

1) INSTALLATION QUALIFICATION



Laboratory: Atrea Healthcare - Bangalore

Address : 26, 11th Cross Rd, K.R.Road, 7th Block, Jayanagar, Bengaluru, Karnataka

Country : India

Serial Number : 117910

Installation Date : 23/12/2021

Installation Qualification

Transport damage

Package damaged: Yes No

Parts damaged Yes No

If yes, please specify:

Initial Check

Parts missing?	Part number	Part description
(Check against packing list)	_____	_____
<input type="checkbox"/> Yes → Please specify parts	_____	_____
<input checked="" type="checkbox"/> No	_____	_____
	_____	_____
	_____	_____

* Please return parts, including a malfunction report.

Line Voltage / Main Supply: 210 – 270V: 230V

Earthing Voltage (0-5V): 1V

Room Air conditioned: Yes No

Stabiliser / UPS: Brand: Hykon Rating :

The System is ready for Performing Operational Qualification.

-----END OF QUALIFICATION-----

<p>The customer confirms that the conditions required to ensure the proper functioning of the device according to the supplier's recommendations have been inspected and qualified.</p>			
<p><input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</p>			
<p>Customer's Comment:</p>		<p>Installer's Comment:</p>	
		<p>Done the Installation successfully.</p>	
<p>Customer (Name and position)</p>	<p>Signature</p>	<p>Installer (Name and position)</p>	<p>Signature</p>
		<p>Adarsh K FSE-Boule Equipment LabX Medical Systems</p>	
<p>This document is established and signed in duplicate. Each page must be initialed by the installer.</p>			

2) OPERATIONAL QUALIFICATION



Laboratory: **Atrea Healthcare - Bangalore**

Address: **26, 11th Cross Rd, K.R.Road, 7th Block, Jayanagar, Bengaluru, Karnataka**

Country: **India**

Serial Number: **117910**

Installation Date: **23/12/2021**

Operational Qualification

- Remove all the Transpiration accessories / Clips / Packing.**
- Connect all the Tubing & place the Diluent and Lyser probes in respective reagents.**
- Switch ON the system and check the Display**
- Check the initialising process.**
- Set System Parameters**
- Run Fill system.**
- Run a Prime Cycle**
- Check Tubing, Valves and motor in the service Menu.**
- Check noise interference for RBC and WBC chambers (ideally should be 0)**
- Check Photometer and Lamp Voltage (Should be 60V)**
- Check RBC and WBC metering unit timings (Time should be less than 17 Seconds)**

The System is ready for Performing Performance Qualification.

-----END OF QUALIFICATION-----

<p>The customer confirms that the conditions required to ensure the proper functioning of the device according to the supplier’s recommendations have been inspected and qualified.</p>			
<p style="text-align: center;"><input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</p>			
<p>Customer’s Comment:</p>		<p>Installer’s Comment:</p>	
		<p style="text-align: center;">Done the Operation Successfully.</p>	
<p>Customer (Name and position)</p>	<p>Signature</p>	<p>Installer (Name and position)</p>	<p>Signature</p>
		<p style="text-align: center;">Adarsh K FSE- Boule Equipment LabX Medical Systems</p>	
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2) PERFORMANCE QUALIFICATION



Laboratory: **Atrea Healthcare - Bangalore**

Address: **26, 11th Cross Rd, K.R.Road, 7th Block, Jayanagar, Bengaluru, Karnataka**

Country: **India**

Serial Number: **117910**

Installation Date: **23/12/2021**

Performance Qualification

Lot No of Boule Controls: Low: 22202-41 Normal: 22202-42 High: 22202-43

Low Control	Target Value	Tolerance	Measured Value	Status
RBC	2.23	0.12	2.23	OK
WBC	3.3	0.3	3.2	OK
MCV	66.1	5.0	65.5	OK
HGB	5.5	0.3	5.5	OK
PLT	80	15	76	OK
Normal Control				
RBC	4.15	0.18	4.06	OK
WBC	8.5	0.6	8.2	OK
MCV	81.4	5.0	81.0	OK
HGB	12.0	0.4	11.7	OK
PLT	223	30	225	OK
High Control				
RBC	5.08	0.22	4.97	OK
WBC	20.8	1.8	20.3	OK
MCV	89.5	5.0	88.7	OK
HGB	15.7	0.5	15.7	OK
PLT	513	60	531	OK

-----END OF QUALIFICATION-----

The customer confirms that the conditions required to ensure the proper functioning of the device according to the supplier’s recommendations have been inspected and qualified.

YES

NO

Customer’s Comment:

Installer’s Comment:

Done the Performance Successfully.

Customer (Name and position)	Signature	Installer (Name and position)	Signature
		Adarsh K FSE- Boule Equipment LabX Medical Systems	

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