# Medonic™ M32 analyzer design and maintenance procedures for optimized system performance

Medonic M32 is purpose-built to fit the needs of the smaller clinical laboratory. The analyzer comes equipped with many features that help keep service and maintenance needs to a minimum. To ensure a reliable and long-term performance, however, some user intervention is still required, and adherence to determined service schedules is recommended. This document highlights instrument components that are critical for an accurate and reliable performance of the Medonic M32 analyzer, and maintenance requirements for the instrument and individual components are discussed.

## Introduction

A complete blood count (CBC) is the most requested analysis by physicians to assess and monitor patients' health conditions. For this, automated hematology analyzers are frequently used in clinical laboratories to measure the oxygen-carrying red blood cells (RBC), the platelets (PLT) that help clot the blood, and the white blood cells (WBC) of the immune system.

As part of the CBC, a differentiation of the WBCs into their subgroups is typically conducted. In normal blood, neutrophils (NEU) account for about 60% of the WBCs. NEUs help fight bacteria (and fungi), and a high count (> 85%) can therefore indicate a bacterial infection. Lymphocytes (LYM), accounting for about 30% of all WBC, help fight viruses. A high LYM count can therefore be an indication of a viral infection. The last 10% comprises monocytes (MONO), eosinophils (EOS), and basophils (BASO). These cell types are typically associated with allergies or parasite infections. A high MONO count (2%–8% normal), for example, can indicate a chronic inflammatory disease, whereas high EOS counts (1%–4% normal) give an indication of asthma, an allergic reaction, or a parasite infection. A high BASO count (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.

### *Measurement technologies*

Impedance is commonly used for the RBC, PLT, and WBC counts, and for the differentiation of the WBCs into LYM, granulocytes (GRA) and MID cells (Fig 1). The LYM region constitutes mainly of lymphocytes. Other cells that might reside in this region include nucleated red blood cells, clumped platelets, macrocyte platelets, variant (atypical) lymphocytes, or blasts. The MID-cell area consists mainly of MONOs but can also correlate to degranulated NEU, precursor cells, blasts and plasmacytes. The GRA region mainly comprise NEU but can also include EOS and BASO (Fig 2).

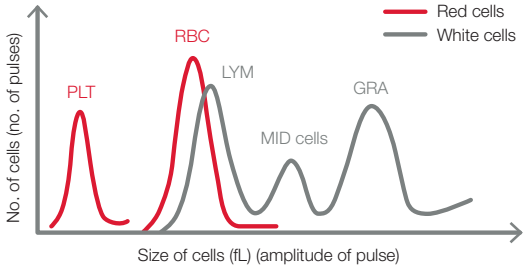



**Fig 2.** Hematology analysis results are visualized in histograms.

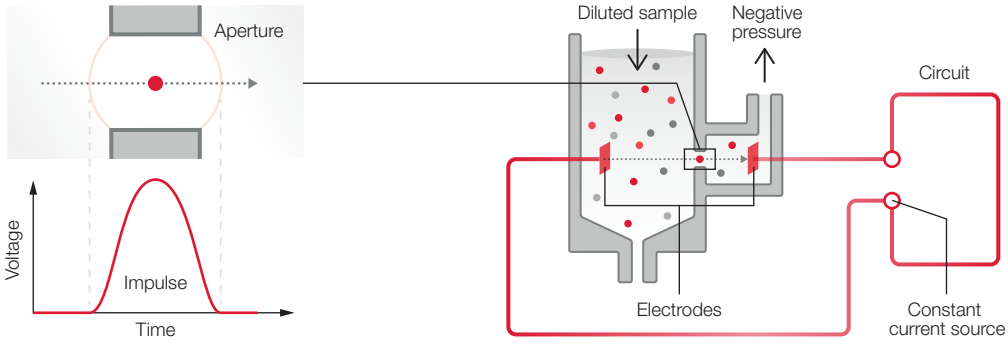



**Fig 1.** The principle for measuring changes in the electrical impedance produced by a cell passing through an aperture. Each cell passing through the aperture causes a drop in the electrical current (a pulse). The number of generated pulses correlates with the number of cells, whereas the size of the pulse is related to the cell size.

For specialty laboratories, distinguish eosinophils and basophils from neutrophils can provide a more detailed and targeted assessment of the blood status. With the more advanced instruments capable of such a reporting, however, comes increased complexity and costs. Such analyzers often also require more maintenance (1). This type of analysis is typically requested by oncology clinics or physicians investigating allergies or dealing with patients subjected to parasite infection.

For general screenings, hematology analyses based on impedance technology will provide sufficient information. A simple CBC will help detect anemia and blood clotting problems and answer the question of a viral infection or a bacterial infection that can be treated with antibiotics.

In addition to a CBC, an analyzer also determines a range of other parameters such as hematocrit (HCT), the mean corpuscular volume (MCV), RBC distribution width (RDW), mean PLT volume (MPV), and PLT distribution width (PDW), and measures the oxygen-containing hemoglobin (HGB). HGB measurements are commonly conducted by photometry.

### *Sampling technologies*

The sampling technique is critical for accurate and reliable analysis results. An exact volume of blood needs to be precisely diluted in a highly repeatable manner. Two different sampling techniques are commonly used in today's hematology analyzers: (i) a micro-pipette connected to a vacuum-generating, step motor-controlled syringe pump or (ii) a rotating shear valve. The suction process of the syringe pump is often time-based, and the technology is considered less complex and therefore a more cost-efficient solution. However, a syringe doser is more sensitive to variable pressure conditions and requires a mechanism for moving the sample probe in horizontal and vertical directions.

In contrary, the rotating shear valve allows cutting an absolute volume for analysis, and is not sensitive to altitude and other factors that might affect pressor conditions. On the other hand, shear valve technology is considered more complex and therefore a more expensive solution. Many shear valves also have a design that makes them sensitive to environmental impurities that might cause leakage and thus will require regular cleaning.

## Medonic M32 - innovation built of total quality

Medonic M32 is an automated hematology analyzer tailored to the smaller laboratory (Fig 3). The analyzer features a high-precision shear valve for accurate sample aspiration and dilution. A closed shear valve design minimizes leakage risk, ultimately reducing maintenance requirements.

Medonic M32 employs well-proven and robust measurement technologies. The analyzer uses impedance for WBC, RBC, and PLT counts, while hemoglobin (HGB) is determined spectrophotometrically. The analyzer provides quantitative results for 22 parameters, with histograms for WBC, RBC, and PLT (Fig 4).

The sample analysis software displays intelligent information messages related to pathology that might be present in the sample. The sample pathology information includes a short message, defining the sample abnormality followed by recommendations for that sample. The information can be triggered by the following mechanisms:

- Histogram shape abnormalities detected by system software calculations.
- Selected values that exceed defined limits outside the reference range. These messages occur when selected values are moderately to markedly abnormal. Values slightly outside the reference range are typically treated as cautionary by the clinician.

Medonic M32 provides a robust performance, with analysis results comparable with those from a more advanced reference instrument (Fig 5 and 6).

| Model characteristics | M32B  | M32M  | M32C  | M32S  |
|---|---|---|---|---|
| Built-in tube mixer | | • | | • |
| Micro-pipette adapter (MPA) | | • | • | • |
| Maintenance-free shear valve | • | • | • | • |
| Pre-dilution mode | • | • | • | • |
| Cap-piercing device | | | • | • |
| Autoloader | | | | • |

**Fig 3.** Medonic M32 is available in four models to fit the needs of various users.

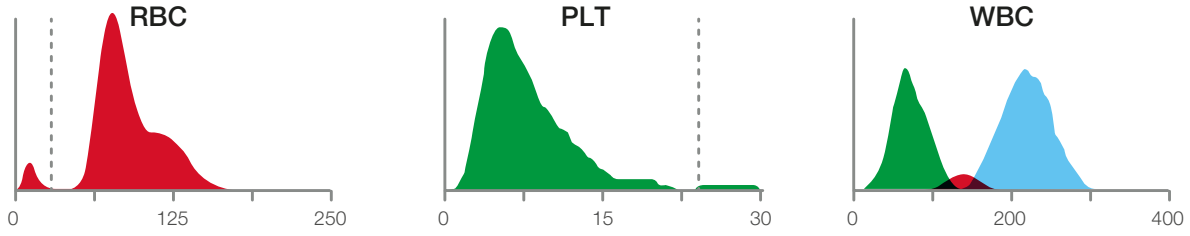



**Fig 4.** Medonic M32 analysis results visualized in histograms for WBC, RBC, and PLT.

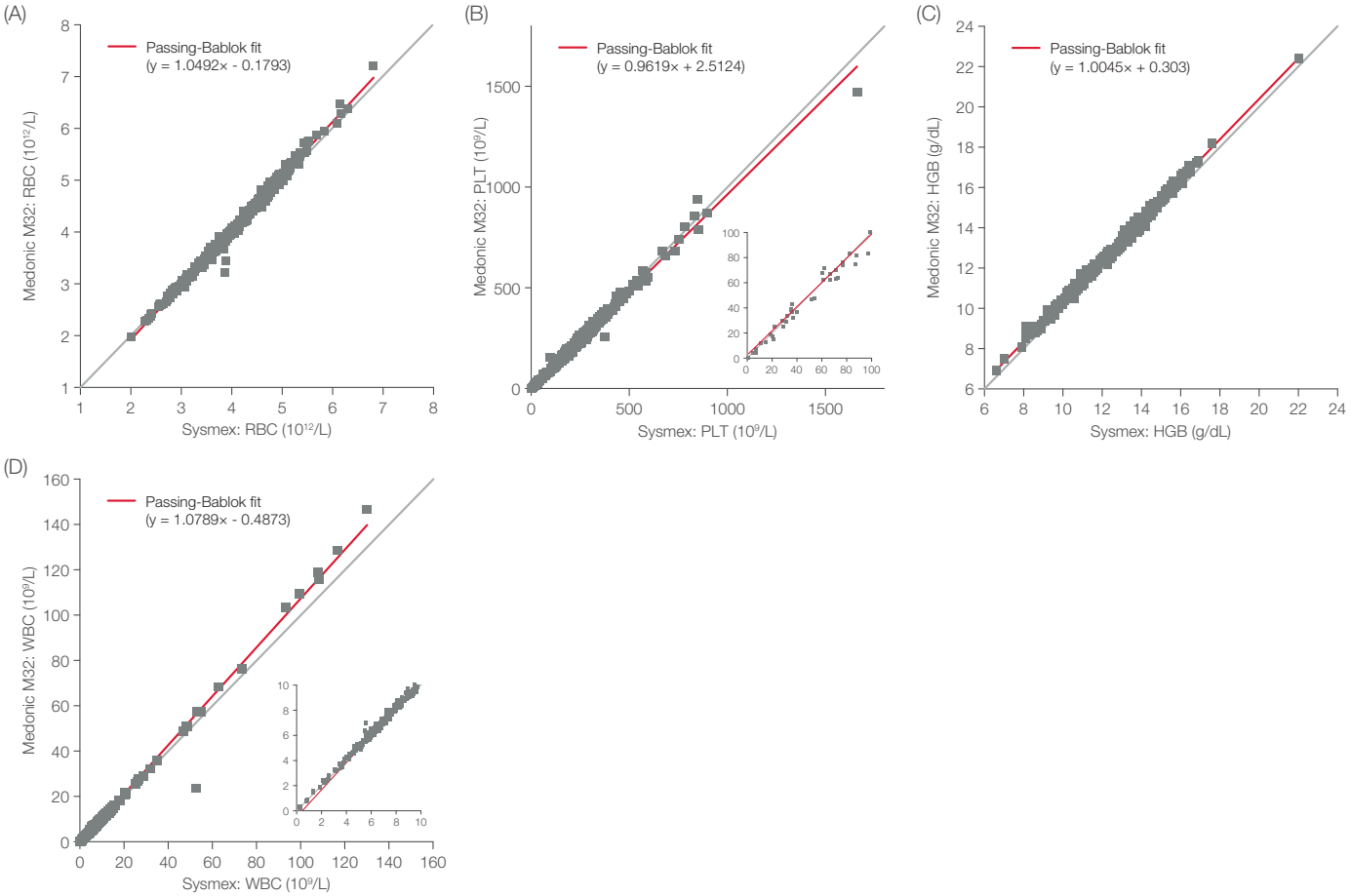
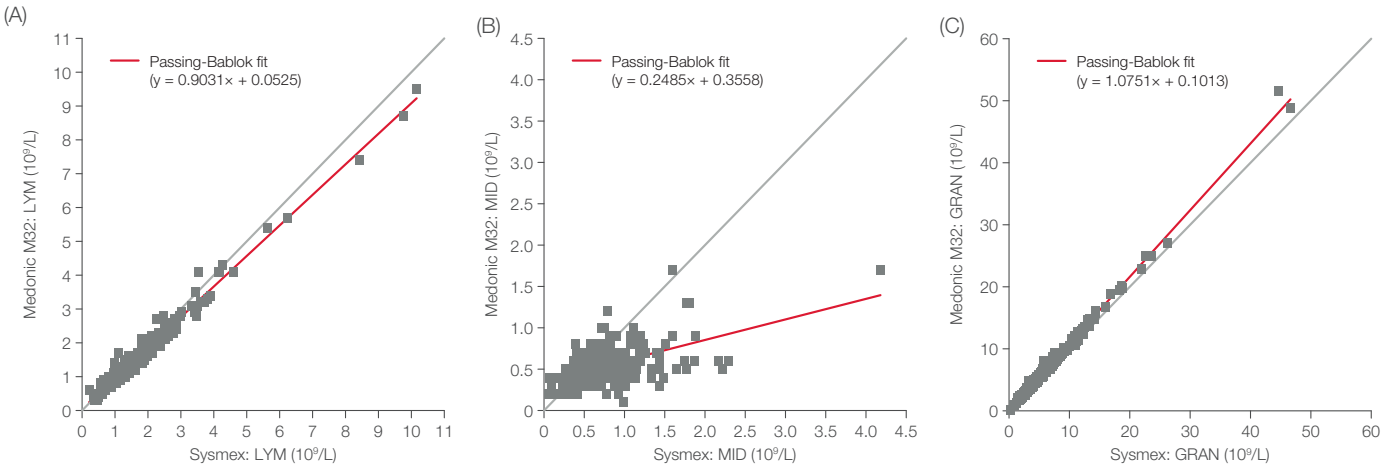



**Fig 5.** Agreement, using both unflagged and flagged samples, between Medonic M32 hematology system and a more advanced Sysmex™ XN-5000 reference systems intended for the larger hospital laboratory. Correlation plots for (A) RBC, (B) PLT, (C) HGB, and (D) WBC. In the regression plots, the gray line corresponds to identity (x = y) and the red line corresponds to best fit.




| Medonic M32 | Sysmex XE-5000 |
|---|---|
| GRAN | Neutrophils + eosinophils + basophils (+ bands if present) |
| MID | Monocytes |
| LYM | Lymphocytes |

**Fig 6.** Agreement, using unflagged samples, between Medonic M32 hematology system and a more advanced Sysmex XN-5000 reference systems intended for the larger hospital laboratory. For comparison with the Medonic M32 3-part differentiation of the WBCs, results from the Sysmex 5-part differentiation of the WBCs were combined into GRAN, MID and LYM. Correlation plots for (A) LYM, (B) MID, and (C) GRAN. In the regression plots, the gray line corresponds to identity (x = y) and the red line corresponds to best fit.

# System components

## *Shear valve technology*

Every Medonic M32 analyzer comes equipped with a high-precision shear valve that cuts out an absolute sample volume to be used for analysis (Fig 7). The design makes the shear valve maintenance-free, thereby lowering maintenance costs. The closed design prevents entry of environmental impurities that might cause contamination and leakage. Additionally, the shear valve is flushed with Diluent to prevent build-up of salt deposits that might also cause leakage. To avoid wear and tear of the shearing discs, the shear valve is soaked in Diluent, ultimately mitigating the need for replacement.

Atmospheric pressure variations will not affect the blood cell count. High altitude compensation only needs to be activated if various indicators related to HGB measurement problems repeatedly appear (see Section 9 in User manual). At higher elevations, the mode might need to be changed to Moderate or Maximum compensation. For high altitude compensation, the software incorporates some minor timing sequences for the wash cycles, no other functions are affected.

A blood sensor prevents inaccurate results caused by air in the sample. When enabled, aspiration stops when blood is detected by the blood detector sensor. This functionality can be disabled by the operator to instead employ a fixed aspiration type.

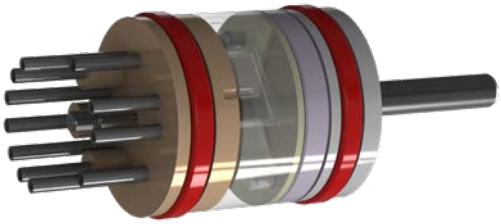


**Fig 7.** Maintenance-free Medonic M32 shear valve secures accurate results and lowers maintenance costs.

## *Sample aspiration modules*

To maximize utilization of the Medonic M32 analyzer, sample aspiration can be performed with a variety of aspiration modes (Fig 8). The whole blood sample probe aspirates from open tube for analysis. For samples with high cell concentrations, the pre-dilute inlet can be used to dispense diluent and thereafter aspirate the pre-diluted samples for analysis. Analysis from closed tubes can be performed with analyzer models equipped with a cap piercer device or an autosampler Most standard 5 mL tubes can be used. After aspiration, the analyzer will perform an automatic probe flush for cleaning of the sample probe.

Aspiration fails can be caused, for example, by sample shortage, clogging, or air bubbles in sample tube. Ensure that there is no blockage of tubing or leakage that might cause sample not to be aspirated properly, using built-in maintenance tools.

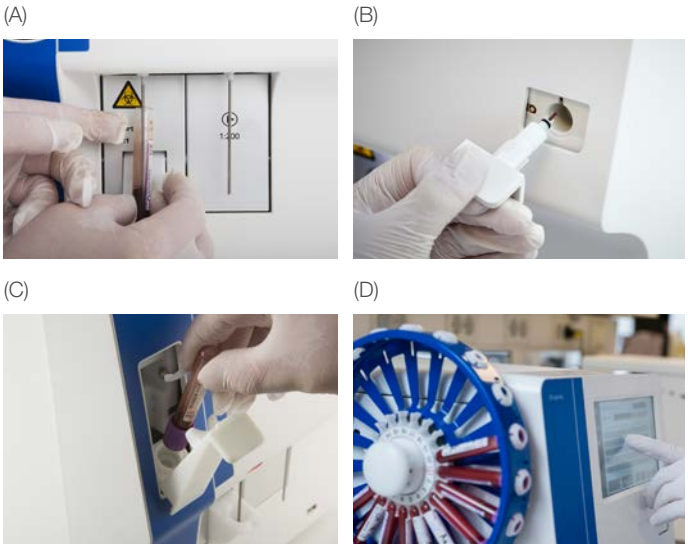



**Fig 8.** Medonic M32 allows sample aspiration from (A) open tubes (whole blood or predilute), (B) micro-pipette adapter (capillary whole blood), or closed tubes, using (C) the cap-piercing device or (D) autosampler.

## *Micro-pipette adapter (MPA) inlet*

The micro-pipette adapter (MPA) enables CBC from one drop of blood using a capillary sample tube. Only use Boule supplied, plastic, high precision EDTA capillary tubes with the MPA inlet. Glass tubes can cause damage to the analyzer if inserted incorrectly.

As the MPA inlet bypasses the shear valve sample aspiration, it is of utmost importance to ensure correct volume is collected by making sure the whole capillary is filled with blood and by wiping of any excess blood outside of the capillary before sliding it into the MPA module (Fig 9).

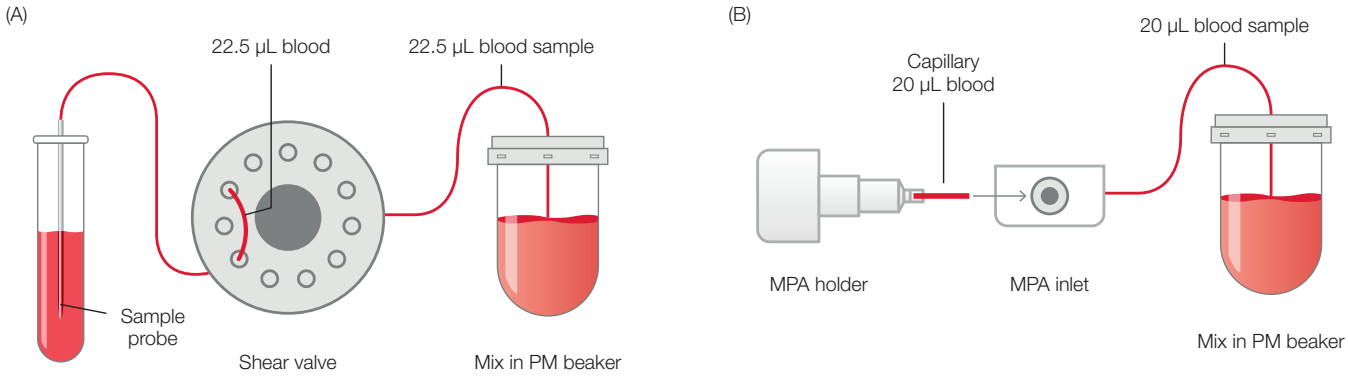



**Fig 9.** Sampling for (A) tube inlets, using the shear valve, as well as for (B) the MPA inlet, bypassing the shear valve. The difference in sample volume is compensated for in the instrument software.

## *Measurement chambers*

RBC and PLT counts are conducted in the RBC chamber, using floating discriminators. For samples with low PLT levels, the extended PLT counting time functionality can be enabled. In case of a patient sample with a severe thrombocytopenia detected, the analyzer will activate PLT extended counting time, counting three times as many platelets as in normal count mode, to be able to provide a more accurate result in the critically low PLT range (Fig 10).

WBC count is conducted in the WBC chamber. As for RBC and PLT, the WBC differential is performed using floating discriminators to estimate the best separation between the cell populations (Fig 11).

Sample Result

| | |
|---|---|
| Seq No | 347 |
| Date | 2018-11-28 14:32 |
| Profile | Blood |
| Method | Open Tube |
| Operator | |
| Sample ID 1 | |

30261084

| Parameter values | | | Scales | Graphs |
|---|---|---|---|---|
| WBE DE | 10.2 | | 3.5 | 10.5 |
| LYM | 1.4 | 14.4 % ↓ | 0.9 | 2.9 |
| MID | 0.6 | 6.2 % | 0.3 | 0.9 |
| GRA | 8.2 ↑ | 79.4 % | 1.2 | 8.0 |
| HGA | 11.2 ↓ | | 11.5 | 16.5 |
| MCH | 31.5 | | 25.0 | 35.0 |
| MCHC | 35.7 | | 31.0 | 38.0 |
| RBC | 3.57 ↓ | | 3.90 | 5.72 |
| MCV | 88.0 | | 81.2 | 98.3 |
| HCT | 31.4 ↓ | | 35.0 | 55.0 |
| RDW | 13.5 % | 62.7 | 11.8 % | 15.6 % |
| PLT* | 24 ↓ | | 150 | 450 |
| MPV | | | 6.5 | 11.0 |
| PDW% | | | 0.1 % | 99.9 % |
| PCT | | | 0.01 | 9.99 |
| P-LCR | | | 0.1 % | 99.9 % |

**Fig 10.** If PLT extended counting time is enabled and a low PLT is detected during analysis, the extended counting time will be displayed on the counting phase screen, and then indicated by an asterisk (*) adjacent to the PLT parameter on the result screen and in printouts and exported PDFs.

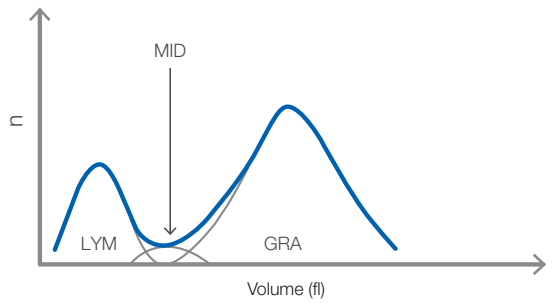



**Fig 11.** The Medonic M-series M32 system uses a floating discriminator technology to estimate the best separation between three populations of white blood cells (LYM, GRA, and MID cell fractions).

HGB is determined from the same dilution as the WBC (Fig 12). The HGB reading is slightly corrected for turbidity in case of extreme WBC counts. When the analyzer is in standby mode, the LED lamp is switched off to extend its lifetime.

## *Liquid system*

The fluidic system is controlled by pumps that generate pressure and vacuum. Reagent pipettes, featuring optical sensors, ensure accurate dilution of the sample. No pistons or other moving parts are used in the dilution system to minimize the maintenance and service needs. For the cell count, measuring pipettes equipped with liquid start and stop sensors ensure that a correct volume is used for analysis. The air pump generates a pressure that pushes the finally diluted sample through the aperture in the measuring chambers. To reduce risk for clogging, high voltage burning of the aperture is automatically carried out, but only when needed to reduce ware and tare.

To minimize user intervention, the analyzer performs automatic cleaning every 12 hours. Boule designed maintenance-free valves automatically relieve upon standby or after a power down cycle to prevent wearing of the tubing.

It is recommended to keep the analyzer switched on at all times. The instrument will automatically enter standby after a user-settable idle time. In case the analyzer needs to be turned off, for example, for transportation (< 12 h), use the ***Power Down*** button in the ***Maintenance*** menu. Power down ensures proper shutdown of the software and preparation of the liquid system prior to power off. When the display goes blank, the analyzer can be securely turned off. For long-term storage (> 12 h), the analyzer should be cleaned and emptied before power down. For more information, please refer to Section 10 ”Analyzer care and maintenance” in the user manual.

When put into use after being turned off, use the ***Power-up*** function to prime the analyzer. Upon selecting ***Power-up*** or ***Exit standby***, the valves will close and the analyzer will be ready for use.

In the event of an error message, verify that the analyzer is filled and run a prime cycle, using built-in maintenance tools. The prime cycle is used to reset the analyzer after an error has been indicated or a failure in running a sample occurs.

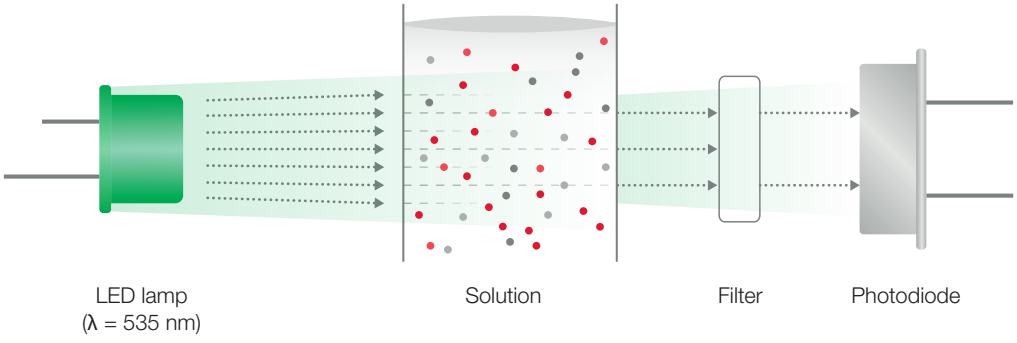



**Fig 12.** HGB is determined spectrophotometrically, using a LED lamp mounted on one side of the WBC chamber. The light is allowed to pass the flow chamber and transmitted light is detected by an optical sensor mounted on the opposite side. HGB concentration is calculated as a difference of a blank and a blood measure with and without illumination to reduce the effect of liquid refraction and disturbing light.

## Reagents

Only two reagents are required for the Medonic M32 analyzer—Diluent and Lyse—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 13.

Non only is the blood dilution ratio critical for an accurate count. The reagent composition is also of utmost importance for reliable results. The Diluent should provide an isotonic environment for the RBCs and PLTs, while the Lyse reagent should be capable of lysing the RBCs to release HGB and shrink the WBCs to allow differentiation of these cells into their subgroups. Boule's cell count processes have been tested and optimized for decades for robust and reliable analysis results. The use of the reagents designed by Boule Diagnostics for the specific instrument ensures analytical quality and performance of the hematology system.

To avoid reagent shortage and to ensure an exact sample dilution each time, Boule adds a small extra volume to each reagent container. To prevent air from entering the system, the small volume that is left in the container when all cycles are consumed should not be used. To mitigate the contamination risk, the left-over volume should not be mixed with reagent in a newly opened container.

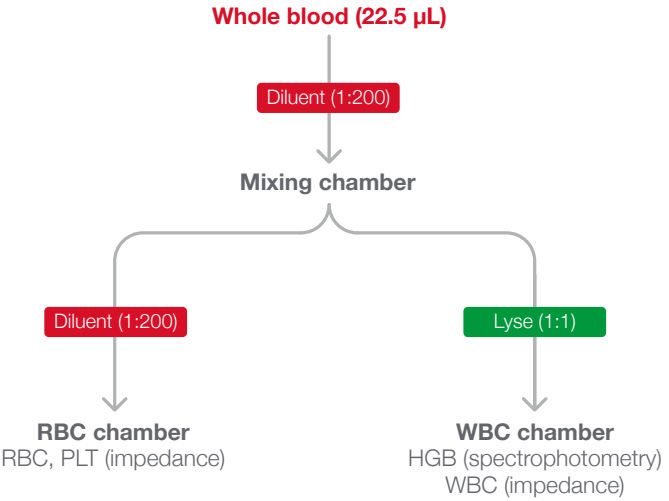



**Fig 13.** Medonic M32 measurement principle.

## Instrument maintenance

Designed with few moving parts, a maintenance-free closed shear valve design, and with the majority of the instrument cleaning procedures being automated, the user maintenance of Medonic M32 analyzer is kept to a minimum. However, some user intervention is still required. Section 10 "Analyzer care and maintenance" in User manual contains information on how to maintain the Medonic M32 analyzer. An overview of maintenance procedures is given in Table 1.

**Table 1.** Scheduled maintenance

| Procedure | Description | Frequency |
|---|---|---|
| Sample probe cleaning | Clean with paper tissue moistened with a 70% alcohol solution. Remove possible traces of salt crystals or blood at the top of the sample probe and probe rinse cup using a paper tissue moistened with the alcohol solution. | Daily |
| Surface cleaning | Gently clean the display and/or outside of the analyzer with a soft cloth, slightly moistened with water and a mild soap. Dry carefully. | When necessary |
| Monthly cleaning | Fill a cup with 10 mL 2% hypochlorite, from Boule Cleaning Kit, and one cup with 18 mL Diluent.<br>Aspirate the hypochlorite as a pre-dilute sample.<br>Run 2 blank samples by aspirating Diluent as a pre-diluted sample.<br>Perform a background check, in pre-dilute mode, to verify all values are within range. | Monthly |
| Clot prevention | Fill a small container with 5 mL of Enzymatic Cleaner from Boule Cleaning Kit.<br>If analyzer has the optional cap piercer or autosampler, fill a clean standard 4.0–5.0 mL tube half full with Enzymatic Cleaner.<br>From ***Main Menu***, press ***Maintenance*** and then press ***Clot Prevention***.<br>- For cap piercer: place filled cleaner tube into cap piercer, same as a normal sample analysis, close the door.<br>- For autosampler: place filled cleaner tube into Position 1 on wheel, lock wheel into place, and follow instructions.<br>- For open tube, hold the cleaner container under the OT probe, submerged in cleaner, press OK to confirm.<br>The system will perform the cleaning process for all analysis modes simultaneously, and upon completion, the analyzer is ready for next analysis.<br>Perform a background check to verify that all values are within range. | Monthly or every 1000 samples |
| Cleaning procedure | Select ***Main Menu***, then ***Maintenance***, and arrow over to next page to enter the ***Cleaning Menu***.<br>Follow instruction for use (IFU) for the Boule Cleaning Kit to clean the analyzer. | Less than 50 samples/day = every six months<br>More than 50 samples/day = every three months<br>100–200 samples/day = every month. |
| Preventive maintenance (PM) | Inspection, and adjustments upon need, performed by an authorized service technician.<br>PM kit available and included components should be exchange by an authorized service technician. | Every year or 20 000 samples |

Good practice also dictates keeping the instrument clean from dust and other impurities. Regularly, check if there is dust inside the instrument. At the same time, check that reagent connection or waste tubes are not bent or squeezed. Also, regularly check for possible leakages from components inside the instrument.

The system software monitors a number of system functions and will display information that alerts the operator to check the system or sample, or institute selected troubleshooting procedures.

## Quality control

Medonic M32 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-Diff and Boule Cal) ensure that Medonic M32 performs accurately and delivers quality-controlled hematology results. Advanced quality control capabilities built into the Medonic M32 software include Mean, SD, CV, Levey-Jennings charts, XB-function, and QC reports.

The analyzer has been factory calibrated prior to shipment. If necessary, however, a calibration functionality is available. Good laboratory practice dictates regular checks and calibration of the measured parameters. Only authorized operators can update or change calibration factors.

## Conclusion

Medonic M32 is an automated 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 more advanced reference instrument intended for larger hospital laboratories. To maximize instrument uptime and ensure a reliable performance, adhering to determined maintenance procedures and service schedules is recommended. Following these guidelines, Medonic M32 will constitute a powerful tool that aids physicians in diagnosis and monitoring of disease progression and efficacy of treatment.

## Reference


1. Whitepaper: Hematology analyzers: 3-part or 5-part, that is the question. Boule Diagnostics, 31183, Edition 1 (2019).


## Ordering information

| Product | Product code | |
|---|---|---|
| | EU | US |
| Medonic M-series M32B | 1420021 | |
| Medonic M-series M32M | 1420022 | |
| Medonic M-series M32C | 1420023 | |
| Medonic M-series M32C AR | 1420024 | |
| Medonic M-series M32S BD AR | 1420026 | |
| Medonic M-series M32S SA AR | 1420028 | |
| Medonic M-series Diluent, RFID, > 900 cycles | 1504460 | |
| Medonic M-series Lyse, RFID, > 900 cycles | 1504461 | |
| Medonic M-serie DualPack, RFID, > 200 cycles | 1504465 | |
| Medonic M-series Diluent (21 kg) > 900 cycles | 1504122 | 501-212 |
| Medonic M-series Lyse (6 kg) > 900 cycles | 1504123 | 501-211 |
| Medonic M-series Dual pack (Diluent+Lyse) (7 kg) > 200 cycles | 1504128 | |
| Boule Cleaning Kit, 3 × 450 ml | 1504111 | 501-036 |
| Boule Enzymatic Cleaner, 100 mL | 1504112 | |
| Boule Hypochlorite 2,0% Cleaner, 500 mL | 1504113 | |
| Boule Con-Diff Normal, 1 × 4.5 mL | 1504019 | |
| Boule Con-Diff Low, 1 × 4.5 mL | 1504020 | |
| Boule Con-Diff High, 1 × 4.5 mL | 1504021 | |
| Boule Con-Diff Tri-Level, 2 × 3 × 4.5 mL | 1504022 | 502-012 |
| Boule Con-Diff Normal, 6 × 4.5 mL | 1504043 | |
| Boule Con-Diff Low, 6 × 4.5 mL | 1504176 | |
| Boule Con-Diff High, 6 × 4.5 mL | 1504216 | |
| Boule Cal, 1 × 3 mL | 1504025 | 502-018 |
| Boule Cal, 3 × 3 mL | 1504045 | |

AR = automatic barcode reader
BD = autosampler for BD tubes
SA = autosampler for Sarstedt tubes

| Related literature | Product code |
|---|---|
| User manual: Medonic M32 | 1504493 |
| Brochure: Medonic M32 | 31735 |
| Application Note: Clinical performance of Medonic M32 3-part hematology analyzer compared with a reference 5-part instrument | 31784 |
| Application Note: Comparison of capillary and venous blood samples on Medonic M32 hematology analyzer | 31782 |
| Application Note: Medonic M32 hematology analyzer helps ensure secure and efficient use of blood donations | 31881 |

**boule.com**


Boule Diagnostics AB, Domnarvsgatan 4, SE-163 53 Spånga, Sweden
TNM33227-2 09/2019