

## CALIBRATION CERTIFICATE

ULR-CC278222030005900F

Certificate No. : BRMTL/01/522100228-A3	Date of Issue : 06-06-2022
Name and address of the Customer M/s. ALPHA LIFECARE, No.17 Bashyam Street, Manjakuppam, Cuddalore - 607001.	Date of Receipt of Item : 02-06-2022
	Date of Calibration : 02-06-2022
	Calibration Due : 01-06-2023 (As Per Customer Request)
	Customer Reference : On-Site Confirm 02-06-2022

### 1. DESCRIPTION OF DEVICE UNDER CALIBRATION (DUC)

Name of the DUC : SEMI AUTO ANALYZER	Receiving Condition of DUC : Satisfactory
Make : ERBA	Reference Document : As Per Manufacturer Specification
Model : CHEM-7	Cal. Procedure Ref. No. : BRMTL/WI/418
Sl.No. : C170181	Environmental Condition : Temp : 23.5°C / RH : 52 %
Identification : ---	Calibrated at : Onsite
Location : LAB	

### 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	ACCS211066	10.09.2022
Electrical Safety Analyzer	Rigel Medical / 288+	48K-0413 BRMTL-315	CRMTL/01/422100328-A1	22.04.2023

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	√	

### 4. ELECTRICAL SAFETY

#### 4.1 LOAD TEST (MAINS VOLTAGE)

SL. NO.	Specification	Measured Value (V)	Allowable Limit (V)	Uncertainty ± (%)	Remarks
1	Live to Neutral	227	230 ± 10 %	7.59	Pass
2	Live to Earth	230	230 ± 10 %	7.59	Pass

CALIBRATED BY (CALIBRATION ENGINEER)

AUTHORIZED BY (QM/TM/DY.TM/Str.Er)

UDAIYAPPAN S

KAMALAKANNAN R

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### 4.2 GROUND WIRE RESISTANCE

SL. No.	Specification	Measured Value (Ω)	Allowable Limit (Ω)	Uncertainty ± (%)	Remarks
1	Earth Wire Resistance	0.132	<0.2	9.14	Pass

### 4.3 INSULATION TEST

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

### 4.4 EARTH LEAKAGE

SL. NO.	Specification	Measured Value (μA)	Allowable Limit (μA)	Uncertainty ± (%)	Remarks
1	Normal Condition	120	<5000	8.21	Pass
2	Open Neutral (SFC*)	174	<10000	8.21	Pass

### 4.5 ENCLOSURE LEAKAGE

SL. NO.	Specification	Measured Value (μA)	Allowable Limit (μA)	Uncertainty ± (%)	Remarks
1	Normal Condition	39	<100	8.21	Pass
2	Open Neutral (SFC*)	75	<500	8.21	Pass

### 4.6 PATIENT LEAKAGE

SL. NO.	Specification	Measured Value (μA)	Allowable Limit (μA)	Uncertainty ± (%)	Remarks
1	Normal Condition	6	<10	8.21	Pass
2	Open Neutral (SFC*)	12	<50	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  $k=1.96$ , which for a normal distribution corresponds to a coverage probability 95%.
- SFC - Single Fault Condition.

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Calibration Label / Status :

White : Calibrated



Green : Accepted - Valid for use



Yellow : Limited use (Refer report)



Red : Rejected-Out of use (Refer report)



\* NEXT CALIBRATION DUE AS PER CUSTOMERS PLAN AND REQUIREMENT