Data sheet

Medonic™ M51 hematology system

Hematology analysis provides a cost-efficient tool for general health screenings and in initial disease investigations, and the results form the basis for decisions on further testing or initiation of treatment.

Medonic M51 hematology system delivers accurate results in a compact design well suited for the smaller laboratory. The interphase is designed to be simple to understand and easy to navigate. Robust software and hardware components minimize service and maintenance needs to maximize instrument uptime. Medonic M51 provides the possibility to leverage high-quality diagnostics, while keeping costs to a minimum.

Medonic M51 - explore your possibilities:

- Developed for ease of use.
- Designed to ensure uptime and a reliable performance.
- Low maintenance needs support cost-efficient operations.

System overview

Medonic M51 is an entry-level 5-part hematology analyzer intended for the smaller laboratory (Fig 1). Sample analysis can be performed in either CBC+DIFF mode or in CBC mode to save on reagents when a WBC differential count is not required. In CBC+DIFF mode, the analyzer provides quantitative analysis results for 29 parameters (20 for clinical use, 9 for research use), histograms for WBC, RBC, and PLT, and scattergrams for the WBC differential. In CBC mode, the analyzer provides quantitative analysis results for 15 parameters (10 for clinical use, 5 for research use), with histograms for WBC, RBC, and PLT (Fig 2).

Fig 1. Medonic M51 hematology analyzer.

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.

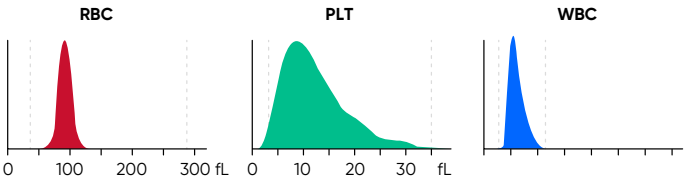

Fig 2. Results for red blood cell (RBC), platelet (PLT), and white blood cell (WBC) counts are visualized in histograms.

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Key components

RBC chamber

Medonic M51 uses an impedance method for the red blood cell (RBC) and platelet (PLT) counts (Fig 3). 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.

WBC chamber

Medonic M51 uses a laser-based flow cytometry method for differential count of the white blood cell (WBC) subpopulations—neutrophils (NEU), lymphocytes (LYM), monocytes (MONO), eosinophils (EOS), and basophils (BASO)—based on cell size and complexity (granularity) (Fig 4). 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. To determine HGB concentration, the reagent lyses the RBCs so that HGB is released and can be measured spectrophotometrically (Fig 5).

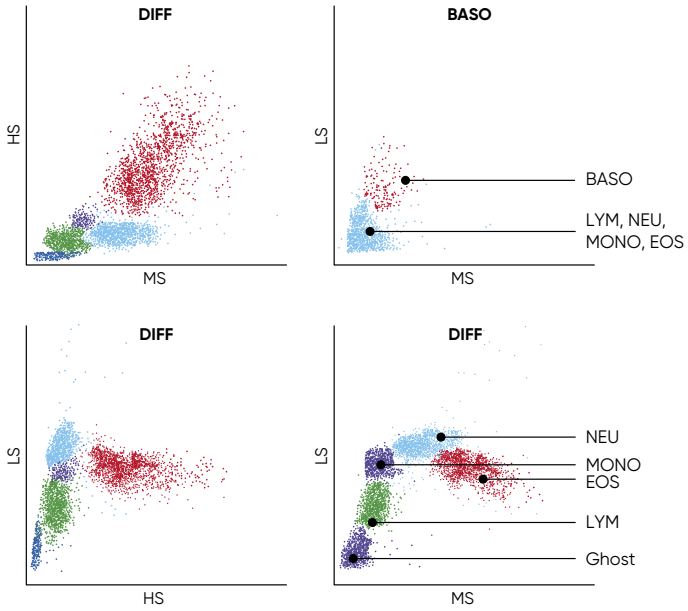

Fig 4. In Medonic M51, test results from the WBC differential count are visualized in a 4-part scattergram and a separate scattergram for BASO. Ghost = nucleated RBC, lyse-resistant RBC, and platelet clumps.

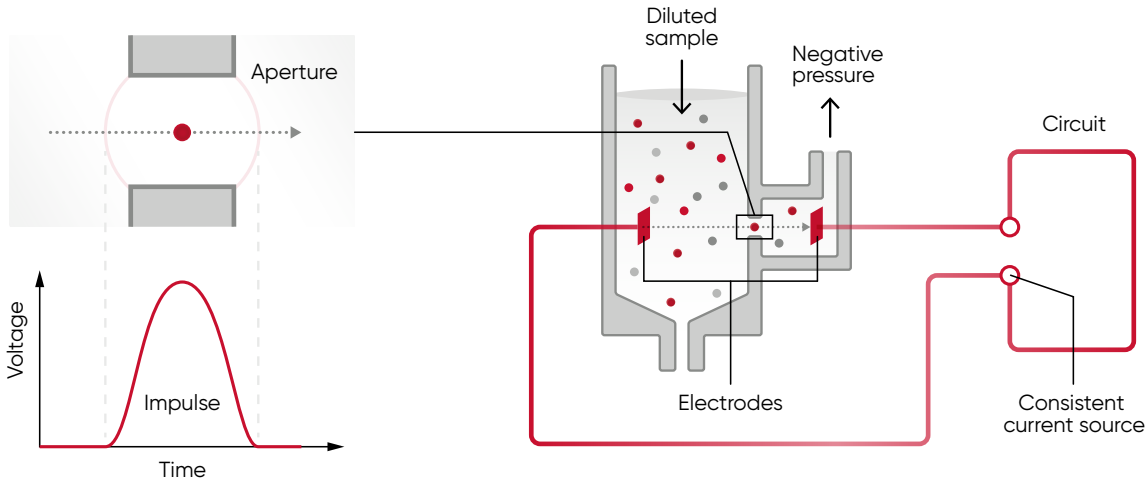

Fig 3. The principle for measuring changes in the electrical impedance produced by a cell passing through an aperture.

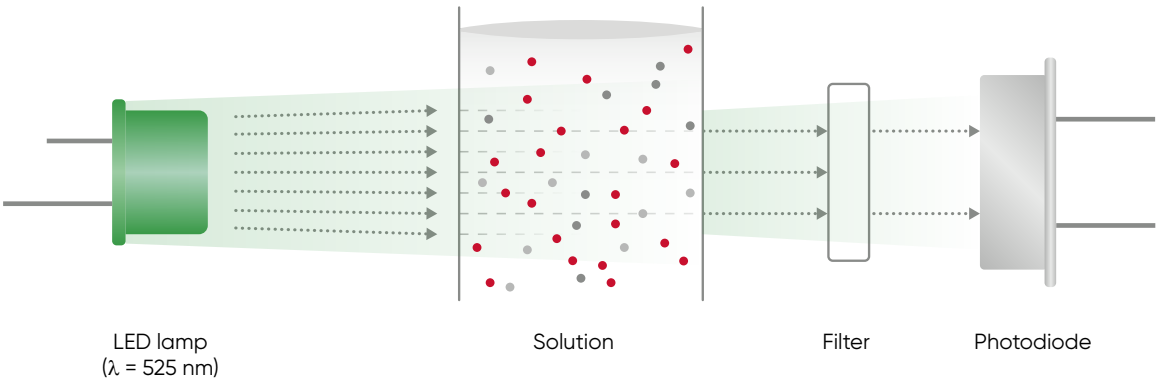

Fig 5. HGB is determined spectrophotometrically, using a LED lamp mounted on one side of the WBC chamber. The light is allowed to pass the flow chamber and transmitted light is detected by an optical sensor mounted on the opposite side. HGB concentration is calculated as a difference of a blank and a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

Optical flow cell

In flow cytometry, cells are forced to flow in a single file through the aperture by a sheath fluid, created by a 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. The number of generated impulses correlates with the number of cells, whereas the light scatter is used to determine cell granularity, shape, and size (Fig 6).

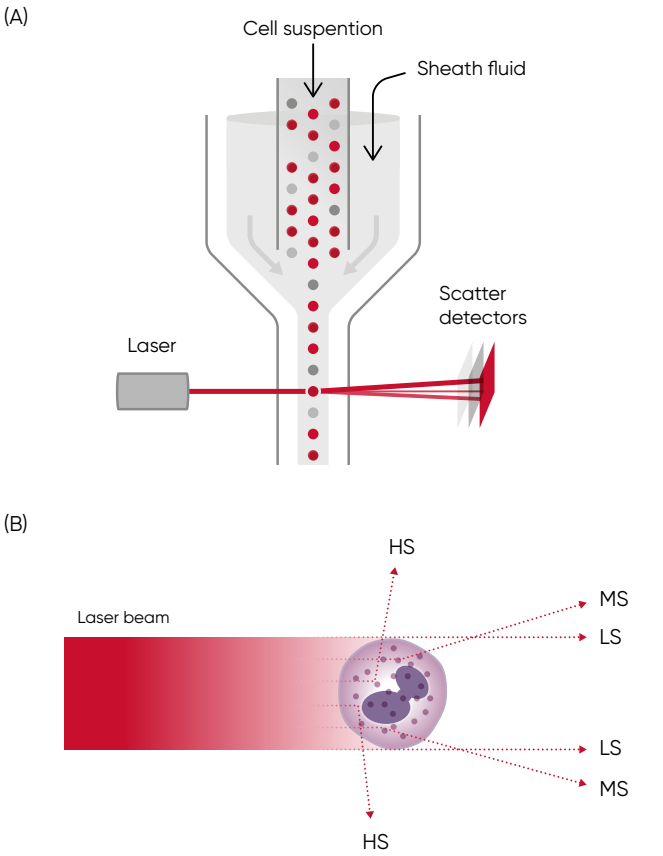

Fig 6. (A) Laser-based flow cytometry for 5-part differential of white blood cells. (B) Three-angle laser-scatter method, where the low angle signal (about 1° to 5°) represents the cell volume information, the middle angle signal (about 7° to 20°) represents the cell nucleus information, and the high 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 use of the reagents supplied by Boule Diagnostics ensures analytical quality and performance of the hematology system. The measurement principle is depicted in Figure 7.

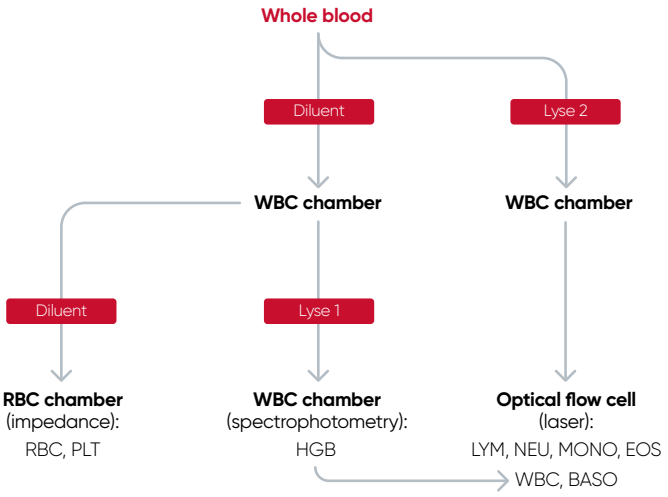

Fig 7. Medonic M51 measurement principle.

Quality control

Calibrator and Control material are key elements of quality assurance. Boule QC products (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.

System performance

Medonic M51 provides a robust performance, with analysis results comparable with those from a reference instrument intended for the larger hospital laboratory (Fig 8).

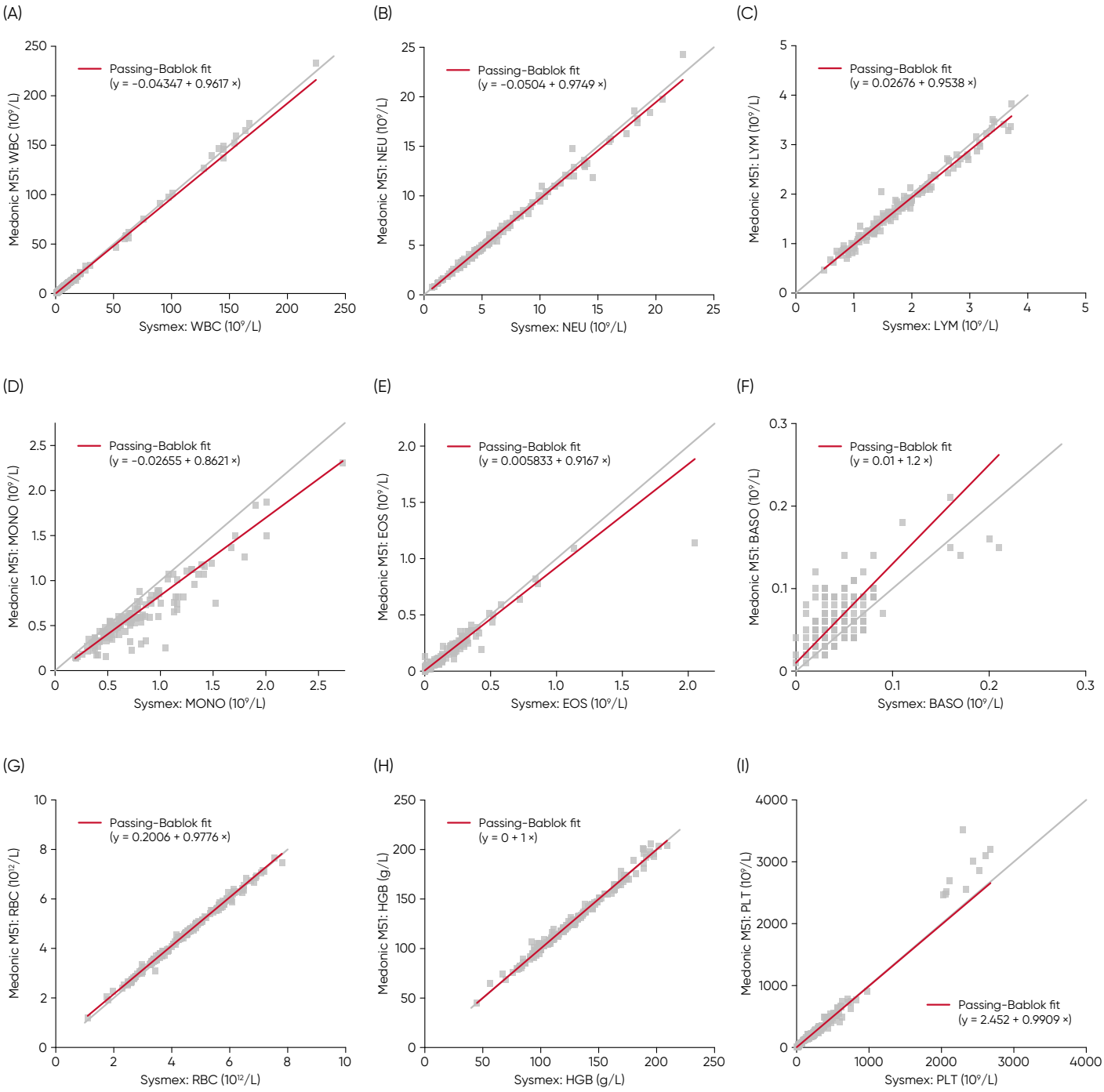

Fig 8. Agreement between Medonic M51 test and Sysmex™ XN-1000 reference systems. Passing-Bablok regression graphs for (A) WBC, (B) NEU, (C) LYM, (D) MONO, (E) EOS, (F) BASO, (G) RBC, (H) HGB, (I) and PLT. In regression plots, the gray line corresponds to identity (x = y) and the red line corresponds to best fit.

Instrument maintenance

Regular instrument maintenance is key for a reliable system performance. Although the majority of the analyzer cleaning procedures are automated to keep the user maintenance to a 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. It is also good practice to keep the analyzer clean from dust and other impurities.

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

Specifications

System specifications are listed in Table 2.

Table 2. Medonic M51 system specifications

Parameters	
20 for diagnostic use	RBC, MCV, HCT, RDW-CV, HGB, MCH, MCHC, PLT, MPV, WBC, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%
9 for research use	RDW-SD, PCT, PDW, P-LCC, P-LCR, AL#, AL%, IG#, IG%
Throughput	Up to 60 samples/h in CBC mode Up to 45 samples/h CBC + 5-part WBC differential
Sample analysis	
Samples	Venous blood, capillary blood, and pre-diluted
Sampling system	Open tube aspiration
Aspiration volume	CBC: 20 µL and CBC + DIFF: 25 µL
Precision	CV WBC: ≤ 2.0%* CV RBC: ≤ 1.5%* CV MCV: ≤ 1.0% CV HGB: ≤ 1.5% CV PLT: ≤ 6.0%
Reagents	3 RFID locked reagents and one cleaner used for analysis: Medonic M51-D Diluent, Medonic M51-L1 Lyse, Medonic M51-L2 Lyse, and Boule EasyCleaner
Display	10.4 inch TFT touch screen
Data storage capacity	50 000 samples
Interface ports	4 USB ports, 1 LAN port that supports bidirectional HL7 protocol
Printout	External laser printer or inkjet printer, various printout formats and user-defined formats
Dimension	364 mm (L) × 431 mm (W) × 498 mm (H)
Weight	28 kg

* Above 2000 m, CV WBC ≤ 3.5% and CV RBC ≤ 1.8%.

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

* Location of manufacturing. For availability in your country, please contact your local Boule representative.

Related literature	Product code
User manual: Medonic M51	30624
Flyer: Medonic M51	38937
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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