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Assessing the ABL 500 blood gas analyser

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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 pO_2 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 pO_2 and ≤0·52% for pCO_2. A CV of 1·76% was found for day-to-day precision for both pO_2 and pCO_2. In the linearity study, with both tonometry methods, and in the inter-instrument comparisons (the ABL was compared with the Ciba Corning 178), pO_2 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 pO_2 electrode, the algorithm for pO_2 correction and the tonometry procedure. The results reported in this paper stress the importance of pO_2 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 remembraning 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 pO_2 accuracy [2] – built-in corrections apply to the directly measured pO_2 values. The accuracy of pO_2 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 pO_2 accuracy. In order to test the validity of the ABL 500 algorithm for pO_2 correction, two kinds of tonometry were used (film and bubble) and the reliability of pO_2 measurement was assessed according to the results obtained by the two methods.

Materials and methods

Blood gas analysers

The ABL 500 measures pH, pCO_2 and pO_2. 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 CO_2: G1: 5·6% CO_2, 19·76% O_2; G2: 10% CO_2 is the high point of calibration of the pCO_2 electrode; G3 is 100% CO_2 and is used for the zero calibration of the pO_2 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 control 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 excentric 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
		Mean	CV%	Mean	CV%	Mean	CV%	Mean	CV%
pCO_2	mmHg	59·1	0·26	39·8	0·43	18·2	0·33	102·4	0·43
	(kPa)	(7·89)		(5·31)		(2·43)		(13·65)	
pO_2	mmHg	54·9	0·73	106·2	0·29	171·8	0·27	305·1	0·47
	(kPa)	(7·32)		(14·15)		(22·90)		(40·67)	
Blood tonometry		Assigned value	Mean	CV%		Assigned value	Mean	CV%	
pCO_2	mmHg	20	20·3	0·36		80	81·3	0·52	
	(kPa)	(2·66)	(2·70)			(10·64)	(10·84)		
pCO_2	mmHg	40	40·1	0·37		160	158·8	0·30	
	(kPa)	(5·32)	(5·33)			(21·28)	(21·17)		

Precision study

Within-run precision was estimated with Qualicheck solutions and two levels of tonometry (L1: CO_2 = 20 mmHg [2·66 kPa], O_2 = 40 mmHg [5·32 kPa]; L2: CO_2 = 80 mmHg [10·64 kPa] O_2 = 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 O_2 for 0 to 85% and CO_2 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 pCO_2 and 0·73% for pO_2 at each level of Qualicheck solutions. With film tonometry CVs were ⩽0·52% for pCO_2 and ⩽0·37% for pO_2. 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 pCO_2, linearity was verified between 0 and 150 mmHg (0 and 20 kPa). Figure 1 reports the aggregate results for pO_2 linearity by film tonometry between 0 and 600 mmHg (80 kPa) with a simple regression line y = 1·03x–1·09; $r > 0{\cdot}999$. 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 pO_2 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, pCO_2, pO_2 and indicate that values for pH (6·95–7·63) were similar on the ABL 500 and Ciba Corning 178 analysers. pCO_2 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 pCO_2 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
		Mean	CV%	Mean	CV%	Mean	CV%
pCO_2	mmHg	59·6	0·97	39·8	1·20	18·3	1·90
	(kPa)	(7·94)		(5·31)		(2·45)	
pO_2	mmHg	54·6	1·95	104·3	1·60	172·2	0·84
	(kPa)	(7·28)		(13·90)		(22·96)	

Blood tonometry		Assigned value	Mean	CV%	Assigned value	Mean	CV%
pCO_2	mmHg	20	20·5	1·76	80	82·6	1·07
	(kPa)	(2·66)	(2·73)		(10·64)	(11·01)	
pCO_2	mmHg	40	40	1·75	160	157·8	1·05
	(kPa)	(5·32)	(5·32)		(21·28)	(21·03)	

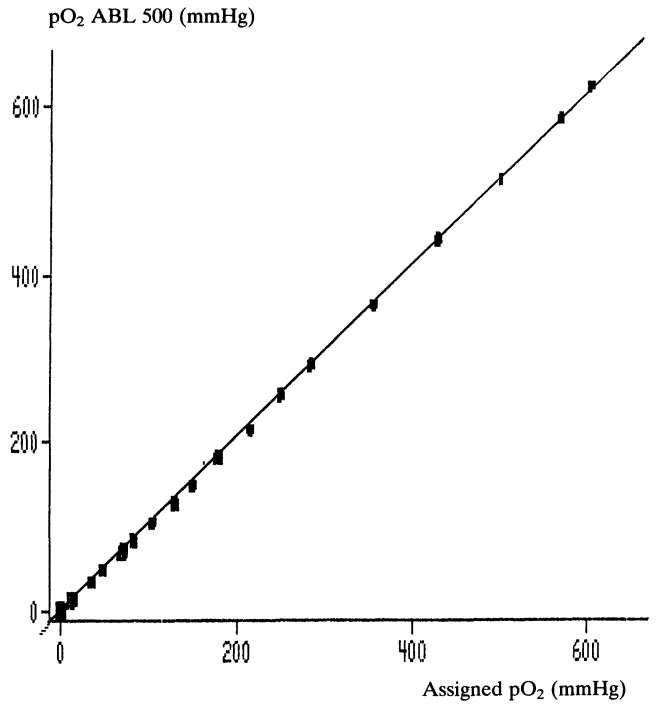


Figure 1. pO_2 linearity on the ABL 500 analyser using film tonometry (N = 134) between 0 and 600 mmHg (y = 1·03, x − 1·09, r ≥ 0·999).

Corning 178 are often higher than on other modern analysers (this was demonstrated by a recent French interlaboratory quality control program). For pO_2 (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.

Practicability

The ABL 500 is based on a modular design with a wet section located in the front part of the measuring station, sensitive electronics in an independent module, and a small CO_2 cylinder inside a cabinet frame, saving space and costs. The measuring chamber is clearly visible. Remembraning time is reduced with disposable membrane units, which are prefilled with electrolytes solutions. The PC-style software is ingenious and easily accessible (finger wheel, pop-up windows etc.). Maintenance is guided by an adaptable self-diagnostic program. The mechanical steps are simple and easily learnt. Reagents and waste containers are designed to conform to strict biological safety rules. The inlet section provides easy access for sample introduction and cleaning of the protective flap. The automatic results print-out is easily edited and items can be selected from it.

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 pO_2 values.

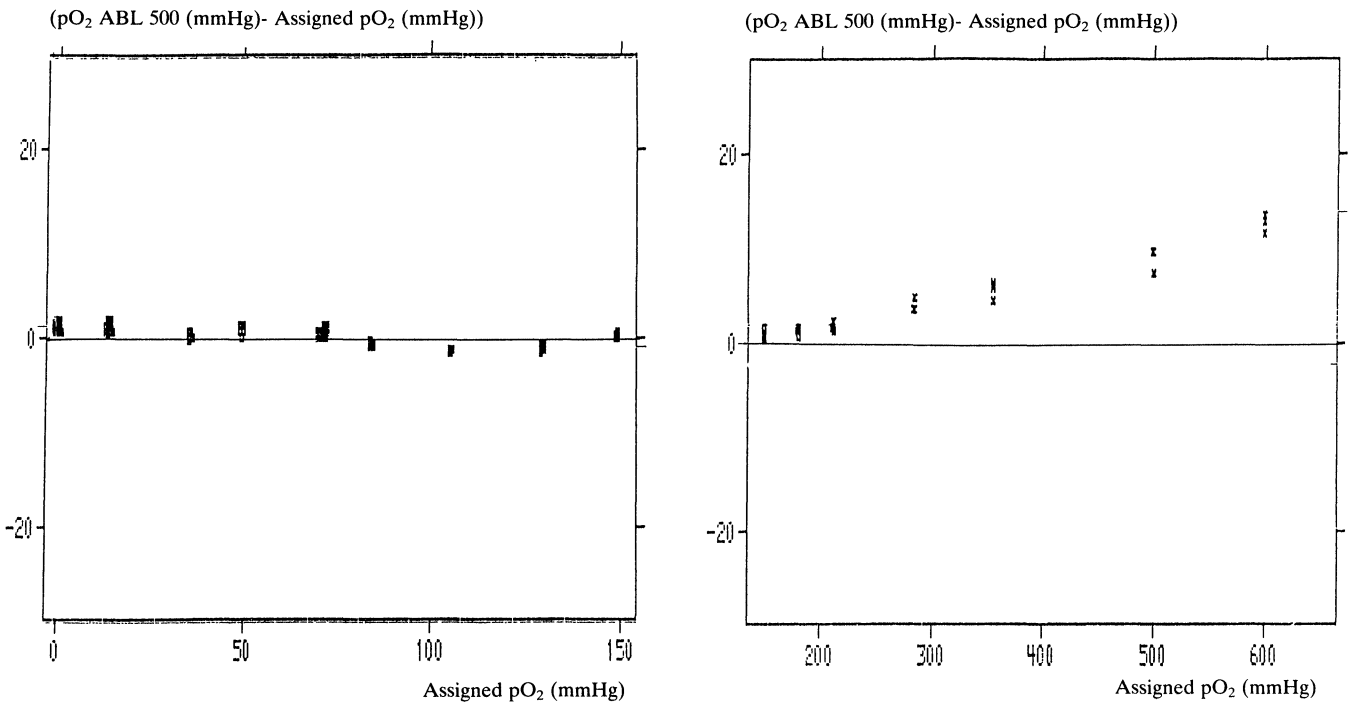
The linearity study gave the following results:

(1) The zero point calibration was verified by tonometry. The measurement of the electrode response, at zero pO_2, increases the accuracy of the subsequent determinations.

(2) Near the second calibration point of the slope (O_2 = 20%), the measured values were identical to the expected ones.

(3) Discrepancies appeared above 150 mmHg (20 kPa) of pO_2. 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 pO_2 electrode, calculated during the last calibration of the high pO_2 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



(*a*) (*b*)

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.

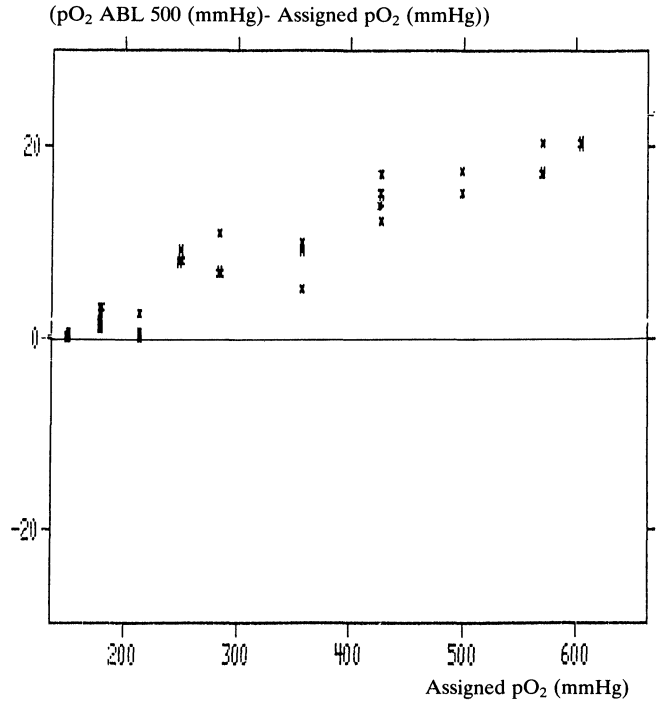


Figure 3. pO_2 linearity using bubble tonometry between 150 and 600 mmHg (20–80 kPa), N = 50. x and y axes as figure 2.

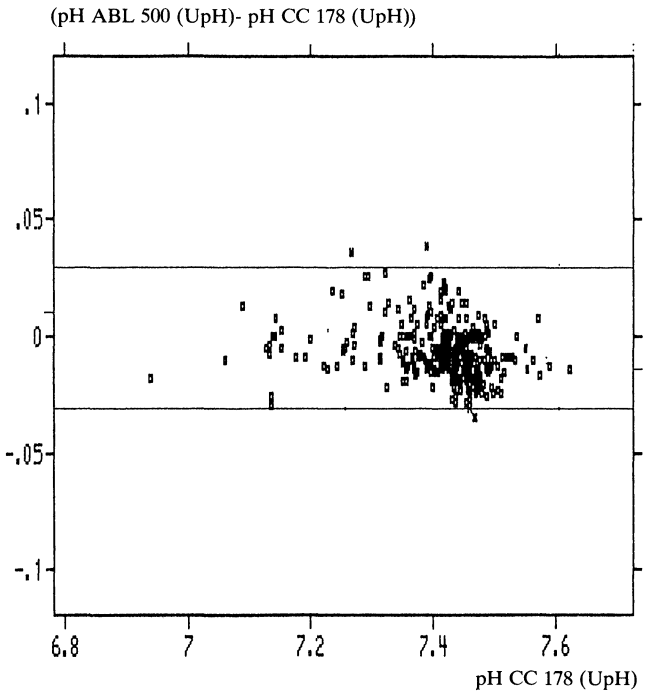


Figure 4. Inter-instrument comparison for pH, N = 291 samples for hospitalized patients (y = 0·975x +0·18, r = 0·992). The x axis represents measurements performed on Ciba Corning 178 analyser; and the y axis represents the difference in pH values between the ABL 500 and the Ciba-Corning 178 analysers. The solid horizontal lines represent pre-established limits (±0·03 UpH) of acceptable imprecision.

ratio between sample volume and contact surface, the oxygen buffer capacity of the sample and the surface layer of the walls and finally the time of contact between sample and wall.

Although tonometered, fresh blood remains the best means for testing instrument accuracy. It requires a strict

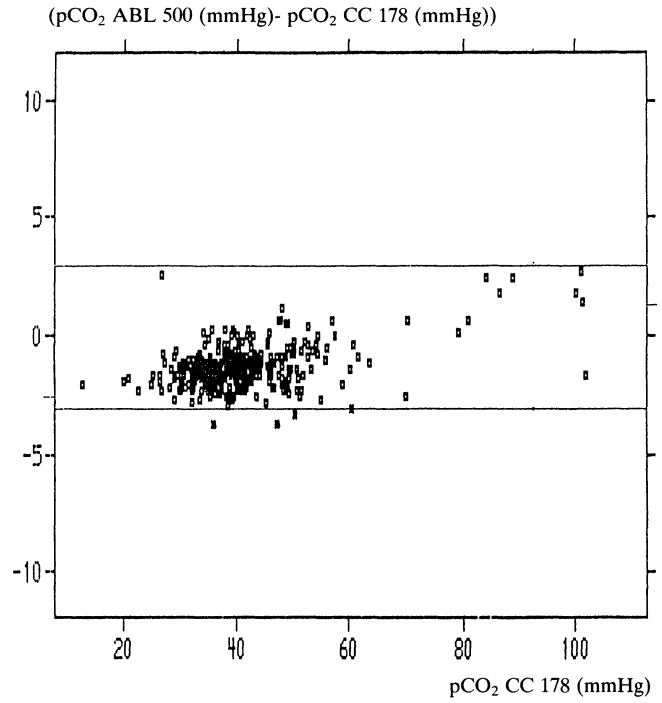


Figure 5. Inter-instrument comparison for pCO_2 ($N = 291$), y and x axes as figure 4. The pre-established limits for pCO_2 are ±3 mmHg. ($y = 1{\cdot}04x - 2{\cdot}71$, $r = 0{\cdot}998$).

control of working conditions: the IFCC method was followed for tonometry of blood, particularly in terms of procedure and equilibrating conditions [6]. Improper handling during the anaerobic use of the Laue tonometer and gas humidification, for instance, yield inaccurate values [7]. Even at gas flow rates of 60 ml/min and

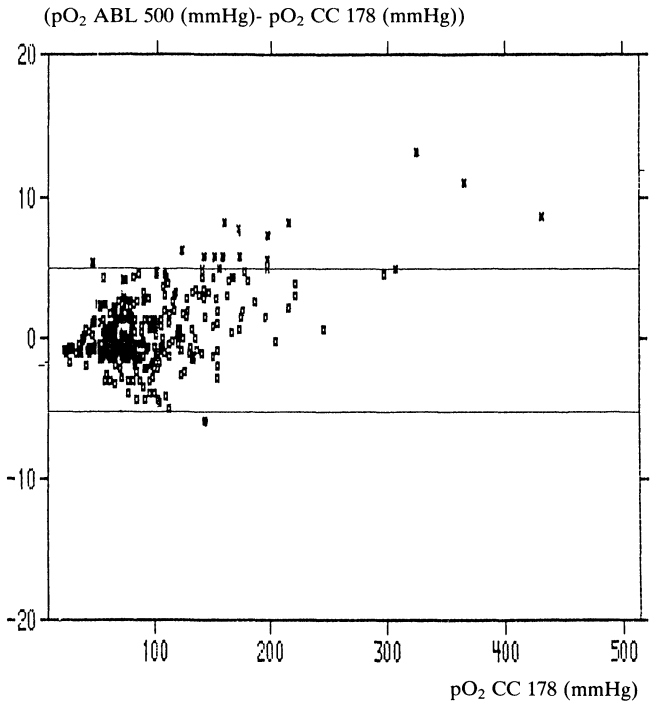


Figure 6. Inter-instrument comparison for pO_2 ($N = 291$), y and x axes as figure 4. The pre-established limits for pO_2 are ±5 mmHg. ($y = 1{\cdot}03x + 1{\cdot}94$, $r = 0{\cdot}999$).

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 pO_2 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 pO_2. 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].

The difference in pO_2 between the Corning 184 and the Laue tonometer at a level of 600 mmHg (80 kPa) was 7·5 mmHg (1 kPa) and was due to the bubble effect. An estimation of this bubble effect has previously been calculated at 13·5 mmHg (1·8 kPa) for pO_2 at 675 mmHg (90 kPa) between the Corning 184 and IL 237 tonometers [10].

However, beside the discrepancies demonstrated by tonometry, an overestimation of high pO_2 values persists on the ABL 500 analyser. For example, the measuring time on blood samples is not constant for the pO_2 electrode. The value calculated from the second reading is used to determine the measuring time. When pO_2 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 pO_2 electrode. Theoretically, these new features should have improved the stability and the accuracy of the pO_2 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, pO_2 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 pO_2 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 pO_2 values above 550 mmHg. To further improve pO_2 accuracy, the algorithm for correction should take into account high pO_2 tensions and the mode of sample introduction.

In conclusion, this study emphasizes that assessment of pO_2 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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