



**POCT SERVICES**

**Complete Medical Solution**

298-281, Transport Nagar, Kanpur Road, Adjacent  
Transport Nagar Metro Station, Lucknow- 226 023, UP, INDIA

Tel.: 0522-2433023

E-mail: poctlko@pocservices.com www.pocservices.com

Date: 25 Oct 2022

## Certificate of Calibration

Name & Address of Customer: ICU Stat lab, Department of Biochemistry

King Georg's Medical University, Lucknow

City: Lucknow State: U.P. PIN: 226003

Phone 09208052893

E-Mail

Name of Instrument: Selectra PRO M

Type: Random Access Fully Automatic Biochemistry Analyser

Serial No: 16-4035

Calibration Date: 12 Oct. 2022

Next Calibration Due: 11 Oct. 2023

This is to certify that above said instrument has been validated of hardware calibration for Filters, Aspiration, and 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:- Mr. Ashish

Signature & Stamp

Name of Engineer/ Application Specialist: - Ajit Mohan Dubey  
Asst. Sr. Manager Application  
POCT Services



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



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## Validation / Calibration - SOP

Selectra ProM

**Name of the Customer & Address :** ICU Stat lab, Department of Biochemistry

**Address:** King Georg's Medical University Lucknow U.P.

Sr No: 16-4035

**Status :** Under warranty

Validation & Preventive Maintenance

➤ **Power Supply**

Measure Input power Supply Voltage: 229\_V (230 V AC  $\pm$  10 V )

Check Earthling: 2.1 \_\_\_\_\_ V ( 0 - 5 V )

➤ Ambient temperature: 23 \_\_\_\_\_ ° C ( 10 - 35 ° C )

➤ Appearance : Clean \_\_\_\_\_ (Clean/Dusty)

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

➤ **Analyser 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

**Note:** Filter checked status was ok no need of replacement.

**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**



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**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.

**Note:-** Condition of cuvette drier block is clean. No need to change.

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

**Note:-** Mixer belts are good no need to change.

**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.

**Note:-** All cuvette blank OD values are in range no need to replace



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## 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 4.000, 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
3.8278 Abs	1.800 to 4.200abs	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 – 3.5	2.5719	OK	Not required
405	0.1 - 2.6	1.4888	OK	Not required
505	0.1 - 2.6	0.7112	OK	Not required
546	0.1 - 2.6	0.6578	OK	Not required
578	0.1 - 2.6	0.5339	OK	Not required
620	0.1 - 1.2	0.6959	OK	Not required
660	0.1 - 0.7	0.6806	OK	Not required
700	0.1 - 0.75	0.5390	OK	Not required
<b>Over all Remarks</b>	Filter gains within acceptable range. No replacement required.			

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

## ➤ 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" or 10x "Check-R" as QC samples.

Test	Target Value	Target CV [%]	Mean Result	CV [%]
Check-S	0.08(0.060-0.100)	≤2%	0.086	0.976
Check-R	1.75(1.500-2.000)	≤2%	1.729	0.386

### 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 ( $\mu$ l)	Dispensed volume checked and found complying as full stroke volume? (Yes/No)	Remarks
<b>Sample Syringe:</b>		
100	Yes	OK
100	Yes	OK
100	Yes	OK
<b>Reagent syringe:</b>		
1000	Yes	OK
1000	Yes	OK
1000	Yes	OK

### 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.

Pippettor Calibration Data using distilled Water				
Measured Volume taken in sample cup( $\mu$ L) (A)	Water to be aspirated by syringe( $\mu$ L) (B)	Water that should be remaining in cup after aspiration( $\mu$ L) (C=A-B)	Is the remaining volume inside the cup was found to be the same as in column C? (Yes/No)	Remarks
<b>Reagent syringe:</b>				
5000 $\mu$ L	300 $\mu$ L X 3 test =900 $\mu$ L	4100 $\mu$ L	Yes	OK
<b>Sample syringe:</b>				
300 $\mu$ L	30 $\mu$ L X 3 test =90 $\mu$ L	210 $\mu$ L	Yes	OK

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## ➤ Temperature Calibration

Select Temperature in Service Menu. It should be  $37\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$

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
37°C	$37\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$	36.7°C	No	0 °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

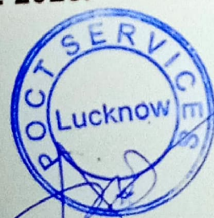
We hereby certify that Validation have been carried out under the MOU. Hardware Calibration of Lamp, Filters, Temperature & Aspiration (Pump) has been done successfully.

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

**Next Calibration is due on: 11 Oct. 2023.**

Signature of Application Specialist

Place  
Date.





Water  
Check R

12-Sep-2022 11:07:24 AM

Control

READY A1

Check R 1.729 dAbs

COMPLETED

Graph Info

**Target:** 1.750 dAbs  
**Low limit:** 1.500 dAbs  
**High limit:** 2.000 dAbs  
**Max value:** 1.739 dAbs  
**Min value:** 1.720 dAbs  
**Max diff:** 0.020 dAbs  
**SD:** 0.007 dAbs  
**CV:** 0.386 %  
**AV:** 1.729 dAbs

Test name	Value	Flags
Check R	1.729 dAbs	
#1 Check R	1.736 dAbs	
#2 Check R	1.739 dAbs	
#3 Check R	1.727 dAbs	
#4 Check R	1.720 dAbs	
#5 Check R	1.723 dAbs	
#6 Check R	1.728 dAbs	
#7 Check R	1.721 dAbs	
#8 Check R	1.732 dAbs	
#9 Check R	1.726 dAbs	
#10 Check R	1.735 dAbs	

	Concentration [dAbs]	Absorbance [dAbs]
#1	1.736	1.736
#2	1.739	1.7394
#3	1.727	1.7267
#4	1.720	1.7195
#5	1.723	1.7228
#6	1.728	1.7283
#7	1.721	1.7213
#8	1.732	1.7316
#9	1.726	1.7256

Control name: 8-Abs  
 Batch number: Check S  
 Expiry date:  
 Measurement date: 12-Sep-2022 12:23:56 PM  
 Sample type: Control  
 Status: READY A2

Check S 0.086 Abs

COMPLETED

Test name	Value	Flags
Check S	0.086 Abs	
#1 Check S	0.087 Abs	
#2 Check S	0.085 Abs	
#3 Check S	0.086 Abs	
#4 Check S	0.086 Abs	
#5 Check S	0.086 Abs	
#6 Check S	0.087 Abs	
#7 Check S	0.085 Abs	
#8 Check S	0.085 Abs	
#9 Check S	0.085 Abs	
#10 Check S	0.084 Abs	

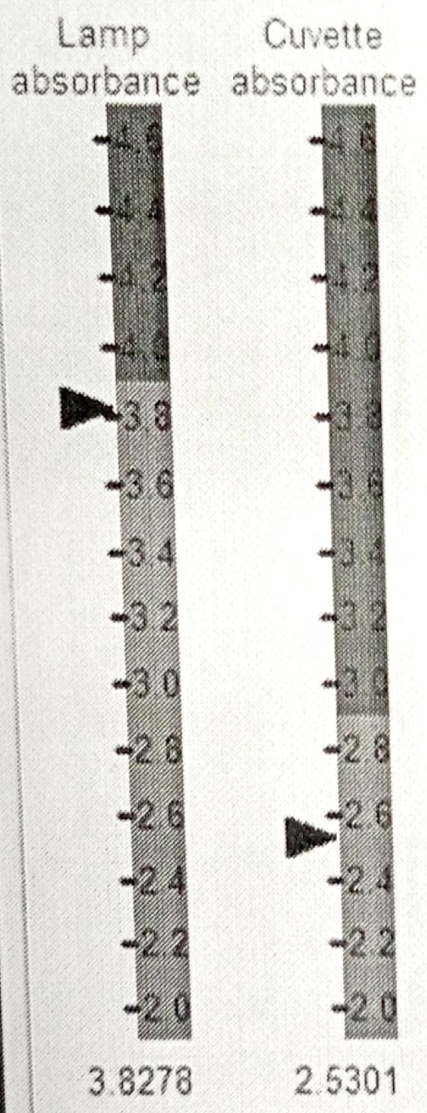
Graph Info

**Target:** 0.080 Abs  
**Low limit:** 0.060 Abs  
**High limit:** 0.100 Abs  
**Max value:** 0.087 Abs  
**Min value:** 0.084 Abs  
**Max diff:** 0.003 Abs  
**SD:** 0.001 Abs  
**CV:** 0.976 %  
**AV:** 0.086 Abs

	Concentration [Abs]	Absorbance [Abs]
#1	0.087	0.085
#2	0.085	0.0851
#3	0.086	0.0862
#4	0.086	0.0858
#5	0.086	0.0857
#6	0.087	0.0867
#7	0.085	0.0846
#8	0.085	0.0854
#9	0.085	0.0854

- Adjust Lamp
- Reagent Arm
- Sample Arm
- Reagent Disk
- Sample Disk / Barcode
- Measurement Disc/Filter
- Wash Arm
- Pipettor
- Vacuum system
- Water system
- Optical electronics
- Electronics

Lamp adjustment



04 : 53

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.