

# Accu-Chek Compact Plus Glucose Accu-Chek Aviva Glucose Accu-Chek Sensor Glucose

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Summary of three evaluations organised by SKUP  
Report SKUP/2005/43, SKUP/2005/44 and SKUP/2006/48

## Background

In order to give reimbursement for glucose test strips in Norway, The National Social Insurance Office (Rikstrygdeverket) instructs the companies to carry out an evaluation that includes a user-evaluation among diabetics. The results of the evaluation must fulfil the quality goals set in ISO 15197. Accu-Chek Compact Plus, Accu-Chek Aviva and Accu-Chek Sensor are meters designed for glucose self-measurements by diabetics. The meters are produced and supplied by Roche Diagnostics. Accu-Chek Compact Plus was launched onto the Norwegian market in May 2005, Accu-Chek Aviva in July 2005 and Accu-Chek Sensor in 1998. The evaluations of Compact Plus and Aviva were done under the direction of SKUP during the spring of 2005, and the evaluation of Sensor during the autumn of 2005.

## The aim of the evaluations

*The aim of the evaluations is to*

- reflect the analytical quality under standardised and optimal conditions, performed by biomedical laboratory scientists
- reflect the analytical quality achieved by the users (approximately 240 diabetics participated in the three evaluations)
- 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 the user-friendliness of the device
- evaluate the user-manual

## Materials and methods

Approximately 80 diabetics took part in each evaluation. One group of participants had two consultations (the "training group") and the other group had one consultation (the "mail group"). At the first consultation the diabetics in the "training group" were given a standardised instruction about the device before they did a finger prick and performed two measurements with the meter. The biomedical laboratory scientist also took capillary samples of the diabetics and measured twice at the device. In addition, two capillary samples were taken to a designated comparison method. The "mail group" received the device by mail and no training was given. Both groups of diabetics carried out a practice period of three weeks at home, before they were called for a second consultation. The same blood glucose sampling and measurement procedures were repeated, and in addition a sample for hematocrit was taken. Three different lots of test strips were used in the evaluation. All the participants finally answered questionnaires about the user-friendliness and the user-manual.

## Results, Accu-Chek Compact Plus

Accu-Chek Compact Plus shows acceptable precision. The CV is approximately 3 % under standardised and optimal measuring conditions and between 3 and 6 % when the measurements are performed by diabetics.

The agreement with a designated comparison method is good. Quality goals set in ISO 15197 are

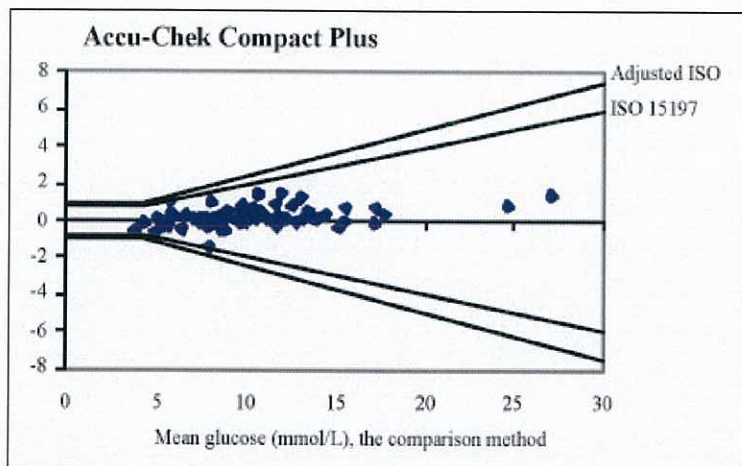


Figure 1. Accuracy. The diabetics' self-measurements at the final consultation. Two lots of test strips.

The x-axis represents the mean value of the duplicate results at the comparison method. The y-axis shows the difference between the first measurement at Compact Plus and the mean value of the duplicate results at the comparison method. n = 75.

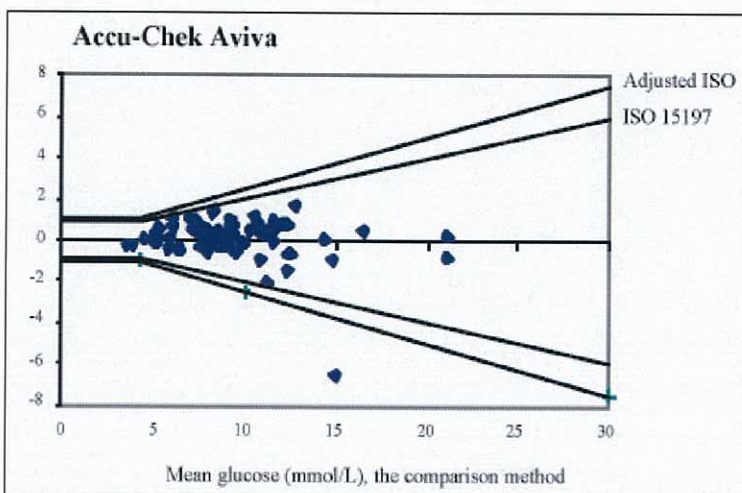


Figure 2. Accuracy. The diabetics' self-measurements at the final consultation. Three lots of test strips.

The x-axis represents the mean value of the duplicate results at the comparison method. The y-axis shows the difference between the first measurement at Accu-Chek Aviva and the mean value of the duplicate results at the comparison method, n = 77. The outlier with the negative bias is probably due to problems with the comparison method.

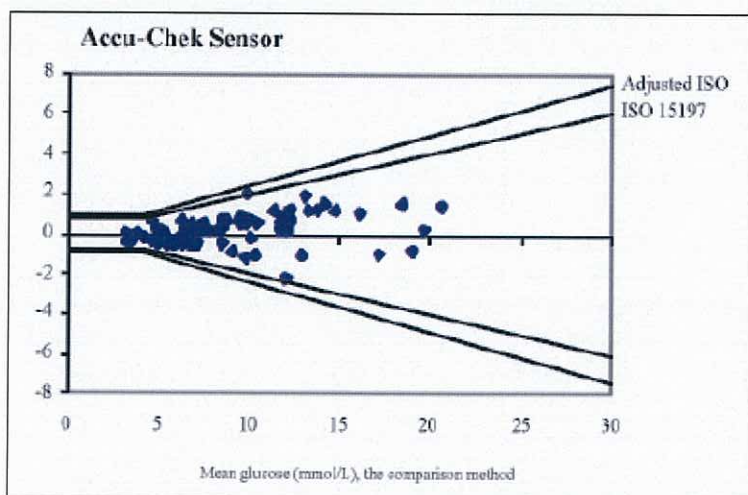


Figure 3. Accuracy. The diabetics' self-measurements at the final consultation. Three lots of test strips.

The x-axis represents the mean value of the duplicate results at the comparison method. The y-axis shows the difference between the first measurement at Accu-Chek Sensor and the mean value of the duplicate results at the comparison method, n = 77.

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achieved under standardised and optimal measuring conditions, and at the final consultation even the quality goals set by ADA are achieved. When handled by the diabetics, Accu-Chek Compact Plus also shows accurate results. All these results are within the "adjusted ISO-goal" ( $\pm 25\%$ ) and the results also fulfil the quality goals set in ISO 15197 (Fig. 1).

One of the three lots of test strips that were used showed significantly lower values than the comparison method. In spite of this deviation, the results attain the quality goal.

Glucose measurements at Accu-Chek Compact Plus seem to be affected by the hematocrit values of the samples in higher degree than described in the package insert. Glucose values are over-estimated when the hematocrit is below 35 %. With hematocrit values over approximately 45 % the glucose values are under-estimated.

The diabetics summarise the Accu-Chek Compact Plus device as easy to use. Most of them were pleased with the device. The diabetics that had used the user manual were satisfied with the manual.

#### **Results, Accu-Chek Aviva**

Accu-Chek Aviva shows acceptable precision. The CV is  $< 5\%$  under standardised and optimal measuring conditions and approximately 5 % when the measurements are performed by diabetics.

The agreement with a designated comparison method is good. Quality goals set in ISO 15197 are achieved under standardised and optimal measuring conditions. When handled by the diabetics, Accu-Chek Aviva also shows accurate results. These results are within the "adjusted ISO-goal" and also within the quality goals set in ISO 15197 (Fig. 2).

Two of the three lots of test strips that were used showed significantly higher values than the comparison method. In spite of this deviation, the results attain the quality goal.

Glucose measurements with Accu-Chek Aviva do not seem to be affected by hematocrit values between 28 - 49 %. Hematocrit outside this range has not been tested.

The diabetics summarise the Accu-Chek Aviva device as easy to use. Most of them were pleased with the device. The diabetics that had used the user manual were satisfied with the manual.

#### **Results, Accu-Chek Sensor**

Accu-Chek Sensor shows acceptable precision. The CV is approximately 3 % under standardised and optimal measuring conditions and between 2 and 6 % when the measurements are performed by diabetics.

Accu-Chek Sensor gives glucose values from 0,1 - 0,3 mmol/L higher than the comparison method. This bias has no importance.

The agreement with a designated comparison method is good. Quality goals set in ISO 15197 are achieved under standardised and optimal measuring conditions. When handled by the diabetics, Accu-Chek Sensor also shows accurate results. These results are within the "adjusted ISO-goal" and also within the quality goals set in ISO 15197 (Fig. 3).

Two of the three lots of test strips that were used showed significantly higher values than the comparison method. The bias is small, and the results still attain the quality goals.

Glucose measurements at Accu-Chek Sensor do not seem to be affected by hematocrit values between 35 - 50 %. Hematocrit outside this range has not been tested.

The diabetics summarise the Accu-Chek Sensor device as easy to use. Most of them were pleased with the device. The diabetics that had used the user manual were satisfied with the manual.

#### **Conclusion**

Glucose measurements with Accu-Chek Compact Plus, Accu-Chek Aviva and Accu-Chek Sensor have acceptable precision. The accuracy is good. The results are within the quality goals set in ISO 15197. Glucose results at Accu-Chek Compact Plus seem to be affected by hematocrit in a higher degree than described in the package insert, while the glucose results at Accu-Chek Aviva and Accu-Chek Sensor do not seem to be affected by the hematocrit. The users find the devices easy to use and are quite satisfied with the devices and the user manuals.

*The complete evaluation reports are available at [www.skup.nu](http://www.skup.nu)*