



Date: 23 June 2023

## Certificate of Calibration

Name & Address of Customer: Rani Laxmibai Combined Hospital,  
Department of Pathology

, RAJAJIPUR Lucknow

City: Lucknow State: U.P. PIN: 226004

Phone \_

E-Mail \_

Name of Instrument: Selectra PRO M

Type: Random Access Fully Automatic Biochemistry Analyser

Serial No: 16-4110

Calibration Date: 17 June. 2023

Next Calibration Due: 16 June. 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. Ashwani

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

|   |  |
|---|--|
| <b>Name of the Customer &amp; Address</b> : Rani Laxmibai Combined Hospital Rajipuram |  |
| Address: , <u>Lucknow</u>   |  |
| Sr No: <u>16-4110</u>   |  |
| <b>Status</b> : Under warranty  | <b>Validation &amp; Preventive Maintenance</b> |

➤ 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)

$\rho$  340nm  $\rho$  405nm  $\rho$  505nm  $\rho$  546 nm  $\rho$  578 nm  $\rho$  620 nm  $\rho$  660 nm  $\rho$  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  |
| 3.6448 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  | 2.2950        | OK      | Not required      |
| 405                     | 0.1 - 2.6  | 1.5562        | OK      | Not required      |
| 505                     | 0.1 - 2.6  | 0.8524        | OK      | Not required      |
| 546                     | 0.1 - 2.6  | 0.5755        | OK      | Not required      |
| 578                     | 0.1 - 2.6  | 0.5540        | OK      | Not required      |
| 620                     | 0.1 - 1.2  | 0.4842        | OK      | Not required      |
| 660                     | 0.1 - 0.7  | 0.4875        | OK      | Not required      |
| 700                     | 0.1 - 0.7  | 0.4425        | 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%           | 0.094       | 1.355  |
| Check-R | 1.75(1.500-2.000) | ≤2%           | 1.971       | 0.902  |

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.

| Pippetor 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      |



## ➤ 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 Elitol I & Elitol 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: 16 June 2024.**

Signature of Application Specialist

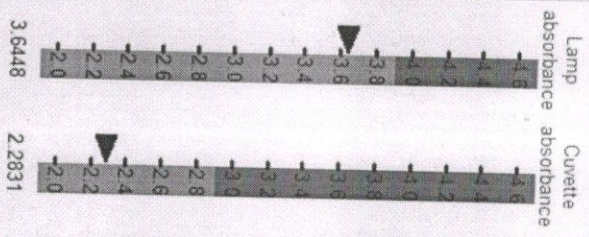
Place  
Date.



▶ Adjust Lamp

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

Lamp adjustment



04 : 39

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

| Wavelength (nm) | 340  | 405  | 505  | 546  | 578  | 620  | 660  | 700  |
|-----------------|------|------|------|------|------|------|------|------|
| 2.2950          | -2.6 | -2.6 | -2.6 | -2.6 | -2.6 | -2.6 | -2.6 | -2.5 |
| 1.5562          | -2.4 | -2.4 | -2.4 | -2.4 | -2.4 | -2.4 | -2.4 | -2.4 |
| 0.8524          | -2.2 | -2.2 | -2.2 | -2.2 | -2.2 | -2.2 | -2.2 | -2.2 |
| 0.5755          | -2.0 | -2.0 | -2.0 | -2.0 | -2.0 | -2.0 | -2.0 | -2.0 |
| 0.5540          | -1.8 | -1.8 | -1.8 | -1.8 | -1.8 | -1.8 | -1.8 | -1.8 |
| 0.4842          | -1.6 | -1.6 | -1.6 | -1.6 | -1.6 | -1.6 | -1.6 | -1.6 |
| 0.4875          | -1.4 | -1.4 | -1.4 | -1.4 | -1.4 | -1.4 | -1.4 | -1.4 |
| 0.4425          | -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  |

F1

Lamp adjustment

F10

Return


- 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

|         | 1-12    | 13-24   | 25-36   | 37-48 |
|---------|---------|---------|---------|-------|
| 0.33097 | 0.32877 | 0.31491 | 0.30988 |       |
| 0.32217 | 0.31080 | 0.31459 | 0.31001 |       |
| 0.31044 | 0.33194 | 0.30636 | 0.31390 |       |
| 0.31639 | 0.31776 | 0.31042 | 0.30676 |       |
| 0.31807 | 0.31930 | 0.31690 | 0.30748 |       |
| 0.31318 | 0.31426 | 0.32586 | 0.31224 |       |
| 0.33663 | 0.32215 | 0.32646 | 0.33066 |       |
| 0.31883 | 0.31457 | 0.32570 | 0.30770 |       |
| 0.33420 | 0.31679 | 0.32280 | 0.31511 |       |
| 0.34924 | 0.31410 | 0.30957 | 0.31733 |       |
| 0.34475 | 0.31318 | 0.30961 | 0.31396 |       |
| 0.31668 | 0.31224 | 0.30856 | 0.32043 |       |


Cuvette AV: 0.3184 SD: 0.0097 Cuvette Gain: 9.0000  
 Lamp AV: 2.1251 SD: 0.0007 Lamp Gain: 14.0000  
 Last blank date: 17-Jun-2023  
 time: PM 01:48:24

F1  Print

F2  Blank Rotor

F7  Graph Mode

F8  Maintenance Report

F10  Special Functions

Control name: Water  
 Batch number: Check R  
 Expiry date:

Measurement date: 17-Jun-2023 PM 02:19:03  
 Sample Type: Control  
 Status: READY A1

| Test name  | Value      | Flags |
|------------|------------|-------|
| Check R    | 1.971 dAbs |       |
| #1 Check R | 1.983 dAbs |       |
| #2 Check R | 1.989 dAbs |       |
| #3 Check R | 1.954 dAbs |       |
| #4 Check R | 1.979 dAbs |       |
| #5 Check R | 1.950 dAbs |       |

Check R 1.971 dAbs  
 READY

Graph Info

Target: 1.750 dAbs  
 Low limit: 1.500 dAbs  
 High limit: 2.000 dAbs  
 Max value: 1.989 dAbs  
 Min value: 1.950 dAbs  
 Max diff: 0.039 dAbs  
 SD: 0.018 dAbs  
 CV: 0.902 %  
 AV: 1.971 dAbs

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

Control name: 8-Abs  
 Batch number: Check S  
 Expiry date:

Measurement date 17-Jun-2023 PM 02:11:16  
 Sample type: Control  
 Status: READY A2

| Test name  | Value     | Flags |
|------------|-----------|-------|
| Check S    | 0.094 Abs |       |
| #1 Check S | 0.094 Abs |       |
| #2 Check S | 0.093 Abs |       |
| #3 Check S | 0.094 Abs |       |
| #4 Check S | 0.096 Abs |       |
| #5 Check S | 0.095 Abs |       |

Check S 0.094 Abs  
 READY

Graph Info

Target: 0.080 Abs  
 Low limit: 0.060 Abs  
 High limit: 0.100 Abs  
 Max value: 0.096 Abs  
 Min value: 0.093 Abs  
 Max diff: 0.003 Abs  
 SD: 0.001 Abs  
 CV: 1.355 %  
 AV: 0.094 Abs

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