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RESEARCH ARTICLE

Comparative Test of the Results of the Examination of the I-Stat POCT Device and the EPOC POCT Device in ICU Patients

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ABSTRACT

Acid-base balance is essential to human physiology, as it regulates free hydrogen ions (H+) in body fluids, impacting enzyme activity. Blood gas analysis or arterial blood gas (ABG) test is crucial for understanding the acid-base status, oxygenation, and ventilation. Key components measured include pH, pCO2, HCO3-, pO2, base excess (BE), and oxygen saturation (SO2). This study aims to compare the performance of two point-of-care testing (POCT) devices—i-STAT and EPOC—used for blood gas analysis in ICU settings. POCT devices enable rapid bedside testing, facilitating quicker clinical decisions. An observational cross-sectional study was conducted using 28 arterial blood samples from ICU patients. Both the i-STAT and EPOC devices were utilized to measure blood gas parameters (pH, pCO2, pO2, HCO3-, BE, SO2, TCO2, and lactate). Data were analyzed for distribution and correlation between the two systems. PH, pO2, HCO3-, BE, SO2, and TCO2 levels were normally distributed for both devices. However, pCO2 and lactate levels were abnormally distributed across both platforms. A significant difference in lactate levels was observed between the two tools. Correlation analysis revealed strong agreement between i-STAT and EPOC for all parameters. The Epoc system demonstrated great accuracy and strong correlation with the i-STAT device across the parameters measured. These findings confirm that the Epoc platform is analytically acceptable for ICU blood gas analysis. Further research with larger sample sizes and comparisons to standard laboratory instruments is recommended.

INTRODUCTION

The balance of acidity and alkalinity is crucial in the human body. This equilibrium refers to the accurate regulation of free hydrogen ions in body fluids (Sherwood, 2023). Proper regulation of hydrogen ions is essential because nearly all enzymatic activity in the blood is affected by the concentration of these ions (Guyton & Hall, 2011). Measuring acidity and alkalinity is a key component of the blood gas analysis. This analysis offers a comprehensive understanding of the acid-base status, oxygenation, and ventilation. Key components analyzed in this analysis include oxygen saturation (SO2), base excess (BE), partial pressure of oxygen (pO2), bicarbonate ions (HCO3-), partial pressure of carbon dioxide (pCO2), and the potential of hydrogen (pH) (Davis et al., 2013). This analysis requires arterial blood samples to evaluate the respiratory component of acid-base balance, as the pCO2 in these samples reflects this aspect of the patient's condition. This analysis can also use a venous blood sample if this sampling method is impossible.

A faster blood gas analysis is achievable with a point-of-care test (POCT) device, which makes it possible to run the analysis closer to the patient, allowing testing in the same room without needing to transport the specimen to a laboratory. Decision-making and treatment planning can be expedited, as test results are available immediately (Burtis & Bruns, 2014). POCT devices also allow health workers, not just laboratory technicians, to perform the analysis. The smaller size of POCT devices, compared to laboratory blood gas analyzers, makes them more space-efficient and portable (Price, 2002).

Blood gas analysis is an important test in treating critically ill patients (ApS, 2011). The primary goal of intensive care is to ensure adequate oxygen delivery to the body's organs. This analysis offers a comprehensive understanding of acid-base status, oxygenation, and ventilation, with arterial blood gas (ABG) test as the standard. The analysis technique is relatively fast but yields important information for dealing with acute and chronic diseases. Blood gas analysis includes respiratory and metabolic components. The respiratory component is beneficial for assessing lung conditions and disorders affecting the removal of carbon dioxide from the blood and the transfer of oxygen through the blood. Meanwhile, the metabolic component in blood gas analysis is beneficial for assessing and diagnosing metabolic conditions that lead to abnormal pH levels in the blood (Setyawan, 2021).

Interpreting blood gas analysis results requires consideration of the patient's clinical condition. Patients needing blood gas measurements typically experience respiratory failure or are critically ill due to various etiologies. Normal ABG results that do not align with clinical symptoms may indicate compensation by the body for an underlying issue (Apriadi, 2015).

Blood gas analysis consists of three phases: pre-analytical, analytical, and post-analytical. The first phase focuses on sample collection, the second phase focuses on sample analysis, and the last phase focuses on interpreting results and determining patient care. Various factors can affect blood gas analysis results. These factors include sampling techniques, specimen handling, and environmental conditions (ApS, 2011).

There are various types of POCT blood gas analyzers available at different unit costs. In this study, the authors conduct a comparative study of blood gas analysis results from the i-STAT and EPOC POCT devices in adult ICU patients. Both devices may assist clinicians in managing critically ill patients, with a particular focus on adult patients treated in the ICU of Dr. Soetomo General Academic Hospital.

METHOD

This observational research employed a cross-sectional design, where data were gathered using consecutive sampling. The study was conducted in the ICU unit of the Gedung Bedah Pusat Terpadu (GBPT) of Dr. Soetomo General Academic Hospital (RSUD Dr. Soetomo), Surabaya. The study included 28 samples, with clinical laboratory measurements for pH, pCO2, pO2, HCO3, BE, SO2, TCO2, and lactate. For each sample, the i-STAT and EPOC readings were compared in the ICU unit based on the inclusion and exclusion criteria. The study was conducted from February 2023 to April 2023 and received ethical approval from RSUD Dr. Soetomo.

The study sample included adult patients undergoing blood gas analysis in the ICU unit. Arterial blood was collected using a syringe with heparin as an anticoagulant, with a sample volume of 2 ml. Samples were rejected if they exhibited hemolysis, icterus, or lipemia.

RESULTS

This observational study employed a cross-sectional design, where data were collected using consecutive sampling. The study was conducted in the ICU unit of the GBPT of RSUD Dr. Soetomo, Surabaya. The study included 28 samples, with clinical laboratory measurements for pH, pCO2, pO2, HCO3, BE, SO2, TCO2, and lactate. For each sample, the i-STAT and EPOC readings were compared in the ICU unit based on the inclusion and exclusion criteria.

Descriptive data

Laboratory examinations in this study included pH, pCO2, pO2, HCO3, BE, SO2, TCO2, and lactate levels using the i-STAT and EPOC devices. The following is a descriptive summary of the results for pH, pCO2, pO2, HCO3, BE, SO2, TCO2, and lactate based on the i-STAT and EPOC devices:

Table 1: Descriptive table of pH, pCO2, pO2, HCO3, BE, SO2, TCO2, and lactate levels based on the i-STAT and EPOC devices

Laboratory Results	i-STAT		EPOC	
	Range (median)	Mean ± SD	Range (median)	Mean ± SD
pH	6.741-7.616 (7.376)	7.311 ± 0.201	6.885-7.607 (7.359)	7.309 ± 0.184
pCO2	21.7 - 174.7 (41.00)	49.04 ± 29.85	20.1 - 174.9 (41.50)	49.70 ± 29.51
pO2	34.0-179.0 (105.50)	105.75 ± 38.65	47.0-189.6 (107.45)	108.06 ± 39.43
HCO3	11.1-43.2 (21.50)	23.48 ± 9.03	11.2-44.7 (24.30)	24.33 ± 8.69
ANONYMOUS	−24.0-21.0 (−2.50)	−2.13 ± 10.64	−18,5-17,4 (−2,05)	−2.45 ± 10.40
SO2	83.0 - 100.0 (98.0)	96.36 ± 4.29	84.4-100.2 (98.35)	96.85 ± 3.96
TCO2	12.0-44.0 (23.0)	24.48 ± 9.03	11.4-45.4 (21.80)	23.78 ± 8.71
Lactate	0.30-9.17 (1.76)	2.40 ± 2.38	0.38-9.00 (1.40)	1.83 ± 1.78

Based on the laboratory results from 28 test samples presented in Table 1, the lowest pH value on the i-STAT device was 6.741, the highest was 7.616, and the mean ± SD was 7.311 ± 0.201. On the EPOC device, the lowest pH value was 6.885, the highest was 7.607, and the mean ± SD was 7.309 ± 0.184. For pCO2 levels, the i-STAT device yielded as low as 21.7 and as high as 174.7, with a mean ± SD of 49.04 ± 29.85, while the EPOC device yielded as low as 20.1, as high as 174.9, and a mean ± SD of 49.70 ± 29.51. For pO2 levels, the i-STAT device yielded as low as 34.0 and as high as 179.0, with a mean ± SD of 105.75 ± 38.65, while the EPOC device yielded as low as 47.0, as high as 189.6, and a mean ± SD of 108.06 ± 39.43. For HCO3 levels, the i-STAT device yielded as low as 11.1 and as high as 43.2, with a mean ± SD of 23.48 ± 9.03, while the EPOC device yielded as low as 11.2, as high as 44.7, and a mean ± SD of 24.33 ± 8.69. For BE levels, the i-STAT device yielded as low as -24.0 and as high as 21.0, with a mean ± SD of −2.13 ± 10.64, while the EPOC device yielded as low as −18.5 and as high as 17.4, with a mean ± SD of −2.45 ± 10.40. For SO2 levels, the i-STAT device yielded as low as 83.0 and as high as 100.0, with a mean ± SD of 96.36 ± 4.29, while the EPOC device yielded as low as 84.4 and as high as 100.2, with a mean ± SD of 96.85 ± 3.96. For TCO2 levels, the i-STAT device yielded as low as 12.0 and as high as 44.0, with a mean ± SD of 24.48 ± 9.03, while the EPOC device yielded as low as 11.4 and as high as 45.4, with a mean ± SD of 23.78 ± 8.71. For lactate levels, the i-STAT device yielded as low as 0.30 and as high as 9.17, with a mean ± SD of 2.40 ± 2.38, while the EPOC device yielded as low as 0.38 and as high as 9.00, with a mean ± SD of 1.83 ± 1.78.

Normality test

The normality test for each result of pH, pCO2, pO2, HCO3, BE, SO2, TCO2, and lactate data was performed utilizing the Shapiro-Wilk test for the i-STAT and EPOC devices, as the sample size was less than 50. The data were considered normally distributed if the p-value in the Shapiro-Wilk test was greater than 0.05.

According to the outcomes of the normality test, pH, pO2, HCO3, BE, SO2, and TCO2 levels were normally distributed for both the i-STAT and EPOC devices, while pCO2 and lactate levels were abnormally distributed in both devices. Therefore, the comparison test for pH, pO2, HCO3, BE, SO2, and TCO2 levels utilized the Paired t-test, while the Wilcoxon test was utilized for pCO2 and lactate levels. Meanwhile, the correlation test for pH, pO2, HCO3, BE, SO2, and TCO2 levels utilized the Pearson test, while the Spearman test was utilized for pCO2 and lactate levels.

Comparative test analysis

A comparative test of pH, pCO2, pO2, HCO3, BE, SO2, TCO2, and lactate levels on the i-STAT and EPOC devices was conducted to assess measurement differences between the two devices. The test applied was either the Wilcoxon test or the Paired t-test. A difference was considered significant if the p-value in the Wilcoxon test or the Paired t-test was < 0.05. The following are the results of the comparative test between the i-STAT and EPOC devices (Table 2, Figure 1):

Table 2: Comparative test results for pH, pCO2, pO2, HCO3, BE, SO2, TCO2 and lactate levels between the i-STAT and EPOC devices

Laboratory Results	i-STAT	EPOC	p-value
	Mean ± SD	Mean ± SD	
pH	7.311 ± 0.201	7.309 ± 0.184	0.862
pCO2	49.04 ± 29.85	49.70 ± 29.51	0.946
pO2	105.75 ± 38.65	108.06 ± 39.43	0.173
HCO3	23.48 ± 9.03	24.33 ± 8.69	0.239
ANONYMOUS	−2.13 ± 10.64	−2.45 ± 10.40	0.447
SO2	96.36 ± 4.29	96.85 ± 3.96	0.342
TCO2	24.48 ± 9.03	23.78 ± 8.71	0.607
Lactate	2.40 ± 2.38	1.83 ± 1.78	0.026

Declared different if the p-value is lower than 0.05

According to the outcomes of the comparative test using various statistical methods (Paired t-test and Wilcoxon test), there was no significant difference in pH, pCO2, pO2, HCO3, BE, SO2, and TCO2 levels between the two devices, with p-values > 0.05. However, there was a meaningful difference in lactate levels, with the lactate values in the i-STAT device tending to be higher than those in the EPOC device, with a p-value lower than 0.05. However, a meaningful difference in lactate levels was observed, with higher levels recorded by the i-STAT device compared to the EPOC device, with a p-value lower than 0.05.

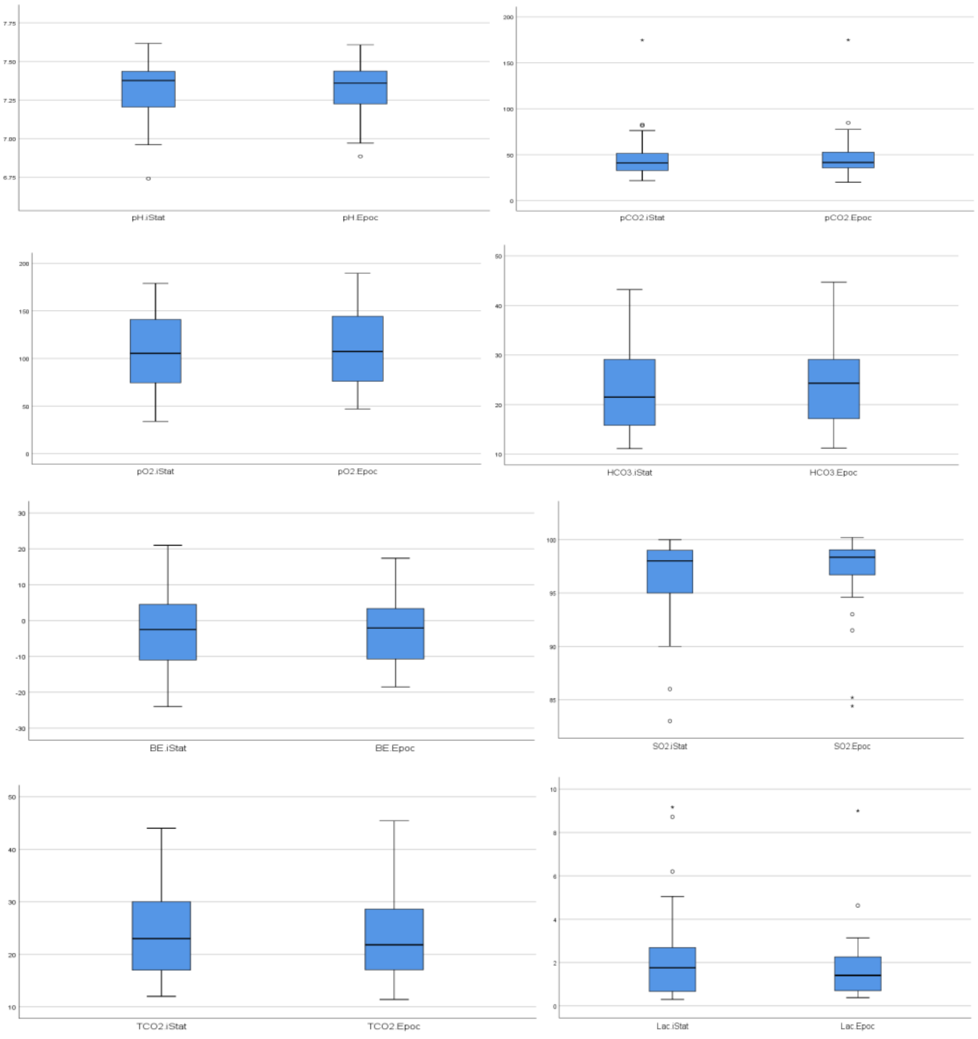


Figure 1. Box Plot Chart Comparison between the i-STAT and EPOC devices

Correlation test analysis

A correlation test of pH, pCO2, pO2, HCO3, BE, SO2, TCO2, and lactate levels on the i-STAT and EPOC devices was conducted to determine if these parameters are correlated between the two devices. The test applied was either the Pearson correlation test or the Spearman rank correlation test. A correlation was considered significant if the p-value in the Pearson or Spearman test was less than 0.05. The following are the results of the correlation test for pH, pCO2, pO2, HCO3, BE, SO2, TCO2, and lactate levels between the i-STAT and EPOC devices (Table 3, Figure 2):

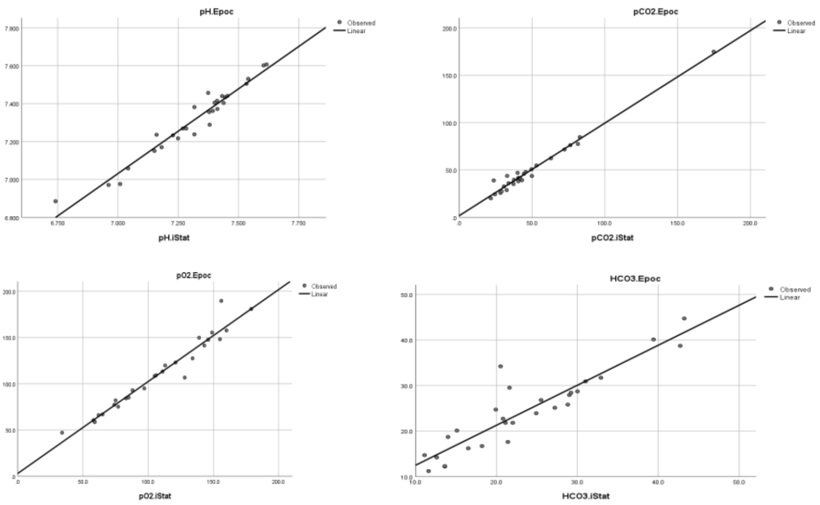
Table 3: Correlation test results for pH, pCO2, pO2, HCO3, BE, SO2, TCO2 and lactate levels between the i-STAT and EPOC devices

Correlation Test	**r**	**p-value**
Between **pH levels** on i-STAT and EPOC	0.973	0.000
Between **pCO2 levels** on i-STAT and EPOC	0.916	0.000
Between **pO2 levels** on i-STAT and EPOC	0.975	0.000
Between **HCO3 levels** on i-STAT and EPOC	0.911	0.000
Between **BE levels** on i-STAT and EPOC	0.979	0.000
Between **SO2 levels** on i-STAT and EPOC	0.765	0.000
Between **TCO2 levels** on i-STAT and EPOC	0.694	0.000
Between **lactate levels** on i-STAT and EPOC	0.834	0.000

*Declared correlated if the p-value is lower than 0.05

According to the outcomes presented in Table 5.3, the Pearson correlation test of the pH levels from the i-STAT and EPOC devices yielded a p-value of 0.000, below the 0.05 threshold. This suggests a meaningful correlation between the pH levels of the two devices. The correlation coefficient (r) was 0.973, suggesting a very strong correlation, as shown in the scatterplot. This demonstrates a unidirectional correlation between the pH levels yielded by the two devices.

This correlation test revealed that the readings of the two devices ($p < 0.05$) for all parameters tested (pCO2, pO2, HCO3, BE, SO2, TCO2, and lactate) were meaningfully correlated. The correlation was very strong for pCO2 ($r = 0.916$), pO2 ($r = 0.975$), HCO3 ($r = 0.911$), BE ($r = 0.979$), and lactate ($r = 0.834$), and strong for SO2 ($r = 0.765$) and TCO2 ($r = 0.694$). The scatterplot demonstrates a unidirectional correlation for all these parameters.



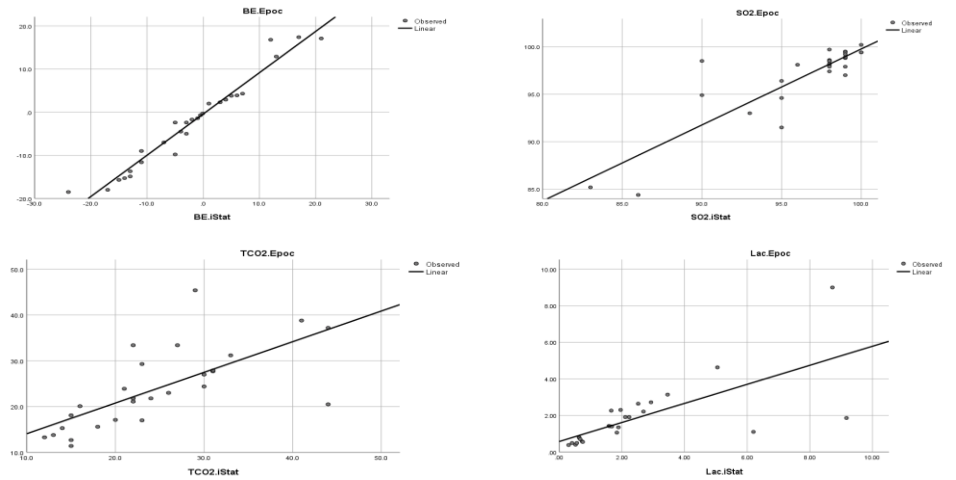


Figure 2: Scatterplot displaying the correlation between the i-STAT and EPOC devices

Bland-Altman test analysis

A Bland-Altman curve test was conducted to assess the limits of agreement for the differences in pH, pCO2, pO2, HCO3, BE, SO2, TCO2, and lactate levels between the i-STAT and EPOC devices. The Bland-Altman curve helps to identify the extent to which the data deviates from the differences in these parameters between each device. The following are the results of the comparative test for the differences in pH, pCO2, pO2, HCO3, BE, SO2, TCO2, and lactate levels, along with the Bland-Altman curve for both devices (Table 4, Figure 3):

Table 4: Comparison of pH, pCO2, pO2, HCO3, BE, SO2, TCO2 and lactate levels between the i-STAT and EPOC devices

Laboratory Results	Mean Difference	95% CI Limit Agreement
pH levels on i-STAT and EPOC	0.001	−0.091-0.094
pCO2 levels on i-STAT and EPOC	−0.660	−9.305-7.984
pO2 levels on i-STAT and EPOC	−2.310	−19.417-14.795
HCO3 levels on i-STAT and EPOC	−0.853	−8.205-6.498
BE levels on i-STAT and EPOC	0.317	−3.950-4.586
SO2 levels on i-STAT and EPOC	-0.489	−4.733-3.755
TCO2 levels on i-STAT and EPOC	0.696	−12.925-14.318
Lactate levels on i-STAT and EPOC	0.578	−2.776-3.932

The outcomes of the Bland-Altman curve test reveal that:

- The difference in pH levels between the i-STAT and EPOC devices had a mean value of 0.001, with 1 out of 28 samples falling outside the limit of agreement.
- The difference in pCO2 levels had a mean value of -0.660, with 2 out of 28 samples outside the limit of agreement.
- The difference in pO2 levels had a mean value of -2.310, with 2 out of 28 samples outside the limit of agreement.
- The difference in HCO3 levels had a mean value of -0.853, with 1 out of 28 samples outside the limit of agreement.
- The difference in BE levels had a mean value of 0.317, with 3 out of 28 samples outside the limit of agreement.
- The difference in SO2 levels had a mean value of -0.489, with 2 out of 28 samples outside the limit of agreement.
- The difference in TCO2 levels had a mean value of 0.696, with 2 out of 27 samples outside the limit of agreement.
- The difference in lactate levels had a mean value of 0.578, with 3 out of 26 samples outside the limit of agreement.

Overall, the Bland-Altman analysis demonstrates that most of the parameters tested had differences within the limits of agreement between the i-STAT and EPOC devices, with a few exceptions.

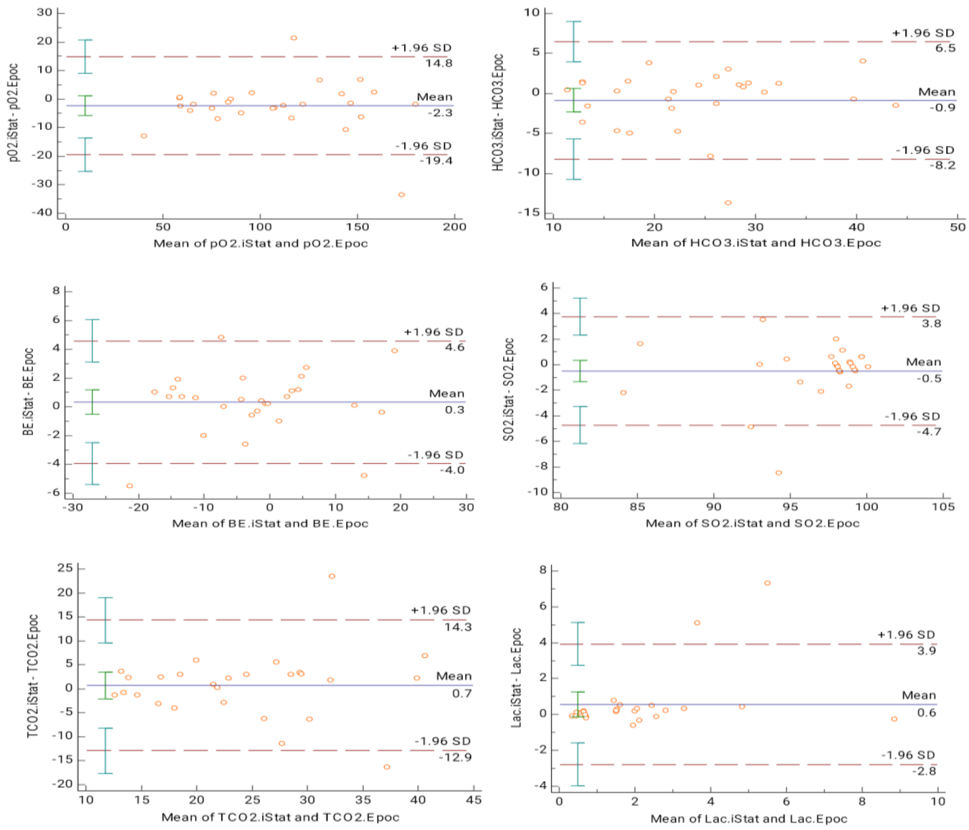


Figure 3: Bland-Altman curve for the i-STAT and EPOC devices

DISCUSSION

The outcomes of this study could be influenced by errors occurring at different points, whether in the pre-analytical, analytical, or post-analytical phases, the need for expertise in arterial blood sampling techniques, and the accuracy of entering samples into the i-STAT cartridge, which does not have an indicator to show whether the sample entered is sufficient or not, creating a risk of cartridge error and the inability to read the sample.

In a study by Gomaa et al. (2017), two point-of-care (POC) blood analysis devices, i-STAT and EPOC, were compared under normal conditions, with expired cartridges, and with cartridges that had been exposed to extreme temperatures. Both devices (i-STAT and EPOC) demonstrated acceptable accuracy under normal conditions (Gomaa et al., 2017). Expired cartridges and exposure to extreme temperatures reduce accuracy on several variables. Extreme temperatures (130 °F) cause both devices to lose accuracy and experience a higher number of failed readings. Exposing both devices to heat and using expired cartridges, particularly when measuring blood gases (PaO2, PaCO2, and pH), can lead to wrong results. Although there were statistically significant mean differences for PaO2, PaCO2, Glu, and HCO3, most of these differences were not clinically significant. When working with data from cartridges that have been exposed to heat or expired, these findings are crucial for both clinical care and logistical considerations (Blanchard et al., 2019).

According to Blanchard et al. (2018), who conducted research aimed at validating POCT, i-STAT, and POCT, in 8.4% of individual comparisons, the difference between the lab results and POCT exceeded what is considered acceptable; this was frequently higher in EPOC® (10.7%) than in i-STAT® (6.1%) (Nichols et al., 2008).

CONCLUSION

Based on this study, the EPOC device demonstrates excellent precision and meaningful correlation with the i-STAT device for all parameters measured directly. This aligns with previous findings that point to a meaningful correlation between the i-STAT and EPOC systems.[9] The results of the study provide evidence for the analytical acceptability of the EPOC blood analysis system for intensive care unit (ICU) testing. Further research needs to be conducted with a larger sample population, as well as comparisons with routine laboratory analysis instruments.

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Author's contribution: All authors contributed to data analysis, article preparation, and paper revision and have collectively assumed responsibility for all aspects of this work.

Ethical consideration: Ethical approval for this study was obtained from the Medical Research Ethical Committee of Dr. Soetomo General Academic Hospital - Faculty of Medicine, Universitas Airlangga, under approval certificate number **1703/121/3/X/2022**.

Data availability: The article contains all the necessary data to support the results; no supplementary source data is needed.

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