

Date: 07/09/2024

Certificate of Calibration

Name & Address of Customer: Pathology Lab, Combined/TB Hospital
Lucknow, UP

City -Lucknow

State- Uttar Pradesh

PIN: 226003

Name of Instrument: Selectra Pro-M

Type: Random Access Fully Automatic Biochemistry Analyser

Serial No: 16-4033

Calibration Date: 07/09/2024

Next Calibration Due: 06/09/2025

This is to certify that above said instrument has been validated of hardware calibration for Filters, Aspiration, Temperature & Lamp according to the procedures provided by Elitech Group Clinical Systems, France.

This calibration is carried out by using Standard Operating Procedures (S.O.P.) provided by Elitech Group, shown in the attachment.

These instruments conform to CE-IVD & EU directives of use.

Calibration carried out on site by

Signature & Stamp

Name of Engineer: MR. Shivam Yadav
POCT Services Pvt. Ltd

Encls.- SOP of Validation/Calibration along with data.

Validation / Calibration - SOP

Selectra Pro S/ Pro M

Name of the Customer:	Pathology Lab, Combined/TB Hospital
Address:	Thakurganj, Lucknow, UP
Sr No:	16-4033
Status: Warranty/ AMC	Validation & Preventive Maintenance

➤ Power Supply

Measure Input power Supply Voltage: 228V (230 V AC \pm 10 V)

Check Earthing: 2V (0 - 5 V)

➤ Ambient temperature: 27.5° C (10 - 35 ° C)

➤ Appearance: Clean_ (Clean/Dusty)

➤ Bellow Pumps: Open the pump assays and clean it thoroughly.

➤ Analyzer Control

Filter: Select the desired position through the Service menu.

Filter wheel sets the desired Filter: Yes

Filter Status: Needs replacement (Yes/ NO)

ρ 340nm ρ 405nm ρ 505nm ρ 546 nm ρ 578 nm ρ 620 nm ρ 660 nm ρ 700 nm

Temperature: Select the desired Options through the Service mode.

Temperature OK: Yes

Pump: Select the desired volume through the Service mode

Verify by aspirating the same Quantity: OK

Valve: Select the desired position through the service mode.
Valve is energized: Yes

Syringes: Check for syringe leakage by physical inspection of syringes.
No water leakage Found.

Cuvette Drier Block: Check the condition of cuvette drier block by removing the cover of cuvette rotor and lifting the wash arm through service menu. It should be reasonably clean. If dirty, please change the drier block

Mixer Belts – Check the elasticity of mixer belts. Should be reasonably good or replace the belts.

Cuvette Rotor Blank: Perform rotor blank and check the OD values of cuvettes. All cuvette blank OD values should be within acceptable range. If required replace the cuvette rotor.

Hardware Calibration of Selectra Pro S/Pro M

➤ Lamp Calibration/Alignment

Lamp Adjustment: -

1. Flush the system with distilled water by doing Rotor Blank.
2. Select Adjust Lamp in service menu. Check Value obtained on Display. (Adjust the lamp, if it is out of 1.800 to 3.800, to as low as possible)

Do not touch lamp !! It may be Hot !!

Lamp alignment Data @ 340 nm wavelength			
Lamp Abs Obtained	Acceptable Range	Alignment	Remarks
3.57Abs	1.800 to 3.800 abs	Done	Lamp O.D.in acceptable range. No replacement required.

➤ Checking the filters

Perform filter check in adjust lamp mode in service menu.

All the arrows must be in Green area. If not, then adjust lamp or replace filter if necessary.

Note:

When the absorbance value is too low to measure, i.e., the gain is too high, in this case, instead of the absorbance value, the value -99999 is shown.

Filter (Wavelength)	Gain Range	Gain Achieved	Remarks	Corrective Action
340	0.1 - 3.2	2.91	OK	Not required
405	0.1 - 2.6	1.94	OK	Not required
505	0.1 - 2.6	1.10	OK	Not required
546	0.1 - 2.6	1.02	OK	Not required
578	0.1 - 2.6	0.88	OK	Not required
620	0.1 - 0.9	0.47	OK	Not required
660	0.1 - 0.7	0.28	OK	Not required
700	0.1 - 0.7	0.37	OK	Not required
Over all Remarks	Filter gains within acceptable range. No replacement required.			

If it is necessary to replace defective filters, please contact service department.

REGISTERED OFFICE : 280/9-Kha, Blunt Square, Lucknow-226004, Uttar Pradesh, INDIA
DELHI NCR : 20A, Basement Floor, Main Shivaji Marg, Najafgarh Road, Near Moti Nagar Police Station, New Delhi-110015, Delhi, INDIA
Tel.: 011-45577407, E-mail : poctdelhi@pocservices.com, Website : www.pocservices.com



➤ Calibration/Verification of performance of Pipetting system & measuring unit

- Install dichromate solution on reagent rotor(s) & as sample on sample rotor (Use service disk which has Pre-defined protocol installed for dichromate run).
- Run 10x "Check-S" and 10x "Check-R" as QC samples.

Test	Target Value	Target CV%	Mean Result	CV[%]
Check-S	0.08(0.060-0.100)	<1%	0.077	0.689

Remarks:

Rotor Blank Acceptable. Instrument ready for chemical installation & calibration.

- Change reagent disk from Service to Standard
- Install the various reagents on reagent rotor(s)
- Install ISE reagents on reagent rotor(s) (If applicable)
- Run Reagent Blanks(s)
- Run Calibrations

Volume calibration of pipettors:-

It is possible to check a predetermined amount of water to check the correct functioning of the pump. Before carrying out this check, the instrument must first carry out a flush routine to ensure that all system tubes are completely filled with water by doing fill system.

1. Go to Sample syringe full stroke. (For Pro M Model Only)
2. Collect the dispensed water. Check the dispensed volume using calibrated pipette. (For Pro M only)

Pipettor Calibration Data using distilled Water		
Full stroke volume to be dispensed (µl)	Dispensed volume checked and found complying as full stroke volume? (Yes/No)	Remarks
Sample Syringe:		
100	Yes	Pass
100	Yes	Pass
100	Yes	Pass
Reagent syringe:		

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Tel.: 011-45577407, E-mail : pocktdelhi@pocservices.com, Website : www.pocservices.com



1000	Yes	Pass
1000	Yes	Pass
1000	Yes	Pass

Data for volumes other than full stroke: -

This can be verified using pre-determined amount of distilled water in sample/regent cups and running any dummy program. As soon as the reagent probe/sample probe takes up the sample/reagent, those cups/bottles are taken back and verified for remaining volume using calibrated pipette. Same can be repeated for variable volumes by changing the aspiration volumes in test programmes.

Pipettor Calibration Data using distilled Water				
Measured Volume taken in sample cup(μL) (A)	Water to be aspirated by syringe(μL) (B)	Water that should be remaining in cup after aspiration(μL) (C=A-B)	Is the remaining volume inside the cup was found to be the same as in column C? (Yes/No)	Remarks
Reagent syringe:				
5000	250*4=1000	4000	Yes	Pass
Sample syringe:				
500	6*4=24	476	Yes	Pass

Note- Calibrated pipette of Device ID:16308037 was used for volume calibration. Calibration certificate of the pipette is attached herewith.

➤ **Temperature Calibration**

Select Temperature in Service Menu. It should be $37\text{ }^{\circ}\text{C} \pm 0.2\text{ }^{\circ}\text{C}$
Verify with temperature Indicator by surface probe in cuvette rotor. If any discrepancy add the offset of difference in actual & desired temperature.

Temperature Calibration Data				
Displayed Temp	Ref. Range	Temp. Indicator	Temp Offset Required	Temp. offset Value
$^{\circ}\text{C}$	$37\text{ }^{\circ}\text{C} \pm 0.2\text{ }^{\circ}\text{C}$	$35.1\text{ }^{\circ}\text{C}$	No	$0\text{ }^{\circ}\text{C}$
Remarks	Temp. Calibration OK. No offset required.			



➤ Reagent Calibration of the Instrument

Customer is advised to verify the hardware calibration by reagent calibration. Use Elitech Calibrator Elical 2 for the calibration of all parameters.

User can do the same & attach the results in separate sheet with factors after verifying the same with Elitech Elitrol I & Elitrol II controls. All control values should fall within acceptable range.

Data sheets of the same should be attached along with this document.

- Switch Off the instrument.
- Ensure all the Recommended Spares / Consumables have been replaced. (if not done during PM and required)
- Clean the instrument.
- Close the cover.

Recommended Spares for replacement: NIL

We hereby certify that Validation have been carried out under the AMC/Warranty. Hardware Calibration of Lamp, Filters, Temperature & Aspiration (Pump) has been done successfully.

Please perform the standardization / Calibration and verify by evaluating controls before processing patient samples.

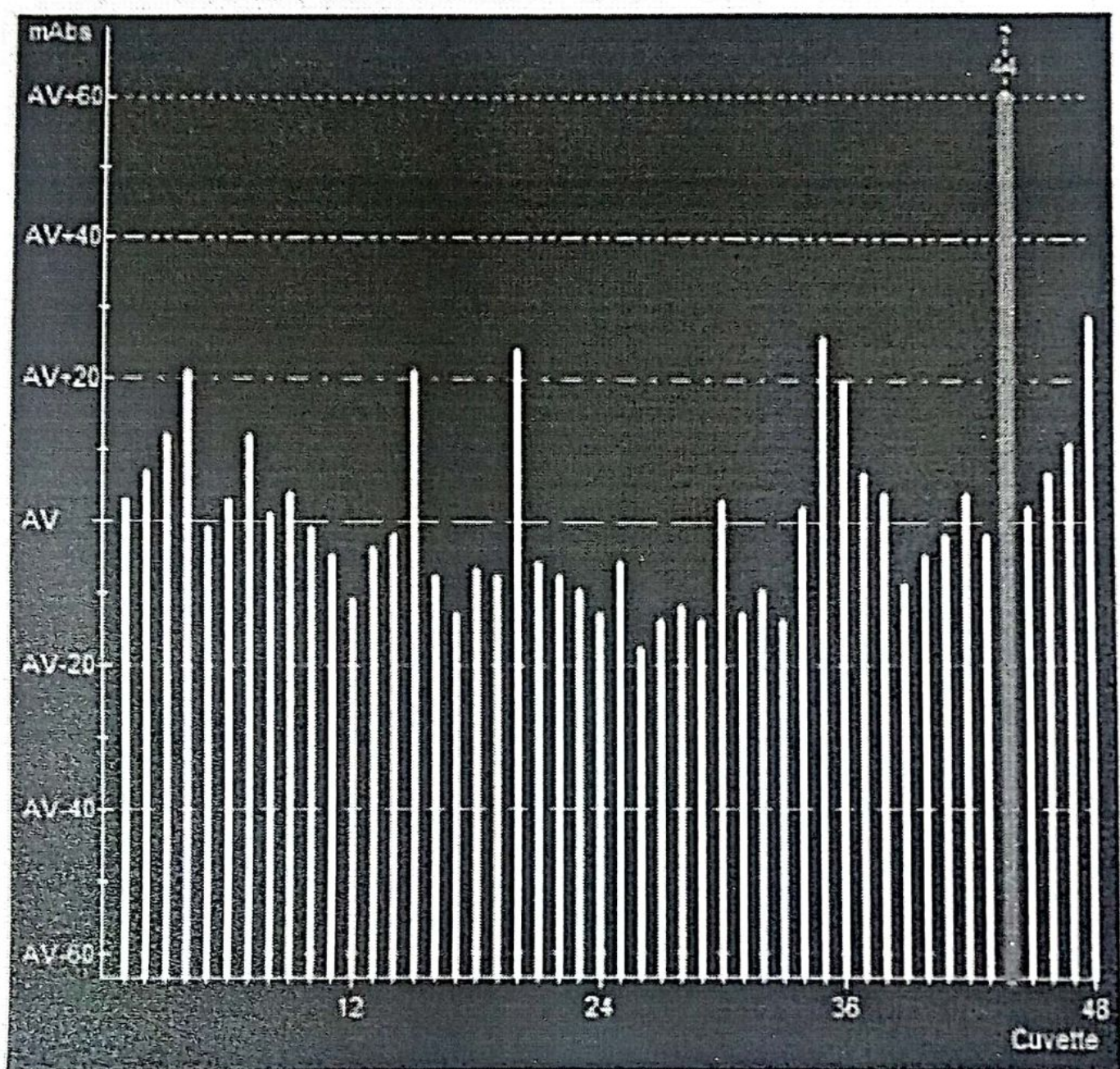
Next Calibration is due on -06/09/2024

Signature of Service Engineer

Place: 7-9-24

Date: Lucknow

- 340 nm
- 405 nm
- 505 nm
- 546 nm
- 578 nm
- 620 nm
- 660 nm
- 700 nm



Cuvette AV: 0.8371 SD: 0.0118 Cuvette Gain: 11.0000
 Lamp AV: 2.0519 SD: 0.0004 Lamp Gain: 13.0000
 Last blank date: 07-09-2024
 time: 10:30:02

Lamp adjustment

Lamp
absorbance

3.5778

Cuvette
absorbance

2.8900

04 : 47

Please wait for 5 minutes (see above clock) to let the lamp stabilize.

Loosen the screw with the spring.

Adjust the other two screws such that the lamp absorbance and the cuvette absorbance fall within the green range and are as low as possible.

Also, check for the first 5 filters, if the absorbance has a decreasing "profile".

Then do a filter check by inspecting if all values fall within the green range. If not, adjust the lamp again such that the absorbance values are a little bit higher.

When finished, tighten the screw with the spring.

Control name: 8-Abs
 Batch number: Check S
 Expiry date:
 Measurement date: 07-09-2024 10:51:20
 Sample type: Control
 Status: READY A2

Test name	Value	Flags
Check S	0.077 Abs	
#1 Check S	0.076 Abs	
#2 Check S	0.076 Abs	
#3 Check S	0.076 Abs	
#4 Check S	0.077 Abs	
#5 Check S	0.077 Abs	
#6 Check S	0.077 Abs	
#7 Check S	0.077 Abs	
#8 Check S	0.077 Abs	
#9 Check S	0.078 Abs	
#10 Check S	0.077 Abs	

Check S 0.077 Abs
 READY

Graph Info

Target: 0.080 Abs
 Low limit: 0.060 Abs
 High limit: 0.100 Abs
 Max value: 0.078 Abs
 Min value: 0.076 Abs
 Max diff: 0.002 Abs
 SD: 0.001 Abs
 CV: 0.689 %
 AV: 0.077 Abs

	Concentration [Abs]	Absorbance [Abs]
#1	0.076	0.0764
#2	0.076	0.0764
#3	0.076	0.0765
#4	0.077	0.0772
#5	0.077	0.0771
#6	0.077	0.0772
#7	0.077	0.0774
#8	0.077	0.0769
#9	0.078	0.0782

► Adjust Lamp

Reagent Arm

Sample Arm

Reagent Disk

Sample Disk / Barcode

Measurement Disc/Filter

Wash Arm

Pipettor

Vacuum system

Water system

Optical electronics

Electronics

Filter check

