



**REPORT ON
ELECTRICAL SAFETY TESTING/ PERFORMANCE ANALYSIS/ CALIBRATION**

Report No : TR/APHC/022/23-24
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Calibration Date : 08/03/2023
Calibration Due : 07/03/2024

1.1 CUSTOMER DETAILS

Name and address of the organisation

Primary Health Centre
New Gh Road, Opposite State Bank Of India, Ayalur,
Gobichettipalayam, Erode District,
Tamil Nadu, 638453

Reference and Date
Date of receipt of item

Letter dated 08-03-2023
08/03/2023

1.2 DESCRIPTION OF DEVICE UNDER TEST (DUT)

NOMENCLATURE

VDRL SHAKER

Manufactured by

KEMI

Model

KVDRL

Serial No.

3039

Biomedical Product ID

APHC/LAB /VDRLS/001

Supply

220V-240V AC

Device Type

Type B

Device Classification

Class II equipment

Location

LABORATORY

1.3 CONDITION OF THE ITEM WHEN RECEIVED

No visible damage and in working order

1.4 ENVIRONMENTAL CONDITION OF MEASUREMENTS

A.Temperature

26.6°C

B.Relative Humidity

45-75%

C.Ambient Barometric Pressure

756mmHg

1.5 Applicable Specification

IEC Specification IEC 60601-1, IEC 60601 -2-27

1.6 Test Done

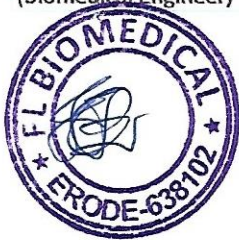
Electrical Safety and Performance Testing

Tested by :

Approved by :

Balamuralikrishnan K
(Biomedical Engineer)

Priya M
(Quality Manager)



FL BIOMEDICAL
189, Vasantham Paradise,
Chithode, Erode-638102.
Cell: 7092848995



1.7 STATUS

Manuf Specification	Users Specification	Within Specification	Out of Specification	Calibration	Electrical Safety Test	Performance Analysis
✓	-	✓	-	✓	✓	✓

1.8 TRACEABILITY DETAILS OF INSTRUMENTS USED FOR TESTING

SI No	Name of the Instrument	Make	Model	Serial No	Cal Due	Traceability Reference
1	Digital Tachometer	WACO	DT-2234C	1804160817	14-Aug-23	Annexure 1
2	ESA	RGM	288+	05H-0600	14-Aug-23	Annexure 3

1.9 PERFORMANCE ANALYSIS OF VDRL SHAKER

Speed Output In RPM	50	100	150	200	ACCURACY	RESULT
T1	51.61	109.48	157.24	200.71	±10 RPM	PASS
T2	52.59	103.18	156.08	201.5		PASS
T3	55.88	100.89	151.2	207.22		PASS
T4	51.67	103.55	155.77	207.35		PASS
T5	59.42	104.14	157.81	200.25		PASS
N	5	5	5	5		
MEAN	54.234	104.248	155.62	203.406		
UNCERT Δδ	1.82	1.41	1.26	1.51		
(K=2) CI @95%	50 ± 1.82	100 ± 1.41	150 ± 1.26	200 ± 1.51		

2.0 ELECTRICAL SAFETY TEST

SI.No	Parameter	Observed value	Cal & M.capl	Acceptable limits as per the Std.	Remarks
1	Protective earth resistance	0.297 Ω	±3%	0.0 Ω - 0.3 Ω	ok
2	Chassis Leakage	95 μA	±5%	1 μA - 100 μA NC	ok
		354 μA	±5%	1 μA - 500 μA SFC	ok
3	Patient leakage current	154 μA	±5%	1 μA - 100 μA B & BF(NC)	ok
		10 μA	±5%	1 μA - 10 μA CF (SFC)	ok
4	Earth Leakage	497 μA	±5%	1 μA - 1000 μA B.BF.CF (NC)	ok
		4398 μA	±5%	1 μA - 5000 μA B.BF.CF (SFC)	ok
5	Insulation Resistance 500 V DC	Success	±5%	≥2 MΩ	ok
6	Equipment current	0.1 A	-	As per manufacture spec	ok
7	Mains voltage	234V	-	As per manufacture spec	ok

3.0 REMARKS

- 3.1 This report is applicable to the sample tested only.
- 3.2 The instruments used for testing are under valid calibration and are traceable to National Standards.
- 3.3 Parameter of the DUT were verified and found to be within the specified limits.
- 3.4 refer NABL Doc No. 121 Clause 7.0 Accommodation and environmental Conditions sub Clause see 7.2.11 below in line with ISO/IEC 17025:2005 Clause 5.3

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