Mendor Discreet

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

Report from the evaluation SKUP/2012/95

The evaluation was organised by SKUP

at the request of Mendor Oy in Finland

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For more details about SKUP, see attachment 1.

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Attachments with raw data are included only in the copy to Mendor Oy.

1. Summary

Background
Mendor Discreet is a new blood glucose meter produced by Mendor Oy. The system is an "all-in-one" blood glucose meter with integrated lancing device and 25 test strips in a cartridge. The device is operated by pulling two covers up and down making access to the lancet and test strip. The evaluation was carried out at the request of Mendor Oy during the first months of 2012.

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

Materials and methods
A total of 108 diabetes patients took part in the evaluation; 85 completed. The participants were randomly divided into two groups. The "training group" received personal training in how to use the device, and the "mail group" received the device and instructions by mail. Both groups used the device for approximately two weeks at home, before they attended for an end-meeting.

Results
- The quality goal for imprecision (CV <5%) was fulfilled for all results except the high glucose results as achieved by the mail group. The repeatability CV was between 2,8 and 4,1% as obtained by the biomedical laboratory scientists and between 2,5 and 5,2% as achieved by the diabetes patients.
- The glucose measurements on Mendor Discreet gave slightly lower glucose results than the comparison method. The deviation from the comparison method was between (-0,1) and (-0,4) mmol/L. The deviation is small, but statistically significant.
- The accuracy quality goal in ISO 15197:2003 (deviation <20%) was fulfilled. 100% of the results obtained by the biomedical laboratory scientists and 99% of the results obtained by the diabetes patients were inside the limits.
- The three lots of test strips used in the evaluation gave corresponding glucose results.
- Glucose measurements on Mendor Discreet were marginally, but statistically significant, affected by haematocrit (range 31 – 48%).
- The response from the users about the user-friendliness was mixed. A great number of participants had some kind of difficulties with handling the device, reporting various types of problems. Approximately 2/3 of the participants did not find the meter easy to operate. The rest of the participants were principally positive to the device but their answers differed substantially. A total of 23 participants withdrew from the evaluation for various reasons.
- The fraction of technical errors was <2%, and the quality goal for this was fulfilled.

Conclusion
The precision and the accuracy were good. The accuracy quality goal set in ISO 15197:2003 was fulfilled. The response from the users about the user-friendliness was mixed.

Comments from Mendor Oy
A letter with comments from Mendor Oy is attached to the report.

2. Abbreviations

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

3. Quality goals

3.1. Analytical quality goals

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

Precision

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

Accuracy

The ISO-standard 15197:2003, In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus [4], is an international protocol for evaluating meters designed for glucose monitoring, and gives the following minimum acceptable accuracy requirement:

Ninety-five percent (95%) of the individual glucose results shall fall within ±0,83 mmol/L of the results of the comparison method at glucose concentrations <4,2 mmol/L and within ±20% at glucose concentrations ≥4,2 mmol/L.

This is a quality goal for measurements made by trained laboratory staff. In Norway the results achieved by the diabetes patients have been discussed towards a *modified* goal suggested by NOKLUS:

Ninety-five percent (95%) of the individual glucose results shall fall within ±1,0 mmol/L of the results of the comparison method at glucose concentrations <4,2 mmol/L and within ±25% at glucose concentrations ≥4,2 mmol/L.

Recent evaluations performed by SKUP [5,6], show that the diabetes patients also can achieve the quality goal set by ISO 15197:2003.

Quality goals in Denmark

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

Other analytical quality limits

The number of results within fixed quality limits (without cut offs) of ±15% and ±10% will be reported, but not further assessed in this report.

3.2. Evaluation of user-friendliness

The evaluation of user-friendliness is carried out by asking the diabetes patients (the intended users) to fill in a questionnaire. The first table in the questionnaire covers the user guide; the second deals with the user-friendliness of Mendor Discreet. Two tables concerning assessment of time factors and assessment of quality control possibilities are filled in by SKUP. See section 5.5. It is a wish from the National Danish Committee for General Practice Laboratory Testing, that the percentage of "tests wasted" caused by technical errors should not exceed 2%.

3.3. SKUP´s quality goals in this evaluation

SKUP has decided to assess the results from the evaluation of Mendor Discreet against the following quality goals:

Repeatability CV: <5%
Accuracy according to ISO 15197:2003
Accuracy according to goal modified by NOKLUS
Fraction of technical errors: <2%

3.4. Principles for the assessments

To qualify for an overall good assessment in a SKUP evaluation, the measuring system must show satisfactory analytical quality as well as satisfactory user-friendliness.

Assessment of the analytical quality
The analytical results are assessed according to the quality goals set for the evaluation. The principles for the assessment of precision, and the distinction between rating the results as good or poor are shown in table 1.

Table 1. The rating of precision

Good	The achieved result is within the quality goal
Inconclusive	The achieved result is outside the quality goal, but the lower confidence interval (CI) limit is within. Data is inconclusive on fulfilling the quality goal
Poor	The lower confidence interval of the achieved result is outside the quality goal

The accuracy is illustrated in a difference-plot. The number of results within the quality goal limits is counted.

Assessment of the user-friendliness
The user-friendliness is assessed according to the answers and comments given in the questionnaire (see section 5.5.). For each question, the user must choose between three given ratings, as for instance satisfactory, intermediate or unsatisfactory. The response from the users is reviewed and summed up. To achieve the overall rating "satisfactory", the tested equipment must reach the total rating of "satisfactory" in all four sub-areas of characteristics mentioned in section 5.5.

The biomedical laboratory scientists (BLSs) register the fraction of error codes and technical errors during the evaluation.

4. Materials and methods

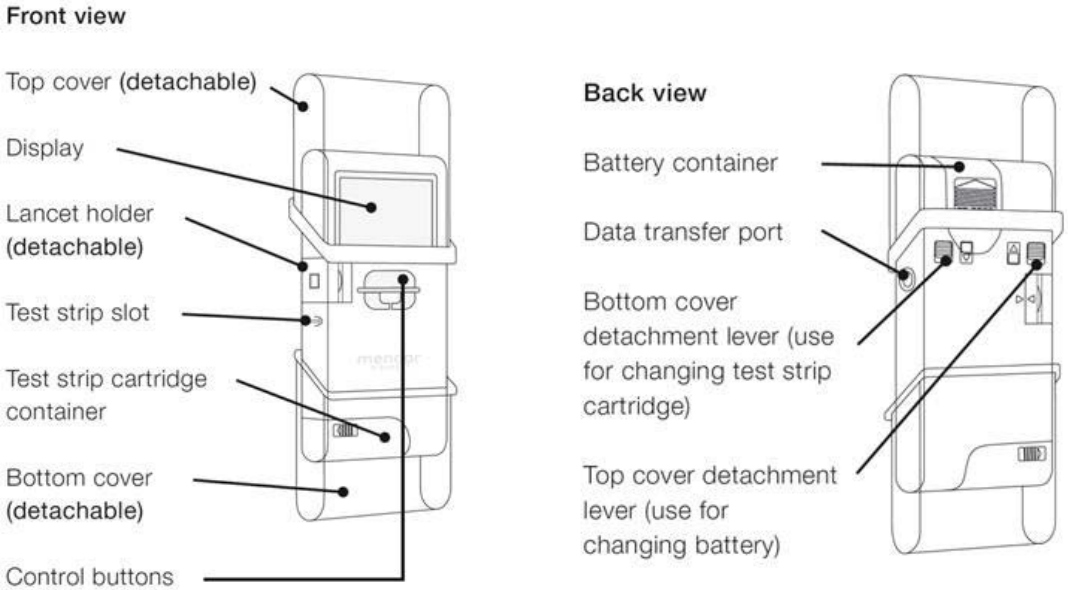
4.1. Definition of the measurand

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

4.2. The evaluated measurement system; Mendor Discreet

The Mendor Discreet system is an “all-in-one” blood glucose meter with integrated lancing device and 25 test strips in a cartridge. The system is designed for self-monitoring of blood glucose of diabetes patients and for personal use only. The glucose measurement is based on biosensor technology with the enzyme glucoseoxidase and cofactor flavin-adenine dinucleotide (FAD). Mendor Discreet reports plasma glucose values.

The system is automatically calibrated when a test strip cartridge is inserted.
The device is operated by pulling two covers up and down making access to the lancet and test strip. When not in use the covers are closed. The covers can be removed by sliding the cover release latches on the back of the meter and then pulling the covers. The upper cover has to be removed when changing the battery. The lower cover must be removed when changing the test strip cartridge. A test strip is “loaded” by opening the meter and pulling the lower cover downwards until a click is heard and the test strip appears. The number of remaining test strips is displayed. The lancet device is loaded by pulling the lower cover further down. A new lancet needle must be used for every measurement. To change the lancet needle the upper cover must be in its highest position and the lower cover must be pulled approximately 5 mm downwards or removed. The lancet needle is placed in the lancet holder.



A summary of technical data from the manufacturer is shown in table 2. For name of the manufacturer, the suppliers in the Scandinavian countries and more technical data about Mendor Discreet, see attachment 2. For product information, see attachment 3.

Table 2. Technical data from the manufacturer

Technical data for Mendor Discreet	
Sample material	Capillary blood
Sample volume	At least 0,5 µL
Measuring time	5 seconds
Measuring range	1,1 – 33,3 mmol/L
Tolerated haematocrit range	20 – 60%
Memory capacity	250 results
Electrical power supply	One 3-volt lithium battery (disposable, type CR2032)

4.3. The selected comparison method

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

4.3.1. The selected comparison method in this evaluation

The selected comparison method in this evaluation is the routine method for quantitative determination of glucose in human serum and plasma (e.g. lithium heparin) in the Laboratory at Haraldsplass Diaconal Hospital (HDH) in Bergen. The method is a photometric hexokinase method. The method is implemented on Architect *ci*8200 System from Abbott Laboratories. The Laboratory can document good analytical quality of the method through participation in an external analytical quality assessment program.

4.3.2. Verification of the analytical quality of the comparison method

Precision

The repeatability of the comparison method was estimated from duplicate measurements of capillary patient samples.

Trueness

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

Internal quality control

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

External quality control

Human serum controls, produced by NOKLUS, with glucose concentrations at two levels were analysed. These controls have target values determined with an isotope-dilution gas chromatography/mass spectrometry method in a Reference laboratory in Belgium [9]. The controls are used in NOKLUS's External Quality Assessment (EQA) program.

4.4. The evaluation

4.4.1. Planning of the evaluation

Background for the evaluation
Mendor Discreet is a new blood glucose meter produced by Mendor Oy. The Mendor Discreet glucose monitoring system has not been launched onto the Scandinavian market yet.

Inquiry about an evaluation
Rolf Erbismann, Mendor Oy Finland, applied to SKUP in June 2011 for an evaluation of Mendor Discreet meter with Mendor Discreet test strips. SKUP accepted to carry out this evaluation.

Contract, protocol and arrangements
In November 2011 Mendor Oy and SKUP signed the contract for the evaluation. The protocol for the evaluation was approved in January 2012. The laboratory at HDH agreed to analyse the samples for the comparison method.

Preparations and training program
Preparations for the evaluation started in November 2011. The BLSs Karina Hill Bjerkestrand and Randi Rekkebo, NOKLUS, were hired to do the practical work with the evaluation. They were educated in the evaluation procedures by SKUP. In February 2012, Maria Leminen from Mendor Oy demonstrated Mendor Discreet for the BLSs. Training for approximately three hours was given.

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

4.4.2. Evaluation sites and persons involved

Persons responsible for the evaluation are shown in table 3.

Table 3. Persons responsible for various parts of the evaluation

Name	Title	Place	Responsibility
Rolf Erbismann	Sales manager	Mendor Oy	Ordered the evaluation
Christian Lardot	Marketing support manager	Mendor Oy	Contact person
Grete Monsen	BLS Organisation Secretary	SKUP/NOKLUS	Responsible for the evaluation
Marianne Risa	BLS	SKUP/NOKLUS	Preparations for the evaluation Statistical calculations Author of the report
Randi Rekkebo	BLS	NOKLUS, Levanger Hospital	Practical work with the evaluation
Karina Hill Bjerkestrand	BLS	NOKLUS, St. Olavs Hospital	Practical work with the evaluation
Grethe Kalleklev	BLS	Laboratory at HDH	Practical work with the comparison method

4.4.3. The evaluation model

The SKUP evaluation

SKUP evaluations for quantitative methods are based upon the fundamental guidelines in the book "*Evaluation of analytical instruments. A guide particularly designed for evaluations of instruments in primary health care*" [10]. In principle, an evaluation of a self-monitoring blood glucose device follows the guidelines in the book, but the evaluation in primary health care is replaced by a user-evaluation conducted among diabetes patients, based on a model worked out by the NOKLUS-project "*Diabetes-Self-measurements*" [11].

The model for the evaluation of Mendor Discreet

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

Diabetes patients performed the other part of the evaluation in order to determine the analytical quality of Mendor Discreet by the users. The diabetes patients were randomly divided into two groups. One group received personal training in how to use the device, hereafter called the "training group". The other group received the device and instructions by mail, hereafter called the "mail group". Three lots of test strips were distributed evenly between the participants in the two groups (random distribution). The model for the evaluation among diabetes patients is shown in figure 1.

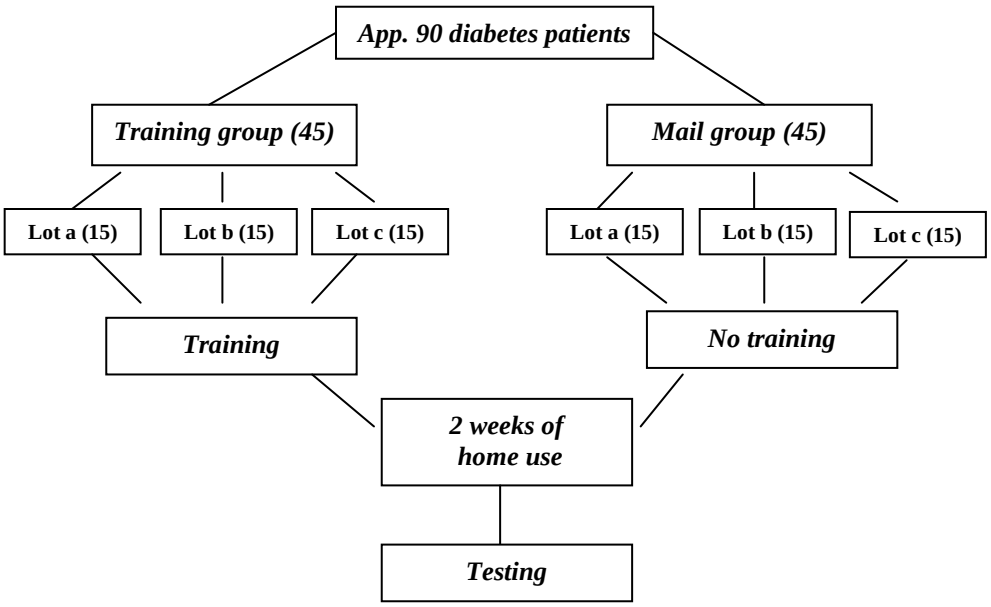


Figure 1. The model for the evaluation among the intended users

The aim of the evaluation
The evaluation of Mendor Discreet comprises the following studies:

- An examination of the analytical quality under standardised and optimal conditions, performed by two BLSs in a hospital environment
- An examination of the analytical quality among approximately 90 diabetes patients
- A comparison of the analytical quality among diabetes patients with and without a training program
- An examination of the variation between three lots of test strips
- An examination to see if haematocrit interferes with the measurements
- An evaluation of the user-friendliness of Mendor Discreet and the user guide

Test strip lots
The evaluation was carried out using three different lot numbers of test strip from separated and time-spread productions.

4.4.4. Recruitment and selection of the diabetes patients

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

Selection
The participants were selected at random, but with the criterion to get variety in the group according to sex, diabetes type, age and how often the participants performed blood glucose measurements. For comments regarding the selection, see section 5.1.

4.4.5. The evaluation procedure under standardised and optimal conditions

The two BLSs each used two Mendor Discreet blood glucose meters for the evaluation. On meter A, one lot of test strips was used for all the measurements. Meter B was used for the same three lots as distributed among the diabetes patients. All possibilities for disturbance of, and interference with the measurements were tried to be kept at a minimum.

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

Blood sampling
All samples for Mendor Discreet, as well as the glucose samples for the comparison method, were collected from finger capillaries. The blood sample for the duplicate measurements was mainly collected from the same finger prick. The BLS wiped off the first drop of blood before the first measurement and between the two sets of duplicates (meter A and B). In order to reduce the possible change in the glucose concentration during the sampling sequence, the sampling time ought not to exceed 10 minutes.

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

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

Comparison method results
Two capillary samples were collected of each diabetes patient for measurement on the comparison method. The second sample was analysed in duplicate. The duplicate results were used for calculations of imprecision. The mean value of the first sample result and the two results of the second sample is referred to as the mean result of the comparison method. The mean result of the comparison method is an estimate of the true glucose value in the samples, and is used for the assessment of trueness and accuracy of Mendor Discreet, and for the assessment of bias with three lots of Mendor Discreet test strips and for the effect of haematocrit.

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

Measurement of haematocrit
Haematocrit may influence on blood glucose measurements. A venous sample was collected from each diabetes patient (voluntarily) and the haemotocrit was measured within six hours with one of the routine methods; Sysmex XE 2100 at St. Olavs Hospital or Sysmex XT-2000i at Levanger Hospital.

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

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

4.4.6. Evaluation among the intended users

The training group

The diabetes patients who participated in the training programme were invited in groups of between two and nine participants. They received the Mendor Discreet meter along with test strip cartridges, lancets, user manual and an information letter with explanations regarding what to do with the Mendor Discreet device when practising at home. Karina Hill Bjerkestrand and Randi Rekkebo, NOKLUS, were in charge of the training of the diabetes patients. The training programme covered a simple demonstration of how to use Mendor Discreet. The training lasted for approximately one hour, and reflects the training that is usually given the users of this blood glucose meter. The training programme was standardised to make sure that all the diabetes patients received the same instruction. Mendor approved the programme.

The mail group

The diabetes patients in the "mail group" received the Mendor Discreet meter by mail, along with test strip cartridges, lancets, user manual and an information letter with explanations regarding what to do with the Mendor Discreet device during the period at home. No training was given.

Use of Mendor Discreet at home

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

Internal analytical quality control

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

The evaluation end-meeting

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

5. Results and discussion

Statistical expressions and calculations used by SKUP are shown in attachment 4.

5.1. Number of samples

A total of 108 diabetes patients signed up for the evaluation. 85 of them completed the evaluation; 40 diabetes patients in the "training group" and 45 in the "mail group". The difference between the number of enrolled participants (108) and the number of participants at the end of the study (85) is explained in section 5.1.1. A venous sample for haematocrit was collected from 82 of the 85 participants.

Characteristics of the diabetes patients that completed the evaluation
The Mendor Discreet glucose meter was tested in use by 46 men and 39 women with diabetes. The average age was 55 years (range 19 – 74). A total of 38 participants had Type1 diabetes and 47 had Type2 diabetes. The group included diabetes patients from a range of self-monitoring frequencies, i.e. diabetes patients who perform self-monitoring often and those who perform self-monitoring less frequently.

Comments to the selection of participants
The recruitment and selection of participants was performed as described in the protocol, approved by Mendor. In retrospect, Mendor has expressed that the target group for this device could have been better defined. According to the manufacturer, the device is most suitable for users measuring their blood glucose often, specially the group that measures many times a day.

5.1.1. Feedback and problems

In total 23 participants withdrew from the evaluation, stating various reasons for this. Seven of them clearly expressed that they found the meter difficult to use. Six participants withdrew giving personal reasons and some participants did not explain the reason for withdrawal. The drop-outs occurred in the mail group as well as in the training group. Attempts were made to try to get the withdrawn participants to finalize the evaluation. Several participants were guided and assisted on the phone, until they were able to handle the meter properly.

Because of feedback given from the first group of participants in the mail group, it was decided to send a letter to the rest of the participants in the mail group, trying to motivate them to read the user manual carefully, and encourage them to contact the BLSs for help or with any question they might have about handling the device.

The BLSs got phone calls from approximately 35 participants during the evaluation. The phone calls came from the mail group as well as the training group, and some of the participants phoned more than once. Some of them needed more detailed explanation to get started, some of them did not manage to change the test strip cartridge and three participants did not get the device to work. Some participants called just to inform the BLS that they withdrew from the evaluation for various reasons. The issues that arose were approximately the same for the two groups of participants. Because participants in both groups got extra assistance by phone, the distinction between the training group and the mail group was reduced and more vague in this evaluation.

As the total number of participants in the evaluation decreased due to withdrawal, new diabetes patients were recruited on the way. This explains the difference between the number of enrolled participants (108) and the number of participants at the end of the study (85).

5.1.2. The glucose concentration stability during sampling

Out of 85 pairs of results measured with the comparison method, two showed a difference >10%, which means that these two participants had unstable glucose concentration during the sampling sequence time. This applied to ID 40 and ID 47.

5.1.3. Excluded or missing results

The following results are missing or excluded:

- ID 40 and ID 47 had a deviation of >10% between the first and second sample for the comparison method. All results from ID 40 and ID 47 were removed before the assessment of accuracy and haematocrit influence, and before the calculation of trueness and lot variation
- ID 65, ID 94 and ID 98 were classified as outliers according to Burnett's model in the calculation of repeatability of the comparison method. These results were removed before the assessment of accuracy and haematocrit influence, and before the calculation of trueness and lot variation
- ID 38 was classified as an outlier according to Burnett's model in the calculation of repeatability on meter B and was excluded from the calculation of lot variation.

5.1.4. Failed measurements

The BLSs performed 424 measurements on Mendor Discreet. Three of these measurements failed; two with error code Er4 and one with error code Er2. The diabetes patients performed 170 measurements (2 test strips x 85 patients). One of these measurements failed with error code Er4.
Total fraction of technical errors was: $(4 / 594) \times 100 = 0{,}7\%$

Comments

Error code description from the user guide:

Er2 The blood sample was applied before the test strip icon appeared.

Er4 The blood sample did not fill the confirmation window of the test strip during measurement because of abnormally high viscosity or insufficient volume.

Discussion

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

5.2. Analytical quality of the selected comparison method

5.2.1. Internal quality control

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

5.2.2. The precision of the comparison method

Repeatability

To achieve a measure for the repeatability, one capillary sample collected of each diabetes patient was analysed in duplicate. The formula used for the calculation of repeatability (formula 1) is shown in attachment 4. The repeatability of the comparison method is shown in table 4. Raw data is shown in attachment 5.

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

Glucose level Comparison method (mmol/L)	n	Excluded results	Comparison method, mean (mmol/L)	CV% (95% CI)
<7	30	2*	5,6	1,1 (0,9 – 1,5)
7 – 10	23	0	8,4	0,6 (0,5 – 0,9)
≥10	32	1**	13,6	1,0 (0,8 – 1,3)

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

* Two statistical outliers (ID 65 and ID 94) according to Burnett's model

** One statistical outliers (ID 98) according to Burnett's model

Discussion

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

5.2.3. The trueness of the comparison method

In order to demonstrate the trueness of the comparison method calibration, the SRM 965b from NIST were analysed. The agreement between the comparison method and the NIST-standards is shown in table 5.

Table 5. Standard Reference Material (SRM 965b) measured on the comparison method

SRM 965b	Date	Certified glucose concentration, mmol/L (uncertainty)	n	Mean value glucose (mmol/L)	% deviation from target value
Level 1	22.05.12	1,836 (1,809 — 1,863)	5	1,85	+0,9
	23.05.12		5	1,86	+1,2
	Total		10	1,86	+1,0
Level 2	22.05.12	4,194 (4,135 - 4,253)	5	4,32	+3,1
	23.05.12		5	4,35	+3,8
	Total		10	4,34	+3,5
Level 3	22.05.12	6,575 (6,481 — 6,669)	5	6,64	+1,0
	23.05.12		5	6,69	+1,8
	Total		10	6,67	+1,4
Level 4	22.05.12	16,35 (16,15 — 16,55)	5	16,73	+2,3
	23.05.12		5	16,77	+2,6
	Total		10	16,75	+2,5

Comments

Table 5 shows that the glucose results of the NIST-standards on level 2, 3 and 4 were above the upper uncertainty limits. All results from Architect were therefore adjusted according to the certified NIST-targets. The adjustment was carried out by means of inverse calibration [12, 13] by the following regression equation: **y = 0,9755x + 0,0175**.
Further on in the report, whenever any result from the comparison method is presented, the result has already been adjusted according to this equation.

To verify the trueness of the adjusted comparison method results, human serum controls produced by NOKLUS, were analysed. The agreement between the comparison method and target values from the Reference laboratory in Belgium is shown in table 6.

Table 6. Trueness of the comparison method

Control	Date	Target value glucose (mmol/L)	n	Mean value glucose (mmol/L)	% deviation from target value
NOKLUS 1	22.05.12	5,71	5	5,77	1,0
	23.05.12		5	5,77	1,0
	Total		10	5,77	1,0
NOKLUS 2	22.05.12	11,94	4	11,86	-0,6
	24.05.12		5	11,90	-0,3
	Total		9	11,88	-0,5

Discussion

The trueness of the comparison method was good.

5.3. Analytical quality of Mendor Discreet

5.3.1. Internal quality control

The Mendor Discreet meters used by the diabetes patients, were checked with the manufacturer's control solution by the BLS at the end-meeting. The reproducibility CV was approximately 4,5% (n=84), and all results were within the control range. The four Mendor Discreet meters used by the BLSs, were checked with control solution every day they were used. The reproducibility CV was approximately 3% (n=22), and all results were within the control range. Raw data is shown in attachment 6.

5.3.2. Comparison of the 1st and 2nd measurement

Two capillary samples were collected of each diabetes patient for measurements on meter A and meter B at the end-meeting. In addition, the diabetes patients took two capillary samples for measurements on their assigned meter at the end-meeting. For the calculation of imprecision, all results have been checked to meet the assumption for using formula 1 in attachment 4. No systematic difference was pointed out between the paired measurements on meter A, meter B, or the diabetes patients' meter (data not shown).

5.3.3. The precision of Mendor Discreet

Repeatability under standardised and optimal conditions

The repeatability obtained by the BLSs with capillary blood samples is shown in table 7. The results are sorted and divided into three glucose levels according to the first measurement on Mendor Discreet. Raw data is shown in attachment 7.

Table 7. Repeatability, Mendor Discreet. Results achieved by the BLSs

Mendor Discreet	Glucose level (mmol/L)	n	Excluded results	Mean value glucose (mmol/L)	CV% (95% CI)
Meter A	<7	34	0	5,5	3,1 (2,5 – 4,1)
Meter B	<7	34	0	5,5	3,8 (3,1 – 5,0)
Meter A	7 – 10	21	0	8,5	2,8 (2,2 – 4,1)
Meter B	7 – 10	19	1*	8,3	3,6 (2,7 – 5,4)
Meter A	≥10	30	0	13,1	4,1 (3,3 – 5,5)
Meter B	≥10	32	0	13,4	3,9 (3,1 – 5,2)

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

*One statistical outlier (ID 38) according to Burnett's model

Comments

There was no error message related to the outlier (ID 38) at glucose level 7 – 10 mmol/L, meter B.

Repeatability obtained by the diabetes patients
The repeatability obtained by the diabetes patients with capillary blood samples is shown in table 8. The results are sorted into "training group" and "mail group", and divided into three glucose levels according to the first measurement on Mendor Discreet. Raw data is shown in attachment 8.

Table 8. Repeatability, Mendor Discreet. Results achieved by the diabetes patients

Group	Glucose level (mmol/L)	n	Excluded results	Mean value glucose (mmol/L)	CV% (95% CI)
Training group	<7	14	0	5,6	4,3 (3,1 – 6,9)
Mail group	<7	14	0	5,4	3,5 (2,6 – 5,7)
Training group	7 – 10	11	0	8,4	2,5 (1,8 – 4,5)
Mail group	7 – 10	13	0	8,2	3,7 (2,6 – 6,0)
Training group	≥10	15	0	13,3	3,3 (2,4 – 5,2)
Mail group	≥10	18	0	13,6	5,2 (3,9 – 7,7)

Discussion, repeatability
The precision was good. The repeatability CV obtained under standardised and optimal conditions was between 2,8 and 4,1%. The repeatability CV obtained at NOKLUS when the measurements were performed by the diabetes patients was between 2,5 and 5,2%. The recommended quality goal for precision was fulfilled for all results except the high glucose results achieved by the mail group. The CV for this group was 5,2% with a 95% CI from 3,9 to 7,7%.

As a whole, all the diabetes patients performed the measurements with approximately the same precision, regardless of participating in the training group or mail group. According to the evaluation model, the mail group should learn how to handle the device on their own. In this evaluation, many participants in the mail group, as well as in the training group, needed extra assistance. The distinction between the two groups was thereby vague.

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

5.3.4. The trueness of Mendor Discreet

The mean deviation of Mendor Discreet from the comparison method (bias) was calculated from the results achieved by the BLSs with one lot of test strips on meter A. The results are sorted and divided into three glucose levels according to the mean results on the comparison method. The trueness of Mendor Discreet is shown in table 9.

Table 9. Trueness of Mendor Discreet

Glucose level Comparison method (mmol/L)	**n**	**Excluded results**	**Comparison method, mean (mmol/L)**	**Mendor Discreet, mean (mmol/L)**	**Bias, mmol/L (95% CI)**
<7	31	0	5,6	5,5	-0,11 ((-0,20) – (-0,02))
7 – 10	19	0	8,5	8,3	-0,22 ((-0,39) – (-0,05))
≥10	30	0	13,2	12,9	-0,37 ((-0,56) – (-0,18))

Discussion

The glucose measurements on Mendor Discreet gave systematic lower glucose results than the comparison method. The deviation from the comparison method was between (-0,1) and (-0,4) mmol/L. The deviation is small, but statistically significant.

5.3.5. The accuracy of Mendor Discreet

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

The accuracy of Mendor Discreet meter B, with three lots of test strips, under standardised and optimal measuring conditions is shown in figure 2. The accuracy of Mendor Discreet, as measured by all the diabetes patients is shown in figure 3. The accuracy is summarised in table 10.

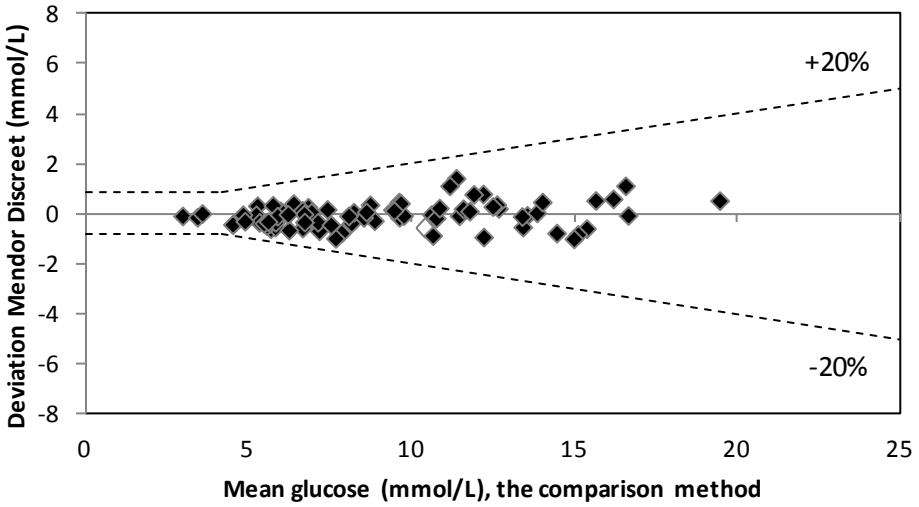


Figure 2. Accuracy. Mendor Discreet meter B (three lots of test strips) under standardised and optimal measuring conditions. The x-axis represents the mean result on the comparison method. The y-axis shows the difference between the first measurement on Mendor Discreet and the mean result of the comparison method. Stippled lines represent quality goal limits suggested in ISO 15197:2003. ID 38, statistical outlier from the calculation of repeatability on meter B, is represented with an open symbol. n = 80

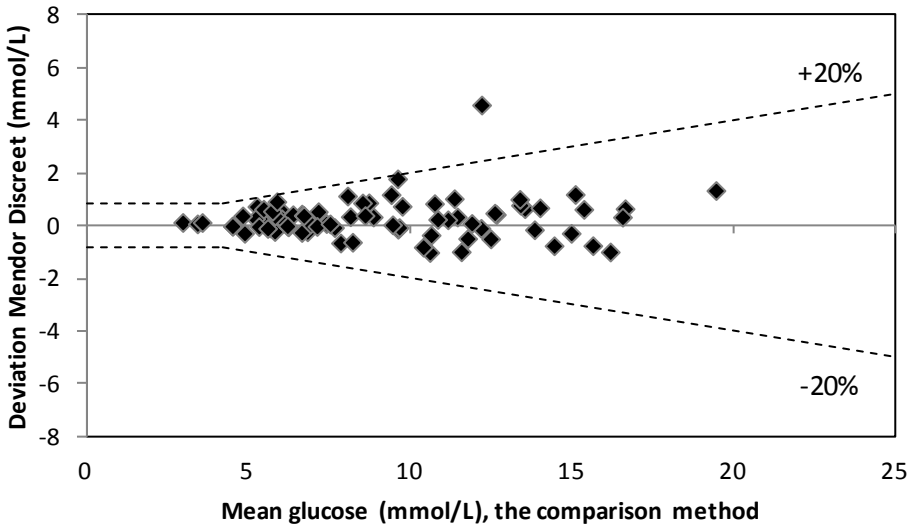


Figure 3. Accuracy. The diabetes patients' self-measurements on Mendor Discreet (three lots of test strips). The x-axis represents the mean result of the comparison method. The y-axis shows the difference between the first measurement on Mendor Discreet and the mean result of the comparison method. Stippled lines represent quality goal limits suggested in ISO 15197:2003. n = 80

Table 10. Accuracy of Mendor Discreet

Measure performed by	Meter, measurement	n	Number of results (%) within the limits			
			"Adjusted ISO" <± 25% and <±1,0 mmol/L at conc. <4,2	**ISO 15197:2003 <±20% and <±0,83 mmol/L at conc. <4,2**	**Fixed limit without cut off**	
					±15%	**±10%**
BLS	A (one lot) 1st measurement	80		100	100	98
	B (three lots) 1st measurement	80		100	100	94
Diabetes patients at NOKLUS	1st measurement	80	99	99	96	88

Comment

One result in figure 3 has a deviation of 37,6% from the comparison method. The results of the duplicate measurements were 16,8 and 15,1 mmol/L, and thereby precise enough. A matrix effect in this patient sample is not likely because then it should have come forward also in figure 2. The deviating result could be caused by user errors such as improper storage of the test strips, but this explanation was not possible to check or prove. There were no error messages related to these two measurements.

Discussion

Figure 2 and 3 show Mendor Discreet results in agreement with the comparison method. The summing up in table 10 shows that 100% of the results obtained by the BLSs as well as 99% of the results obtained by the diabetes patients were inside the accuracy quality limits proposed in

ISO 15197:2003. Table 10 also shows the number of results within fixed limits of ±15% and ±10%, but these results are for information only, and will not be further assessed.

5.3.6. Bias with three lots of test strips

The measurements on Mendor Discreet meter B were performed with three different lots of test strips from three productions. The mean deviation with 95% confidence interval for each of the three lots from the comparison method (bias) was calculated as an indirect measure of the lot variation. To get a sufficient number of results in each group, the bias was calculated for the entire glucose concentration range. The bias with three lots of test strips is shown in table 11.

Table 11. Bias with three lots of test strips

Mendor Discreet, lot number of test strips	**n**	**Excluded results**	**Comparison method, mean (mmol/L)**	**Mendor Discreet, mean (mmol/L)**	**Bias, mmol/L (95% CI)**
IU15QA10HC111111	20	0	8,4	8,4	-0,06 ((-0,23) – (+0,11))
IL07QA11HC301111	27	0	9,8	9,7	-0,11 ((-0,26) – (+0,04))
IA18QA08HC150911	32	0	9,0	9,0	0,05 ((-0,09) – (+0,20))

Conclusion

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

5.4. Effect of haematocrit

According to the technical specifications, glucose measurements on Mendor Discreet are not influenced by haematocrit values from 20 to 60%. To measure the effect of haematocrit on Mendor Discreet, a venous sample for haematocrit was collected of the diabetes patients at the evaluation end-meeting. The investigation of the effect is based on the measurements on Mendor Discreet meter A (one lot of test strips) under standardised and optimal measuring conditions. The glucose concentration range was 3,0 – 19,5 mmol/L. The haematocrit range was 31 – 48%. The effect of haematocrit with a trend-line and the regression equation is shown in figure 4. The raw data is shown in attachment 9.

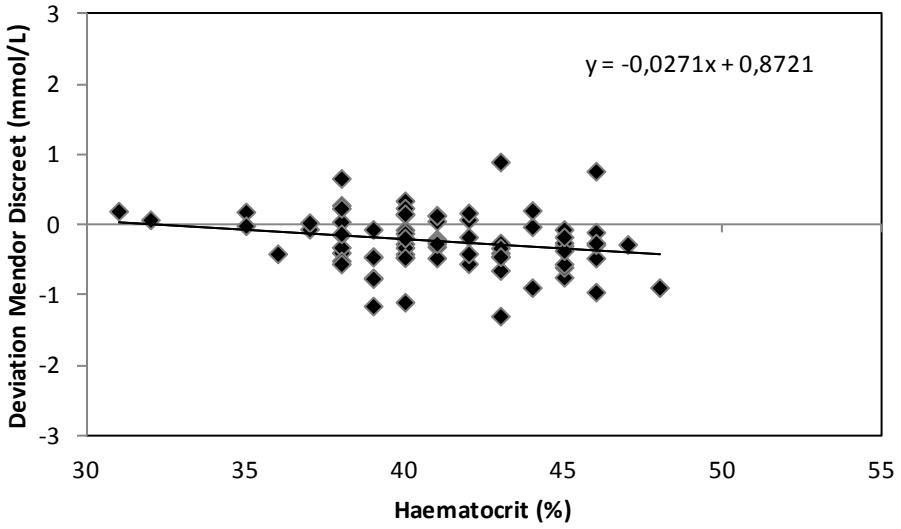


Figure 4. The effect of haematocrit on glucose measurements on Mendor Discreet meter A measured under standardised and optimal conditions. The x-axis shows the haematocrit value in percent. The y-axis shows the difference in glucose concentration between Mendor Discreet and the mean result of the comparison method in mmol/L, n= 77

Discussion

The slope of the trend-line is approximately (-0,03), with a 95% CI from (-0,0538) to (-0,0003). The slope is statistically significant different from zero. Glucose measurements on Mendor Discreet in the evaluation were slightly affected by haematocrit values within the range 31 – 48%. The glucose results still fulfil the accuracy quality goal set by ISO.

5.5. Evaluation of user-friendliness

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

Questionnaire

When attending the evaluation end-meeting, the diabetes patients filled in a questionnaire about the user-friendliness of the manual and the operation facilities of the meter. The BLS was available for clarifying questions, and there was free space for commenting. Each diabetes patient was first asked whether he/she had used the user manual. If the answer was no, they were to ignore the questions regarding the user manual.

The questionnaire and the expressed opinions are presented in table 12 and 13. The first column shows what is up for consideration. The second to fourth column show the rating options as well as the number of evaluators who chose this alternative. The last row in each table summarises the total rating in the table. The total rating is an overall assessment of the described property, and not necessarily the arithmetic mean of the rating in the rows. Consequently, a single poor rating can justify an overall poor rating, if this property seriously influences on the user-friendliness of the system. The principles for the assessment made in this evaluation, is explained below.

Assessment of time factors and of quality control possibilities are shown in table 14 and 15. These questions are answered by SKUP.

Principles of assessment in this evaluation

The assessment of user friendliness is based on the results in the tables filled in by the participants (table 12 – 13), the tables filled in by SKUP (table 14 – 15), the BLSs' evaluation (table 16) and the additional comments from the participants (section 5.5.1.). Three of the questions in table 12 and 13 (marked with grey) are attached greater importance than the rest of the questions in these tables. Viewpoints emphasised by approximately 1/3 of the participants or more are marked with coloured frames, also when their assessments lead to different ratings.

Table 12. Assessment of the information in the manual

Information in the manual	**Rating Number of responses (Response in %)**	**Rating Number of responses (Response in %)**	**Rating Number of responses (Response in %)**
General impression (76/77 responses)	Unsatisfactory 7 (9%)	Intermediate 41 (54%)	Satisfactory 28 (37%)
Description/illustration regarding specimen collection (74/77 responses)	Unsatisfactory 5 (7%)	Intermediate 26 (35%)	Satisfactory 43 (58%)
Description of how to perform a blood glucose measurement with the meter (74/77 responses)	Unsatisfactory 6 (8%)	Intermediate 16 (22%)	Satisfactory 52 (70%)
Description of how to insert/change the test strip cartridge (74/77 responses)	Unsatisfactory 7 (9%)	Intermediate 26 (35%)	Satisfactory 41 (55%)
Description of how to change the lancet (74/77 responses)	Unsatisfactory 12 (16%)	Intermediate 29 (39%)	Satisfactory 33 (45%)
Explanation of error sources (67/77 responses)	Unsatisfactory 2 (3%)	Intermediate 31 (46%)	Satisfactory 34 (51%)
Fault-tracing / Troubleshooting (64/77 responses)	Unsatisfactory 3 (5%)	Intermediate 33 (52%)	Satisfactory 28 (44%)
Readability / Clarity of presentation (73/77 responses)	Unsatisfactory 3 (4%)	Intermediate 26 (36%)	Satisfactory 44 (60%)
All in all, how satisfied are you with the user manual (77/77 responses)	Unsatisfied 6 (8%)	Intermediate 42 (55%)	Satisfied 29 (38%)
Rating for the information in the manual	The response from the participants was mixed. See 5.5.4.		

Comment
A total of 77 diabetes patients had used the user manual.

Table 13. Assessment of the operation facilities

Operation facilities	**Rating Number of responses (Response in %)**	**Rating Number of responses (Response in %)**	**Rating Number of responses (Response in %)**
All in all, to operate the meter (85/85 responses)	Difficult 8 (9%)	Intermediate 49 (58%)	Easy 28 (33%)
To perform a blood glucose measurement with the meter (83/85 responses)	Difficult 3 (4%)	Intermediate 32 (39%)	Easy 48 (58%)
To load a test strip (84/85 responses)	Difficult 1 (1%)	Intermediate 6 (7%)	Easy 77 (92%)
To fill the test strip with blood (85/85 responses)	Difficult 2 (2%)	Intermediate 11 (13%)	Easy 72 (85%)
To read the figures in the display (85/85 responses)	Difficult 2 (2%)	Intermediate 11 (13%)	Easy 72 (85%)
To remove the covers (83/85 responses)	Difficult 17 (20%)	Intermediate 38 (46%)	Easy 28 (34%)
To insert a test strip cartridge (76/85 responses)	Difficult 7 (9%)	Intermediate 24 (32%)	Easy 45 (59%)
To insert/change a lancet (70/85 responses)	Difficult 29* (41%)	Intermediate 25 (36%)	Easy 16 (23%)
To sample with the integrated lancing device (72/85 responses)	Difficult 23 (32%)	Intermediate 25* (35%)	Easy 24 (33%)
The device, design and handling (82/85 responses)	Unsatisfactory 13 (16%)	Intermediate 40 (49%)	Satisfactory 29 (35%)
Sources of errors, error codes (57/85 responses)	Unsatisfactory 4 (7%)	Intermediate 16 (28%)	Satisfactory 37 (65%)
Cleaning / Maintenance; scale and time (59/85 responses)	Unsatisfactory 4 (7%)	Intermediate 24 (41%)	Satisfactory 31 (53%)
Hygiene, when using the test (76/85 responses)	Unsatisfactory 14 (18%)	Intermediate 21 (28%)	Satisfactory 41 (54%)
Size and weight of package (83/85 responses)	Unsatisfactory 6 (7%)	Intermediate 26 (31%)	Satisfactory 51 (61%)
Rating of operation	The response from the participants was mixed. See 5.5.4.		

*For additional comments from the participants, see 5.5.1.

Table 14. Assessment of time factors

Time factors	**Ratings**	**Red**	**Yellow**	**Green**
Time for preparations / Pre-analytical time		>10 min	6 to 10 min.	<6 min.
Analytic time		>20 min	10 to 20 min.	<10 min.
Required training time		>8 hours	2 to 8 hours	<2 hours
Stability of test, unopened package		<3 months	3 to 5 months	>5 months
Stability of test, opened package*		<14 days	14 to 30 days	>30 days
Other comments about time factors (please specify)		Unsatisfactory	Intermediate	Satisfactory
Rating of time factors				**Satisfactory**

Negative comment: *Not suitable for diabetes patients who measure less than 25 measurements a month (because of the test strips' durability)

Table 15. Assessment of quality control possibilities

Quality control	**Ratings**	**Red**	**Yellow**	**Green**
Internal quality control		Un-satisfactory	Intermediate	Satisfactory
External quality control		Un-satisfactory	Intermediate	Satisfactory
Stability of quality control material, unopened		<3 months	3 to 5 months	>5 months
Stability of quality control material, opened		≤1 day	2 to 6 days	>6 days or disposable
Storage conditions for quality control materials, unopened		–20°C	+2 to +8°C	+15 to +30°C
Storage conditions for quality control materials, opened		–20°C	+2 to +8°C	+15 to +30°C
Usefulness of the quality control		Unsatisfactory	Intermediate	Satisfactory
Other comments about quality control (please specify)		Unsatisfactory	Intermediate	Satisfactory
Rating of quality control				**Satisfactory**

5.5.1. Additional comments from the participants

In total 64 of the 85 participants reported positive and/or negative comments.

Positive comments

29 participants reported one or more advantages with Mendor Discreet. The most often reported advantages were:

1. All-in-one (9)
2. The meter has short measuring time (6)
3. Covers protect the meter, no need for carrying case (5)
4. Test strip cartridges instead of single test strips (5)

Negative comments

50 participants reported one or more disadvantages with Mendor Discreet. The most often reported disadvantages were:

1. Various problems with the integrated lancing device / lancets (39); inconvenient, difficult to change the lancet, the penetration depth is too small, difficult to adjust the penetration depth, the marks are difficult to see
2. Problems with the removing of the test strip (11); difficult, unhygienic (blood on the test strip)
3. No light in the display (8)
4. The device is too big (6)

5.5.2. The biomedical laboratory scientists' evaluation

The two BLSs' evaluation of Mendor Discreet is shown in table 16.

Table 16. The two BLSs' evaluation of Mendor Discreet

	Positive comments	Negative comments
Control solution	– Stable even if it had been opened several times – Positive with controls in different concentrations levels (only control solution in one concentration level was used in this evaluation)	– Too wide range
To operate the meter	– Short measuring time – Small blood volume – Nice design – All-in-one – Covers and packing in rubber may protect the meter from humidity	– Difficult to remove the covers (especially the lower one) – Small and dark buttons. Difficult for elder and visually-handicapped – Spill of blood when used test strip has to be taken out. Should have been a button for "shooting" the used strip out – Cleaning of the covers – The last result disappears too fast from the display – Not suitable for elder users – Not suitable for diabetes patients who measure less than 25 measurements a month (because of the test strips' durability)
The user manual	– Simple and easy to understand (one of the BLS) – Simple illustrations	– The translation to Norwegian needs to be improved (one of the BLS) – Many pictures result in a rather complex impression
The lancing device	– Integrated lancing device is positive	– Difficult to use. Small and difficult to replace a lancet – Easy to prick oneself when feeding and removing a lancet – Not good enough penetration even at max penetration depth – Difficult to adjust the penetration depth – Not good enough marking on the lancing device (small black lines and arrows on black background)

5.5.3. Technical problems

Two of the diabetes patients commented that their assigned meter didn't function or just functioned from time to time. The BLSs also commented that they had noticed some meters that didn't function or just functioned for a period.

5.5.4. Assessment of the user-friendliness

The feed-back from the participants in this evaluation was mixed, which made the summing up for a total rating difficult. As shown in table 12 and 13, the participants' points of view often spread out over two answer alternatives and for one question even over all three categories. The assessments in table 12 and 13 are made at discretion, trying to give a fair picture of the spectrum of opinions.

As seen in table 12 the response from the users regarding the information given in the manual, was rather mixed.

Table 13 shows that quite a number of users had difficulties with handling the device. Approximately 40 % of the participants answered that they thought it was difficult to insert/change the lancet. The answers to the other question about the lancing device spread out evenly over the three answer categories.

Time factors and quality control possibilities are assessed as satisfactory (table 14 and 15).

The two BLSs had positive as well as negative comments regarding the user manual and the device (table 16).

In total 64 of the 85 participants reported additional comments; 29 participants reported one or more advantages with Mendor Discreet and 50 participants reported one or more disadvantages with Mendor Discreet.

As described in section 5.1.1.Feedback and problems, 23 participants withdrew from the evaluation for various reasons. Some of them withdrew from the evaluation because they found the meter difficult to use. None of these 23 participants have evaluated the user-friendliness of Mendor Discreet.

Conclusion

The conclusion is based on the results in the four tables (table 12 – 15), the BLSs' evaluation (table 16) and the additional comments from the participants (5.5.1.).

The feed-back regarding user-friendliness in this evaluation was mixed, which made the summing up for a total rating difficult. A great number of users had some kind of difficulties with handling the device, reporting various types of problems. Approximately 2/3 of the participants did not find the meter easy to operate. The rest of the participants were principally positive to the device, but their answers differed substantially. In total 64 of the 85 participants reported additional comments; 29 participants reported one or more advantages with Mendor Discreet and 50 participants reported one or more disadvantages with Mendor Discreet. The two BLSs had positive as well as negative comments regarding Mendor Discreet. In total 23 participants withdrew from the evaluation. Their points of view are not included in the assessment.

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Attachments

1. The organisation of SKUP
2. Facts about Mendor Discreet. Name of manufacturer and suppliers
3. Product information, Mendor Discreet
4. Statistical expressions and calculations
5. Raw data glucose, results from the comparison method
6. Raw data glucose, internal quality control, Mendor Discreet
7. Raw data glucose, Mendor Discreet results under standardised and optimal conditions
8. Raw data glucose, Mendor Discreet results from the diabetes patients' measurements at NOKLUS
9. Raw data haematocrit
10. "SKUP-info". Summary for primary health care (in Norwegian)
11. List of previous SKUP evaluations
12. Comments from Mendor Oy

Attachments with raw data are included only in the report to Mendor Oy.

The organisation of SKUP

Scandinavian evaluation of laboratory equipment for primary health care, *SKUP*, is a co-operative commitment of NOKLUS[1] in Norway, DAK-E[2] in Denmark, and Equalis[3] in Sweden. SKUP was established in 1997 at the initiative of laboratory medicine professionals in the three countries. SKUP is led by a Scandinavian *steering committee* and the secretariat is located at NOKLUS in Bergen, Norway.

The purpose of SKUP is to improve the quality of near patient testing in Scandinavia by providing objective and supplier-independent information on analytical quality and user-friendliness of laboratory equipment. This information is generated by organising SKUP *evaluations*.

SKUP offers manufacturers and suppliers evaluations of equipment for primary health care and also of devices for self-monitoring. Provided the equipment is not launched onto the Scandinavian market, it is possible to have a confidential pre-marketing evaluation. The company requesting the evaluation pays the actual testing costs and receives in return an impartial evaluation.

There are *general guidelines* for all SKUP evaluations and for each evaluation a specific *SKUP protocol* is worked out in co-operation with the manufacturer or their representatives. SKUP signs *contracts* with the requesting company and the evaluating laboratories. A *complete evaluation* requires one part performed by experienced laboratory personnel as well as one part performed by the intended users.

Each evaluation is presented in a *SKUP report* to which a unique *report code* is assigned. The code is composed of the acronym SKUP, the year and a serial number. If suppliers use the SKUP name in marketing, they have to refer to www.skup.nu and to the report code in question. For this purpose the company can use a logotype available from SKUP containing the report code.

SKUP reports are published at www.skup.nu.

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[1] NOKLUS (Norwegian Quality Improvement of Primary Care Laboratories) is an organisation founded by Kvalitetsforbedringsfond III (Quality Improvement Fund III), which is established by The Norwegian Medical Association and the Norwegian Government. NOKLUS is professionally linked to "Seksjon for Allmennmedisin" (Section for General Practice) at the University of Bergen, Norway.

[2] SKUP in Denmark is placed in Hillerød Hospital. SKUP in Denmark reports to DAK-E (Danish Quality Unit of General Practice), an organisation that is supported by KIF (Foundation for Quality and Informatics) and Faglig udvalg (Professional Committee), which both are supported by DR (The Danish Regions) and PLO (The Organisation of General Practitioners in Denmark).

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

Facts about Mendor Discreet. Name of manufacturer and suppliers.

This form is filled in by Mendor.

Table 1. Basic facts

Name of the measurement system:	Mendor Discreet Blood Glucose Monitoring System
Dimensions and weight:	Width: 59 mm Depth: 20 mm Height: 107 mm Weight: 100 g
Components of the measurement system:	Blood glucose meter, lancing device and test strip cartridge containing 25 test strips
Measurand:	Blood glucose in mmol/L
Sample material:	Fresh capillary whole blood
Sample volume:	At least 0.5 ul
Measuring principle:	Electrochemical, amperometric method, glucose oxidase
Traceability:	According to ISO13485 traceability
Calibration:	Plasma-equivalent
Measuring range:	(1.1 - 33.3 mmol/L)
Linearity:	Linearity range: 1,5 mmol/L … 33,3 mmol/L y = 0.98x – 2.07, Pr = 0.9989, up to 33,3 mmol/L Lo and Hi symbols are displayed below 1.1 mmol/L and above 33.3 mmol/L)
Measurement duration:	5 seconds
Operating conditions:	Operating temperature 10 – 40 °C
Electrical power supply:	3 V lithium battery
Recommended regular maintenance:	Regular cleaning, disinfectant 70% isopropanol can be used. User-changeable battery
Package contents:	Blood glucose meter, one Mendor Discreet test strip cartridge with 25 strips, Mendor Discreet lancets, (25 in a separate package), battery (already fitted), user manual, control solution, USB cable
Necessary equipment not included in the package:	-

Table 2. Post analytical traceability

Is input of patient identification possible?	No
Is input of operator identification possible?	No
Can the instrument be connected to a bar-code reader?	No
Can the instrument be connected to a printer?	No
What can be printed?	None
Can the instrument be connected to a PC?	Yes
Can the instrument communicate with LIS (Laboratory Information System)? If yes, is the communication bidirectional?	Diasend & Balance Software No
What is the storage capacity of the instrument and what is stored in the instrument?	Memory size is 250 measurements, including glucose value, date, time, and "mark" function
Is it possible to trace/search for measurement results?	Yes, possible to view previous measurement results, and view average of measurements conducted during previous 14 days

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

Name of the reagent/test strips/test cassettes:	Mendor Discreet Test Strip Cartridge
Stability in unopened sealed vial:	18 months
Stability in opened vial:	30 days
Package contents:	Sales package contains two cartridges individually sealed in aluminium foil, and a user manual. One test strip cartridge contains 25 test strips

Table 4. Quality control

Electronic self check:	No
Recommended control materials and volume:	Mendor Discreet Control Solution (4ml)
Stability in unopened sealed vial:	18 months
Stability in opened vial:	3 months after vial has been opened
Package contents:	One vial each of control solution A and B, user manual

Table 5. Marketing information

Manufacturer:	Mendor Oy, Kägelstranden 16, 02150 Esbo, Finland tel: +358 45321 8693, fax: +358 207818 101 e-mail: info@mendor.com
Suppliers in Scandinavia:	Finland: Mendor Oy, Kägelstranden 16, 02150 Esbo, Finland tel: +358 45321 8693, fax: +358 207818 101 e-mail: info@mendor.com Sweden: Mendor Oy, Kägelstranden 16, 02150 Esbo, Finland tel: +358 45321 8693, fax: +358 207818 101 e-mail: info@mendor.com Logistical partner in Sweden pending Denmark: Pending Norway: Pending
In which countries is the system marketed:	Globally X Scandinavia Europe
Date for start of marketing the system in Scandinavia:	Sales started in November 2010 in Finland, and simultaneously through Mendor web-store delivering within EU, including Scandinavia
Date for CE-marking:	6th July 2010
In which Scandinavian languages is the manual available:	Swedish, Norwegian and Finnish currently

Product information, Mendor Discreet
SKUP/2012/95

Mendor Discreet serial numbers
A total of 89 Mendor Discreet blood glucose meters were used in this evaluation.
Four meters (serial no. SA37110103001742, SA37110103001114, SA37110103001573 and SA37110103001579) were used by the biomedical laboratory scientists under the standardised and optimal conditions.

Mendor Discreet test strip cartridges

Lot IU15QA10HC111111	Expiry 2013-02
Lot IL07QA11HC301111	Expiry 2013-02
Lot IA18QA08HC150911	Expiry 2012-12

Mendor Discreet Control Solution

Control A	Lot CSIO24AN	Expiry 2013-05
Target value lot IU15QA10HC111111:	6,3 – 9,5 mmol/L	
Target value lot IL07QA11HC301111:	6,3 – 9,5 mmol/L	
Target value lot IA18QA08HC150911:	6,5 – 9,7 mmol/L	

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

Medlance Plus Extra (2,4 mm)	Lot R2G66E8	Expiry 2016-10

Blood sampling device used by the diabetes patients
The diabetes patients could choose whether to use Mendor Discreet integrated lancet device, or the lancet device they usually use.

Statistical expressions and calculations

This chapter with standardised text deals with the statistical expressions and calculations used by SKUP. The chapter is a short extract of the comprehensive SKUP-document "Statistics in SKUP reports", presented at www.skup.nu, under the option "The SKUP evaluation". The statistical calculations will change according to the type of evaluation. The descriptions are valid for evaluations of quantitative methods with results on the ratio scale.

Statistical terms and expressions

The definitions in this section come from the ISO/IEC Guide 99; International Vocabulary of Metrology, VIM [a].

Precision

Definition: Precision is the closeness of agreement between measured quantity values obtained by replicate measurements on the same or similar objects under stated specified conditions.

Precision is measured as *imprecision*. Precision is descriptive in general terms (good, poor e.g.), whereas the imprecision is expressed by means of the standard deviation (SD) or coefficient of variation (CV). SD is reported in the same unit as the analytical result. CV is usually reported in percent.

To be able to interpret an assessment of precision, the precision conditions must be defined.
Repeatability is the precision of consecutive measurements of the same component carried out under identical measuring conditions (within the measuring series).
Reproducibility is the precision of discontinuous measurements of the same component carried out under changing measuring conditions over time.

Trueness

Definition: Trueness is the closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value.

Trueness is inversely related to systematic measurement error. Trueness is measured as *bias*. Trueness is descriptive in general terms (good, poor e.g.), whereas the bias is reported in the same unit as the analytical result or in percent.

Accuracy

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

Accuracy is not a quantity and cannot be expressed numerically. A measurement is said to be more accurate when it offers a smaller measurement error. Accuracy can be illustrated in a difference-plot. Accuracy is descriptive in general terms (good, poor e.g.).

a. ISO/IEC Guide 99:2007, International vocabulary of metrology – Basic and general concepts and associated terms, VIM, 3rd edition, JCGM 200:2008

Statistical calculations

Statistical outliers

The criterion promoted by Burnett [b] is used for the detection of outliers. The model takes into consideration the number of observations together with the statistical significance level for the test. The significance level is set to 5%. The segregation of outliers is made with repeated truncations, and all results are checked. Where the results are classified according to different concentration levels, the outlier-testing is carried out at each level separately. Statistical outliers are excluded from the calculations.

Calculation of imprecision

The precision of the field method is assessed by use of paired measurements of genuine patient sample material. The results are divided into three concentration levels, and the estimate of imprecision is calculated for each level separately, using the following formula [c,d]:

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

d = difference between two paired measurements
n = number of differences

(formula 1)

This formula is used when the standard deviation can be assumed reasonable constant across the concentration interval. If the coefficient of variation is more constant across the concentration interval, the following formula is preferred:

$$CV = \sqrt{\frac{\sum (d/m)^2}{2n}}$$

m = mean of paired measurements

(formula 2)

The two formulas are based on the differences between paired measurements. The calculated standard deviation or CV is still a measure of the imprecision of single values. The assumption for using the formulas is that there is no systematic difference between the 1st and the 2nd measurement of the pairs.

Calculation of bias

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

Assessment of accuracy

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

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

Raw data glucose, internal quality control, Mendor Discreet

Mendor Discreet Control Solution	Lot-no	Expiry	Lot-no Mendor Discreet test strip cartridge	Target value Glucose (mmol/L)
Control Solution A	CSIO24AN	2013-05	IU15QA10HC111111	6,3 – 9,5
			IL07QA11HC301111	6,3 – 9,5
			IA18QA08HC150911	6,5 – 9,7

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

Date	Mendor Discreet Control Solution A Glucose (mmol/L)		
	Value	Meter	Lot-no test strip cartridge
07.03.2012	7,6	A	a
07.03.2012	7,7	B	
09.03.2012	7,7	A	a
09.03.2012	7,5	B	
19.03.2012	7,2	A	a
19.03.2012	7,6	B	
22.03.2012	7,8	A	a
22.03.2012	7,5	B	
23.03.2012	7,6	A	a
23.03.2012	6,9	B	c
28.03.2012	7,8	A	a
28.03.2012	7,4	B	a
29.03.2012	7,6	A	a
29.03.2012	7,4	B	b
30.03.2012	7,6	A	a
30.03.2012	7,3	B	c
13.04.2012	7,6	A	a
13.04.2012	7,8	B	c
08.05.2012	7,3	A	a
08.05.2012	7,5	B	
14.05.2012	7,6	A	a
14.05.2012	7,5	B	

Lot a: IU15QA10HC111111
Lot b: IL07QA11HC301111
Lot c: IA18QA08HC150911

Mendor Discreet Control Solution A analysed on the diabetes patients' meters

Training group

ID	Lot-no Mendor Discreet test strip cartridge	Mendor Discreet Control Solution A Glucose (mmol/L)
34	a	8,2
49	b	7,6
54	a	8,0
55	b	7,5
56	c	8,2
57	a	8,1
59	c	7,8
60	a	7,5
61	b	7,6
62	c	7,6
63	a	8,5
64	b	7,8
65	c	8,5
66	a	8,0
67	b	7,8
68	c	8,3
69	a	8,1
70	b	7,7
72	a	8,4
73	b	8,7
74	c	8,0
76	b	7,7
77	c	8,1
81	a	8,0
82	b	7,8
83	c	8,0
84	a	8,5
85	b	8,3
90	a	8,0
91	b	8,5
92	c	8,3
94	b	8,0
98	a	8,0
102	c	7,7
103	b	7,7
104	a	8,0
105	c	8,0
106	c	7,6
107	b	7,6
108	c	8,0

Mail group

ID	Lot-no Mendor Discreet test strip cartridge	Mendor Discreet Control Solution A Glucose (mmol/L)
1	a	8,2
2	b	7,8
4	a	8,5
5	b	7,5
7	a	7,5
8	b	8,2
9	c	9,0
10	a	8,1
11	b	8,0
12	c	8,1
13	a	8,4
14	b	8,3
15	c	8,4
16	a	7,7
17	b	8,3
18	c	8,2
19	a	7,8
20	b	8,2
21	c	8,9
23	b	7,6
24	c	7,3
25	a	7,8
26	b	8,1
27	c	8,0
28	a	8,4
29	a	8,0
30	c	7,5
31	a	8,1
32	b	8,5
33	c	7,4
35	b	7,3
36	c	7,9
37	a	8,6
38	b	8,3
39	c	8,4
40	a	7,9
41	b	7,6
44	b	8,3
45	c	No result
47	b	7,8
51	a	8,2
95	c	7,6
96	a	7,8
97	c	8,0
99	b	8,1

Raw data haematocrit

ID	Haematocrit
1	0,37
2	0,43
4	0,35
5	0,46
7	0,44
8	0,40
9	0,40
10	0,46
11	0,46
12	0,36
13	0,41
14	0,45
15	0,45
16	0,38
17	0,46
18	0,40
19	0,39
20	0,48
21	0,42
23	0,42
24	0,45
25	0,38
26	0,38
27	0,41
28	No result
29	0,40
30	0,41
31	0,43
32	0,42
33	0,45
34	0,37
35	0,39
36	0,40
37	0,43
38	0,43
39	0,41
40	0,40
41	0,40
44	0,38
45	No result
47	0,40
49	0,41
51	0,39

ID	Haematocrit
54	0,41
55	0,41
56	0,45
57	0,43
59	0,45
60	0,41
61	0,43
62	0,39
63	0,35
64	0,41
65	0,35
66	0,42
67	0,40
68	0,40
69	0,47
70	No result
72	0,38
73	0,38
74	0,39
76	0,42
77	0,40
81	0,46
82	0,38
83	0,45
84	0,38
85	0,40
90	0,44
91	0,38
92	0,32
94	0,45
95	0,45
96	0,43
97	0,39
98	0,38
99	0,44
102	0,43
103	0,40
104	0,40
105	0,46
106	0,38
107	0,31
108	0,40

SKUP-info

Mendor Discreet blodsukkerapparat fra Mendor Oy
Sammendrag fra en utprøving i regi av SKUP

Konklusjon
Presisjonen og nøyaktigheten på Mendor Discreet var god.
Variasjonen (CV) var mellom 2,8 og 4,1 % når målingene ble utført av laboratorieutdannet personale, og mellom 2,5 og 5,2 % når målingene ble utført av personer med diabetes. Mendor Discreet ga nøyaktige resultater, selv om resultatene var systematisk litt lavere ((-0,1) – (-0,4) mmol/L) enn resultatene fra sammenligningsmetoden. Kvalitetsmålet fra ISO 15197:2003, som tillater avvik opp til ± 20 % fra en anerkjent metode for måling av glukose, ble oppnådd. Hematokrit, i området 31 – 49 %, påvirket glukosemålingene på Mendor Discreet i liten grad.
Det var delte meninger om brukervennligheten.

Mendor Discreet er beregnet til egenmåling av blodsukker. Målesystemet er et "alt-i-ett" blodsukkerapparat med integrert stikkepenn og 25 teststrimler i en kassett. Systemet kalibreres når man setter inn ny teststrimmel-kassett. Det kreves 0,5 µL blod til hver måling, og måletiden er 5 sekunder. Mendor Discreet kan lagre 250 resultat.

Utprøvingen ble utført under optimale betingelser av laboratorieutdannet personale og blant personer med diabetes. Totalt 108 personer med diabetes deltok i utprøvingen; 85 av dem fullførte. Deltakerne ble delt inn i to grupper. Opplæringsgruppen fikk opplæring i bruk av Mendor Discreet. Postgruppen fikk apparat og instruksjon tilsendt pr. post og fikk ikke opplæring. En del deltakere måtte ha ekstra oppfølging. Alle deltakerne brukte Mendor Discreet hjemme i to uker og møtte deretter til et avslutningsmøte.

Resultater
Presisjonen var god. Variasjonen (CV) var mellom 2,8 og 4,1 % når målingene ble utført av laboratorieutdannet personale. Når målingene ble utført av personer med diabetes, var CV mellom 2,5 og 5,2 %. Mendor Discreet ga nøyaktige resultater, selv om resultatene var systematisk litt lavere ((-0,1) – (-0,4) mmol/L) enn resultatene fra sammenligningsmetoden. Kvalitetsmålet fra ISO 15197:2003, som tillater avvik opp til ± 20 % fra en anerkjent metode for måling av glukose, ble oppnådd. Hematokrit, i området 31 – 49 %, påvirket glukosemålingene på Mendor Discreet i liten grad.

Brukervennlighet
Det var delte meninger om brukervennligheten. Ca. 2/3 av deltakerne syntes ikke det var lett å bruke apparatet. Resten av deltakerne var i hovedsak positive til apparatet.

Tilleggsinformasjon
Den fullstendige rapporten fra utprøvingen av Mendor Discreet, SKUP/2012/95, finnes på SKUPs nettside www.skup.nu. Opplysninger om pris fås ved å kontakte leverandør. Laboratoriekonsulentene i NOKLUS kan gi nyttige råd om analysering av glukose på legekontor. De kan også orientere om det som finnes av alternative metoder/utstyr.

List of previous SKUP evaluations

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

Recent SKUP evaluations

Evaluation no.	Component	Instrument/testkit	Producer
SKUP/2012/95	Glucose[1]	Mendor Discreet	Mendor Oy
SKUP/2012/94	Glucose[1]	Contour XT	Bayer HealthCare
SKUP/2011/93*	Glucose	Accu-Chek Performa	Roche Diagnostics
SKUP/2012/91	HbA1c	Quo-Test A1c	Quoient Diagnostics Ltd
SKUP/2011/90	CRP	*i*-Chroma	BodiTech Med. Inc.
SKUP/2010/89*	Glucose	FreeStyle Lite	Abbott Laboratories
SKUP/2010/88*	HbA1c	*Confidential*	
SKUP/2011/86	Glucose[1]	OneTouch Verio	LifeScan, Johnson & Johnson
SKUP/2011/84*	PT-INR	Simple Simon PT and MixxoCap	Zafena AB
SKUP/2010/83*	Glucose	*Confidential*	
SKUP/2010/82*	Glucose, protein, blood, leukocytes, nitrite	Medi-Test URYXXON Stick 10 urine test strip and URYXXON Relax urine analyser	Macherey-Nagel GmBH & Co. KG
SKUP/2010/81*	Glucose	mylife PURA	Bionime Corporation
SKUP/2010/80	PT (INR)	INRatio2	Alere Inc.
SKUP/2010/79*	Glucose, protein, blood, leukocytes, nitrite	CombiScreen 5SYS Plus urine test strip and CombiScan 100 urine analyser	Analyticon Biotechnologies AG
SKUP/2010/78	HbA1c	In2it	Bio-Rad
SKUP/2011/77	CRP	*Confidential*	
SKUP/2009/76*	HbA1c	*Confidential*	
SKUP/2009/75	Glucose	Contour	Bayer HealthCare
SKUP/2009/74	Glucose[1]	Accu-Chec Mobile	Roche Diagnostics
SKUP/2010/73	Leukocytes	HemoCue WBC	HemoCue AB
SKUP/2008/72	Glucose[1]	*Confidential*	
SKUP/2009/71	Glucose[1]	GlucoMen LX	A. Menarini Diagnostics
SKUP/2011/70*	CRP	smartCRP system	Eurolyser Diagnostica GmbH
SKUP/2008/69*	Strep A	Diaquick Strep A test	Dialab GmbH
SKUP/2010/67	Allergens	*Confidential*	
SKUP/2008/66	Glucose[1]	DANA DiabeCare IISG	SOOIL Developement co. Ltd
SKUP/2008/65	HbA1c	Afinion HbA1c	Axis-Shield PoC AS
SKUP/2007/64	Glucose[1]	FreeStyle Lite	Abbott Laboratories
SKUP/2007/63	Glucose[1]	*Confidential*	
SKUP/2007/62*	Strep A	QuikRead	Orion Diagnostica Oy
SKUP/2008/61	CRP	i-CHROMA	BodiTech Med. Inc.
SKUP/2007/60	Glucose[1]	*Confidential*	
SKUP/2007/59	Glucose[1]	Ascensia BREEZE2	Bayer HealthCare
SKUP/2006/58	HbA1c	*Confidential*	
SKUP/2007/57*	PT (INR)	Simple Simon PT	Zafena AB
SKUP/2007/56*	PT (INR)	*Confidential*	
SKUP/2007/55	PT (INR)	CoaguChek XS	Roche Diagnostics
SKUP/2007/54*	Mononucleosis	*Confidential*	
SKUP/2006/53*	Strep A	*Confidential*	

*A report code followed by an asterisk indicates evaluations at special request from the supplier, or evaluations that are not complete according to SKUP guidelines, e.g. the part performed by the intended users was not included in the protocol.

[1] Including a user-evaluation among diabetes patients

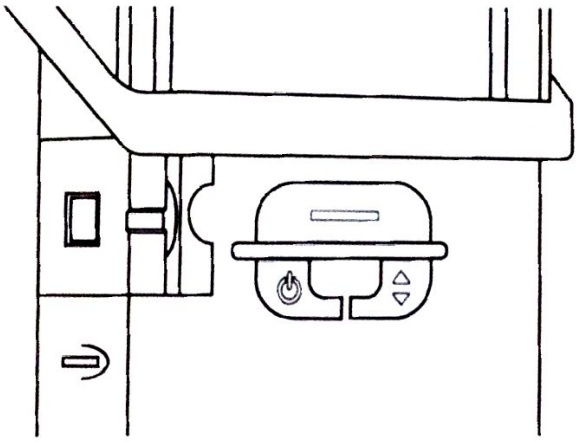
mendor
The new diabetes movement

Comments from Mendor **20th September 2012**

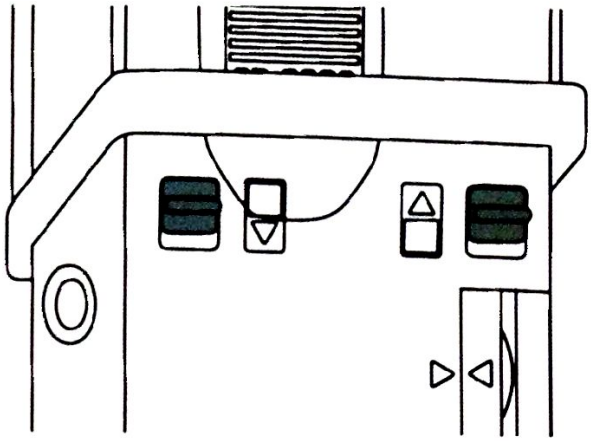
Mendor wishes to thank SKUP for conducting this evaluation on the technical performance and usability of the Mendor Discreet™ blood glucose monitoring system. As the results of this study have shown, the technical performance of the system meets all the quality goals set in the ISO 15197 standard with good precision and accuracy.

After the completion of this SKUP test, a new improved version of the Mendor Discreet™ blood glucose monitoring system has been launched. The modifications introduced to this new meter design include several improvements to the handling and use of the lancing device and for cover removal.

The lancet holder has been reshaped to clearly show the correct orientation of the lancet holder when reattaching it to the meter. Inserting a new lancet to a correct position can also easily be verified visually due to the new shape of the lancet holder. Adjusting the lancing depth has been made simpler by introducing clear-cut markings on the lancet holder to indicate the chosen depth. In addition, the removal of the lower and upper covers is simpler as the release latches on the back side of the meter have been modified for easier grip, and have also been color-marked. The operating buttons have also been adapted for improved operation.



Meter front side: the new design of the lancet holder for improved usability



Meter back side: improved release latches for easier operation and better grip with color markings

Best regards,

Karla Asikainen // Mendor