Assessing the ABL 500 blood gas analyser

B. Gouget, R. Andriamahatratra, Y. Gourmelinand A. Truchaud
Laboratoire de Biochimie, Centre hospitalier général, BP 218, F77108 Meaux, France

The ABL 500 blood gas analyser from Radiometer has cordless electrodes and does not use a humidifier for calibrating gases. During the evaluation of the analytical performance of this instrument, the problem of pO2 accuracy was approached by comparing the values obtained with two kinds of tonometry (film and bubble). An acceptable level of imprecision was demonstrated for all measured parameters. For within-run precision, with tonometry, coefficients of variation (CV) were ≤0.37% for pO2 and ≤0.52% for pCO2. A CV of 1.76% was found for day-to-day precision for both pO2 and pCO2. In the linearity study, with both tonometry methods, and in the inter-instrument comparisons (the ABL was compared with the Ciba Corning 178), pO2 values obtained on the ABL 500 exhibited a slight overestimation above 150 mmHg (2.2-3.4% at 600 mmHg). This minor discrepancy is discussed with reference to the new design of the pO2 electrode, the algorithm for pO2 correction and the tonometry procedure. The results reported in this paper stress the importance of pO2 accuracy assessment for the evaluation of blood gas analysers.

The Radiometer ABL 500 blood gas analyser is modular and includes some highly innovative features, such as cordless electrodes and a remembranising system. The analyser was evaluated for analytical performance and practicability, using both tonometry and commercial aqueous control solutions [1]. A recurrent problem in evaluation in blood gas instrumentation is pO2 accuracy [2] – built-in corrections apply to the directly measured pO2 values. The accuracy of pO2 displayed by the instrument depends upon the quality of the algorithms used for correction.

The equation needed for this adjustment is determined empirically during the development of a new instrument by comparing data from several uncorrected analysers to a reference method [3]. There is no standard method for determining the partial pressures of blood gases with absolute accuracy [4]. However, tonometry of fresh whole blood is considered the reference method for assessing pO2 accuracy. In order to test the validity of the ABL 500 algorithm for pO2 correction, two kinds of tonometry were used (film and bubble) and the reliability of pO2 measurement was assessed according to the results obtained by the two methods.

Materials and methods

Blood gas analysers

The ABL 500 measures pH, pCO2 and pO2. Electrodes are based upon reference technology with miniaturized cordless electrodes, which are colour coded to ensure correct placement. The built-in gas mixer supplies the following gas mixtures from atmospheric air and from pure CO2: G1: 5.6% CO2, 19.76% O2; G2: 10% CO2 is the high point of calibration of the pCO2 electrode; G3 is 100% CO2 and is used for the zero calibration of the pO2 electrode. The ever-present film of rinse solution inside the tubing is sufficient to achieve the necessary humidification of the calibration gases. The pH electrode is calibrated using two reagent buffers. Automatic calibrations are adjusted according to individual requirements. The ABL 500 accepts two sample sizes: 35 μl for pH in a special micromode; a total blood gas analysis is available from 70 μl using injection or an aspiration mode.

The Ciba Corning 178 blood gas analyser was used as comparison instrument.

Materials

Solutions

Phosphate buffer solutions at pH 6.838 and 7.384 were prepared in line with the recommendations of National Bureau of Standards [5]. Qualicheck Radiometer aqueous controls solutions were used at three levels (acidosis, normal and alkalosis) and a fourth high oxygen level was used for the within-run study.

Tonometers

Tonometry was performed according to the IFCC reference method [6] on a Laue Bulb (Eschweiler, Germany) and on the Corning 184 (Ciba-Corning Medical and Scientific, Medfield, Massachusetts, USA) tonometers.

The Laue bulb tonometer consists of a rotating glass bulb, placed in a water-bath at 37-0°C with a gas humidifier and a gas vent. Due to the eccentric rotation of the bulb a thin film of the sample is formed. The Corning 184 tonometer is designed as a syringe tonometer according to the bubble equilibration principle. Antifoam solution was added to blood samples (Corning antifoam solution). Both tonometers were operated and maintained according to the manufacturer’s instruments.

Blood samples

Fresh heparinized venous or arterial blood was obtained from healthy donors for tonometry and from hospitalized patients for comparison studies.

Protocol

pH accuracy

The two phosphate buffers were run in triplicate over five days.
Table 1. Within-run precision (N = 6).

| Qualicheck solutions | Mean ± SD | Mean | ± SD | Mean ± SD | Mean ± SD |
|----------------------|----------|------|------|----------|----------|
| pH                   | 7·121    | 0·002| 7·385| 0·001    | 7·610    | 0·001    | 7·108    | 0·002 |
| pCO₂ (mmHg)          | 59·1 (7·89)| CV% 0·26 | 39·8 (5·51)| CV% 0·43 | 18·2 (2·43)| CV% 0·33 | 102·4 (13·65)| CV% 0·43 |
| pO₂ (mmHg)           | 54·9 (7·32)| 0·73 | 106·2 (14·15)| 0·29 | 171·8 (22·90)| 0·27 | 305·1 (40·67)| 0·47 |

Blood tonometry

| Assigned value | Mean | CV% | Assigned value | Mean | CV% |
|----------------|------|-----|----------------|------|-----|
| pCO₂ (KPa)     | 20 (2·66)| 20·3 (2·70)| 0·36 | 80 (10·64)| 81·3 (10·84)| 0·52 |
| pO₂ (mmHg)     | 40 (5·32)| 40·1 (5·33)| 0·37 | 160 (21·28)| 158·8 (21·17)| 0·30 |

Precision study

Within-run precision was estimated with Qualicheck solutions and two levels of tonometry (L1: CO₂ = 20 mmHg [2·66 kPa], O₂ = 40 mmHg [5·32 kPa]; L2: CO₂ = 80 mmHg [10·64 kPa] O₂ = 160 mmHg [21·28 kPa]). Six measurements were performed at each level.

Day-to-day precision

The same solutions and same levels of tonometry were run daily for 25 days.

Drift was assessed using tonometered blood tested immediately after one calibration and before the subsequent one.

Linearity was tested using successive measurements of tonometered blood containing O₂ for 0 to 85% and CO₂ from 1 to 20%. The sequence was repeated three times with the two systems of tonometry.

Inter-instrument comparisons

About 300 samples from patients were simultaneously measured on both instruments. The values covered the patho-physiological ranges for the three parameters under investigation.

Practicability

Special attention was paid to quantifying the most important specifications of the instrument, to maintenance requirements and to safety.

Results

The mean pH values from the triplicate measurements were never separated by ±0·01 UpH from the assigned values of the two buffers.

Precision study

Within-run precision

Coefficients of variation never exceeded 0·43% for pCO₂ and 0·73% for pO₂ at each level of Qualicheck solutions. With film tonometry CVs were ≤0·52% for pCO₂ and ≤0·37% for pO₂. Results for a representative sequence of the within run precision study are given in table 1.

Results for day-to-day precision are given in table 2 and illustrate that the measured values by tonometry were very close to the assigned values.

Linearity

For pCO₂, linearity was verified between 0 and 150 mmHg (0 and 20 kPa). Figure 1 reports the aggregate results for pO₂ linearity by film tonometry between 0 and 600 mmHg (80 kPa) with a simple regression line y = 1·03x – 1·09; r > 0·999. When the data were examined in more detail, two patterns of linearity could be observed (see figure 2). In the range 0–150 mmHg (20 kPa), the assigned and measured values were identical. Above 150 mmHg (20 kPa), a slight over-estimation was observed (+2·2% at 600 mmHg (80 kPa)); using bubble tonometry, this discrepancy was even larger (+3·4% at 600 mmHg (80 kPa)) (see figure 3). Differences between pO₂ results obtained under aspiration and injection modes, with film tonometry, were found to be statistically significant above 350 mmHg (8·2 and 10·4 mmHg at 500 and 600 mmHg respectively), but not clinically unacceptable.

No drift was observed between calibrations.

Inter-instrument comparisons

Figures 4, 5 and 6 report data on the inter-instrument comparisons for pH, pCO₂, pO₂ and indicate that values for pH (6·95–7·63) were similar on the ABL 500 and Ciba Corning 178 analysers. pCO₂ values on the ABL 500 (10–102 mmHg) were slightly lower than on the Ciba Corning 178 (the means were 40·3 and 41·5 mmHg, respectively). This is not unexpected, because pCO₂ values on the Ciba
Table 2. Day-to-day precision (N = 25).

| QualiCHECK solutions | Mean ± SD | Mean ± SD | Mean ± SD |
|-----------------------|-----------|-----------|-----------|
| pH                    | 7.120 0.003 | 7.376 0.004 | 7.611 0.002 |
| CO₂ (mmHg)            | Mean CV%  | Mean CV%  | Mean CV%  |
| (kPa)                 |           |           |           |
| 59.6                  | 0.97      | 39.8      | 1.20      |
| 7.94                  | (2.45)    | (6.25)    | (3.31)    |
| O₂ (mmHg)             | Mean CV%  | Mean CV%  | Mean CV%  |
| (kPa)                 |           |           |           |
| 54.6                  | 1.95      | 104.3     | 1.60      |
| 7.28                  | (2.94)    | (13.90)   | (22.96)   |

| Blood tonometry       | Assigned value | Mean CV% | Assigned value | Mean CV% |
|-----------------------|----------------|----------|----------------|----------|
| CO₂ (mmHg)            | 20             | 20.5     | 1.76           | 80       |
| (kPa)                 | 2.66           | (2.73)   | (10.64)        | (11.01)  |
| O₂ (mmHg)             | 40             | 40       | 1.75           | 160      |
| (kPa)                 | 5.32           | (5.32)   | (21.28)        | (21.03)  |

Figure 1. pO₂ linearity on the ABL 500 analyser using film tonometry (N = 134) between 0 and 600 mmHg (y = 1.03 x - 1.09, r ≥ 0.999).

Corning 178 are often higher than on other modern analysers (this was demonstrated by a recent French interlaboratory quality control program). For pO₂ (12–432 mmHg (1.6–57.5 kPa)), a trend for overestimation on the ABL 500 versus Ciba Corning 178 above 150 mmHg (20 kPa) was observed.

**Discussion**

The evaluation demonstrated a high degree of precision for all measured parameters. Inter-instrument comparisons and reference method application identified some discrepancies especially for high pO₂ values.

The linearity study gave the following results:

(1) The zero point calibration was verified by tonometry. The measurement of the electrode response, at zero pO₂, increases the accuracy of the subsequent determinations.

(2) Near the second calibration point of the slope (O₂ = 20%), the measured values were identical to the expected ones.

(3) Discrepancies appeared above 150 mmHg (20 kPa) of pO₂. Several hypotheses can be discussed.

The values given by the analyser are always corrected values. The algorithm for correction is dependent upon the gas/liquid ratio and the sensitivity of the pO₂ electrode, calculated during the last calibration of the high pO₂ gas. There are also corrections for systematic deviations arising from the contamination of the sample by the amount of oxygen present on the inner walls of the tubing and/or measuring chamber. The magnitude of this effect is influenced by different factors, such as the
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Figure 2. $pO_2$ linearity for low (0–150 mmHg [0–20 kPa], N = 101) (a), and high (150–600 mmHg [20–80 kPa], N = 33) (b), $pO_2$ values with film tonometry. The x axis represents assigned $pCO_2$ values with film tonometry; and the y axis represents the difference between the actual values measured on ABL 500 and the assigned values.

Figure 3. $pO_2$ linearity using bubble tonometry between 150 and 600 mmHg (20–80 kPa), N = 50. x and y axes as figure 2.

Figure 4. Intrument comparison for $pH$, N = 291 samples for hospitalized patients ($y = 0.975x + 0.18$, r = 0.992). The x axis represents measurements performed on Ciba Corning 178 analyser; and the y axis represents the difference in $pH$ values between the ABL 500 and the Ciba-Corning 178 analysers. The solid horizontal lines represent pre-established limits ($\pm 0.03$ UpH) of acceptable imprecision.
Figure 5. Inter-instrument comparison for pCO₂ (N = 291), y and x axes as figure 4. The pre-established limits for pCO₂ are ±3 mmHg. (y = 1.04x - 2.71, r = 0.998).

equilibrating temperature maintained at 37.0 ± 0.10°C could not account for the differences observed between the assigned and the measured values at high pO₂ levels. In the Corning 184 tonometer, the blood sample is transferred directly from the equilibration syringe to the blood gas instrument, but changes in the sample may have several explanations:

(a) Haemolysis due to the antifoam solution, but the consequence of this is minor magnitude [8].

(b) A bubble effect, which raises pO₂. This bubble effect is related to the surface tension of the liquid surrounding the bubble, the bubble diameter and the hydrostatic pressure in the tonometer vessel [9].

However, beside the discrepancies demonstrated by tonometry, an overestimation of high pO₂ values persists on the ABL 500 analyser. For example, the measuring time on blood samples is not constant for the pO₂ electrode. The value calculated from the second reading is used to determine the measuring time. When pO₂ is very low or very high, this time is maximal. In addition, the inner side of the polypropylene membrane is covered by platinum black, resulting in a faster and more stable pO₂ electrode. Theoretically, these new features should have improved the stability and the accuracy of the pO₂ electrode.

The algorithm was established using capillary tubes and aspiration mode, as on the previous models of analysers by Radiometer [11]. Under these conditions the volume of the sample and the magnitude of the contamination were precisely known. However, for the present evaluation, syringes and the injection mode were used. The volume of the sample is probably larger and more variable and the contamination not identical to the conditions defined by the aspiration mode. However, the injection mode with a syringe is more generally used for routine measurements. Moreover, pO₂ values were not identical above 150 mmHg (20 kPa) between the Ciba Corning 178 and the ABL 500, when comparing patients’ samples. These two facts suggest that the small overestimations of the ABL 500 pO₂ determinations at elevated oxygen pressures are of minor importance. Difficulties in handling samples with very high oxygen tensions must be noted. Most performance specifications given by the manufacturers do not reach pO₂ values above 550 mmHg. To further improve pO₂ accuracy, the algorithm for correction should take into account high pO₂ tensions and the mode of sample introduction.

In conclusion, this study emphasizes that assessment of pO₂ accuracy is still difficult. The quality control materials which are available today are not ideal. However, commercially prepared materials are appropriate on a routine basis [12]. Tonometry is still questionable, but it is the only way to assess the characteristic
properties of the blood gas analysers: imprecision, inaccuracy and inter-instrument variations [13]. The slight inaccuracy observed for hyperoxic levels on the ABL 500 analyser should be balanced by the reduced clinical interest in the $pO_2$ reliability in this high range. The technical innovations associated with the up-to-date computer style of this analyser makes it particularly easy to run after a short period of training.

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