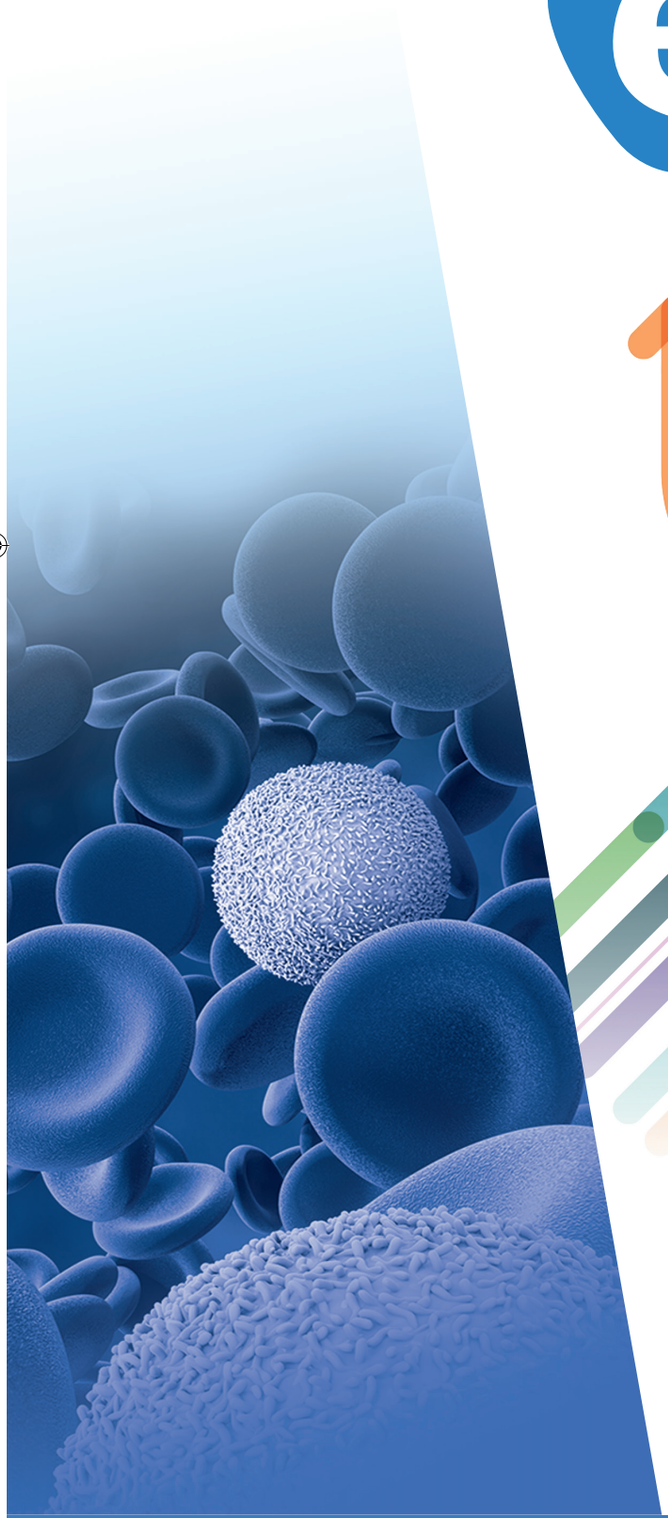
HORIBA
Medical

Connecting Labs
everywhere and beyond





Yumizen
H500 & H550

Shaping new

Delivering Safe Hematology Care

Affordable Hematology Solutions for Small-Mid Laboratories

Yumizen H500 Closed Tube



Yumizen H500 Open Tube



Compact Hematology Solution

- Open Tube & Closed Tube versions
- CBC/DIFF Analysis
- 2 reagents use
- 37 parameters menu

Yumizen H550 Auto Loader



Full Walk Away Solution

- Auto loader version
- Integrated auto sampler
- Positive identification
- 40 tubes in continuous loading
- Urgent mode

Dimensions for Hematology

New Dimensions for Hematology Diagnosis

Enhanced Performance, New Features, Increased Benefits

#1 Workflow Management — Optimize your daily routine

#2 Clinical Performances — Ensure effective diagnosis

#3 Infectious Screening — Cost effective flagging: Malaria & Dengue

#4 Remote Connection — Connect the lab with Yumicare

Extensive Applications

Variety of clinical lab environments and clinical settings

Critical care

- Capillary Blood Compatibility
- Fast Testing
- Prediluted Mode

Backup System

- Satellite Labs
- Night Shift Analysis
- Back up to HELO Solution

Oncology Care

- WBC Diff Separation
- WBC Immature Cells: IMG, IML, IMM
- Blasts Flagging

Health Centers

- Simplicity of use
- HL7
- Infectious Screening Flags

Infectious Care

- Malaria & Dengue Screening Flags
- Scoring Flags
- Neutrophils-To-Lymphocyte Ratio

Blood Banks

- QC testing: RBC & PLT concentrates
- Residual Cells Detection of WBC concentrates in cellular therapy

#1 Workflow Management

Optimize your daily routine

Expend your analysis possibilities

Different analysis modes

- **Standard Patient mode**
- **Prediluted mode** with customized dilution ratio for micro sample volumes
- **QC mode** for dedicated Difftrol ® QC kits



Safe blood testing against pathogens exposure with:

- **Closed tube with the H500**
- **Sample rack auto loading with the H550**





Capillary blood compatibility

Yumizen H500 and H550 have been **validated on capillary blood samples** with correlation to venous blood.

Fully walkaway system with new usability

High automation level

- **Continuous loading** (40 tubes)
- Automatic and scheduled **start up and shutdown**
- Secured **reagent management** with unique identification code
- **Positive tube identification** in rack mode
- Automated **user maintenance**



Improved usability

- **New graphical interface** with color-coded menus
- **Only 2 reagents** for hematology analysis and 1 reagent for cleaning maintenance

Data Management

Data Management options

- **Yumizen P8000 Connection**
- **Data printout** with optional printer
- Paperless patient reports results in **PDF formats**
- **10,000 patient data storage** with easy USB export
- Bidirectional host communication: **ASTM** and **HL7** standards
- **Save & Restore** database and settings

Quality Control Management

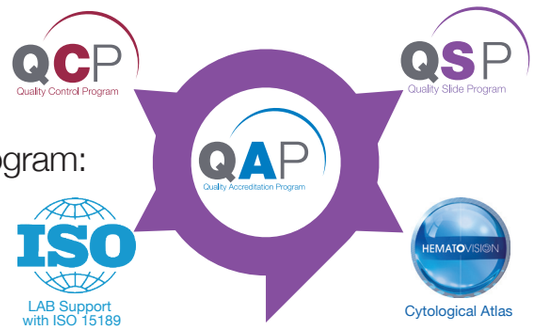
Embedded quality control indicators

- **iQC indicators:** Levey-Jennings flags, Radar Graphs view, XB means
- **Overlapping QC** when switching QC batches
- **eQC testing** in different modes
- **Repeatability testing mode**

Full quality tools package

HORIBA Medical provides a full Quality Assurance Program:

- **QCP**: inter-laboratory comparison program
- **QSP**: cytology skills staff monitoring
- **Accreditation** Help Support
- **Cytological Atlas**



Report Results Faster

Increase throughput

60 tests per hour: 3 models able to process whole blood samples on **20µL**.

Urgent mode

Yumizen H550 able to manage urgent samples in **real STAT mode** to run closed, open tubes or micro-tubes during routine workflow.



#2 Clinical Performances

Ensure effective diagnosis

WBC: Full Leukocytes Menu for Oncology Care Monitoring

Large Immature Cells (LIC) differentiation:

- **IML**: Immature cells of lymphoid lineage with large and granulocytic lymphocytes.
- **IMM**: Immature cells of monocytic lineage which could include promonocytes or monoblasts.
- **IMG**: Immature cells of granulocytic lineage with precursors cells of myelocytes, promyelocytes and metamyelocytes.

Exclusive Lymphocytes differentiation:

- **ALY**: Atypical Lymphocytes as sub population of Lymphocytes for detecting activated lymphocytes, granulocytic lymphocytes, Sezary cells, tricholeucocytes,…

RBC: Full Digital Technology Measurement for Accurate Results

Patented RBC Filtering Technology

New digital filtering technology: RBCs pulses optimization by rejecting the rotated cells and other flow induced particles.

- **Accurate measurement of RBCs volume** and **distribution widths**.
- **Very good correlation** of MCV and RDW parameters between **hydro-focused system** and **classical impedance** with digital filters.

Diagnostics Tools for Anemias and Thalassemia Pathologies

Complete parameters menu for flagging RBCs disorders:
HGB (cyanide free lysis), MCV, MCHC, MIC (Microcytes), MAC (Macrocytes), RDW-CV, RDW-SD

PLT: Reliable Counting and Markers for Platelets Disorders

Low Limit Of Quantification: below 10.10^9/L fitting to support clinicians taking **blood transfusion decision**.

Specific Indices for Platelets Activation at no extra cost

P-LCC and **P-LCR** (Platelet Large Cells Count & Ratio), into **large platelets size flagging**:
immature platelets in cases of thrombocytopenia, reactive thrombocytosis or Giant platelets either from inherited disorders or in myeloproliferative syndrome.

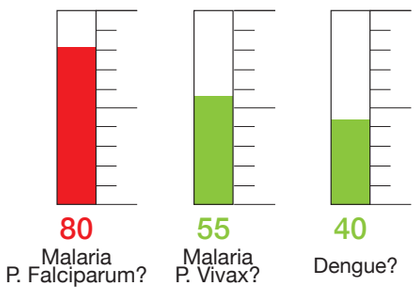
#3 Infectious Screening

Cost effective flagging Malaria & Dengue

Infectious Screening Flags Combined with Full Blood Count

The Automated Suspicion Flags are optionally available in routine use with Diff hematology test and without any specific reagent or dedicated mode for:

- Malaria *Plasmodium falciparum*
- Malaria *Plasmodium vivax*
- Dengue fever



Flag's methodology and efficiency

- Innovative **machine-learning** techniques
- **3 different labs** assessment: India and Africa
- **Clinical accuracy: 70 to 85%**
- **S-Flags**: triggering levels & displaying relevancy
- **NLR**: marker of inflammation & infectious monitoring

Infectious Screening Flags are optionally available on Yumizen H500 and H550 upon request towards your HORIBA Medical representative

#4 Remote Connection

Connect the lab with Yumicare

Increasing Analyzer Availability

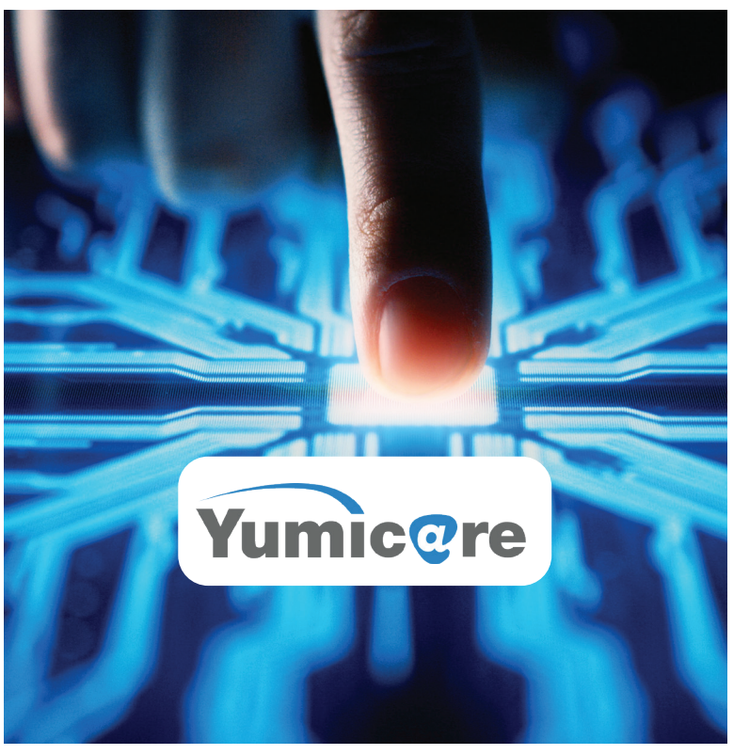
- Remote Software Update
- Predictive Maintenance

Easing Quality Control

- Remote QC target values
- Automated QC results transfer to QCP

Monitoring Hematology Activity

- Daily Routine Overview
- Consumption Monitoring



Safe Data Protection & GDPR Compliance : Encrypted Connection, Anonymous Patient Data, Firewall

Specifications

PHYSICAL SPECIFICATIONS

Dimensions & Weight:
Height Width Depth Weight

Yumizen H500 OT
39.7 x 47.7 x 48.3 cm 22 kg
15.63 x 18.78 x 19.02 in. 49 lbs

Yumizen H500 CT
39.7 x 47.7 x 48.3 cm 23.5 kg
15.63 x 18.78 x 19.02 in. 51 lbs

Yumizen H550
53 x 66.8 x 62.1 cm 35 kg
20.87 x 26.3 x 24.45 in. 78 lbs

Printer (optional):
Compatible models with Linux drivers

Throughput:
60 samples/hour

Sample Management (Yumizen H550):
Autonomy of 40 tubes in 1 hour
Continuous Loading
STAT Mode
Rack Automatic Mixing
Tubes Positive Identification

Analysis Mode:
Patient, Prediluted, iQC (Difftrol),
eQC (External)

Sound Level: 60 dBa

Operating Temperature & Humidity:
+15°C (+59°F) to + 30°C (+86°F)
Relative humidity up to 80% maximum,
without condensation

Specimen Type & Volume:
Human venous and capillary blood
EDTA K2, EDTA K3 anticoagulant
CBC mode: 20µL
DIF mode: 20µL

Power Requirements:
Power Supply: AC/DC adapter (external) 24 Vdc
Power consumption: 180 VA
Heat output: 378 KJ/h

Reagents:
2 reagents for analysis :
ABX Diluent (10L or 20L)
Whitediff 1L (cyanide free)
1 reagent for daily shutdown : ABX Cleaner 1L

ECO FRIENDLY SOLUTION

LED light source
Cyanide free lysis reagent
Low reagents consumption: < 20 µL/test
WEEE Standard compliance

MEASUREMENT PRINCIPLES

WBC & Differential

Methods:
- Cytometry :
  Double Hydrodynamic Sequential System 'DHSS'
- Optical Reading : Absorbance
- Impedance Variation

HGB Measurement

Method:
- Spectrophotometry

RBC & PLT Detection

Methods:
- Impedance Variation
- Analogic Digital Conversion

HCT Measurement
Method:
- Analogical integration

SOFTWARE SPECIFICATIONS

- Data Processing

Color LCD touch screen: 12,1 in.
Operating System: Linux™
Connection: RS232, Ethernet, USB
Communication: ASTM & HL7 protocols
Capacity: 10 000 results + graphs
Options: keyboard, mouse and bar code reader

- Quality Control

3 controls levels (low, normal, high)
Target values download
QC results compatible with
HORIBA Medical Quality Control Program (QCP)
Levey-Jennings graphs
Radar graphs
XB on 3 or 9 parameters
Overlapping QC (6 active QC files)

- Yumicare®

Connected service option:
LAN, Wifi, 4G
Automatic QC management
(target values download and QC results
upload to QCP)
Analyzer activity monitoring
Consumption management
Remote software update
Predictive maintenance

PARAMETERS & PERFORMANCE DATA

37 Parameters:
WBC
NEU# & NEU%
LYM# & LYM%
MON# & MON%
EOS# & EOS%
BAS# & BAS%
IMG# & IMG%
IML# & IML%
IMM# & IMM%
ALY# & ALY%
LIC# & LIC%

RBC
HGB
HCT
MCV
MCH
MCHC
RDW-CV
RDW-SD
MIC
MAC

PLT
MPV
PCT
PDW
P-LCC
P-LCR

NLR (Neutrophil-To-Lymphocyte Ratio)

Infectious Screening Flags (Option)
Plasmodium falciparum, *Plasmodium vivax*, Dengue fever
Scoring flags

Analytical Measurements Range:

Linearity Limits	Visible Range	Unit
WBC 0 - 300	300 - 999	10^9/L
RBC 0 – 8	8 - 18	10^{12}/L
HGB 0 – 240	240 - 300	g/L
HCT 0 - 0.67	0.67 - 0.80	L/L
PLT 0 - 2500	2500 - 4000	10^9/L
PLT (concentrate) 0 – 4000	4000 - 5000	10^9/L

Limit Of Quantification	Unit
WBC 0,2	10^9/L
RBC 0,2	10^{12}/L
HGB 1	g/L
PLT 10	10^9/L

Precision (Repeatability):

Parameters CV (%)	Range	Unit
WBC <3.0	4 – 10	10^9/L
RBC <2.0	3.6 – 6.2	10^{12}/L
HGB <1.5	120 – 180	g/L
HCT <2.0	0.36 – 0.54	L/L
PLT <5.0	180 – 500	10^9/L

Subject to modifications / Réf. **1300103305** © 2022 HORIBA Medical - HORIBA ABX SAS - France - RCS Montpellier 328 031 042
HORIBA Medical invites users of its systems to carefully read the instructions for use in user manuals

HORIBA CARE
1800-103-4470

CE IVD

Certified
ISO 9001 :2015
ISO 14001 :2015
ISO 13485 :2016
MDSAP – Medical Device Single Audit Program

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