



# POCT SERVICES

Complete Medical Solution

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Date 23 June, 2023

## Certificate of Calibration

Name & Address of Customer Pathology Lab Department of JTKMCH Madhepura

City Madhepura State Bihar PIN \_\_\_\_\_

Phone \_\_\_\_\_ E-Mail \_\_\_\_\_

Name of Instrument Selectra PRO M

Type Random Access Fully Automatic Biochemistry Analyser

Serial No: 21-4093

Calibration Date: 21/06/2023

Next Calibration Due 20/6/2024

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

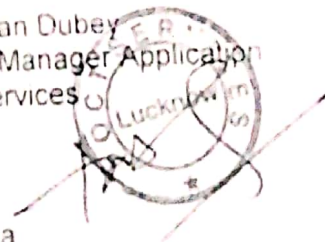
This calibration is carried out by using Standard Operating Procedures (S O P ) provided by Elitech Group, shown in the attachment

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

Calibration carried out on site by - Mr Manish Kumar

Signature & Stamp

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



Encls - SOP of Validation/Calibration along with data

[Signature]  
7/10/23

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स्वच्छ अस्पताल  
एन सीटी, एन सीटी, एन सीटी, एन सीटी  
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## Validation / Calibration - SOP

Selectra ProM

Name of the Customer & Address : Pathology Lab

Address: -----JTKMCH Madhepura

Sr No 21-4093

Status : Under warranty : Validation & Preventive Maintenance

➤ Power Supply

Measure Input power Supply Voltage 229\_V (230 V AC ± 10 V )

Check Earthling: 2.2 V ( 0 - 5 V)

➤ Ambient temperature: 26 ° 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)

p 340nm p 405nm p 505nm p 546 nm p 578 nm p 620 nm p 660 nm p 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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7/10/23

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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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7/10/23

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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
3.7229 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	2.7333	OK	Not required
405	0.1 - 2.6	1.5266	OK	Not required
505	0.1 - 2.6	1.0578	OK	Not required
546	0.1 - 2.6	0.5435	OK	Not required
578	0.1 - 2.6	0.7665	OK	Not required
620	0.1 - 1.2	0.6806	OK	Not required
660	0.1 - 0.7	0.6906	OK	Not required
700	0.1 - 0.7	0.6263	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

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7/10/23

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➤ **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	0.03(0.060-0.100)	≤2%	0.078	1.378
Check-R	1.75(1.500-2.000)	≤2%	1.573	0.323

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)

Nebel



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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





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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: 20/06/2024.

Signature of Application Specialist

Place  
Date

*Nehal*



Control name: Water  
Batch number: Check R  
Copy date:  
Measurement date: 21-06-2023 14:11:40  
Sample type: Control  
Status: READY A2

Check R 1.592 dAbs  
COMPLETED

Test name	Value	Flags
1.592 dAbs	1.592 dAbs	

Graph: abs

Target: 1.759 dAbs  
Low limit: 1.500 dAbs  
High limit: 2.000 dAbs

Max value: 1.691 dAbs  
Min value: 1.673 dAbs  
Max dR: 0.017 dAbs  
SD: 0.005 dAbs  
CV: 0.323 %  
nR: 1.682 dAbs

Concentration (dAbs)	Absorbance (dAbs)
#1 1.677	1.6771
#2 1.681	1.6812
#3 1.677	1.6772
#4 1.685	1.6853
#5 1.673	1.6735
#6 1.681	1.6805
#7 1.682	1.6875
#8 1.684	1.6844
#9 1.687	1.6870
#10 1.683	1.6809

Control name: 8-Abs  
Batch number: Check S  
Expiry date:  
Measurement date: 21-06-2023 13:40:29  
Sample type: Control  
Status: READY A1

Check S 0.078 Abs  
COMPLETED

Test name	Value	Flags
Check S	0.078 Abs	

Graph Info

Target: 0.000 Abs  
Low limit: 0.060 Abs  
High limit: 0.100 Abs  
Max value: 0.000 Abs  
Min value: 0.078 Abs  
Max diff: 0.001 Abs  
SD: 0.001 Abs  
CV: 1.271 %  
AV: 0.078 Abs

	Concentration [Abs]	Absorbance [Abs]
#1	0.078	0.0781
#2	0.078	0.0778
#3	0.078	0.0776
#4	0.078	0.0778
#5	0.080	0.0800

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



Cuvette AV: 0.3801    SD: 0.0103    Cuvette Gain: 9.0000  
Lamp AV: 2.2039    SD: 0.0066    Lamp Gain: 14.0000  
Last blank date: 21-06-2023  
time: 12:25:47



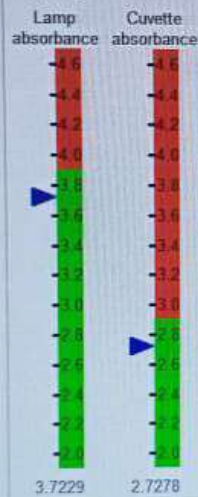
- Reset system
- Change cuvette rotor
- Change syringes
- Fill/Empty system
- Clean system
- Rotor/needle rinse
- ▶ Blank rotor

	1-12	13-24	25-36	37-48
405 nm	0.37293	0.40825	0.37426	0.36735
505 nm	0.38317	0.38184	0.39602	0.38034
546 nm	0.38510	0.37747	0.39353	0.38247
578 nm	0.38164	0.37051	0.38561	0.37100
620 nm	0.37148	0.37181	0.39623	0.36863
660 nm	0.37152	0.37199	0.39351	0.36708
700 nm	0.37818	0.37275	0.37967	0.36533
	0.39160	0.38756	0.39250	0.36528
	0.38613	0.39710	0.38317	0.37080
	0.38128	0.39638	0.37854	0.36804
	0.38581	0.38857	0.37509	0.37318
	0.39154	0.37325	0.37437	0.36593

► 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 : 22

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.

- Adjust Lamp
- Dropout Arm
- Sample Arm
- Reagent Disk
- Sample Disk / Barcode
- Measurement Disc/Filt.
- Wash Arm
- Reagent
- Waste system
- WIP system
- Optical electronics
- Electronics

