Ascensia® BREEZE®2

Ascensia® BREEZE™2 test strips

Meter and test strips designed for glucose self-measurement manufactured by Bayer HealthCare

Report from an evaluation organised by

SKUP

The evaluation was ordered by Bayer AS

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The organisation of SKUP

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

The aim of SKUP is to produce reliable, objective and independent information about analytical quality and user-friendliness of laboratory equipment for primary healthcare. This information is generated by organising *SKUP evaluations*.

SKUP offers manufacturers and suppliers evaluations of equipment for primary healthcare and also of devices for self-monitoring of blood glucose. 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 and summaries are distributed to physicians' offices, councils for laboratory medicine, laboratory instructors and healthcare authorities.

For a detailed list of previous SKUP evaluations, please see attachment 12 of this report.

[1] NOKLUS (Norwegian Quality Improvement of Primary Care Laboratories) is an organisation professionally linked to "Seksjon for Allmennmedisin" (Section for General Practice) at the University of Bergen, in Bergen, Norway.

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

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

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Attachments with raw data are included only in the copy to Bayer AS.

1. Summary

Background
The Ascensia BREEZE2 blood glucose meter and the Ascensia BREEZE2 test strips are designed for glucose self-measurements by diabetics. The meter and the test strips are produced by Bayer HealthCare and are supplied in Scandinavia by Bayer. Ascensia BREEZE2 and Ascensia BREEZE2 test strips have not yet been launched onto the Norwegian market. In order to give reimbursement for the test strips, the Norwegian Labour and Welfare Organisation (NAV) instructs the companies in Norway to carry out an evaluation that includes a user-evaluation among diabetics. The evaluation of Ascensia BREEZE2 and Ascensia BREEZE2 test strips was done under the direction of SKUP from October to December 2006.

The aim of the evaluation
The aim of the evaluation of Ascensia BREEZE2 is to

- reflect the analytical quality under standardised and optimal conditions (performed by biomedical laboratory scientists)
- reflect the analytical quality by the users (78 diabetics)
- compare the analytical quality among diabetics with and without training
- compare the analytical quality among diabetics before and after three weeks of practise
- check the variation between three lots of test strips
- examine if hematocrit interferes with the measurements
- evaluate Ascensia BREEZE2 regarding user-friendliness
- evaluate the Ascensia BREEZE2 user guide

Materials and methods
78 diabetics took part in the evaluation. 38 participants had two consultations (the "training group") and the rest had one consultation (the "mail group"). The diabetics in the "training group" were given a standardised instruction about the Ascensia BREEZE2 before they did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also took capillary samples of the diabetics and measured twice on Ascensia BREEZE2. In addition, two capillary samples were taken to a designated comparison method. The diabetics in the "mail group" received the Ascensia BREEZE2 by mail and no training was given. Both groups of diabetics carried out a practice period of approximately three weeks at home, before they were called for a final consultation. The blood glucose sampling and measurement procedures at the first consultation were repeated, and in addition a sample for hematocrit was taken. Three different lots of test strips were used in the evaluation. All the participants answered questionnaires about the user-friendliness and the user guide of Ascensia BREEZE2.

Results

- Ascensia BREEZE2 shows good precision. The CV is approximately 3 % under standardised and optimal measuring conditions and between 3 and 5 % when the measurements are performed by the diabetics.
- The trueness of Ascensia BREEZE2 was good. For glucose values <10 mmol/L no significant bias between Ascensia BREEZE2 and the comparison method was pointed out. For glucose values >10 mmol/L there was a small, but statistically significant bias between Ascensia BREEZE2 and the comparison method. Ascensia BREEZE2 gave glucose

values approximately 0,3 mmol/L lower than the comparison method at this glucose level. In spite of this deviation the results still fulfil the quality goal.

- The agreement with a designated comparison method is good. The quality goal set in ISO 15197 is achieved under standardised and optimal measuring conditions. When handled by the diabetics, Ascensia BREEZE2 also shows accurate results. These results are within the "adjusted ISO-goal" and also within the quality goal set in ISO 15197.
- The three lots of test strips used in this evaluation gave glucose results in agreement with the comparison method. No significant difference was pointed out.
- Glucose measurements on Ascensia BREEZE2 seem to be affected by hematocrit. Hematocrit outside the range 33 – 50 % has not been tested.
- The diabetics summarise the Ascensia BREEZE2 device as easy to use. Most of them were pleased with the device. The diabetics that had used the user guide were satisfied with the guide.

Conclusion

The analytical quality of Ascensia BREEZE2 is good. The results are within the quality goal for the total error set in the ISO-guide 15197. The precision of Ascensia BREEZE2 is also good. The glucose results seem to be affected by hematocrit. The users find the Ascensia BREEZE2 device easy to use and they are quite satisfied with the device.

2. Analytical quality goals

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. Ascensia BREEZE2 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 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 Ascensia BREEZE2 is derived from 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 diabetics. 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 diabetics have been discussed towards a *modified* goal suggested by NOKLUS, with a total error of ± 25 %. This modified goal has wide, and not ideal, limits. The intention was to tighten up the modified requirements for the diabetics over time, as the meters would hopefully improve due to technological development. More recent evaluations performed by SKUP [6] clearly show that the quality goals set by ISO 15197 now can be achieved also by the diabetics. But for the time being, the quality demands adjusted to the diabetics' self-measurements, still apply.

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

3. Materials and methods

3.1. Ascensia BREEZE2

Ascensia BREEZE2 is a blood glucose monitoring system based on biosensor technology. The system consists of a meter, Ascensia BREEZE2, and dry reagent test strips, Ascensia BREEZE2 test strips in 10-test discs. The system is designed for capillary blood glucose testing by persons with diabetes or by health care professionals. Ascensia BREEZE2 reports plasma glucose values. Ascensia BREEZE2 is automatically coded each time a new 10-test disc is inserted. When pulling and pushing the meter handle a test strip is exposed and the meter is automatically turned on. The test principle of Ascensia BREEZE2 is as follows: When fresh capillary blood fills the capillary of the Ascensia BREEZE2 test strip, a chemical reaction occurs in which an enzyme causes electrons to pass from glucose molecules to "mediator" molecules in the test strip. The meter applies an electric potential across the electrodes where the reaction takes place. The electrons gained by the mediator from glucose molecules are then drawn into the electrode, creating a flow of electricity. The meter measures the current, which is proportional to the glucose concentration in the sample. The active ingredients in the Ascensia BREEZE2 test strip are the enzyme glucose oxidase and the electron mediator potassium ferricyanide. When the strip is inoculated with a fluid the following chemical reaction takes place:

$$glucose + ferricyanide \xrightarrow{Glucose Oxidase} gluconolactone + ferrocyanide$$

$$ferrocyanide + potential \rightarrow ferricyanide + e^{-}$$

The current measured at the end of the 5 second testing period is used to calculate the glucose concentration.

The test strips are packed in 10-test discs. The system requires a blood volume of approximately 1 µL. The blood is automatically drawn into the test strip. When an insufficient volume of sample is applied to the test strip, a signal is generated in the meter indicating the under fill occurrence and the meter displays an error code instead of giving a wrong result. If the patient attempts to add additional blood during the 5 second reaction, the movement of the new blood into the reagent chamber will modify the reaction rate and may result in an incorrect glucose result. The result is provided within 5 seconds. It is possible to test with blood from the forearm, palm, abdomen or thigh. The meter has the capacity of storing 420 results in the memory. When analysing a BREEZE2 Control Solution, the user has to mark the control result to exclude it from the test averages. Technical data from the manufacturer is shown in table 1.

Table 1. Technical data from the manufacturer

Technical data for Ascensia BREEZE2	
Normal operating temperature	10 – 45 °C
Sample volume	Ca. 1 µL
Measuring time	5 seconds
Measuring range	0,6 – 33,3 mmol/L
Hematocrit	Normal glucose concentrations are not considerably affected by hematocrit values from 20 to 55 %. In a glucose range > 16,7 mmol/L, the glucose result is lowered if the hematocrit is > 55 % and elevated if the hematocrit is < 20 %
Memory	420 test results
Power source	One 3-volt lithium battery (CR2032)
Operating time	Approximately 1000 tests or two years
Humidity	10 – 80 % RH
Dimensions	10,2 x 5,1 x 2,5 (cm)
Weight	102 g (including the battery)

3.1.1. Product information, Ascensia BREEZE2

Ascensia BREEZE2 blood glucose meter system
Manufactured by Bayer HealthCare

Suppliers of Ascensia BREEZE2 in the Nordic countries:

Denmark:
Bayer A/S
Diabetes Care
Nørgårdsvej 32
Postboks 2090
DK-2800 Kgs. Lyngby

Phone: +45 45 23 50 00
www.bayerdiabetes.dk

Norway:
Bayer AS
Diabetes Care
Drammensveien 147B
Postboks 14
N-0212 Oslo

Phone: +47 24 11 18 00
www.bayerdiabetes.no

Sweden:
Bayer AB
Diabetes Care
Drakegatan 1
Box 5237
S-402 24 Göteborg

Phone: +46 31 83 98 00
www.bayerdiabetes.se

Finland:
Bayer Oy
Diabetes Care
Suomalaistentie 7
PL 13
FIN-02271 Espoo

Phone: +358 9 887 887
www.bayerdiabetes.fi

84 Ascensia BREEZE2 blood glucose meters were used in this evaluation. Serial no. SN1447-P000446 (called meter A), serial no. SN1447-P000414 (used as meter B from 30/10-06 to 28/11-06) and serial no. SN1447-P000534 (used as meter B from 28/11-06 to 15/12-06) were used by the biomedical laboratory scientists under the standardised and optimal conditions. Attachment 1 gives serial numbers for the 81 meters used by the diabetics.

Ascensia BREEZE2 Test Strips:

Lot-no. 1T1367BB	Expiry 2007-04
Lot-no. 1T1367AA	Expiry 2007-04
Lot-no. 1T1367CC	Expiry 2007-04

BREEZE2 Controls:

Control Normal	Lot-no. BSG0603-02(02)	Expiry 2007-03
Control High	Lot-no. BSG0603-03(02)	Expiry 2007-03

3.2. Designated comparison method

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

Verifying of trueness
The comparison method should be a plasma method, hexokinase by preference. The method has to show traceability equivalent to that of an internationally accepted reference solution, such as the standards supplied by the National Institute of Standards & Technology, NIST. The NIST-standard SRM 965a with four levels of glucose concentrations was used in this evaluation. In addition, freshly frozen, human serum controls from NOKLUS with glucose concentrations at two levels were analysed. The NOKLUS-controls have target values determined with an isotope-dilution gas chromatography/mass spectrometry method on a Reference laboratory in Belgium; Laboratory for Analytical Chemistry, University of Gent, Belgium [7]. The results are summarized in chapter 6.1.2.

The designated comparison method in this evaluation
In this evaluation, the routine method for quantitative determination of glucose in human serum, plasma (e.g. lithium heparin), urine and cerebrospinal fluid 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 NADP to NADPH. The NADPH produced absorbs light at 340 nm and can be detected spectrophotometrically as an increased absorbance.

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

3.2.1. Product information, the comparison method

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

Reagents
Glucose Reagent Kit, List No. 7D66
Lot-no. 38075HW00 Expiry 2007-02-09

Calibrator
Multiconstituent Calibrator, List No. 1E65
Lot-no. 40460M200 Expiry 2007-03-31 Reference value, cal 1 = 5,33 mmol/L
Reference value, cal 2 = 23,81 mmol/L

Internal quality controls
Seronorm Autonorm Human Liquid 1 and 2, Sero AS
Liquid 1: Value = 4,62 ±0,32 mmol/L Lot-no. 501002 Expiry 2007-02-28
Liquid 2: Value = 16,0 ±1,12 mmol/L Lot-no. 509415 Expiry 2007-10-31

NOKLUS controls
Reference value from Laboratory for Analytical Chemistry, University of Gent, Belgium; ID-GCMS method
Level 1: Value = 7,43 ±0,06 mmol/L
Level 2: Value = 10,40 ±0,08 mmol/L

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

Blood sampling device
Accu-Chek Softclix Pro: Lot-no. WIP 012
Accu-Chek Softclix Pro lancets: Lot-no. WIP 45 G 5 Expiry 2008-12-31
Accu-Chek Softclix Pro lancets: Lot-no. WIS 19 C 5 Expiry 2010-06-30

Tubes used for sampling for the designated comparison method
Microvette CB 300 LH (lithium-heparin) manufactured by Sarstedt AS
Lot-no. 5070201 Expiry 2008-01
Lot-no. 6071901 Expiry 2009-05

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

3.3. The planning of the evaluation

Torstein Myhre from Bayer AS applied to SKUP in the spring of 2006 for an evaluation of the glucose meter Ascensia BREEZE2 with Ascensia BREEZE2 test strips. In October 2006 a preliminary suggestion regarding how to organise the evaluation of Ascensia BREEZE2 was sent to Bayer AS. The protocol for the evaluation was accepted in November 2006 and a contract was set up between Bayer AS and SKUP. The Laboratory at HDH accepted to carry out the analytical part of the evaluation dealing with the samples for the comparison method.

The Ascensia BREEZE2-system is produced by Bayer HealthCare and supplied by Bayer. The system has not yet been launched onto the Norwegian market. SKUP carried out the user-evaluation of Ascensia BREEZE2 from October to December 2006.

SKUP evaluations are based upon the guidelines in the book "*Evaluation of analytical instruments. A guide particularly designed for evaluations of instruments in primary health care*" [8]. The evaluation of a self-monitoring blood glucose device follows the guidelines in the book, but the evaluation in primary health care is replaced by a user-evaluation conducted among diabetics, based on the model by the NOKLUS-project "*Diabetes-Self-measurements*" [9].

The evaluation comprises the following studies:

- An examination of the analytical quality under standardised and optimal conditions performed by biomedical laboratory scientists
- An examination of the analytical quality among approximately 80 diabetics
- An examination of the agreement between Ascensia BREEZE2 and a designated comparison method
- A comparison of the analytical quality among diabetics with and without a training programme
- A comparison of the analytical quality among diabetics before and after three weeks of practise
- 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 Ascensia BREEZE2
- An evaluation of the user guide of Ascensia BREEZE2

3.3.1. Evaluation sites and persons involved

The blood sampling of the diabetics and the measurements on Ascensia BREEZE2 under standardised and optimal conditions, were done by Camilla Eide Jacobsen, Grete Monsen and Marianne Risa, biomedical laboratory scientists, SKUP/NOKLUS. Two biomedical laboratory scientists, Wenche Eilifsen Hauge and Kjersti Østrem, were given the responsibility for the practical work with the comparison method on the Laboratory at HDH. The statistical calculations and the report writing are done by Marianne Risa, SKUP/NOKLUS in Bergen.

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3.4. The evaluation procedure

3.4.1. The model for the evaluation

The practical work with the evaluation was carried out during seven weeks from October to December 2006 at NOKLUS Centre, Bergen, Norway. The practical work was done by the biomedical laboratory scientists Camilla Eide Jacobsen, Grete Monsen and Marianne Risa.

The evaluation consisted of two parallel parts. One part of the evaluation was done by biomedical laboratory scientists under standardised and optimal conditions. This part of the evaluation was done by laboratory educated personnel, completely according to the protocol and 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 as good conditions as possible. The other part of the evaluation was done by diabetics. In order to determine the analytical quality of Ascensia BREEZE2 by the users, 81 diabetics tested their blood glucose using Ascensia BREEZE2. The diabetics were divided into two groups (random distribution). 41 diabetics received personal training in how to use the blood glucose meter, here called the "training group". 40 diabetics received the blood glucose meter and instructions by mail, here called the "mail group". Dividing the diabetics into a "training group" and a "mail group" reflects the actual market situation regarding training when diabetics acquire blood glucose meters [9]. The model for the evaluation is shown in figure 1.

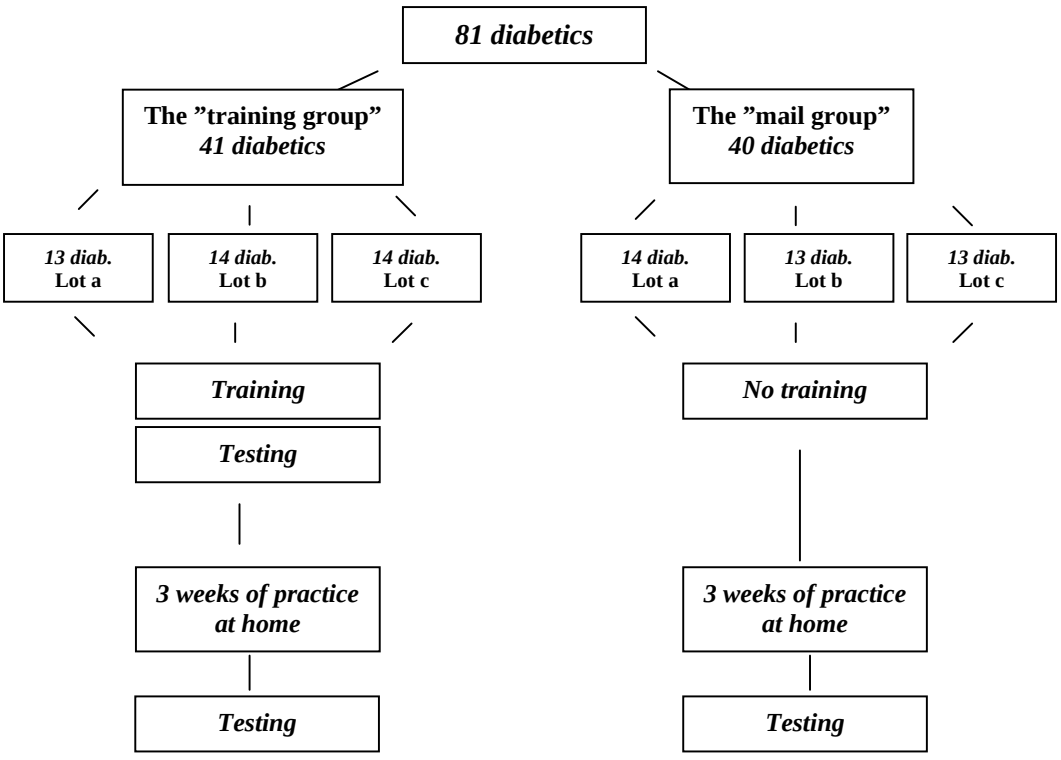

Figure 1. Model for the evaluation

3.4.2. Recruitment of the diabetics

The Ascensia BREEZE2 glucose meter was tested in use by approximately 80 diabetics. The evaluation started with 81 diabetics and 78 diabetics completed the evaluation. The diabetics were recruited through advertisement in the daily press and by mail inquiry sent to members of the local branch of the Norwegian Diabetes Association. The group of diabetics was representative for diabetics who carry out self-monitoring of blood glucose (SMBG). The group included diabetics from across a range of self-monitoring frequencies, i.e. diabetics who perform self-monitoring often (once or more a day) and those who perform self-monitoring less frequently (once a week). Characteristics of the diabetics are shown in table 2.

Table 2. Characteristics of the diabetics (n=81)

		Number of diabetics
Total		81
Sex	Men	50
	Women	31
Age (years), median and range		53 (18 – 75)
Diabetes	Type 1	26
	Type 2	54
	Don't know	1
Treatment	Insulin	35
	Insulin and tablets	12
	Tablets	22
	Diet	8
	No treatment	2
	Unspecified	2
Frequency of SMBG	Less than weekly	2
	1 – 3 per week	7
	4 – 6 per week	11
	7 – 10 per week	18
	>10 per week	33
	Not registered	3
	Do not measure	5
	Others *	2

* One diabetic didn't manage to perform a measurement on his own because of a physical handicap, but had a personal assistant to measure for him. Another diabetic stated that the frequency of SMBG varied depending on the status of her diabetes.

The SMBG-devices that the diabetics used regularly were: Accu-Chek (model not specified) (1), Accu-Chek Aviva (3), Accu-Chek Comfort/Compact/Compact Plus (12), Accu-Chek Sensor (2), Ascensia Breeze (1), Ascensia Contour (14), Ascensia Elite/Elite XL (5), FreeStyle/FreeStyle Mini (9), MediSense (model not specified) (1), MediSense Precision Xtra/Xceed (11), OneTouch GlucoTouch (4), OneTouch Ultra/Ultra Smart (12), unregistered (1). Some of the diabetics used more than one SMBG-device at home, but only one device is registered here. Five of the diabetics did not have a SMBG-device.

3.4.3. The "training group" at the first consultation

The 41 diabetics that were selected to participate in a training programme met two at a time. They received the Ascensia BREEZE2 device along with test strips, lancet pen, lancets, user guide, and an instruction letter with explanations regarding what to do with the Ascensia BREEZE2 device during the period at home. The instruction letter is attached to the report (in Norwegian), see attachment 2. The responsibility for the training programme was undertaken by SKUP. Camilla Eide Jacobsen, Grete Monsen and Marianne Risa were in charge of the training of the diabetics, after having been trained themselves by two representatives from Bayer AS.

Training programme

The training programme covered a simple demonstration of how to use Ascensia BREEZE2, with an explanation of the display and error messages, insertion of the 10 test-disc, blood sampling and drawing of the blood into the test strip, as well as precautions for storage and the shelf-life of test strips, etc. The training programme was standardised to make sure that all the diabetics received the same instruction.

Blood sampling

After having been trained, 40 of the 41 diabetics made duplicate blood glucose tests on Ascensia BREEZE2. These results were registered for the evaluation. One of the diabetics was not able to do measurements at all. The biomedical laboratory scientist collected samples for the evaluation under standardised and optimal conditions (see chapter 3.4.7.). Afterwards the diabetics took the Ascensia BREEZE2 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 40 diabetics in the "mail group" received the Ascensia BREEZE2 device by mail, along with test strips, lancet pen, lancets, user guide and an instruction letter with explanations regarding what to do with the Ascensia BREEZE2 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 Ascensia BREEZE2 by the diabetics at home

The diabetics used Ascensia BREEZE2 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 diabetics 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 diabetics used Ascensia BREEZE2 in addition to their own glucose meter and they continued to carry out self-measurements with their own meter as normal.

The first and the second week

The diabetics familiarised themselves with the new device during the first two weeks. Each diabetic used approximately 25 test strips to measure his/her blood glucose with Ascensia BREEZE2. They could choose when to do the measurements themselves. Fasting was not necessary. If more convenient to them, they could perform the measurements at the same time as they measured with their own meter.

The third week
During the third week the diabetics performed duplicate measurements on Ascensia BREEZE2 on five different days. The results were recorded on a provided form. They pricked a finger and made two consecutive measurements with blood from the same prick. If necessary they pricked another finger for the second measurement. They were free to choose when to perform the measurements, and it was not necessary to be fasting. They could choose whether to use the lancets provided for the evaluation, or the lancets they use ordinarily.

Internal quality control
The diabetics are not familiar with control solutions for self-measurements. Therefore they were not instructed to use control solution on Ascensia BREEZE2 in the evaluation. To document correct functioning of the Ascensia BREEZE2 meters used by the diabetics during the test period, the biomedical laboratory scientist in charge of the practical work checked the meters with the control solution when the diabetics met at the consultations.

3.4.6. The final consultation

Blood sampling
After the three-week practice period at home, the 81 diabetics met, one by one, for a consultation. Each diabetic brought their assigned Ascensia BREEZE2 and the remaining test strips to the consultation. Before the samples were collected the Ascensia BREEZE2 device had to equilibrate to room temperature for approximately 20 minutes. Then the diabetics made duplicate blood glucose tests on their assigned meter. These results were registered for the evaluation. The biomedical laboratory scientist collected samples for the evaluation under standardised and optimal conditions. Finally, a venous sample for hematocrit was taken.

Evaluation of the user-friendliness and the user guide
Before the blood samples were collected and the measurements on Ascensia BREEZE2 were done, the diabetics filled in two questionnaires. The first questionnaire deals with the user-friendliness of Ascensia BREEZE2; the second covers the user guide. The questionnaires (in Norwegian) are attached to the report. After the evaluation, the diabetics returned the Ascensia BREEZE2 device to the project.

3.4.7. Evaluation under standardised and optimal conditions

The biomedical laboratory scientist used two Ascensia BREEZE2 blood glucose meters for the evaluation (meter A and B). At meter A one lot of test strips was used for all the measurements. Meter B was used for the same three lots as distributed among the diabetics. The variation between the three lots, or more precisely, the agreement of the three lots to the comparison method, will be assessed. The number of samples for each lot of strips measured under standardised and optimal conditions is shown in table 3.

Table 3. The number of samples (n) for each lot of strips measured under standardised and optimal conditions

Ascensia BREEZE2		Lot 1T1367BB (n)	Lot 1T1367AA (n)	Lot 1T1367CC (n)
Meter A	1st consultation	41 x 2		
	2nd consultation	78 x 2		
Meter B	1st consultation	19 x 2	15 x 2	7 x 2
	2nd consultation	22 x 2	22 x 2	34 x 2
Total		160 x 2	37 x 2	41 x 2

Blood sampling
Meter A and B were checked by means of the manufacturer's control solutions every day they were used. The biomedical laboratory scientist measured an internal quality control on the diabetic's meter at each consultation.

The blood sampling and analysis were done in the following order:

1. The biomedical laboratory scientist took a sample for the comparison method
2. The biomedical laboratory scientist took samples and analysed on meter A, B, A and B
3. The diabetic took duplicate samples for his/her assigned meter
4. The biomedical 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 should not 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 below in the paragraph "*Analysing the samples for the comparison method*" and in section 5.1.3.

The order of meter A and B was changed between each diabetic, but the blood samples for the comparison method were always taken first and last in accordance with ISO 15197. The biomedical laboratory scientist registered whether the diabetics used correct cleaning, drying, and skin puncture procedures, applied the blood sample correctly to the test strip, and otherwise followed manufacturer's instructions for performing a blood glucose test. At the final consultation a venous sample for hematocrit determination was taken. Hematocrit may influence blood glucose readings, especially in meters designed for self-monitoring. The product insert of Ascensia BREEZE2 test strips states that normal glucose concentrations are not considerably affected by hematocrit values from 20 to 55 %. In a glucose range >16,7 mmol/L, the glucose result is lowered if the hematocrit is >55 % and elevated if the hematocrit is <20 %.

Handling of the samples for the comparison method
The samples for the comparison method were capillary taken using Microvette Li-heparin tubes from Sarstedt. The samples were centrifuged immediately for three minutes at 10000 g, and plasma was separated into sample vials. The plasma samples were frozen directly and stored at minus 80 °C where they were kept until the analysis took place [10].

Analysing the samples for the comparison method
The samples were analysed on an Architect instrument. Recommended minimum volume for analysis of glucose on Architect in this evaluation was 120 µL plasma. The samples were thawed at NOKLUS Centre just before they were analysed. The first and the second sample for the

comparison method, taken at the start and at the end of each blood sampling sequence, reflect the stability of the glucose concentration during the sampling time. When the paired measurements gave agreeable glucose concentrations on the comparison method, the mean of the two results was looked upon as the estimate of the true value of the sample. Basically, the difference between the first and the second comparative reading must not be more than 4 % or 0,22 mmol/L (per ISO 15197 Section 7.3.2.). If the difference between any paired results exceeded these limits, the samples were re-analysed. If the results from the re-run confirmed the difference, the difference was looked upon as a real difference in the glucose concentration in the two samples. Deviations >10 % were regarded as not acceptable and such results were excluded. As a consequence of this, the matching Ascensia BREEZE2 results were excluded for assessment of accuracy and calculation of trueness. Differences between 4 and 10 % are discussed and included in the calculations (see chapter 5.1.3.). If the deviation between the two results was not confirmed by the re-run, the result from the re-run was used as the accepted result. All the samples for the comparison method were analysed within a two-week period.

Evaluation of the user-friendliness and the user guide
The biomedical laboratory scientists evaluated the user-friendliness of Ascensia BREEZE2 and the user guide. The biomedical laboratory scientists provided a description in the form of key words and looked for any defects and deficiencies or whether there was anything with the system that did not function optimally.

3.4.8. Evaluation of analytical quality

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

1. Results from 40 diabetics in the "training group" who had participated in the training programme, but not practised using the blood glucose meter at home
2. Results from 38 of the same diabetics after they had practised using Ascensia BREEZE2 at home for three weeks
3. Results from 40 diabetics in the "mail group" who had not participated in the training programme, but who had practised using Ascensia BREEZE2 at home for three weeks
4. Results from 119 measurements under standardised and optimal conditions in duplicate
5. Results from 119 measurements from the comparison method in duplicate

The results from the diabetics with and without training were compared (item 2 and 3) as well as the results from the diabetics with and without practise at home (item 1 and 2). All the diabetics' measurements were evaluated against the results achieved under standardised and optimal conditions. All the measurements were compared with the results from the comparison method.

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

4. Statistical calculations

4.1. Statistical terms and expressions

4.1.1. Precision

The often used terms within-series imprecision and between-series imprecision are often misinterpreted. Especially the terms between-series and between-day imprecision are often not precisely defined. In this report, the terms are replaced by *repeatability* and *reproducibility*. Repeatability is the agreement between the results of consecutive measurements of the same component carried out under identical measuring conditions (within the measuring series). Reproducibility is the agreement between the results of discontinuous measurements of the same component carried out under changing measuring conditions over time. The reproducibility includes the repeatability. The two terms are measured as imprecision. Precision is descriptive in general terms (good, acceptable, poor e.g.), whereas imprecision is expressed by means of the standard deviation (SD) or coefficient of variation (CV). SD is reported in the same unit as the analytical result and CV is usually reported in percent. The imprecision will be summarised in tables.

4.1.2. Accuracy

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

4.1.3. Trueness

Trueness is the agreement between an average value obtained from a large number of measuring results and a true value. Trueness is measured as bias (systematic errors). Trueness is descriptive in general terms (good, poor), whereas bias is the estimate, reported in the same unit as the analytical result or in %. The bias at different glucose concentration levels will be summarised in tables.

4.2. Number of samples

78 diabetics completed the evaluation. 38 of the diabetics in the "training group" met at two consultations while 3 of the diabetics in this group just met at the first consultation. The 40 diabetics in the "mail group" met at one consultation. Blood samples were taken at each consultation. The total number of samples is: ((41 x 2 (duplicates)) + (38 x 2) + (40 x 2)) x 4 (meter A, meter B, diabetic's meter, comparison method) = 952 samples.

4.3. Statistical outliers

The criterion promoted by Burnett [11] was used for detection of outliers. All the results are checked with repeated truncations. The model takes into consideration the number of observations together with the statistical significance level for the test. The significance level is often set to 5 %, so also in this evaluation. Where the results are classified according to different glucose concentration levels, the outlier-testing is done at each level separately. Statistical outliers are excluded from the calculations. Possible outliers will be commented on under each table.

4.4. Missing or excluded results

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

- One diabetic in the "mail group" returned the sent Ascensia BREEZE2 and is missing.
- ID 48 and ID 57 dropped out of the evaluation and are missing from the final consultation as well as from the home measurements.
- ID 98 was not able to do any measurements. ID 98 has only measurements performed by the biomedical laboratory scientist at the first consultation.
- ID 69 (at the first consultation) and ID 119 (at the final consultation) had a difference >10 % between the paired results on the comparison method. The difference was confirmed by a rerun. As a consequence of this, these results are excluded when Ascensia BREEZE2 is compared with the comparison method (accuracy and trueness). The results are included in the calculations regarding the imprecision of Ascensia BREEZE2 because each set of duplicate measurements on Ascensia BREEZE2 is completed in less than a minute. ID 119 is also excluded from the calculation regarding hematocrit.
- ID 49 didn't manage to perform a measurement on his own because of a physical handicap. The diabetic's measurements are performed by the biomedical laboratory scientist and the results are therefore excluded in the calculations regarding the imprecision and accuracy of Ascensia BREEZE2 obtained by the diabetics.
- At the final consultation ID 109 used test strips he had got from the chemist's. These results are therefore excluded as well as the diabetic's home measurements since he might have used these test strips for the home measurements.
- In the calculation of repeatability based on the diabetics' measurements at home some measurements are missing. Some of the diabetics had not done five duplicate measurements and totally 48 results are missing from this calculation.

- At the first consultation BREEZE2 Control High was analysed on ID 72's assigned meter. This result is excluded from the calculation since BREEZE2 Control Normal was used on all the other diabetics' meters.
- ID 39, ID 49, ID 109, ID 124, ID 128 and ID 131 had no hematocrit result and are missing from the calculation regarding the effect of hematocrit.

4.5. Calculations of imprecision based on duplicate results

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

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

Even if this formula is based on the differences between the two parallel measurements of every duplicate, the calculated standard deviation is still a measure of the imprecision of single values, and completely comparable with the more commonly used calculation based on repeated measurements of only one sample. The assumption for using this formula is that no systematic difference between the 1st and the 2nd measurement of the duplicate is acceptable. Table 4 shows that there is no systematic difference in the glucose concentration between the paired measurements on Ascensia BREEZE2 in this evaluation.

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

		Glucose level mmol/L	Mean 1st measurement mmol/L	Mean 2nd measurement mmol/L	Mean difference 2nd – 1st measurement mmol/L	95 % CI for the mean difference, mmol/L	n
Ascensia BREEZE2	Meter A	< 7	5,8	5,8	-0,01	-0,10 – 0,07	32
		7 – 10	8,4	8,5	0,01	-0,07 – 0,10	45
		> 10	12,9	12,9	-0,07	-0,25 – 0,10	42
	Meter B	< 7	5,8	5,8	0,05	-0,06 – 0,16	31
		7 – 10	8,3	8,3	0,01	-0,08 – 0,10	43
		> 10	12,7	12,7	-0,04	-0,17 – 0,09	45

4.6. Calculation of trueness

To assess the trueness of the results on Ascensia BREEZE2, the average bias at three glucose concentration levels is calculated based on the results obtained under standardised and optimal measuring conditions. A paired t-test is used with the mean values of the duplicate results on the comparison method and the mean values on Ascensia BREEZE2 meter A. The mean difference is shown with a 95 % confidential interval.

4.7. Calculation of accuracy

To evaluate the accuracy of the results on Ascensia BREEZE2, the agreement between Ascensia BREEZE2 and the comparison method is illustrated in difference-plots. In the plots the x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on Ascensia BREEZE2 meter B with three lots and the mean value of the duplicate results on the comparison method.

5. Results and discussion

5.1. Precision and trueness of the designated comparison method

5.1.1. The precision of the comparison method

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

The repeatability of the comparison method is shown in table 6 and table 7. The results are obtained with the SRM 965a standards supplied by the National Institute of Standards & Technology, NIST, and freshly frozen, human serum controls from NOKLUS.

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

The raw data is shown in attachment 3.

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

Control Solution	Target value glucose, mmol/L	Mean value glucose, mmol/L	n	Outliers	CV % (95 % CI)
Autonorm 1	4,62 ±0,32	4,5	42	0	1,7 (1,4 – 2,2)
Autonorm 2	16,0 ±1,12	15,6	42	0	1,4 (1,2 – 1,8)

Discussion

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

5.1.2. The trueness of the comparison method

In order to demonstrate the trueness of the comparison method, the SRM 965a standards supplied by the National Institute of Standards & Technology, NIST, were analysed. SRM 965a consists of ampoules with human serum with certified concentrations and uncertainties for glucose at four levels. The SRM 965a materials cover a glucose concentration range from 1,9 to 16,2 mmol/L.

The agreement between the comparison method and the NIST-standards is shown in table 6.

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

SRM 965a	Date	Certified glucose concentration mmol/L (uncertainty)	Mean value glucose mmol/L	n	CV % (95 % CI)	% deviation from target value
Level 1	17.01.07	**1,918** (1,898 - 1,938)	1,9	5	0,0*	-0,9
Level 2	17.01.07	**4,357** (4,309 - 4,405)	4,4	5	1,3 (0,8 – 3,6)	0,07
Level 3	17.01.07	**6,777** (6,704 - 6,850)	6,7	5	0,7 (0,4 – 1,9)	-0,8
Level 4	17.01.07	**16,24** (16,05 - 16,43)	16,1	5	0,4 (0,3 – 1,3)	-0,9

* The comparison method gives values with only one decimal. All the measurements at level 1 gave the result 1,9 mmol/L, and therefore there is no variation pointed out at this level.

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

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

Control solution	Date	Target value glucose mmol/L	Mean value glucose mmol/L	n	Outliers	Combined CV% (95% CI)	% deviation from target value
NOKLUS control 1	25.01.07	7,43	7,20	5		1,1 (0,7 – 2,0)	-3,1
	01.02.07		7,28	5			-2,0
	Total		**7,24**	**10**	**0**		**-2,6**
NOKLUS control 2	30.01.07	10,4	10,10	5		0,8 (0,5 – 1,4)	-2,9
	31.01.07		10,08	5			-3,1
	Total		**10,09**	**10**	**0**		**-3,0**

Discussion
The trueness of the comparison method is satisfactory.

5.1.3. Stability of the glucose concentration during the sampling time

The first and the second sample for the comparison method, taken at the start and at the end of each blood sampling sequence, reflect the stability of the glucose concentration during the sampling time (see chapter 3.4.7, *Analysing the samples for the comparison method*). In this evaluation, deviations >10 % were regarded as not acceptable and such results were excluded without further discussion. This applies to ID 69 (1st consultation) and ID 119 (2nd consultation). For further explanation, see chapter 4.3. 20 of 119 paired results on the comparison method gave deviations between 4 and 10 %. For 17 of these 20 samples the deviation was less than 6 %. After a general evaluation of all the results, the paired measurements with differences between 4 and 10 % are included in the calculations in this evaluation. The summing up in table 13 has been done with and without these 20 results. The percentage number of results that falls within the different quality limits is not dependent on keeping or excluding these results.

5.2. Precision, trueness and accuracy of Ascensia BREEZE2

5.2.1. The precision of Ascensia BREEZE2

The Ascensia BREEZE2-meters in the user evaluation were checked with the manufacturer's control solutions by the biomedical laboratory scientists. All the results were inside the limits of the controls.

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

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

The raw data is shown in attachment 4.

Table 8. Ascensia BREEZE2 – Repeatability (results with blood samples from the diabetics) measured under standardised and optimal conditions

Ascensia BREEZE2	Glucose level mmol/L	Mean value glucose, mmol/L	n	Outliers	CV % (95 % CI)
Meter A	< 7	5,8	32	0	2,9 (2,3 – 3,8)
Meter B	< 7	5,8	31	0	3,7 (3,0 – 4,9)
Meter A	7 – 10	8,5	45	0	2,4 (2,0 – 3,0)
Meter B	7 – 10	8,3	43	0	2,5 (2,0 – 3,1)
Meter A	> 10	12,9	42	0	3,1 (2,6 – 4,0)
Meter B	> 10	12,7	45	0	2,5 (2,0 – 3,1)

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

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

Table 9. Ascensia BREEZE2 – Repeatability (results with diabetic samples) measured by the "training group" and the "mail group"

Ascensia BREEZE2	Consultation/ diabetic group	Glucose level mmol/L	Mean value glucose mmol/L	n	Outliers	CV % (95 % CI)
At NOKLUS	1st/training group	< 7	5,9	11	0	3,2 (2,2 – 5,6)
	2nd/training group	< 7	6,4	8	0	2,9 (1,9 – 5,9)
	The mail group	< 7	5,6	11	0	2,9 (2,1 – 5,2)
At home**		< 7	5,6	105	2	5,6 (4,9 – 6,5)
At NOKLUS	1st/training group	7 – 10	8,3	15	0	2,9 (2,1 – 4,5)
	2nd/training group	7 – 10	8,3	15	0	5,3 (3,9 – 8,4)
	The mail group	7 – 10	8,6	14	0	4,7 (3,4 – 7,6)
At home**		7 – 10	8,4	142	6	5,1 (4,6 – 5,8)
At NOKLUS	1st/training group	> 10	11,7	14	0	4,0 (2,9 – 6,4)
	2nd/training group	> 10	13,2	14	1*	2,2 (1,6 – 3,6)
	The mail group	> 10	13,2	13	0	4,1 (2,9 – 6,7)
At home**		> 10	13,0	87	0	6,6 (5,8 – 7,8)

* One statistical outlier according to Burnett

** 48 home measurements are missing and 8 statistical outliers among the home measurements are excluded

Reproducibility with Internal Quality Control

The reproducibility is assessed with BREEZE2 Control Normal and BREEZE2 Control High. The measurements are carried out on meter A and meter B during the whole evaluation period. The reproducibility of Ascensia BREEZE2 on meter A and meter B is shown in table 10.

Table 10. Ascensia BREEZE2 – Reproducibility (results with BREEZE2 Control Normal and BREEZE2 Control High) measured by the biomedical laboratory scientists on meter A and meter B

Ascensia BREEZE2	Lot of strips	QC	Target value mmol/L	Mean value glucose mmol/L	n	Outliers	CV % (95 % CI)
Meter A	1T1367BB	N	5,5 – 7,1	6,1	27	0	2,9 (2,3 – 3,9)
		H	13,9 – 16,8	14,9	27	0	2,4 (1,9 – 3,3)
Meter B	1T1367BB	N	5,5 – 7,1	6,1	8	0	4,1 (2,7 – 8,4)
		H	13,9 – 16,8	14,8	8	0	2,5 (1,7 – 5,1)
	1T1367AA	N	5,4 – 7,0	6,2	11	0	3,0 (2,1 – 5,3)
		H	14,0 – 16,9	15,0	11	0	2,1 (1,5 – 3,7)
	1T1367CC	N	5,3 – 6,9	6,1	13	0	2,8 (2,0 – 4,6)
		H	13,2 – 16,0	14,4	13	0	2,4 (1,7 – 3,9)

Internal Quality Control on the diabetics' meters
The control measurements on the diabetics' meters were performed with BREEZE2 Control Normal. All the control measurements are performed by the biomedical laboratory scientists with the test strips that were distributed to each diabetic. The control solutions were kept at NOKLUS during the evaluation period. The imprecision on the meters of the diabetics is shown in table 11.

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

Table 11. Ascensia BREEZE2 – Reproducibility (results with BREEZE2 Control Normal) measured by the biomedical laboratory scientists on the diabetics' meters

Ascensia BREEZE2	Lot of strips	Target value mmol/L	Mean value glucose mmol/L	n	Outliers	CV % (95 % CI)
1st consultation						
The diabetics' meters	1T1367BB	5,5 – 7,1	6,1	13	0	2,4 (1,7 – 4,0)
	1T1367AA	5,4 – 7,0	5,9	13	0	2,5 (1,8 – 4,1)
	1T1367CC	5,3 – 6,9	5,9	13	0	3,0 (2,2 – 5,0)
2nd consultation						
The diabetics' meters	1T1367BB	5,5 – 7,1	6,2	27	0	3,6 (2,9 – 5,0)
	1T1367AA	5,4 – 7,0	6,3	27	0	3,3 (2,6 – 4,6)
	1T1367CC	5,3 – 6,9	6,1	24	0	3,3 (2,5 – 4,6)

Discussion
The precision of Ascensia BREEZE2 was good. The repeatability obtained under standardised and optimal conditions was approximately 3 %. The repeatability obtained at NOKLUS when the measurements were performed by the diabetics, was acceptable with a CV between 3 and 5 %. The CVs for the diabetics with and without training programme (the "training group" and the "mail group") were not significantly different. The CVs for the diabetics with and without practise at home (1st and 2nd training) were not significantly different either. This indicates that Ascensia BREEZE2 is a robust system, easy to use, and that training is not essential for a good result. The results at home show that the diabetics had been practising with the new system according to the instructions, but one should not make a point of the calculated CV values.

The reproducibility on Ascensia BREEZE2 was good when measured with internal quality control solutions. The CV was approximately 3 %.

5.2.2. The trueness of Ascensia BREEZE2

The trueness of Ascensia BREEZE2 is calculated from the results achieved by the biomedical laboratory scientists at the final consultation (the "training group" and the "mail group"). The calculations are based on measurements on meter A and are shown in table 12. All the measurements on meter A are performed with lot-no. 1T1367BB.

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

Table 12. Mean difference between Ascensia BREEZE2 and the comparison method. Results under standardised and optimal conditions from the final consultation

	< 7 mmol/L		**7 – 10 mmol/L**		**> 10 mmol/L**	
	The comparison method	**Meter A**	**The comparison method**	**Meter A**	**The comparison method**	**Meter A**
Mean glucose, mmol/L	5,8	5,8	8,4	8,4	13,5	13,1
Mean deviation from the comparison method, mmol/L (95 % CI)	0,00 (-0,12 – 0,13)		-0,03 (-0,25 – 0,19)		-0,34 (-0,58 – (-0,10))	
n	20		28		29	
Outliers	0		0		0	

Discussion

The trueness of Ascensia BREEZE2 was good. Table 12 shows that no significant bias between Ascensia BREEZE2 and the comparison method for glucose values < 10 mmol/L was pointed out. For glucose values > 10 mmol/L there was a small, but statistically significant bias between Ascensia BREEZE2 and the comparison method. Ascensia BREEZE2 gave glucose values approximately 0,3 mmol/L lower than the comparison method at this glucose level. In spite of this deviation the results still fulfil the quality goal.

5.2.3. The accuracy of Ascensia BREEZE2

To evaluate the accuracy of the results on Ascensia BREEZE2, the agreement between Ascensia BREEZE2 and the comparison method is illustrated in two difference-plots. The plots show the deviation of single measurement results on Ascensia BREEZE2 from the true value, and give a picture of both random and systematic deviation and reflect the total measuring error on Ascensia BREEZE2. The total error is demonstrated for the first measurements of the paired results, only. On meter A only one lot of test strips was used. On meter B three different lots were used. The same three lots were randomly distributed between the diabetics.

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 diabetics' self-measurements the "adjusted ISO-goal" at ±25 % is used.
The accuracy, Ascensia BREEZE2 meter B, under standardised and optimal measuring conditions, at the final consultation is shown in figure 2. The accuracy, Ascensia BREEZE2, as measured by the diabetics at the final consultation is shown in figure 3. The accuracy is summarised in table 13 and discussed afterwards.

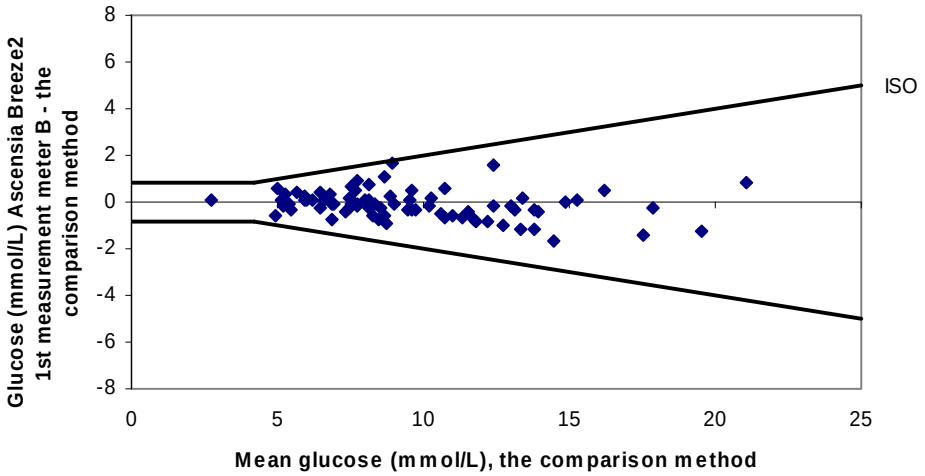

Figure 2. Accuracy. Ascensia BREEZE2 meter B (three lots of test strips) under standardised and optimal measuring conditions at the final consultation. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on Ascensia BREEZE2 and the mean value of the duplicate results on the comparison method, n = 77

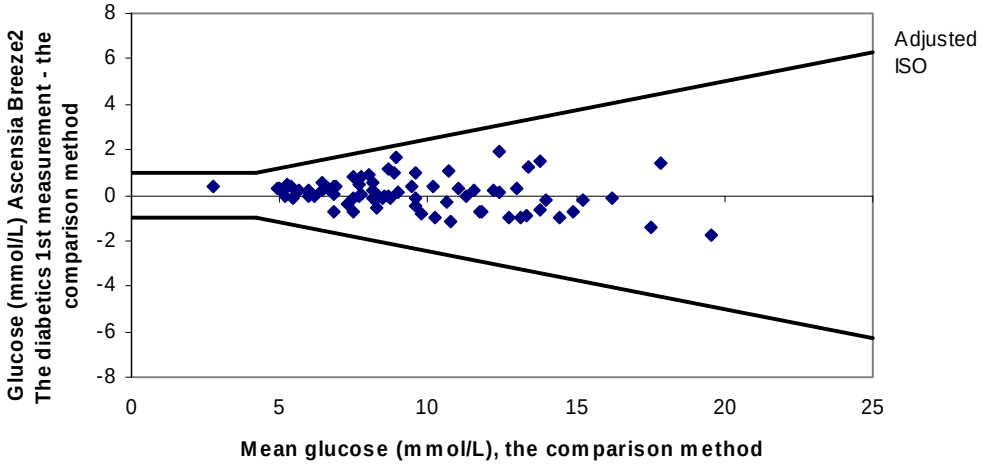

Figure 3. Accuracy. The diabetics' self-measurements at the final consultation. Three lots of test strips. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on Ascensia BREEZE2 and the mean value of the duplicate results on the comparison method, n = 75

Table 13. Total error of Ascensia BREEZE2 results compared to the comparison method. Percentage Ascensia BREEZE2 results within the limits

Measurements performed by	Consultation	Meter	n	Number of results (%)			Shown in figure
				< ADA < ±10 %	**< ISO** < ±20 % and < ±0,83 mmol/L at concentrations ≤4,2mmol/L	**< "adjusted ISO"** < ±25 % and < ±1,0 mmol/L at concentrations ≤4,2mmol/L	
Biomedical laboratory scientist	1st	A 1st measurement	40	95	100		
		B 1st measurement	40	73	100		
Biomedical laboratory scientist	2nd	A 1st measurement	77	91	100		
		B 1st measurement	77	88	100		2
Diabetics at NOKLUS	1st	1st measurement	39	79	100	100	
	2nd	1st measurement	75	84	100	100	3

Discussion

Figure 2 shows that all the results obtained under standardised and optimal measuring conditions are within the ISO-limits. The summing up in table 13 shows that all the first measurements at the first, as well as the final consultation are within the ISO-limits.

Figure 3 shows that all the diabetics' first self-measurements at the final consultation are within the "adjusted ISO-goal". The summing up in table 13 shows that all the diabetics' first self-measurements at the first and the final consultation are within the "adjusted ISO-goal" and also within the ISO-goal.

Assessment of accuracy

The Ascensia BREEZE2 device fulfils the quality goal set in ISO 15197 when used under standardised and optimal conditions. The "adjusted ISO-goal" and the ISO-goal is met by the measurements of the diabetics.

5.3. Variation between three lots of test strips

All the measurements on meter A were performed with one lot of test strips. The measurements on meter B were performed with three different lots of test strips, in three different groups of diabetics. The three lots can not be compared with each other directly because the mean glucose concentrations in the three groups of diabetics are different. To measure the variation between the three lots, the mean glucose results on Ascensia BREEZE2 obtained under standardised and optimal conditions on meter B were compared with the mean of the paired values from the comparison method (paired t-test). The results are shown in table 14.

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

	The comparison method	**Meter B Lot 1T1367BB**	**The comparison method**	**Meter B Lot 1T1367AA**	**The comparison method**	**Meter B Lot 1T1367CC**
Mean glucose, mmol/L	9,0	8,9	9,3	9,4	10,2	10,1
Mean deviation from the comparison method, mmol/L (95 % CI)	-0,11 (-0,37 – 0,15)		0,05 (-0,23 – 0,32)		-0,17 (-0,38 – 0,03)	
n	22		21		34	
Outliers	0		0		0	

Discussion

The three lots of test strips used in this evaluation gave glucose results in agreement with the comparison method. No significant difference was pointed out.

5.4. Effect of hematocrit

The product insert of Ascensia BREEZE2 test strips states that normal glucose concentrations are not considerably affected by hematocrit values from 20 to 55 %. In a glucose range >16,7 mmol/L, the glucose result is lowered if the hematocrit is > 55 % and elevated if the hematocrit is <20 %. To measure the effect of hematocrit on Ascensia BREEZE2, a hematocrit sample was taken of the diabetics at the second consultation.

The investigation of the effect of hematocrit is based on the measurements on Ascensia BREEZE2 under standardised and optimal measuring conditions. The glucose concentration range in the samples was 2,8 – 19,6 mmol/L. The hematocrit range was 33 – 50 %.

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 Ascensia BREEZE2 and the comparison method (Ascensia BREEZE2 – the comparison method) in mmol/L. The trend-line is shown in the figure.

The raw data is shown in attachment 9.

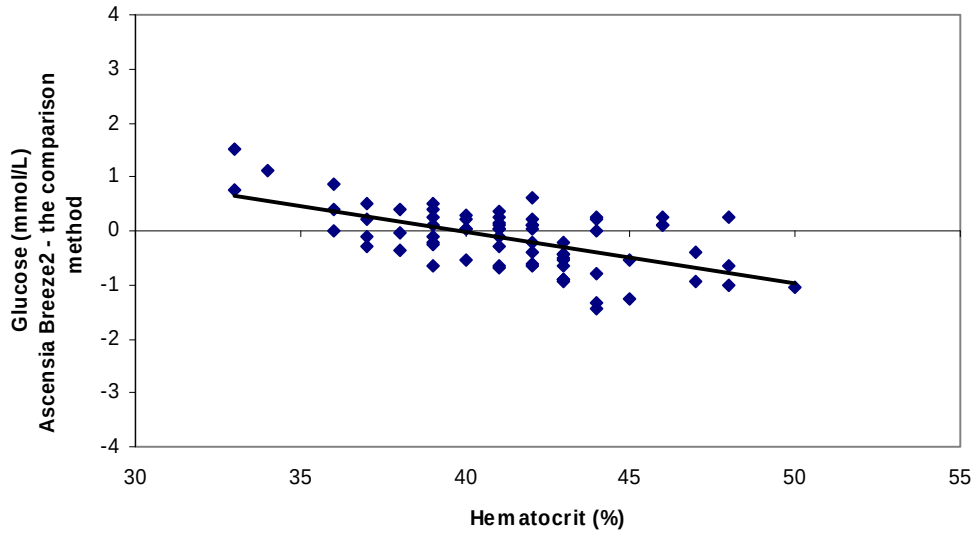

Figure 4. The effect of hematocrit at glucose measurements on Ascensia BREEZE2 measured under standardised and optimal conditions. The x-axis shows the hematocrit value in %. The y-axis shows the difference in glucose concentration between Ascensia BREEZE2 and the comparison method (Ascensia BREEZE2 – the comparison method) in mmol/L, n= 71

Discussion

Glucose measurements on Ascensia BREEZE2 seem to be affected by hematocrit in this study. Only three of the glucose results were > 16,7 mmol/L. Hematocrit outside the range 33 – 50 % has not been tested.

5.5. Practical points of view

Questionnaires

Each diabetic filled in a questionnaire about the user-friendliness and a questionnaire about the user guide of Ascensia BREEZE2 when they attended the final consultation (n = 78). The biomedical laboratory scientist was available for clarifying questions, and there was room for free comments.

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

5.5.1. Evaluation of the user-friendliness of Ascensia BREEZE2

The questionnaire about the user-friendliness contained eleven questions concerning Ascensia BREEZE2. Table 15 summarizes seven questions where the diabetics were asked to rank the answers on a scale from 1 to 6, where 1 is difficult and 6 is simple. The mean score is 5,7, 5,8, 5,4 and 5,3 on the questions about inserting or changing a 10-test disc, pushing out a strip, filling the strip with blood and releasing the used strip, respectively. This indicates that the diabetics seemed satisfied with the use of the test strip and the 10-test disc. The mean score is 5,9 on the question about reading the figures in the display. The diabetics also seemed satisfied with operating the meter, all in all. The mean score is 5,4. Regarding Ascensia Microlet lancet pen the mean score is 5,2, which indicates that the diabetics were satisfied with the lancet pen too.

Table 15. Ascensia BREEZE2 - Questions about the meter

Questions about Ascensia BREEZE2		Mean	Range	Not answered (% of total)	Total number
How will you rank the following questions on a scale from 1 to 6, where 1 is difficult and 6 is simple	To insert or change a 10-test disc	5,7	2 – 6	0	78
	To push out a test strip	5,8	3 – 6	0	78
	To fill the strip with blood	5,4	2 – 6	0	78
	To release the used test strip	5,3	2 – 6	0	78
	To read the figures in the display	5,9	4 – 6	0	78
	All in all, to operate the meter	5,4	2 – 6	0	78
	To operate Ascensia Microlet lancet pen	5,2	2 - 6	19	78

The diabetics were asked if they had any positive and/or negative comments about Ascensia BREEZE2. They were also asked to give their opinion of the carrying case.

Positive comments
62 diabetics reported one or more advantages with Ascensia BREEZE2. The most often reported advantages are distinctly grouped as follows:

1. 10-test disc (29)
2. Easy to use (23)
3. The meter has short measuring time (17)
4. Different advantages with the memory (7)
5. The meter/strip needs little blood sample volume (5)
6. Good display (5)
7. Hygienically (3)

Negative comments
44 diabetics reported one or more disadvantages with Ascensia BREEZE2. The most often reported disadvantages are distinctly grouped as follows:

1. The meter is too big (26)
2. The meter/strip needs large blood sample volume (6)
3. Difficult to release the used test strip (6)
4. Disadvantages with the lancet pen (3)
5. Disadvantages with the pull and push-function (3)

One of the diabetics meant that the beep signal from the meter was delayed compared to the filling of the strip. He meant that this could lead to removing the strip too early. Another diabetic meant that the rotor mechanism for the disc was not satisfactory. One of the diabetics commented that the number of strips left should also be displayed during the filling of the test strip.

The carrying case
The diabetics were satisfied with the carrying case.

Table 16 shows the answers to the last question about Ascensia BREEZE2. 15 % of the diabetics answered that they had technical problems with the meter during the testing period. One of the diabetics wrote that the meter didn't hold the disc in place. If he opened the meter the disc fell out. Another diabetic wrote that the pull and push-function failed. At some occasions one diabetic experienced that he didn't get any result because the meter stopped to function through count down. Written comments from the other diabetics indicate that their problems were not technical ones.

Table 16. Ascensia BREEZE2 – Questions about the meter

Question about Ascensia BREEZE2	Yes (%)	No (%)	Not answered (%)	Total number
Did you have any technical problems with the meter during the testing period?	15	77	6	78

5.5.2. Evaluation of the Ascensia BREEZE2 user guide

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

Table 17 shows that 76 % of the diabetics had used the guide, i.e. 59 of the 78 diabetics that completed the study. Most of them answered that they were satisfied with the description of how to perform a blood glucose measurement with the meter. None of them thought the guide had essential shortcomings. Most of the diabetics were satisfied with the user guide. One of the diabetics commented on a part of the user guide which he felt could cause unnecessary worry. He reacted on the instruction to contact a doctor if the glucose-result is <2,8 mmol/L or >13,9 mmol/L.

Table 17. Ascensia BREEZE2 – Questions about the user guide

Questions about the user guide	Yes (%)	No (%)	Not answered (%)	Number
Have you been reading in the user guide?	76	22	3	78
If yes, did you read the entire user guide?	46	39	15	59
And/or did you consult the user guide when needed?	66	15	19	59
Are you satisfied with the description of how to perform a blood glucose measurement with the meter?	97	2	2	59
Do you think the user guide has essential shortcomings?	0	93	7	59
All in all, are you satisfied with the user guide?	95	0	5	59

5.5.3. The biomedical laboratory scientists' evaluation

The biomedical laboratory scientists thought Ascensia BREEZE2 was easy to use. Since it was unnecessary to touch the test strip, the meter was hygienically to work with. The biomedical laboratory scientists were satisfied with the 10-test disc. They thought the meter was rather big. Sometimes it was difficult to release the used test strip from the meter. Even if the necessary sample volume is small, it was an advantage to have a small excess of blood on the finger tip. The biomedical laboratory scientists also thought the beep signal was delayed compared to the filling of the strip. There were some technical problems connected to the rotor mechanism at meter B during the evaluation period. Meter B had to be replaced. The biomedical laboratory scientists found four meters among the diabetics' meters with problems connected to the rotor mechanism. The biomedical laboratory scientists were satisfied with the user guide but reacted on the instruction to the diabetics to contact a doctor if the glucose-result was <2,8 mmol/L or >13,9 mmol/L.

6. References

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Attachments

1. Serial numbers, Ascensia BREEZE2 blood glucose meters
2. Information letter to the diabetics (in Norwegian)
3. Raw data, internal quality control, Architect
4. Raw data, Ascensia BREEZE2 results under standardised and optimal conditions
5. Raw data, Ascensia BREEZE2 results, the diabetics measurements at NOKLUS
6. Raw data, Ascensia BREEZE2 results, the diabetics measurements at home
7. Raw data, internal quality control, Ascensia BREEZE2
8. Raw data, Architect results, diabetic blood samples
9. Raw data, hematocrit
10. Questionnaire, user-friendliness (in Norwegian)
11. Questionnaire, user guide (in Norwegian)
12. List of evaluations organised by SKUP

Attachments with raw data are included only in the report to Bayer AS.

Attachment 1

Serial numbers, Ascensia BREEZE2 instruments used by the diabetics

ID	Serial number
1	SN1447-P000172
2	SN1447-P000518
4	SN1447-P000430
7	SN1447-P000222
9	SN1447-P000498
10	SN1447-P000236
13	SN1447-P000535
14	SN1447-P000433
15	SN1447-P000523
16	SN1447-P000306
20	SN1447-P000249
22	SN1447-P000591
25	SN1447-P000595
26	SN1447-P000557
31	SN1447-P000605
32	SN1447-P000539
34	SN1447-P000171
35	SN1447-P000421
37	SN1447-P000218
39	SN1447-P000499
41	SN1447-P000519
42	SN1447-P000590
43	SN1447-P000574
45	SN1447-P000227
47	SN1447-P000259
48	SN1447-P000459
49	SN1447-P000328
50	SN1447-P000465
51	SN1447-P000596
53	SN1447-P000502
54	SN1447-P000418
57	SN1447-P000569
58	SN1447-P000561
61	SN1447-P000579
65	SN1447-P000521
66	SN1447-P000327
68	SN1447-P000178
69	SN1447-P000604
70	SN1447-P000231
71	SN1447-P000471
72	SN1447-P000206

ID	Serial number
74	SN1447-P000225
75	SN1447-P000422
76	SN1447-P000244
78	SN1447-P000258
81	SN1447-P000230
82	SN1447-P000223
83	SN1447-P000225
84	SN1447-P000513
85	SN1447-P000582
88	SN1447-P000565
89	SN1447-P000511
91	SN1447-P000428
92	SN1447-P000501
94	SN1447-P000429
95	SN1447-P000552
96	SN1447-P000177
97	SN1447-P000562
98	SN1447-P000515
102	SN1447-P000217
105	SN1447-P000423
106	SN1447-P000432
107	SN1447-P000420
109	SN1447-P000512
110	SN1447-P000506
111	SN1447-P000554
114	SN1447-P000251
115	SN1447-P000309
119	SN1447-P000252
121	SN1447-P000246
124	SN1447-P000522
125	SN1447-P000570
126	SN1447-P000510
127	SN1447-P000566
128	SN1447-P000577
131	SN1447-P000257
132	SN1447-P000497
135	SN1447-P000568
137	SN1447-P000338
138	SN1447-P000461
139	SN1447-P000416

NORSK KVALITETSFORBEDRING AV
LABORATORIEVIRKSOMHET UTENFOR SYKEHUS

NOKLUS

Navn flettes inn
Adresse flettes inn
Postadresse flettes inn

ID-nr: flettes inn

November 2006

Utprøving av blodsukkerapparat

Du har fått utlevert en eske med:

- Ascensia BREEZE2 blodsukkerapparat i etui
- 5 disketter med Ascensia BREEZE2 teststrimler (totalt 50 teststrimler)
- Ascensia Microlet prøvetakingspenn
- 30 lansetter
- Brukerveiledning
- Lommeguide

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

1. og 2. uke:
De to første ukene skal benyttes til å bli kjent med apparatet. I løpet av disse to ukene skal du bruke ca. 25 strimler til å måle ditt eget blodsukker med utprøvingsapparatet.

Du kan selv velge når på dagen du vil gjøre disse målingene (du trenger ikke å være fastende). Passer det best slik, kan du utføre blodsukkermålingen med utprøvingsapparatet samtidig som du måler med ditt vanlige apparat. Dersom du ønsker det, kan du benytte ditt eget utstyr for prøvetaking i stedet for Ascensia Microlet prøvetakingspenn.

3. uke:
Etter at du har brukt de 25 første strimlene, skal du i løpet av den tredje uken måle blodsukkeret med utprøvingsapparatet på 5 forskjellige dager. Du kan selv velge når på dagen du vil gjøre disse målingene (du trenger ikke å 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.

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

ID-nr: Flettes inn
Lot nr. teststrimler: Flettes inn
Serienr. apparat: Flettes inn

Dato	Ascensia BREEZE2 Svar 1 (mmol/L)	Ascensia BREEZE2 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 Ascensia Microlet prøvetakingspenn til prøvetakingen?

☐Ja ☐Nei ☐Noen ganger

Av de 50 strimlene du fikk sammen med apparatet, skal du nå ha ca. 15 strimler igjen. Du må spare fem av strimlene til målingene du skal gjøre når du kommer hit til NOKLUS Senter for den avsluttende utprøvingen. Til den avsluttende utprøvingen skal du ta med Ascensia BREEZE2, resten av strimlene og Ascensia Microlet 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:

Marianne	55 97 95 04 / 55 97 95 00	Tirsdag – fredag	09:00 – 14:30
Camilla	55 97 95 15 / 55 97 95 00	Mandag – fredag	09:00 – 15:00

Lykke til!

Med vennlig hilsen

Grete Monsen	Marianne Risa	Camilla Eide Jacobsen
Prosjektansvarlig (sign.)	Avdelingsingeniør (sign.)	Avdelingsingeniør (sign.)

ID-nummer (diabetiker):_____

Ascensia BREEZE2

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 inn eller bytte strimmeldiskett

Vanskelig *Enkelt*

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

☐ ☐ ☐ ☐ ☐ ☐

2. Å få fram en teststrimmel

Vanskelig *Enkelt*

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

☐ ☐ ☐ ☐ ☐ ☐

3. Å fylle strimmelen med blod

Vanskelig *Enkelt*

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

☐ ☐ ☐ ☐ ☐ ☐

4. Å fjerne strimmelen fra apparatet

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

Ascensia BREEZE2

7. Å betjene Ascensia Microlet prøvetakingspenn (skal kun besvares hvis Ascensia Microlet prøvetakingspenn 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 ved Ascensia BREEZE2?

- _____
- _____
- _____

10. Synes du det er noen ulemper ved Ascensia BREEZE2?

- _____
- _____
- _____

11. Hva synes du om etuiet?

_____

Evt. andre kommentarer:_____

_____

_____

ID-nummer (diabetiker):_____

Ascensia BREEZE2

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:_____

   _____

   _____

   _____

List of evaluations organised by SKUP

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

Evaluations performed in 2004 – 2007

Evaluation no.	Component	Instrument/testkit	Producer
SKUP/2007/59	Glucose[1]	Ascensia BREEZE2	Bayer HealthCare
SKUP/2007/62*	Strep A	*Confidential*	
SKUP/2007/57*	PT (INR)	Simple Simon PT	Zafena AB
SKUP/2007/55	PT (INR)	CoaguChek XS	Roche Diagnostics
SKUP/2006/53*	Strep A	*Confidential*	
SKUP/2005/52*	Strep A	Clearview Exact Strep A Dipstick	Applied Biotech, Inc.
SKUP/2005/51*	Glucose[1]	FreeStyle	Abbott Laboratories
SKUP/2006/50	Glucose[1]	Glucocard X-Meter	Arkray, Inc.
SKUP/2006/49	Glucose[1]	Precision Xtra Plus	Abbott Laboratories
SKUP/2006/48	Glucose[1]	Accu-Chek Sensor	Roche Diagnostic
SKUP/2006/47	Haematology	Chempaq XBC	Chempaq
SKUP/2005/46*	PT (INR)	*Confidential*	
SKUP/2006/45	Glucose[1]	HemoCue Monitor	HemoCue AB
SKUP/2005/44	Glucose[1]	Accu-Chek Aviva	Roche Diagnostics
SKUP/2005/43	Glucose[1]	Accu-Chek Compact Plus	Roche Diagnostics
SKUP/2005/42*	Strep A	Twister Quick-Check Strep A	ACON laboratories, Inc.
SKUP/2005/41*	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

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

[1] Including a user-evaluation among diabetic patients.

Evaluations performed in 1999 - 2003

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

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

[1] Including an user-evaluation among diabetic patients.

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