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Accuracy of pO2 – a 20 year overview of blood gas performance

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Introduction

Over the last 2 decades industry has provided us with an increasing number of smaller, portable analysers, utilising single or multi-use cartridges for Point of Care (POCT) Blood Gas analysis. Most EQA Providers distribute aqueous material for performance assessment of blood gas analysers, however annual studies conducted by Weqas using tonometered haemolysate have identified significant matrix issues with aqueous material especially for pO_2. The aim of this retrospective study was to assess the performance of Laboratory and POCT analysers for pO_2 using both fresh haemolysate and aqueous material.

Method

Tonometered blood haemolysate with oxygen saturation kinetics identical to that of fresh blood was distributed on an annual basis to all participants in the Weqas Blood Gas Scheme over a 20-year period. The performance for pO_2, expressed as coefficient of variation (CV) and bias against the All Method Average was calculated for each analyser for the haemolysate and concentration matched aqueous samples. The All Method Average was used in preference to the overall mean to allow equal weighting for each method group.

Review of Results 2010 to 2022

An increase in the use of POCT analysers was observed over this period, representing 95% of analysers in 2023, 43% in 2010 and 7% in 2001 respectively, Table 1. There was little change in the overall precision profile from 2001 to 2021 using the aqueous based material, Figure 1, however a much lower overall method CV was observed at a pO_2 < 15 kPa for analysers prior to 2000. At low pO_2 concentration, there was a significant improvement in the interlaboratory variation for the haemolysate material compared with aqueous material, Figure 2. A CV of 14% and 30% at a concentration of 8KPa, and a CV of 10% and > 50% at a concentration of 4kPa was observed for the haemolysate and aqueous materials respectively. The analyser interlaboratory variation expressed as ± 2 SD from the instrument mean and the bias to the Average of all method mean at a concentration of ≅ 4 kPa is shown in Figures 3 *a* to *e* over the 20 year period.

Figure 1. Precision profile for pO_2 using proteinated aqueous material from 1995 to 2020

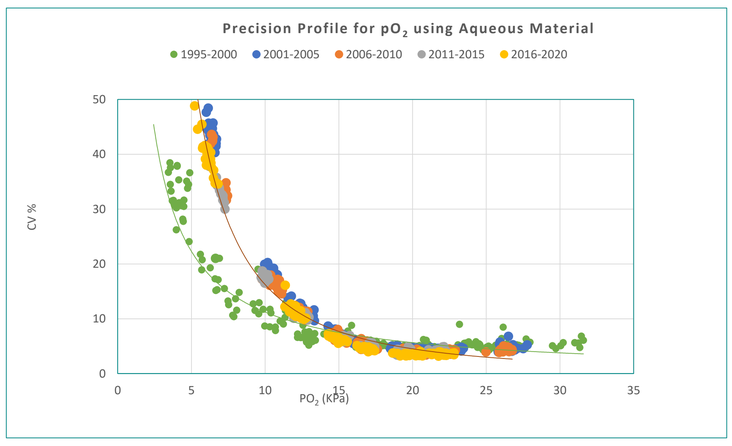


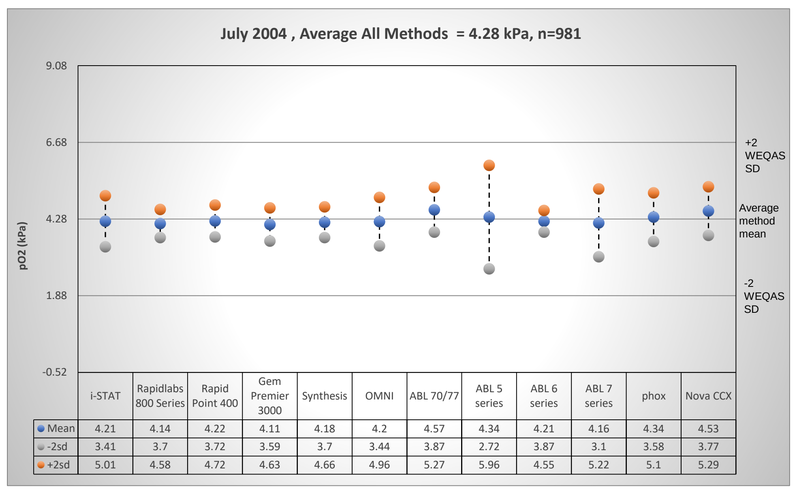
Figure 2. Precision profile for pO_2 using fresh Tonometered haemolysate material from 2004 to 2023

Table 1. Change in Blood gas analyser type and growth of POCT analysers from 2001 to 2023

Analyser Type	Year					
	2023	2020	2016	2010	2006	2001
Conventional electrodes	127	244	541	947	853	505
Multi use Cartridge	1876	1440	1033	541	239	14
Optical sensor	13	16	28	39	34	13
Single use Cartridge	427	338	269	137	84	11
% POCT Analysers	**94.8**	**88**	**71.1**	**43.1**	**29.5**	**7**
Total	2443	2038	1871	1664	1210	543

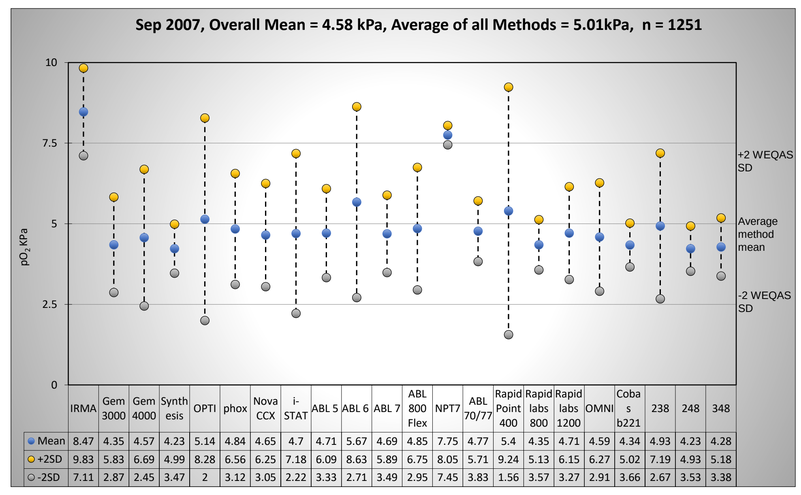
Figure 3a,b,c,d,e. Performance of Blood Gas analysers for pO_2 over the last 2 decades assessed using Fresh tonometered haemolysate material

2004



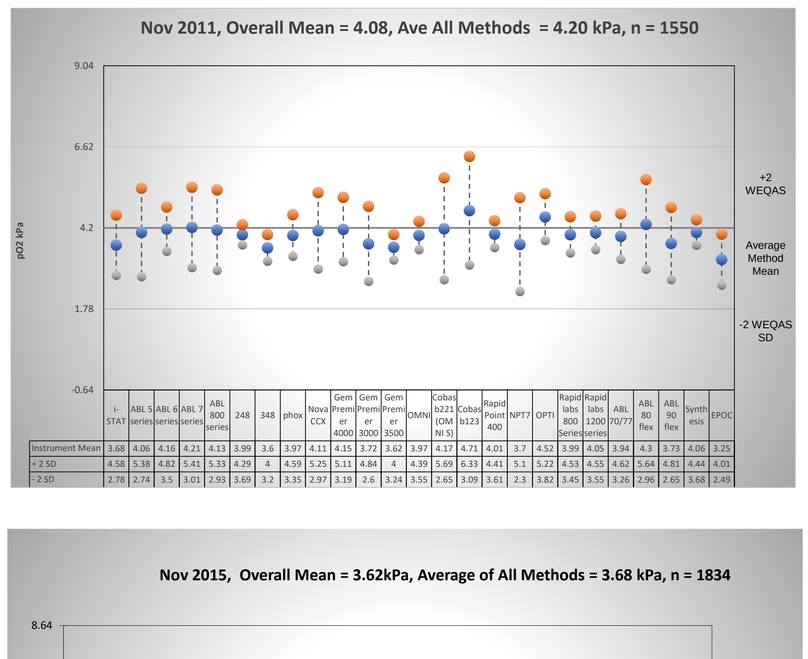
	i-STAT	Rapidlabs 800 Series	Rapid Point 400	Gem Premier 3000	Synthesis	OMNI	ABL 70/77	ABL 5 series	ABL 6 series	ABL 7 series	phox	Nova CCX
Mean	4.21	4.14	4.22	4.11	4.18	4.2	4.57	4.34	4.21	4.16	4.34	4.53
-2sd	3.41	3.7	3.72	3.59	3.7	3.44	3.87	2.72	3.87	3.1	3.58	3.77
+2sd	5.01	4.58	4.72	4.63	4.66	4.96	5.27	5.96	4.55	5.22	5.1	5.29

2007



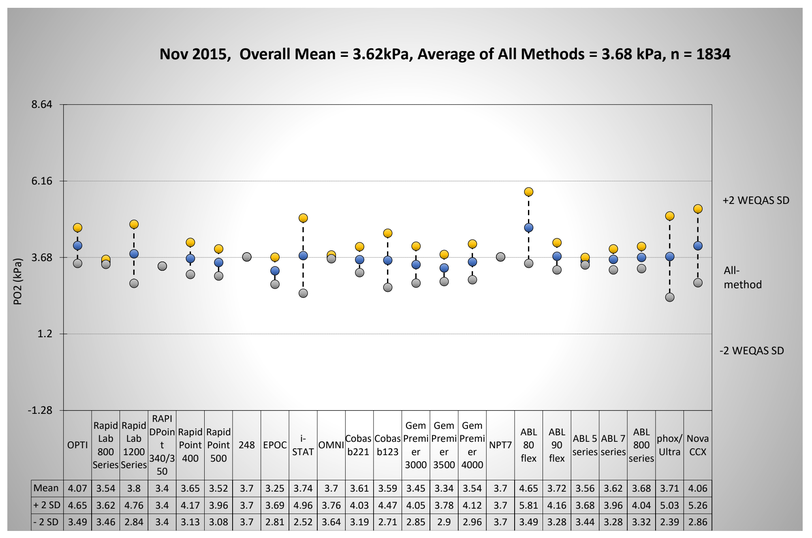
	IRMA	Gem 3000	Gem 4000	Synthesis	OPTI	phox	Nova CCX	i-STAT	ABL 5	ABL 6	ABL 7	ABL 800 Flex	NPT7	ABL 70/77	Rapid Point 400	Rapid labs 800	Rapid labs 1200	OMNI	Cobas b221	238	248	348
Mean	8.47	4.35	4.57	4.23	5.14	4.84	4.65	4.7	4.71	5.67	4.69	4.85	7.75	4.77	5.4	4.35	4.71	4.59	4.34	4.93	4.23	4.28
+2SD	9.83	5.83	6.69	4.99	8.28	6.56	6.25	7.18	6.09	8.63	5.89	6.75	8.05	5.71	9.24	5.13	6.15	6.27	5.02	7.19	4.93	5.18
-2SD	7.11	2.87	2.45	3.47	2	3.12	3.05	2.22	3.33	2.71	3.49	2.95	7.45	3.83	1.56	3.57	3.27	2.91	3.66	2.67	3.53	3.38

2011



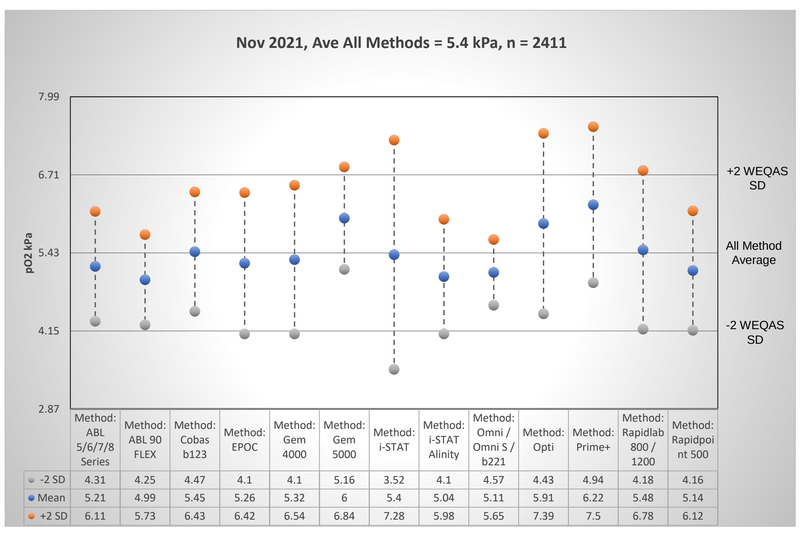
	i-STAT	ABL 5 series	ABL 6 series	ABL 7 series	ABL 800 series	248	348	phox	Nova CCX	Gem Premier 4000	Gem Premier 3000	Gem Premier 3500	OMNI	Cobas b221 (OMNI S)	Cobas b123	Rapid Point 400	NPT7	OPTI	Rapid labs 800 Series	Rapid labs 1200 series	ABL 70/77	ABL 80 flex	ABL 90 flex	Synthesis	EPOC
Instrument Mean	3.68	4.06	4.16	4.21	4.13	3.99	3.6	3.97	4.11	4.15	3.72	3.62	3.97	4.17	4.71	4.01	3.7	4.52	3.99	4.05	3.94	4.3	3.73	4.06	3.25
+ 2 SD	4.58	5.38	4.82	5.41	5.33	4.29	4	4.59	5.25	5.11	4.84	4	4.39	5.69	6.33	4.41	5.1	5.22	4.53	4.55	4.62	5.64	4.81	4.44	4.01
- 2 SD	2.78	2.74	3.5	3.01	2.93	3.69	3.2	3.35	2.97	3.19	2.6	3.24	3.55	2.65	3.09	3.61	2.3	3.82	3.45	3.55	3.26	2.96	2.65	3.68	2.49

2015



	OPTI	Rapid Lab 800 Series	Rapid Lab 1200 Series	RAPIDPoint 340/350	Rapid Point 400	Rapid Point 500	248	EPOC	i-STAT	OMNI	Cobas b221	Cobas b123	Gem Premier 3000	Gem Premier 3500	Gem Premier 4000	NPT7	ABL 80 flex	ABL 90 flex	ABL 5 series	ABL 7 series	ABL 800 series	phox/ Ultra	Nova CCX
Mean	4.07	3.54	3.8	3.4	3.65	3.52	3.7	3.25	3.74	3.7	3.61	3.59	3.45	3.34	3.54	3.7	4.65	3.72	3.56	3.62	3.68	3.71	4.06
+ 2 SD	4.65	3.62	4.76	3.4	4.17	3.96	3.7	3.69	4.96	3.76	4.03	4.47	4.05	3.78	4.12	3.7	5.81	4.16	3.68	3.96	4.04	5.03	5.26
- 2 SD	3.49	3.46	2.84	3.4	3.13	3.08	3.7	2.81	2.52	3.64	3.19	2.71	2.85	2.9	2.96	3.7	3.49	3.28	3.44	3.28	3.32	2.39	2.86

2021



	Method: ABL 5/6/7/8 Series	Method: ABL 90 FLEX	Method: Cobas b123	Method: EPOC	Method: Gem 4000	Method: Gem 5000	Method: i-STAT	Method: i-STAT Alinity	Method: Omni / Omni S / b221	Method: Opti	Method: Prime+	Method: Rapidlab 800 / 1200	Method: Rapidpoint 500
-2 SD	4.31	4.25	4.47	4.1	4.1	5.16	3.52	4.1	4.57	4.43	4.94	4.18	4.16
Mean	5.21	4.99	5.45	5.26	5.32	6	5.4	5.04	5.11	5.91	6.22	5.48	5.14
+2 SD	6.11	5.73	6.43	6.42	6.54	6.84	7.28	5.98	5.65	7.39	7.5	6.78	6.12

Conclusion

Blood gas analysis in a POCT rather than Laboratory environment continues to grow, with a wide variation in performance for these analysers. Aqueous material has a low buffer capacity and poor ability to dissolve gases compared with fresh whole blood. It is extremely sensitive to changes of oxygen pressure due to contamination by atmospheric air, especially at low pO2. EQA providers using aqueous material alone need to consider these pre-analytical effects in their interpretation of analytical performance. The use of fresh tonometered haemolysate provides commutable material that overcomes this issue and allows for the true assessment of accuracy of pO2.