Data sheet

# Medonic™ M32 hematology system

Laboratory diagnostics is one of the cornerstones of healthcare, and test results form the basis for patient diagnosis. Hematology analysis constitutes a cost-efficient tool for health screenings and initial disease investigations.

With its compact design, highly accurate results, and low maintenance needs, Medonic M32 provides laboratories with an efficient tool for hematology analysis.

**Medonic M32 - hematology system beyond compromise:**

- Shear valve-guided aspiration ensures measurement quality.
- Optional space-saving automation solution provides constant mixing of queued samples.
- Robust equipment design helps ensure instrument uptime.


**Fig 1.** Medonic M32 hematology analyzer.

## System overview

Medonic M32 is an automated hematology analyzer tailored to the smaller hospital or clinical laboratory (Fig 1). 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 white blood cell (WBC), red blood cell (RBC), and platelet (PLT) counts, while hemoglobin (HGB) is determined spectrophotometrically. The analyzer provides quantitative results for 22 parameters, with histograms for WBC, RBC, and PLT (Fig 2).

The sample analysis software displays 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 interval are typically treated as cautionary by the clinician.

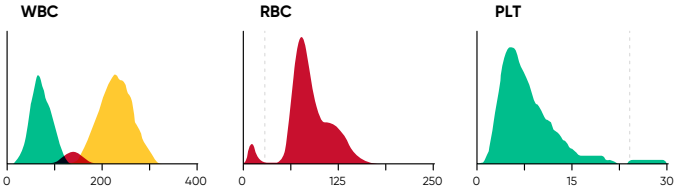



**Fig 2.** Medonic M32 analysis results visualized in histograms for WBC, RBC, and PLT.

# Key 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 3). The closed design minimizes user maintenance needs, thereby maximizing instrument uptime. The closed design prevents entry of environmental impurities that might cause contamination and leakage. Additionally, the shear valve is automatically 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.

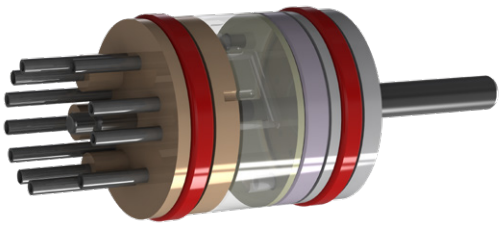


**Fig 3.** Medonic M32 shear valve design secures accurate results and lowers maintenance costs.

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.

## *Sample aspiration modules*

To maximize utilization of the Medonic M32 analyzer, sample aspiration can be performed with a variety of aspiration modes (Fig 4). 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.

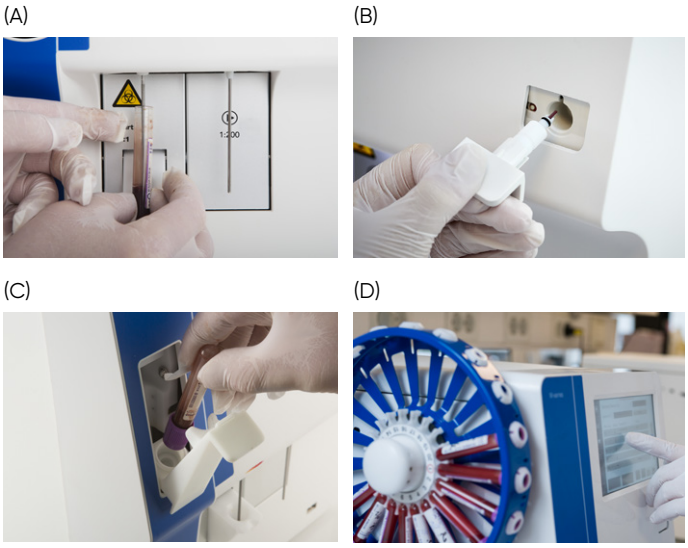



**Fig 4.** Medonic M32 allows sample aspiration from (A) open tubes (whole blood or predilute), (B) micro-pipette adapter (capillary whole blood), or closed tubes, using (C) the cap-piercing device or (D) autosampler.

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

The micro-pipette adapter (MPA) enables a complete blood count (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 5).

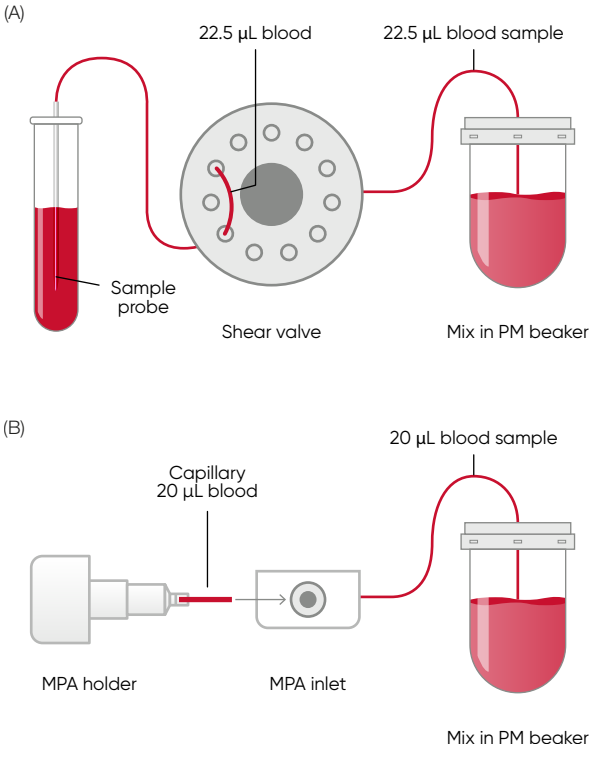



**Fig 5.** Sampling for (A) tube inlets, using the shear valve, as well as for (B) the MPA inlet, bypassing the shear valve. The difference in sample volume is compensated for in the instrument software.

## *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 6).

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 6.** 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.

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 7).

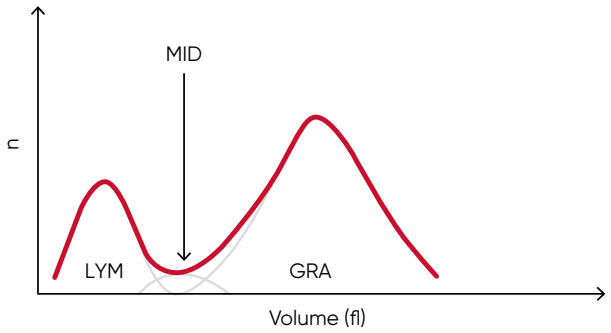



**Fig 7.** The Medonic M-series M32 system uses a floating discriminator technology to estimate the best separation between three populations of white blood cells: lymphocytes (LYM), granulocytes (GRA), and mid-sized (MID) cell fractions.

HGB is determined from the same dilution as the WBC (Fig 8). 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.

$$HGB\ (g/L) = Constant \times Ln\left[\frac{Blank\ photocurrent}{Samlpe\ photocurrent}\right]$$

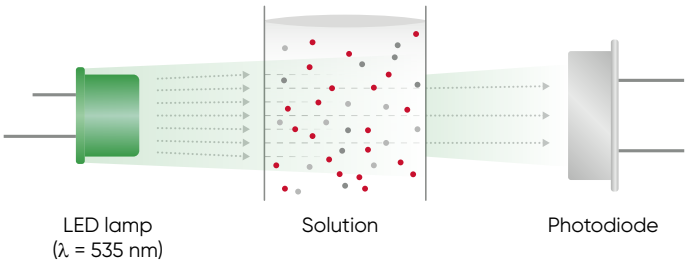



**Fig 8.** HGB is determined spectrophotometrically, using a LED lamp mounted on one side of the WBC chamber. The light is allowed to pass the flow chamber and transmitted light is detected by an optical sensor mounted on the opposite side. HGB concentration is calculated as a difference of a blank and a blood measure with and without illumination to reduce the effect of liquid refraction and disturbing light.

## *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 (based on generated air bubbles) is automatically carried out, but only when needed to reduce wear and tear.

To minimize user intervention, the analyzer performs automatic cleaning every 12 hours. Boule designed low-maintenance 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.

### *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 9.

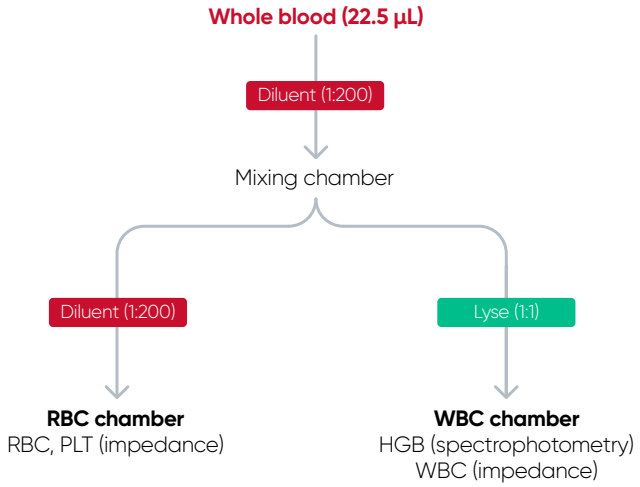



**Fig 9.** Medonic M32 measurement principle.

Not 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.

## System performance

Medonic M32 provides a robust performance, with analysis results comparable with those from a reference instrument (Fig 10 and 11).

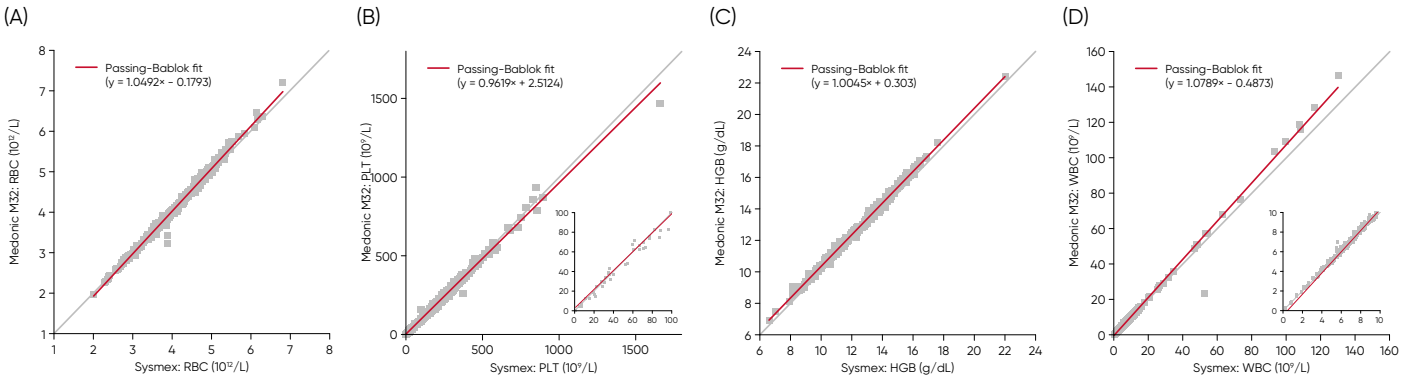
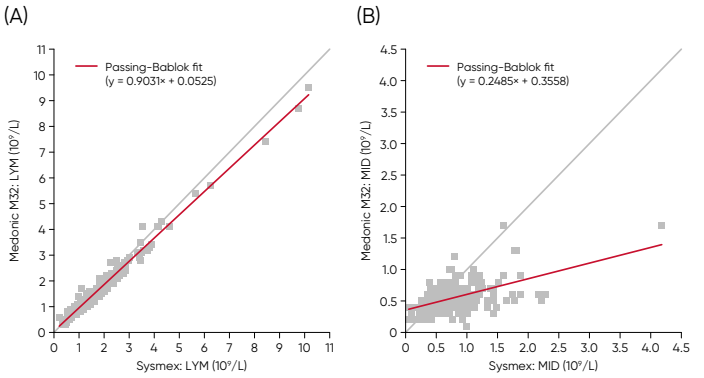



**Fig 10.** Agreement, using both unflagged and flagged samples, between Medonic M32 hematology system and a Sysmex™ XN-5000 reference systems intended for the larger hospital laboratory. Correlation plots for (A) RBC, (B) PLT, (C) HGB, and (D) WBC. In the regression plots, the gray line corresponds 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 11.** Agreement, using unflagged samples, between Medonic M32 hematology system and a 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.

## 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.

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.

**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 |

## 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.

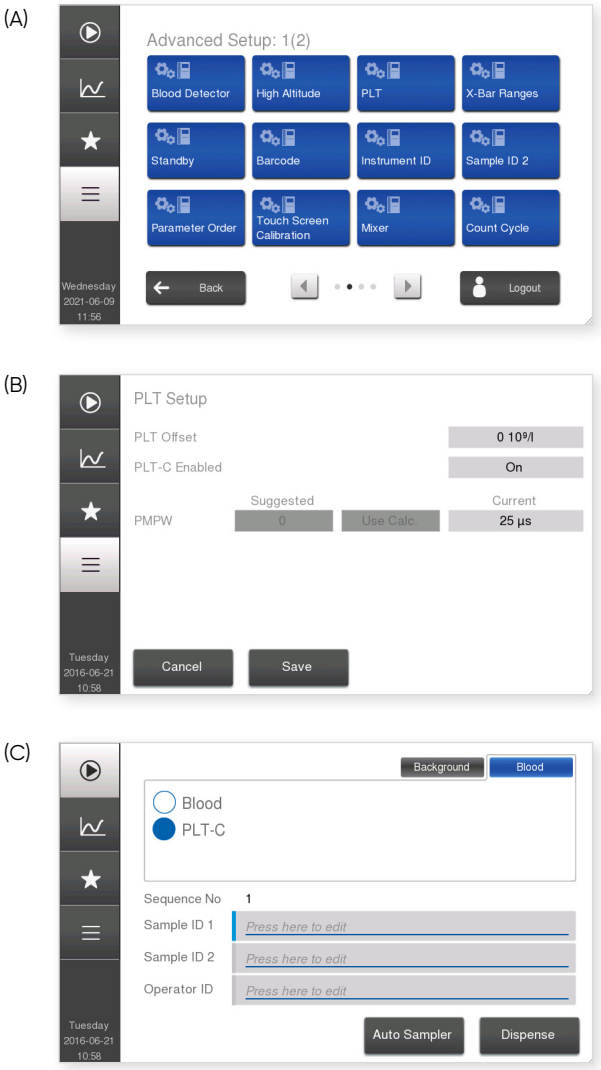



**Fig 12.** PLT-C profile is available in all analyzers with software version 1.3 or higher. (A) The profile is activated in ***Advanced Setup***. (B) After entering the login code, go to ***PLT Setup*** menu and (C) enable ***PLT-C***. In the ***Start*** menu, the PLT-C profile will thereafter be available as an option.

## Blood bank application for PLT concentrates

The Medonic M32 blood bank application resides in the Medonic M32 analyzer as a special analysis profile. The factory default blood bank profile is named PLT-C (i.e., PLT concentrate). This profile is pre-installed in the instrument and can be activated by the service technician upon delivery of the instrument (Fig 12).

The PLT linearity range in the PLT-C profile is 10–5000 × $10^9$/L, as compared with 10–1800 × $10^9$/L in the normal blood profile. RBC concentrates are analyzed in the normal blood profile, with a linearity range of 0.30–7.00 × $10^{12}$/L. Plots of recovered versus theoretical values show good conformity over the linearity range for both PLT and RBC concentrates (Fig 13).

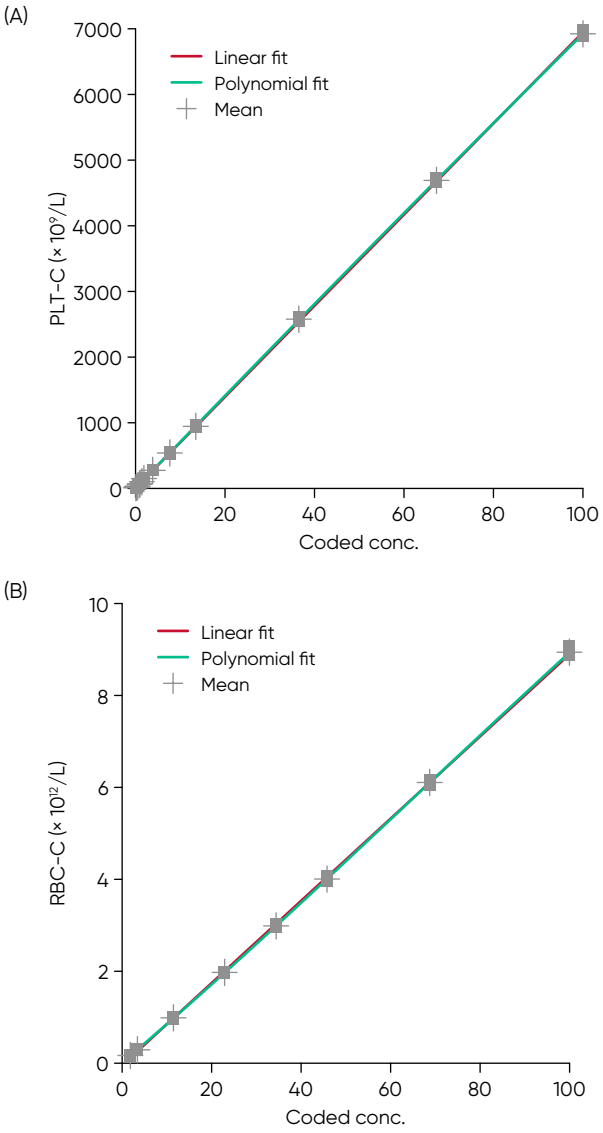



**Fig 13.** Recovered vs theoretical values for (A) PLT linearity and (B) RBC linearity. PLT concentrates were analyzed using the PLT-C profile, while RBC concentrates were analyzed using the normal blood profile.

# Specifications

Medonic M32 is available in multiple models to fit the needs of various users (Table 2).
Main system specifications are listed in Table 3.

**Table 2.** Medonic M32 analyzer models




| Model characteristics | M32B | M32M | M32C | M32S |
|---|---|---|---|---|
| Built-in tube mixer | | • | | • |
| Micro-pipette adapter (MPA) | | • | • | • |
| Shear valve sample aspiration | • | • | • | • |
| Pre-dilution mode | • | • | • | • |
| Cap-piercing device | | | • | • |
| Autosampler | | | | • |

**Table 3.** Medonic M32 system specifications

| | |
|---|---|
| Parameters | |
| 16 for diagnostic use | WBC, LYM, MID, GRAN, LYM%, MID%, GRAN%, RBC, MCV, HCT, PLT, MPV, HGB, MCH, MCHC, RDW% |
| 6 for research use | RDW, PCT, PDW%, PDW, P-LCR, P-LCC |
| Throughput | 60 samples/hour<br>50 seconds, time to results, OT inlet |
| Sample volume | |
| Open tune (OT) | 110 µL |
| Capillary (MPA) | 20 µL |
| Prediluted | 20 µL |
| Cap piercer | 250 µL |
| Autosampler | 300 µL |
| Reagents | 2 RFID locked reagents are used for analysis:<br>• Medonic M-series Diluent<br>• Medonic M-series Diluent Lyse |
| Display | 7 inch TFT touch screen |
| Data storage capacity | 50 000 samples |
| Interface ports | 4 USB ports, 1 LAN port that supports LIS/HIS communication through HL7 protocol |
| Printout | Postscript-compatible printers supporting PCL 3/5e |
| Precision | WBC CV ≤ 3.5%<br>RBC CV ≤ 1.8%<br>MCV CV ≤ 1.5%<br>HGB CV ≤ 1.5%<br>PLT CV ≤ 5.2% |
| Dimension | 295 (W) × 475 (D) × 395 (H) mm (M32B/M32S/M32C)<br>340 (W) × 475 (D) × 395 (H) mm (M32S) |
| Weight | ≤ 18 kg (M32B/M32S/M32C)<br>≤ 22 kg (M32S) |

# 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, 2 × 3 mL | 1504045 | |

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

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

| Related literature | Product code |
|---|---|
| User manual: Medonic M32 | 1504586 |
| Flyer: Medonic M32 | 38938 |
| 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 |

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