Date: 07 Sep. 2024

Certificate of Calibration

Name & Address of Customer: Pathology department, Sadar hospital, Araria, BiharCity: Araria State: Bihar PIN: 854311

Phone _

E-Mail _

Name of Instrument: Selectra PRO MType: Random Access Fully Automatic Biochemistry AnalyserSerial No: 22-4068Calibration Date: 07 Sep. 2024Next Calibration Due: 08 Sep. 2025

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.Rohit

Signature & Stamp

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

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





Validation / Calibration - SOP

Selectra ProM

Name of the Customer & Address : Pathology department, Sadar hospital Araria,Bihar

Address-Araria,Bihar.

Sr No: 22-4068

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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Complete Medical Solution

298-281, Transport Nagar, Kanpur Road, Adjacent
Transport Nagar Metro Station, Lucknow-226023, UP, INDIA

Tel.: 0522-2433023

E-mail: pocitko@pocit-services.com www.pocit-services.com

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.

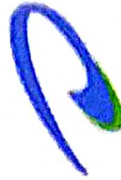
Note:- Condition of cuvette drier block is clean. No need to change.

Mixer Bolts – 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



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
3.3892 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.

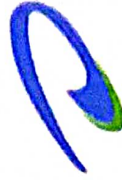
All the arrows must be in Green area. If not, then adjust lamp or replace filter if necessary.

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	2.3326	OK	Not required
405	0.1 - 2.6	1.6356	OK	Not required
505	0.1 - 2.6	0.7005	OK	Not required
546	0.1 - 2.6	0.6597	OK	Not required
578	0.1 - 2.6	0.5213	OK	Not required
620	0.1 - 1.2	0.4719	OK	Not required
660	0.1 - 0.7	0.5177	OK	Not required
700	0.1 - 0.75	0.3627	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.



➤ 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%	0.081	0.599
Check-R	1.75(1.500-2.000)	≤2%	1.778	0.121

Remarks:

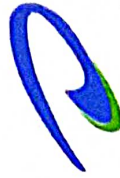
Rotor Blank acceptable. Instrument ready for chemical installation & calibration.

- 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)



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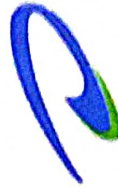
E-mail: pocltko@poctservices.com www.poctservices.com

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	OK
100	Yes	OK
100	Yes	OK
Reagent syringe:		
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/reagent 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.

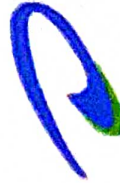
Pippettor Calibration Data using distilled Water				
Measured Volume taken in sample cup(μL) (A)	Water to be aspirated by syringe(μL) (B)	Water that should be remaining in cup after aspiration(μL) (C=A-B)	Is the remaining volume inside the cup was found to be the same as in column C? (Yes/No)	Remarks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



➤ 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.

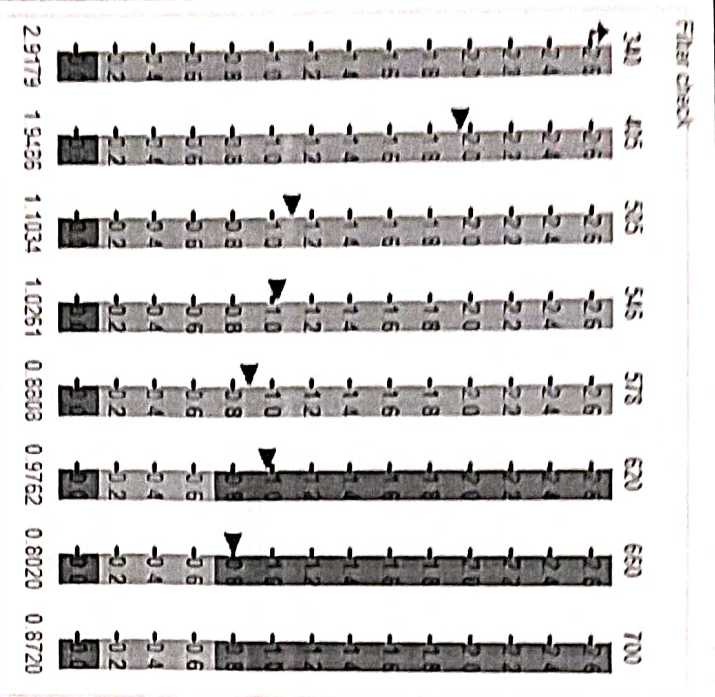
Next Calibration is due on: 08 Sep. 2024.

Signature of Application Specialist

Place

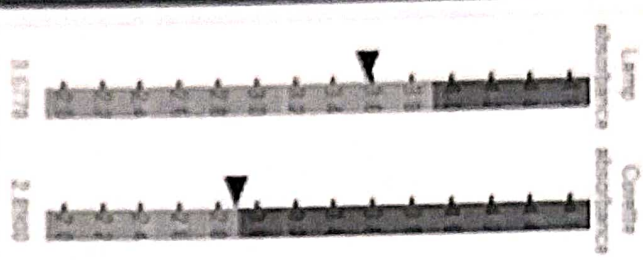
Date.

- ▶ Adjust Unit
- Reagent Arm
- Sample Arm
- Reagent Deck
- Sample Deck / Barcode
- Measurement Deck/Fiber
- Wash Arm
- Pipettor
- Vacuum system
- Water system
- Optical electronics
- Electronics



- Adjust Lamp
- Adjust slit
- Sample slit
- Sample Dia
- Sample Dia / Diameter
- Measurement Direction
- Mount slit
- Probe
- Wavelength system
- Wavelength system
- Slit/ aperture
- Diaphragm

Lamp adjustment



04 : 47

Please wait for 5 minutes (see above check) 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

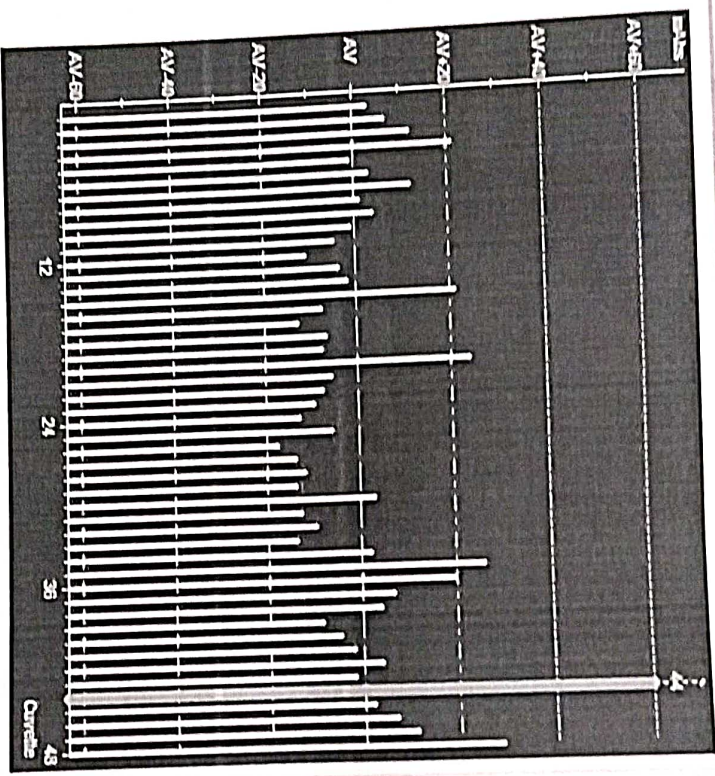
When finished, tighten the screw with the spring

	340 nm	1-12	13-24	25-36	37-48
Reset system	405 nm	0 84036	0 83341	0 83072	0 84425
Change cuvette rotor	505 nm	0 84375	0 83471	0 81853	0 84061
Change syringes	546 nm	0 84947	0 85650	0 82322	0 82764
Fill/Empty system	578 nm	0 85816	0 82883	0 82522	0 83150
Clean system	620 nm	0 83615	0 82387	0 82322	0 83487
Rotor/Needle mse	660 nm	0 84045	0 82982	0 83974	0 84068
	700 nm	0 84869	0 82892	0 82362	0 83480
		0 83781	0 86103	0 82717	1 00982
		0 84106	0 83105	0 82282	0 83929
		0 83597	0 82939	0 83900	0 84389
		0 83164	0 82733	0 86327	0 84781
		0 82629	0 82439	0 85661	0 86606

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

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

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

Evaluate Results

Control name: Water
 Batch number: Check R
 Expiry date: _____
 Measurement date: 07-09-2024 10:46:58
 Sample type: Control
 Status: READY A1

Test name	Value	Flags
Check R	1.669 dAbs	
#1 Check R	1.657 dAbs	
#2 Check R	1.656 dAbs	
#3 Check R	1.646 dAbs	
#4 Check R	1.634 dAbs	
#5 Check R	1.674 dAbs	
#6 Check R	1.670 dAbs	
#7 Check R	1.695 dAbs	
#8 Check R	1.665 dAbs	
#9 Check R	1.685 dAbs	
#10 Check R	1.699 dAbs	

Check R 1.669 dAbs
 READY

Graph Info

Target: 1.750 dAbs
 Low limit: 1.500 dAbs
 High limit: 2.000 dAbs
 Max value: 1.699 dAbs
 Min value: 1.634 dAbs
 Max diff: 0.065 dAbs
 SD: 0.020 dAbs
 CV: 1.226 %
 AV: 1.669 dAbs

#	Concentration [dAbs]	Absorbance [dAbs]
#1	1.657	1.6571
#2	1.666	1.6658
#3	1.646	1.6459
#4	1.634	1.6312
#5	1.674	1.6710
#6	1.670	1.6698
#7	1.695	1.6950
#8	1.665	1.6647
#9	1.685	1.6851

Control name: B-As
 Batch number: Check S
 Expiry date:

Measurement date: 07-09-2024 10:51:20
 Sample type: Control
 Status: READY A2

Test name	Value	Flags
#1 Check S	0.077 Abs	
#2 Check S	0.076 Abs	
#3 Check S	0.076 Abs	
#4 Check S	0.076 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: 0.090 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: 0.693 %
 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

Control name ELITROL-1
 Batch number 1200
 Expiry date
 Measurement date 07-09-2024 12 50 53
 Sample type Control
 Status READY A1

Test name	Value	Flags
GLUCOSE	84 mg/dl	
UREA	37 mg/dl	
CREATININE	0.61 mg/dl	
URIC ACID	7.0 mg/dl	
SGOT	38 IU/l	
SGPT	45 IU/l	
BIL-TOTAL	1.66 mg/dl	
BIL-DIRECT	1.28 mg/dl	
TOTAL PROTEIN	4.4 g/dl	
ALBUMIN	2.9 g/dl	
ALP	160 IU/l	
CHOLESTROL	117 mg/dl	
TRIGLYCERIDES	98 mg/dl	
HDL	26 mg/dl	
LDL	56 mg/dl	
TOTAL CALCIUM	9.0 mg/dl	
AMYLASE	85.0 U/l	
LDH	332 U/l	
GLUCOSE	1110* mg/dl	C
UREA	1110* mg/dl	C
HDL	1110* mg/dl	C
CREATININE	1110* mg/dl	C

Type	Sample ID	Patient name
C	ELITROL-1	
C	ELITROL 2	

Standard by

Loadable | DUAL MODE | Req /Tray buffer 0/3

Standard

13 04 57

07-09-2024 HOST

Evaluate Results

Control name ELITROL 2
Batch number 2210
Expiry date

Measurement date 07-09-2024 13 02 41

Sample type Control
Status READY A2

Test name	Value	Flags
GLUCOSE	217 mg/dl	
UREA	103 mg/dl	
CREATININE	2.28 mg/dl	
URIC ACID	11.2 mg/dl	
SGOT	134 IU/l	
SGPT	154 IU/l	
BIL-TOTAL	6.23 mg/dl	
BIL-DIRECT	3.56 mg/dl	
TOTAL PROTEEN	6.8 g/dl	
ALBUMIN	4.4 g/dl	
ALP	266 IU/l	
CHOLESTROL	168 mg/dl	
TRIGLYCERIDES	194 mg/dl	
HDL	37 mg/dl	
LDL	85 mg/dl	
TOTAL CALCIUM	12.0 mg/dl	
AMYLASE	245.9 IU/l	
LDH	654 IU/l	
ALBUMIN	*HFO* g/dl	C
HDL	*HFO* mg/dl	C
CREATININE	*HFO* mg/dl	C
HDL	*HFO* mg/dl	C

Type	Sample ID	Patient name
C	ELITROL-1	
C	ELITROL 2	