Research article

Assessment of the Analytical Performance of 14 Analytes using the Epoc® Blood Analysis System

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Objective: **To evaluate the analytical performance of Epoc® Blood Analysis System for 14 analytes (pH, pCO_2, pO_2, HCO_3^-, BE, sO_2, Na^+, K^+, iCa^{2+}, Cl^-, Glu, Lac, Crea and BUN)**

Material and Methods: **The coefficient of variation (CV%) was calculated based on a between-day replication study using internal quality control material at two concentrations. The relative mean difference (BIAS%) was calculated based on method comparisons of 53 to 55 arterial patient samples using ABL 835 Flex Blood Gas Analyzer (Radiometer) and Dimension Vista 1500 System (Siemens Healthineers). The total analytical error (TAE%) was estimated by calculation of the 95% confidence interval, which incorporates the observed CV% from the replication study and BIAS% from the method comparison study. Each analyte's precision, trueness and accuracy were assessed by comparing the observed CV%, BIAS% and TAE% to the analytical performance specifications (APS) from Westgard for imprecision (I%), bias (B%) and total allowable error (TE%), respectively. The analytical performance using the Epoc were considered acceptable in clinical settings if at least the minimum specifications for accuracy were achieved.**

Results: **pH, BE, K^+, Glu, Lac and BUN fulfilled the minimum specifications for precision, while pCO_2, HCO_3^-, Na^+, iCa^{2+}, Cl^- and Crea did not. pH, pCO_2, Na^+, K^+, Glu, Lac and BUN fulfilled the minimum specifications for trueness, while HCO_3^-, iCa^{2+}, Cl^- and Crea did not. pH, pCO_2, BE, K^+, Glu, Lac and BUN fulfilled minimum specifications for accuracy, while iCa^{2+} did not. No specifications were specified for pO_2 and sO_2.**

Conclusions: **pH, pCO_2, BE, K^+, Glu, Lac and BUN showed analytical performances considered acceptable for use in clinical settings, since at least the minimum specifications regarding accuracy were achieved. iCa^{2+} showed unacceptable analytical performance for use in clinical settings, whereas the results for HCO_3^-, Na^+, Cl^- and Crea were inconclusive.**

Key words: Point-of-care testing, POCT, Epoc, Method comparison, Biological variation

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Introduction

Epoc® Blood Analysis system (Siemens Healthineers, Erlangen, Germany) is a handheld point-of-care testing (POCT) device intended to be used by professionals in the healthcare setting as an *in vitro* diagnostic quantitative test for blood gasses, electrolytes, metabolites, haematocrits and other calculated parameters. The wide variety of tests available using the customized Epoc® BGEM Test Cards and rapid turnaround of results using only 92 µL of sample material makes it an attractive and useful device in emergency situations.[1]

Epoc's analytical performance against various reference methods has been assessed in prior studies.[2-14] Most of the studies were limited as they evaluated the clinical use of Epoc solely from the observed correlation between the Epoc and a reference method, whereas predefined analytical performance specification (APS) has only been included in four studies.[3-14] However, none of those studies included base excess (BE) or blood urea nitrogen (BUN), while saturated oxygen (sO_2) and standard bicarbonate (HCO_3^-) have only been included one and two times, respectively. Further, only four studies used ABL and Vista as the reference methods.[3,4,10,13]Therefore, there is still a need for further evaluation of the Epoc to get a better picture of the full capacity of the device. This study aimed to assess the analytical performance of the Epoc system to determine if the observed analytical performance can be considered acceptable for use in clinical settings according to the chosen assessment method.

Material and methods

Assessment criteria

The predefined APS used in this study was derived from intra- and interindividual biological variation taken from Westgard's database.[15] Epoc's precision, trueness and accuracy for each of the analytes was assessed by comparing the observed analytical performance to the predefined minimum, desired and optimal APS calculated based on the formulas by Fraser et al.[16] APS for pO_2 and sO_2 are not specified. The analytes precision was assessed by comparing the observed coefficient of variation (CV%) to the predefined APS expressed as imprecision (I%). The analytes trueness was assessed by comparing the observed relative mean difference (BIAS%) to the predefined APS expressed as inaccuracy (B%). The analytes accuracy was assessed by comparing the observed total analytical error (TAE%) to the allowable total error (TE%).

Sample collection

Fifty-five arterial whole blood samples were collected during two weeks in October 2020 from 16 different patients admitted at an intensive care unit (ICU) at a Danish Hospital. The samples were drawn from the patient's arterial lines by trained nurses using safePICO syringe with safeTIPCAP containing lithium heparin (Radiometer, Brønshøj, Denmark). No special permission was needed as the material was used in a quality assessment process of a new device prior to implementation. All patient sensitive information was anonymized before data was processed.

Assessment of precision

The observed CV% for each analyte was based on results from a replication study using Eurotrol GAS-ISE-Metabolite (Eurotrol Inc., Netherland) as quality control (QC) material at concentration levels one (L1) and three (L3). The QC material was analysed according to the operation instructions once a day for 10 consecutive days using the same Epoc device.[1] CV% was calculated as the standard deviation (SD) / mean x 100.

Assessment of trueness

The observed BIAS% was estimated based on a method comparison study between Epoc against ABL 835 Flex Blood Gas Analyser (ABL) and Dimension Vista® 1500 System (VISTA) as reference methods. First, the patient samples were analyzed using the ABL for all analytes except for Crea and BUN. Subsequently and within three minutes samples were analyzed using the Epoc system. Then leftover sample material was transferred from the syringe to VACUETTE® blood collection tubes with CAT

serum separator clot activator (Greiner Bio-One, Australia). Within 1.5 hours from ABL and EPOC analysis, the samples were centrifuged for 10 min / 2,500g at 20°C and hereafter stored at 2-8 °C. The samples were then analyzed for Crea and BUN the same or following day using VISTA. BIAS% was calculated as the relative mean difference (Epoc mean – reference method mean)/ average of methods (Epoc mean + reference method mean)/2) x 100.

Assessment of accuracy

The estimation of the observed TAE% was calculated as BIAS% (from the method comparison study) ± 1,96 x CV% (from the replication study) and represented the 95% confidence interval of the analytes analytical error.[15-18] For this calculation, the higher CV% value of L1 and L3 observed was used. The analytes overall analytical performance was considered acceptable in clinical settings if both TAE% limits fell within the minimum APS for TE%. The performance was considered unacceptable in clinical settings if both TAE% limits fell outside the minimum APS for TE% and inconclusive if the one TAE% limit fell within and one outside the minimum APS for TE%, since data was insufficient to assess the performance.[15-18]

Statistics

The statistical analysis and difference plots were performed using Microsoft Excel (Microsoft Corp., Redmond, WA, USA). The Passing Bablok regression plots were performed using R Core Team (2021) (Vienna, Austria).

Results

Assessment of precision

The pH, BE, K^+, Lac and BUN met the optimal APS for I% (Table 1). pCO_2 met the optimal APS for I% for L1, whereas L3 exceeded minimum APS with as little as +0,02%. HCO_3^- met desired.

Table 1. The observed mean, standard deviation (SD) and variation coefficient (CV%) from the replication study using the Epoc system with two levels of QC material. Minimum, desired and optimal APS for I% were based on biological variation from Westgard and calculated according to Fraser et al.[15,16]

Analyte (unit)	Eurotrol QC L1		Eurotrol QC L3		APS for I%		
	Mean (SD)	CV%	Mean (SD)	CV%	Minimum	Desired	Optimal
pH	7.009 (0.012)	0.156	7.724 (0.012)	0.157	≤ 2.63	≤ 1.75	≤ 0.88
pCO2 (kPa)	9.36 (0.103)	1.10	2.94 (0.106)	**3.62**	≤ 3.6	≤ 2.4	≤ 1.2
pO2 (kPa)	9.00 (0.335)	3.745	25.27 (0.972)	3.848	N/A	N/A	N/A
HCO3- (mmol/L)	17.7 (0.32)	1.80	28.8 (1.33)	**4.61**	≤ 3.0	≤ 2.0	≤ 1.0
BE (mmol/L)	-13.45 (0.48)	3.56	9.3 (1.43)	15.43	≤ 57.3	≤ 38.2	≤ 19.1
sO2 (%)	80.6 (2.16)	2.69	99.9 (0.00)	0.00	N/A	N/A	N/A
Na+ (mmol/L)	115 (0.8)	**0.72**	162 (0.8)	0.49	≤ 0.53	≤ 0.35	≤ 0.18
K+ (mmol/L)	2.1 (0.00)	0.00	5.8 (0.07)	1.16	≤ 3.6	≤ 2.4	≤ 1.2
iCa2+ (mmol/L)	1.54 (0.023)	**1.52**	0.64 (0.016)	**2.52**	≤ 1.28	≤ 0.85	≤ 0.43
Cl- (mmol/L)	79.6 (0.94)	**1.18**	113.4 (2.01)	**1.77**	≤ 0.9	≤ 0.6	≤ 0.3
Glu (mmol/L)	1.9 (0.07)	3.73	14.6 (0.37)	2.50	≤ 4.2	≤ 2.8	≤ 1.4
Lac (mmol/L)	0.82 (0.045)	5.39	5.78 (0.391)	6.78	≤ 20.4	≤ 13.6	≤ 6.8
Crea (µmol/L)	69 (3.8)	**5.6**	340 (9.8)	2.9	≤ 4.5	≤ 3.0	≤ 1.5
BUN (mmol/L)	18.7 (0.37)	1.97	1.7 (0.05)	2.89	≤ 9.3	≤ 6.2	≤ 3,1

Values printed in bold indicate that the respective QC level exceeded the minimum APS defined for I%, thus showing unacceptable precision.

N/A: performance specification for the analyte not available. APS: Analytical performance specifications.

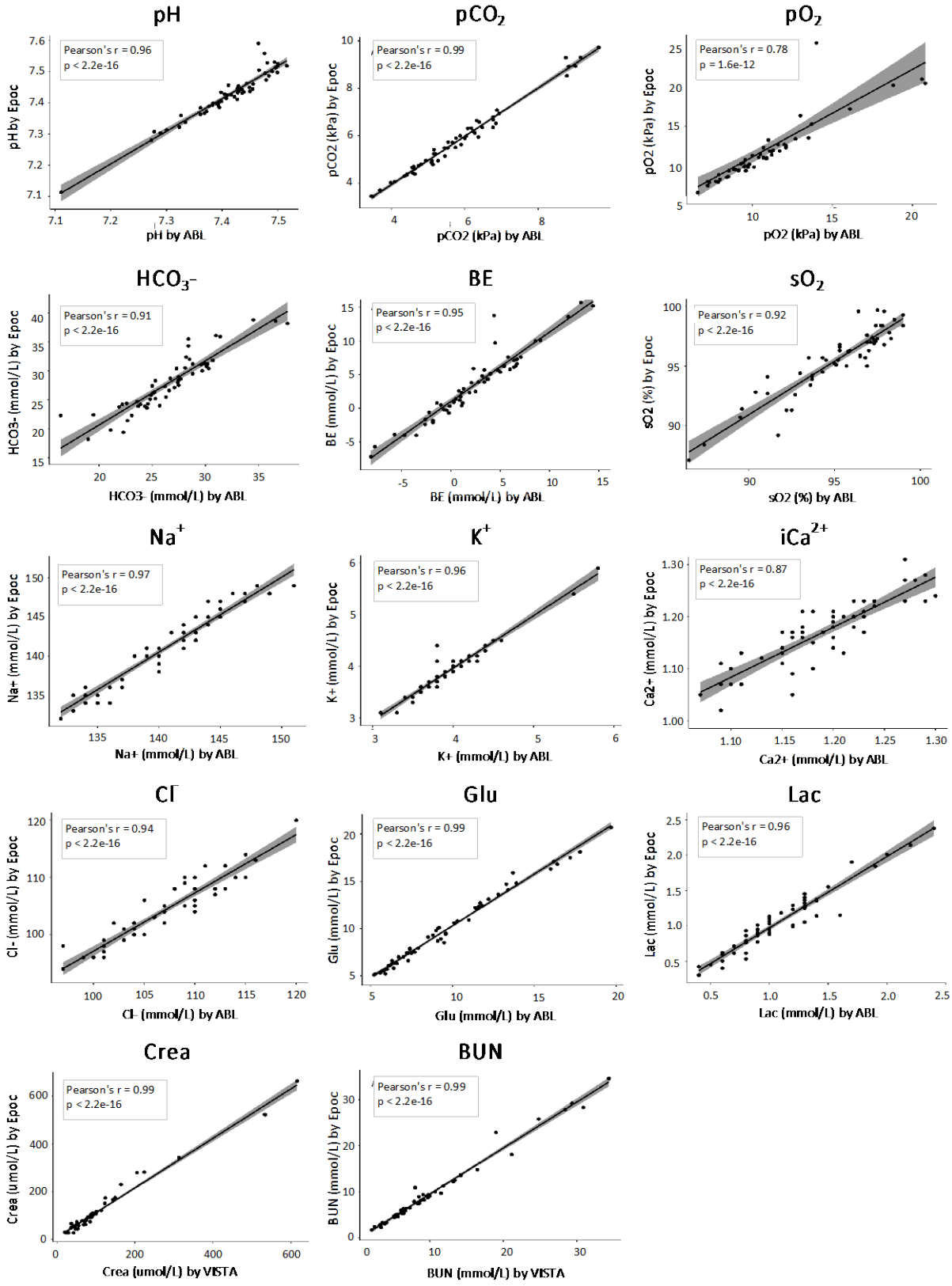

Figure 1. Passing Bablok regression with the reference measurements by ABL/VISTA on the x-axis as function of the Epoc measurements on the y-axis as well as Pearson's correlation coefficient (r) and p-value for each of the analytes.[22]

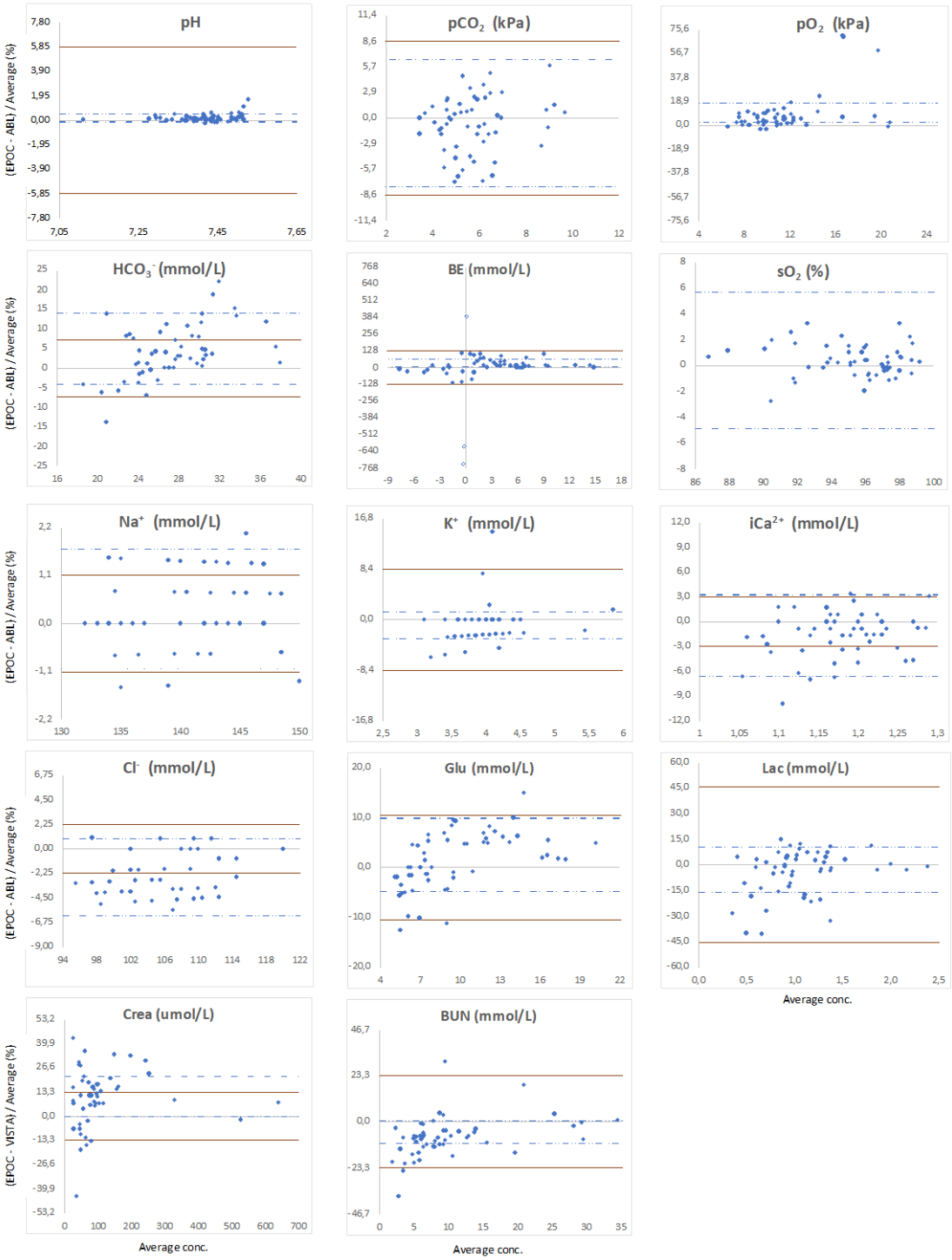

Figure 2. The relative difference between Epoc and the reference method as function of the average concentrations of both methods. Following analytes are included: pH, pCO2, pO2, HCO3-, BE, sO2, Na+, K+, iCa2+, Cl-, Glu, Lac, Crea and BUN.

The broken lines represent the observed TAE%, which was calculated using following formula: TAE% = BIAS% (from the method comparison) ± 1.96 x CV% (the higher CV% value of L1 and L3 from the replication study). The solid red lines represent the minimum APS for TE% from Westgard (15) and was calculated according to Fraser et al.16 If both TAE% limits (broken lines) fell within the minimum APS for TE%, then the analyte's analytical performance was considered acceptable in clinical settings.17 If both broken lines fall outside the minimum APS for TE%, then the analyte's analytical performance was considered unacceptable. If only one of the broken lines fall within the minimum APS for TE%, then the analyte's analytical performance was considered inconclusive.

APS for I% for L1, whereas L3 exceeded minimum APS. Glu met the minimum APS for I% for L1 and desired APS for L3. Na^+ met minimum APS for I% for L3, whereas L1 did not. Crea met desired APS for I% for L3, whereas L1 exceeded minimum APS. iCa^{2+} and Cl^- exceeded the minimum APS for I% for both L1 and L3

Assessment of trueness

Passing Bablok regression with the reference measurements by ABL/VISTA on the x-axis as function of the Epoc measurements on the y-axis as well as Pearson's correlation coefficient(r) for each of the analytes are shown in Figure 1.

The pH, pCO_2, K^+ and Lac met the optimal APS for B%. BUN met the desired APS for B%, while Na^+ and Glu met the minimum APS for B%. BE, HCO_3^-, iCa^{2+}, Cl^- and Crea do not meet any of the APS for B% (Table 2).

Assessment of accuracy

The estimated TAE% for pH met the optimal APS for TE%. TAE% for BE, K^+, Lac and BUN met the desired APS for TE%. pCO_2 and Glu met the minimum APS for TE%.TAE% for iCa^{2+} exceeded the minimum APS for TE%, whereas TAE% for HCO_3^-, Na^+, Cl^- and Crea overlapped with the minimum APS for TE%. (Figure 2 and Table 3).

Discussion

The assessment of Epoc's analytical performance using arterial blood showed that Epoc could be considered acceptable in clinical settings for pH, pCO_2, BE, K^+, Glu, Lac and BUN. These analytes fulfilled the defined minimum, desired or optimal APS for TE% based on Westgard's biological variations database.[15] The iCa^{2+} did not fullfill the defined APS for TE%, while HCO_3, Na^+, Cl^- and Crea showed inconclusive analytical performance. To our knowledge this is the first study to evaluate BE

Table 2. The observed mean difference (BIAS%) between Epoc and the reference method from the comparison study and the defined specifications for the trueness (B%). The minimum, desired and optimal APS for B% were based on biological variation from Westgard and calculated according to Fraser et al.15,16

Analyte (unit)	**Epoc** Mean (SD)	**Reference** Mean (SD)	**BIAS%** Epoc-Reference/(Average)	**APS for B%**		
				Minimum	Desired	Optimal
Epoc vs ABL 835 FLEX						
pH	7.425 (0.0791)	7.412 (0.0725)	0.184	±1.51	±1.01	±0.50?
pCO2 (kPa)	5.76 (1.491)	5.79 (1.467)	-0.53	±2.68	±1.79	±0.89
pO2 (kPa)	11.91 (4.200)	10.77 (2.935)	10.06	N/A	N/A	N/A
HCO3- (mmol/L)	27.91 (4.810)	26.55 (3.960)	**4.99**	±2.3	±1.6	±0.8
BE (mmol/L)	3.5 (5.12)	2.6 (4.70)	**35.6**	±32.85	±21.9	±10.95
sO2 (%)	95.6 (2.87)	95.2 (2.96)	0.39	N/A	N/A	N/A
Na+ (mmol/L)	141 (5.0)	141 (5.0)	0.33	±0.46	±0.31	±0.15
K+ (mmol/L)	4.0 (0.46)	4.0 (0.44)	-0.91	±2.77	±1.84	±0.92
iCa2+ (mmol/L)	1.17 (0.063)	1.19 (0.056)	**-1.68**	±0.96	±0.64	±0.32
Cl- (mmol/L)	104 (5.6)	107 (5.2)	**-2.61**	±0.72	±0.48	±0.24
Glu (mmol/L)	9.9 (3.98)	9.6 (3.61)	2.6	±3.51	±2.34	±1.17
Lac (mmol/L)	1.05 (0.447)	1.08 (0.426)	-2.7	±11.97	±7.98	±3.99
Epoc vs Dimension VISTA 1500						
Crea (µmol/L)	122 (129.6)	110 (123.8)	**10.7**	±5.95	±3.97	±1.98
BUN (mmol/L)	9.7 (7.53)	10.2 (7.47)	-5,1	±8.3	±5.5	±2.8

Values printed in bold indicate that BIAS% exceeded the minimum APS for B%, thus showing unacceptable trueness. N/A: performance specification for the analyte not available. APS: Analytical performance specifications. SD: Observed standard deviations from the method comparison.

Table 3. The overall analytical performance of each analyte using the Epoc System compared to the predefined minimum, desired and optimal analytical performance specifications (APS) for precision, trueness, and accuracy.

	Blood gases						Electrolytes				Metabolites			
	pH	pCO2	pO2	HCO3	BE	sO2	Na+	K+	iCa2+	Cl-	Glu	Lac	Crea	BUN
	-	kPa	kPa	mM	mM	mM	mM	mM	mM	mM	mM	mM	uM	mM
Precision(L1)	✓o	✓o	N/A	✓d	✓o	N/A	—	✓o	—	—	✓m	✓o	—	✓o
Precision(L3)	✓o	—	N/A	—	✓o	N/A	✓m	✓o	—	—	✓d	✓o	✓d	✓o
Trueness	✓o	✓o	N/A	—	—	N/A	✓m	✓o	—	—	✓m	✓o	—	✓d
Accuracy	✓o	✓m	N/A	?	✓d	N/A	?	✓d	—	?	✓m	✓d	?	✓d

Optimal APS met (✓o). Desired APS met (✓d). Minimum APS met (✓m). Defined APS not met (—). Inconclusive data (?). N/A: No APS for the analyte available.

and BUN using the Epoc system, whereas HCO_3^- and sO_2 have been evaluated two and one times before, respectively.[4,6,7]

The HCO_3^- is calculated as Log HCO_3^- = *pH* + *LOG* pCO_2 - *7.608*, thus making HCO_3^- dependent on pH and pCO_2's performance.[1] The analytical performance for HCO_3^- was concluded as inconclusive based on the APS from Westgard, although pH and pCO_2 showed acceptable analytical performance.[15] Previous studies concluded HCO_3^- analysis using Epoc to be equivalent to the reference method when using cappillary blood.[6,7] However, if this study adopted the target ±15% for TE% used by those studies, HCO_3^- would be considered acceptable in clinical settings.[6,7]

No APS were available for pO_2. The estimated TAE% for pO_2 was 2.52 to 17.61%. However, if the three outliers for pO_2 above the reference interval (>14.4 kPa) were removed from the dataset the estimated TAE% would be -2.69 to 12.40% as a result of the BIAS% improving with 5.21%. Thus, the TAE% would fall within the ±15% limits used by Kim et al. and Shin et al. and pO_2 could be considered acceptable in clinical settings.[6,7] The EPOC has a tendency of high measurements of O_2 in the range above the reference interval observed in prior studies.[3,7,14] Further examinations are needed in order to determine if this could be linked to a general characteristic of the Epoc in regard to pO_2 testing. The observed correlations (r=0.78) between Epoc and ABL for pO_2 was lower compared to prior studies (r=0.99) using the same methods.[3,4]

No APS based on biological variaiton was available for sO_2. The estimation of TAE% (-4.9 to 5,7%) for sO_2 was based on the highest CV% (QC Level 1). Using the lower CV% (QC Level 3) for the estimation of TAE% might have contributed to a precision that better reflected the values of the actual measurements, and thereby a more narrow TAE. Use of sO_2 in clinical settings can be considered acceptable if the laboratory is willing to accept a relative difference between EPOC and ABL of ±3.3% (equivalent to the maximum difference observed).

This study demonstrated a strong correlation (r=0.92) between Epoc and ABL for sO_2. This is close to the correlation (r=0.98) reported by Agarwal et al., which to our best knowledge is the only other study to include sO_2 using Epoc.[4] Although according to expert consensus, directly measured sO_2 such as with ABL (co-oximetry) are preferred for critically ill patients, whereas calculated sO_2 values should be interpreted with caution.[19,20]

The K^+ is the only electrolyte considered acceptable in clincial settings with all APS fullfilled at either optimal or desired APS. This is in line with previous studies.[2-5,9,10,14] None of the APS for iCa^{2+} were fullfilled, thus making the analyte unfit for use in clinical settings based on the defined APS. The observed correlation between Epoc and ABL (r=0.87) for iCa^{2+} was lower compared to the correlations

(r=0.98) reported in two prior studies.[3,4] Another study reported a weaker correlation between the methods (r=0.80) compared to this present study. However, that study used capillary blood and a limited sample size (n=8-10).[10]

Three of the previous studies concluded Na^+ to be useful based on TE% limits between ±2.0% and ±4%.[6,7,14] If those limits were adopted in this study, the conclusion would also be that Na^+ could be considered acceptable in clinical settings. The observed correlation in this present study for Na^+ (r=0.97) was stronger than the correlations found in other studies with ABL as the reference method (r=0.84-0.86).[3,4] The observed correlation for Crea (r=0.99) was in line with correlations reported in other studies across different reference methods.[4,10,13] However, only one of these studies concluded, that Crea was not fit for use in clinical settnigs and reported a larger BIAS% compared to the observed BIAS% in this present study.[8] In this study, a strong correlation between Epoc and the reference method for BE (r=0.95) and BUN (r=0.99) was observed. This is in line with prior studies using other available POCT devices with strong correlations.[21]

Limitations and Strengths

One limitation of this study, is that samples were analyzed on the ABL first and subsequently on the Epoc. This could potentially induce systematic bias to the measurements. Another limitation is that the used reference methods are not considered the golden standard for each individual analyte. The strength of this study was the number of samples being from admitted patients, thus making it possible to cover a wide range of concentrations with exception of the lower and higher concentration range for Glu and iCa^{2+}.

Conclusion

Of the 14 studied analytes pH, pCO_2, BE, K^+, Glu, Lac and BUN showed analytical performance acceptable to use in clinical settings according to the chosen assessment criteria. The iCa^{2+} showed unacceptable analytical performance, whereas HCO_3^-, Na^+, Cl^- and Crea showed inconclusive analytical performance compared to the APS for TE%. No APS for TE% are available for pO_2 and sO_2. However, the results showed that if the laboratory is willing to accept an estimated TAE% within ±17.61% for pO_2 and ≥ ±3.3% for sO_2, then the analytes can be considered acceptable in clinical settings.

Declarations of interest

All authors have no conflict of interest to declare.

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