

HORIBA

Medical

IQ, OQ AND PQ PROTOCOL

FOR

PENTRA ES 60

Fully Automated Hematology Analyzer

MARKETED BY:

HORIBA Medical - HORIBA India Pvt. Ltd,

246, Okhla Industrial Estate, Phase III,

New Delhi – 110 020, India.

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GENERAL INSTRUCTIONS:

- HORIBA India Pvt. Ltd. is responsible for installation of PENTRA ES 60, Fully Automated Five Part Hematology Analyzer, at INLAKS 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.
- After the installation of the system, Instrument calibration & QC will be performed by the authorized HORIBA India Pvt. Ltd. representative.
- 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 INLAKS 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:	Mr. Sagar /Mr.Krunal		
Title:	Sign:	Date:	
Engineer-Customer Support		23/10/2021	
Reviewed by:	INLAKS HOSPITAL		
Name:	NISHA MAM		
Title: Lab incharge	Sign:	Date:	
		23/10/2021	
Approved by:	INLAKS HOSPITAL		
Name:	NISHA MAM		
Title: Lab incharge	Sign:	Date:	
		23/10/2021	

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PENTRA ES 60

Fully Automated Hematology Analyzer

INSTALLATION QUALIFICATION

FOR

INLAKS HOSPITAL ,

CHEMBUR

MARKETED BY:

HORIBA Medical - HORIBA India Pvt. Ltd,

246, Okhla Industrial Estate, Phase III,

New Delhi – 110 020, India.

A. INSTALLATION QUALIFICATION

1. Installation Requirement :

Sr. No.	Description	Compliance (Yes/No)	Verified by & Date
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	23/10/2021
2.	Physical Space Requirement: 120 x 55 x 73 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 800VA 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)	Verified by & Date
1.	Instrument is identified Instrument Serial No. :607PES14349	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	23/10/2021
5.	Instrument User Manual	YES	

3. Equipment Description :

PENTRA ES 60, Fully Automated Hematology Analyzer

Instrument Identification	Verified Yes/No	Verified by / Date
Equipment Type :Hematology Analyzer	YES	23/10/2021
Model :PENTRA ES 60	YES	
Manufacturer : HORIBA Medical, France	YES	
Marketed By :HORIBA Medical - HORIBA India Pvt. Ltd.	YES	
Equipment # : One	YES	
Serial Number :607PES14349	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.

HORIBA TRAINER NAME	SIGNATURE	DATE
Mr. Sagar /Mr.Krunal		23/10/2021

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.
4. Connect the Power cord to the PENTRA ES 60
6. Connect the instrument to the Printer.
7. All the operating software has been loaded in to PENTRA ES 60
8. Switch ON the Printer. Now from Right side of the instrument turn the power switch ON. PENTRA ES 60 goes through its power up and self-test sequence.
9. The PENTRA ES 60 Main Menu is displayed after the start up sequence is completed.

C. INSTALLATION CERTIFICATE:

Instrument Name : PENTRA ES 60
Serial Number :607PES14349
Customer Address : INLAKS HOSPITAL ,CHEMBUR
Installation Date : 23/10/2021
Warranty expires on : NA

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. Sagar /Mr.Krunal		
Title:Engineer– Customer Support	Sign:	Date: 23/10/2021	
Reviewed by:	INLAKS HOSPITAL		
Name:	NISHA MAM		
Title: Lab incharge	Sign:	Date: 23/10/2021	
Approved by:	INLAKS HOSPITAL		
Name:	NISHA MAM		
Title: Lab incharge	Sign:	Date: 23/10/2021	

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

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OPERATIONAL QUALIFICATION

FOR

INLAKS HOSPITAL ,

CHEMBUR

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246, Okhla Industrial Estate, Phase III,

New Delhi – 110 020, India.

A. OPERATIONAL QUALIFICATION

1. Instrument Identification:

Instrument Name : PENTRA ES 60

Serial Number : 607PES14349

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

Sr. No.	Test Name	Test Purpose	Method	Observation	Verified Sign/Date
1.	SYSTEM SWITCH ON	TO CHECK THE ERROR FREE POWER UP.	Switch on the main, switch on the system. System will perform the self-test sequence. PENTRA ES 60 MAIN MENU is displayed after the completion. Check for any errors on the screen.	YES	
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.	YES	
3.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.	YES	
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.	YES	

5.	SAMPLE ANALYSIS	TO CHECK PROPER FUNCTIONING OF SAMPLE ANALYSIS	To run Manual sample, press on stat icon and enter the sample ID and press on validate and run the sample	YES	
6.	ARCHIVE AND CURRENT REPORTS	TO RECOVER THE SAMPLE RESULT FROM ARCHIVE AND CURRENT REPORTS	Press on Reports Icon and view the current results. To view archived reports, press on Archive Icon and select the date of the reports and view the report.	YES	
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. and press on Print Icon to print LJ graph. To view the raw data click on Zoom icon and view the data.	YES	
8..	FLAGS AND ALARMS	TO CHECK THE PROPER FLAGS AND ALARMS FOR SAMPLES	Run sample to verify alarms and flags.	YES	

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:

Sr. No.	Operators	Horiba Trainer Name & Sign	Date
1.	Mrs. Nisha mam	Mr. Sagar /Mr.Krunal	23/10/2021
2.	Mrs. Sukanya mam		
3.	Mrs.varsha mam		
4.			
5.			

C. OPERATOR MAINTENANCE PROTOCOL

Maintenance and Troubleshooting: Run Cytometer rinsing during shutdown and cleaning whenever required. Run Concentrated Cleaning Procedure once in a week or whenever required.

D. OPERATIONAL CERTIFICATE:

Instrument Name : PENTRA ES 60
 Serial Number : 607PES14349
 Customer Address : INLAKS HOSPITAL , CHEMBUR
 Installation Date : 23/10/2021
 Warranty expires on : NA

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.		
Name:	Mr. Sagar /Mr.Krunal		
Title:Engineer– Customer Support	Sign:	Date: 23/10/2021	
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Name:	NISHA MAM		
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Approved by:	INLAKS HOSPITAL		
Name:	NISHA MAM		
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New Delhi – 110 020, India.

PERFORMANCE QUALIFICATION

A. Instrument Identification :

Instrument Name : PENTRA ES 60

Serial Number : 607PES14349

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:Parameters	Acceptable Range	Observed Value	Verified by Sign/Date
WBC	$\leq 0.2 \text{ } 10^3 / \text{mm}^3$	0.0	
RBC	$\leq 0.01 \text{ } 10^6 / \text{mm}^3$	0	
HGB	$\leq 2 \text{ g/dl}$	0	
PLT	$\leq 5 \text{ } 10^3 / \text{mm}^3$	0	

- **Precision Study:** Precision is checked by running blood sample in 11 replicates & without taking the values of first run, replicates the instrument using average of the last 10 runs CV%. Precision print out hand it over to incharge.

Parameters	CV % Acceptance	CV % Observed	Comments
RBC	< 2.0	0.76	Pass
HGB	< 1.0	0.40	Pass
HCT	< 2.0	0.77	Pass
MCV	< 1.5	0.22	Pass
MCH	< 1.5	0.62	Pass
MCHC	< 1.5	0.62	Pass
RDW	< 6.0	1.41	Pass

PLT	< 5.0	3.08	Pass
MPV	< 5.0	1.39	Pass
WBC	< 3.0	1.1	Pass

- **Calibration:** To calibrate the Instrument using calibrator (ABX MinoCal) and verify the same.
- **Procedure:** Go to Quality Assurance icon on main screen and then Calibration icon. Run Calibrator (ABX Minocal) 5 times, calibrates the instrument using average of the last 5 runs CV%. Run Calibrator as a sample to verify the calibration.

Calibrator Used: ABX MINOCAL

Lot No.: CX463

Expiry Date: 05/11/2021

Parameter	Target Value (As per Kit Insert)	Mean Value	Observed CV%	Acceptance CV%	Comments
WBC	9.0	10.0	1.34	<2%	PASSED
RBC	4.40	4.66	0.62	<2%	PASSED
HGB	13.3	13.1	0.46	<1%	PASSED
HCT	36.3	37.9	0.68	<2%	PASSED
PLT	245	259	2.31	<5%	PASSED

Conducted By & Verified By: Mr. Sagar /Mr.Krunal

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 PX432N; Exp: 05/01/2022
 - Lot: ABX DIFFTROL PX432H :Exp; 05/01/2022
 - Lot: ABX DIFFTROL PX432L :Exp; 05/01/2022

Serial No:607PES14349

LEVEL	STATUS
LOW (PX432L)	OK
NORMAL (PX432N)	OK
HIGH (PX432H)	OK

Conducted and Verified By: Mr. Sagar /Mr.Krunal.

B. PERFORMANCE CERTIFICATE:

Instrument Name : PENTRA ES 60

Serial Number :607PES14349

Customer Address : INLAKS HOSPITAL ,CHEMBUR

Installation Date : 23/10/2021

Warranty expires on : NA

Prepared by:	HORIBA Medical - HORIBA India Pvt. Ltd.	
Name:	Mr. Sagar /Mr.Krunal	
Title:Engineer – Customer Support	Sign:	Date: 23/10/2021
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Name:	NISHA MAM	
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Approved by:	INLAKS HOSPITAL	
Name:	NISHA MAM	
Title: LAB incharge	Sign:	Date: 23/10/2021

Conclusion: Instrument has been qualified for Installation. Hence it has been taken for sample process.