Instrument Specifications

Physical

Size (Instrument versions with sampler)	HWD ≤ 395 x 340 x 475
Size (Instrument version without sampler)	HWD ≤ 395 x 295 x 475
Weight (Instrument)	≤ 18 kg
Weight (Autoloader additional weight)	The additional weight of the Autoloader including two sample wheels is less than 6 kg
Display	Depth: True color (24-bit); Resolution: 800 x 480 pixels
Keyboard	Virtual incorporated keyboard
Communication interface ports	1 USB device/4 USB host/1 LAN port
Barcode reader input	Yes (via USB)

Operating Environment

Temperature	18 - 32 °C
Humidity	10% - 90%

Electrical

Main Voltage	100 - 240 V
Frequency	50 - 60 Hz
Maximum power consumptions	100 VA (operating); 50 VA (standby)

Measuring principles

MCV, MPV, RBC, WBC, and PLT	Impedance
HGB	Photometric
Sampling system	Closed shear valve
Floating RBC/PLT discriminator	Yes (position printed)
Programmable WBC Discriminator	Yes
Mathematical 3-part diff. WBC calculation	Yes
Parameters Reported	20-parameters: RBC, MCV, HCT, PLT, MPV, HGB, MCH, MCHC, WBC, RDW%, RDW abs, PCT, PDW, LPCR, LYM abs, MID abs, GRAN abs, LYM%, MID%, GRAN%

Performance

Sample volume (Open Tube)	≤ 110 µL
Sample volume (Sampling Device)	≤ 300 µL
Sample volume (Cap Piercer)	≤ 250 µL
Sample volume (Micro Pipette Adapter)	20 µL
Pre-diluted mode	1:200 to 1:300 using min. 20 µl e.g. 20 µl sample to 4.5 mL diluent (1:225)
Dispenser precision (CV)	≤0.9%
Number of Samples per hour (Open Tube)	≥ 60 samples
Number of Samples per hour (Cap Piercer)	≥ 45 samples
Number of Samples per hour (Sampling Device)	≥ 43 samples
Built-in test / adjustment programs	Yes
QC capabilities	Mean, SD, CV, Levey-Jennings and Xb
System Information Indicators on parameter abnormalities	Yes
Memory capacity	≥ 50,000 samples
Reagent Stability	36 months

Boule Medical AB
Domnarvsgatan 4
SE-163 53 Spånga, Sweden
E-mail: info@boule.se
www.boule.se

Performance

Parameter	Correlation(R)	Carry-over (%)	Reproducibility (%)
RBC	≥ 0.98	≤ 1	≤ 0.8
MCV	≥ 0.98	N/A	≤ 0.5
HGB	≥ 0.98	≤ 1	≤ 0.6
PLT	≥ 0.95	≤ 1	≤ 2.9
WBC	≥ 0.97	≤ 0.5	≤ 1.6

***** Typical values measured as an average of 10 measurements each on 9 different vein K2-EDTA collected normal samples, on 3 instruments, in open tube mode.

Product Conformity

Directives	Standards
98/79/EEC In Vitro Diagnostic Medical Device Directive (IVD)	Using Annex III as the conformity assessment procedure
2004/108/EEC Electro Magnetic Compatibility Directive (EMC) with amendment 92/31/EEC	Emission: EN 61326-1:2006, SS-EN55011:2009, +A1:2010, Class B, EN 61000-3-2:2006 Immunity: EN 61326-1:2006, EN 61000-4-2, -3, -4, -5, -6, -11
2006/95/EEC Low Voltage Directive (LVD)	IEC 61010-1: 2001 IEC 61010-2-081:2001 + A1 IEC 61010-2-101:2002 CAN/CSA-C22.2 No 61010-1: second edition UL 61010-1: second edition
2012/19/EU Waste of electrical and electronic equipment (WEEE)	--

Quality Control/Calibration

The instrument has been factory calibrated by Boule prior to shipment. Customers are advised to check the daily performance of the Medonic M-series M32 system with a certified blood control authorized by Boule.

Packaging and Weight

≤ 24 kg (standard version); Double corrugated cardboard outer packaging with shock absorbent inner packaging.

Warning and Precautions

As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, blood controls, calibrators and waste, these products should be handled as potentially biohazardous. See User manual for biohazard symbol placement and further instructions.

Customers are advised to be knowledgeable of applicable local, state and federal requirements, and the content of effluent streams, before disposing of waste in public sewer systems or recycling decontaminated equipment. The instructions for decontamination can be found on the Medonic home page, www.medonic.se, under Support.

Boule Medical AB
Domnarvsgatan 4
SE-163 53 Spånga, Sweden
E-mail: info@boule.se
www.boule.se