

## CALIBRATION FACTOR DATA

The calibrator of below mentioned lot no. has been run Ten times and its MEAN and CV% is calculated automatically and the factors are automatically obtained by the instrument.

**Calibrator Lot No.** PLUS0222  
**Calibrator Exp.** 05/03/2022  
**Instrument** H33s  
**Sr. No.** TH-17010237  
**Calibration Date** 19/02/2022

WB calibration data							
	Select	WBC	RBC	HGB	MCV	PLT	
		10 <sup>9</sup> /L	10 <sup>12</sup> /L	g/dL	fL	10 <sup>9</sup> /L	
<b>Target</b>		9.6	4.51	13.7	88.9	259	
1	Yes	9.9	4.49	13.9	89.9	255	
2	Yes	9.9	4.47	13.6	89.9	251	
3	Yes	9.7	4.46	13.8	89.6	241	
4	Yes	9.9	4.47	13.8	89.7	247	
5	Yes	9.6	4.42	13.6	89.6	236	
6	Yes	9.8	4.48	13.7	89.5	245	
7	Yes	9.8	4.47	13.5	89.7	246	
8	Yes	9.8	4.48	13.8	89.7	242	
9	Yes	9.7	4.45	13.8	89.6	243	
10	Yes	9.9	4.46	13.9	89.6	243	
<b>Mean</b>		9.8	4.47	13.7	89.7	245	
<b>CV (%)</b>		1.1	0.4	0.9	0.2	2.2	
<b>New Factor (%)</b>		97.98	100.99	99.77	99.13	105.77	
<b>Old Factor (%)</b>		97	100	94	100	100	

### CALIBRATION FACTOR: -

Parameter	Calibration Factor (%)	Date
WBC	97.98	19-02-2022
RBC	100.99	19-02-2022
HGB	99.77	19-02-2022
MCV	99.13	19-02-2022
PLT	105.77	19-02-2022

Date:19.02.2022

## **CALIBRATION CERTIFICATE**

**To whom So Ever It May Concern**

This is to certify that the below mentioned instrument installed Wellness Diagnostic Pvt. Ltd., Dharamveer Market 2<sup>nd</sup> Floor, Near, Seble Cinema & Metro Station Mathura Road, Badarpur, New Delhi-110044 Has Been Calibrated by Us On 19/02/2022, The Next Calibration is due on before 18/02/2023, The values are falling within the specified range.

The calibration is done by the service team of Avantor performance materials India Ltd.

The next calibration is due on 18<sup>th</sup> Feb 2023

Validity: -One year for Calibration factor data.

For Avantor Performance Materials India Ltd

Signature: -

A handwritten signature in blue ink that reads 'Sanjeev'.

Name: Sanjeev Kumar  
Customer Service Executive  
Mobile: +91 9811459701

Email: [sanjeev.kumar@avantorsciences.com](mailto:sanjeev.kumar@avantorsciences.com)

Date: 19/12/2021

**BENESPHERA™ H33s**

**3-PART DIFFERENTIAL HAEMATOLOGY ANALYSER**

**INSTALLATION QUALIFICATION (IQ) / OPERATIONAL QUALIFICATION (OQ)**

**FOR**

**WELLNESS DIAGNOSTIC PVT. LTD.**


**BY**

**AVANTOR PERFORMANCE MATERIALS INDIA LIMITED**

### CERTIFICATE OF INSTALLATION

INSTRUMENT NAME	BENESPHERA™ H33S
SR. NO.	TH-17010237
CUSTOMER NAME	Wellness Diagnostic Pvt. Ltd.
ADDRESS	Dharamveer Market 2 <sup>nd</sup> Floor, Near, Seble Cinema & Metro Station Mathura Road, Badarpur, New Delhi-110044

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE INSTALLATION QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE ABOVE MENTIONED INSTRUMENT

ENGINEER	
SIGNATURE	
NAME	SANJEEV KUMAR
DESIGNATION	CUSTOMER SERVICE EXECUTIVE
COMPANY	AVANTOR PERFORMANCE MATERIALS INDIA LIMITED

QUALITY MANAGER	
SIGNATURE	
NAME	MR. ARUN KUMAR
DESIGNATION	DIRECTOR
COMPANY	Wellness Diagnostic Pvt. Ltd.

## INSTALLATION REPORT

CUSTOMER NAME	Wellness Diagnostic Pvt. Ltd.
PLACE	Dharamveer Market 2 <sup>nd</sup> Floor, Near, Seble Cinema & Metro Station Mathura Road, Badarpur, New Delhi-110044
DEPARTMENT	Laboratory
CONTACT PERSON	MR. Arun Kumar
INSTRUMENT NAME	BENESPHERA™ H33s
SERIAL NUMBER	TH-17010237
DATE OF INSTALLATION	11/01/2022
WARRANTY EXPIRY	10/01/2027

THE ANALYSER WAS INSTALLED ALONG WITH THE STANDARD APPLICABLE ACCESSORIES. ALL BASIC PARAMETERS WERE CHECKED AND ADJUSTED AND FOUND TO BE SATISFACTORY. THE PRELIMINARY SET UP AND TRAINING WERE PROVIDED TO THE CUSTOMER AND ANALYSER WAS HANDED OVER IN WORKING CONDITION.

FOR AVANTOR PERFORMANCE MATERIALS INDIA LIMITED



SANJEEV KUMAR

CUSTOMER SERVICE EXECUTIVE

## INSTALLATION QUALIFICATION

### IQ PROTOCOL

1. SYSTEM UNPACKING
2. CHECK FOR ANY PHYSICAL DAMAGE
3. VERIFY ACCESSORIES LIST
4. SPACE REQUIREMENT
5. POWER REQUIREMENT
6. OPERATING ENVIRONMENT
7. REAGENTS VERIFICATION

### 1 SYSTEM UN PACKING / 2 CHECK FOR ANY PHYSICAL DAMAGE

BENESPHERA™ H33s WAS UNPACKED AND CHECKED FOR ANY PHYSICAL DAMAGES. FOUND TO BE INTACT

### 3 VERIFY ACCESSORIES LIST

ACCESSORIES LIST WAS COMPARED WITH THE PHYSICALLY AVAILABLE ITEMS AND FOUND TO BE OK

### 4 SPACE REQUIREMENT

CHECKED AS PER THE BELOW INSTRUMENT DIMENSIONS

DIMENSIONS	
DEPTH (mm)	410
WIDTH (mm)	300
HEIGHT (mm)	400

### 5 POWER REQUIREMENT

PARAMETER	REQUIRED	REMARKS
INPUT VOLTAGE THROUGH UPS	230 ±10V	OK
LINE FREQUENCY	50-60 Hz	OK
GROUNDING VOLTAGE	0-5 V AC	OK

**6 OPERATING ENVIRONMENT**

OPERATING ENVIRONMENT		
PARAMETER	REQUIRED	REMARKS
TEMPERATURE	10°C - 40°C	OK
HUMIDITY	10% - 90%	OK
AIR PRESSURE	70kPa - 106kPa	OK

**7 REAGENTS VERIFICATION**

NAME	AVAILABILITY	REMARKS
M-30D DILUENT	YES	OK
M-30 CFL LYSE	YES	OK
PROBE CLEANSER	YES	OK

THE INSTALLATION QUALIFICATION POINTS WERE CHECKED AND FOLLOWED AND FOUND TO BE OK AND FURTHER CERTIFIES THE INSTRUMENT TO BE INSTALLED AT THE GIVEN PREMISES

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CUSTOMER SERVICE EXECUTIVE

## OPERATIONAL QUALIFICATION

THE OPERATION QUALIFICATION PROTOCOL IS A COLLECTOIN OF TEST CASES USED TO VERIFY THE PROPER FUNCTIONING OF A SYSTEM. SUCCESSFUL COMPLETION OF THE PROCEDURES IDENTIFIES THAT THE SYSTEM IS READY FOR OPERATION AND SUBSEQUENT PERFORMANCE ANALYSIS.

### OQ PROTOCOL

1. SYSTEM CONNECTIONS
2. DILUENT / WASTE CONNECTIONS
3. LYSE CONNECTION
4. SYSTEM BOOTING / INITIALISATION CHECK
5. MAINTENANCE

### SYSTEM CONNECTIONS

NAME	CHECK	REMARKS
3-PIN POWER CORD	CONNECTED	OK
EXTERNAL PRINTER (OPTIONAL)	AS PER MANUAL 2.4.6	NA

### DILUENT / WASTE CONNECTIONS

AS PER FIGURE BELOW

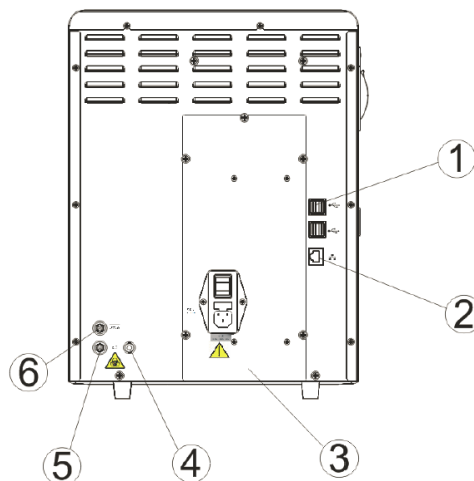


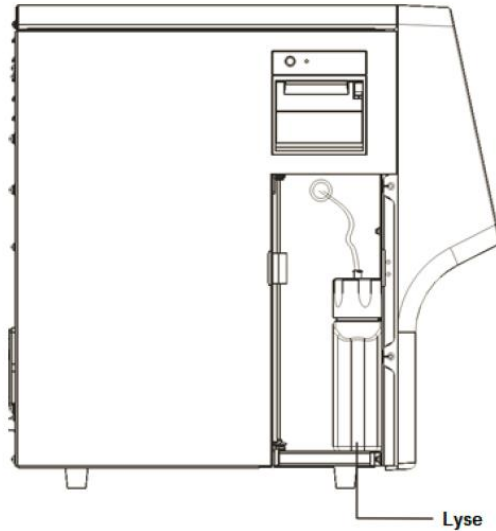
Figure 2-2 Back of the main unit

- |                      |                              |
|----------------------|------------------------------|
| 1 --- USB port       | 2 --- Network interface      |
| 3 --- Power assembly | 4 --- Waste sensor connector |
| 5 --- Waste outlet   | 6 --- Diluent inlet          |



**LYSE CONNECTION**

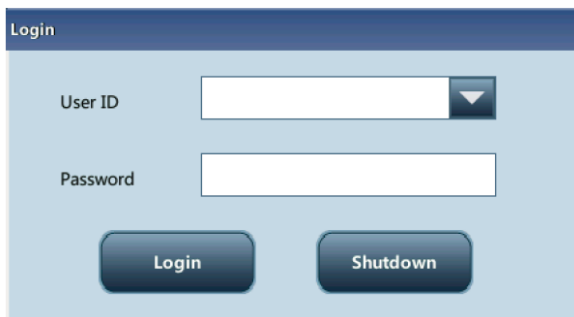
OPEN SIDE DOOR AND CONNECT THE LYSE



LOAD THE DILUENT & LYSE BARCODES FROM THE REAGENT SET UP MENU, AS MENTIONED IN THE OPERATOR MANUAL 9.2.6.

**4 SYSTEM BOOTING / INITIALISATION CHECK**

- POWER ON THE ANALYSER
- MAKE SURE THE POWER INDICATOR ON THE ANALYSER IS ON
- ENTER USER ID & PASSWORD WHEN PROMPTED



- CHECK IF THE SYSTEM SEQUENTIALLY COMPLETES THE SELF TEST & INITIALISATION

NORMAL BACK GROUND CHECK				
NO.	PARAMETER	ACTUAL	RANGE	REMARKS
1	WBC	0.0	< 0.3	OK
2	RBC	0.0	< 0.03	OK
3	HGB	0.0	< 1.0	OK
4	HCT	0.0	< 0.5%	OK
5	PLT	0.0	< 10	OK

**OTHER PARAMETERS**

NO.	PARAMETER	ACTUAL	RANGE	REMARKS
1	POWER +12 V	13.0 V	11V - 14V	OK
2	POWER +24 V	28.5 V	20V - 30V	OK
3	ANALOG +12 V	12.1 V	11V - 13V	OK
4	ANALOG -12 V	(-11.9 V)	(-14V) - (-9.0V)	OK
5	DIGITAL +56 V	56.0 V	47V - 63V	OK
6	HGB BLANK	4.12 V	3.85V - 4.85V	OK
7	APERTURE VOLTAGE RBC	13.29 V	9.3V - 17.3V	OK
8	APERTURE VOLTAGE WBC	9.68 V	7.2V - 13.5V	OK
9	DILUENT TEMPERATURE	30.7°C	5°C - 45°C	OK
10	REGENT PRE-HEATING TEMP	30.7°C	22.4°C - 45°C	OK
11	VACUUM	-28.6kPa	(-29.9)kPa - (-25.9)kPa	OK

**5 MAINTENANCE**
**MAINTENANCE**

NO.	PARAMETER	CHECK	REMARKS
1	MAINTENANCE	OPERATOR MANUAL 10.2.1	OK
2	CLEANING	OPERATOR MANUAL 10.2.2	OK
3	OVERALL MAINTENANCE	OPERATOR MANUAL 10.2.3	OK

OPERATIONAL QUALIFICATION VERIFICATION WAS CARRIED OUT AS PER THE PROTOCOL AND INSTRUMENT WAS DEEMED FIT FOR PERFORMANCE QUALIFICATION.

FOR AVANTOR PERFORMANCE MATERIALS INIA LIMITED



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