

Parashar Micro Measurement Pvt. Ltd.

Unit-II : J-22, Site-C, Surajpur Industrial Area, UPSIDC, Greater Noida (U.P.)

PH.: 0120-4252360-65, Email : pmmpl.india@gmail.com

Website : www.pmmpl.in, www.parashar.info



The way to Technology
(17 Years of Excellence)

Calibration Certificate

Certificate Number : PMM/BM/731434		Page 1	
Calibrated For	M/s. Som Datt Medical Centre S - 524, School Block , Shakarpur Delhi - 110092	Calibrated on	31.01.2022
		Valid Upto	30.01.2023
		Cert. Issue Date	01.02.2022

Description of Equipments

Nomenclature	Bio Chemistry Analyzer	Accuracy/Class	As per specification
Test Type	Electrical Safety Test	Condition of UUC	Physically Ok
Make	ELI Techogroup	Party ID Mark No.	2
Model No.	Microlab 300	Location	Path Lab
Mfr. S.No.	17-43307		

Master Equipment / Standard Used

Sr.No.	Nomenclature	Make & Model	Serial No. / I/D Mark	Calibrated From	Certificate No.	Due Date of Calibration
1	Electrical Safety Analyzer	Fluke/ ESA612	PMM/BM/ESA-01	FLUKE CORPORATION	PC-EVT-0D3B	31.03.2022

Standard used for calibration are traceable to National/International Standards through unbroken chain of calibration.

Calibration Performed at	AT SITE	Environmental	Temperature = 25 ± 5° C
Calibration Procedure No.	PMM/II/BMCP/01	Condition(s)	Humidity = 50 ± 10 % RH
Reference Standard / Guideline	IEC-60601-1		

CALIBRATION RESULTS

1.0 Main Line Test

a. Main Line Voltage supply working properly	Yes
b. Main Line ground connected properly	Yes

2.0 Earth Resistance Test

Sr.No.	Max Limit (Ω)	Actual Observed Value (Ω)	Remark
1	2.0	0.231	Pass

3.0 Polarity Test Pass

	Yes
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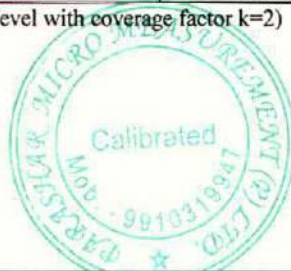
4.0 Safety test

Sr.No.	Parameter	Permitted Values	Measured Values	Deviation%	Remarks (Pass/Fail)
1	Ground Wire Resistance	<0.3Ω	0.246	-0.00054	Pass
2	Chassis Leakage	<100 μANC	94 μA	-0.06	Pass
		<500 μASFC	N/A	N/A	N/A
3	Pateint Leakge Current	<100 μABandB F	N/A	N/A	N/A
		<10 μACF	1.2 μA	-0.088	Pass
4	Patient Lead Leakage Current, Isolation Test	<100 μABF	N/A	N/A	N/A
		<10 μACF	1.0 μA	-0.09	Pass
5	Insulation (Optional) 500V	<2MΩ	OR MΩ	N/A	N/A

Uncertainty of measurement (at approx. 95% confidence level with coverage factor k=2)

1.22%

Calibrated By : Gordhan Bairwa
Designation : Calibration Engineer



Approved By: Vikram Parashar
Designation : Technical Manager

- Conditions : 1. This certificate refers only to the particular item submitted for calibration.
2. The calibration result reported in this certificate are valid at the time of and under the stated conditions of measurement.
3. This particular certificate can not be reproduced except in full, without prior permission of chief executive officer of the lab.

Name & Address of Customer : Sahdatt Medical Centre
S-224, School Block, Motarapur - Delhi
- 110092
STATE: Delhi PIN: 110092

Phone: 7065123669E-Mail: Sahdattmedicalcentre@shajid.comName of Instrument : **Microlab 300 LX**(w/o inbuilt printer) **Microlab 300 EX**(with inbuilt printer) Type : **Semi Automatic Biochemistry Analyser**Serial No : 17-43307Installation Date : 08-05-2018Calibration Date : 19-05-2022Next Calibration Due on : 18-05-2023

This is to certify that above said instrument has been validated by hardware calibration for Filters, Aspiration (Pump), Temperature & Lamp according to the procedures provided by Vital Scientific, Netherlands (Elitech Group).

This calibration is carried out by using Standard Operating Procedures (S.O.P.) provided by Vital Scientific (Elitech Group Company) and traceable to Vital Scientific standards.

This instrument conform to IVD & EU directives of use.

Calibration carried out on site by:Sahj

Signature

Name of Service Engineer : Gantabulohy

Instrument Service Division

Q-Line Biotech Pvt. Ltd.

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28/5/22**Q-LINE BIOTECH PRIVATE LIMITED (Formerly known as "POCT Services Pvt. Ltd.")**Corp. Office: 20A (Basement), Main Shivaji Marg, Najafgarh Road, Near Moti Nagar Police Station, New Delhi-110015, INDIA. Tel.: 011-45577407
Regd. Office: 298-281, Transport Nagar, Kanpur Road, Adjacent Transport Nagar Metro Station, Lucknow-226023 (U.P.), INDIA. Tel.: 0522-2433023

E-mail: info@qlinebiotech.com | Website: www.qlinebiotech.com

12-01-2022

Installation Qualification(IQ)



Company (Name & Add) : POCT
Services

Customer (Name & Add) : Sahdev
Medical Centre
Shakti Nagar - Delhi - 110022

Contact Person : Mr. Gaurav

Contact Person : Mrs. - Jyoti

Telephone No. : 9310777135

Telephone No. : 7065123663

Name of instrument : **Microlab 300 LX** **Microlab 300 EX (with inbuilt printer)** (Select by \checkmark)

Serial no. : 17-43307

Installation Date : 18-05-2018

Installation (Perform the Following steps)

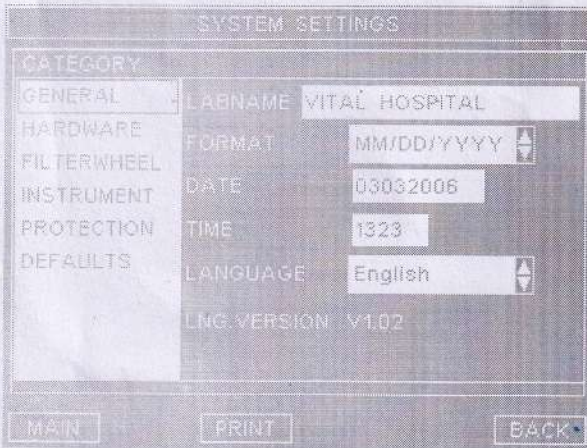
- Check Power Supply 230 V ($\pm 10V$)
- Check Earth ... 0.3 V (< 5.0 V)
- Room Temperature ... 25.2 ... ($15^{\circ}C$ to $30^{\circ}C$)
- Install Instrument on Flat & Dry Surface by leaving a gap between instrument & back wall
- Install waste Tube by connecting it from back side of instrument & attach waste container with tube.
- Install internal/external printer (If required)
- Install Power Supply by connecting power chord to the back side of instrument
- Start up the Analyser by switching on from backside power on button.
- Check display & wait for instrument to boot up/initialise. Press exit key to exit washing step.
- Check the keypad key functioning & adjust the display contrast from '+' '-' Key as per suitability
- Place distilled water under the sipper tube
- Check the aspiration of the system by pressing FLUSH key (approx Asp 1500 μ l in one cycle)
- Perform wash with cleaning solution & then with Distilled water (5 Cycles each) from FLUSH key

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28/5/22

Operational Qualification (OQ)

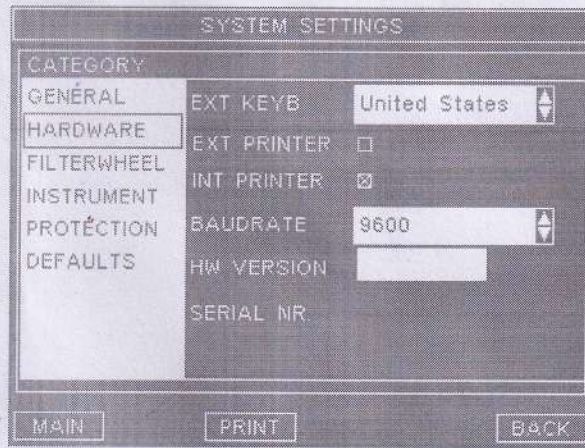


- Set the System Parameters from Main Menu->PROGRAM->SYSTEM SETTINGS->Type Password
- Input the GENERAL details in the various fields as per picture (FIG 1) shown below by making selections with cursor keys for Lab Name, Date format, Date & Time.



SYSTEM SETTINGS	
CATEGORY	
GENERAL	LABNAME VITAL HOSPITAL
HARDWARE	FORMAT MM/DD/YYYY
FILTERWHEEL	DATE 03032006
INSTRUMENT	TIME 1323
PROTECTION	LANGUAGE English
DEFAULTS	LNG VERSION V1.02

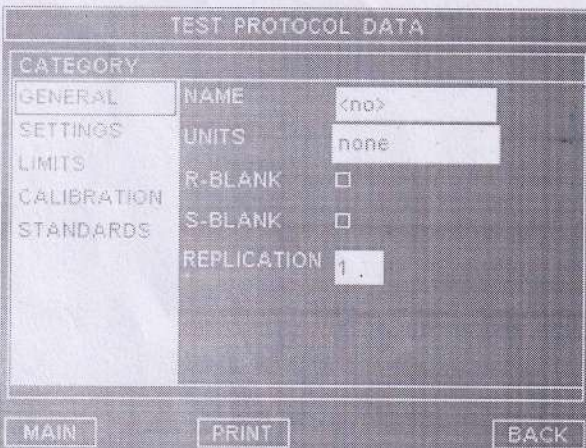
(FIG 1)



SYSTEM SETTINGS	
CATEGORY	
GENERAL	EXT KEYB United States
HARDWARE	EXT PRINTER <input type="checkbox"/>
FILTERWHEEL	INT PRINTER <input checked="" type="checkbox"/>
INSTRUMENT	BAUDRATE 9600
PROTECTION	HW VERSION
DEFAULTS	SERIAL NR.

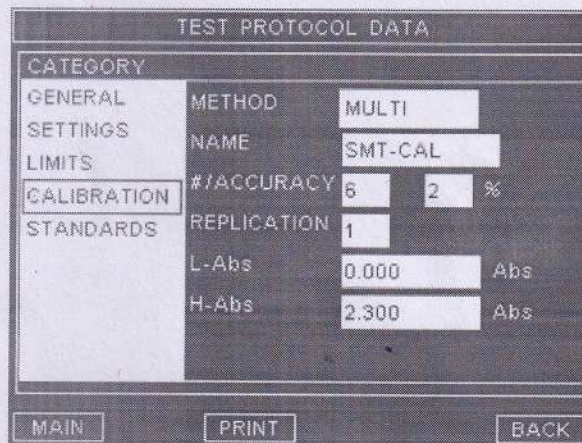
(FIG 2)

- Set the Hardware Parameter & deactivate the printers (if inbuilt/external printers not available) as per picture (FIG 2) above. All entries are Autosaved.
- Program a user defined test: New, Edit, Del. from Main Menu->PROGRAM->Select TESTS->Type Password
- Press the softkey NEW to add a new test to the analyzer, or use the UP and DOWN keys to select a test and press the softkey EDIT to edit the test or DEL to delete the test.
- Input various technical parameters like Name, units, Wavelength, calibration etc as per requirement of test protocols as per below pictures (FIG 3 & FIG 4).Make Selection by using cursor
- All entries are autosaved.



TEST PROTOCOL DATA	
CATEGORY	
GENERAL	NAME <no>
SETTINGS	UNITS none
LIMITS	R-BLANK <input type="checkbox"/>
CALIBRATION	S-BLANK <input type="checkbox"/>
STANDARDS	REPLICATION 1

(FIG 3)



TEST PROTOCOL DATA	
CATEGORY	
GENERAL	METHOD MULTI
SETTINGS	NAME SMT-CAL
LIMITS	#/ACCURACY 6 2 %
CALIBRATION	REPLICATION 1
STANDARDS	L-Abs 0.000 Abs
	H-Abs 2.300 Abs

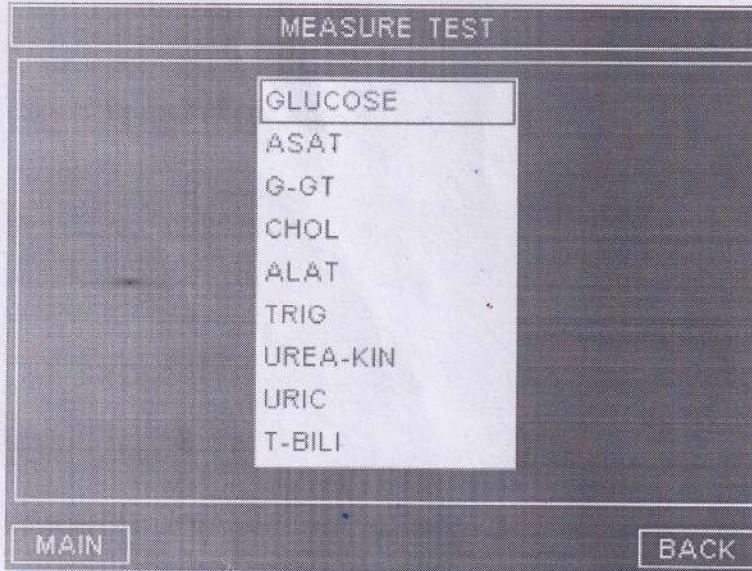
(FIG 4)

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Operational Qualification (OQ)



- From the MAIN MENU, select MEASURE. Press ENTER. The below screen shows.



- Use the UP and DOWN arrow keys to select the required test. Press ENTER.
- Start the test and do water blank
- Run Reagent Blank for the test programmed (whichever test requires)
- Run Calibrations for programmed tests by using standards or calibrators (whichever test requires)
- System is now ready for performance check.

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28/5/22

PERFORMANCE QUALIFICATION (PQ)



- Run Reagent Blank
- Run Calibrations
- Run QC material for several clinical chemistry applications
(a few enzymes, a few substrate tests using customer's reagent)

Test	QC Range Level 1	Test Result	QC Range Level 2	Test Result
GLUCOSE	[68-93] 81	72	[158-218] 188	195
CHOL	[147-193] 170	1.81	[186-254] 220	236
ALT/GPT	[39-57] 48	51	[131-209] 170	168
AST/GOT	[31-45] 38	40	[177-263] 220	197
CREAT	[0.78-1.42] 1.10	0.93	[2.02-3.32] 2.67	1.92
UREA	[18-33] 26	28	[68-96] 82	91

Remarks:

We hereby certify that Instrument standardization / calibrations have been carried out under the Warranty/ AMC. Verified by evaluating controls before processing patients Samples and obtained results are satisfactory. Instrument is ready for regular use.

Technical acceptance

Date (dd-mm-yyyy) : 18-05-2018

Service Engineer/Application Person Name

Gantabudhi

Customer Name

Jayallas

Jay 18/5/2018

Signature :

Jay

Signature & Stamp

SOM DATT MEDICAL CENTRE
Polyclinic & Diagnostic Centre
Shakarpur, Delhi-110 092

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