ACCU-CHEK® Guide

A system for measurement of glucose
manufactured by Roche Diabetes Care GmbH

Report from the evaluation

SKUP/2017/112

organised by SKUP at the request of Roche Diabetes Care Norge AS

SKUP in Denmark, DEKS, Rigshospitalet-Glostrup, DK-2600 Glostrup, Phone +45 38634400, www.skup.nu
SKUP in Norway, Noklus, Box 6165, NO-5892 Bergen, Phone +47 55979502, www.skup.nu
SKUP in Sweden, Equalis, Box 977, SE-751 09 Uppsala, Phone: +46 18 490 31 44, www.skup.nu

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

SKUP in Denmark (under reorganisation)
Gitte M. Henriksen (gitte.m.henriksen@deks.dk)
DEKS
Rigshospitalet – Glostrup
Nordre Ringvej 29-57
DK-2600 Glostrup
+45 38 63 44 00

SKUP in Norway
Grete Monsen (grete.monsen@noklus.no)
Anne Christin Breivik (anne.breivik@noklus.no)
Marianne Risa (marianne.risa@noklus.no)
Sverre Sandberg (sverre.sandberg@noklus.no)
Noklus
Boks 6165
NO-5892 Bergen
+47 55 97 95 02

SKUP in Sweden
Elisabet Eriksson Boija (elisabet.eriksson.boija@equalis.se)
Gunnar Nordin (gunnar.nordin@equalis.se)
Equalis AB
Box 977
SE-751 09 Uppsala
+46 18 490 31 44

www.SKUP.nu

SKUP would like to acknowledge with thanks those who contributed to the practical work with this evaluation including Hege Alvheim, Grethe Kalleklev, Eva Rønneseth, Sveinung Fosen Simonsen, Henriette Mohn Soldal and Kjersti Østrem.

The report was written by SKUP, November/December 2016. Main author was Marianne Risa, SKUP in Norway. In order to use the SKUP name in marketing, it has to be referred to www.skup.nu and the report code in question; SKUP/2017/112. For this purpose, the company can use a logotype containing the report code available for the requesting company together with the final report. A correct format of referral in scientific publications will be "SKUP. Report from the evaluation SKUP/year/number. Name-of-the-measurement-system (name-of-producer), a system for measurement of name-of-the-component, www.skup.nu (accessed date)." The organisation of SKUP is described in attachment 1.

Table of contents

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

1. Summary

Background
Accu-Chek Guide is an in vitro device for the quantitative measurement of glucose and is designed for monitoring. The product is intended for persons with diabetes and health care professionals. The sample material is whole blood, preferably capillary blood. The system is produced by Roche Diabetes Care GmbH and was launched into the Scandinavian market in October 2016. The SKUP evaluation was carried out in October 2016 at the request of Roche Diabetes Care Norge AS.

The aim of the evaluation
The aim of the evaluation was to assess the analytical quality and user-friendliness of Accu-Chek Guide, both when used under optimal conditions by experienced laboratory personnel and under real-life conditions by intended users (persons with diabetes). The analytical results were assessed according to pre-set quality goals.

Materials and methods
A total of 90 persons with diabetes participated in the evaluation. All the participants received the device and instructions by mail and no training was given. They used the device for approximately two weeks at home, before they attended an evaluation meeting at SKUP. Fresh whole blood capillary samples from each participant were analysed on Accu-Chek Guide under optimal conditions as well as by the participants. Three lots of test strips were used. Capillary samples from the same individuals were analysed on a comparison method (a glucose hexokinase method for measurement of glucose in plasma, implemented on Roche Cobas 6000, Roche Diabetes Care). The quality goal for imprecision was a repeatability (CV) ≤5,0 %. The quality goal for accuracy was set according to the International Organization for Standardization (ISO) ISO 15197:2013. This quality goal states that at least 95 % of the individual glucose results shall be within <±0,83 mmol/L of the average measured values of the reference measurement procedure at glucose concentration <5,55 mmol/L or <±15 % at glucose concentration ≥5,55 mmol/L. The quality goal for the user-friendliness was a total rating of "satisfactory".

Results
The CV achieved under optimal conditions was between 1,5 and 2,6 %. The intended users achieved a CV between 1,8 and 3,9 %. There was a negative bias of (–0,1) — (–0,8) mmol/L between Accu-Chek Guide and the comparison method. Both under optimal conditions and when handled by the intended users, 100 % of the results were within the quality goal for accuracy. Glucose measurements on Accu-Chek Guide were not affected by haematocrit in this evaluation (tested haematocrit range 31—50 %). The user-friendliness was rated as satisfactory. The fraction of tests wasted caused by technical errors was 0,8 %.

Conclusion
The quality goal for repeatability was fulfilled under optimal conditions as well as by intended users. The quality goal for accuracy was fulfilled both under optimal conditions and when measurements were performed by intended users. The quality goal for user-friendliness was fulfilled.

Comments from Roche Diabetes Care Norge AS
Roche Diabetes Care Norge AS has accepted the report without further comments.

2. Abbreviations and Acronyms

ADA	American Diabetes Association
BLS	Biomedical Laboratory Scientist
CI	Confidence Interval
C-NPU	Committee on Nomenclature, Properties and Units
CV	Coefficient of Variation
DEKS	Danish Institute of External Quality Assurance for Laboratories in Health Care
EQA	External Quality Assessment
Equalis	External quality assessment for clinical laboratory investigations in Sweden
FAD	Flavin Adenine Dinucleotide
HDH	Haraldsplass Deaconess Hospital
HELFO	Norwegian Health Economics Administration
ISO	International Organization for Standardization
LADA	Latent Autoimmune Diabetes of Adults
NIST	National Institute of Standards & Technology
Noklus	Norwegian Quality Improvement of Laboratory Examinations
NS-EN ISO	Norsk Standard_Europeisk Norm International Organization for Standardization
SKUP	Scandinavian evaluation of laboratory equipment for primary health care
SRM	Standard Reference Material

3. Introduction

3.1. Background for the evaluation

Accu-Chek Guide is an in vitro device for the quantitative measurement of glucose and is designed for monitoring. The product is intended for persons with diabetes and health care professionals. The sample material is whole blood, preferably capillary blood. The system is produced by Roche Diabetes Care GmbH and was launched into the Scandinavian market in October 2016. The SKUP evaluation was carried out in October 2016 at the request of Roche Diabetes Care Norge AS.

3.2. The aim of the evaluation

The aim of the evaluation was to assess the analytical quality and user-friendliness of Accu-Chek Guide, both when used under optimal conditions by experienced laboratory personnel and when used under real-life conditions by intended users (persons with diabetes).

The evaluation includes:

- Examination of the analytical quality (precision and accuracy) under optimal conditions
- Examination of the analytical quality (precision and accuracy) in the hands of intended users
- Evaluation of the user-friendliness of Accu-Chek Guide and it's manual
- Examination of haematocrit effect on the glucose measurements

3.3. The model for the evaluation

SKUP evaluations for quantitative methods are based upon the fundamental guidelines in a book concerning evaluations of laboratory equipment in primary health care [1]. SKUP's model for glucose user-evaluations is based on a standard model used by Norwegian Health Economics Administration (HELFO) for test strip reimbursement in Norway [2].
A SKUP evaluation consists of two parts. One part of the evaluation is carried out under optimal conditions by experienced laboratory personnel. This part documents the quality of the system under conditions as favourable as possible for achieving good analytical quality. The other part of the evaluation is carried out by intended users. This part documents the quality of the system under real-life conditions.

The evaluation under optimal conditions includes:

- Repeatability with 90 x 6 patient samples
- Comparison with an established hospital laboratory method
- Examination of haematocrit effect on the glucose measurements

The evaluation performed by the intended users includes:

- Repeatability with 90 x 2 patient samples
- Comparison with an established hospital laboratory method
- Evaluation of user-friendliness

If possible, SKUP evaluations are carried out using three lot numbers of test strips from separate and time-spread productions.

Some evaluation codes are followed by an asterisk (*). The asterisk is explained on the front page of the report. Only evaluations where the end-users are involved will fully demonstrate the quality of the product. This evaluation of Accu-Chek Guide was performed both under optimal conditions and by the intended users.

4. Quality goals

4.1. Analytical quality

Accu-Chek Guide is designed for monitoring blood glucose, and the quality goals are set according to this.

For blood glucose meters intended for monitoring, good precision of the method is important [3]. According to the American Diabetes Association (ADA) the imprecision of new glucose devices must be less than 5 % [4]. Other authors also recommend an imprecision of 5 % or less [5-7].

The International Organization for Standardization (ISO) 15197:2013 standard [8], is an international protocol for evaluating meters designed for glucose monitoring, and gives the following minimum acceptable accuracy requirement for measurements made by trained laboratory staff as well as measurements performed by persons with diabetes:
At least 95 % of the individual glucose results shall fall within ±0,83 mmol/L of the average measured values of the reference measurement procedure at glucose concentrations <5,55 mmol/L or within ±15 % at glucose concentrations ≥5,55 mmol/L.

In the HELFO standard protocol [2] the quality goal in ISO 15197:2013 [8] is in use.

In Sweden, national quality goals for glucose measurements follow the requirements in ISO 15197:2013. Glucose meters used for monitoring some groups of patients, for example those using continuous glucose monitoring, where the glucose meter is used as a calibrator unit, and women with gestational diabetes, should fulfil stricter quality goals for accuracy. At least 95 % of the individual glucose results shall fall within ±0,42 mmol/L of the results of the comparison method at glucose concentrations <4,2 mmol/L or within ±10 % at glucose concentrations ≥4,2 mmol/L [9].

In Denmark the analytical quality goals for point of care glucose measurement systems (capillary whole blood measurements) are a coefficient of variation (CV) <4 % and a bias <3 % [6, 7].

4.2. User-friendliness

The evaluation of user-friendliness is carried out by asking the participants to fill in a questionnaire, see section 6.5.

Technical errors
SKUP recommends that the fraction of tests wasted caused by technical errors should not exceed 2 %.

4.3. Principles for the assessments

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

4.3.1. Assessment of the analytical quality

The analytical results are assessed according to pre-set quality goals.

Precision

The decision whether the achieved CV fulfils the quality goal or not, is made on a 5 % significance level. The distinction between the ratings, and the assessment of precision according to the quality goal, are shown in table 1.

Table 1. The rating of precision

Distinction between the ratings	Assessment according to the quality goal
The CV is lower than the quality goal (statistically significant)	The quality goal is fulfilled
The CV is lower than the quality goal (not statistically significant)	Most likely the quality goal is fulfilled
The CV is higher than the quality goal (not statistically significant)	Most likely the quality goal is not fulfilled
The CV is higher than the quality goal (statistically significant)	The quality goal is not fulfilled

Bias

SKUP does not set separate quality goals for bias. The confidence interval (CI) of the measured bias is used for deciding if a difference between the evaluated method and the comparison method is statistically significant (two-tailed test, 5 % significance level). The bias is discussed in connection with the accuracy. The bias is only calculated for the results achieved under optimal conditions.

Accuracy

The accuracy is illustrated in a difference plot with limits for the allowable deviation according to the quality goal. The fraction of results within the limits is counted for each lot separately. The accuracy is assessed as either fulfilling the quality goal or not fulfilling the quality goal.

Bias with three lots of test strips

Separate lot calculations are performed for the results achieved under optimal conditions. If distinct differences between the lots are shown, this will also be pointed out and discussed in the assessment of accuracy in the difference plot.

Effect of haematocrit

The effect of haematocrit is shown with a trend-line and a regression equation in a difference plot.

4.3.2. Assessment of the user-friendliness

The user-friendliness is assessed according to the answers and comments given in the questionnaire (see section 6.5). For each question, the participant can choose between three given ratings. The responses from the participants are reviewed and summed up. To achieve the overall rating "satisfactory", the tested equipment must reach the total rating of "satisfactory" in all four subareas of characteristics described in section 6.5.

Technical errors

The evaluating persons register error codes, technical errors and failed measurements during the evaluation. The fraction of tests wasted caused by technical errors is calculated and taken into account in connection with the assessment of the user-friendliness.

4.4. SKUP´s quality goals in this evaluation

As agreed upon when the protocol was drawn up, the results from the evaluation of Accu-Chek Guide are assessed against the following quality goals:

Repeatability (CV) ..... ≤5,0 %

Allowable deviation in the individual result from the comparison method result (according to ISO 15197:2013) *
for glucose concentrations <5,55 mmol/L ..... ≤±0,83 mmol/L
and for glucose concentrations ≥5,55 mmol/L ..... ≤±15 %

Required percentage of individual results
within the allowable deviations……..... ≥95 %

User-friendliness, overall rating..... Satisfactory

* The number of results within a stricter Swedish quality goal (allowable deviation in the individual result from the comparison method result <±0,42 mmol/L at glucose concentration <4,2 mmol/L or <±10 % at glucose concentration ≥4,2 mmol/L) will be reported, but not assessed in the report.

5. Materials and methods

5.1. Definition of the measurand

The measurement system intends to measure the substance concentration of glucose in blood plasma. The sample material in this evaluation is capillary blood. The results are traceable to SI (The International System of Units) and are expressed by the unit mmol/L. The Committee on Nomenclature, Properties and Units (C-NPU) systematically describes clinical laboratory measurands in a database [10]. The NPU code related to the measurand in this evaluation is NPU22089 (for random sample). In this report the term "glucose" will be used for the measurand.

5.1.1. Other variables measured

Another variable measured in the evaluation is haematocrit expressed with the unit %.

5.2. The evaluated measurement system Accu-Chek Guide

The information in this section derives from the company´s information material. The Accu-Chek Guide system is designed for blood glucose testing performed by persons with diabetes or by health care professionals. The system consists of an Accu-Chek Guide meter and dry reagent test strips (figure 1). The glucose measurement is based on biosensor technology. Glucose dehydrogenase converts glucose in the blood sample to gluconolactone. The enzyme in the reaction is a flavin adenine dinucleotide (FAD) dependent glucose dehydrogenase. The system is automatically switched on and calibrated when a test strip is inserted. Coding of the meter is not necessary. The sample material is whole blood, preferably capillary blood from a finger prick, but it is also possible to use blood samples from alternative sites. Accu-Chek Guide reports plasma glucose values. Analytical quality controls are not included in the starting set, but can be purchased separately.

Figure 1. The Accu-Chek Guide system

For technical details about the Accu-Chek Guide system, see table 2. For more information about the Accu-Chek Guide system, and name of the manufacturer and the suppliers in the Scandinavian countries, see attachment 2 and 3. For product specifications in this evaluation, see attachment 4.

Table 2. Technical details from the manufacturer

Technical details for Accu-Chek Guide	
Sample material	Whole blood, preferably capillary blood
Sample volume	0,6 µL
Measuring time	<4 seconds
Measuring range	0,6 — 33,3 mmol/L
Tolerated haematocrit range	10 — 65 %
Storage capacity	720 blood glucose results and 32 control results
Electrical power supply	Two 3-volt lithium batteries (CR 2032 coin cell batteries)

5.3. The selected comparison method

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

5.3.1. The selected comparison method in this evaluation

The selected comparison method in this evaluation is a method for measurement of glucose in plasma implemented on Roche Cobas 6000 in the clinical chemistry laboratory at Haraldsplass Deaconess Hospital (HDH) in Bergen. The method is a glucose hexokinase method and uses reagents from Roche Diabetes Care. The method is accredited according to NS-EN ISO 15189 (2012) (Norsk Standard_Europeisk Norm International Organization for Standardization). The method is hereafter called "the comparison method".

The samples for haematocrit were measured with Advia 2120i or Cell-Dyn Sapphire at the laboratory at HDH.

Internal analytical quality control

Internal analytical quality control samples, two levels (Autonorm Human Liquid Control Solutions, Sero AS), were measured daily on the comparison method.

External analytical quality control

Human serum controls, produced by Norwegian Quality Improvement of Laboratory Examinations (Noklus), with glucose concentrations at two levels were analysed. These controls have target values determined with an isotope-dilution gas chromatography/mass spectrometry method in a Reference laboratory in Belgium [11]. The target value is given with an expanded uncertainty of 1,5 — 2 % (k=2). The controls are used in Noklus' External Quality Assessment (EQA) scheme.

5.3.2. Verification of the analytical quality of the comparison method

Precision

The repeatability (CV) of the comparison method was calculated from duplicate measurements of capillary patient samples collected under optimal conditions.

Trueness

To document the trueness of the comparison method, the standard reference material (SRM) 965b from National Institute of Standards & Technology (NIST) was used [12]. SRM 965b consists of ampoules with human serum with certified concentrations of glucose at four levels with given uncertainties.

5.4. The evaluation

5.4.1. Planning of the evaluation

Inquiry about an evaluation

Roche Diabetes Care Norge AS via Head of Market Access & Business Development Mette Engebretsen applied to SKUP in January 2015 for an evaluation of Accu-Chek Guide. The new meter was expected ready for use in summer 2016. Roche and SKUP agreed that the practical work with the evaluation should start in autumn 2016.

Protocol, arrangements and contract

In June 2016 the protocol for the evaluation was approved. In September 2016 Roche Diabetes Care and SKUP signed a contract for the evaluation. The laboratory at HDH agreed to analyse the samples for the comparison method.

Training

In September 2016, Frode Sortland, product specialist in Roche Diabetes Care Norge AS, demonstrated Accu-Chek Guide for approximately one and a half hour for the biomedical laboratory scientists (BLSs) involved in the practical work under optimal condition. All the participants (intended users) received the device and instructions by mail and no training was given.

5.4.2. Evaluation sites and persons involved

The practical work, including sampling and measurements on Accu-Chek Guide, was carried out at Noklus during October 2016. Four BLSs were involved in the practical work. At the laboratory at HDH three BLSs were responsible for analysing the samples on the comparison method.

5.4.3. The evaluation model for Accu-Chek Guide

The evaluation consisted of two parallel parts. One part of the evaluation was carried out under optimal conditions by BLSs at Noklus. Persons with diabetes performed the other part of the evaluation. Three lots of test strips were distributed evenly between the participants (random distribution). The model for the evaluation among the participants is shown in figure 2.

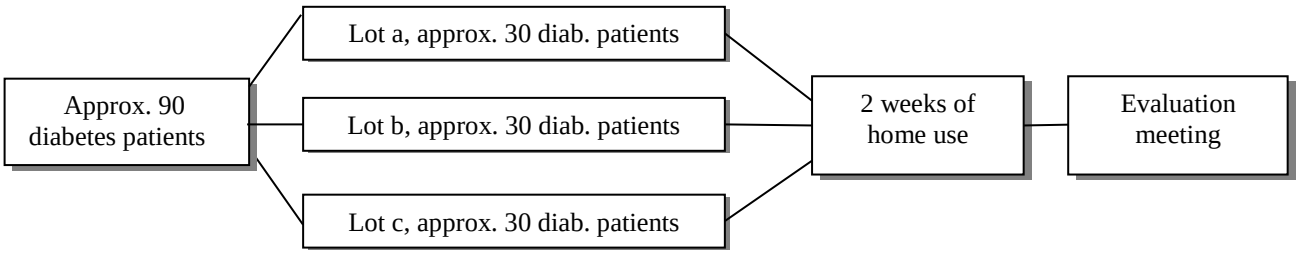

Figure 2. The model for the evaluation among the intended users

5.4.4. Recruitment and selection of the participants

Recruitment

The participants were recruited by mail inquiry sent to members of the local branch of The Norwegian Diabetes Association.

Selection

The participants were selected at random, but with the criterion to get variety in the group according to gender, diabetes type, age and how often the participants normally performed blood glucose measurements.

5.4.5. The evaluation procedure

For the evaluation performed under optimal conditions, the BLSs used three Accu-Chek Guide blood glucose meters (called meter A, B and C). For all the participants two measurements were performed with each of the three meters (totally six measurements for each diabetes patient). Three lot numbers of test strips were used. On meter A, lot 906086 (called lot a) was used, on meter B, lot 906087 (called lot b) was used, and on meter C, lot 906089 (called lot c) was used for all the measurements.

The participants received the Accu-Chek Guide meter by mail, along with test strips, lancet pen, lancets, user manual and an information letter with explanations regarding what to do with the Accu-Chek Guide device during the period at home. The participants could choose whether to use the distributed lancing device, or the lancet device they usually use.

Use of Accu-Chek Guide at home

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

The evaluation meeting

After the two-week practice period at home, the participants met, one by one, for the evaluation meeting with the BLS. The participants brought their assigned Accu-Chek Guide to the meeting.

Internal analytical quality control

Meter A, B and C were checked with the manufacturer's control solutions, Control 1 (range 1,7 — 3,3 mmol/L) and Control 2 (range 14,0 — 19,0 mmol/L), every day in use. To document correct functioning of the Accu-Chek Guide meters used by the participants, the BLS checked these meters with Control 2 at the evaluation meeting. The reproducibility (CV) as achieved with the quality control material was calculated.

Handling of samples and measurements
Before samples were collected, the participants' assigned devices were equilibrated to room temperature while the participants filled in the questionnaire regarding user-friendliness of Accu-Chek Guide and the user manual.

All samples for Accu-Chek Guide, as well as the glucose samples for the comparison method, were capillary samples collected from a finger prick. The blood samples for the duplicate measurements on Accu-Chek Guide under optimal conditions were mainly collected from the same finger prick. The BLS wiped off the first drop of blood before the first measurement and between the sets of duplicates (meter A, B and C). The sampling sequence should be carried out as quickly as possible, in order to reduce the possible change in the glucose concentration during the sampling.

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

In case of error codes, the test was repeated if possible until a result was obtained.

Most of the participants used the distributed Accu-Chek FastClix lancing device for the blood sampling. The participants' measurements were performed with the test strips delivered to them for the evaluation.

Samples for the comparison method were collected into Microvette Li-heparin tubes (300 µL) from Sarstedt. The samples were centrifuged immediately for three minutes at 10 000 g, and plasma was separated. The plasma samples were frozen directly and stored at minus 80°C at Noklus until the analysis took place (according to the storing procedure for the SRM from NIST [12]). The samples were analysed during four days in November 2016. The first samples for the comparison method were analysed once; the second samples were analysed in duplicate. The duplicate results of the second samples were used for calculation of repeatability of the comparison method. The mean of the comparison method is calculated as the mean of the first sample result and the first result of the second sample. This mean is an estimate of the true glucose value and is referred to as the mean result of the comparison method.

Stability of the glucose concentration during the sampling time
The stability of the glucose concentration during sampling was supervised by means of the capillary samples for the comparison method taken at the start and in the end of each sampling sequence. Based on experience from several previous glucose meter user-evaluations, a stability criteria with a change <10 % between the first and second comparative result is regarded as reasonable. Changes >10 % are regarded as unacceptable and these results will be excluded.

Measurement of haematocrit
Haematocrit may influence blood glucose measurements. The venous sample for haematocrit collected from each diabetes patient (voluntarily) was measured within six hours.

6. Results and discussion

Statistical expressions and calculations used by SKUP are shown in attachment 5.

6.1. Number of samples

A total of 93 persons with diabetes signed up for the evaluation and 90 of them completed. Three participants withdrew from the evaluation for various reasons. The BLSs performed 540 glucose measurements (6 measurements x 90 patients) on Accu-Chek Guide under optimal conditions. In addition, the BLSs collected 180 capillary samples (2 samples x 90 patients) for glucose measurement on the comparison method. A venous sample for measurement of haematocrit was collected from all the 90 participants. The intended users (persons with diabetes) performed 180 glucose measurements (2 measurements x 90 patients) on Accu-Chek Guide.

The concentration range for the glucose samples was 3,5 — 24,0 mmol/L (results from the comparison method).

The concentration range for the haematocrit samples was 31 — 50 %.

The Accu-Chek Guide glucose meter was tested in use by 45 men and 45 women with diabetes. The average age of the participants was 57 years (range 20 — 82 years). A total of 37 participants had Type 1 diabetes, two had Latent Autoimmune Diabetes of Adults (LADA), 50 had Type 2 diabetes and one participant did not know his/her type of diabetes. The group included persons from a range of self-monitoring frequencies, i.e. persons who perform self-monitoring often and those who perform self-monitoring less frequently.

An account of the number of samples not included in the calculations is given below.

Missing results
Two participants had problems with their test strips. ID 11 got no results on the measurements (either patient samples or control) at the evaluation meeting. ID 122 only got one result from patient samples and no control result.

Omitted results
For ID 62 the deviation between the first and the second sample for the comparison method was >10 % which means that this participant had an unstable glucose concentration during the sampling sequence time. Sample results from ID 62 were removed before the calculation of bias and the assessment of accuracy, and before the assessment of haematocrit effect.

The second measurements of the second samples for the comparison method gave systematically higher results than the first measurements. The reason for this is most likely evaporation from the second sample before the rerun. The sample volumes are small and the samples have to be left inside the machine, where the temperature is above room temperature, during the analysing time. Due to this difference, the second measurements for the second samples were only used in the calculation of repeatability of the comparison method.

Excluded results
Statistical outliers were detected by the criterion promoted by Burnett [13]. The results for ID 41 and ID 56 were detected as outliers in the calculation of repeatability achieved by the intended users and are excluded from this calculation. The result for ID 57 was detected as an outlier in the calculation of bias for meter A/lot a and meter B/lot b (optimal condition) and is excluded from this calculation.

Comment
ID 37 had used all test strips at home, and performed the measurements at the evaluation meeting with test strips made available there. The results are included in the calculations.

Recorded error codes, technical errors and failed measurements
In total the BLSs got error codes on six of their measurements and the intended users got error codes on seven of their measurements during the evaluation. Seven of these error codes were due to user errors, and one of them was achieved on a control measurement. Totally six error codes were technical errors/tests wasted; one E-1 error ("test strip error"), two E-3 errors ("errors in measurement, retest using a new test strip"), one E-4 error ("blood drop too small", but in this case this was not correct) and one E-7 error ("electronic failure").

The percentage of tests wasted in this evaluation was:
(6 errors /(540 measurements + 180 measurements)) x 100 = 0,8 %

The SKUP recommendation of a fraction of ≤2 % tests wasted caused by technical errors was achieved.

6.2. Analytical quality of the selected comparison method

6.2.1. Internal analytical quality control

All results from the internal analytical quality control (Autonorm Human Liquid Control Solutions, Sero AS), two levels, were within the limits the laboratory has set for the controls (data not shown).

6.2.2. The precision of the comparison method

To achieve a measure for the repeatability of the comparison method, one of the capillary samples collected of each diabetes patient was analysed in duplicate. The results were checked to meet the imposed condition for using formula 1 in attachment 5. There was a small systematic difference pointed out between the paired measurements for all levels (data not shown). The second measurements were systematically higher than the first measurements (see section 6.1.). When using highly precise methods, even negligible differences are easily pointed out as statistically significant. The systematic differences pointed out lead to an overestimation of the CVs of the comparison method.

The precision is presented as repeatability (CV). The CV with a 90 % CI is shown in table 3. The results are sorted and divided into three glucose concentration levels according to the first measurement of the comparison method. Raw data is attached for the requesting company only, attachment 6.

Table 3. Repeatability, glucose, capillary blood samples, comparison method

Glucose level, Comparison method, mmol/L	n	Excluded results	Mean value glucose, mmol/L	CV (90 % CI), %
<7	20	0	5,5	2,1 (1,6 — 2,9)
7 – 10	34	0	8,1	1,6 (1,4 — 2,0)
>10	36	0	12,8	1,5 (1,2 — 1,9)

An account of the number of samples is given in section 6.1.

Discussion

The CV for the comparison method was between 1,5 and 2,1 %.

6.2.3. The trueness of the comparison method

In order to demonstrate the trueness of the comparison method, SRM 965b standards purchased from NIST were analysed. The agreement between the comparison method and the NIST-standards is shown in table 4.

Table 4. SRM 965b measured on the comparison method

SRM 965b	Date	Certified glucose concentration, (uncertainty) mmol/L	n	Mean value glucose, mmol/L	Deviation from target value, %
Level 1	02.11.16	**1,836** (1,809 — 1,863)	5	1,83	–0,5
	08.11.16		5	1,84	+0,1
	Total		**10**	**1,83**	**–0,2**
Level 2	02.11.16	**4,194** (4,135 — 4,253)	5	4,19	–0,1
	08.11.16		5	4,25	+1,2
	Total		**10**	**4,22**	**+0,5**
Level 3	02.11.16	**6,575** (6,481 — 6,669)	5	6,50	–1,1
	08.11.16		5	6,62	+0,7
	Total		**10**	**6,56**	**–0,2**
Level 4	02.11.16	**16,35** (16,15 — 16,55)	5	16,07	–1,7
	08.11.16		5	16,40	+0,3
	Total		**10**	**16,24**	**–0,7**

To verify the trueness of the comparison method results, human serum controls produced by Noklus, were analysed. The agreement between the comparison method and target values from the Reference laboratory in Belgium is shown in table 5.

Table 5. Trueness of the comparison method

Control	Date	Target value glucose, (expanded uncertainty) mmol/L	n	Mean value glucose, mmol/L	Deviation from target value, %
Noklus 1	02.11.16	**5,71** (5,62 — 5,80)	5	5,72	+0,2
	08.11.16		5	5,80	+1,6
	Total		**10**	**5,76**	**+0,9**
Noklus 2	02.11.16	**11,94** (11,70 — 12,18)	5	11,88	–0,5
	08.11.16		5	12,05	+1,0
	Total		**10**	**11,97**	**+0,2**

Discussion

The glucose results of the NIST-standards on the comparison method were within the limits for the certified target values except for level 4 the first day. The comparison method gave glucose values in agreement with the glucose values from the Reference laboratory in Belgium. The trueness of the comparison method was confirmed.

6.3. Analytical quality of Accu-Chek Guide under optimal conditions

The results below reflect the analytical quality of Accu-Chek Guide under optimal conditions. The results document the quality of the system under conditions as favourable as possible for achieving good analytical quality.

6.3.1. Internal analytical quality control

All results from the internal analytical quality control (Accu-Chek Guide Controls), two levels, were within the allowable control limits (data not shown). The reproducibility (CV) achieved with the internal analytical quality control samples was 3,2 % for level 1 (n=57) and 1,9 % for level 2 (n=57). Raw data is attached for the requesting company only, attachment 7.

6.3.2. The precision of Accu-Chek Guide

Two capillary samples were collected of each diabetes patient for measurements on meter A, meter B and meter C at the evaluation meeting. The results were checked to meet the imposed condition for using formula 1 in attachment 5. There were no systematic differences pointed out between the paired measurements (data not shown).

The precision is presented as repeatability (CV). The CV with a 90 % CI is shown in table 6. The results are sorted and divided into three glucose concentration levels according to the first measurement on Accu-Chek Guide. Raw data is attached for the requesting company only, attachment 8.

Table 6. Repeatability, glucose, capillary samples, Accu-Chek Guide. Results achieved under optimal conditions.

Accu-Chek Guide	Glucose level, mmol/L	n	Excluded results	Mean value glucose, mmol/L	CV (90% CI), %
Meter A	<7	22	0	5,4	2,6 (2,0 — 3,5)
Meter B	<7	24	0	5,6	1,9 (1,6 — 2,5)
Meter C	<7	25	0	5,6	2,5 (2,0 — 3,2)
Meter A	7 — 10	36	0	8,1	2,0 (1,7 — 2,6)
Meter B	7 — 10	33	0	8,1	2,1 (1,7 — 2,7)
Meter C	7 — 10	35	0	8,2	2,4 (1,9 — 3,0)
Meter A	>10	32	0	12,2	1,8 (1,5 — 2,3)
Meter B	>10	33	0	12,2	2,2 (1,9 — 2,8)
Meter C	>10	30	0	12,3	1,5 (1,2 — 1,9)

An account of the number of samples is given in section 6.1.

Discussion

The CV achieved under optimal conditions was between 1,5 and 2,6 %. As the upper CI values for all levels are ≤5,0 %, the CVs are statistically significant below the quality goal.

Conclusion

Under optimal conditions the quality goal for repeatability (CV ≤5,0 %) was fulfilled.

6.3.3. The bias of Accu-Chek Guide

The mean deviation (bias) of Accu-Chek Guide results from the comparison method was calculated. The bias of Accu-Chek Guide with three lots of test strips is presented with a 95 % CI in table 7. The results are sorted and divided into three glucose concentration levels according to the mean results of the comparison method. Raw data is attached for the requesting company only, attachment 6 and 8.

Table 7. Bias, glucose, capillary samples, Accu-Chek Guide. Results achieved under optimal conditions.

Accu-Chek Guide (lot number of test strips)	Glucose level Comparison method, mmol/L	n	Excluded results	Mean value Comparison method, glucose mmol/L	Mean value Accu-Chek Guide, glucose mmol/L	Bias (95 % CI), mmol/L	Bias, %
906086 (lot a)	<7	20	0	5,5	5,3	–0,2 ((–0,2) — (–0,1))	–2,8
	7 — 10	34	0	8,1	7,8	–0,3 ((–0,4) — (–0,2))	–3,6
	>10	35	1*	12,3	11,7	–0,7 ((–0,8) — (–0,5))	–5,6
906087 (lot b)	<7	20	0	5,5	5,3	–0,1 ((–0,2) — (–0,0))	–2,4
	7 — 10	34	0	8,1	7,8	−0,3 ((−0,4) — (−0,2))	–3,9
	>10	35	1*	12,3	11,6	–0,7 ((–0,8) — (–0,6))	–5,7
906089 (lot c)	<7	20	0	5,5	5,3	–0,2 ((–0,3) — (–0,1))	–3,6
	7 — 10	34	0	8,1	7,7	–0,3 ((–0,4) — (–0,3))	–4,3
	>10	35	0	12,7	11,9	–0,8 ((–0,9) — (–0,7))	–6,3

*The given numbers of results (n) are counted before the exclusion of results. Mean and bias are calculated after the exclusion of results. ID 57 is statistical outlier (for lot a and b) according to Burnett's model [13] and therefore excluded. An account of the number of samples is given in section 6.1.

Discussion

The glucose measurements on Accu-Chek Guide showed systematic lower glucose results than the comparison method. The bias from the comparison method was between –0,1 and –0,8 mmol/L ((–2,4 %) — (–6,3 %)).

6.3.4. The accuracy of Accu-Chek Guide

To evaluate the accuracy of glucose results on Accu-Chek Guide, the agreement between Accu-Chek Guide and the comparison method is illustrated in a difference plot (figure 3). The limits for the allowable deviation according to the quality goal (ISO 15197:2013) are shown with stippled lines. All the first measurements from Accu-Chek Guide are included in the plot. The plot illustrates both random and systematic errors, reflecting the total measuring error in the Accu-Chek Guide results. Raw data is attached for the requesting company only, attachment 6 and 8.

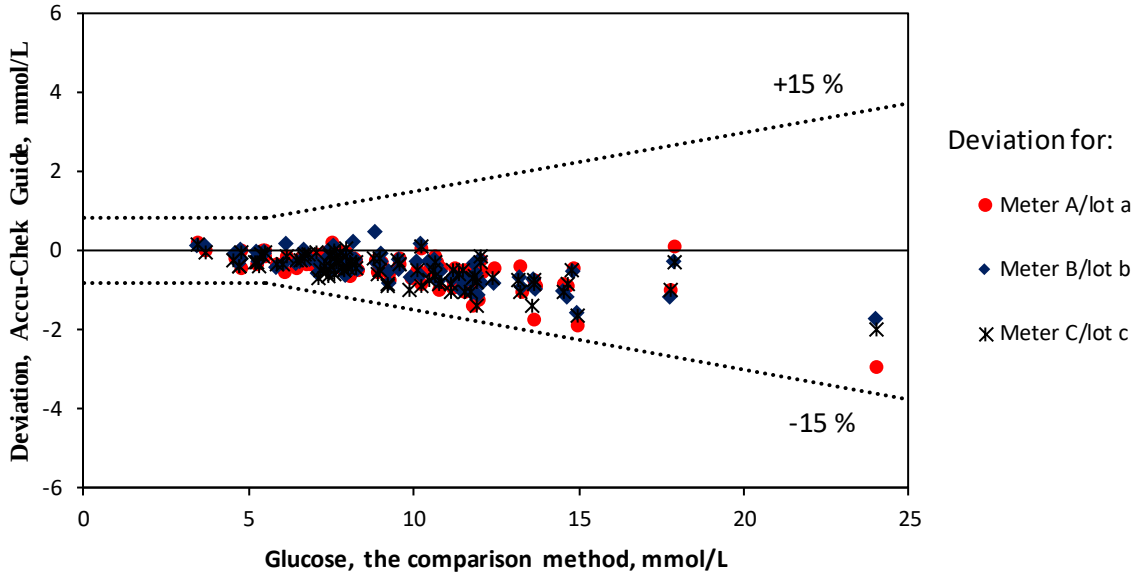

Figure 3. Accuracy of glucose results on Accu-Chek Guide under optimal conditions. The x-axis represents the mean glucose result of the comparison method. The y-axis represents the glucose deviation in mmol/L of the first measurement on Accu-Chek Guide from the mean result of the corresponding sample of the comparison method. The different lots of test strips are illustrated as lot A (●), lot B (♦) and lot C (x). Stippled lines represent quality goal limits set in ISO 15197:2013 (within ±0,83 mmol/L of the results of the comparison method for glucose concentrations <5,55 mmol/L and within ±15 % for glucose concentrations ≥5,55 mmol/L). Number of results (n) = 89. An account of the number of samples is given in section 6.1.

Table 8. Accuracy, glucose, capillary samples, Accu-Chek Guide. Results achieved under optimal conditions.

Lot	n	Percentage of results within given limits, %	
		ISO 15197:2013[1]	**Stricter Swedish quality goal[2]**
a	89	100	94
b	89	100	99
c	89	100	96

[1] ISO 15197:2013: <±0,83 mmol/L at conc. <5,55 mmol/L or <±15 % at conc. ≥5,55 mmol/L
[2] Stricter Swedish quality goal: <±0,42 mmol/L at conc. <4,2 mmol/L or <±10 % at conc. ≥4,2 mmol/L
An account of the number of samples, and excluded and missing results, is given in section 6.1.

Discussion
Figure 3 shows that the Accu-Chek Guide glucose results were slightly lower than the results from the comparison method, which correspond to the small negative calculated bias in section 6.3.3. The summing up in table 8 shows that all the results obtained under optimal conditions were within the accuracy quality limits specified in ISO 15197:2013. The accuracy quality goal was fulfilled. Table 8 also shows the number of results within the stricter Swedish quality goal (see section 4.1). These results are for information only.

Conclusion
Under optimal conditions the quality goal for accuracy was fulfilled.

6.3.5. Bias with three lots of test strips
As can be seen in figure 3 no apparent lot differences were observed.

6.3.6. Effect of haematocrit

According to the technical specifications for Accu-Chek Guide, the glucose measurements are not effected by haematocrit values from 10 to 65 %. To measure the effect of haematocrit on Accu-Chek Guide, a venous sample for haematocrit was collected from the participants at the evaluation meeting. The investigation of the effect is based on the measurements on Accu-Chek Guide meter A (with lot a) under optimal conditions. The effect of haematocrit is shown with a trend-line and a regression equation in figure 4. Raw data is attached for the requesting company only, attachment 6 and 9.

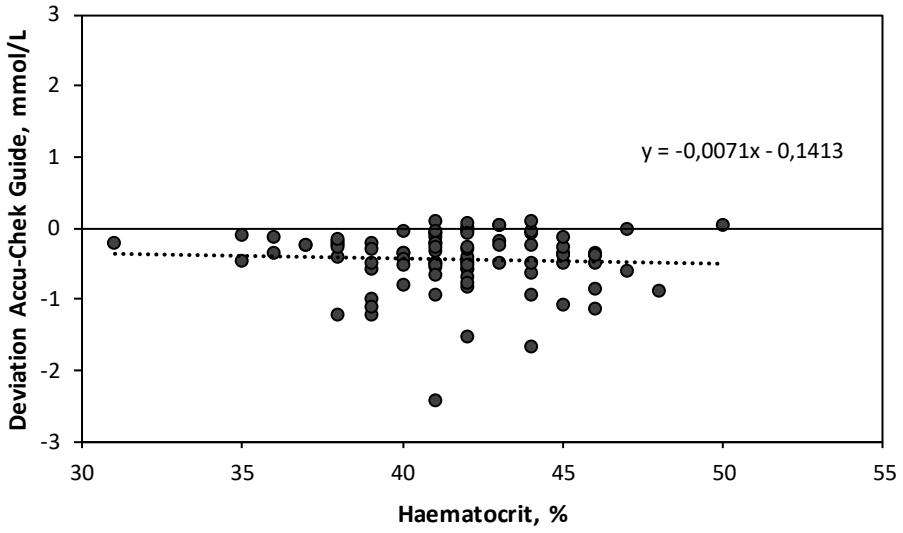

Figure 4. The effect of haematocrit on glucose measurements on Accu-Chek Guide meter A (with lot a) measured under optimal conditions. The x-axis shows the haematocrit value in percent. The y-axis shows the difference in glucose concentration between Accu-Chek Guide and the mean result of the corresponding sample of the comparison method in mmol/L. Number of results (n) = 89.

Discussion

The slope of the trend-line in figure 4 is (–0,007), with a 95 % CI from (–0,035) to (+0,021). The slope is not statistically significant different from zero. Glucose measurements on Accu-Chek Guide were not affected by haematocrit within the range tested (31 — 50 %).

6.4. Analytical quality of Accu-Chek Guide achieved by intended users

The results below reflect the analytical quality of Accu-Chek Guide under real-life conditions in the hands of intended users (persons with diabetes). The results may deviate from the results achieved under optimal conditions.

6.4.1. Internal analytical quality control

The Accu-Chek Guide meters used by the intended users were checked with the internal analytical quality control (Accu-Chek Guide Control 2), by the BLS at the evaluation meeting. All results were within the allowable control limits (data not shown). The reproducibility (CV) achieved with the internal analytical quality control was 1,9 % (n=88). Raw data is attached for the requesting company only, attachment 10.

6.4.2. The precision of Accu-Chek Guide

The participants collected two capillary samples for measurements on their assigned Accu-Chek Guide at the evaluation meeting. The results were checked to meet the imposed condition for using formula 1 in attachment 5. There were systematic differences pointed out between the paired measurements for glucose concentration level <7 mmol/L (data not shown). The differences were small, but statistically significant. The systematic differences were considered negligible, but lead to an overestimation of the CV for this glucose level. For the two other glucose concentration levels, no systematic differences were pointed out (data not shown).

The precision is presented as repeatability (CV). The CV with a 90 % CI is shown in table 9. The results are sorted and divided into three glucose concentration levels according to the first measurement on Accu-Chek Guide. Raw data is attached for the requesting company only, attachment 11.

Table 9. Repeatability, glucose, capillary samples, Accu-Chek Guide. Results achieved by intended users.

Glucose level Accu-Chek Guide, mmol/L	n	Excluded results	Mean value glucose, mmol/L	CV (90 % CI), %
<7	26	0	5,8	3,9 (3,1 — 5,0)
7 — 10	32	0	8,3	2,7 (2,3 — 3,5)
>10	30	2*	12,1	1,8 (1,5 — 2,3)

*The given numbers of results (n) are counted before the exclusion of results. Mean and CV are calculated after the exclusion of results. ID 41 and ID 56 are statistical outliers according to Burnett's model [13] and therefore excluded. An account of the number of samples is given in section 6.1.

Discussion

The CV achieved by the intended users was between 1,8 and 3,9 %. As the upper CI values for all levels are ≤5,0 %, the CVs are statistically significant below the quality goal.

Conclusion

When measurements were performed by the intended users the quality goal for repeatability (CV≤5,0 %) was fulfilled.

6.4.3. The accuracy of Accu-Chek Guide

To evaluate the accuracy of glucose results on Accu-Chek Guide, the agreement between Accu-Chek Guide and the comparison method is illustrated in a difference plot (figure 5). The limits for the allowable deviation according to the quality goal (ISO 15197:2013), are shown with stippled lines. All the first measurements from Accu-Chek Guide are included in the plot. The plot illustrates both random and systematic errors, reflecting the total measuring error in the Accu-Chek Guide results. Raw data is attached for the requesting company only, attachment 6 and 11.

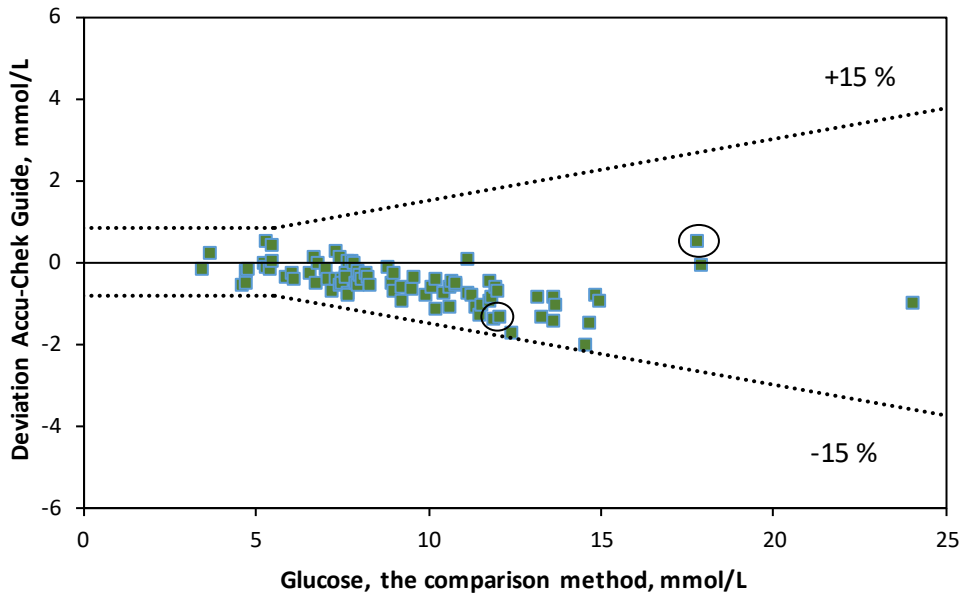

Figure 5. Accuracy of glucose results on Accu-Chek Guide achieved by the intended users (three lots of test strips). The x-axis represents the mean glucose result of the comparison method. The y-axis represents the glucose deviation in mmol/L of the first measurement on Accu-Chek Guide from the mean result of the corresponding sample of the comparison method. Stippled lines represent quality goal limits set in ISO 15197:2013 (within ±0,83 mmol/L of the results of the comparison method for glucose concentrations <5,55 mmol/L and within ±15 % for glucose concentrations ≥5,55 mmol/L). Number of results (n) = 88. Statistical outliers from the calculations of repeatability, are illustrated with a circle around the symbol. An account of the number of samples is given in section 6.1.

Table 10. Accuracy, glucose, capillary samples, Accu-Chek Guide. Results achieved by intended users (three lots of test strips)

n	Percentage of results within given limits, %	
	ISO 15197:2013[1]	**Stricter Swedish quality goal[2]**
88	100	85

[1] ISO 15197:2013: <±0,83 mmol/L at conc. <5,55 mmol/L or <±15 % at conc. ≥5,55 mmol/L
[2] Stricter Swedish quality goal: <±0,42 mmol/L at conc. <4,2 mmol/L or <±10 % at conc. ≥4,2 mmol/L
An account of the number of samples is given in section 6.1.

Discussion

Figure 5 shows that the Accu-Chek Guide glucose results were slightly lower than the results from the comparison method. This correspond to the results found under optimal conditions. The summing up in table 10 shows that all the results obtained by the intended users were within the accuracy quality limits specified in ISO 15197:2013. The accuracy quality goal was fulfilled. Table 10 also shows the number of results within the stricter Swedish quality goal (see section 4.1). These results are for information only.

Conclusion

When measurements were performed by the intended users the quality goal for accuracy was fulfilled.

6.5. Evaluation of user-friendliness

6.5.1. Questionnaire to the evaluators

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

When attending the evaluation meeting, the participants filled in a questionnaire about the user-friendliness of the measurement system. There was free space for commenting, and the BLS was available for clarifying questions. Each participant was first asked whether he/she had used the user manual. If the answer was no, they were to ignore the questions regarding the user manual.

The questionnaire is divided into four subareas:

Table A) Rating of the information in the manual / insert / quick guide
Table B) Rating of operation facilities. Is the system easy to handle?
Table C) Rating of time factors for the preparation and the measurement
Table D) Rating of performing internal and external analytical quality control

The participants filled in table A and B. SKUP filled in table C and D and in addition, topics marked with grey colour in table A and B.

In the tables, the first column shows what is up for consideration. The other columns in table A and B show the rating options as well as the number and percentage of participants who chose this alternative. The number (n) in the tables is the number of participants who responded to the particular question and the calculation of percent is based on this number.
The last row in each table will summarise the total rating in the table. The total rating is an overall assessment by SKUP of the described property, and not necessarily the arithmetic mean of the rating in the rows. Consequently, a single poor rating can justify an overall poor rating, if this property seriously influences on the user-friendliness of the system.

The intermediate category covers neutral ratings assessed as neither good nor bad.

An assessment of the user-friendliness is subjective, and the topics in the questionnaire may be emphasised differently by different users. The assessment can therefore vary between different persons and between the countries. This will be discussed and taken into account in the overall assessment of the user-friendliness.

Comment
In this evaluation, the user-friendliness was assessed by 90 persons with diabetes.

A total of 67 participants had used the manual.

Table A. Rating of the information in the manual

Topic (n)	**Rating** n (%)	**Rating** n (%)	**Rating** n (%)	**Option** n (%)
General impression (65)	Satisfactory 54 (83 %)	Intermediate 9 (14 %)	Unsatisfactory 2 (3 %)	No opinion 0 (0 %)
Specimen collection; description and illustrations (65)	Satisfactory 56 (86 %)	Intermediate 9 (14 %)	Unsatisfactory 0 (0 %)	No opinion 0 (0 %)
Description of measurement procedure (65)	Satisfactory 60 (92 %)	Intermediate 5 (8 %)	Unsatisfactory 0 (0 %)	No opinion 0 (0 %)
Description of how to insert a test strip (65)	Satisfactory 60 (92 %)	Intermediate 4 (6 %)	Unsatisfactory 0 (0 %)	No opinion 1 (2 %)
Description of how to read the result (64)	Satisfactory 56 (88 %)	Intermediate 5 (8 %)	Unsatisfactory 1 (2 %)	No opinion 2 (3 %)
Description of the sources of error (63)	Satisfactory 34 (54 %)	Intermediate 11 (17 %)	Unsatisfactory 1 (2 %)	No opinion 17 (27 %)
Help for troubleshooting (63)	Satisfactory 31 (49 %)	Intermediate 9 (14 %)	Unsatisfactory 1 (2 %)	No opinion 22 (34 %)
Readability / Clarity of presentation (65)	Satisfactory 53 (82 %)	Intermediate 8 (12 %)	Unsatisfactory 2 (3 %)	No opinion 2 (3 %)
In total; how satisfied are you with the manual (64)	Satisfactory 47 (73 %)	Intermediate 15 (24 %)	Unsatisfactory 1 (2 %)	No opinion 1 (2 %)
Table of contents/index	**Satisfactory**	Intermediate	Unsatisfactory	
Preparations / Pre-analytic procedure	**Satisfactory**	Intermediate	Unsatisfactory	
Measurement principle	Satisfactory	Intermediate	**Unsatisfactory**[1]	
Available insert in Danish, Norwegian, Swedish	**Satisfactory**	Intermediate	Unsatisfactory	
Total rating by SKUP	**Satisfactory**			

[1] Measuring principle not mentioned in the manual.

Positive comments
A total of 14 participants had one or more positive comments regarding the manual. The most often reported positive comments were:

1. The manual is easily understood, easily read, clear and easy to follow (5)
2. The manual has good explanations/illustrations (4)

Negative comments
A total of nine participants had a negative comment regarding the manual. Four of these participants commented that the manual was too comprehensive.

Table B. Rating of operation facilities

Topic (n)	**Rating** n (%)	**Rating** n (%)	**Rating** n (%)	**Option** n (%)
To measure a sample (88)	Easy 81 (92 %)	Intermediate 7 (8 %)	Difficult 0 (0 %)	No opinion 0 (0 %)
To insert the test strip (89)	Easy 80 (90 %)	Intermediate 7 (8 %)	Difficult 2 (2 %)	No opinion 0 (0 %)
To apply blood (89)	Easy 80 (90 %)	Intermediate 8 (9 %)	Difficult 1 (1 %)	No opinion 0 (0 %)
Reading of the test result (89)	Easy 88 (99 %)	Intermediate 1 (1 %)	Difficult 0 (0 %)	No opinion 0 (0 %)
Specimen volume (86)	Satisfactory 71 (83 %)	Intermediate 12 (14 %)	Unsatisfactory 1 (1 %)	No opinion 2 (2 %)
Number of procedure step (87)	Satisfactory 73 (84 %)	Intermediate 12 (14 %)	Unsatisfactory 0 (0 %)	No opinion 2 (2 %)
Instrument design (88)	Satisfactory 81 (92 %)	Intermediate 7 (8 %)	Unsatisfactory 0 (0 %)	No opinion 0 (0 %)
Test strip design including package (89)	Satisfactory 62 (70 %)	Intermediate 22 (25 %)	Unsatisfactory 5 (6 %)	No opinion 0 (0 %)
Sources of errors (87)	Satisfactory 42 (48 %)	Intermediate 8 (9 %)	Unsatisfactory 2 (2 %)	No opinion 35 (41 %)
Cleaning / Maintenance (88)	Satisfactory 50 (57 %)	Intermediate 4 (5 %)	Unsatisfactory 1 (1 %)	No opinion 33 (38 %)
Hygiene, when using the test (88)	Satisfactory 72 (83 %)	Intermediate 6 (7 %)	Unsatisfactory 2 (2 %)	No opinion 8 (9 %)
Size and weight of package (89)	Satisfactory 78 (89 %)	Intermediate 9 (10 %)	Unsatisfactory 1 (1 %)	No opinion 1 (1 %)
In total; how easy did you find the usage of the instrument (88)	Easy 76 (86 %)	Intermediate 11 (13 %)	Difficult 0 (0 %)	No opinion 1 (1 %)
Storage conditions for tests, unopened package	**+15 to +30°C***	+2 to +8°C	–20°C	
Storage conditions for tests, opened package	**+15 to +30°C***	+2 to +8°C	–20°C	
Environmental aspects: waste handling	**No precautions**	Sorted waste	Special precautions	
Intended users	**Health care personnel or patients**	Laboratory experience	Biomedical laboratory scientists	
Total rating by SKUP	**Satisfactory**			

* According to the package insert of the test strips, the test strips can be stored between 4 and 30°C.

Positive comments

A total of 50 participants had one or more positive comments regarding the operation facilities of Accu-Chek Guide. The most often reported positive comments were:

1. Comments regarding the use of the meter (32); the meter is easy to use, needs a small amount of blood, has short measuring time
2. Comments regarding the test strip box and the test strips (13); the test strip box has a convenient design, easy to open and close the box, easy to take the test strip out of the box, good test strips
3. The meter has a convenient size, small (10)
4. Light in the test strip port (5)
5. Comments regarding the display (5); easy to read the result, clear numbers, nice display

Negative comments

A total of 38 participants had one or more negative comments regarding the operation facilities of Accu-Chek Guide. The most often reported negative comments were:

1. Comments regarding the test strips (18); difficult to get the strip out of the box, small test strips, difficult to see which end of the test strip to be inserted into the meter, difficult to insert the strip into the meter, difficult not to touch the test area (Comment from SKUP: There is no information in the manual regarding whether the test strip field may be touched or not. According to information given of Roche during the training of the BLSs, the test strip field may be touched.)
2. Not “all-in-one” (8)
3. No soft case (4)

Table C. Rating of time factors (filled in by SKUP)

Topic	Rating	Rating	Rating
Required training time	**<2 hours**	2 to 8 hours	>8 hours
Durations of preparations / Pre-analytical time	**<6 min.**	6 to 10 min.	>10 min.
Duration of analysis	**<10 sec.**	10 to 30 sec.	>30 sec.
Stability of test, unopened package	**>5 months**	**3 to 5 months**	<3 months
Stability of test, opened package	**>30 days**	14 to 30 days	<14 days
Stability of quality control material, unopened	**>5 months**	3 to 5 months	<3 months
Stability of quality control material, opened	**>6 days or disposable**	2 to 6 days	≤1 day
Total rating by SKUP	**Satisfactory**		

The control material is stable until the given expiration date if stored at +2 to +32°C. The stability of the control material is three months after opening the vial.

Table D. Rating of analytical quality control (filled in by SKUP)

Topic	Rating	Rating	Rating
Reading of the internal quality control	**Satisfactory**	Intermediate	Unsatisfactory
Usefulness of the internal quality control	**Satisfactory**	Intermediate	Unsatisfactory
External quality control	**Satisfactory**	Intermediate	Unsatisfactory
Total rating by SKUP	**Satisfactory**		

6.5.2. Assessment of the user-friendliness

Assessment of the information in the manual (table A)
The manual was assessed as satisfactory.

Assessment of the operation facilities (table B)
The operation facilities were assessed as satisfactory. The users had different views on the test strip design. A total of 62 participants assessed the test strip design as satisfactory, 22 as intermediate and five as unsatisfactory. Their positive and negative comments show the same disagreement.

Assessment of time factors (table C)
The time factors were assessed as satisfactory.

Assessment of analytical quality control possibilities (table D)
The analytical quality control possibilities were assessed as satisfactory.
The imprecision achieved with the internal analytical quality control material (Accu-Chek Guide Control 1 and Control 2), equals the imprecision of the patient samples.

Conclusion
In all, the user-friendliness of Accu-Chek Guide and its manual was rated as satisfactory. The quality goal for user-friendliness was fulfilled.

7. References

1. Christensen NG., Monsen G. & Sandberg S. Utprøving av analyseinstrumenter, 1997. Alma Mater Forlag.

2. www.helfo.no

3. Stöckl D. *et al.* Desirable routine analytical goals for quantities assayed in serum. *Eur J Clin Biochem* 1995; **33** (3): 157 – 169.

4. American Diabetes Association. Self-monitoring of blood glucose. *Diabetes Care* 1996; **19** (suppl 1): 62 – 66.

5. Skeie S., Thue G. & Sandberg S. Patient-derived quality specifications for instruments used in self-monitoring of blood glucose. *Clin Chem* 2001; **47** (1): 67 – 73.

6. Kvalitetskrav og kvalitetsvurdering for hyppigt udførte klinisk biokemiske og klinisk mikrobiologiske analyser i almen praksis. Konsensus dokument udarbejdet af Laboratorieudvalget under Sygesikringens og PLO´s Faglige Udvalg vedr. Almen Praksis i samarbejde med DEKS og Dansk Selskab for Klinisk Biokemi's Videnskabelige udvalg. Nov 2003. www.skup.nu (menu The SKUP evaluations – Quality goals).

7. Kvalitetssikring og kvalitetskrav til laboratoriemedicinske aktiviteter i almen praksis. Udarbejdet af Regionernes Lønnings- og Takstnævn (RTLN) og Praktiserende Lægers Organisation (PLO). 2010. www.skup.nu (menu The SKUP evaluations – Quality goals).

8. In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, ed. ISO 15197:2013.

9. http://www.equalis.se/media/127118/pr008_eng_swedish-national-quality-goals-for-measurement-of-glucose-v-2015-07-01.pdf

10. http://www.ifcc.org/ifcc-scientific-division/sd-committees/c-npu/npusearch/

11. Thienpont LM. *et al.* Determination of reference method values by isotope dilution-gas chromatography/mass spectrometry: a five years' experience of two European Reference Laboratories. *Eur J Clin Chem Clin Biochem* 1996; **34**(10): 853 – 860.

12. National Institute of Standards and Technology, Certificate of Analysis, Standard Reference Material®965b, Glucose in Frozen Human Serum.

13. Burnett RW. Accurate estimation of standard deviations for quantitative methods used in clinical chemistry. *Clin Chem* 1975; **21** (13): 1935 – 1938.

Attachments

1. The organisation of SKUP
2. Facts about Accu-Chek Guide
3. Information about manufacturer, retailers and marketing
4. Product specifications for this evaluation, Accu-Chek Guide
5. Statistical expressions and calculations
6. Raw data glucose, results from the comparison method
7. Raw data glucose, internal analytical quality control results, Accu-Chek Guide, optimal conditions
8. Raw data glucose, Accu-Chek Guide results, optimal conditions
9. Raw data haematocrit
10. Raw data glucose, internal analytical quality control results, Accu-Chek Guide, intended users
11. Raw data glucose, Accu-Chek Guide results, intended users
12. "SKUP-info". Summary for primary health care (in Norwegian)
13. List of previous SKUP evaluations

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

The organisation of SKUP

Scandinavian evaluation of laboratory equipment for primary health care, *SKUP*, is a co-operative commitment of Noklus[1] in Norway, DEKS[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 about analytical quality and user-friendliness of laboratory equipment. This information is generated by organising SKUP *evaluations*.

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

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

Each evaluation is presented in a *SKUP report* to which a unique *report code* is assigned. The code is composed of the acronym SKUP, the year the report was completed 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.

SKUP reports are published at www.skup.nu.

---

[1] Noklus (Norwegian Quality Improvement of Laboratory Examinations) is an organisation founded by Kvalitetsforbedringsfond III (Quality Improvement Fund III), which is established by The Norwegian Medical Association and the Norwegian Government.

[2] DEKS (Danish Institute for External Quality Assurance for Laboratories in Health Care) is a non-profit organisation owned by the Capital Region of Denmark on behalf of all other Regions in Denmark.

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

Facts about Accu-Chek Guide

This form was filled in by Roche Diabetes Care.

Table 1. Basic facts

Name of the measurement system:	Accu-Chek Guide Blood Glucose Monitoring System
Dimensions and weight: Kit Box	Width: 134 mm Depth: 67 mm Height: 159 mm Weight: 270 g
Components of the measurement system:	Accu-Chek Guide meter with batteries Accu-Chek FastClix lancing device Accu-Chek FastClix lancets Accu-Chek Guide 50 test strips Instructions for Use
Measurand:	Glucose
Sample material:	Fresh whole blood (capillary, venous, arterial or neonatal whole blood)
Sample volume:	0,6 µL
Measuring principle:	The enzyme on the test strip, a FAD-dependent glucose dehydrogenase (GDH), converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless DC electrical current that the meter interprets for the blood glucose result. The sample and environmental conditions are evaluated using AC and DC signals.
Traceability:	The ID-GCMS method as the method of highest metrological quality (order) is traceable to a primary NIST standard. Using this traceability chain, the results achieved with the control solutions can also be traced back to the NIST standard.
Calibration:	The system (meter and test strips) is calibrated with venous blood containing various glucose concentrations as a calibrator. The reference values are obtained using the hexokinase method which is calibrated using the ID-GCMS method.
Measuring range:	0,6 —33,3 mmol/L
Linearity:	Each linearity test kit consists of 6 levels of linearity solutions manufactured to produce a linear relationship within the set. Record the following values as the target values on the x-axis of the linearity log. LINEARITY L1 L2 L3 L4 L5 L6 mmol/L 1,5 2,5 6,4 16,5 27,6 30,2
Measurement duration:	<4 seconds
Operating conditions:	Use the test strips at temperatures between 4 and 45°C.
Electrical power supply:	Two 3 volt lithium batteries (coin cell type CR2032).
Recommended regular maintenance:	Gently wipe the meter's surface with a soft cloth slightly dampened (wring out any excess liquid) with one of these cleaning solutions:

	• 70 % isopropyl alcohol • Mild dishwashing liquid mixed with water • 10 % household bleach solution (1 part bleach plus 9 parts water) made the same day
Package contents:	1 Accu-Chek Guide meter with batteries 1 Accu-Chek FastClix lancing device 1 Accu-Chek FastClix lancetdrum with 6 lancets Carry Case Instructions for Use
Necessary equipment not included in the package:	Accu-Chek Guide test strips and Accu-Chek Guide controls

Table 2. Post analytical traceability

Is input of patient identification possible?	Yes: the software user can manually enter patient identification information related to the data that has be transferred from the device.
Is input of operator identification possible?	Yes: the software user/operator can manually enter any information, including operator identification, as a note.
Can the instrument be connected to a bar-code reader?	No
Can the instrument be connected to a printer?	With Accu-Chek Smart Pix PC software
What can be printed?	Data from the device and any other data that the user manually enters into the PC software
Can the instrument be connected to a PC?	Yes with USB cable
Can the instrument communicate with LIS (Laboratory Information System)? If yes, is the communication bidirectional?	Yes: the device can communicate to a LIS if it complies with the Continua USB standard interface. The Smart Pix PC software is bi-directional in that the software user can update the date/time and blood glucose target range settings in the device.
What is the storage capacity of the instrument and what is stored in the instrument?	720 blood glucose results and 32 control results with time and date
Is it possible to trace/search for measurement results?	The software allows the user to search for blood glucose results after the data has been transferred from the device.

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

Name of the reagent/test strips/test cassettes:	Accu-Chek Guide test strips
Stability in unopened sealed vial:	18 months from manufacture date
Stability in opened vial:	18 months from manufacture date
Package contents:	Pack containing test strips and package insert

Table 4. Quality control

Electronic self check:	Yes
Recommended control materials and volume:	Accu-Chek Guide controls (2 × 2,5 mL control solutions), volume of 0,6 µL per test
Stability in unopened sealed vial:	24 months from manufacture date
Stability in opened vial:	3 months
Package contents:	Pack containing 2 × 2,5 mL control solutions and package insert

Information about manufacturer, retailers and marketing

Table 1. Marketing information

Manufacturer:	Roche Diabetes Care GmbH Sandhofer Strasse 116 68305 Mannheim, Germany
Suppliers in Scandinavia:	Denmark: Roche Diagnostics A/S Industriholmen 59 2650 Hvidovre-Copenhagen Norway: Roche Diabetes Care Norge AS Brynsengfaret 6B PB 6610 Etterstad 0607 Oslo Sweden: Roche Diagnostics Scandinavia AB Karlsbodavägen 30 Box 147 SE-161 26 Bromma
In which countries is the system marketed:	Globally ☒ Scandinavia ☒ Europe ☒
Date for start of marketing the system in Scandinavia:	August 2016 (Denmark)
Date for CE-marking:	16 December 2015
In which Scandinavian languages is the manual available:	Swedish, Norwegian, Danish

Product specifications for this evaluation, Accu-Chek Guide

Accu-Chek Guide serial numbers
A total of 93 Accu-Chek Guide blood glucose meters were used in this evaluation.
Three meters (serial no. 92900102125 (meter A), 92900101947 (meter B) and 92900100594 (meter C)) were used by the biomedical laboratory scientists under standardised and optimal conditions.

Accu-Chek Guide test strips
Lot 906086 Expiry date 2017-09-20
Lot 906087 Expiry date 2017-09-20
Lot 906089 Expiry date 2017-09-20

Accu-Chek Guide Control Solutions (Control 1 and Control 2)
Lot 60102101 Expiry date 2018-05-31
Target value Control 1 1,7 – 3,3 mmol/L
Target value Control 2 14,0 – 19,0 mmol/L

Blood sampling device used by the biomedical laboratory scientists (single use only)
Accu-Chek Softclix Pro
Accu-Chek Softclix Pro Lancets

Blood sampling device used by the diabetes patients
The diabetes patients could choose whether to use the distributed Accu-Chek FastClix lancing device with Accu-Chek FastClix lancets, or the lancet device and lancets they usually use.

Accu-Chek FastClix lancets
Lot GRD 168 Expiry date 2020-05

Tubes used for sampling for the designated comparison method
Microvette CB 300 LH (lithium-heparin) manufactured by Sarstedt AS
Lot 6071111 Expiry date 2019-04

Statistical expressions and calculations

This chapter with standardised text deals with the statistical expressions and calculations used by SKUP. The statistical calculations will change according to the type of evaluation. The descriptions in this document are valid for evaluations of quantitative methods with results on the ratio scale.

Statistical terms and expressions

The definitions in this section come from the International Vocabulary of Metrology - Basic and general concepts and associated terms; VIM [a].

Precision

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

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

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

Trueness

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

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

Accuracy

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

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

a. International vocabulary of metrology – Basic and general concepts and associated terms, VIM, 3rd edition, JCGM 200;2012. www.bipm.org

Statistical calculations

Statistical outliers

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

Calculation of imprecision

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

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

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

(formula 1)

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

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

m = mean of paired measurements

(formula 2)

The two formulas are based on the differences between paired measurements. The calculated standard deviation or CV is still a measure of the imprecision of single values. The imposed condition for using the formulas is that there is no systematic difference between the 1st and the 2nd measurement of the pairs. The CV is given with a 90 % confidence interval.

Calculation of bias

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

Assessment of accuracy

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

b. Burnett RW. Accurate estimation of standard deviations for quantitative methods used in clinical chemistry. *Clin Chem* 1975; **21** (13): 1935 – 1938.
c. Dahlberg G. Statistical methods for medical and biological students, 1940. Chapter 12, Errors of estimation. George Allen & Unwin Ltd.
d. Saunders E. Tietz textbook of clinical chemistry and molecular diagnostics, 2006. Chapter 14, Linnet K., Boyd J. Selection and analytical evaluation of methods – with statistical techniques. Elsevier Saunders ISBN 0-7216-0189-8.
e. Fraser C.G. Biological variation: From principles to practice, 2006. Chapter 1, The Nature of Biological Variation. AACC Press ISBN 1-890883-49-2.

SKUP-info

Sammendrag av en utprøving i regi av SKUP
Accu-Chek Guide for måling av glukose
Produsent: Roche Diabetes Care GmbH
Norsk forhandler: Roche Diabetes Care Norge AS

Konklusjon
Kvalitetsmålene for presisjon og nøyaktighet ble oppfylt både under optimale betingelser og blant personer med diabetes. Kvalitetsmålet for brukervennlighet ble oppfylt.

Bakgrunn
Accu-Chek Guide er et apparat for måling av glukose og er designet for monitorering. Systemet er beregnet for personer med diabetes og for helsepersonell. Prøvematerialet er fullblod, fortrinnsvis kapillærblod. Systemet produseres av Roche Diabetes Care GmbH og ble lansert i det skandinaviske markedet i oktober 2016. Denne SKUP-utprøvingen ble utført i oktober 2016 på oppdrag fra Roche Diabetes Care Norge AS.

Utprøvingen
Målet med utprøvingen var å vurdere den analytiske kvaliteten og brukervennligheten til Accu-Chek Guide, både i bruk under optimale forhold av erfarent laboratoriepersonell og under reelle forhold av brukere (personer med diabetes). Resultatene ble vurdert i forhold til kvalitetsmål satt av SKUP i forkant av utprøvingen.

Material og metode
Totalt 90 personer med diabetes deltok i utprøvingen. Alle deltakerne fikk apparat og instruksjoner tilsendt pr. post, og ingen opplæring ble gitt. Deltakerne brukte apparatet hjemme i ca. to uker, før de møtte til et utprøvingsmøte hos SKUP. Ferske, kapillære fullblodsprøver fra hver deltaker ble analysert på Accu-Chek Guide både under optimale betingelser og av deltakerne. Det ble brukt tre lotnummer med teststrimler. Kapillære prøver av de samme deltakerne ble også analysert på en sammenligningsmetode (en glukose-heksokinase metode for måling av glukose i plasma, på Roche Cobas 6000, Roche Diabetes Care). Kvalitetsmålet for presisjon var en variasjonskoeffisient (CV) ≤ 5,0 %. Kvalitetsmålet for nøyaktighet var satt i henhold til ISO 15197:2013 (minst 95 % av resultatene skal være innenfor <±0,83 mmol/L fra resultatene fra sammenligningsmetoden ved glukosekonsentrasjon <5,55 mmol/L eller <±15 % ved glukosekonsentrasjon ≥5,55 mmol/L). Kvalitetsmålet for brukervennlighet var at den totale vurderingen skulle være tilfredsstillende.

Resultater
CV oppnådd under optimale betingelser var mellom 1,5 og 2,6 %. Brukerne oppnådde en CV mellom 1,8 og 3,9 %. Det ble påvist en negativ bias på (–0,1) — (–0,8) mmol/L mellom Accu-Chek Guide og sammenligningsmetoden. Både under optimale betingelser og når målingene ble gjort av brukerne, var 100 % av resultatene innenfor kvalitetsmålet for nøyaktighet. Glukosemålinger på Accu-Chek Guide ble ikke påvirket av hematokrit i denne utprøvingen (testet område 31 — 50 %). Brukervennligheten ble vurdert som tilfredsstillende. Totalt ble 0,8 % av teststrimlene forkastet pga. tekniske feil.

Tilleggsinformasjon
Fullstendig rapport fra utprøvingen av Accu-Chek Guide, SKUP/2017/112, finnes på SKUPs nettside www.skup.nu. Laboratoriekonsulentene i Noklus kan gi råd om analysering av glukose på legekontor. De kan også orientere om det som finnes av alternative metoder/utstyr.

List of previous SKUP evaluations

The 30 latest SKUP evaluations

Evaluation no.	Component	Instrument/testkit	Producer
SKUP/2017/112	Glucose[1]	Accu-Chek Guide	Roche Diabetes Care GmbH
SKUP/2016/110	PT (INR)	Xprecia Stride Coagulation system	Siemens Healthcare Diagnostics INC
SKUP/2015/107	Strep A	QuickVue Dipstick Strep A Test	Quidel Corporation
SKUP/2015/109	PT (INR)	microINR portable coagulometer	iLine Microsystems S.L.
SKUP/2015/108	HbA1c	*Confidential*	
SKUP/2015/102	HbA1c	*Confidential*	
SKUP/2015/106*	Strep A	QuikRead go	Orion Diagnostica Oy
SKUP/2014/101	HbA1c	InnovaStar analyzer	DiaSys Diagnostic Systems GmbH
SKUP/2014/104	PT (INR)	ProTime InRythm	ITC International Technidyne Corporation
SKUP/2014/105	Glucose[1]	Accu-Chek Aviva	Roche Diagnostics
SKUP/2014/103	PT (INR)	*Confidential*	
SKUP/2013/87	Glucose[1]	Wella Calla Light	Med Trust Handelsges.m.b.H.
SKUP/2013/100	Glucose[1]	Mylife Unio	Bionime Corporation
SKUP/2013/97	NT-proBNP	Cobas h 232 POC system	Roche Diagnostics GmbH
SKUP/2013/92	CRP	Eurolyser smart 700/340	Eurolyser Diagnostica GmbH
SKUP/2013/99*	Glucose	Accu-Chek Mobile	Roche Diagnostics
SKUP/2013/98*	Glucose	Accu-Chek Aviva	Roche Diagnostics
SKUP/2013/85	Glucose, β-Ketone	Nova StatStrip	Nova Biomedical Corporation, USA
SKUP/2013/96	Hemoglobin	DiaSpect Hemoglobin T	DiaSpect Medical GmbH
SKUP/2013/68	Allergens	ImmunoCap Rapid	Phadia AB Marknadsbolag Sverige
SKUP/2012/95	Glucose[1]	Mendor Discreet	Mendor Oy
SKUP/2012/94	Glucose[1]	Contour XT	Bayer Healthcare
SKUP/2012/91	HbA1c	Quo-Test A1c	Quoient Diagnostics Ltd
SKUP/2011/93*	Glucose	Accu-Chek Performa	Roche Diagnostics
SKUP/2011/90	CRP	*i*-Chroma	BodiTech Med. Inc.
SKUP/2011/84*	PT (INR)	Simple Simon PT and MixxoCap	Zafena AB
SKUP/2011/86	Glucose[1]	OneTouch Verio	LifeScan, Johnson & Johnson
SKUP/2011/77	CRP	*Confidential*	
SKUP/2011/70*	CRP	smartCRP system	Eurolyser Diagnostica GmbH
SKUP/2010/83*	Glucose	*Confidential*	

*A report code followed by an asterisk indicates that the evaluation is not complete according to SKUP guidelines, since the part performed by the intended users was not included in the protocol, or the evaluation is a follow-up of a previous evaluation, or the evaluation is a special request from the supplier.
[1] Including a user-evaluation among diabetes patients