Accu-Chek® Mobile

Meter and test cassettes designed for glucose self-testing manufactured by Roche Diagnostics GmbH

Report from an evaluation organised by

SKUP

The evaluation was ordered by Roche Diagnostics Norge AS

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SKUP/2009/74

The organisation of SKUP

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

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

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

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

Each evaluation is presented in a *SKUP report* to which a unique *report code* is assigned. The code is composed of the acronym SKUP, the year and a serial number. A report code, followed by an asterisk (*), indicates a special evaluation, not complete according to the guidelines, e.g. the part performed by the intended users was not included in the protocol. If suppliers use the SKUP name in marketing, they have to refer to www.skup.nu and to the report code in question. For this purpose the company can use a logotype available from SKUP containing the report code.

SKUP reports are published at www.skup.nu. A detailed list of previous SKUP evaluations is included in this report.

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

[2] SKUP in Denmark is placed in Hillerød Hospital, which is one of several hospitals comprising Copenhagen University Hospital. SKUP refers to DAK-E (Danish Quality Unit of General Practice), an organisation that refers to KIF, founded by Danish Regions and PLO (The Organisation of General Practitioners in Denmark).

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

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Attachments with raw data are included only in the copy to Roche Diagnostics Norge AS.

1. Summary

Background
Accu-Chek Mobile blood glucose meter and Accu-Chek Mobile test cassettes are designed for glucose self-measurements performed by diabetes patients. The meter and test strips are produced by Roche Diagnostics GmbH and supplied in Scandinavia by Roche. The system has not yet been launched onto the Norwegian market. In order to give reimbursement for the test strips in Norway, the Norwegian Labour and Welfare Organisation (NAV) requires from the companies to carry out an evaluation that includes a user-evaluation among diabetes patients.
The SKUP-evaluation of Accu-Chek Mobile was carried out under the direction of SKUP from Mars to September 2009.

The aim of the evaluation
The aim of the evaluation of Accu-Chek Mobile is to

- reflect the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
- reflect the analytical quality by the intended users
- compare the analytical quality among trained and un-trained diabetes patients
- examine the variation between three lots of test cassettes
- examine if hematocrit interferes with the measurements
- evaluate Accu-Chek Mobile regarding user-friendliness
- evaluate the Accu-Chek Mobile user guide

Materials and methods
88 diabetes patients took part in the evaluation. 44 participants had two consultations and the rest had one consultation. The diabetes patients in the "training group" were given a standardised instruction about Accu-Chek Mobile before they did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also collected capillary samples from the diabetes patients and measured twice on Accu-Chek Mobile. In addition, two capillary samples were taken for measurements with a designated comparison method. The diabetes patients in the "mail group" received Accu-Chek Mobile by mail and no training was given. Both groups of diabetes patients used the equipment for approximately three weeks at home, before they attended for a final consultation. The blood glucose sampling and measurement procedures at the first consultation were repeated, and in addition a sample for hematocrit was taken. Three different lots of test cassettes were used in the evaluation. All the participants answered questionnaires about the user-friendliness and the user guide of Accu-Chek Mobile.

Results

- The overall precision of Accu-Chek Mobile was good. The repeatability CV obtained under standardised and optimal conditions was <3%. When the measurements were performed by the diabetes patients an improvement in repeatability was seen at the second consultation. This led to a repeatability CV at approximately 4%.
- For glucose concentrations <10 mmol/L, the results on Accu-Chek Mobile were systematic higher than the results from the comparison method. The mean deviation from the comparison method at this concentration level was approximately +0,3 mmol/L. For glucose concentrations >10 mmol/L Accu-Chek Mobile gave results in agreement with the comparison method.
- The accuracy of Accu-Chek Mobile was good. The results fulfilled the quality goal proposed in ISO 15197. More than 95% of the results achieved under standardised and optimal conditions were within the limits described in ISO 15197. The "adjusted ISO-goal" was met by the measurements of the diabetes patients, and >95% of the results achieved by the diabetes patients also fulfilled the ISO-goal.
- Two of the three lots of test cassettes used in the evaluation gave significantly higher values than the comparison method. The mean deviation from the comparison method was approximately +0,4 mmol/L .
- Glucose measurements on Accu-Chek Mobile seemed to be slightly affected by hematocrit in this study. Hematocrit outside the range 27 – 49% has not been tested.
- Most of the diabetes patients thought that the Accu-Chek Mobile device was easy to operate. Some of the participants had problems related to opening the tip cover. Most of the diabetes patients that had used the user guide were satisfied with the guide.

Conclusion

The precision of Accu-Chek Mobile was good. The repeatability CV was between 2,5 and 5%. The accuracy of Accu-Chek Mobile was good, and the results fulfilled the quality goal based on ISO 15197. Glucose measurements on Accu-Chek Mobile seemed to be slightly affected by hematocrit in this study. Most of the users found the Accu-Chek Mobile device easy to use.

Comments from Roche Diagnostics

There is no additional information or comments from producer attached to the report.

2. Analytical quality specifications

There are different criteria for setting quality specifications for analytical methods. Ideally the quality goals should be set according to the medical demands the method has to meet. For glucose it is natural that the quality specification is set according to whether the analysis is used for diagnostic purpose or for monitoring diabetes. Accu-Chek Mobile is designed for monitoring blood glucose, and the quality goals must be set according to this.

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

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

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

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

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

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

3. Materials and methods

3.1. Accu-Chek Mobile

Accu-Chek Mobile is a blood glucose monitoring system based on reflectometrical technology. The system consists of an Accu-Chek Mobile meter and an Accu-Chek Mobile test cassette containing a film with 50 test spots. The Accu-Chek FastClix lancet pen is fastened to the meter. The lancet pen has six lancets in a preloaded drum, and the pen can be used either when fastened or taken off the meter. The system is designed for capillary blood glucose testing performed by persons with diabetes. The system is not recommended in us by health care professionals because of danger of infection from patient to patient. The Accu-Chek Mobile device reports plasma glucose values. The system does not require calibration by the user.

The test principle of Accu-Chek Mobile is as follows: When blood is applied to the test spot a chemical reaction occurs (glucose-oxidoreductasemediator reaction). This causes a change in the colour at the test spot. The colour is read reflectormetrically.

The system requires a blood volume of 0,3 µL. According to the package insert the measurement only starts when the correct amount of blood is applied to the test spot. The result is shown within 5 seconds. It is possible to test with blood from alternate test sites as the palm and forearm. 500 results are automatically stored in the memory with date and time, offering the possibility of taking an average over 7, 14 or 30 days. Results can be downloaded to a PC using a software product from Roche. Technical data from the manufacturer is shown in table 1. For more details about the system, see attachment 1.

3.1.1. Product information, Accu-Chek Mobile

Accu-Chek Mobile blood glucose meter

Manufactured by:
Roche Diagnostics GmbH
68298 Mannheim
Germany

Table 1. Technical data from the manufacturer

TECHNICAL DATA FOR ACCU-CHEK MOBILE	
Optimal operating temperature	10 - 40 °C
Sample volume	0,3 µL
Measuring time	5 seconds
Measuring range	0,6 – 33,3 mmol/L
Hematocrit	25-55%
Memory	500 test results
Power source	Two 1,5V; type AAA, LR 03, AM. One Lithium battery (CR1025)
Operating time	Approximately 500 tests
Humidity	15 – 85% RH (operation). 15 – 93% RH (storage)
Dimensions	123 mm x 66mm x 28mm (included lancet pen)
Weight	Approximately 150g

176 Accu-Chek mobile blood glucose meters were used in this evaluation. The biomedical laboratory scientist used one separate Accu-Chek Mobile meter for each of the participants. Attachment 2 gives serial numbers for the 88 meters used by the biomedical laboratory scientist, and for the 88 meters used by the diabetes patients.

Accu-Chek Mobile test cassetts:
Lot 27700239 Expiry 2010-06
Lot 29685031 Expiry 2010-05
Lot 27700333 Expiry 2010-07

Accu-Chek Mobile Control:
Glucose (0,12%), preservative (0,24%) in phosphate buffer
Control 2 Lot 22470001 Expiry 2010-01

Suppliers of Accu-Chek Mobile in the Scandinavian countries:

Denmark:	Norway:	Sweden:
Roche A/S	Roche Diagnostics Norge AS	Roche Diagnostics Scandinavia AB
Industriholmen 59	Brynsengfaret 6 B	Box 147
2650 Hvidovre-	P.O.Box 6610 Etterstad	S-161 26 Bromma
Copenhagen	NO-0607 OSLO	
Denmark		
Phone: +45 36 399999	Phone: +47 23 37 33 00	Phone: +46 08-404 88 00
Fax: +45 36 399900	Fax: +47 23 37 33 99	
	mette.engebretsen@roche.com	info@Accu-Chek.se
www.accu-chek-dk	www.accu-chek.no	www.accu-chek.se

3.2. The designated comparison method

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

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

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

Verifying of trueness
The comparison method has to show traceability equivalent to that of an internationally accepted reference solution, such as the standards supplied by the National Institute of Standards & Technology, NIST. The NIST-standard SRM 965a [7] consists of ampoules with human serum with certified concentrations of glucose (and their given uncertainties) at four levels. The uncertainty is defined as an interval estimated to have a level of confidence of at least 95%. The SRM 965a materials cover a glucose concentration range from 1,9 to 16,2 mmol/L, and were used in this evaluation to verify the trueness. In addition, freshly frozen, human serum controls, produced by SERO AS, with glucose concentrations at two levels were analysed. These controls have target values determined with an isotope-dilution gas chromatography/mass spectrometry method in a Reference laboratory in Belgium; Laboratory for Analytical Chemistry, University of Gent, Belgium [8]. The controls are included in NOKLUS's External Quality Assessment program. The results are summarized in chapter 5.1.3.

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

3.2.1. Product information, the comparison method

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

Reagents
Glucose Reagent Kit
Lot 72041HW00 Expiry 2009-09

Calibrator
Multiconstituent Calibrator, List No. 1E65, Lot 63421M100 Expiry 2009-09-30
Reference value, cal 1 = 5,27 mmol/L
Reference value, cal 2 = 24,42 mmol/L

Internal quality controls
Autonorm Human Liquid 1 and 2, SERO AS
Liquid 1: Value = 3,50 ± 0,21 mmol/L Lot 0802102 Expiry 30.04.10
Liquid 2: Value = 14,92 ± 0,75 mmol/L Lot 0806267 Expiry 31.08.10

External Quality controls, SERO AS
Reference value from Laboratory for Analytical Chemistry, University of Gent, Belgium; ID-GCMS method
Serum TM Gluc L-1 Value = 4,78 ±0,09 mmol/L Lot 0809361
Serum TM Gluc L-2 Value = 11,80 ±0,16 mmol/L Lot 0809362

NIST standards
Standard Reference Material® 965a, National Institute of Standards & Technology
Expiry 2009-12-31
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 WIS028
Accu-Chek Softclix Pro lancets: Lot WIT 44 H 2 Expiry 2011-10-31

Tubes used for sampling for the designated comparison method
Microvette CB 300 LH (lithium-heparin) manufactured by Sarstedt AS
Lot 7074501 Expiry 2010-10

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

3.3. Planning of the evaluation

Background for the evaluation
Accu-Chek Mobile is a blood glucose monitoring system designed for capillary blood testing performed by diabetes patients. The Accu-Chek Mobile system is produced by Roche Diagnostics and supplied in Scandinavia by Roche. The system is marketed in Denmark, but has not been launched onto the Swedish or Norwegian market yet.

Contract, protocol and agreements
Roche Diagnostics Norge and SKUP signed a contract about the evaluation in October 2008. The protocol for the evaluation was approved in February 2009. The laboratory at Haraldsplass Diaconale Hospital (HDH) in Bergen agreed to carry out the analytical part of the evaluation concerning analysing the samples for the comparison method.

Preparations and training program
The preparations for the evaluation started in March 2009. The biomedical laboratory scientist Torny Bjerketvedt was hired to do the practical work with the evaluation. She was educated in the evaluation procedures by SKUP. Thereafter, Mette Engebretsen and Lene K. Lindberg, Roche Diagnostics, trained Torny for the practical work with Accu-Chek Mobile. The meters and test cassettes for the evaluation were received in the beginning of March, and the equipment was directly unpacked and prepared for distribution among the diabetes patient.

Recruitment of the diabetes patients
The diabetes patients were recruited in January through advertisements in three local newspapers. Diabetes patients were also recruited by mail inquiry sent to the members of the local branch of The Norwegian Diabetes Association.

The SKUP evaluation
SKUP evaluations are based upon the fundamental guidelines in the book "*Evaluation of analytical instruments. A guide particularly designed for evaluations of instruments in primary health care*" [9]. The evaluation of a self-monitoring blood glucose device in principle follows the guidelines in the book, but the evaluation in primary health care is replaced by a user-evaluation conducted among diabetes patients, based on the model worked out by the NOKLUS-project "*Diabetes-Self-measurements*" [10]. This model has become basis for the quality specifications used when The Norwegian Labour and Welfare Organisation (NAV) decides whether or not to give reimbursement for glucose test strips [11]. The evaluation model has been used by SKUP since 2002, and has recently been evaluated and discussed in an article presenting the results from nine of the SKUP evaluations [12].

The evaluation comprises the following studies:
- An examination of the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
- An examination of the analytical quality among approximately 80 diabetes patients
- The agreement between Accu-Chek Mobile and a designated comparison method
- A comparison of the analytical quality among diabetes patients with and without a training programme

- An examination of the variation between three lots of test strips
- An examination to see if hematocrit interferes with the measurements
- An evaluation of the user-friendliness of Accu-Chek Mobile
- An evaluation of the user guide of Accu-Chek Mobile

Evaluation sites and persons involved
The blood sampling of the diabetes patients and the measurements on Accu-Chek Mobile under standardised and optimal conditions, were carried out by Torny Bjerketvedt, biomedical laboratory scientist, SKUP/NOKLUS at Moss Hospital in Østfold, Norway. Grethe Kalleklev, biomedical laboratory scientist, was 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 Camilla Eide Jacobsen, SKUP/NOKLUS in Bergen.

3.4. The evaluation procedure

3.4.1. The model for the evaluation

The practical work with the evaluation was carried out from March to September. The evaluation consisted of two parallel parts. One part of the evaluation was carried out under standardised and optimal conditions in a hospital laboratory. This part of the evaluation was performed by laboratory educated personnel, in exact accordance with the protocol and the user guide and after having received thorough training. All possibilities for disturbance of, and interference with, the measurements were tried kept at a minimum. The evaluation under standardised and optimal conditions documents the quality of the system under conditions as favourable as possible for achieving good analytical quality. The other part of the evaluation was performed by diabetes patients. In order to determine the analytical quality of Accu-Chek Mobile by the users, 88 diabetes patients tested their blood glucose using the device. The diabetes patients were divided into two groups (random distribution). Half of the diabetes patients received personal training in how to use the blood glucose meter, here called the "training group". The other group received the blood glucose meter and instructions by mail, here called the "mail group". Dividing the diabetes patients into a "training group" and a "mail group" reflects the actual market situation regarding training when diabetes patients acquire blood glucose meters [10]. The model for the evaluation is shown in figure 1.

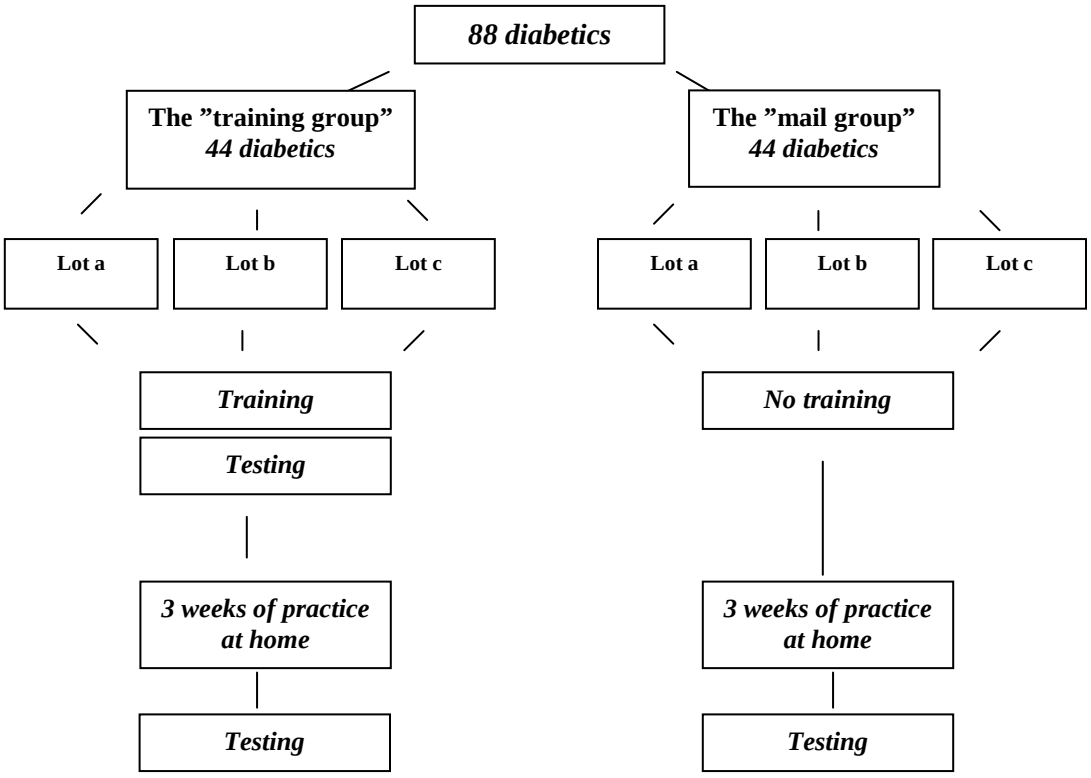

Figure 1. Model for the evaluation

3.4.2. Selection of diabetes patients

The Accu-Chek Mobile glucose meter was tested in use by 88 diabetes patients. The group of diabetes patients was representative for diabetes patients who carry out self-monitoring of blood glucose (SMBG). The group included diabetes patients from across a range of self-monitoring frequencies, i.e. diabetes patients who perform self-monitoring often (once or more a day) and those who perform self-monitoring less frequently (once a week).
Characteristics of the diabetes patients are shown in table 2.

Table 2. Characteristics of the diabetes patients (n=88)

		Number of diabetes patients
Total		88
Sex	Men	52
	Women	36
Age, median in years (range)		62,5 (25 – 72)
Diabetes	Type 1	31
	Type 2	57
Treatment	Insulin	37
	Insulinpump	4
	Insulin and tablets	6
	Tablets	31
	Diet	10
Frequency of SMBG	Less than weekly	4
	1 – 3 per week	17
	4 – 6 per week	6
	7 – 10 per week	14
	>10 per week	46
	No measuring	1*

*One of the diabetes patients did not have a SMBG-device

The SMBG-devices that the diabetes patients used regularly were: Accu-Chek (model not specified) (3), Accu-Chek Aviva (9), Accu-Chek Compact/Compact Plus (14), Accu-Chek Sensor (4), Ascensia (model not specified) (1), Ascensia Breeze/Breeze2 (10), Ascensia Contour (16), FreeStyle (2), FreeStyle Fredom (1), Freestyle Lite (7), FreeStyle Mini (5), Glucometer DEX2 (1), Glucometer Elite (1), OneTouch (model not specified) (3), OneTouch Ultra/Ultra2 (7), OneTouch UltraEasy (2) and Precision Xceed (1).

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

3.4.3. The "training group" at the first consultation

The 44 diabetes patients who were selected to participate in a training programme were invited in pairs for training. They received the Accu-Chek Mobile device along with one test cassette, Accu-Chek FastClix Mobile lancet pen, 9 lancet drums, user guide (in Norwegian), and an information letter with explanations regarding what to do with the Accu-Chek Mobile device during the training period at home. The information letter is attached to the report (in Norwegian), see attachment 3. The responsibility for the training programme was undertaken by SKUP. Torny Bjerketvedt was in charge of the training of the diabetes patients, after having been trained herself by a representative from Roche.

The training programme

The training programme covered a simple demonstration of how to use Accu-Chek Mobile, with an explanation of the display and error messages, insertion of the test cassette, blood sampling and drawing of the blood onto the test spot, as well as precautions for storage and the shelf life of test cassettes, etc. The training programme was standardised to make sure that all the diabetes patients received the same instruction.

Blood sampling

After having been trained, the 44 diabetes patients made duplicate blood glucose tests on Accu-Chek Mobile. These results were registered for the evaluation. The biomedical laboratory scientist collected samples for the evaluation under standardised and optimal conditions (see chapter 3.4.7.). Afterwards the diabetes patients brought the Accu-Chek Mobile home to use it over a three-week period. After this period they attended a final consultation (see chapter 3.4.6).

3.4.4. The "mail group"

The 44 diabetes patients in the "mail group" received the Accu-Chek Mobile device by mail, along with one test cassette, lancet pen, 9 lancet drums, user guide (in Norwegian) and an information letter with explanations regarding what to do with the Accu-Chek Mobile device during the period at home. No training was given. They used the meter over a three-week period at home. After this period they attended a final consultation (see chapter 3.4.6).

3.4.5. Use of Accu-Chek Mobile by the diabetes patients at home

All the diabetes patients used Accu-Chek Mobile 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 guide at once when they receive the meter. As the diabetes patients should evaluate the user guide at the final consultation, it would be unfortunate if the practice period at home was too long. During the practice period the diabetes patients used Accu-Chek Mobile in addition to their own glucose meter, and they continued to carry out self-measurements with their own meter as usual.

The first and the second week

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

The third week
During the third week the diabetes patients performed duplicate measurements on Accu-Chek Mobile 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 lancet pen provided for the evaluation, or the lancet pen they use ordinarily.

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

3.4.6. The final consultation

Blood sampling
After the three-week practice period at home, 88 diabetes patients met, one by one, for a consultation. Each diabetes patient brought their assigned Accu-Chek Mobile to the consultation. Before the samples were collected, the Accu-Chek Mobile device was equilibrated to room temperature while the diabetes patients filled in the questionnaires. Then the diabetes patients made duplicate blood glucose tests on their assigned meter. These results were registered for the evaluation. The biomedical laboratory scientist collected samples for the evaluation under standardised and optimal conditions. Finally, a venous sample for hematocrit was taken.

Evaluation of the user-friendliness and the user guide
The diabetes patients filled in two questionnaires. The first questionnaire deals with the user-friendliness of Accu-Chek Mobile; the second covers the user guide. The questionnaires (in Norwegian) are attached to the report.

3.4.7. Evaluation under standardised and optimal conditions

The biomedical laboratory scientist used one separate Accu-Chek Mobile device for each of the diabetes patients for the evaluation. All of the meters were used with the same three lots of test cassettes as distributed among the diabetes patients. The number of samples for each lot of test cassettes measured under standardised and optimal conditions is shown in table 3.

Table 3. The number of samples for each lot of test cassettes

Accu-Chek Mobile	Lot a 27700239	Lot b 29685031	Lot c 27700333
1st consultation	9 x 2	19 x 2	16 x 2
2nd consultation	29 x 2	29 x 2	30 x 2
Total	38 x 2	48 x 2	46 x 2

Blood sampling
All the meters were checked by means of the manufacturer's control solution every day they were used. The biomedical laboratory scientist measured the internal quality control (Accu-Chek Mobile Control 2) on the diabetes patient's meter at each consultation.

All the samples for Accu-Chek Mobile, as well as the samples for the comparison method, were collected from finger capillaries.

The blood sampling and analysis were carried out in the following order:
1. The biomedical laboratory scientist took a first sample for the comparison method
2. The biomedical laboratory scientist took duplicate samples and analysed on the Accu-Chek Mobile device
3. The diabetes patient took duplicate samples for his/her assigned meter
4. The biomedical laboratory scientist took a second sample for the comparison method

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

The blood samples for the comparison method were always taken at the start and in the end of each sampling sequence, in accordance with ISO 15197. The biomedical laboratory scientist registered whether the diabetes patients used correct cleaning, drying and skin puncture procedures, applied the blood sample correctly to the test spot, and otherwise followed the manufacturer's instructions for performing a blood glucose test. At the final consultation a venous sample for hematocrit determination was taken. Hematocrit may influence on blood glucose readings, especially in meters designed for self-monitoring. The product insert of Accu-Chek Mobile test cassette states that the glucose measurements are not influenced by hematocrit values from 25 to 55%.

Handling of the samples for the comparison method
The samples for the comparison method were taken from a finger capillary using Microvette Li-heparin tubes from Sarstedt (300 µL). The samples were centrifuged immediately for three minutes at 10.000g, and plasma was separated into sample vials. The plasma samples were frozen directly and stored at minus 80° C. The samples were transported under cold storage to NOKLUS where they were kept at minus 80° C until the analysis took place [7].

The samples were analysed on an Architect instrument in August/September. The samples were thawed at NOKLUS just before they were analysed.

Stability of the glucose concentration during the sampling time
For each sampling sequence, two samples for the comparison method were collected. These pairs of samples, taken at the start and at the end of each blood sampling sequence, reflect the stability of the glucose concentration during the sampling time. When the paired measurements give agreeable glucose concentrations on the comparison method, the mean of the two results is

looked upon as the estimate of the true value of the sample. To secure the decision regarding the stability of the glucose concentration, all the second samples were analysed in duplicate.

Assessment of the glucose concentration stability
According to ISO 15197, the difference between the first and the second comparative reading must not be more than 4% or 0,22 mmol/L. This is a strict demand. 32 of 131 paired results on the comparison method gave deviations between 4 and 10%. For 16 of these 32 samples the deviation was less than 6%. After a general evaluation of all the results, the paired measurements with differences between 4 and 10% were included in the calculations, as they did not affect the outcome of the assessment of accuracy and bias. The conclusions in the report are not dependent on keeping or excluding these results.

Deviations >10% are regarded as not acceptable. Such results are always excluded, and the matching meter results removed before assessment of accuracy and hematocrit influence, and before calculation of trueness. This applied to ID 14 and ID 45.

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

3.4.8. Evaluation of analytical quality

The following sets of data give the basis for the evaluation of the analytical quality (for missing or excluded results, see 4.2.3.):

1. Results from 44 diabetes patients in the “training group” who had participated in the training programme, but not practiced using the blood glucose meter at home
2. Results from 44 of the same diabetes patients after they had practiced using Accu-Chek Mobile at home for three weeks
3. Results from 44 diabetes patients in the “mail group” who had not participated in the training programme, but had practiced using Accu-Chek Mobile at home for three weeks
4. Results from 132 measurements in duplicate under standardised and optimal conditions
5. Results from 132 measurements in duplicate from the comparison method

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

The three lots of test cassettes were distributed evenly between the diabetes patients in the group with and without training (random distribution in each group). The agreement of the three lots to the comparison method was assessed.

4. Statistical expressions and calculations

4.1. Statistical terms and expressions

The definitions in this section come from the International Vocabulary of Metrology, VIM [13].

4.1.1. Precision

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

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

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.

To be able to interpret an assessment of precision, the precision conditions must be defined. The "specified conditions" can be, for example, repeatability, intermediate precision or reproducibility conditions of measurement. The precision conditions in this evaluation are close to the defined *repeatability* and *reproducibility* conditions, and the imprecision is expressed as repeatability CV and reproducibility CV. The imprecision is summarised in tables.

4.1.2. Accuracy

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

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

4.1.3. Trueness

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

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

4.2. Statistical calculations

4.2.1. Number of samples

88 diabetes patients completed the evaluation. The diabetes patients in the "training group" met at two consultations. The diabetes patients in the "mail group" met at one consultation. Blood samples were taken at each consultation. The total number of samples is:
[(44 x 2 (duplicates)) + (44 x 2) + (44 x 2)] x 3 (the biomedical scientist's meter, diabetes patient's meter, comparison method) = 792 samples.

4.2.2. Statistical outliers

The criterion promoted by Burnett [14] was used for the detection of outliers. The model takes into consideration the number of observations together with the statistical significance level for the test. The significance level is often set to 5%, so also in this evaluation. The segregation of outliers was made with repeated truncations. All the results were checked. Where the results are classified according to different glucose concentration levels, the outlier-testing is done at each level separately. Statistical outliers are excluded from the calculations. Possible outliers will be commented on under each table.

4.2.3. Missing or excluded results

Besides the statistical outliers, the following results are missing or excluded for other reasons:

- ID 86: The first of the two samples for the comparison method is missing. To get an estimate of the true value of the glucose concentration for this patient, the mean of the duplicate measurement of the second sample is used alone
- All glucose results from ID 14 and ID 45 are excluded because the glucose concentration was not stable enough during the sampling time

4.2.4. Calculations of imprecision based on duplicate results

Two capillary samples were taken of each diabetes patient for the biochemical laboratory scientist's meter, the diabetes patient's meter and for the comparison method at each consultation. The imprecision was calculated by use of paired measurements [15, 16], based on the following formula:

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

Even if this formula is based on the differences between the two parallel measurements of every duplicate, the calculated standard deviation is a measure of the imprecision of single values, and completely comparable with the more commonly used calculation based on repeated measurements of only one sample. The assumption for using this formula is that no systematic difference between the 1st and the 2nd measurement of the duplicate is acceptable. Table 4 shows that no systematic difference was pointed out between the paired measurements. This conclusion is also supported by observations in previous user-evaluations carried out by SKUP.

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

Accu-Chek Mobile	Glucose level (mmol/L)	n	Mean 1st measurement (mmol/L)	Mean 2nd measurement (mmol/L)	Mean difference 2nd – 1st measurement (mmol/L)	95% CI for the mean difference, (mmol/L)
The biochemical laboratory scientists' meter	<7	20	5,7	5,8	0,01	-0,01 – +0,18
	7 – 10	52	8,5	8,5	-0,04	-0,12 - +0,04
	≥10	59*	13,1	13,2	0,10	-0,04 - +0,24
The diabetes patients' meter	<7	21**	5,9	5,8	-0,03	-0,14 - +0,08
	7 – 10	48	8,5	8,7	0,13	-0,02 - +0,29
	≥10	61	13,2	13,2	-0,05	-0,21 - +0,12

*One statistical outlier according to Burnett's model (ID 58)
** Two statistical outliers according to Burnett's model (ID 56 and 64)

4.2.5. Calculation of trueness

To assess the trueness of the results on Accu-Chek Mobile, the mean deviation from the comparison method at three glucose concentration levels is calculated based on the results obtained under standardised and optimal measuring conditions. A paired t-test is used with the mean values of the duplicate results on the comparison method and the mean values on Acuu-Chek Mobile. The mean difference is shown with a 95% confidence interval.

4.2.6. Assessment of accuracy

To evaluate the accuracy of the results on Accu-Chek Mobile, the agreement between Accu-Chek Mobile and the comparison method is illustrated in two difference-plots. In the plots the x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on Accu-Chek Mobile with three lots and the mean value of the duplicate results on the comparison method.

5. Results and discussion

5.1. Analytical quality of the designated comparison method

5.1.1. 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. The control results from the evaluation period were inside the limits of the target values for the controls.
The internal quality control raw data is shown in attachment 4.

5.1.2. The precision of the comparison method

Repeatability

The best estimate of the repeatability of a method is achieved by using patient samples. By doing so, the matrix effects in artificially produced materials are avoided. In this evaluation, two capillary samples were taken of each individual for measurement on the comparison method. The blood sampling was carried out with a small time gap between the first and the second sample for each diabetes patient. The paired measurements reflect the stability of the glucose concentration during the sampling time, and not the precision of the method. To achieve a measure for the repeatability of the comparison method, the second sample was analysed in duplicate.
The repeatability of the comparison method is shown in table 5.
The raw data is shown in attachment 5.

Table 5. Repeatability, the comparison method. Results achieved with capillary blood samples

Glucose level (mmol/L)	n*	Outliers	Mean value, the comparison method (mmol/L)	CV% (95% confidence interval)
<8	40	0	6,4	1,4 (1,1 – 1,7)
8 – 10	27	0	8,9	1,2 (0,9 – 1,7)
≥10	65	1**	13,2	1,3 (1,1 – 1,6)

*The given numbers of results (n) are counted before exclusion of outliers. Mean and CV are calculated after exclusion of outliers.
**One outlier (ID27) according to Burnett's model.

Discussion

The precision of the comparison method was good. The repeatability CV was approximately 1,3%.

5.1.3. The trueness of the comparison method

In order to demonstrate the trueness of the comparison method, the SRM 965a standards supplied by the National Institute of Standards & Technology, NIST, were analysed. The agreement between the comparison method and the NIST-standards is shown in table 6.

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

SRM 965a	Date	Certified glucose concentration mmol/L (uncertainty)	n	Mean value glucose (mmol/L)	% deviation from target value
Level 1	31.08.09	**1,918**	5	1,90	
	01.09.09	(1,898 — 1,938)	5	1,90	
	Total		**10**	**1,90**	**-0,9**
Level 2	31.08.09	**4,357**	5	4,35	
	01.09.09	(4,309 - 4,405)	5	4,37	
	Total		**10**	**4,36**	**+0,1**
Level 3	31.08.09	**6,777**	5	6,92	
	01.09.09	(6,704 — 6,850)	5	6,91	
	Total		**10**	**6,92**	**+2,1**
Level 4	31.08.09	**16,24**	5	16,88	
	01.09.09	(16,05 — 16,43)	5	17,05	
	Total		**10**	**16,97**	**+4,5**

Table 6 shows that the glucose results of the NIST-standards at level 3 and 4 at Architect ci8200 were slightly higher than the certified target values. The achieved results were just outside the uncertainty limits. All results from Architect are therefore adjusted according to the certified NIST-targets. The adjustment was carried out by means of inverse calibration [17, 18] by the following regression equation: **y = 0,948x + 0,182.**

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

To verify the trueness of the comparison method, freshly frozen, human serum controls, produced by SERO AS, with glucose concentrations at two levels were analysed. The agreement with target values from the Reference laboratory in Belgium is shown in table 7.

Table 7. Trueness of the comparison method

Control	Date	Target value glucose (mmol/L)	n	Mean value glucose (mmol/L)	% deviation from target value
TM Gluc L-1	31.08.09	4,78	5	4,78	
	02.09.09		5	4,78	
	Total		**10**	**4,78**	**0**
TM Gluc L-2	31.08.09	11,8	5	11,82	
	02.09.09		5	11,86	
	Total		**10**	**11,84**	**0**

Discussion

The trueness of the comparison method was good.

5.2. Analytical quality of Accu-Chek Mobile

5.2.1. Internal quality control

The Accu-Chek Mobile meters in the user evaluation were checked with the manufacturer's control solutions by the biomedical laboratory scientist. All results were within the control range given on the Accu-Chek Mobile test cassette cartons.
The raw data from the measurements with the internal quality control is shown in attachment 6.

5.2.2. The precision of Accu-Chek Mobile

Repeatability under standardised and optimal measuring conditions
The repeatability obtained under standardised and optimal conditions with capillary blood samples from the diabetes patients, is shown in table 8. The table gives the results from the biomedical laboratory scientist's measurements at the first and the final consultation together.

The raw data is shown in attachment 7.

Table 8. Repeatability, Accu-Chek Mobile. Results achieved by the biomedical laboratory scientist

Glucose level (mmol/L)	n*	Outliers	Accu-Chek Mobile mean (mmol/L)	CV% (95% confidence interval)
<8	37	0	6,5	2,6 (2,1 – 3,4)
8 – 10	35	0	9,0	2,3 (1,8 – 2,9)
≥10	60	1**	13,2	2,9 (2,5 – 3,6)

*The given numbers of results (n) are counted before exclusion of outliers. Mean and CV are calculated after exclusion of outliers.
**One outlier (ID58) according to Burnett's model.

Comments:
The results in table 8 are achieved under standardised and optimal conditions. One result was segregated as an outlier according to Burnett. The measuring procedure was carried out without any obvious or visible mistakes, and there were no error messages related to the measurements. The repeatability CV was <3%. The precision was good.

Repeatability obtained by the diabetes patients
The repeatability obtained by the diabetes patients with capillary blood samples is shown in table 9. The table gives the results from the measurements at the first and the second consultation for the "training group" and the results from the measurements at the consultation for the "mail group". The results obtained at home have a higher degree of uncertainty since it is impossible to check what has actually been done. The reporting of these home-values revealed that some of the diabetes patients did not quite understand the instruction on how to perform and report the five duplicate measurements they were supposed to carry out. The results obtained by the diabetes patients at home document their training efforts, but repeatability is not calculated on the basis of these results.

The raw data from the diabetes patients' measurements at NOKLUS is shown in attachment 8.
The raw data from the diabetes patients' measurements at home is shown in attachment 9.

Table 9. Repeatability, Accu-Chek Mobile. Results achieved by the diabetes patients

Consultation/ diabetic group	Glucose level (mmol/L)	n*	Outliers	Accu-Chek Mobile mean (mmol/L)	CV% (95% confidence interval)
1st/training group	<8	12	0	6,4	7,1 (5,0 – 11,8)
2nd/training group	<8	13	1**	6,5	2,4 (1,7 – 4,1)
The mail group	<8	11	0	6,5	3,1 (2,1 – 5,4)
1st/training group	8 – 10	7	0	8,8	4,6 (3,0 – 10,3)
2nd/training group	8 – 10	15	0	9,2	4,3 (3,1 – 6,8)
The mail group	8 – 10	13	0	9,0	4,9 (3,5 – 8,1)
1st/training group	≥10	25	0	13,1	4,0 (3,1 – 5,6)
2nd/training group	≥10	16	0	13,2	3,5 (2,6 – 5,4)
The mail group	≥10	20	0	13,3	2,6 (2,0 – 3,8)

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

**One outlier (ID56) according to Burnett's model.

Comments

The results in table 9 are achieved by the diabetes patients. One result was segregated as outliers according to Burnett. The measuring procedure was carried out without any obvious or visible mistakes, and there were no error messages related to the measurements.

The results achieved after three weeks of training tend to be better than at the first consultation. For glucose concentrations <8 mmol/L the improvement in repeatability is significant.

Reproducibility with Internal Quality Control Solution

The reproducibility is assessed with Accu-Chek Mobile Control 2. Artificially produced control materials have other matrix effects than whole blood, and may therefore give other results than results achieved with blood. The measurements are carried out on the biomedical laboratory scientists' meters during the whole evaluation period (three different lots of test cassettes). The reproducibility of Accu-Chek Mobile is shown in table 10.

Table 10. Reproducibility, Accu-Chek Mobile –. Results from the biomedical laboratory scientists' meters

Accu-Chek Mobile QC level	n*	Outliers	Target value (mmol/L)	Mean value glucose (mmol/L)	CV% (95% confidence interval)
2	130	0	8,2 – 11,1	9,7	3,3 (3,0 – 3,8)

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

Internal Quality Control on the diabetes patients' meters
The control measurements on the diabetes patients' meters (totally 88 meters) were performed with Accu-Chek Mobile Control 2. All the control measurements are performed by the biomedical laboratory scientist with the test cassettes that were distributed to each diabetes patient (three different lots of test cassettes). The control solutions were kept according to the instructions in the product insert through out the evaluation period.

The raw data from the measurements with the internal quality control is shown in attachment 6.

Table 11. Reproducibility, Accu-Chek Mobile. Results from the diabetes patients' meters

Accu-Chek Mobile QC level 2	n*	Outliers	Target value (mmol/L)	Mean value glucose (mmol/L)	CV% (95% confidence interval)
1st consultation					
The diabetes patients' meters	44	0	8,2 – 11,1	9,7	2,8 (2,3 – 3,6)
2nd consultation					
The diabetes patients' meters	87	0	8,2 – 11,1	9,6	3,7 (3,2 – 4,4)

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

Comments
The results of the internal quality control Accu-Chek Mobile Control 2 were inside the limits of the control.

Discussion, repeatability and reproducibility
The precision obtained under standardised and optimal conditions was good. The repeatability CV was <3%. A recommended quality goal for precision was obtained.
The precision achieved when the measurements were performed by the diabetes patients after three weeks at home, was good (CV was approximately 4%). The results achieved after three weeks of training tend to be better than at the first consultation. The Accu-Chek Mobile meter introduces a new procedure regarding applying blood onto a film with 50 test spots. The diabetes patients seem to need some time to get familiar with the new system.

The reproducibility on Accu-Chek Mobile under standardised and optimal conditions was good when measured with Accu-Chek Mobile Control 2. The CV was approximately 3%. The reproducibility CV obtained with measurements on the diabetes patients' meters was approximately 3% at the first consultation and approximately 4% at the second consultation.

5.2.3. The trueness of Accu-Chek Mobile

The trueness of Accu-Chek Mobile is calculated from the results achieved by the biomedical laboratory scientist at the final consultation (the "training group" and the "mail group"). The calculations are based on measurements on the biomedical laboratory scientist's meters and the results are shown in table 12. The measurements are performed with three lots of test cassettes.

Table 12. Trueness of Accu-Chek Mobile.

	<8 mmol/L		8 – 10 mmol/L		≥10 mmol/L	
	The comparison method	Accu-Chek Mobile	The comparison method	Accu-Chek Mobile	The comparison method	Accu-Chek Mobile
Mean glucose (mmol/L)	6,3	6,6	8,8	9,1	13,1	13,2
Mean deviation from the comparison method, mmol/L (95% CI)	0,30 ((+0,18) — (+0,43))		0,24 ((+0,06) — (+0,42))		0,08 ((-0,16) — (+0,31))	
n*	24		26		36	
Outliers	0		0		0	

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

Discussion

Table 12 shows a small, but statistical significant bias between Accu-Chek Mobile and the comparison method at two of the three concentrations levels. For glucose levels <10 mmol/L, Accu-Chek Mobile gave significantly higher values than the comparison method. For glucose levels >10 mmol/L, Accu-Chek Mobile showed agreement with the comparison method.

5.2.4. The accuracy of Accu-Chek Mobile

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

The accuracy, Accu-Chek Mobile, with three lots of test cassettes, under standardised and optimal measuring conditions, at the final consultation is shown in figure 2.

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

The accuracy is summarised in table 13 and discussed afterwards.

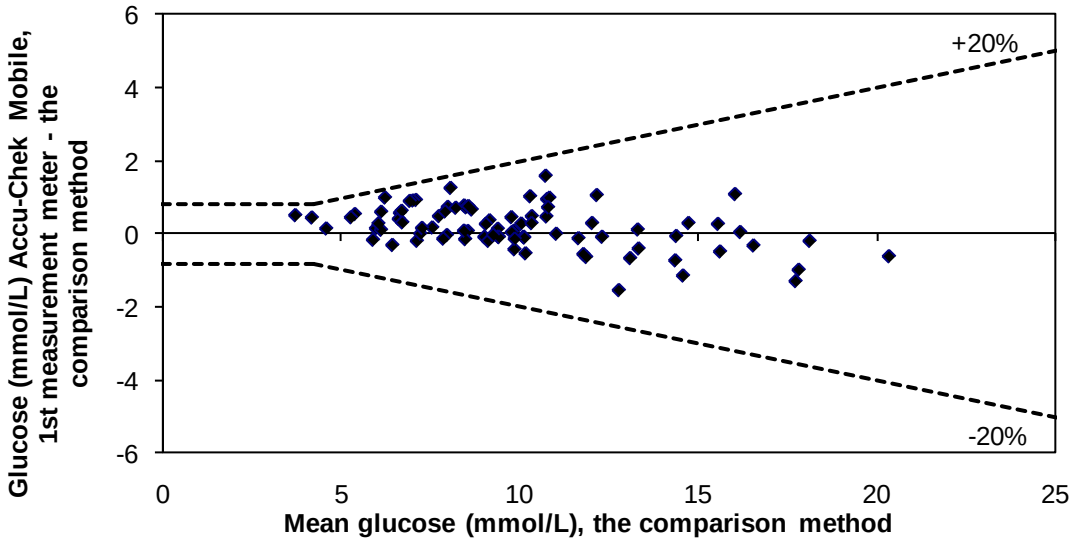

Figure 2. Accuracy. Accu-Chek Mobile with three lots of test strips under standardised and optimal measuring conditions at the final consultation. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on Accu-Chek Mobile and the mean value of the duplicate results on the comparison method. Lines represent limits suggested in ISO 15197 [±20%], n = 86

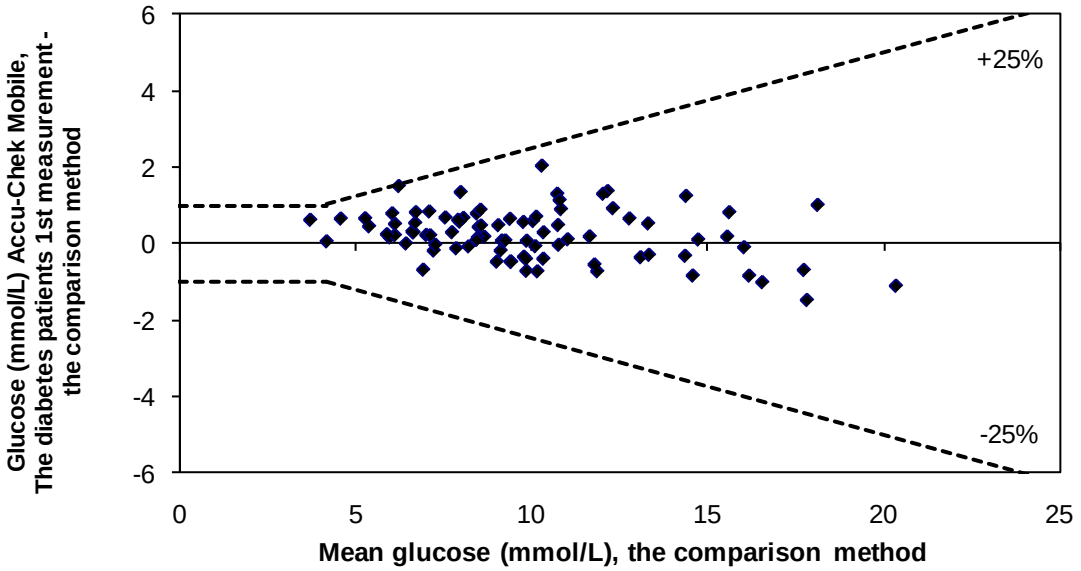

Figure 3. Accuracy. The diabetes patients' self-measurements at the final consultation. Three lots of test strips. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on Accu-Chek Mobile and the mean value of the duplicate results on the comparison method. Lines represent modified ISO limits suggested by NOKLUS [±25%], n = 86

Table 13. Total error of Accu-Chek Mobile results compared to the comparison method. Percentage Accu-Chek Mobile results within the limits

Measure performed by	Cons.	Accu-Chek Mobile	n	Number of results within the limits (%)			Shown in figure
				ADA <±10%	**ISO** <±20% and <±0,83 mmol/L at conc. ≤4,2	**"Adjusted ISO"** <± 25% and <±1,0 mmol/L at conc. ≤4,2	
Biomedical laboratory scientist	1st	1st measurement	44	68	93		
	2nd	1st measurement	86	87	100		2
Diabetes patients at NOKLUS	1st	1st measurement	44	73	93	98	
	2nd	1st measurement	86	84	99	100	3

Discussion

Figure 2 and 3 show that the Accu-Chek Mobile results are slightly higher than the comparison method for glucose concentrations <10 mmol/L. The summing up in table 13 shows that 100% of the results achieved under optimal measuring conditions at consultation 2, were within the quality limits proposed in ISO 15197. For the diabetes patients the correspondingly result was 99%. The accuracy was good and the quality goal was attained.

5.3. Variation between three lots of test strips

The measurements were performed with three different lots of test cassettes. The three lots were distributed randomly among the patients. One test cassette with 50 test spots was used per patient. The deviation from the comparison method for each of the three lots was calculated (paired t-test), as an indirect measure of the lot variation. Obviously, the mean glucose concentration in different groups of diabetes patients is not identical, and therefore the results achieved with the three different lots can not be used directly as a measure of the inter-lot-variation.

For the calculation of lot variation, the 86 results were sorted according to the lot of test cassettes. To keep a sufficient number of results in each group, the deviation of each lot must then be calculated for the whole concentration range together.

The results are shown in table 14.

Table 14. Variation between three lots of test cassettes.

	The comparison method	Accu-Chek Mobile Lot 27700239	The comparison method	Accu-Chek Mobile Lot 29685031	The comparison method	Accu-Chek Mobile Lot 2770333
Mean glucose (mmol/L)	10,2	10,5	9,5	9,9	9,7	9,6
Mean deviation from the comparison method, mmol/L (95% CI)	+0,36 ((+0,18) — (+0,54))		+0,39 ((+0,24) — (+0,55))		-0,12 ((-0,32) — (+0,07))	
n*	28		29		29	
Outliers	0		1**		0	

*The given numbers of results (n) are counted before exclusion of outliers
**One outlier (ID61) according to Burnett's model.

Discussion
Lot 2770333 gave glucose results in agreement with the comparison method. Lot 27700239 and lot 29685031 gave significantly higher glucose values than the comparison method. The deviation is small and did not affect the achievement of the quality goal proposed in ISO 15197.

5.4. Effect of hematocrit

The product insert of the Accu-Chek Mobile test cassette states that glucose measurements are not influenced by hematocrit values from 25 to 55%. To measure the effect of hematocrit on Accu-Chek Mobile, a hematocrit sample was taken of the diabetes patients at the second consultation. The investigation of the effect of hematocrit is based on the measurements on Accu-Chek Mobile meters (three lot of test cassettes) under standardised and optimal measuring conditions. The glucose concentration range in the samples was 3,7 – 20,3 mmol/L. The hematocrit range was 27 – 49%.

The effect of hematocrit is shown in figure 4. The x-axis in the plot shows the hematocrit value in percentage and the y-axis shows the difference in glucose concentration between Accu-Chek Mobile and the comparison method (Accu-Chek Mobile - the comparison method) in mmol/L. The trend-line is shown in the figure.

The raw data is shown in attachment 10.

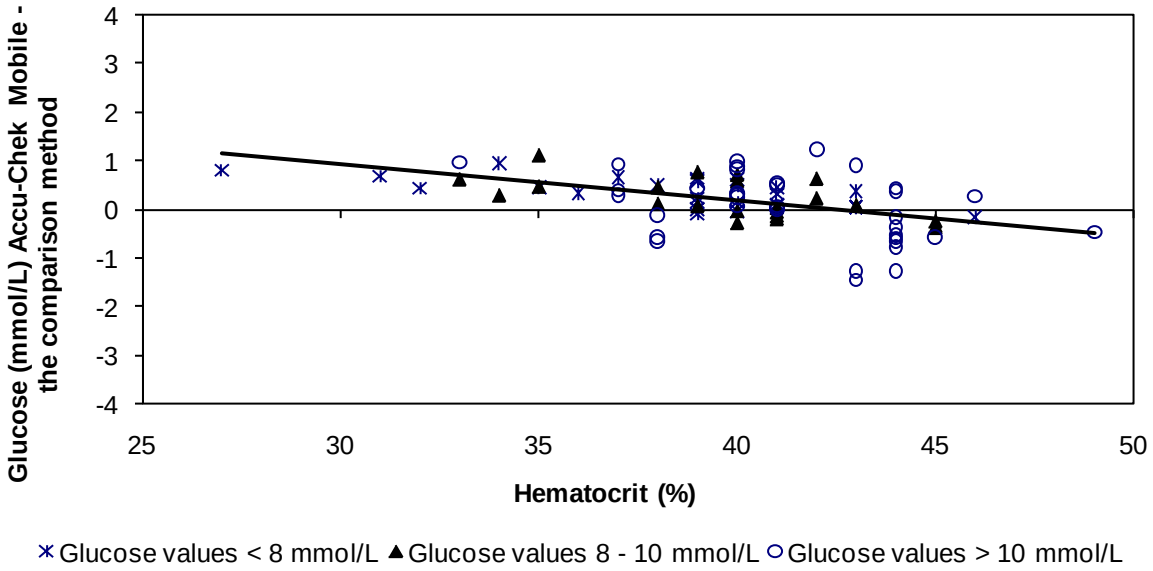

Figure 4. The effect of hematocrit on glucose measurements on Accu-Chek Mobile measured under standardised and optimal conditions. The x-axis shows the hematocrit value in percent. The y-axis shows the difference in glucose concentration between Accu-Chek Mobile and the comparison method (Accu-Chek Mobile – the comparison method) in mmol/L, n= 84.

Discussion

Glucose measurements on Accu-Chek Mobile seem to be affected by the hematocrit values of the samples. The trend line in figure 4 shows that the glucose measurements on Accu-Chek Mobile are overestimated when hematocrit is in the lower part of the reference range, and underestimated when hematocrit is in the upper part of the reference range. The effect of hematocrit does not seem to be related to the glucose concentration. Hematocrit outside the range 27 – 49% has not been tested.

5.5. Practical points of view

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

Questionnaires
87 of the 88 diabetes patients filled in a questionnaire about the user-friendliness and a questionnaire about the user guide of Accu-Chek Mobile when they attended the final consultation. The biomedical laboratory scientist was available for clarifying questions, and there was room for free comments. The questionnaires about the user-friendliness and user guide are attached to the report (in Norwegian), see attachment 11 and 12.

5.5.1. Evaluation of the user-friendliness of Accu-Chek Mobile

The questionnaire about the user-friendliness was made up of ten questions concerning Accu-Chek Mobile. Table 15 summarizes seven questions where the diabetes patients were asked to rank the answers on a scale from 1 to 6, where 1 is difficult and 6 is simple.

The mean score is 5,3 on the questions about inserting a test cassette, hearing the sound signal and filling the test spot with blood. This indicates that the diabetes patients seemed satisfied with these three procedures. The mean score is 4,8 on the question about opening the tip cover, and this indicates that some of the participants thought it was a bit difficult. The mean score is 5,9 on the question about reading the figures in the display. The mean score is 4,8 on the question about operating the meter, all in all. Regarding FastClix Mobile lancet pen the mean score is 5,1, but 23 percent of the diabetes patients did not answer this question. The diabetes patients that used the pen were satisfied with it.

Table 15. Accu-Chek Mobile - Questions about the meter

Questions about Accu-Chek Mobile		Total number	Range	Mean score	No answer (% of total)
How will you rank the following questions on a scale from 1 to 6, where 1 is difficult and 6 is simple	To insert a test cassette into the meter	87	1 - 6	5,3	2
	To open the tip cover	87	1 - 6	4,8	2
	To hear the sound signal	87	1 - 6	5,3	2
	To fill the test spot with blood	87	1 - 6	5,3	1
	To read the figures in the display	87	1 - 6	5,9	1
	All in all, to operate the meter	87	1 - 6	4,8	1
	To operate the FastClix Mobile lancet pen	87	1 - 6	5,1	23

The diabetes patients were asked if they had any positive and/or negative comments about Accu-Chek Mobile.

Positive comments
64 diabetes patients reported one or more advantages with Accu-Chek Mobile. The most often reported advantages are distinctly grouped as follows:

1. All in one (27)
2. Easy to use (20)
3. The test cassette contains several test spots (17)
4. Readable display (7)
5. The meter has short measuring time (4)
6. Hygienic to work with (3)

Negative comments
48 diabetes patients reported one or more disadvantages with Accu-Chek Mobile. The most often reported disadvantages are distinctly grouped as follows:

1. The device/etui/lancet pen: too big, too heavy, too lumpy (33)
2. Different problems with the lancet pen (10); the pen is not good, it is difficult to adjust the depth of the puncture, the pen do not prick deep enough
3. The tip cover is too hard and difficult to open (8)
4. The device is unmanageable and inconvenient (4)

Table 16 shows the answers regarding technical problems with Accu-Chek Mobile. Eight of the diabetes patients (9%) answered that they had technical problems with the meter during the testing period. Two of them had problems regarding the lancet pen and not the meter. One patient had problems with opening the tip cover. Two patients got several E3 errors. Other written comments indicate that the problems were not technical ones after all, but were problems related to the test cassettes and the measurements.

Table 16. Accu-Chek Mobile – Questions about the meter

Question about Accu-Chek mobile	Total number	Yes (%)	No (%)	No answer (%)
Did you have any technical problems with the meter during the testing period?	87	9	82	9

5.5.2. Evaluation of the Accu-Chek Mobile user guide

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

Table 17 shows that 84% of the diabetes patients had used the guide. Two of the diabetes patients who had used the guide answered that he/she was not satisfied with the description of how to perform a blood glucose measurement with the meter. Two of the diabetes patients thought the guide had essential shortcomings; but he/she didn't write what was missing. Several of the diabetes patients had general comments about the user guide; the guide is too large, it contains complicated descriptions, too many pictures and figures, and the guide is too comprehensive. In spite of these comments, most of them were satisfied with the user guide.

Table 17. Accu-Chek Mobile – Questions about the user guide

Questions about the user guide	Number	Yes (%)	No (%)	No answer (%)
Have you been reading in the user guide?	87	84	16	0
If yes, did you read the entire user guide?	73	34	59	7
And/or did you consult the user guide when needed?	73	75	11	14
Are you satisfied with the description of how to perform a blood glucose measurement with the meter?	73	97	3	0
Do you think the user guide has essential shortcomings?	73	3	95	2
All in all, are you satisfied with the user guide?	73	90	7	3

5.5.3. The biomedical laboratory scientists' evaluation

Positive comments:

- The meter is easy to operate
- No coding
- The figures is easy to read
- Waste is produced only when changing the test cassette and the lancet drum
- Short measuring time
- The test spot requires a small blood sample volume, and it is easy to apply the blood onto the spot
- Accu-Chek Fastclix Mobile lancet pen has six lancets available in a preloaded drum, and the preloaded drum cause no hazardous waste
- The Accu-Chek Mobile manual has fine informative illustrations

Negative comments:

- Large and heavy
- The tip cover is too hard to open. Several of the participants had problems with the tip cover, especially older people with weak eyesight and little strength in the fingers. Some of the participants, who received the system by mail, did not get the system to work because they had problems opening the tip cover properly
- Accu-Chek Mobile has too complicated menu for older people
- The etui was not well fitted. It was too big in proportion to the size of the system. Black colour makes it difficult to find the etui in a messy handbag
- Accu-Chek FastClix Mobile lancet pen was to "kind". It was difficult to adjust the depth of the puncture because of inertia of the cap
- The Accu-Chek Mobile manual is too extensive. Some of the participants got frustrated of all the information in the illustrations

6. References

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Attachments

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

Attachments with raw data are included only in the report to Roche Diagnostics.

Fakta om instrumentet

a) Navn på instrument	**Accu-Chek Mobile**
Fysiske dimensjoner	bredde: 66 dybde: 28 høyde: 123 mm
Produsent	Roche Diagnostics Gmbh 68298 Mannheim Germany
Forhandler	**Danmark:** Roche A/S Industriholmen 59 2650 Hvidovre-Copenhagen Denmark
	Norge: Roche Diagnostics Norge Brynsengfaret 6 B P.O.Box 6610 Etterstad NO-0607 OSLO
	Sverige: Roche Diagnostics Scandinavia AB Box 147 S-161 26 Bromma

b) Analysemeny, prøvemateriale og analysevolum

Komponent	Prøvemateriale	Analysevolum
Glukose	Kapillært fullblod	Ca. 0,3 µL

c)Analyseprinsipp

Komponent: Glukose
Glukose i blodprøven reagerer med reagensene på testfeltet, og det produseres en farge som avleses reflektometrisk (glukose-dye-oksidoreduktasemediator-reaksjon).

d) Analyseområde

Komponent	Analyseområde	Benevning
Glukose	0,6 – 33,3	mmol/L

e) Tid for analysering pr. komponent

Komponent	Preanalysetid	Analysetid
Glukose	Ca. 1 minutt: klargjøre stikkeredskap, ta en kapillær blodprøve, tørke vekk første dråpe.	Ca. 5 sek

f) Kalibrering

Mulighet for kalibrering	❑ Ja x Nei
Hvor ofte anbefales kalibrering?	Apparatet kalibreres (kodes) automatisk via RFID merkelapp på testkassettens overflate.
Antall standarder	-
Hvem skal utføre kalibrering	-

g) Anbefalt vedlikehold

Hva gjøres	Hvor ofte
Rengjøring utside og innside av apparatet ved å tørke med fuktig duk/vattpinne med kaldt vann eller med 70 % etanol.	Ved behov

h) Kontrollmateriale

Finnes det kontrollmateriale fra leverandør eller andre? Accu-Chek Mobile Control på 2 nivå (normal og høy).

i) Markedsføring

I hvilke land er instrumentet markedsført?	x Skandinavia (kun Danmark) x Europa x Globalt
Når kom instrumentet på det Skandinaviske markedet?	Lansert i Danmark vår 2009
Når ble instrumentet CE-godkjent?	CE0088 13.januar 2009.

j) Språk

Hvilke skandinaviske språk er manualen på? x Dansk x Norsk x Svensk

k) Minne

Hvor stor lagringskapasitet har instrumentet og hva lagres?

500 måleresultater med klokkeslett og dato

Er der mulighet for pasientidentifikasjon? ❑ Ja x Nei

Hvis ja, beskriv dette:

l) Strømforsyning

El-nett tilkobling	❑ Ja x Nei
Batteri	x Ja ❑ Nei
Hvis ja, hvilken type og hvor mange batteri	2 stk 1,5V AAA, LR03, AM4 eller mikro. 1 stk 3V Li-knappcelle CR1025

a) Navn på instrument	Accu-Chek Mobile

m) Elektronisk kommunikasjon

Kan printer kobles til instrumentet?	❑ Ja x Nei
Kan barkodeleser kobles til instrumentet?	❑ Ja x Nei
Interface	x Ja ❑ Nei
Hvis ja, hvilken utgang kreves?	Infrarødt grensesnitt
Kommunikasjonsmåte	x enveis ❑ toveis
Overføringsmåte	❑ filoverføring x serielloverføring ❑ ethernet
Overføringsprotokoll	❑ ASDM standard x annen protokoll

n) Standarder og kontroller

	Standard	Kontroll
Navn		Accu-Chek Mobile Control 1 og 2
Volum		Ca. 0,5 µL
Holdbarhet uåpnet		Til utløpsdato notert under flasken
Holdbarhet åpnet		Brukes straks etter åpning av flasken
Evt. kommentarer: Kontrollene kommer i applikatorflasker til engangsbruk.		

o) Reagenser

Komponent	Tid og temperatur, uåpnet	Tid og temperatur, åpnet
Glukose, Accu-Chek Mobile testkassett med 50 testfelt	Til utløpsdato på forpakning (18 mnd fra produksjonsdato), +2 til +30 °C	3 mnd, +2 til +30 °C
Evt. kommentarer: Apparatet sperrer for bruk av utgåtte tester, og meldingen" Holdbarhetsfrist overskredet. Sett inn ny testkassett." kommer opp på skjermen når testene er gått ut på dato. For å minne brukeren på å sørge for å få tak i nye testkassetter kommer følgende melding opp på skjermen 10 dager før holdbarheten går ut: "Kassetten er holdbar i 10 dager til".		

p) Tilleggsopplysninger

Attachment 2

Serial numbers, Accu-Chek Mobile blood glucose meters used by the diabetes patients and by the laboratory scientist

ID	Serial number	
	Diabetes patients	Laboratory scientist
1	U800132829	U800133852
2	U800134205	U800132541
3	U800134205	U800133875
4	U800132823	U800133596
5	U800134212	U800134192
6	U800134188	U800133870
7	U800133975	U800133543
8	U800133118	U800133873
9	U800133265	U800134098
10	U800133603	U800133727
11	U800133382	U800133717
12	U800133983	U800133759
13	U800132627	U800133760
14	U800133026	U800133595
15	U800132855	U800133541
16	U800132971	U800133143
17	U800132852	U800134099
18	U800133022	U800133600
19	U800133021	U800133592
20	U800132595	U800133588
21	U800132861	U800133854
22	U800131632	U800133860
23	U800132592	U800133858
24	U800133023	U800133986
25	U800132620	U800132719
26	U800132621	U800134254
27	U800132845	U800134203
28	U800132723	U800133874
29	U800132208	U800133968
30	U800132212	U800133276
31	U800133141	U800132830
32	U800133125	U800133209
33	U800133159	U800133129
34	U800133138	U800133117
35	U800133851	U800133969
36	U800131452	U800133223
37	U800132854	U800133114
38	U800133264	U800133376
39	U800133853	U800133384
40	U800133110	U800133219
41	U800133453	U800133447
42	U800133378	U800133278
43	U800133144	U800133457
44	U800133454	U800133383

ID	Serial number	
	Diabetes patients	Laboratory scientist
45	U800133868	U800133277
46	U800133465	U800133608
47	U800133610	U800133355
48	U800133862	U800133462
49	U800133605	U800133444
51	U800132738	U800133863
52	U800132936	U800133274
53	U800132939	U800133354
54	U800132736	U800133356
55	U800132629	U800132827
56	U800132727	U800133357
57	U800132726	U800133966
58	U800132739	U800133272
59	U800132934	U800133604
60	U800132942	U800132944
61	U800132643	U800132650
62	U800132648	U800132647
63	U800132642	U800132643
64	U800132639	U800132641
65	U800132635	U800132640
66	U800132653	U800132594
67	U800132672	U800132668
68	U800132673	U800132671
69	U800132676	U800132679
70	U800132677	U800132674
71	U800132730	U800132696
72	U800132732	U800132702
73	U800132718	U800132703
74	U800132688	U800132708
75	U800132694	U800132706
76	U800132687	U800132695
77	U800132712	U800132698
78	U800132716	U800132690
79	U800132593	U800132685
80	U800132704	U800132692
81	U800132720	U800132968
82	U800132964	U800132276
83	U800132725	U800132734
84	U800132812	U800132597
85	U800132728	U800132973
86	U800132243	U800132807
87	U800132729	U800132805
88	U800132623	U800132806
89	U800132965	U800132970

NORSK KVALITETSFORBEDRING AV
LABORATORIEVIRKSOMHET UTENFOR SYKEHUS

NOKLUS

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

«ID-nr.» flettes inn

Mars 2009

Utprøving av blodsukkerapparat

Du har fått utlevert:

- 1 Accu-Chek Mobile blodsukkerapparat i etui.
- 1 pakke Accu-Chek Mobile testkassett (50 testfelt for glukosemåling)
- 1 Accu-Chek FastClix Mobile blodprøvetaker (er tilkoblet på siden av apparatet).
- 9 Accu-Chek Fast Clix lansettromler á 6 lansetter.
- Brukerveiledning

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

1. og 2. uke:
De to første ukene skal benyttes til å bli kjent med apparatet. I løpet av disse to ukene skal du bruke ca. 25 testfelt til å måle ditt eget blodsukker med utprøvingsapparatet. Du kan selv velge når på dagen du vil gjøre disse målingene (du trenger ikke være fastende). Passer det best slik, kan du utføre blodsukkermålingen med utprøvingsapparatet samtidig som du måler med ditt vanlige apparat. Dersom du ønsker det, kan du benytte ditt eget utstyr for prøvetaking i stedet for Accu-Chek Mobile FastClix prøvetakingspenn.

3. uke:
Etter at du har brukt de 25 første testfeltene, 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-nummer teststrimler» flettes inn
«Serie-nummer apparat» flettes inn

Dato	Accu-Chek Mobile Svar 1 (mmol/L)	Accu-Chek Mobile 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 Accu-Chek Mobile FastClix prøvetakingspenn til prøvetakingen?

☐Ja ☐Nei ☐Noen ganger

Av de 50 testfelt du fikk sammen med apparatet, skal du nå ha ca. 15 testfelt igjen. Du må spare fem av testfeltene til målingene du skal gjøre når du kommer til laboratoriet ved Moss Sykehus for den avsluttende utprøvingen. Til den avsluttende utprøvingen skal du ta med dette skjemaet, Accu-Chek Mobile med testkassetten i og Accu-Chek Mobile FastClix 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:
Torny Bjerketvedt Tlf.nr.:69861509 (kontor i Fr.stad) Dagtid: kl. 09-15
Mobil: 48290731
E-post: torny.bjerketvedt@so-hf.no

Lykke til!

Med vennlig hilsen

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

Torny Bjerketvedt (sign.)
Bioingeniør SKUP/Noklus

Attachment 4

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

Date	Res. Autonorm 1 glucose, mmol/L	Res. Autonorm 2 glucose, mmol/L
31.08.09	3,46	15,07
31.08.09	3,50	15,35
01.09.09	3,45	14,99
01.09.09	3,48	15,26
02.09.09	3,42	14,99
02.09.09	3,52	15,26

Attachment 6

Raw data glucose, internal quality control, Accu-Chek Mobile

Accu-Chek Mobile	Lot-no	Expiry	Glucose level mmol/L
Control 2	22470001	2010-01	8,2 – 11,1

Accu-Chek Mobile Control 2 analysed on the biomedical laboratory scientist's meters Trained group

ID	Date	1st consultation Accu-Chek Mobile, glucose mmol/L	Date	2nd consultation Accu-Chek Mobile, glucose mmol/L
2	23. mar 2009	9,6	14. apr 2009	9,5
3	23. mar 2009	9,6	14. apr 2009	9,2
6	2. apr 2009	10,3	22. apr 2009	9,3
7	2. apr 2009	9,8	21. apr 2009	9,7
8	2. apr 2009	9,7	16. apr 2009	9,7
16	23. mar 2009	9,7	16. apr 2009	10,0
18	23. mar 2009	9,9	14. apr 2009	10,0
19	23. mar 2009	9,6	14. apr 2009	9,5
20	24. mar 2009	9,4	14. apr 2009	9,9
22	24. mar 2009	10,0	15. apr 2009	10,0
25	26. mar 2009	10,3	22. apr 2009	9,8
30	30. mar 2009	9,5	21. apr 2009	10,1
33	31. mar 2009	9,5	28. apr 2009	9,5
35	23. mar 2009	9,3	16. apr 2009	8,8
39	23. mar 2009	9,8	14. apr 2009	9,7
43	24. mar 2009	9,7	14. apr 2009	10,1
46	24. mar 2009	9,9	15. apr 2009	9,8
47	24. mar 2009	9,9	15. apr 2009	10,0
51	26. mar 2009	9,8	16. apr 2009	9,5
52	31. mar 2009	9,5	21. apr 2009	9,5
54	26. mar 2009	9,7	16. apr 2009	8,9
56	30. mar 2009	10,0	20. apr 2009	9,3
58	23. mar 2009	10,8	16. apr 2009	9,9
59	26. mar 2009	9,5	16. apr 2009	8,8
61	26. mar 2009	10,0	15. apr 2009	9,4
62	30. mar 2009	9,7	20. apr 2009	9,9
63	26. mar 2009	9,4	16. apr 2009	9,5
64	23. mar 2009	9,8	14. apr 2009	9,8
65	24. mar 2009	9,9	15. apr 2009	9,7
66	24. mar 2009	10	15. apr 2009	9,4
69	26. mar 2009	9,8	16. apr 2009	9,2
70	30. mar 2009	9,1	20. apr 2009	10,2
72	30. mar 2009	9,8	20. apr 2009	9,8
73	30. mar 2009	9,5	20. apr 2009	9,0
74	30. mar 2009	9,9	20. apr 2009	9,9
75	30. mar 2009	9,7	20. apr 2009	9,9
77	2. apr 2009	9,8	22. apr 2009	10,0
78	2. apr 2009	10,2	22. apr 2009	9,5
80	15. apr 2009	9,7	6. mai 2009	9,5
83	1. apr 2009	9,8	22. apr 2009	9,8
84	31. mar 2009	9,4	21. apr 2009	9,9
85	30. mar 2009	9,8	20. apr 2009	10,0
86	31. mar 2009	9,6	21. apr 2009	9,8
89	2. apr 2009	9,9	22. apr 2009	9,9

Accu-Chek Mobile Control 2 analysed on the biomedical laboratory scientist's meters
Mail group

ID	Date	2nd consultation Accu-Chek Mobile, glucose mmol/L
1	28. apr 2009	9,4
4	27. apr 2009	10,1
5	5. mai 2009	10,0
9	6. mai 2009	9,5
10	25. mai 2009	9,7
11	28. apr 2009	9,8
12	27. apr 2009	10,0
13	25. mai 2009	9,3
14	6. mai 2009	9,8
15	5. mai 2009	9,8
17	25. mai 2009	9,4
21	28. apr 2009	9,4
23	28. apr 2009	10,0
24	28. apr 2009	9,4
26	19. mai 2009	9,6
27	27. apr 2009	9,3
28	28. apr 2009	9,0
29	27. apr 2009	No result
31	5. mai 2009	10,0
32	6. mai 2009	10,0
34	28. apr 2009	9,0
36	20. mai 2009	9,6
37	28. apr 2009	9,5
38	5. mai 2009	9,3
40	5. mai 2009	9,5
41	19. mai 2009	9,7
42	6. mai 2009	10,0
44	5. mai 2009	8,9
45	15. mai 2009	9,9
48	6. mai 2009	9,5
49	6. mai 2009	9,7
53	28. mai 2009	9,2
55	19. mai 2009	9,5
57	28. mai 2009	10,0
60	20. mai 2009	9,8
67	19. mai 2009	9,8
68	19. mai 2009	No result
71	5. mai 2009	9,5
76	19. mai 2009	9,9
79	19. mai 2009	9,5
81	19. mai 2009	9,4
82	19. mai 2009	9,7
87	19. mai 2009	9,4
88	28. mai 2009	9,9

Accu-Chek Mobile Control 2 analysed on the diabetes patients' meters
Trained group

ID	Date	1st consultation Accu-Chek Mobile, glucose mmol/L	Date	2nd consultation Accu-Chek Mobile, glucose mmol/L
2	23. mar 2009	9,4	14. apr 2009	9,3
3	23. mar 2009	9,5	14. apr 2009	9,7
6	2. apr 2009	9,8	22. apr 2009	9,5
7	2. apr 2009	9,2	21. apr 2009	9,3
8	2. apr 2009	9,7	16. apr 2009	9,5
16	23. mar 2009	9,9	16. apr 2009	10
18	23. mar 2009	9,6	14. apr 2009	9,3
19	23. mar 2009	9,4	14. apr 2009	9,3
20	24. mar 2009	9,6	14. apr 2009	9,8
22	24. mar 2009	10,0	15. apr 2009	No result
25	26. mar 2009	9,6	22. apr 2009	10,4
30	30. mar 2009	9,7	21. apr 2009	9,5
33	31. mar 2009	9,5	28. apr 2009	8,7
35	23. mar 2009	9,3	16. apr 2009	8,9
39	23. mar 2009	9,7	14. apr 2009	9,7
43	24. mar 2009	10,0	14. apr 2009	10,0
46	24. mar 2009	9,9	15. apr 2009	9,7
47	24. mar 2009	9,9	15. apr 2009	9,7
51	26. mar 2009	9,8	16. apr 2009	9,0
52	31. mar 2009	9,8	21. apr 2009	9,4
54	26. mar 2009	9,5	16. apr 2009	10,1
56	30. mar 2009	10,0	20. apr 2009	9,7
58	23. mar 2009	9,8	16. apr 2009	10,0
59	26. mar 2009	9,5	16. apr 2009	8,7
61	26. mar 2009	9,5	15. apr 2009	9,0
62	30. mar 2009	9,9	20. apr 2009	9,7
63	26. mar 2009	9,5	16. apr 2009	9,4
64	23. mar 2009	10,1	14. apr 2009	9,8
65	24. mar 2009	10,0	15. apr 2009	9,8
66	24. mar 2009	9,7	15. apr 2009	9,5
69	26. mar 2009	9,3	16. apr 2009	9,2
70	30. mar 2009	9,9	20. apr 2009	9,1
72	30. mar 2009	9,8	20. apr 2009	9,9
73	30. mar 2009	8,9	20. apr 2009	9,5
74	30. mar 2009	10,3	20. apr 2009	10,0
75	30. mar 2009	9,8	20. apr 2009	9,5
77	2. apr 2009	9,9	22. apr 2009	10,2
78	2. apr 2009	9,7	22. apr 2009	9,3
80	15. apr 2009	9,3	6. mai 2009	9,6
83	1. apr 2009	9,9	22. apr 2009	10,0
84	31. mar 2009	9,9	21. apr 2009	9,7
85	30. mar 2009	9,9	20. apr 2009	9,2
86	31. mar 2009	9,4	21. apr 2009	9,4
89	2. apr 2009	9,8	22. apr 2009	9,7

Accu-Chek Mobile Control 2 analysed on the diabetes patients' meters Mail group

ID	Date	2nd consultation Accu-Chek Mobile, glucose mmol/L
1	28. apr 2009	9,8
4	27. apr 2009	9,6
5	5. mai 2009	9,3
9	6. mai 2009	10,0
10	25. mai 2009	9,8
11	28. apr 2009	9,4
12	27. apr 2009	9,3
13	25. mai 2009	9,9
14	6. mai 2009	9,7
15	5. mai 2009	9,8
17	25. mai 2009	9,4
21	28. apr 2009	9,0
23	28. apr 2009	9,7
24	28. apr 2009	9,9
26	19. mai 2009	9,7
27	27. apr 2009	9,0
28	28. apr 2009	9,1
29	27. apr 2009	9,9
31	5. mai 2009	9,8
32	6. mai 2009	9,2
34	28. apr 2009	9,5
36	20. mai 2009	9,0
37	28. apr 2009	9,4
38	5. mai 2009	9,7
40	5. mai 2009	9,4
41	19. mai 2009	9,6
42	6. mai 2009	9,9
44	5. mai 2009	8,9
45	15. mai 2009	9,5
48	6. mai 2009	9,9
49	6. mai 2009	9,7
53	28. mai 2009	9,8
55	19. mai 2009	10,0
57	28. mai 2009	9,4
60	20. mai 2009	9,0
67	19. mai 2009	10,0
68	19. mai 2009	9,2
71	5. mai 2009	9,6
76	19. mai 2009	9,8
79	19. mai 2009	10,0
81	19. mai 2009	9,7
82	19. mai 2009	9,7
87	19. mai 2009	9,2
88	28. mai 2009	9,9

ID-nummer (diabetiker):_____

Accu-Chek Mobile

Spørreskjema om blodsukkerapparatets brukervennlighet

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

1. Å sette testkassetten inn i apparatet

Vanskelig *Enkelt*

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

2. Å åpne beskyttelsesluken

Vanskelig *Enkelt*

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

3. Å oppfatte lydsignalet

Vanskelig *Enkelt*

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

4. Å fylle blod på testfeltet

Vanskelig *Enkelt*

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

5. Å lese tallene i displayet

Vanskelig *Enkelt*

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

6. Å betjene apparatet, totalt sett

Vanskelig *Enkelt*

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

Snu arket

Accu-Chek Mobile

7. Å betjene Accu-Chek FastClix Mobile blodprøvetaker (skal kun besvares hvis Accu-Chek FastClix Mobile blodprøvetaker er benyttet i utprøvingen)

Vanskelig *Enkelt*

1 2 3 4 5 6

☐ ☐ ☐ ☐ ☐ ☐

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

Hvis ja, kan du beskrive problemet/ene:_____

_____

_____

9. Synes du det er noen fordeler med Accu-Chek Mobile?

- _____
- _____
- _____

10. Synes du det er noen ulemper med Accu-Chek Mobile?

- _____
- _____
- _____

Evt. andre kommentarer:_____

_____

_____

_____

ID-nummer (diabetiker):_____

Accu-Chek Mobile

Spørreskjema om brukerveiledning til apparatet

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

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

Hvis du svarer ja:

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

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

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

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

   _____

   _____

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

   Hvis ja, kan du beskrive hva som mangler: _____

   _____

   _____

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

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

   _____

   _____

   Evt. andre kommentarer:_____

   _____

   _____

SKUP-info

Accu-Chek Mobile blodsukkerapparat fra Roche Diagnostics
Sammendrag fra en utprøving i regi av SKUP

Konklusjon
Presisjonen på Accu-Chek Mobile var god. CV var ca. 2,5 % når målingene ble utført av laboratorieutdannet personale, og rundt 5 % når målingene ble utført av personer med diabetes (brukerne). Målingene i denne utprøvingen oppfylte internasjonale kvalitetskrav (ISO 15197) med et avvik på mindre enn ± 20 % fra en anerkjent glukosemetode. Hematokrit så ut til å påvirke glukosemålingene på Accu-Chek Mobile i mindre grad. Accu-Chek Mobile er beregnet til egenmåling av glukose. Systemet er ikke egnet til profesjonell bruk innen helsevesenet pga infeksjonsfaren som kan oppstå hvis blodsukkerapparatet brukes av mer enn en person.

Accu-Chek Mobile er beregnet til egenmåling av glukose. Målesystemet består av apparatet Accu-Chek Mobile, Accu-Chek FastClix lansettpenn som er festet til apparatet og Accu-Chek Mobile testkassetter. Hver testkassett inneholder en analysefilm med 50 målepunkt. Apparatet trenger ikke kodes. Måling av glukose starter kun når korrekt mengde blod er tilført målepunktet på analysefilmen. Det kreves 0,3 µL blod til hver måling. Målingen tar 5 sekunder. Accu-Chek Mobile har minnekapasitet til å lagre 500 målinger med dato og klokkeslett. Resultatene kan overføres til PC ved bruk av programvare fra Roche.

Utprøvingen ble utført under optimale betingelser av laboratorieutdannet personale og blant de brukere apparatet er beregnet for. I utprøvingen deltok 88 personer med diabetes. Deltakerne i "opplæringsgruppen" fikk opplæring i bruken av apparatet før det ble utført målinger med apparatet. Deltakerne i "postgruppen" fikk apparat og instruksjon tilsendt pr. post og fikk ingen opplæring. Alle deltakerne brukte apparatet hjemme i tre uker og møtte deretter til en avsluttende konsultasjon.

Resultater

Presisjonen var god. CV var mindre enn 3 % når målingene ble utført av laboratorieutdannet personale. Når målingene ble utført av personer med diabetes, var upresisheten ca. 5 %. Ved glukoseverdier under 10 mmol/L gav Accu-Chek Mobile ca. 0,3 mmol/L for høye verdier. Ved glukoseverdier over 10 mmol/L samsvarte resultatene på Accu-Chek Mobile med resultatene på sammenligningsmetoden. Målingene på Accu-Chek Mobile gav nøyaktige resultater. Den totale målefeil var innenfor kvalitetsmålet (ISO 15197), som tillater avvik opp til ± 20 % fra en anerkjent metode for måling av glukose. Hematokrit i området 27 – 49 %, så ut til å påvirke glukosemålinger på Accu-Chek Mobile i mindre grad.

Brukervennlighet

De fleste brukerne som deltok i utprøvingen syntes at Accu-Chek Mobile var enkel å bruke, og de var fornøyde med apparatet. Noen av brukerne hadde problemer med å få åpnet beskyttelsesluken som sitter over analysefilmen. De fleste av brukerne som hadde lest i brukermanualen, var fornøyde med denne.

Tilleggsinformasjon

Den fullstendige rapporten fra utprøvingen av Accu-Chek Mobile, SKUP/2009/74, finnes på SKUPs nettside, www.skup.nu. Opplysninger om pris fås ved å kontakte leverandør. Laboratoriekonsulentene i NOKLUS kan gi nyttige råd om analysering av glukose på legekontor. De kan også orientere om det som finnes av alternative metoder/utstyr.

List of previous SKUP evaluations

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

SKUP evaluations from number 51 and further

Evaluation no.	Component	Instrument/testkit	Producer
SKUP/2009/75	Glucose	Contour	Bayer HealthCare
SKUP/2009/74	Glucose[1]	Accu-Chek Mobile	Roche Diagnostics
SKUP/2008/72	Glucose[1]	*Confidential*	
SKUP/2009/71	Glucose[1]	GlucoMen LX	A. Menarini Diagnostics
SKUP/2008/69*	Strep A	Diaquick Strep A test	Dialab GmbH
SKUP/2008/66	Glucose[1]	DANA DiabeCare IISG	SOOIL Development co. Ltd
SKUP/2008/65	HbA1c	Afinion HbA1c	Axis-Shield PoC AS
SKUP/2007/64	Glucose[1]	FreeStyle Lite	Abbott Laboratories
SKUP/2007/63	Glucose[1]	*Confidential*	
SKUP/2007/62*	Strep A	QuikRead	Orion Diagnostica Oy
SKUP/2008/61	CRP	i-CHROMA	BodiTech Med. Inc.
SKUP/2007/60	Glucose[1]	*Confidential*	
SKUP/2007/59	Glucose[1]	Ascensia BREEZE2	Bayer HealthCare
SKUP/2006/58	HbA1c	*Confidential*	
SKUP/2007/57*	PT (INR)	Simple Simon PT	Zafena AB
SKUP/2007/56*	PT (INR)	*Confidential*	
SKUP/2007/55	PT (INR)	CoaguChek XS	Roche Diagnostics
SKUP/2007/54*	Mononucleosis	*Confidential*	
SKUP/2006/53*	Strep A	*Confidential*	
SKUP/2005/52*	Strep A	Clearview Exact Strep A Dipstick	Applied Biotech, Inc.
SKUP/2005/51*	Glucose[1]	FreeStyle	Abbott Laboratories

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

[1] Including a user-evaluation among diabetes patients

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

SKUP evaluations from number 1 — 50

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

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