

**1) INSTALLATION QUALIFICATION**



<b>Laboratory: DDRC agilus - Kaloor</b>
<b>Address : Ddrc agilus Diagnostics,Building No 70/2195- A, Amicus ground floor Kaloor</b>
<b>Country : India</b>
<b>Serial Number : 121840</b>
<b>Installation Date : 15-06-2023</b>

### 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-----

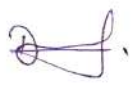
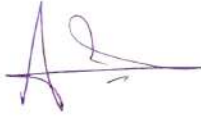
The customer confirms that the conditions required to ensure the proper functioning of the device according to the supplier's recommendations have been inspected and qualified.

YES     NO

Customer's Comment:

Installer's Comment:

Done the Installation successfully.

Customer (Name and position)	Signature	Installer (Name and position)	Signature
Dencyshibu		Abhinav S Raj FSE-Boule Equipment LabX Medical Systems	

This document is established and signed in duplicate. Each page must be initialed by the installer.

## 2) OPERATIONAL QUALIFICATION



**Medonic** 

**Laboratory: DDRC agilus - Kaloor**

**Address: Ddrc agilus Diagnostics, Building No 70/2195- A, Amicus ground floor  
Kaloor**

**Country: India**

**Serial Number: 121840**

**Installation Date: 15-06-2023**

## 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-----


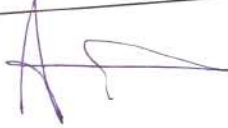
The customer confirms that the conditions required to ensure the proper functioning of the device according to the supplier's recommendations have been inspected and qualified.

YES     NO

Customer's Comment:

Installer's Comment:

Done the Operation Successfully.

Customer (Name and position)	Signature	Installer (Name and position)	Signature
Dency Shibu		Abhinav S Raj FSE- Boule Equipment LabX Medical Systems	

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### 3) PERFORMANCE QUALIFICATION



Laboratory: DDRC agilus - Kaloor

Address: Ddrc agilus Diagnostics, Building No 70/2195- A, Amicus ground floor  
Kaloor

Country: India

Serial Number: 121840

Installation Date: 15-06-2023

## Performance Qualification

Lot No of Boule Controls: Low: 22305-41      Normal: 22305-42      High: 22305-43

Low Control	Target Value	Tolerance	Measured Value	Status
RBC	2.25	0.12	2.27	OK
WBC	3.5	0.3	3.6	OK
MCV	65.3	5.0	66.5	OK
HGB	5.5	0.3	5.5	OK
PLT	77	15	83	OK
<b>Normal Control</b>				
RBC	4.19	0.18	4.13	OK
WBC	8.8	0.6	9.0	OK
MCV	84.9	5.0	82.1	OK
HGB	12.7	0.4	12.0	OK
PLT	232	30	235	OK
<b>High Control</b>				
RBC	5.10	0.22	5.20	OK
WBC	20.5	1.8	20.8	OK
MCV	91.6	5.0	93.5	OK
HGB	16.3	0.5	16.4	OK
PLT	489	60	541	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
Dency Shibu	 19/6/2023.	Abhinav S Raj FSE- Boule Equipment LabX Medical Systems	

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