



### Instrument Calibration/Validation Certificate

<b>Customer Name</b>	Atrea Healthcare - Bangalore
<b>Address</b>	26, 11th Cross Rd, K.R.Road, 7th Block, Jayanagar, Bengaluru, Karnataka 560070
<b>Instrument</b>	Medonic M32B
Serial No.	117910
<b>Contract Type</b>	WARANTY <input type="checkbox"/> AMC <input checked="" type="checkbox"/> RRC <input type="checkbox"/>
<b>Validation Date</b>	29-05-2023
<b>Next due date</b>	29-05-2024

**Instrument Condition:**

Room is Air Conditioned	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Power Supply Earthing less than 5 V	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Room Working Environment is Good	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

**Initial Check:**

- Turn Valve Calibration : OK
- Adjustment of the HB Lamp : OK
- HB LED Current Setting : 3420
- Bi-Stable Solenoid Valves : OK
- Measuring Chamber ( Blank & Noise Test) : OK
- Check functioning of Waste Pump : OK
- Check functioning of Slave Pump : OK
- Check Tubings : OK
- Measured Parameter calibration Factor : OK

### Performance Validation:

Lot No. of Boule Controls: Normal: 22302-42,

High: 22302-43

Normal Control	Observed	Mean	Tolerance	Remarks
RBC	4.09	4.10	0.18	OK
WBC	8.6	8.5	0.6	OK
MCV	79.7	79.3	5.0	OK
HGB	11.8	11.7	0.4	OK
PLT	224	225	30	OK
High Control				
RBC	5	5.04	0.22	OK
WBC	22.3	21.5	1.8	OK
MCV	96.3	94.6	5.0	OK
HGB	16.8	16.5	0.5	OK
PLT	542	531	60	OK

Power Supply				
	Type	Output Voltage	Neu/ Earth	Room Environment
UPS	<input checked="" type="checkbox"/> Online	V	V	Air Conditioned – Yes/No
	<input type="checkbox"/> Offline			Room Temperature 27°C

### Remarks:

Instrument is calibrated and working in good condition. Tested Samples and found results are satisfactory.

This Calibration is valid from 29-05-2023 to 28-05-2024.

Next Calibration is due on 29-05-2024.

Performed by,

Gautham S Kumar  
Service Engineer

## 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><b>Customer’s Comment:</b></p>		<p><b>Installer’s Comment:</b></p>	
		<p style="text-align: center;"><b>Done the Operation Successfully.</b></p>	
<p><b>Customer</b> <b>(Name and position)</b></p>	<p><b>Signature</b></p>	<p><b>Installer</b> <b>(Name and position)</b></p>	<p><b>Signature</b></p>
		<p style="text-align: center;"><b>Adarsh K</b> <b>FSE- Boule Equipment</b> <b>LabX Medical Systems</b></p>	
<p><b>This document is established and signed in duplicate. Each page must be initialed by the installer.</b></p>			



## 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
<b>Normal Control</b>				
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
<b>High Control</b>				
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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