Control	EKF-diagnostic

*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 diabetic patients.

Evaluations performed in 2001 - 2003

Evaluation no.	Component	Instrument/testkit	Producer
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		
SKUP/2003/25*	HbA1c		
SKUP/2003/24*	Strep A	OSOM Strep A test	GenZyme, General Diag.
SKUP/2002/23*	Hematology 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	u-albumin	HemoCue	HemoCue AB
SKUP/2001/17	Hemoglobin	Biotest Hb	Biotest Medizin-technik GmbH
SKUP/2001/16*	Urin teststrip	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	Hematology	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 diabetic patients.

Grey aera – The instrument is not in the market anymore.

Göteborg, 20 March 2006

Information from Tamro MedLab

Glucocard X-METER can not start with insufficient blood sample. After the SKUP test was conducted, X-METER has been technically improved and now displays an error message if too little blood is applied.

Tamro MedLab has noted that the recommendation in the users manual regarding disinfecting the lancing device and the finger might not be applicable to the Nordic countries as it is a practise not used in ordinary life by patients. As a result, Tamro MedLab will during the spring of 2006 revise the text in the manual together with Arkray.
Taking a blood sample from a clean finger gives accurate result and there is no need to use disinfectant.

Even if the user was to loose the lid of the buttons on the meter, there is no risk of malfunction as the user must actively hold in the buttons to change any settings etc.

Tamro MedLab