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Research Article

End-user verification of the Maccura F810 hematology analyzer: A comparison with Mindray BC-6200

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Abstract

Objectives: Analytical performance verification is essential before implementing hematology analyzers in routine clinical practice. This study aimed to evaluate the performance characteristics of the Maccura F810 hematology analyzer.

Methods: This study was conducted at the Medical Biochemistry Laboratory of Çanakkale Onsekiz Mart University Hospital between January and April 2023. Analytical performance was verified by evaluating precision (within-run and between-batch), carry-over, and linearity in accordance with the Clinical and Laboratory Standards Institute and the International Council for Standardization in Hematology guidelines. Additionally, 356 K2-EDTA samples from patients were used for comparative analysis with the Mindray BC-6200, including Passing-Bablok regression, Bland-Altman analysis, and bias estimation at medical decision points. We compared the results with the manufacturer's claimed performance specifications and further evaluated them using state-of-the-art (SOTA) and minimum biological variation (MBV) performance criteria.

Results: All precision results met the manufacturer's performance specifications, whereas only monocyte, eosinophil, and basophil counts exceeded the SOTA precision limits at certain concentration levels. Carry-over was negligible for white blood cell count, red blood cell count, hemoglobin, and platelet count. Linearity was confirmed across the concentration ranges specified by the manufacturer. Bland-Altman analysis showed agreement with the manufacturer's specifications and SOTA criteria for all parameters, while all parameters except monocyte count also fulfilled the MBV criteria. Predicted bias at predefined medical decision points was within the MBV and SOTA limits for all evaluated parameters, except for platelet count at 50 $\times 10^9$/L, where the predicted bias was 8.00% (95% CI, 3.21%-12.89%), exceeding both the MBV (7.5%) and SOTA (6.4%) limits.

Conclusion: Overall, the Maccura F810 demonstrated satisfactory analytical performance and is suitable for routine clinical laboratory use, despite higher CVs observed for a limited number of parameters and a predicted PLT bias at 50 $\times 10^9$/L that exceeded both acceptance criteria.

Keywords: Complete blood count, hematology, instrumental analysis, method verification, performance evaluation

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The complete blood count (CBC) is one of the most commonly requested hematological tests and provides essential information for patient diagnosis and clinical management [1]. It plays a key role in the diagnosis and monitoring of hematological disorders, including anemia, hematologic malignancies, and coagulation disorders. It is also widely used to identify infections, allergic conditions, and immune system disorders [2]. Automated hematology analyzers measure hemoglobin (HGB) concentration, quantify and characterize blood cell populations, differentiate leukocyte subpopulations, and assess cell volume and cellular content. They also calculate diagnostic indices based on these measurements. These analyses are performed simultaneously through fully automated processes, supporting rapid, standardized results [3].

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Technological advances have substantially enhanced the analytical performance of hematology analyzers by integrating multiple measurement technologies [4]. Historically, CBC analysis was performed manually. Automation was introduced following the description of the Coulter principle in the late 1940s, leading to the development of the first automated hematology analyzer in the 1950s [5]. Early analyzers were based on the electrical impedance principle combined with basic optical methods for cell counting and volume measurement. Subsequent technological developments enabled the assessment of intracellular structure and cellular composition. The incorporation of multi-angle light-scatter analysis made comprehensive leukocyte differentiation possible. More recently, fluorescent staining methods targeting intracellular components, particularly nucleic acids, have enabled highly accurate measurement of reticulocytes and nucleated red blood cells (NRBCs). The same technology also supports a six-part leukocyte differential by identifying immature granulocytes (IG) [6]. In addition to quantitative cell counts, analyzer-generated flags provide valuable information about peripheral blood smear abnormalities and help reduce the need for manual microscopic review [7].

Hematology analyzers play a key role in clinical decision-making, so every new device should undergo an extensive manufacturer validation process before routine use to ensure accurate and reliable performance. Following manufacturer validation, clinical laboratories are required to perform instrument verification to confirm analytical performance before patient testing. Validation and verification procedures should be conducted in accordance with the recommendations of the Clinical and Laboratory Standards Institute (CLSI), the International Council for Standardization in Haematology (ICSH), and the ISO 15189 standard [8–10]. Although these guidelines differ in certain aspects, verification typically includes the evaluation of precision, accuracy, method comparability, carry-over, linearity, limit of blank, limit of detection, reference intervals, and the analytical measuring interval [1]. However, current guidelines do not define universally accepted acceptance criteria or minimum performance requirements for individual analytical parameters [11]. Therefore, verification of the manufacturer's performance claims is necessary [1]. Establishing appropriate acceptance criteria and interpreting verification results are the responsibility of laboratory specialists, who should apply professional judgment in accordance with the analyzer's intended clinical use [12].

To the best of our knowledge, no previous verification study of the Maccura F810 hematology analyzer has been reported in the literature. Therefore, this study was designed to verify its analytical performance against the manufacturer's performance claims, state-of-the-art (SOTA) criteria, and minimum biological variation (MBV) specifications. In addition, we compared its performance with that of the Mindray BC-6200 under routine laboratory conditions [3, 13].

Materials and Methods

Analyzer

The F810 (Maccura Biotechnology, Chengdu, China) is a third-generation hematology analyzer designed for high-volume laboratories and capable of processing up to 100 samples per hour. It uses fluorescent dyes that target DNA and RNA to differentiate leukocyte subpopulations by nucleic acid content. The analyzer incorporates multiple dedicated analytical channels. The FCW channel detects white blood cells (WBCs), basophils, and NRBCs, while the FCD channel generates the leukocyte scattergram. Together, these channels provide a six-part WBC differential, including IGs, and generate 29 research parameters. Red blood cells (RBCs) and platelets (PLTs) are measured in a separate channel using the sheath-flow impedance method, whereas HGB concentration is determined by colorimetry. The FCR channel measures reticulocytes, reports six reticulocyte-related parameters, and performs optical platelet counting (PLT-O) for samples with low PLT counts. The FCP channel uses fluorescence-based platelet counting (PLT-F), while the FCA channel is designed to detect immature cells of the bone marrow and lymphoid lineage. In addition, the analyzer includes an LW mode for samples with low WBC counts and a dedicated body-fluid analysis mode.

Comparative analyzer

The operating principle and technological characteristics of the BC-6200 hematology analyzer (Mindray Bio-Medical Electronics, Shenzhen, China) have been described previously [14]. The analyzer provides a six-part WBC differential using SF Cube technology, which combines light scatter (S), fluorescence (F), and three-dimensional (3D) analysis. For leukocyte differentiation, cells are stained with a fluorescent dye according to their nucleic acid content. The WNB channel differentiates WBCs, basophils, and NRBCs. In the RBC/PLT channel, RBCs and PLTs are counted using the electrical impedance method, while HGB concentration is measured by a cyanide-free colorimetric method.

Samples

This study was approved by the Çanakkale Onsekiz Mart University Clinical Research Ethics Committee (Date: 04.01.2023, Decision no: 2023/01-18). Normal and abnormal whole-blood samples were collected from outpatient, inpatient, and intensive care unit patients during routine laboratory practice at the Medical Biochemistry Laboratory of Çanakkale Onsekiz Mart University Hospital between January and April 2023. Blood samples were collected into K2EDTA tubes (Vacusera, Disera Medical, İzmir, Türkiye) and analyzed within 2 hours of collection.

Precision

We evaluated within-run precision (repeatability) and between-batch precision in accordance with the recommendations of ICSH [8]. For repeatability, we selected patient sam-

ples representing low abnormal, clinically relevant (medical decision level), and high abnormal concentrations, and each sample was analyzed 10 consecutive times in a single analytical run. Between-batch precision was assessed using three levels of CBC-X hematology quality control materials (R&D Systems, Minneapolis, MN, USA), which were analyzed over 20 consecutive days. During the between-batch precision study, a single lot was used for each level: Lot No. 23700813 for the low level, Lot No. 23700814 for the normal level, and Lot No. 23700815 for the high level.

Carry-over

The carry-over study was performed in accordance with the ICSH guidelines [8]. For WBC, RBC, HGB, and PLT, a high-level sample was analyzed in triplicate (H1, H2, and H3), followed by a low-level sample diluted with particle-free plasma, which was also analyzed in triplicate (L1, L2, and L3). The carry-over percentage was calculated using the following formula: [(L1−L3) / (H3−L3)] × 100. We compared the calculated values with the SOTA limits and the manufacturer's specifications [3].

Linearity

Linearity was assessed according to the procedure recommended by the ICSH guidelines. For WBC, RBC, HGB, and PLT, we prepared an 11-point serial dilution series (0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, and 100%) from high-concentration samples using the diluent reagent. Each dilution was analyzed in triplicate, and the mean value was calculated. We performed linear regression analysis by comparing the observed and expected values [8]. The results were compared with the manufacturer's claim and MBV total allowable error (TEa) for verification. In addition, linearity was evaluated separately for low-level WBC, mid-level WBC, and low-level PLT samples. In LW mode, we also assessed linearity specifically for low-level WBC samples.

Comparison study

A comparative evaluation with the Mindray BC-6200 was performed in accordance with the CLSI EP09C guideline [15]. A total of 356 normal and abnormal whole-blood samples were analyzed on both analyzers. Method agreement was evaluated using Passing-Bablok regression analysis, Bland-Altman plots, and bias estimation at predefined medical decision points.

Statistical analysis

Statistical analyses were performed using MedCalc version 23.6.1 (MedCalc, Ostend, Belgium). Data distribution was assessed with the Kolmogorov-Smirnov test. For the precision study, the mean, standard deviation (SD), and coefficient of variation (CV) were calculated. The obtained CVs were compared with the MBV, SOTA, and manufacturer-specified performance criteria [3, 13]. Method comparison data were evaluated using Passing-Bablok regression analysis. Analytical performance was considered acceptable when the 95% confidence intervals (CIs) for the intercept and slope included 0.0 and 1.0, respectively. If these values were not included in the corresponding CIs, the deviation was interpreted as a constant bias in the intercept and a proportional bias in the slope. Bland-Altman analysis was performed by plotting the percentage difference between the two analyzers against their mean values. Depending on the data distribution, either the mean or the median percentage difference (MD%) was calculated. Bias at clinical decision points was estimated using Passing-Bablok regression analysis, with 95% CIs generated via nonparametric bootstrap sampling. The predefined medical decision points were determined to reflect clinically important conditions, critical values, or reference intervals, including mild anemia (HGB 12 g/dL), severe anemia (HGB 8 g/dL), polycythemia vera (HGB 16.5 g/dL), severe leukopenia (WBC 2×10^9/L), leukopenia (WBC 4×10^9/L), leukocytosis (WBC 13×10^9/L), neutropenia (Neutrophils 1.8×10^9/L), microcytosis (mean corpuscular volume (MCV) 80 fL), macrocytosis (MCV 100 fL), severe thrombocytopenia (PLT 50×10^9/L), thrombocytopenia (PLT 150×10^9/L), and thrombocythemia (PLT 450×10^9/L) [16–20]. The calculated MD% values and predicted bias at the predefined medical decision points were compared with the SOTA and MBV bias limits [3, 13].

Results

Precision

The within-run and between-batch precision results are summarized in Table 1, along with the manufacturer's performance specifications, MBV, and SOTA limits. The calculated within-run and between-batch CVs for all parameters met the Maccura performance specifications. Except for the between-batch CV for MCV, the within-run CV at the normal level and the between-batch CV at the low level for monocyte count, and the within-run CVs at the normal and high levels together with the between-batch CVs at the low and normal levels for basophil count, all within-run and between-batch CVs satisfied the MBV criteria. Exceedance of the SOTA limits was observed only for the within-run CV at the normal level and the between-batch CVs at all concentration levels for monocyte count, the within-run CV at the high level for eosinophil count, and the within-run CVs at the normal and high levels for basophil count.

Carry-over

No significant carry-over was observed for WBC, RBC, HGB, or PLT. The calculated carry-over rates, together with the manufacturer's specifications and SOTA targets, are presented in Table 2.

Linearity

Linearity was evaluated over the following analytical ranges: low-level WBC, $0–1.00\times10^9$/L; mid-level WBC, $0–25.45\times10^9$/L; high-level WBC, $14.21–140.79\times10^9$/L; RBC, $0–7.85\times10^{12}$/L; HGB, 0–20.8 g/dL; low-level PLT, $0.33–25\times10^9$/L; and high-level PLT,

Table 1. Within run precision using different levels of whole blood samples and between-batch precision using quality control materials

Parameter	Level	Within-run precision			Between-batch precision			Maccura	MBV	SOTA (within-run)	SOTA (between-batch)
		Mean	SD	CV%	Mean	SD	CV%				
WBC (10^9/L)	Low	0.65	0.02	3.08	3.95	0.09	2.28	–	8.3	6.0	6.0
	Normal	6.20	0.08	1.29	7.11	0.10	1.41	≤2.5		2.5	2.5
	High	21.91	0.17	0.78	20.77	0.26	1.25	≤2.5		1.5	1.5
RBC (10^{12}/L)	Low	2.25	0.02	0.89	2.42	0.02	0.83	–	2.0	1.1	1.1
	Normal	5.47	0.04	0.73	4.56	0.03	0.66	≤1.5			
	High	8.31	0.05	0.60	5.76	0.03	0.52	≤1.5			
HGB (g/dL)	Low	5.2	0.04	0.77	6.1	0.06	0.98	–	1.3	0.9	1.0
	Normal	12.7	0.06	0.47	13.7	0.09	0.66	≤1			
	High	17.6	0.07	0.40	18.1	0.09	0.50	≤1			
MCV (fL)	Low	61	0.16	0.26	80	0.61	0.76[a]	–	0.6	0.6	0.8
	Normal	81	0.11	0.14	91	0.70	0.77[a]	≤1			
	High	114	0.29	0.25	95	0.67	0.70[a]	–			
PLT (10^9/L)	Low	23	1.14	4.91	55	2.10	3.83	–	5.5	5.0	4.5
	Normal	274	2.72	0.99	175	4.90	2.80	≤4		3.0	3.0
	High	756	8.58	1.14	336	9.47	2.82	≤4		–	3.0
Neut (10^9/L)	Low	1.06	0.02	1.89	2.37	0.06	2.53	–	9.4	2.5	2.5
	Normal	3.62	0.08	2.21	3.84	0.09	2.34			2.5	
	High	19.73	0.18	0.91	13.23	0.22	1.66			–	
Lymp (10^9/L)	Low	0.49	0.01	2.04	0.58	0.02	3.45	–	7.9	3.5	3.5
	Normal	2.10	0.05	2.38	1.73	0.04	2.31				
	High	1.13	0.03	2.65	3.54	0.09	2.54				
Mono (10^9/L)	Low	0.01	0	0	0.09	0.01	11.11[a,b]	–	10.5	8.5	8.5
	Normal	0.34	0.06	17.65[a,b]	0.23	0.02	8.70[b]				
	High	1.01	0.08	7.92	0.42	0.04	9.52[b]				
Eo (10^9/L)	Low	0.01	0	0	0.86	0.05	5.81	–	11.3	10	10
	Normal	0.11	0.01	9.09	1.20	0.06	5.00				
	High	3.00	0.05	1.67	3.11	0.18	5.79				
Baso (10^9/L)	Low	0	0	-	0.05	0.01	20.00[a]	–	9.5	20	20
	Normal	0.03	0.01	33.33[a,b]	0.11	0.02	18.18[a]				
	High	0.04	0.01	25.0[a,b]	0.48	0.03	6.25				

[a]: The CV values exceeded the minimum biological variation specifications; [b]: The CV values exceeded the state of art limits. MBV: Minimal biological variation; SOTA: State of art; WBC: White blood cell; RBC: red Blood cell; HGB: Hemoglobin; MCV: Mean corpuscular volume; PLT: Platelet; Neut: Neutrophile count; Lymp: Lymphocyte count; Mono: Monocyte count; Eo: Eosinophile count; Baso: Basophile count.

120–1143×10^9/L. In addition, we assessed WBC linearity in LW mode over the concentration range of 0–1.83×10^9/L. The differences between the measured and assigned values were within both the manufacturer's allowable deviation limits and the MBV TEa criteria. The linear regression results are presented in Table 3.

Comparison study

The method comparison results between the Maccura F810 and the Mindray BC-6200 are summarized in Table 4. According to the Passing-Bablok regression analysis, the 95% CIs for both the slope and intercept included 1.0 and 0.0, respectively, for MCV, lymphocyte count, and IG count. For HGB, hematocrit, PLT, and basophil count, the 95% CI for the slope included 1.0, whereas the 95% CI for the intercept did not include 0.0, showing a constant bias. In contrast, the intercept CIs for neutrophil and eosinophil counts included 0.0, while the slope CIs did not include 1.0, indicating a proportional bias. Neither the slope

Table 2. Carry-over rates from high and low level samples

Parameters	Carry-over rate (%)	Maccura (%)	SOTA (%)
WBC	0.01	≤1	<0.2
RBC	0.30	≤1	<0.5
HGB	0	≤1	<0.4
PLT	0.46	≤1	<0.5

SOTA: State of the art; WBC: White blood cell; RBC: Red blood cell; HGB: Hemoglobin; PLT: Platelet.

Table 3. Linearity for Maccura F810

Parameter	Linear range	Regression	r^2	Maccura's allowable deviation range	MBV (TEa)
WBC (Low-level)	0–1.00×10⁹/L	y=-0.014+1.013x	0.9989	0.20×10⁹/L	21.3%
WBC (Mid-level)	0–25.45×10⁹/L	y=0.106+0.989x	0.9992	2%	
WBC (High-level)	14.08–140.79×10⁹/L	y=0.391+0.994x	0.9988	6%	
WBC (LW mode)	0–1.83×10⁹/L	y=-0.001+0.987x	0.9984	0.20×10⁹/L	
RBC	0–7.85×10¹²/L	y=0.077+1.003x	0.9986	2%	6%
HGB	0–20.83 g/dL	y=0.054+ 0.999x	0.9986	2%	5.8%
PLT (Low-level)	0–24.67×10⁹/L	y=0.224+0.982x	0.9968	10×10⁹/L	16.5%
PLT (High-level)	114–1143×10⁹/L	y=9.620+0.995x	0.9991	6%	

MBV: Minimal biological variation; Tea: Total allowable error; WBC: White blood cell; RBC: Red blood cell; HGB: Hemoglobin; PLT: Platelet.

Table 4. Comparison of results between the Maccura F810 and the Mindray BC-6200

Parameters	Intercept (95% CI)	Slope (95% CI)	r	p	MD (95% CI) (%)	Maccura (%)	MBV (%)	SOTA (%)
WBC (10⁹/L)	0.104 (0.057–0.141)	0.982 (0.976–0.988)	0.997	<0.0001	-0.50 (-0.93– -0.17)	15	7.6	4.4
RBC (10¹²/L)	0.096 (0.062–0.128)	0.973 (0.966–0.981)	0.997	<0.0001	-0.44 (-0.64– -0.26)	6	2.8	3.2
HGB (g/dL)	0.100 (0.100–0.100)	1.000 (1.000–1.000)	0.998	<0.0001	1.19 (0.96–1.39)	6	2.8	1.3
HCT (%)	0.741 (0.400–1.288)	0.991 (0.976–1.000)	0.987	<0.0001	1.02 (0.62–1.53)	9	2.3	1.8
MCV (fL)	0.279 (-1.879–2.175)	1.011 (0.988–1.035)	0.963	<0.0001	1.42 (0.93–1.79)	7	1.5	2
PLT (10⁹/L)	4.000 (0.872–6.948)	1.000 (0.990–1.014)	0.990	<0.0001	1.80 (1.17–2.38)	20	7.5	6.4
Neut (10⁹/L)	-0.016 (-0.043–0.011)	0.980 (0.974–0.986)	0.997	<0.0001	-2.40 (-2.80– -2.03)	NS	10.8	3.2
Lymp (10⁹/L)	0.020 (-0.003–0.031)	1.000 (0.993–1.010)	0.995	<0.0001	0.87 (0.19–1.49)	NS	9.4	5
Mono (10⁹/L)	0.017 (0.001–0.033)	1.098 (1.065–1.131)	0.967	<0.0001	12.77 (11.55–14.28)	NS	10.1	15
Eo (10⁹/L)	-0.004 (-0.008–0.000)	0.931 (0.909–0.958)	0.896	<0.0001	-10.00 (-11.44– -8.00)	NS	25.9	13
Baso (10⁹/L)	0.010 (0.010–0.010)	1.000 (1.000–1.000)	0.615	<0.0001	22.22 (0.00–28.57)	NS	11.7	32
IG (10⁹/L)	0.000 (0.000–0.001)	1.000 (0.977–1.000)	0.718	<0.0001	0.00 (0.00–0.00)	NS	–	–

MBV: Minimal biological variation; SOTA: State of art; CI: Confidence interval; NS: Not specified; WBC: White blood cell; RBC: Red blood cell; HGB: Hemoglobin; HCT: Hematocrit; MCV: Mean corpuscular volume; PLT: Platelet; Neut: Neutrophile count; Lymp: Lymphocyte count; Mono: Monocyte count; Eo: Eosinophile count; Baso: Basophile count; IG: Immature granulocyte.

nor the intercept met the acceptance criteria for WBC, RBC, or monocyte count. The MD% obtained from the Bland-Altman analysis was within the SOTA limits and the manufacturer's allowable deviation ranges for all parameters. All parameters, except monocyte count, also met the MBV criteria (Fig. 1). For WBC, neutrophil count, HGB, and MCV, the predicted bias at all predefined medical decision points remained within both the MBV bias and SOTA limits. For PLT, the predicted bias at the medical decision points of 150 and 450×10⁹/L was within the MBV bias and SOTA limits, whereas the predicted bias at 50×10⁹/L exceeded both acceptance criteria (Table 5). The distribution of samples according to the predefined medical decision levels is presented in the Appendix 1.

Discussion

In response to the growing patient population and the increasing demand for laboratory testing, clinical laboratories must provide accurate, reliable, and timely blood cell counts and differential results. To meet these demands, manufacturers continue to develop hematology analyzers with improved throughput and the ability to measure an expanding range of parameters. Before implementation in routine clinical practice, the analytical performance of these systems should be thoroughly verified by laboratory professionals. In the present study, we evaluated the analytical performance of the Maccura F810 hematology analyzer and compared it with that of the Mindray BC-6200, which is routinely used in our laboratory.

The Maccura F810 demonstrated good precision in both the within-run and between-batch studies. Within-run precision was assessed using normal, abnormal, low-, and high-level patient samples, whereas between-batch precision was evaluated using low-, normal-, and high-level quality control materials. All results met the manufacturer's performance specifications, and almost all parameters satisfied both the MBV and SOTA acceptance criteria for within-run and between-batch precision. The between-batch imprecision for MCV exceeded the MBV criterion but remained within the SOTA limit. Similar between-batch precision for MCV has been reported for other hematology analyzers [14, 21, 22]. This finding may be attributed to the limited long-term stability of the quality control materials, which is likely to have a greater impact on between-batch precision

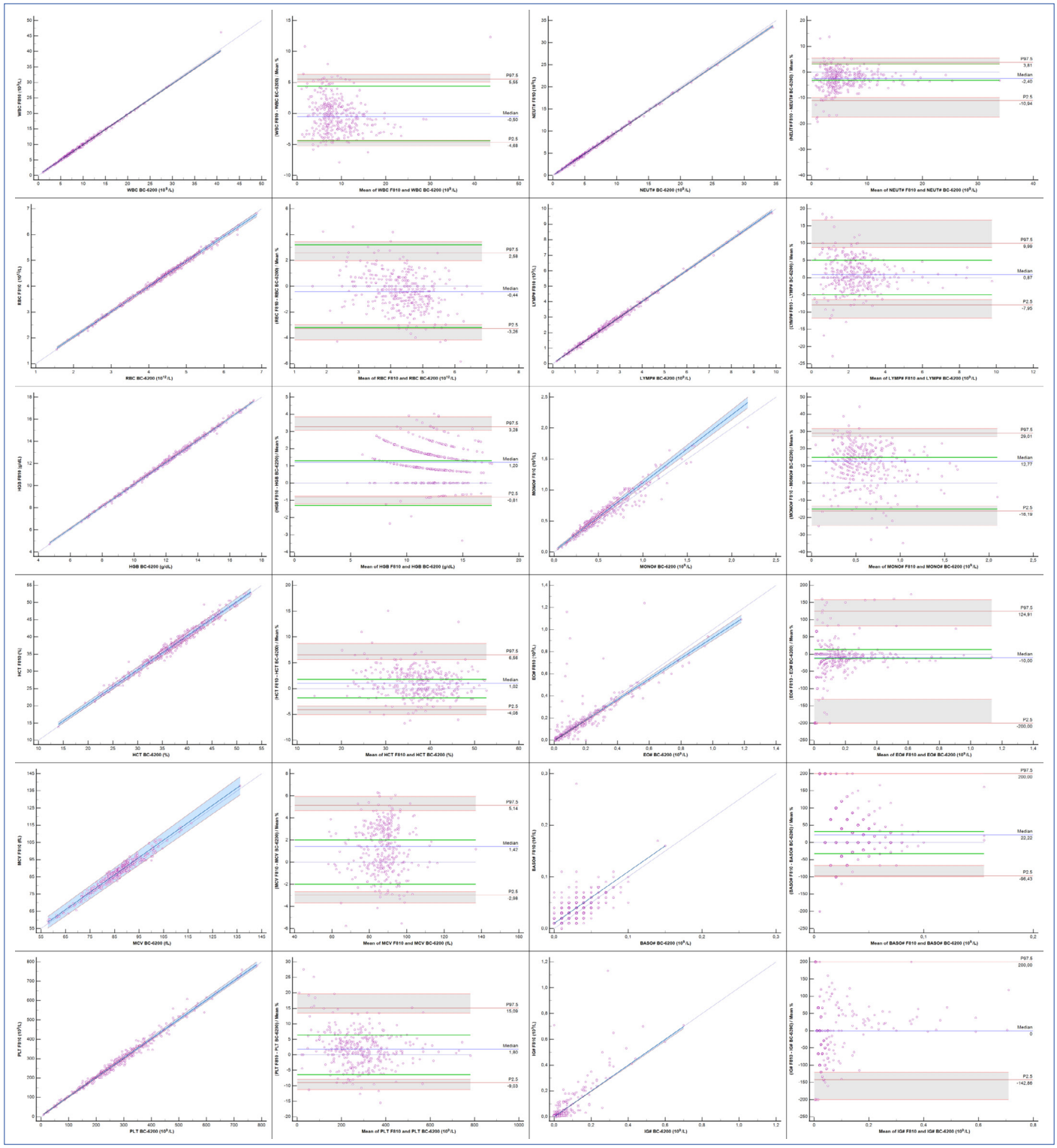

Figure 1. Comparison of CBC parameters between the Maccura F810 and Mindray BC-6200 hematology analyzers using Passing-Bablok regression and Bland-Altman analysis.

CBC: Complete blood count.

than on within-run precision. We evaluated the precision of monocyte, eosinophil, and basophil counts at very low concentrations. At such low concentrations, even minimal changes in the standard deviation can result in substantial increases in the coefficient of variation. Consequently, relatively high CVs were observed for these parameters. A similar phenomenon has been described in previous analytical performance studies [4, 23, 24].

Table 5. Predicted bias at medical decision levels

Parameters	Medical decision level	Predicted result (95% CI)	Difference	Predicted bias (95% CI)	MBV (%)	SOTA (%)
WBC (10^9/L)	2	2.06 (2.02–2.09)	0.07 (0.03–0.09)	3.40 (1.43–4.80)	7.6	4.4
	4	4.03 (3.99–4.05)	0.03 (0.00–0.05)	0.79 (-0.09–1.33)		
	13	12.86 (12.81–12.90)	-0.13 (-0.18– -0.09)	-1.02 (-1.41– -0.72)		
Neut (10^9/L)	1.8	1.74 (1.7–1.76)	-0.05 (-0.07– -0.03)	-2.85 (-4.03– -1.93)	10.8	3.2
HGB (g/dL)	8	8.10 (8.10–8.20)	0.10 (0.10–0.20)	1.25 (1.25–2.50)	2.8	1.3
	12	12.10 (12.10–12.20)	0.10 (0.10–0.20)	0.83 (0.83–1.67)		
	16.5	16.60 (16.60–16.70)	0.10 (0.10–0.20)	0.61 (0.61–1.21)		
MCV (fL)	80	81.14 (80.73–81.50)	1.14 (0.73–1.50)	1.42 (0.91–1.87)	1.5	2
	100	101.35 (100.81–101.84)	1.35 (0.81–1.84)	1.35 (0.81–1.85)		
PLT (10^9/L)	50	54.00 (51.60–56.45)	4.00 (1.60–6.45)	8.00 (3.21–12.89)	7.5	6.4
	150	154.00 (152.63–155.52)	4.00 (2.63–5.52)	2.67 (1.76–3.68)		
	450	454.00 (451.32–457.91)	4.00 (1.32–7.91)	0.89 (0.29–1.76)		

MBV: Minimal biological variation; SOTA: State of art; CI: Confidence intervals; WBC: White blood cell; Neut: Neutrophile count; HGB: Hemoglobin; MCV: Mean corpuscular volume; PLT: Platelet.

In the routine workflow of clinical laboratories, samples with high cellular concentrations, such as those from patients with myeloproliferative neoplasms and lymphoproliferative disorders, are analyzed alongside cytopenic samples. To prevent interference and maintain analytical accuracy, it is necessary to minimize carry-over from high-concentration specimens into subsequently analyzed low-concentration specimens [8]. In the present study, the Maccura F810 demonstrated excellent carry-over performance, with all calculated carry-over rates remaining within both the manufacturer's specifications and the SOTA acceptance limits.

The widest concentration ranges attainable under routine laboratory conditions were selected to verify the manufacturer's linearity claims. No significant bias was seen across the evaluated concentration ranges, confirming excellent linearity. Because very low WBC and PLT levels may be encountered in routine clinical practice, we evaluated these ranges separately and also demonstrated excellent linearity. However, we could not verify the highest WBC (350–500×10^9/L) and PLT (1001–5000×10^9/L) concentrations claimed by the manufacturer because neither suitable patient samples nor commercially available linearity materials spanning these ranges were available at the time of the study.

In the method comparison study, MCV and lymphocyte count showed excellent agreement between the two analyzers. For the remaining parameters, either constant or proportional bias was identified; however, the calculated MD% remained within the SOTA acceptance limits for all parameters, indicating good agreement between the two systems. In addition, all parameters except monocyte count met the MBV acceptance criteria. Overall, the results confirmed the manufacturer's performance specifications for method comparison.

Monocytes are morphologically heterogeneous cells, and their accurate classification largely depends on the detection technology used by hematology analyzers. The comparative study included samples from intensive care units and inpatient wards. In patients with sepsis or other infections, monocytes exhibit considerable morphological variability, particularly during the early stages of disease [25, 26]. In addition to methodological discrepancies between analyzers, this morphological heterogeneity is likely to contribute to both constant and proportional bias. In the present study, the 95% CIs for both the intercept and slope in the Passing-Bablok regression analysis of monocyte count excluded 0.0 and 1.0, respectively. Furthermore, the MD% exceeded the allowable MBV limit. These outcomes are consistent with those reported by İncir and Palaoğlu [11], who also observed a large mean difference in monocyte counts, which they attributed to the morphological complexity of these cells. Similar differences in monocyte counts have also been reported in studies comparing hematology analyzers or automated methods with manual differential counting [14, 27].

For basophil measurements, the median percentage difference between the two methods was 22.2% (95% CI, 0.0%-28.6%). Although the upper limit of the CI exceeded the MBV acceptance limit, the relatively large percentage difference is more likely attributable to the very low absolute basophil counts than to a systematic bias between the two methods. As basophil counts approach zero, even minimal absolute differences can produce disproportionately large relative differences. In addition, differences in measurement principles may contribute to variability among hematology analyzers [24]. The relatively lower correlation coefficients for basophil count (r=0.615) and IG (r=0.718) are primarily related to the narrow concentration ranges and clustering of results at low concentrations, as shown in the Passing-Bablok regression plots (Fig. 1). No specific acceptance specification has been established for IG. However, Passing-Bablok regression yielded a slope of 1.000 (95% CI, 0.977–1.000) and an intercept of 0.000 (95% CI, 0.000-0.001), indicating no significant proportional or systematic bias between the methods. A limitation of this study

is the low number of samples with a prominent left shift and markedly elevated IG values, which restricts performance assessment at higher concentration ranges.

In the present study, MD% for PLT obtained from the Bland-Altman analysis was 1.8% (95% CI, 1.17%-2.38%), remaining within both the SOTA and MBV bias limits. However, at the predefined medical decision level of 50×10^9/L, the predicted bias was 8.0%, exceeding both the MBV (7.5%) and SOTA (6.4%) acceptance limits, although its 95% CI (3.21%-12.89%) included both allowable limits. This estimate was associated with a relatively wide 95% CI, most likely because of the limited number of samples with severe thrombocytopenia included in the study (Appendix 1). On the other hand, the absolute difference at this decision level was 4×10^9/L, corresponding to a relatively small change in PLT concentration, and the bias may have limited clinical significance. Given the importance of PLT in transfusion and perioperative decision-making, laboratories introducing or replacing hematology analyzers should conduct local verification studies to determine whether PLT measurements among different analytical systems are interchangeable, particularly for thrombocytopenic samples.

Limitations

This study has several limitations. Because our hospital does not have a hematology department, extremely low and high cell-count samples were encountered relatively infrequently in routine practice, resulting in a limited number of specimens at the extremes of the analytical measuring range. Another important limitation was that the diagnostic performance of analyzer flags compared with peripheral blood smear review could not be evaluated because an adequate number of qualified examiners was unavailable. In addition, although the Maccura F810 is capable of reticulocyte analysis, we were unable to assess this feature due to logistical and technical issues. Finally, the analytical performance of the analyzer could not be compared with that of reference methods.

Conclusion

In the present study, we evaluated the performance of the Maccura F810 hematology analyzer against the manufacturer's specifications and confirmed all performance claims. Because the manufacturer's acceptance criteria are relatively broad, the analytical performance was also assessed using the more stringent SOTA and MBV criteria to better reflect the requirements of our laboratory [3, 13]. To the best of our knowledge, this is the first verification study of the Maccura F810 hematology analyzer reported in the literature. Overall, the Maccura F810 demonstrated satisfactory analytical performance in terms of precision, carry-over, linearity, and method comparison. However, the predicted PLT bias at the 50×10^9/L medical decision level exceeded both the MBV and SOTA acceptance limits, highlighting the need for careful local verification of PLT results in thrombocytopenic samples. The results indicate that the analyzer is well suited to meet the demands of high-throughput clinical laboratories..

Disclosures

Ethics Committee Approval: The study was approved by the Çanakkale Onsekiz Mart University Clinical Research Ethics Committee (no: 2023/01-18, date: 04/01/2023).

Informed Consent: The study used anonymized residual routine laboratory samples; informed consent was not applicable.

Conflict of Interest Statement: İz Tıbbi Cihaz Medikal San. ve Tic. Ltd. Şti. (Türkiye), the Turkish distributor of the Maccura F810 hematology analyzer, provided the analyzer, reagents, and consumables used in this study. The company had no role in the study design, data collection, data analysis, interpretation of the results, manuscript preparation, or the decision to submit the manuscript for publication. The authors received no personal financial support or other compensation from the company.

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Appendix 1. Distribution of samples across medical decision levels

Parameter	Interval	n (%)
WBC (10^9/L)	≤2.00	5 (1.4)
	2.01–4.00	27 (7.6)
	4.01–13.00	271 (76.1)
	>13.00	53 (14.9)
Neut (10^9/L)	≤1.80	25 (7.0)
	>1.80	331 (93.0)
HGB (g/dL)	≤8.0	20 (5.6)
	8.1–12.0	151 (42.4)
	12.1–16.5	175 (49.2)
	>16.5	10 (2.8)
MCV (fL)	≤80	70 (19.7)
	81–100	263 (73.9)
	>100	23 (6.5)
PLT (10^9/L)	≤50	8 (2.2)
	51–150	31 (8.7)
	151–450	287 (80.6)
	>450	30 (8.4)

The total number of samples was 356 for each parameter. WBC: White blood cell; Neut: Neutrophile count; HGB: Hemoglobin; MCV: Mean corpuscular volume; PLT: Platelet.