

Pinnacle Safety Engineers

(Expert in Healthcare Safety Solutions)

CALIBRATION CERTIFICATE OF BIOCHEMISTRY ANALYSER

Issued to : RNC Hospital, Hyderabad
Certificate No. : PSE/CAL/RNC/23/02
Asset No. : RNC/BME/BIOC/THY/01 Serial No : 0101010012022100956
Model No : MAGLUMI 800 Date : 14.11.2023

CALIBRATION STANDARD USED

S NO	ASSET NO	TEST EQUIPMENT	MODEL NO	SERIAL NO	CAL DATE	CAL DUE DATE
1	PSE / NIBPA / 01	ELECTRICAL SAFETY ANALYSER	ESA - 612	2111026	15.05.2023	14.05.2024

TEST REPORT

ELECTRICAL SAFETY ANALYZER TEST RESULTS		
TEST	RESULTS	LIMITS
Line(Mains)Voltage	233.5	0.0 to 300.0V ac rms
Ground Wire Resistance	0.003Ω	0.000 to 2.000 Ω
Equipment current	1.4A	0 to 20.0 A ac rms
Insulation resistance	2 M Ω	+/-2% +0.2 M Ω
Ground(Earth) Leakage	12 μA(AC+DC)	10 to 199 Ma
Chassis(Enclosure)Leakage	0.6Ma	0.0 to 199.9 μA
Lead to Ground and Lead to lead	0.4 μA(AC+DC)	0.0 to 1999 μA
Lead isolation	0.4Ma	0.0 to 1999 μA
Differential Leakage	0.1Ma	0.0 to 1999 μA
Direct Equipment Leakage	0.3μA	0.0 to 1999 μA
Direct applied part Leakage	0.7Ma	0.0 to 1999 μA
Alternative applied part patient leakage	0.01Ω	0.0 to 1999 Ma
Point to point leakage, Voltage and Resistance	0.2μA,0.2v&OLΩ	+/-2% +0.2V

Electrical safety test passed as per IEC Stand 60601.1

Calibration Passed: Yes No

Calibration Done Date: 14.11.2023

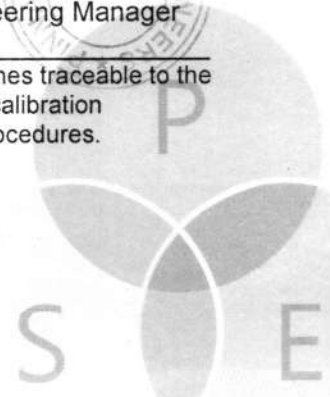
Calibration Due Date: 13.11.2024

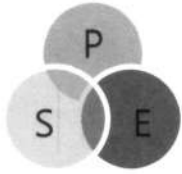
Calibrated By: Mr. D. Utpalendu, Engineer

Approved By:


Engineering Manager

The above mentioned instrument has been certified using standards with accuracy guidelines traceable to the national institute of standards & technology (NIST). Devices, for which there are no NIST calibration standards, were measured against in-house performance standard using accepted test procedures.





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CALIBRATION CERTIFICATE OF PIPETTE

Issued to : RNC Hospital, Hyderabad
Certificate No. : PSE/CAL/RNC/23/04
Asset No. : RNC/BME/BIOC/PIP/01 Serial No : SW01496
Model No : FINNPIPETTIES (100-1000 μ l) Date : 14.11.2023

Description: Pipette

Range: 100 to 1000 μ l

LC: 0.1 μ l

Accuracy: As per manual

Details of Master Equipments:

S/No.: NA, ID No.:MCLES-M-ID-002, Valid upto: 11-Sept-2024, Traceability: PSE Cal. Lab.

Work Instruction: WI-M-03

Reference standards: NABL NEWS ISSUE NO. 40 OCT 2005, IS 878, IS 915, IS 1117, IS 1997, IS 8897, OIML R40, OIML R41, OIML R43, OIML R4.

Environmental details: Temperature: 23 \pm 2⁰c, **Relative Humidity:** 40-60 %RH

TEST REPORT

Measured Value (UUC) μ l	Actual Value μ l	Deviation μ l	Uncertainty (+-) MI
100	100.02	-0.02	0.275
500	500.07	-0.07	
1000	1000.10	-0.10	

Calibration Passed: Yes No

Calibration Done Date: 14.11.2023

Calibration Due Date: 13.11.2024

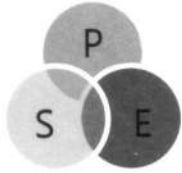
Calibrated By: Mr. D. Utpalendu, Engineer

Approved By:


Engineering Manager

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CALIBRATION CERTIFICATE OF PIPETTE

Issued to : RNC Hospital, Hyderabad
Certificate No. : PSE/CAL/RNC/23/05
Asset No. : RNC/BME/BIOC/PIP/02 Serial No : SW01482
Model No : FINNPIPETTIES (FIXED 200 μ l) Date : 14.11.2023

Description: Pipette

Range: 100 to 1000 μ l

LC: 0.1 μ l

Accuracy: As per manual

Details of Master Equipments:

S/No.: NA, ID No.:MCLES-M-ID-002, Valid upto: 11-Sept-2024, Traceability: PSE Cal. Lab.

Work Instruction: WI-M-03

Reference standards: NABL NEWS ISSUE NO. 40 OCT 2005, IS 878, IS 915, IS 1117, IS 1997, IS 8897, OIML R40, OIML R41, OIML R43, OIML R4.

Environmental details: Temperature: 23 \pm 2⁰c, **Relative Humidity:** 40-60 %RH

TEST REPORT

Measured Value (UUC) μ l	Actual Value μ l	Deviation μ l	Uncertainty (+-) MI
100	100.02	-0.02	0.275
150	150.09	-0.09	
200	200.04	-0.04	

Calibration Passed: Yes No

Calibration Done Date: 14.11.2023

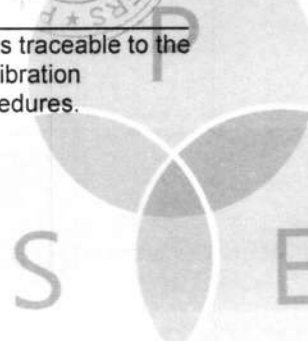
Calibration Due Date: 13.11.2024

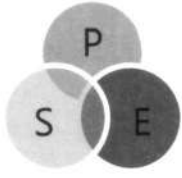
Calibrated By: Mr. D. Utpalendu, Engineer

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CALIBRATION CERTIFICATE OF PIPETTE

Issued to : RNC Hospital, Hyderabad
Certificate No. : PSE/CAL/RNC/23/06
Asset No. : RNC/BME/BIOC/PIP/03 Serial No : RW21879
Model No : (10 - 100 μ l) Date : 14.11.2023

Description: Pipette

Range: 100 to 1000 μ l

LC: 0.1 μ l

Accuracy: As per manual

Details of Master Equipments:

S/No.: NA, ID No.:MCLES-M-ID-002, Valid upto: 11-Sept-2024, Traceability: PSE Cal. Lab.

Work Instruction: WI-M-03

Reference standards: NABL NEWS ISSUE NO. 40 OCT 2005, IS 878, IS 915, IS 1117, IS 1997, IS 8897, OIML R40, OIML R41, OIML R43, OIML R4.

Environmental details: Temperature: 23+-2⁰c, **Relative Humidity:** 40-60 %RH

TEST REPORT

Measured Value (UUC) μ l	Actual Value μ l	Deviation μ l	Uncertainty (+-) MI
10	10.05	-0.05	0.275
50	50.06	-0.06	
100	100.08	-0.08	

Calibration Passed: Yes No

Calibration Done Date: 14.11.2023

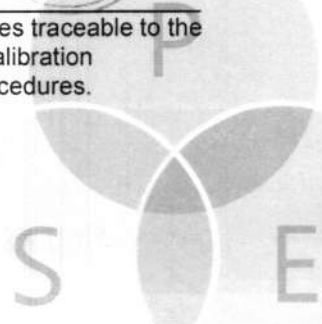
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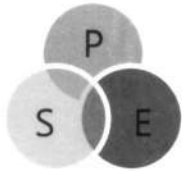
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Approved By:


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CALIBRATION CERTIFICATE OF INCUBATOR

Issued to : RNC Hospital, Hyderabad
Certificate No. : PSE/CAL/RNC/23/07
Asset No. : RNC/BME/BIOC/INC/01 Serial No : 91220146
Model No : SISCO Date : 14.11.2023

METHOD OF CALIBRATION

The calibration certificate was produced in accordance to the instrument was calibrated for the points specified in the relevant in house technical procedure PSE-CP-T01-2023 as defined for the equipment.

The designed instrument has been calibrated at PSE calibration laboratory under the ambient conditions.

RESULT OF CALIBRATION

1. The measured values are average of 3 readings
2. The result stated in the certificate relate only to the item calibrated.
3. The report expanded uncertainty is calculated at 95.45% confidence levels with a coverage factor of $k = 2$

REMARKS

- The result of the calibration are given on the attached following pages
- No adjacement was done unless otherwise stated.
- Corrections / erasing, invalidate the calibration certificate
- The user should determine the suitability of the instrument for its intended use
- The report shall not be reproduced except in full, unless the management representative of PSE Calibration has given approval in writing and comply with the requirements specified in ISO/IEC 17025
- Any error in this certificate should be brought to our knowledge within 30 days from the date.

RANGE	STANDARD READINGS (REF)	TEST READINGS (UUT)	ERROR	UNCERTAINTY (+/-)
$^{\circ}\text{C}$	$^{\circ}\text{C}$	$^{\circ}\text{C}$	$^{\circ}\text{C}$	$^{\circ}\text{C}$
AMP-50	37.6	37	-0.6	0.98
	45.7	45	-0.7	0.98
	50.9	50	-0.9	0.98

Calibration Passed: Yes No

Calibration Done Date: 14.11.2023

Calibration Due Date: 13.11.2024

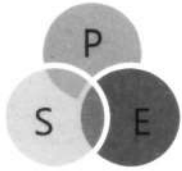
Calibrated By: Mr. D. Utpalendu, Engineer

Approved By:


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CALIBRATION CERTIFICATE OF ABG MACHINE

Issued to : RNC Hospital, Hyderabad
Certificate No. : PSE/CAL/RNC/23/01
Asset No. : RNC/BME/BIOC/ABG/01 Serial No : 754R2738N0019
Model No : ABL800 Date : 14.11.2023

TEST & PERFORMANCE REPORT

PARAMETERS	MEASURED VALUE	MEAN VALUE	ACCEPTABLE RANGE	RAMARKS
Calibration Buffer pH Units				
Cal (7.3 Buffer)	7.388	7.382	7.359 – 7.405	PASS
Slope (6.8 Buffer)	6.837	6.838	6.815 – 6.861	PASS
Calibration Gas mmHg				
pO ₂	76	77	+/- 4	PASS
pCO ₂	33.4	34	+/- 4	PASS
Slope Gas mmHG				
pO ₂	0.4	0.00		PASS
pCO ₂	68	70	+/- 4	PASS

FUNCTIONAL TEST

S No.	PARAMETERS	READINGS OR VALUES	REMARKS
1	Voltage between live & neutral	230 V	OK
2	Load Current (Ia)	0.54 A	OK
3	Differential Current (I)	1.8 mA	OK
4	Power (P)	46 W	OK
5	Apparent Power (AP)	84 VA	OK
6	Power factor (PF)	0.6	OK
7	Energy (W)	0.001 KWH	OK
8	Leaking Current (IL)	0.4 uA	OK
9	Patient Leakage Current (PL)	0.1 Ua	OK
10	Time for Testing (t)	1.3 min	OK


Calibration Passed: Yes No

Calibration Done Date: 14.11.2023

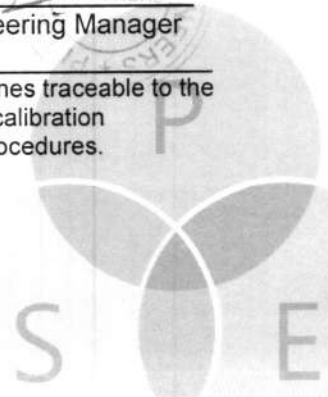
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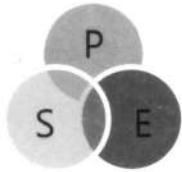
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Issued to : RNC Hospital, Hyderabad
Certificate No. : PSE/CAL/RNC/23/03
Asset No. : RNC/BME/BIOC/BTS/01 Serial No : 000-0000-634
Model No : BTS Date : 14.11.2023

CALIBRATION STANDARD USED

S NO	ASSET NO	TEST EQUIPMENT	MODEL NO	SERIAL NO	CAL DATE	CAL DUE DATE
1	PSE / NIBPA / 01	ELECTRICAL SAFETY ANALYSER	ESA - 612	2111026	15.05.2023	14.05.2024

TEST REPORT

ELECTRICAL SAFETY ANALYZER TEST RESULTS		
TEST	RESULTS	LIMITS
Line(Mains)Voltage	233.5	0.0 to 300.0V ac rms
Ground Wire Resistance	0.003 Ω	0.000 to 2.000 Ω
Equipment current	1.4A	0 to 20.0 A ac rms
Insulation resistance	2 M Ω	+/-2% +0.2 M Ω
Ground(Earth) Leakage	12 μ A(AC+DC)	10 to 199 Ma
Chassis(Enclosure)Leakage	0.6Ma	0.0 to 199.9 μ A
Lead to Ground and Lead to lead	0.4 μ A(AC+DC)	0.0 to 1999 μ A
Lead isolation	0.4Ma	0.0 to 1999 μ A
Differential Leakage	0.1Ma	0.0 to 1999 μ A
Direct Equipment Leakage	0.3 μ A	0.0 to 1999 μ A
Direct applied part Leakage	0.7Ma	0.0 to 1999 μ A
Alternative applied part patient leakage	0.01 Ω	0.0 to 1999 Ma
Point to point leakage, Voltage and Resistance	0.2 μ A,0.2v&OL Ω	+/-2% +0.2V

Electrical safety test passed as per IEC Stand 60601.1

Calibration Passed: Yes No

Calibration Done Date: 14.11.2023

Calibration Due Date: 13.11.2024

Calibrated By: Mr. D. Utpalendu, Engineer

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