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EVALUATION OF THE DIAGNOSTIC PERFORMANCE OF THE HEMOSPARK+ HEMOGLOBIN METER: A COMPARATIVE ANALYSIS AGAINST THE MINDRAY BC760 FULLY AUTOMATED HEMATOLOGY ANALYZER REFERENCE STANDARD

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ABSTRACT

Background: Given that Hemoglobin (Hb) is the vital respiratory protein responsible for oxygen transport and carbon dioxide removal, its accurate estimation remains a cornerstone of diagnostic blood analysis and anemia screening. While laboratory-based Automated Hematology Analyzers remain the gold standard, the increasing need for point-of-care testing by healthcare personnel necessitates the use of portable meters. This study evaluates the diagnostic accuracy and clinical reliability of the HemoSpark+ Hemoglobin meter in comparison to automated analyzers to determine its efficacy for both clinical and bedside monitoring. **Objective:** To evaluate the diagnostic accuracy of the HemoSpark+ Hemoglobin meter, hemoglobin levels were estimated in parallel with an Mindray BC760 Fully Automated hematology analyzer within a NABL-accredited laboratory environment. **Materials and Methods:** To determine the diagnostic correlation for anemia classification, hemoglobin levels were estimated simultaneously using the HemoSpark+ meter and an Mindray BC760 Fully Automated hematology analyzer. The study utilized 631 samples (565 adults and 66 pediatric cases) processed in a NABL-accredited facility between September 2025 and December 2025, ensuring sample integrity through standardized equipment-aided mixing protocols prior

to analysis. **Results:** Comparative analysis confirmed the HemoSpark+ reliability against the Mindray BC760 Fully Automated hematology analyzer reference standard; The linear regression analysis shows an exceptional correlation between the two methods,the study recorded a strong r^2 value of 0.998**.** The 95% LOA were narrow, ranging from -0.230 to +0.259 g/dL. It also has a negligible positive bias of +0.015 g/dL, indicating no systematic overestimation or underestimation by the HemoSpark+ meter. **Conclusion:** This study concludes that the **HemoSpark+** digital hemoglobin meter demonstrates high analytical parity with the **Mindray BC760 Fully Automated Hematology Analyzer** reference standard. Given its strong statistical agreement and cost-efficiency relative to traditional hematology analyzers, the HemoSpark+ is highly suitable for point-of-care applications, particularly where rapid, isolated hemoglobin estimation is required.

INTRODUCTION

Hemoglobin (Hb) testing is a fundamental diagnostic tool used to assess Red Blood Cell (RBC) indices, including hematocrit levels and the clinical severity of anemia. It plays a critical role in high-stakes medical decision-making, such as pre-donation screening for blood donors and determining the necessity for blood transfusions. By utilizing hemoglobin meters to monitor these values, healthcare providers can effectively screen for and diagnose various hematological disorders. Maintaining optimal hemoglobin levels is vital across all age groups; undiagnosed anemia in children can hinder development, while in adults, it often serves as a precursor to or a complication of several systemic diseases.

WHO Hemoglobin Thresholds for Anemia

The following table outlines the diagnostic cut-off points for anemia based on World Health Organization (WHO) standardized guidelines:

Table 1: Age grouping and their reference Hb levels as per WHO.

Age or gender group	Haemoglobin threshold g/dl
Children (0.50-4.99 yrs.)	11.00
Children (5.00-11.99 yrs.)	11.50
Children (12.00-14.99 yrs.)	12.00
Non-pregnant women (> 15 yrs.)	12.00
Male (> 15 yrs.)	13.00

MATERIALS AND METHODS

The **Mindray BC760 Fully Automated** Hematology analyzer serves as the laboratory reference standard, utilizing advanced flow cytometry and photometric principles to deliver

high-precision hemoglobin and multi-parameter hematology results. In contrast, the **HemoSpark**+ (Sensa Core Medical Instrumentation, India) is a portable digital diagnostic device designed for point-of-care utility. While the automated analyzer relies on traditional bench-top optics, the HemoSpark+ employs dual wavelength absorbance photometry to measure hemoglobin levels from either fresh capillary or venous whole blood samples.

To evaluate the diagnostic performance of the **HemoSpark+ meter**, a comparative analysis was conducted on **631 clinical samples** against the **Mindray BC760 Fully Automated** automated reference standard. To ensure analytical objectivity and eliminate observer bias, testing was performed by two independent technicians who recorded results against anonymized Lab IDs. The study population comprised **446 females** and **185 males**, representing a diverse demographic of **565 adults** and **66 children and adolescents**.

Table 2: Baseline Characteristics of the Study Cohort (N=631).

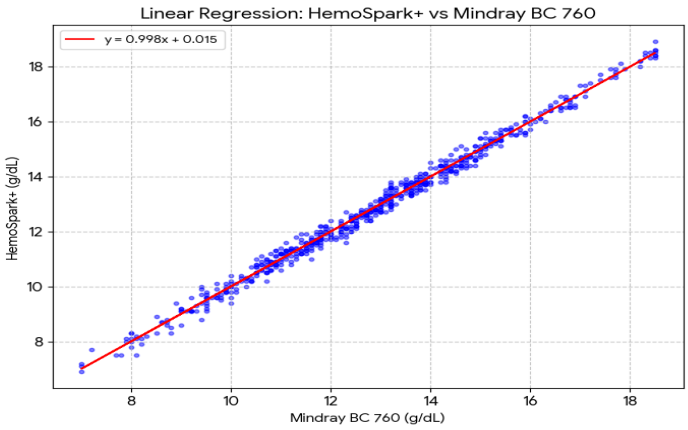
Category	Sub-group	Count (n)	Percentage (%)
Total Samples		**631**	**100%**
Gender	Female	446	70.7%
	Male	185	29.3%
Age Group	Adults	565	89.5%
	Children & Adolescents	66	10.5%

1. Correlation and Linear Regression

The linear regression analysis shows an exceptional correlation between the two methods across the clinical range. The calculated regression equation is:

$$y = 0.998x + 0.015$$

With a coefficient of determination $\mathbf{R^2 = 0.998}$, the HemoSpark+ shows high linearity, suggesting that it can reliably substitute for automated testing in both adult and pediatric populations without significant deviation.



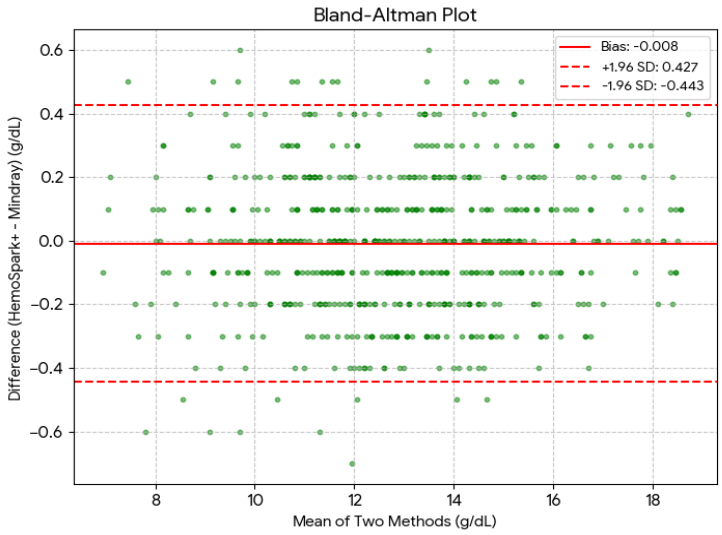
Graph 1: Scatter plot of HemoSpark+ and Mindray BC 760 values.

2. Bland-Altman Agreement and Bias

The Bland-Altman analysis was used to assess the "agreement" rather than just correlation.

Mean Bias: The study found a negligible positive bias of **+0.015 g/dL**, indicating no systematic overestimation or underestimation by the POC device.

Limits of Agreement (LOA): The 95% LOA were narrow, ranging from **-0.230 to +0.259 g/dL**. Since these limits fall well within the clinically acceptable total error (TEa) for hemoglobin, the devices are considered interchangeable.



Graph 2: Bland & Altman Plot.

The **Linear Regression** plot shows the strength of the relationship R^2, while the **Bland-Altman plot** identifies if the meter consistently overestimates or underestimates values

(Bias).

Mean Bias (g/dL)	0.0145
SD of Difference (g/dL)	0.124
Upper LOA (g/dL)	0.259
Lower LOA (g/dL)	-0.22994804

Based on the prevalence of anemia (Hb< 12.0 g/dL) the diagnostic reliability metric PPV and NPV has a good clinical interpretation.

Table 3: Accuracy, Sensitivity, Specificity, PPV and NPV HemoSpark+ results.

Accuracy (%)	97.78
Sensitivity (%)	96.21
Specificity (%)	98.72
Positive Predictive Value (PPV) (%)	97.86
Negative Predictive Value (NPV) (%)	97.73

With the **Sensitivity (96.22%)** and **NPV (97.73%)**, the HemoSpark+ meter is highly effective at "ruling out" anemia, making it a reliable screening tool.

With the **Specificity (98.73%)** and **PPV (97.86%)**, the device is equally effective at "ruling in" anemia, minimizing the risk of false positives.

RESULTS AND CONCLUSION

HemoSpark+ meter is highly correlated with the **Mindray BC 760 Automated Hematology Analyzer**, exhibiting a robust correlation coefficient of **0.998**. Statistical agreement via **Bland-Altman analysis** confirmed high precision, with narrow limits of agreement (**-0.23 to +0.259 g/dL**) and negligible bias. Furthermore, with a **sensitivity of 96.2%** and **specificity of 98.7%**, the HemoSpark+ delivers the diagnostic accuracy required for effective large-scale anemia screening, clinical diagnosis, and therapeutic monitoring."

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