

Maintenance procedures for accurate and reliable performance of Medonic™ M51 hematology analyzer

The automated hematology analyzer constitutes a powerful tool that aids physicians in diagnosis and monitoring of disease progression and efficacy of treatment. As such, a hematology analyzer uses sophisticated techniques to provide quantitative analysis results for a variety of parameters. Medonic M51 hematology analyzer provides information on 29 parameters, including the red blood cells (RBC), platelets (PLT), hemoglobin (HGB), and white blood cells (WBC). Additionally, the analyzer provides a 5-part WBC differential. To ensure a reliable performance, regular instrument maintenance should be conducted, and adherence to determined service schedules is recommended. This document highlights instrument components that are critical for accurate and reliable performance of the Medonic M51 analyzer, and maintenance procedures for the instrument and individual components are discussed.

Introduction

Automated hematology analyzers are frequently used in clinical laboratories to assess patients' health condition. A complete blood count (CBC) is requested by physicians to determine the oxygen-carrying RBCs, the PLTs that help clot the blood, and the WBCs of the immune system. As part of the CBC, a differentiation of the WBCs into neutrophils (NEU), lymphocytes (LYM), monocytes (MONO), eosinophils (EOS), and basophils (BASO) is conducted.

In normal blood, about 60% of the cells constitute NEU that help fight bacteria (and fungi), and a high count (> 85%) can therefore be an indication of a bacterial infection. LYM, accounting for about 30% of all WBC, help fight viruses and a high count can be an indication of a viral infection. The last 10% comprises monocytes, eosinophils, and basophils. These cell types are typically associated with allergies or parasite infections.

A high number of monocytes (2%–8% normal), for example, can indicate a chronic inflammatory disease or a bacterial infection, whereas a high eosinophil count (1%–4% normal) gives an indication of asthma, an allergic reaction, or a parasite infection. A high number of basophils (0.5%–1% normal) is typically associated with inflammatory reactions, especially those causing allergic symptoms. High numbers of the WBCs can also be an indication of certain forms of cancers, such as leukemia or lymphoma.

WBC differentiation into the five subpopulations

Commonly, either a light emitting diode (LED) or laser is used as light source for the WBC differentiation. With LED, light is allowed to pass the cells and transmitted light is detected at zero (0) angle. Unabsorbed (diffused) light passes through the cell, while the absorbed light reflects internal cell structure. A change in the impedance reflects the cell size. Results are displayed in a 2D diagram (Fig 1A).

With laser, cells are exposed to a laser beam and scattered light is detected at three (3) angles. The intensity of the scattered light reflects the cell size and internal structure, while the low-angle signal shows cell size and the middle- and high-angle signals show intracellular (nucleus and cytoplasm) information. With laser-scatter, analysis results are displayed in a 3D diagram (Fig 1B).

Compared with polychromatic LED light, laser constitutes a more complex monochromatic photometry and the technology is thus costlier. In a laser-based 3D scattergram, however, the cell clusters are well separated, facilitating differentiation of the WBC subpopulations. With a 2D LED-based diagram, close cell clusters might overlap, with the risk of misinterpretation of the results (e.g., over-lysis of NEU could falsely increase LYM).

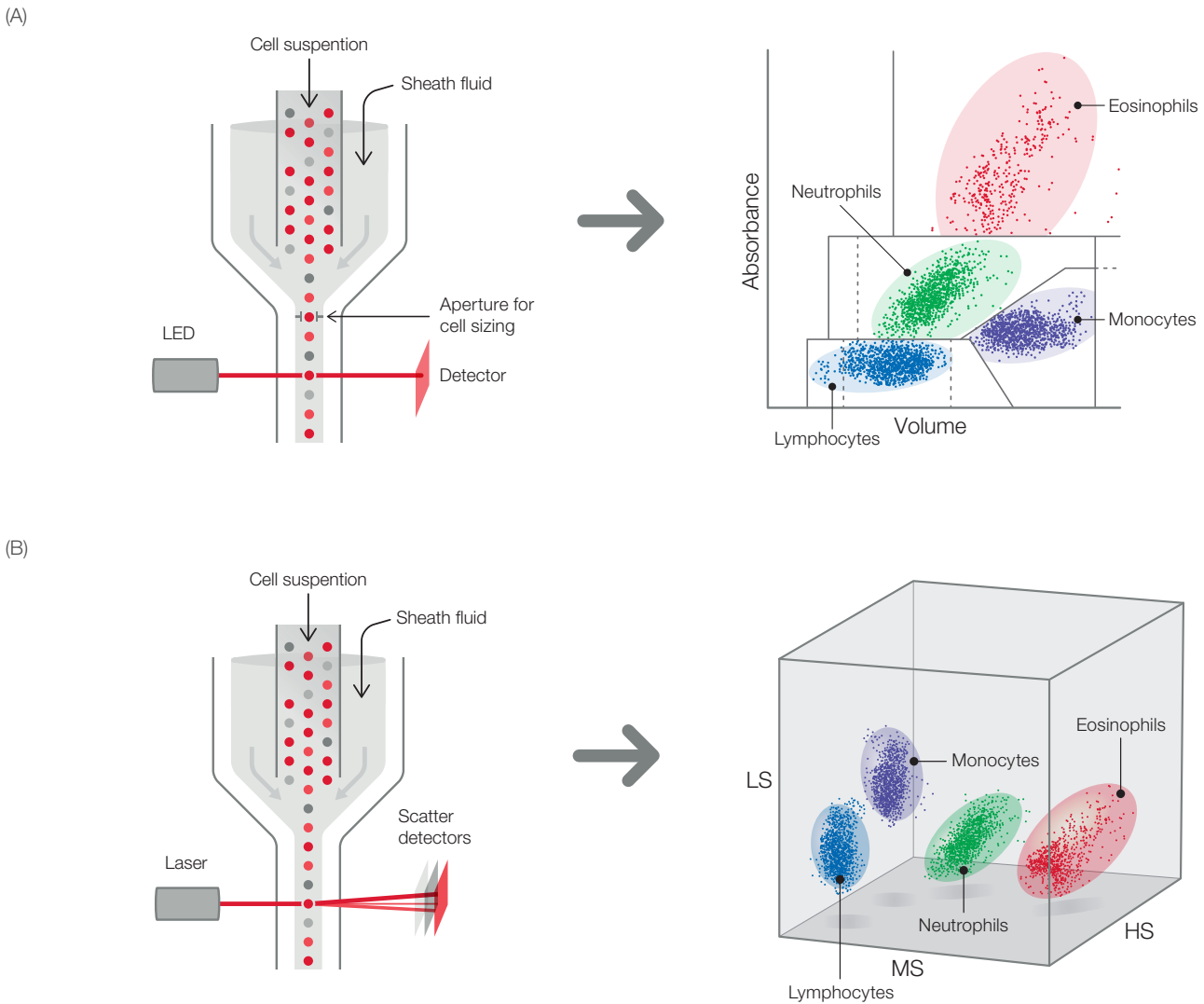


Fig 1. (A) In LED-based WBC differentiation, cell distribution is displayed in a 2D diagram, with cell volume on the x-axis and absorbance on the y-axis. (B) In laser-based WBC differentiation, cell distribution is displayed in a 3D diagram, with the low, mid, and high angle light scatter signals on the axes (scattergram).

Medonic M51 - reliability when it counts

Medonic M51 is an entry level 5-part hematology analyzer intended for the smaller laboratory (Fig 2). Sample analysis is performed in either CBC or CBC+DIFF mode. In CBC+DIFF mode, the analyzer provides quantitative analysis results for 29 parameters, histograms for WBC, RBC, and PLT, and scattergrams for the WBC differential. In CBC mode, the analyzer provides quantitative analysis results for 15 parameters and histograms for WBC, RBC, and PLT.

Medonic M51 employs well-proven measurement technologies. The analyzer uses impedance for RBC and PLT counts, while the WBC differential is conducted by laser-based flow cytometry. Hemoglobin (HGB) is determined spectrophotometrically. Medonic M51 provides a robust performance, with analysis results comparable with those from a reference instrument intended for the larger hospital laboratory (Fig 3).



Fig 2. Medonic M51 is an entry-level 5-part hematology analyzer intended for the cost-minded clinical laboratory. The user-friendly design makes system operations easy. Robust software and hardware components ensure a reliable system performance. With its small footprint, Medonic M51 is well-suited for the typical physician office laboratory.

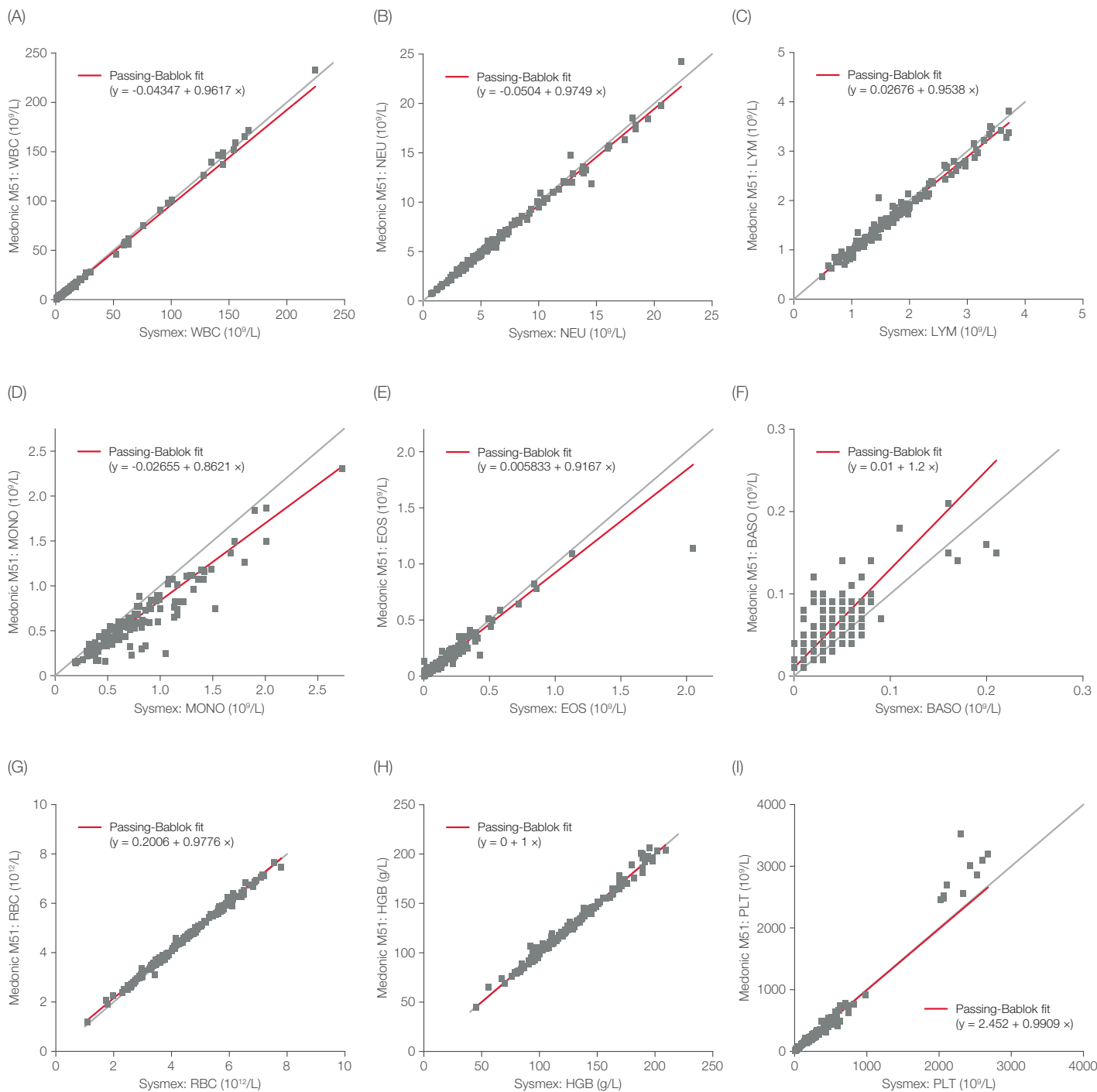


Fig 3. Agreement between the Medonic M51 test system and Sysmex™ XN-1000 reference system. Passing-Bablok regression graphs for (A) WBC, (B) NEU, (C) LYM, (D) MONO, (E) EOS, (F) BASO, (G) RBC, (H) HGB, (I) and PLT. In regression plots, the gray line corresponds to identity ($x = y$) and the red line corresponds to best fit.

Instrument maintenance

Regular instrument maintenance is key for a reliable system performance. Although the majority of the instrument cleaning procedures are automated to keep the user maintenance to an absolute minimum, some user intervention is still required. Section 12 of the User manual contains information on how to maintain the Medonic M51 analyzer. An overview of maintenance procedures is given in Table 1.

Good practice also dictates keeping the instrument clean from dust and other impurities. Regularly, check if there is dust inside the instrument, especially for the upper area of the counting chamber. At the same time, check that reagent connection or waste tubes are not bent or squeezed.

Also, regularly check for possible leakages from the sample probe wipe or other parts inside the instrument. The sample probe should be cleaned when dirty as described in Section 12.2.2 of the User manual.

Maintenance of system components

RBC chamber

As illustrated in Figure 4, with impedance, each cell that passes through the aperture causes a drop in the electrical current (a pulse). The number of generated pulses correlates with the number of cells, whereas the size of the pulse is related to the cell size.

Table 1. Scheduled maintenance based on 60 samples/day

Procedure	Description	Frequency
Cleanser soak	When shut down at the end of the work day, the analyzer will ask for "Cleanser soak", and next time power is turned back on, the analyzer will run cleaning cycle. or Click Service from the menu page and select Maintain in the Maintenance section. Click EasyCleaner Soak and then Yes . Aspirate Boule EasyCleaner according to the instructions. Refer to Section 12.2.3 of the User manual for more information.	Daily
Cleaning procedure	Click Service from the menu page, select Clean in the Maintenance section and follow instructions in Section 12.2.2 of the User manual.	Weekly
Self-test	Click Service from the menu page and follow instructions in Section 12.3 of the User manual.	Monthly
Instrument calibration	Follow instructions in Section 10 of the User manual.	Every 6 month (or according to local regulations)
Preventive maintenance (PM)	PM kit available and included components should be exchange by an authorized service technician.	Every year

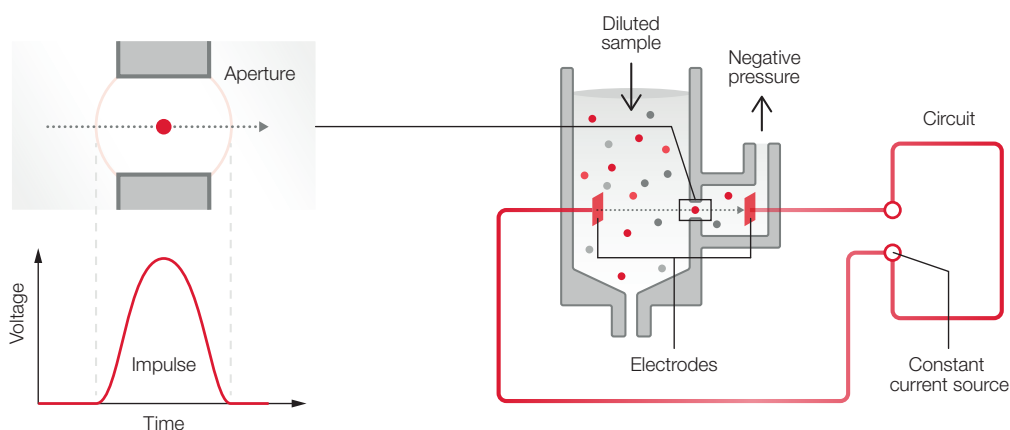


Fig 4. The principle for measuring changes in the electrical impedance produced by a cell passing through an aperture.

If the background of RBC- and/or PLT-specific parameters exceeds the reference range, the RBC chamber should be cleaned according to Section 12.2.2 of the User manual. If the RBC distribution histogram is abnormal, cleanser soak for the RBC channel as described in Section 12.2.3 of the User manual can be performed as part of troubleshooting. If clogging is suspected in the flow chamber, perform the unclogging operations according to Section 12.2.3.1 of the User manual.

WBC chamber

To determine HGB concentration, the reagent lyses the RBCs so that HGB is released and can be measured spectrophotometrically as illustrated in Figure 5.

For the BASO count, the lyse reagent contains a special hemolytic agent that is used to extract the BASOs specifically, while preserving the cell information. BASO count is thereafter determined directly by counting cells passing through the optical flow cell.

If the background of WBC- and/or HGB-specific parameters exceeds the reference range, clean the WBC chamber according to Section 12.2.2 of the User manual. To remove errors for aperture clogging, perform the unclogging operations according to Section 12.2.3.1 of the User manual. If the WBC histogram or BASO scattergram are abnormal, cleanser soak for the WBC channel can be performed as described in Section 12.2.3 of the User manual as part of troubleshooting.

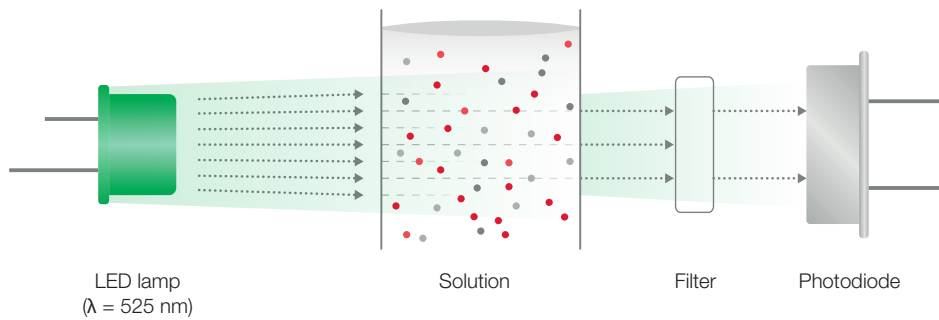


Fig 5. HGB is determined spectrophotometrically, using a LED lamp mounted on one side of the WBC chamber. The light is allowed to pass the flow chamber and transmitted light is detected by an optical sensor mounted on the opposite side. HGB concentration is calculated as a difference of a blank and a blood measure with and without illumination to reduce the effect of liquid refraction and disturbing light.

Optical flow cell

With laser-based flow cytometry, cells are forced to flow in a single file through the aperture by a sheath fluid, created by fast-moving diluent that surrounds the slow-moving sample. A laser beam is passed through the sample, and when a cell passes through the sensing zone, the light is scattered and measured by a photoconductor that converts the light into an electrical impulse (Fig 6).

If the background of the scattergram has abnormal excessive cells or the WBC differential is poor, clean the flow chamber according to Section 12.2.2 of the User manual. If scattergrams are abnormal, a cleanser soak can be performed as described in Section 12.2.3 of the User manual.

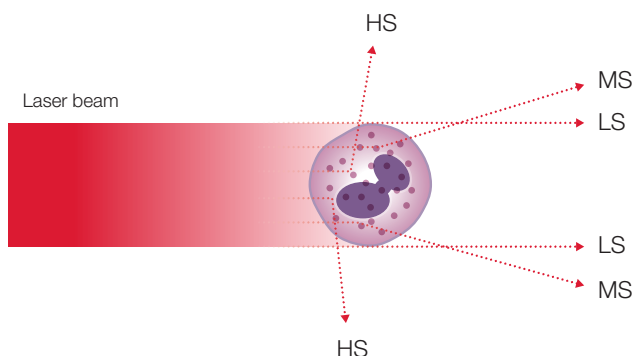


Fig 6. Three-angle laser-scatter method, where the low angle signal (about 1° to 5°) represents the cell volume information, the middle angle signal (about 7° to 20°) represents the cell nucleus information, and the high angle signal (about 90°) represents the cell nucleus and cytoplasm information.

Reagents

Only three reagents are required for the Medonic M51 analyzer—Diluent, Lyse 1, and Lyse 2—which greatly facilitates handling and logistics and helps reduce running costs. Simply scan the RFID card on the reagent container and the analyzer stores key information such as lot number, open and expiry dates, and remaining volume. The measurement principle is depicted in Figure 7.

The use of the reagents supplied by Boule Diagnostics ensures analytical quality and performance of the hematology system (Fig 8).

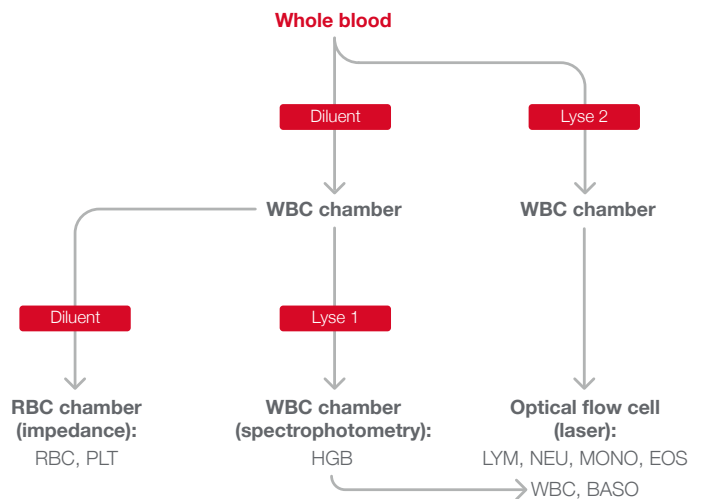


Fig 7. Medonic M51 measurement principle.

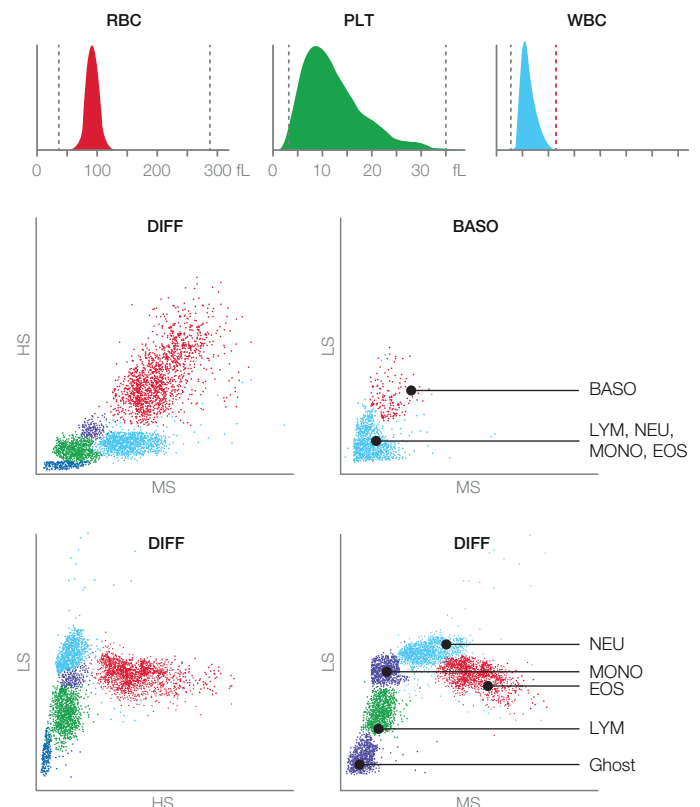


Fig 8. Medonic M51 provides results for 29 parameters, with histograms for RBC, PLT and WBC as well as scattergrams for the WBC differential.

Quality control

Medonic M51 hematology analyzer is part of Boule's Total Quality Concept that is designed to increase the value of reported hematology results. Controls and calibrator are key elements of this initiative. Boule QC materials (Boule Con-5Diff A1 and Boule Cal-5Diff A1) ensure that Medonic M51 performs accurately and delivers quality-controlled hematology results. Advanced quality control functions built into the Medonic M51 software include Levey-Jennings charts, XB-function, and QC reports.

Conclusion

Medonic M51 is an entry-level hematology system intended for the smaller clinical laboratory. Equipped with robust and well-proven technologies, the analyzer provides accurate and reliable analysis results, comparable to those of a reference instrument intended for larger hospital laboratories, to support the physician in decision-making. To maximize instrument uptime and ensure a reliable performance, adhering to determined maintenance procedures and service schedules is recommended.

Ordering information

Product	Product code	
	EU	US
Medonic M51	1620020	
Medonic M51-D Diluent	1504510	
Medonic M51-L1 Lyse	1504511	
Medonic M51-L2 Lyse	1504512	
Boule EasyCleaner	1504513	
Boule Con-5Diff A1 Tri, 3 × 2 × 3 mL	1504518	501-617
Boule Con-5Diff A1 Norm, 6 × 3 mL	1504519	501-622
Boule Con-5Diff A1 Norm, 1 × 3 mL	1504520	501-623
Boule Con-5Diff A1 Low, 1 × 3 mL	1504521	501-624
Boule Con-5Diff A1 High, 1 × 3 mL	1504522	501-625
Boule Cal-5Diff A1, 1 × 3 mL	1504517	501-616

Related literature	Product code
User manual: Medonic M51	30624
Brochure: Medonic M51 5-part hematology system	30658
Application note: Clinical performance of Medonic M51 5-part hematology analyzer	31190
Application note: Performance comparison of the entry-level Medonic M51 hematology system with a reference system intended for use in large hospital laboratory setting	33255
Application note: Evaluation of the performance of Medonic M51 hematology system	33256

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