



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

Report No : TR/GPHC/025/23-24

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Calibration Date : 01-08-2023

Calibration Due : 31-07-2024

1.1 CUSTOMER DETAILS

Name and address of the organisation

Govt Primary Health Center,
The Medical Officer,
mini kovil street, T.pottakollal po,
udayarpalayam, Taluk, Ariyalur district,
Tamilnadu - 62180.
Letter dated 01-08-2023
01-08-2023'

Reference and Date

Date of receipt of item

1.2 DESCRIPTION OF DEVICE UNDER TEST (DUT)

NOMENCLATURE

Manufactured by

Model

Serial No.

Biomedical Product ID

Supply

Device Type

Device Classification

Location

BIOCHEMISTRY ANALYZER

ROBONIK

PRIETEST TOUCH

AT0730211RBK

GPHC/LAB/BCA/01

220V-240V AC

Type CF

Class II equipment

LABORATORY

1.3 CONDITION OF THE ITEM WHEN RECEIVED

No visible damage and in working order

1.4 ENVIRONMENTAL CONDITION OF MEASUREMENTS

A.Temperature

29.6°C

B.Relative Humidity

45-75%

C.Ambient Barometric Pressure

756mmHg

1.5 Applicable Specification

IEC Specification IEC 60601-1

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

Sl No	Name of the Instrument	Make	Model	Serial No	Cal Due	Traceability Reference
1	VITAL SIGNS MONITOR	RGM	UNI SIM LITE	46G-0632	14-Aug-23	Annexure 1
2	ISA	RGM	288+	05H-0600	14-Aug-23	Annexure 3

1.9 PERFORMANCE ANALYSIS OF BIOCHEMISTRY ANALYZER

ELECTRICAL SAFETY TEST

Sl.No	Parameter	Observed value	Cal & M.Cap	Acceptable limits as per the Std.	Remarks
1	Protective earth resistance	0.137 Ω	±3%	0.0 Ω - 0.3 Ω	ok
2	Chassis Leakage	97 μA	±5%	1 μA - 100 μA NC	ok
		370 μA	±5%	1 μA - 500 μA SFC	ok
3	Patient leakage current	167 μA	±5%	1 μA - 100 μA B & BF(NC)	ok
		8 μA	±5%	1 μA - 10 μA CF (SFC)	ok
4	Earth Leakage	453 μA	±5%	1 μA - 1000 μA B.BF.CF (NC)	ok
		3714 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	235V	-	As per manufacture spec	ok

2.0 REMARKS

- 2.1 This report is applicable to the sample tested only.
- 2.2 The instruments used for testing are under valid calibration and are traceable to National Standards.
- 2.3 Parameter of the DUT were verified and found to be within the specified limits.
- 2.4 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

Tested by :

Balamuralikrishnan K
(Biomedical Engineer)



Approved by :

Priya M
(Quality Manager)

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Chithode, Erode-638102,
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FL Biomedical

Leading the Way in Healthcare Excellence



Planned Preventive Maintenance

Customer Name : The Medical Officer,
Government Primary Health Center,
mini kovil street, T.pottakollai po,
Udayarpalayam - Taluk,
Ariyalur district,
Tamilnadu - 62180.



1. Equipment Name : BIOCHEMISTRY ANALYZER
2. Company/Make : ROBONIK
3. Serial No. : AT0730211RBK
4. Reference ID as per inventory : GPHC/LAB/BCA/01
5. Warranty Period : nil
6. Under AMC/CAMC : CAMC
7. CAMC Order & Ref No. & Date : TR/GPHC/025/23-24
8. Frequency of Preventive Maintenance/Calibration : Half Yearly
 - a. as per manufacturer guidelines : Half Yearly
 - b. presently being followed : Quarterly
9. Preventive Maintenance/Calibration Done On : 01.08.2023
10. Preventive Maintenance/Calibration Due On : 31.07.2024
11. Expenditure with cost and details :
12. Engineer Name : Balamuralikrishnan.K
13. Remarks with Functional Status : Good Working Condition
14. TNMSC Equipment ID :
15. CAMC Visit Details : Onsite Call -1
16. Inspected Date : 01.08.2023
17. Customer Remarks :

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District BME Sign & Seal

Hospital's Sign & Seal