



COTEX LAXMI HEALTHCARE PVT. LTD.

Sawangi Meghe ,Wardha-442001

CALIBRATION CERTIFICATE

1.Customer																																														
Name and Address of Customer: SHALINITAI MEGHE HOSPITAL AND RESEARCH CENTER,WANADONGARI HINGNA,NAGPUR,441110	Procedure No. CLH/CAL/20/TI/SOP/12 Date of Calibration: 21-04-2022 Due Date of Calibration 20-04-2023 Location of Calibration ON SITE Equipment Status OK																																													
Ambient Temp.: (25±2)°c RH : 45 %RH to 75 %RH																																														
2.Description of item																																														
Name: LABORATORY CENTRIFUGE Make: REMI Model: NA Sr.no. NA Type : DIGITAL	Department BIOCHEMISTRY LAB Location: BIOCHEMISTRY LAB Asset No.: 3104 Range: 3500RPM Calibration Certificate no.: CLH/CAL/SMHRC/CCL/CENT/01																																													
3.Equipment used for Calibration (Master)																																														
Name: Electrical Safety Analyzer Make/ Model: FlukeBiomedical/ESA612 Sr.No. 5188505 Certificate no. M-220224-2-1 Validity 26-02-2023	Name: Digital thermohygrometer Make/ Model: LUTRON/TM-902C Sr.No. NA Certificate no. ACS/126/CM/106/2100004 Validity 02-05-2023																																													
The Masters are traceable to National/International Standards.																																														
4. ELECTRICAL SAFETY																																														
4.(1) Visual Test Inspection																																														
<table border="1"><thead><tr><th>SR.NO.</th><th>TEST</th><th>REMARK</th></tr></thead><tbody><tr><td>1</td><td>Device clean and Decontaminated</td><td>OK</td></tr><tr><td>2</td><td>Physical Damage</td><td>OK</td></tr><tr><td>3</td><td>Power Cord, Cable checking</td><td>OK</td></tr><tr><td>4</td><td>Mains Socket Checking</td><td>OK</td></tr><tr><td>5</td><td>Alarm function</td><td>OK</td></tr><tr><td>6</td><td>Equipment type(B,BF,CF)</td><td>B</td></tr><tr><td>7</td><td>Equipment class(I,II,III)</td><td>I</td></tr></tbody></table>	SR.NO.	TEST	REMARK	1	Device clean and Decontaminated	OK	2	Physical Damage	OK	3	Power Cord, Cable checking	OK	4	Mains Socket Checking	OK	5	Alarm function	OK	6	Equipment type(B,BF,CF)	B	7	Equipment class(I,II,III)	I																						
SR.NO.	TEST	REMARK																																												
1	Device clean and Decontaminated	OK																																												
2	Physical Damage	OK																																												
3	Power Cord, Cable checking	OK																																												
4	Mains Socket Checking	OK																																												
5	Alarm function	OK																																												
6	Equipment type(B,BF,CF)	B																																												
7	Equipment class(I,II,III)	I																																												
B-Body Type, BF-Body Float Type, CF-Cardiac Float Type. I-Properly Earthed, II-Double Insulated, III-With Extra Safety Low Voltage.																																														
4.(2) Electrical Safety Test																																														
<table border="1"><thead><tr><th>SR.NO.</th><th>PARAMETERS</th><th>DESIRED VALUE</th><th>MEASURED VALUE</th><th>REMARK</th></tr></thead><tbody><tr><td>1</td><td>Voltage between live to neutral (V In)</td><td>220-240 V</td><td>229.8 V</td><td>OK</td></tr><tr><td>2</td><td>Voltage between live to earth (V Ic)</td><td>220-240 V</td><td>228.9 V</td><td>OK</td></tr><tr><td>3</td><td>Voltage between neutral to earth (V In)</td><td>0-5 V</td><td>0.3 V</td><td>OK</td></tr><tr><td>4</td><td>Load Current (Ia)</td><td>0-10 A</td><td>1.2A</td><td>OK</td></tr><tr><td>5</td><td>Earth Leakage Current (IL)</td><td>0-500 µA</td><td>90.5 µA</td><td>OK</td></tr><tr><td>6</td><td>Enclosure Current</td><td>0-10 µA</td><td>0.5 µA</td><td>OK</td></tr><tr><td>7</td><td>Patient Leakage Current (PL)</td><td>BF 0-100 µA,CF 0-10µA</td><td>0.3 µA</td><td>OK</td></tr><tr><td>8</td><td>Ground Wire Resistance</td><td>0Ω -3Ω</td><td>1 Ω</td><td>OK</td></tr></tbody></table>	SR.NO.	PARAMETERS	DESIRED VALUE	MEASURED VALUE	REMARK	1	Voltage between live to neutral (V In)	220-240 V	229.8 V	OK	2	Voltage between live to earth (V Ic)	220-240 V	228.9 V	OK	3	Voltage between neutral to earth (V In)	0-5 V	0.3 V	OK	4	Load Current (Ia)	0-10 A	1.2A	OK	5	Earth Leakage Current (IL)	0-500 µA	90.5 µA	OK	6	Enclosure Current	0-10 µA	0.5 µA	OK	7	Patient Leakage Current (PL)	BF 0-100 µA,CF 0-10µA	0.3 µA	OK	8	Ground Wire Resistance	0Ω -3Ω	1 Ω	OK	
SR.NO.	PARAMETERS	DESIRED VALUE	MEASURED VALUE	REMARK																																										
1	Voltage between live to neutral (V In)	220-240 V	229.8 V	OK																																										
2	Voltage between live to earth (V Ic)	220-240 V	228.9 V	OK																																										
3	Voltage between neutral to earth (V In)	0-5 V	0.3 V	OK																																										
4	Load Current (Ia)	0-10 A	1.2A	OK																																										
5	Earth Leakage Current (IL)	0-500 µA	90.5 µA	OK																																										
6	Enclosure Current	0-10 µA	0.5 µA	OK																																										
7	Patient Leakage Current (PL)	BF 0-100 µA,CF 0-10µA	0.3 µA	OK																																										
8	Ground Wire Resistance	0Ω -3Ω	1 Ω	OK																																										

5. Performance Test

SR.NO.	CALIBRATION POINT °c	STANDERED READING °c	UUC READINGS °c	ERROR IN °c
1	30	29.367	30	0.633
2	80	79.967	80	0.033
3	100	99.333	100	0.667
4	110	111.833	110	-1.833

Remark: 1.The equipment is functioning with in the normal limits

Note:

- 1) Prior to the calibration of this electrical safety parameters such as ground wire resistance, chassis Leakage, Patient Leakage Current, Patient Lead Leakage Current: Isolation Test (mains on applied part), Insulation (optional) 500 V etc. verified as per IEC-60601/62353 and found within limits.
- 2) The standards used for calibration were calibrated by using reference standard traceable to National/International standard & Calibration Points were selected as per customers Specification.
- 3) The reported uncertainty is expanded uncertainty in measurement obtained by multiplying the coverage factor k=2, which corresponds to coverage probability of approximately factor k=2, which corresponds to coverage probability of approximately 95% for normal distribution.
- 4) The certificate refers only to the particular item submitted for calibration. UUC stand for normal distribution.
- 5) The calibration results reported in the certificate are valid at the time for and under the stated condition of measurement.
- 6) Calibration point were selected as per customer specification and calibration report traceable to national or international standard
- 7) This certificate shall not be reproduced, except in full unless written permission for the publication of an approved abstract has been obtained from the Technical manager of COTEX LAXMI HEALTHCARE PVT. LTD. WARDHA.

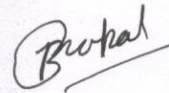
Calibrated By



Calibration Engineer



Approved by



Technical Manager

National Accreditation Board for Testing and Calibration Laboratories

Doc No.:39 Specific Criteria for calibration of Medical Devices

Issue No.:01

Issue Date: 1/01/2021

Amend No.: 1

Amend Date: 1/1/2021

Page No.:02