Date: 12 June 2023

Certificate of Calibration

Name & Address of Customer: Tej Bahadur Sapru Hospital, Department of Pathology, PrayagrajCity: Lucknow State: U.P. PIN: 226001Phone 08707536755E-Mail Name of Instrument: Selectra PRO MType: Random Access Fully Automatic Biochemistry AnalyserSerial No: 16-4037Calibration Date: 02 May, 2023Next Calibration Due: 01 May, 2024

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.

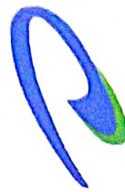
These instruments conform to CE-IVD & EU directives of use.

Calibration carried out on site by:- Mr. Lakhendra

Signature & Stamp

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

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



Validation / Calibration - SOP

Selectra ProM

Name of the Customer & Address : Tej Bahadur Sapru Hospital Dept. of Pathology

Address: Prayagraj

Sr No: 16-4037

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**

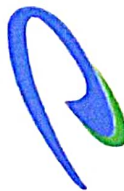
Filter Status: Needs replacement (Yes/ NO)

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**



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.

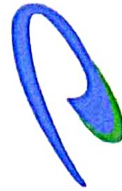
Note:- Condition of cuvette drier block is clean. No need to change.

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



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 |
| 3.3841 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.

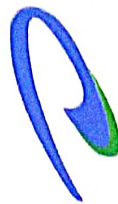
All the arrows must be in Green area. If not, then adjust lamp or replace filter if necessary.

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 | 2.2286 | OK | Not required |
| 405 | 0.1 - 2.6 | 1.3943 | OK | Not required |
| 505 | 0.1 - 2.6 | 0.7219 | OK | Not required |
| 546 | 0.1 - 2.6 | 0.6274 | OK | Not required |
| 578 | 0.1 - 2.6 | 0.5068 | OK | Not required |
| 620 | 0.1 - 1.2 | 0.4314 | OK | Not required |
| 660 | 0.1 - 0.7 | 0.3927 | OK | Not required |
| 700 | 0.1 - 0.7 | 0.3485 | 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% | 0.075 | 0.220 |
| Check-R | 1.75(1.500-2.000) | ≤2% | 1.672 | 0.299 |

Remarks:

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

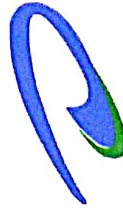
- Change reagent disk from Service to Standard
- Install the various reagents on reagent rotor(s)
- Install ISE reagents on reagent rotor(s) (If applicable)
- Run Reagent Blanks(s)
- Run Calibrations

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)

AKFP4281G1ZY



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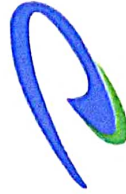
E-mail: poc1ko@pocservices.com www.pocservices.com

| 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.

| 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 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 |

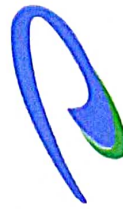


➤ Temperature Calibration

Select Temperature in Service Menu. It should be **37 °C ± 2 °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 °C ± 2 °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.

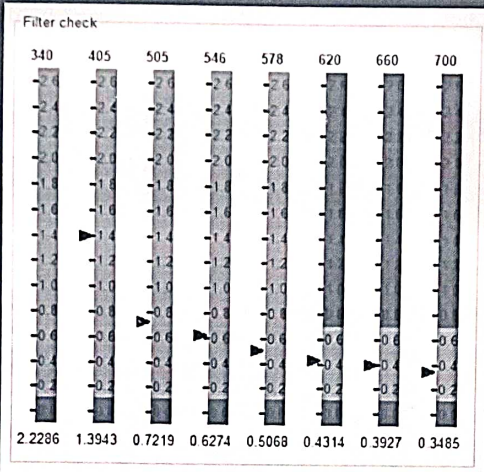
Next Calibration is due on: 01 May 2024.

Signature of Application Specialist

Place

Date.

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



F1

Lamp adjustment

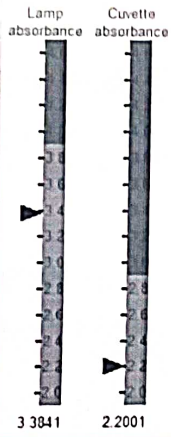
F10



► 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 : 55

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

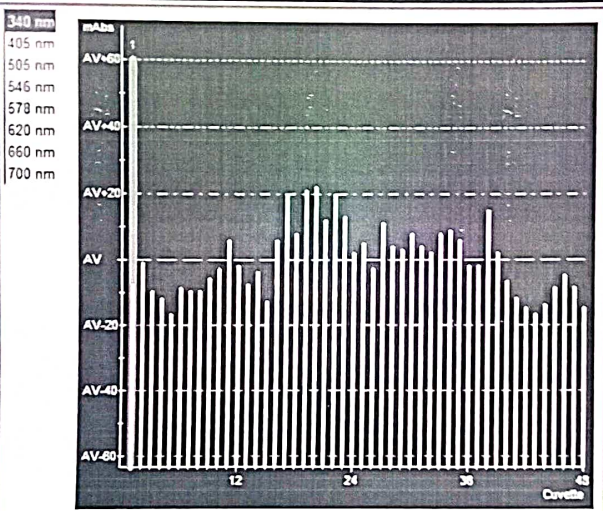
F1

Filter check

F10

Return

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



Cuvette AV 0.3337 SD 0.0107 Cuvette Gain 8.0000
 Lamp AV 1.8610 SD 0.0010 Lamp Gain 12.0000
 Last blank date 02-May-2023
 time 16:41:46

| | | | | | | | |
|-----------------|-----------------------|------------------------|--------------------|----------------|----------------------|------------------------------|------------------------------|
| F1 Print | F2 Blank Rotor | F4 Exclude/ Include | F5 Previous | F6 Next | F7 Table Mode | F8 Maintenance Report | F10 Special Functions |
|-----------------|-----------------------|------------------------|--------------------|----------------|----------------------|------------------------------|------------------------------|

Control name 0-Abs
 Batch number Check S
 Expiry date
 Measurement date 02-May-2023 17:07:19
 Sample type Control
 Status READY A2

Check S 0.075 Abs
 READY

| Test name | Value | Flags |
|-------------|-----------|-------|
| Check S | 0.075 Abs | |
| #1 Check S | 0.075 Abs | |
| #2 Check S | 0.075 Abs | |
| #3 Check S | 0.075 Abs | |
| #4 Check S | 0.075 Abs | |
| #5 Check S | 0.075 Abs | |
| #6 Check S | 0.075 Abs | |
| #7 Check S | 0.075 Abs | |
| #8 Check S | 0.075 Abs | |
| #9 Check S | 0.075 Abs | |
| #10 Check S | 0.075 Abs | |

Graph Info

Target: 0.080 Abs
 Low limit: 0.060 Abs
 High limit: 0.100 Abs
 Max value: 0.075 Abs
 Min value: 0.075 Abs
 Max diff: 0.001 Abs
 SD: 0.000 Abs
 CV: 0.220 %
 AV: 0.075 Abs

| | Concentration [Abs] | Absorbance [Abs] |
|----|---------------------|------------------|
| #1 | 0.075 | 0.0746 |
| #2 | 0.075 | 0.0746 |
| #3 | 0.075 | 0.0745 |
| #4 | 0.075 | 0.0746 |
| #5 | 0.075 | 0.0747 |
| #6 | 0.075 | 0.0746 |
| #7 | 0.075 | 0.0747 |
| #8 | 0.075 | 0.0746 |
| #9 | 0.075 | 0.0751 |

| | | | | | | | | | |
|-----------------|----------------------|-------------------------|-------------------------|-------------------------|-----------------------|-----------------------|---------------------------|---------------------------|----------------------|
| F1 Print | F2 Graph Mode | F3 Accept Result | F4 Reject Result | F5 Measure Again | F6 Measure Run | F7 Sample List | F8 Request Samples | F9 Sample Handling | F10 Main Menu |
|-----------------|----------------------|-------------------------|-------------------------|-------------------------|-----------------------|-----------------------|---------------------------|---------------------------|----------------------|

Control name: Water
 Batch number: Check R
 Expiry date:
 Measurement date: 02-May-2023 17:02:56
 Sample type: Control
 Status: READY A1

Check R 1.672 dAbs
 READY

| Test name | Value | Flags |
|-------------|------------|-------|
| Check R | 1.672 dAbs | |
| #1 Check R | 1.672 dAbs | |
| #2 Check R | 1.675 dAbs | |
| #3 Check R | 1.676 dAbs | |
| #4 Check R | 1.681 dAbs | |
| #5 Check R | 1.676 dAbs | |
| #6 Check R | 1.669 dAbs | |
| #7 Check R | 1.669 dAbs | |
| #8 Check R | 1.667 dAbs | |
| #9 Check R | 1.667 dAbs | |
| #10 Check R | 1.667 dAbs | |

Graph Info

Target: 1.750 dAbs
 Low limit: 1.500 dAbs
 High limit: 2.000 dAbs
 Max value: 1.681 dAbs
 Min value: 1.667 dAbs
 Max diff: 0.015 dAbs
 SD: 0.005 dAbs
 CV: 0.299 %
 AV: 1.672 dAbs

| | Concentration [dAbs] | Absorbance [dAbs] |
|----|----------------------|-------------------|
| #1 | 1.672 | 1.6716 |
| #2 | 1.675 | 1.6748 |
| #3 | 1.676 | 1.6757 |
| #4 | 1.681 | 1.6814 |
| #5 | 1.676 | 1.6763 |
| #6 | 1.669 | 1.6692 |
| #7 | 1.669 | 1.6689 |
| #8 | 1.667 | 1.6668 |
| #9 | 1.667 | 1.6667 |