



<b>Maglumi- X3 Calibration Certificate</b>	
Client Name	S R Metro, Silchar
Client Address: Silchar, Rangirkhari, Cachar	
<b>Analyser Model</b>	Maglumi-X3
Serial No.	0101010034012200060
<b>Calibration Details</b>	
Calibration date	31.07.2022
Next Calibration Due on	30.07.2023
<b>Software Data</b>	
COP firmware Version	1.0.6.N0
Sample arm Version	1.0.2.N0
Multiple Modules Version	1.0.2.N0
Washer Version	1.0.2.N0
Chamber Version	1.0.1.N0
Measuring Devices (Device Model and serial Number)	
Voltmeter details	Victor VC890C+
Conductivity meter	
Calibration Data	

### Scope of this Calibration Certificate:

Maglumi analyser for Chemiluminescence Immunoassay and intended to perform tests of analytes of interest with proprietary kits manufactured by **Shenzhen New Industries Biomedical Engineering Co., Ltd.** only. The major aspects of the system which are inter related to the proper functioning of the analyser are listed below:

- Water quality
- Voltage Measurements
- Mechanical Movement ( position): all alignments are visual .
- Incubation temperatures
- Refrigeration Temperatures
- Fluidics ( Starter reagents and wash volume dispensation )
- Chemiluminescence Measurement module
- Pipetting ( Precision and accuracy with Lightcheck Solution)

The tools needed for carrying out Calibration Adjustments / Verifications are

		Calibration Certificate needed?	Frequency of calibration
1	Voltmeter W/WO temperature measurement	Yes	Annual



2	Conductivity meter	Yes	Internal
3	Precision Thermometer (if used)	Yes	Annual
4	Micropipettes	Yes ( Laboratory equipment, client's property)	As per Lab QC policy

**Calibration Certification Procedure:**  
**During Installation: All protocols applicable for**  
**Successful IQ/OQ/PQ verification is sufficient.**

The procedure mentioned in the trailing documents must be met for successful calibration verification. A certificate of calibration shall be released by *Shenzhen New Industries Biomedical Engineering Co., Ltd* To complete the documentation, a copy of the relevant valid Calibration Certificates of the measuring devices, as mentioned in table above , must be furnished.

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**Procedure:**

Water quality:

- Affects all the assays, BGW recovery and system calibration claims. To be checked with a conductivity meter, onsite.

Voltage Measurements:

- Voltage can be adjusted onsite using a multimeter with a valid calibration. If not in range (after adjustment activity) then the part has to be replaced with new ones. In software, for user display, alignment of the displayed Voltage value to the actual measured value is possible.

Mechanical Positions:

- All position adjustments are adjusted and verified by Visual observations and can be reconfirmed with the markings on a scale, for reference. This includes complete cuvette movement areas, Pipetting aspiration and dispensing positions, washer aspiration and dispensing positions.

Incubation Temperatures:

- No hardware calibration for actual temperature possible. If not in range then the part has to be replaced with new ones. In software, for user display, alignment of the displayed temperature value to the actual measured value is possible.

Refrigeration Temperature:

- No hardware calibration for actual temperature possible. If not in range then the part has to be replaced with new ones. In software, for user display, alignment of the displayed temperature value to the actual value is possible.

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Fluidics:

- Washer dispense volumes can be verified and compared with an equivalent volume dispensed with a calibrated micropipette in another test tube. No calibration possible for the dispensing



pumps. If fluidics tubes and dispense nozzles are ok, then the dispense pumps should be replaced to comply with the requirements.

Measurement:

Dispense volume verification for starter 1 and starter 2 reagents. No calibration of dispense volumes, onsite. If not in range, starter pumps/ associated tubings to be replaced.

Pipetting:

- No calibrations possible for Pipetting volumes.

Calibration of PMT

Requalification :Final Test protocol:

- Confirmation(Light Check should be in range for left and right pipettor )
- Verification (Light check and BGW recovery in terms of RLU).

Alignment Module		Checked status	Comments
Incubator	First position to washer transport	ok	
	Last Position to Washer transport	Ok	
	First position to Back Transport	ok	
Washer	Transport Init Position	ok	
	Washer transport to Pusher – Cuvette transport	ok	
	Washer Lift Adjustments	ok	
Pusher	Init	ok	
	Washer	ok	
	Measure Chamber	ok	
Measure Chamber	Cuvette Locking for all 6 positions and at all star wheel init positions	ok	
	Chamber Lift adjustments	ok	
RM Test	All 13 Position in incubator	ok	
	Washer transport for all 13 cuvettes in washer channel and to Pusher locking pin	ok	
	Pusher to back	ok	



	transport locking pin and back to Incubator		
	RM locking status for all 13 cuvettes for both the locking positions in the measure chamber	ok	

PMT Calibration data							
Plateau Check							
D/A High Voltage	175						
Dark Count	Without Torch Light ( Mean Value)			With Torch Light ( Mean Value)			
Close Position ( range <80 RLU)	27			28			
Open Position ( range <80 RLU)	31			29			
Transport Position ( range <80 RLU)	29			30			
Ref LED ( range 140000-230000 RLU)	192321						
Min Value Cuvette	128257						
Measure Cuvette Value (CV% Range < 8%)	MV1	MV2	MV3	MV4	MV5	MV6	CV %
Measure cuvette 1	332	362	312	342	345	321	5.34
Measure Cuvette 2	352	312	324	347	315	352	5.62
Measure Cuvette 3	346	353	363	345	349	313	4.90

Final Test Protocol						
Parameter	RLU range	Achieved RLU	Max CV% Range	Achieved Max CV %	Avg CV% Range	Achieved AVG CV %
3X LC	400000-650000	544990	<3%	2.4	<3%	1.010
3X BGW	100-1200	395	<8%	4.8	<8%	1.961

## Summary



深圳市新产业生物医学工程股份有限公司  
Shenzhen New Industries Biomedical Engineering Co.,Ltd(SNIBE)

This instrument calibrated sucessfully.l

**Engineer's Signature:**

**Debilal Prajapati**  
**Service Engineer**