



**POCT SERVICES**

Complete Hospital Solution

ISO 9001:2008 CERTIFIED

**POCT SERVICES PVT. LTD.**

CIN : U74120UP2010PTC042528

Corporate Office : 101A-102B, First Floor,

Diamond Tower, Udaiyganj, Cantt Road,

Lucknow-226001, Uttar Pradesh, INDIA

Tel. : +91 522 4009779

E-mail : poctlko@rediffmail.com

Date : \_\_\_ 15/04/2024 \_\_\_

## Certificate of Calibration

Name & Address of Customer: Bhau Rao Devras Combined Hospital

Mahanagar, Lucknow

City -Lucknow

State- Uttar Pradesh

Phone - 94548 88438

E-Mail - hqmbirdlucknownhm@gmail.com

Name of Instrument : Selectra Pro-M

Type: Random Access Fully Automatic Biochemistry Analyser

Serial No: 17-4018

Calibration Date: 15/04/2024

Next Calibration Due: 14/04/2025

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. Ajit Mohan Dubey

POCT Services Pvt. Ltd

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

## Validation / Calibration - SOP

Selectra Pro S/ ProM

Name of the Customer : Bhau Rao Devras Combined Hospital

Address: Mahanagar, Lucknow

Sr No: 17-4018

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)

$\rho$  340nm  $\rho$ 405nm  $\rho$  505nm  $\rho$  546 nm  $\rho$  578 nm  $\rho$  620 nm  $\rho$  660 nm  $\rho$  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

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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 pls 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
3.80 Abs	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	2.85	OK	Not required
405	0.1 - 2.6	1.88	OK	Not required
505	0.1 - 2.6	0.82	OK	Not required
546	0.1 - 2.6	0.75	OK	Not required
578	0.1 - 2.6	0.1	OK	Not required
620	0.1 - 0.9	0.62	OK	Not required
660	0.1 - 0.7	0.56	OK	Not required
700	0.1 - 0.7	0.60	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" and 10x "Check-R" as QC samples.

Test	Target Value	Target CV%	Mean Result	CV[%]
Check-S	0.08(0.060-0.100)	<1%	0.086	0.68

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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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( $\mu$ 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
Reagent syringe:				
5000	250*4=1000	4000	Yes	Pass
Sample syringe:				
500	6*4=24	476	Yes	Pass

## ➤ Temperature Calibration

Select Temperature in Service Menu. It should be  $37^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$   
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
36°C	$37^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$	35 °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 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 -15/04/2024**



Signature of Service Engineer

Place: Lucknow

Date: 15-04-2024

► 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

Lamp absorbance	Cuvette absorbance
4.6	4.6
4.4	4.4
4.2	4.2
4.0	4.0
3.8	3.8
3.6	3.6
3.4	3.4
3.2	3.2
3.0	3.0
2.8	2.8
2.6	2.6
2.4	2.4
2.2	2.2
2.0	2.0
3.8442	2.8389

04 : 44

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.

F1

Filter check

F10



Return



▶ 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

	340	405	505	546	578	620	660	700
	-2.6	-2.6	-2.6	-2.6	-2.6	-2.6	-2.6	-2.6
	-2.4	-2.4	-2.4	-2.4	-2.4	-2.4	-2.4	-2.4
	-2.2	-2.2	-2.2	-2.2	-2.2	-2.2	-2.2	-2.2
	-2.0	-2.0	-2.0	-2.0	-2.0	-2.0	-2.0	-2.0
	-1.8	-1.8	-1.8	-1.8	-1.8	-1.8	-1.8	-1.8
	-1.6	-1.6	-1.6	-1.6	-1.6	-1.6	-1.6	-1.6
	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4
	-1.2	-1.2	-1.2	-1.2	-1.2	-1.2	-1.2	-1.2
	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0	-1.0
	-0.8	-0.8	-0.8	-0.8	-0.8	-0.8	-0.8	-0.8
	-0.6	-0.6	-0.6	-0.6	-0.6	-0.6	-0.6	-0.6
	-0.4	-0.4	-0.4	-0.4	-0.4	-0.4	-0.4	-0.4
	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2
	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0
	2.8590	1.8813	0.8285	0.7515	0.7188	0.6275	0.5636	0.6042

F1

Lamp adjustment

F10

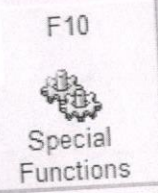
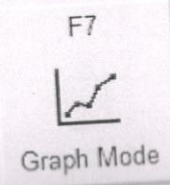
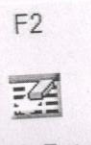


Return

- Reset system
- Change cuvette rotor
- Change syringes
- Fill/Empty system
- Clean system
- Rotor/Needle rinse
- ▶ Blank rotor

340 nm	1-12	13-24	25-36	37-48
405 nm	0.45777	0.46805	0.46863	0.44370
505 nm	0.46899	0.49044	0.46232	0.46463
546 nm	0.45487	0.48777	0.45395	0.45952
578 nm	0.45638	0.46437	0.45499	0.48209
620 nm	0.45079	0.50325	0.45564	0.44848
660 nm	0.44960	0.46555	0.47047	0.44635
700 nm	0.45362	0.46971	0.45526	0.44137
	0.52159	0.49302	0.43513	0.46358
	0.47502	0.48452	0.45532	0.46461
	0.49946	0.48548	0.46459	0.48858
	0.47998	0.48050	0.45588	0.46796
	0.48425	0.47033	0.46663	0.44139

Cuvette AV: 0.4654      SD: 0.0135      Cuvette Gain: 10.0000  
 Lamp AV: 2.3520      SD: 0.0087      Lamp Gain: 14.0000  
 Last blank date: 15-Apr-2024  
 time: 09:19:26 AM



Evaluate Results

Control name: 8-Abs  
 Batch number: Check S  
 Expiry date:  
 Measurement date: 15-Apr-2024 09:32:32 AM  
 Sample type: Control  
 Status: READY A2

Check S 0.086 Abs  
 READY

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

Graph Info

Target: 0.080 Abs  
 Low limit: 0.060 Abs  
 High limit: 0.100 Abs  
 Max value: 0.087 Abs  
 Min value: 0.085 Abs  
 Max diff: 0.002 Abs  
 SD: 0.001 Abs  
 CV: 0.682 %  
 AV: 0.086 Abs

	Concentration [Abs]	Absorbance [Abs]
#1	0.085	0.0853
#2	0.086	0.0856
#3	0.086	0.0856
#4	0.087	0.0866
#5	0.086	0.0857
#6	0.086	0.0863
#7	0.086	0.0864
#8	0.086	0.0860
#9	0.087	0.0868

F1



Print

F2



Graph Mode

F3



Accept Result

F4



Reject Result

F5



Measure Again

F6



Measure Rerun

F7



Sample List

F8



Request Samples

F9



Sample Handling

F10



Main Menu