



**Installation Qualification, Performance,
Qualification and Operational
Qualification**

YUMIZEN H500

(Serial no: 907YOXH02566)

Fully Automated Hematology Analyzer

For

Dr SwadhaHospital

Kachora Road, Rail Mandi, Jaswanth Nagar, Etawah- 206245

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646 5000.

Visit us: <http://www.horiba.com/in/>

Table of Contents:

Section 1 **General Instructions**

Section 2 **Installation Qualification**

- I. Installation Qualification.
- II. Installation Procedure.
- III. Installation Certificate.

Section 3 **Operational Qualification**

- I. Operational Qualification.
- II. Operational Training Record.
- III. Operator Maintenance Protocol.
- IV. Operational Certificate.

Section 4 **Performance Qualifications**


- I. Performance Qualification.
- II. Performance Certificate.

Section 5 **Attachments**

General Instructions:

- HORIBA India Pvt. Ltd. is responsible for installation of YUMIZEN H500, Fully 5 part Part Automated Hematology Analyzer, at SWADHA HOSPITAL. As per the attached protocol.
- An authorized HORIBA India Pvt. Ltd., representative will physically check the system and proceed for the installation.
- This installation protocol will be followed as specified by the manufacturer.
- Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.
- An authorized HORIBA India Pvt. Ltd. representative will also perform the precision check on the system to check if it is as per the claim of the manufacturer.
- The results obtained for Calibration, QC & Precision checks will be verified by the qualified trained employee of
- SWADHA HOSPITAL along with an authorized HORIBA India Pvt. Ltd., representative.
- On completion of the Installation all the necessary documents of the System checks will be used to evaluate the instrument installation in accordance with the manufacturer's protocol and intended use.
- An authorized HORIBA India Pvt. Ltd., representative will verify the documents of the system checks and approve the same.
- Successful completion of this protocol will verify that this instrument has been installed in accordance with the intended usage.

Report Sign Off

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.	
Name:	RAHUL RAJPUT	
Title; Engineer at Customer support	Sign: 	Date: 04/11/2019
Approved by:	SWADHA HOSPITAL	
Name:	Mr. Arun Chand	
Title: Lab Incharge	Sign:	Date: 04/11/2019

YUMIZEN H500

(Serial no: **907YOXH02566**)

Fully Automated Hematology Analyzer

Installation Qualification

For

Dr SwadhaHospital

Kachora Road, Rail Mandi, Jaswanth Nagar, Etawah- 206245

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646 5000.

Visit us: <http://www.horiba.com/in/>

A. Installation Qualification**1. Installation Requirement :**

Sr. No.	Description	Compliance (Yes/No)
1.	Environmental conditions: Indoor Location not exposed to sunlight, water and vibration free platform. Temperature of 16°C to 34°C and maximum relative humidity of 80%.	yes
2.	Physical Space Requirement: 36(W) x 36(D) x 53(H)cm with at least 20 cm space at the back of the instrument from the wall.	yes
3.	Electrical Requirements: Power supply - 100Vac- 240 Vac +/- 10%. Power consumption – Maximum 150VA with earth less than 3 V.	yes
4.	UPS connection available.	yes

2. The instrument has been checked for the following:

Sr. No.	Verification	Provided (Yes/No)
1.	Instrument is identified Instrument Serial No. : 907YOXH02566	Yes
2.	Manufacturer's specifications: Technical and Physical Requirement	Yes
3.	Accessories / consumables are listed as per checklist (Provided along)	Yes
4.	System checked for any External / physical damage.	Yes
5.	Instrument User Manual (Soft Copy)	Yes

3. Equipment Description :

YUMIZEN H500, Fully Automated Hematology Analyzer

Instrument Identification	Verified Yes/No
Equipment Type : Hematology Analyzer	Yes
Model : YUMIZEN H500	Yes
Manufacturer : HORIBA Medical, France	Yes
Marketed By :HORIBA Medical - HORIBA India Pvt. Ltd.	Yes
Equipment # : One	Yes
Serial Number : 907YOXH02566	Yes
Dimensions : 36(W) x 36(D) x 53(H)	Yes
Power Supply: 100Vac to 240Vac (+/-10%) 50Hz to 60Hz Power Consumption: 150 VA	Yes

4. Accessories/Consumables :

The accessories were supplied with the instrument as per the check list. Check &verified in case they are found to be in order.

5. Preventive Maintenance :

The routine preventive maintenance of the system will be carried out by an authorized HORIBA India Pvt. Ltd., engineer at a specified time interval as recommended by the manufacturer.

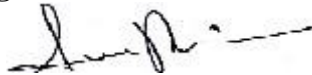
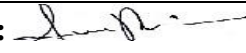
6. Spare Parts :

HORIBA India Pvt. Ltd strongly recommends the end user to maintain a basic consumable parts onsite to minimize down time due to minor failures. Spare parts as provided in the installation kit.

B. Installation Procedure:

1. Putting the system at the predefined and pre inspected location (Having suitable Working Conditions).
2. Removal of the internal packing material of the system.
3. Place the Instrument on the bench top (Vibration free).
4. Connect the Power cord to the Yumizen H500.
6. Turn on the inbuilt Printer.
7. All the operating software has been loaded in to Yumizen H500.
8. Now from back side of the instrument turn the power switch ON. Yumizen H500 goes through its power up and self-test sequence.
9. The Yumizen H500 login menu is displayed after the Start up cycle is completed. Enter the credentials.

C. INSTALLATION CERTIFICATE:**Instrument Name : YUMIZEN H500****Serial Number : 907YOXH02566****Customer Details : SWADHA HOSPITAL****Laboratory with complete address: Kachora Road, Rail Mandi, Jaswanth Nagar, Etawah****Installation Date : 04/11/2021****Warranty expires on : 03/11/2024**

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Rahul Rajput		
Title: Engineer at Customer support	Sign: 	Date:04/11/2021	
Approved by:	SWADHA HOSPITAL		
Name:	Mr. Arun Chand		
Title: Lab Incharge	Sign: 	Date:04/11/2021	

Deviation:**Conclusion:** Instrument has been qualified for Installation. Hence it has been taken for Operational Qualification.



YUMIZEN H500

(Serial no: **907YOXH02566**)

Fully Automated Hematology Analyzer

Operational Qualification

For

Dr SwadhaHospital

Kachora Road, Rail Mandi, Jaswanth Nagar, Etawah- 206245

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646 5000.

Visit us: <http://www.horiba.com/in/>

A. Operational Qualification**1. Instrument Identification:**

Instrument Name : YUMIZEN H500

Serial Number : 907YOXH02566

2. Following is the list of actions performed and verified for running the system routinely.

Sr. No.	Test Name	Test Purpose	Method	Observation
1.	SYSTEM SWITCH ON	TO CHECK THE ERROR FREE POWER UP.	Switch on the main, switch on the system. Login into yumizen Application software. Start up cycle is performed. Login in as User and check for the Screen Errors.	Ok
2.	STARTUP CYCLE	TO CHECK THE BACK GROUND IS OK.	Run a startup cycle from the main menu; check if the background is in the acceptable range.	Ok
3.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.	Ok
4.	REAGENT STATUS	TO CHECK ADEQUATE REAGENT IS AVAILABLE FOR ANALYSIS	Manually check in the reagent bottles or else change the reagent from the Status Menu.	Ok

5.	SAMPLE ANALYSIS	TO CHECK PROPER FUNCTIONING OF SAMPLE ANALYSIS	1. To run Stat/ Manual sample, press on sample identification and enter the sample ID and press on validate.	Ok
6.	ARCHIVE AND CURRENT REPORTS	TO RECOVER THE SAMPLE RESULT FROM ARCHIVE AND CURRENT REPORTS	Press on Results History icon and view the current results. To view archived reports, Select Archive results and select the date of the reports and view the report.	Ok
7.	QUALITY CONTROL DATA	TO RECOVER QUALITY CONTROL DATA AND LJ GRAPH	Press on QC Icon from the Main Menu and select the Lot No. To view on QC Runs , Click on Dates .	Ok
8..	FLAGS AND ALARMS	TO CHECK THE PROPER FLAGS AND ALARMS FOR SAMPLES	Run sample to verify alarms and flags.	Ok

B. Operational Training Record

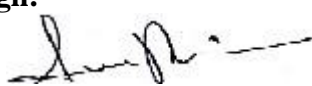
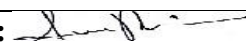
Operator Training: The users responsible for the operation of this instrument will be trained on the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented and the training records will be filled as indicated below:

C. Operator Maintenance Protocol

Maintenance and Troubleshooting: Perform Concentration Cleaning as advised by the HORIBA Medical Representative .Run a Shutdown cycle before switching off the analyzer .

OPERATIONAL**HORIBA**
Medical**Instrument Name****Serial Number** : 907YOXH02566**Customer Details** : SWADHA HOSPITAL
Laboratory with complete address Kachora Road, Rail Mandi, Jaswanth Nagar, Etawah**Installation Date** : 04/11/2021**Warranty expires on** : 03/11/2024

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.
Name:	Rahul Rajput

Title: Engineer at Customer support	Sign: 	Date:04/11/2019
Approved by:	SWADHA HOSPITAL	
Name:	Mr. Arun chand	
Title: Lab incharge	Sign: 	Date:04/11/2019

Deviation:**Conclusion:** Instrument has been qualified for Operational. Hence it has been taken for Performance Qualification.

YUMIZEN H500

(Serial no:907YOXH02566)

Fully Automated Hematology Analyzer

Performance Qualification

For

Dr SwadhaHospital

Kachora Road, Rail Mandi, Jaswanth Nagar, Etawah- 206245

#246, Okhla Industrial Estate, Phase III, New Delhi 110020, India, Tel: 011 4646 5000.

Visit us: <http://www.horiba.com/in/>

A. Performance Qualification**A. Instrument Identification:**

Instrument Name : YUMIZEN H500

Serial Number : 907YOXH02566

B. Following is the list of test to be performed and verified

- **Blank Reference cycle:** To verify the Startup Cycle of the instrument.

Serial No: 907YOXH02566

Parameters	Acceptable Range	Observed Value
WBC $10^3/\text{mm}^3$	$\leq 0.3 \times 10^3/\text{mm}^3$	0.0
RBC $10^6/\text{mm}^3$	$\leq 0.02 \times 10^6/\text{mm}^3$	0.00
HGB g/Dl	$\leq 0.3 \text{ g/dl}$	0.0
PLT $10^3/\text{mm}^3$	$\leq 10 \times 10^3/\text{mm}^3$	0

Conducted By:



Verified By:



- **Control Runs:** The quality of the analyzer is checked by running three levels of Controls & getting the values in the range as per the kit insert.
 - **Lot: ABX Difftrol; PX421; Exp: 10/12/2021.**

Serial No: 907YOXH02566

LEVEL	STATUS
LOW (PX 424L)	OK
NORMAL (PX 424N)	OK
HIGH (PX 424H)	OK

Conducted By:



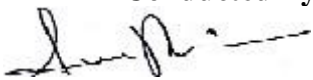
Verified By:

- **Precision Study:** Precision is checked by running blood sample in 10 replicates & getting CV% in within acceptance.

Serial No: 907YOXH02566

Parameters	CV % Acceptance	CV % Observed	Comments
RBC $10^6/\text{mm}^3$	< 2.0	0.6	
HGB g/dL	< 1.5	0.5	
HCT %	< 2.0	0.7	
PLT $10^3/\text{mm}^3$	< 5.0	3.9	
WBC $10^3/\text{mm}^3$	< 2.5	1.2	
GRA %	<4	2.0	
LYM%	<10	1.3	
MON%	<20	6.4	

Conducted By:



Verified By:

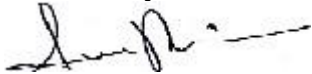


- **Carryover Study:** Carry over is checked by running quality controls (Low & high) in 3 replicates & getting CV% in within acceptance.
 - **Carry Over % = $(L1-L3)*100/(H3-L3)$.**

Serial No: 907YOXH02566

Parameters	WBC 10 ³ /mm ³	RBC 10 ⁶ /mm ³	HGB g/dL	HCT %	PLT 10 ³ /mm ³
Carry Over (%)	0.5	0.9	0	0.6	0.2
Manufacturer acceptable CV%	<1%	<1%	<1%	<1%	<1%
Status	Passed	Passed	Passed	Passed	Passed

Conducted By:



Verified By:



B. PERFORMANCE CERTIFICATE:

Instrument Name : YUMIZEN H500


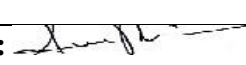
Serial Number : 907YOXH02566

Customer Details : SWADHA HOSPITAL

Laboratory with complete address Kachora Road, Rail Mandi, Jaswanth Nagar, Etawah

Installation Date : 04/11/2021

Warranty expires on : 03/11/2024

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Rahul Rajput		
Title: Engineer at Customer support	Sign: 	04/11/2019	
Approved by:	SWADHA HOSPITAL Laboratory		
Name:	Mr. Arun Chand		
Title: Lab Incharge	Sign: 	Date: 04/11/2019	

Deviation:**Conclusion:** Instrument has been qualified for Performance.**ATTACHMENTS**

Attachment No	Document Title	Page Nos.	Verified By Sign/Date



HORIBA India Private Limited

246, Okhla Industrial Estate Phase-III,
New Delhi 110020, India
Tel : +91 (11) 4646 5000 / 4669 5001
Fax : +91 (11) 4646 5020
http : //www.horiba.com
CIN : U73100DL2006PTC153232

CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	PLT
SCS1	6.80	4.41	12.3	34.00	258
SCS2	6.90	4.42	12.3	34.00	261
SCS3	6.90	4.38	12.3	33.60	257
SCS4	6.70	4.36	12.3	33.40	259
SCS5	6.80	4.42	12.3	33.90	264
MEAN	6.82	4.398	12.30	33.78	259.8
Acceptable Limits	6.51 - 7.09	4.320 - 4.497	12.11 - 12.36	33.06 - 34.55	250.3 - 276.7
Result	PASS	PASS	PASS	PASS	PASS

(Traceability System) :

The traceability system of Sysmex Hematology analyzers are shown in attached sheet.



Shrish Dixit

(Head- Products & Marketing)For
Horiba India Pvt. Ltd.



HORIBA India Private Limited

246, Okhla Industrial Estate Phase-III,
New Delhi 110020, India
Tel : +91 (11) 4646 5000 / 4669 5001
Fax : +91 (11) 4646 5020
http : //www.horiba.com
CIN : U73100DL2006PTC153232

HIN/MED/2023-2024/103514

19th May 2023

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer **YUMIZEN H550** bearing serial number:
907YOXH02566 installed at DR.SUNITA HOSPITAL

Calibrator : ABX MINOCAL
Lot No. : CX440
Expiry Date : 25th June 2023

The reports of Blank Cycle, Repeatability and Calibration Values were all found in acceptable range.

Next calibration cycle is due on 18th May 2024.



Shrish Dixit

(Head- Products & Marketing)
For **Horiba India Pvt. Ltd.**