

CALIBRATION CERTIFICATE

ULR-CC278221030001784F

Certificate No. : BRMTL/01/521100006-A2-A	Date of Issue	: 03-04-2021
Name and address of the Customer M/s. Alpha Lifecare No 17, Bashyam Street, Manjakuppam, Cuddalore - 607001	Date of Receipt of Item	: 02/04/2021
	Date of Calibration	: 02/04/2021
	Calibration Due	: 01/04/2022
	(As Per Customer Request)	
	Customer Reference	: Mail Confirm # 31.03.2021

1. DESCRIPTION OF DEVICE UNDER CALIBRATION (DUC)

Name of the DUC	: ELECTRICAL SAFETY (Hematology Analyser)	Receiving Condition of DUC	: Satisfactory
Identification	: ---	Reference Document	: As Per Manufacturer Specification
Sl.No.	: TK - 69001460	Cal. Procedure Ref. No.	: BRMTL/WI/418
Make	: Mindray	Environmental Condition	: Temp : 24.5°C / RH : 58%
Model	: BC - 20S	Calibrated at	: Onsite
Location	: Biochemistry		

2. DETAILS OF MASTER USED

Standard Instrument Used	Make / Model	SL. No. / ID No.	Traceable To / Certificate No.	Validity
Electrical Safety Analyzer	Rigel Medical / 288+	48K-0413 BRMTL-315	ACCS201093	12.09.2021

The Masters are traceable to National / International standards as per ISO/IEC 17025

FIELD - MEDICAL DEVICES
Calibration Results
3. VISUAL INSPECTION

SL. No.	Description	Remarks	
		Pass	Fail
1	Device Clean and Decontaminated	√	
2	Physical damage	√	
3	Power cord check	√	
4	Display intensity adequate for day time use	√	
5	Alarm Function	√	

CALIBRATED BY (CALIBRATION ENGINEER)

AUTHORIZED BY (QM/TM/DY.TM/Sr.Br)


 DHANARAJA V


 KAMALAKANNAN R

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* NEXT CALIBRATION DUE AS PER CUSTOMER'S PLAN AND REQUIREMENT

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4. ELECTRICAL SAFETY
4.1 INSULATION TEST

SL. NO.	Specification	Measured Value (MΩ)	Allowable Limit (MΩ)	Uncertainty ± (%)	Remarks
1	Mains to Protective Earth	>100	>2	8.1	Pass

4.2 EARTH LEAKAGE

SL. NO.	Specification	Measured Value (μA)	Allowable Limit (μA)	Uncertainty ± (%)	Remarks
1	Normal Condition	122	<5000	8.21	Pass
2	Open Neutral (SFC*)	482	<10000	8.21	Pass

4.3 ENCLOSURE LEAKAGE

SL. NO.	Specification	Measured Value (μA)	Allowable Limit (μA)	Uncertainty ± (%)	Remarks
1	Normal Condition	31	<100	8.21	Pass
2	Open Neutral (SFC*)	67	<500	8.21	Pass

5. REMARKS

- The calibration results reported corresponds to the particular item mentioned above.
- This Certificate refers to the values obtained at the time of calibration and under the above stated conditions.
- All Calibrations are done in SI units and are traceable to National/International standards as required in ISO/IEC/17025.
- Certificate will not be reproduced except in full without the written approval of the Laboratory.
- The reported uncertainty of measurement is stated as the standard uncertainty in measurement multiplied by the coverage factor $k=2$, which for a normal distribution corresponds to a coverage probability 95.45%.
- SFC - Single Fault Condition.

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DHANARAJA V

KAMALAKANNAN R

Calibration Label / Status :	White : Calibrated <input checked="" type="checkbox"/>	Green : Accepted - Valid for use <input type="checkbox"/>	* NEXT CALIBRATION DUE AS PER CUSTOMERS PLAN AND REQUIREMENT
	Yellow : Limited use (Refer report) <input type="checkbox"/>	Red : Rejected-Out of use (Refer report) <input type="checkbox"/>	

CALIBRATION CERTIFICATE

Certificate No. : BRMTL/01/521100006-A2-B	Date of Issue : 03-04-2021
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	Date of Calibration : 02/04/2021
	Calibration Due : 01/04/2022 (As Per Customer Request)
	Customer Reference : Mail Confirm # 31.03.2021

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FIELD - MEDICAL DEVICES

Calibration Results



3. ELECTRICAL SAFETY

3.1 LOAD TEST (MAINS VOLTAGE)

SL. No.	Specification	Measured Value (V)	Allowable Limit (V)	Remarks	
				Pass	Fail
1	Live to Neutral	229	230±10%	√	
2	Neutral to Earth	0	<3	√	
3	Live to Earth	229	230±10%	√	

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