

Comparison between the new AccuChek Inform II glucose meter and the Rapidlab 865 blood gas analyzer: implications for use of the Inform II in tight glycemetic control

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1. Introduction:

Use of point-of-care glucose meters for glucose monitoring is now standard of care in the majority of hospitals. In intensive care units (ICU), handheld meters are alternatively employed with blood gas analyzers for glucose testing and monitoring.

Due to conflicting results in studies aimed to evaluate the benefits of intensive insulin therapy in critically ill patients, the use of glucose meters for tight glycemetic control (TGC, i.e. insulin therapy aiming to maintain blood glucose levels between 80 and 110 mg/dL) is matter of debate since several years.

A reason for the discrepant results may be the weak accuracy of meters used in some of the studies. In order to achieve glucose control, the reliability of the POC glucose measurement is essential.

2. Aims:

The AccuChek Inform II meter is the new generation of Roche's portable device designed for use in hospitals.

As part of its analytical validation in our institution, we realized an original comparison between the glucose meter and the blood gas analyzer Siemens Rapidlab 865.

The goal was to evaluate the analytical performance of the AccuChek Inform II and to assess whether the results obtained with this meter were comparable with those given by the Rapidlab 865 glucose electrode.

4. Results:

The mean glucose concentrations of the three-levelled QC measured with the Rapidlab 865 were 50.3, 100.5 and 208.9 mg/dL.

The accuracy profile built with the predictive tolerance interval method shows that, on average, 95% of the future results obtained with the Inform II meters will be transposable to those that would be obtained with the gas analyzer in the 50.3-202.9 mg/dL (2.78-11.1 mmol/L) range, with a $\pm 10\%$ error margin tolerated (Fig. 1).

Table 1. Method accuracy

| Mean target concentration (mg/dL) | Beta-expectation tolerance limits (mg/dL) | Relative Beta-expectation tolerance limits (%) | Risk ¹ (%) |
|-----------------------------------|---|--|-----------------------|
| 50.28 | [45.38 , 48.78] | [-9.740 , -2.975] | 1.785 |
| 100.5 | [92.01 , 102.0] | [-8.452 , 1.486] | 0.5822 |
| 208.9 | [208.6 , 230.9] | [-0.1588 , 10.51] | 3.727 |

¹ Risk of having measurements falling outside of the acceptance limits.

3. Methods:

We used the internal QC material supplied by Siemens with the Rapidlab 865. The three levels of the QC were simultaneously assessed with two AccuChek Inform II meters and one Rapidlab 865 analyzer in triplicate on six different days.

For each QC level, the mean of the results obtained with the Rapidlab 865 was used as target value for the evaluation of the Inform II accuracy. The method was validated following an approach using accuracy profiles based on β -expectation tolerance intervals for the total error measurement.

Beta-expectation tolerance intervals are intervals that contain a proportion β of the individual values of the population under investigation. These intervals allow the description of the entire population. If $\beta=0.95$, this means that 95% of the future individual values (results) of the population will be included in the interval.

The acceptance limits have been set at $\pm 10\%$ total error. The e.noval software (Arlenda, Liège, Be) was used to compute the results.

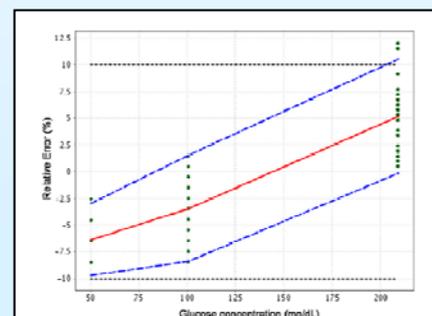


Fig 1. Accuracy profile. The plain line is the relative bias, the dashed lines are the β -expectation tolerance limits and the dotted lines represent the acceptance limits. The dots represent the relative error of the back-calculated concentrations and are plotted with respect to their targeted concentration. The highest concentration beyond which the β -expectation limits go outside the acceptance limits is 202.9 mg/dL.

5. Discussion:

Several difficulties make target of TGC laborious to reach in critically ill patients, including the reliability of measurements with glucose meters and their commutability with results obtained by other methods.

In this preliminary work, the new AccuChek Inform II showed comparable analytical performances with the Rapidlab 865 for the analysis of QC material. We are currently repeating the same experiments in different conditions (other instruments, lot of strips, operators, different QC materials...) in order to confirm these results. Although a validation with patient samples remains mandatory, our approach allowed us to compare both apparatus without any other source of variation (sample type, hematocrit, pO₂...).

We think it is important to evaluate the analytical performance of an instrument before to start a large clinical study. Further investigations are now needed to estimate the efficiency of the Inform II in TGC protocols.