GSTIN : 09AAKFP4281G1ZY

POCT SERVICES
Complete Medical Solution
298-281, Transport Nagar, Kanpur Road, Adjacent
Transport Nagar Metro Station, Lucknow- 226 023, UP. INDIA
Mobile: 9935055557, 9889816176 Tel.: 0522-2433023
E-mail: poctlko@poctservices.com   www.poctservices.com

Date: 09 Jan 2021

Certificate of Calibration

Name & Address of Customer: District Male Hospital Fatehpur

City: Fatehpur   State: U.P.   PIN: 212601

Phone: 79855159747

Name of Instrument: Selectra PRO M

Type: Random Access Fully Automatic Biochemistry Analyser

Serial No: 18-4064

Calibration Date: 09 Jan 2021

Next Calibration Due: 08 Jan 2022

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. Ankit Tiwari

Signature & Stamp
Name of Engineer/ Application Specialist: - Ajit Mohan Dubey
                                    Manager Lab Essentials
                                    POCT Services

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

Validation / Calibration - SOP

Selectra ProM

Name of the Customer & Address : District Male Hospital Fatepur

Address:, Fatepur U.P.

Sr No: 18-4064

Status : Under CMC   **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)
   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
2.3020 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	2.7668	OK	Not required
405	0.1 - 2.6	1.9412	OK	Not required
505	0.1 - 2.6	1.0074	OK	Not required
546	0.1 - 2.6	0.9154	OK	Not required
578	0.1 - 2.6	0.6941	OK	Not required
620	0.1 – 1.2	0.6027	OK	Not required
660	0.1 – 0.7	0.6035	OK	Not required
700	0.1 – 0.7	0.6063	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%	0.069	0.869
Check-R	1.75(1.500-2.000)	≤2%	1.756	0.257

Remarks:

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

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

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➤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.
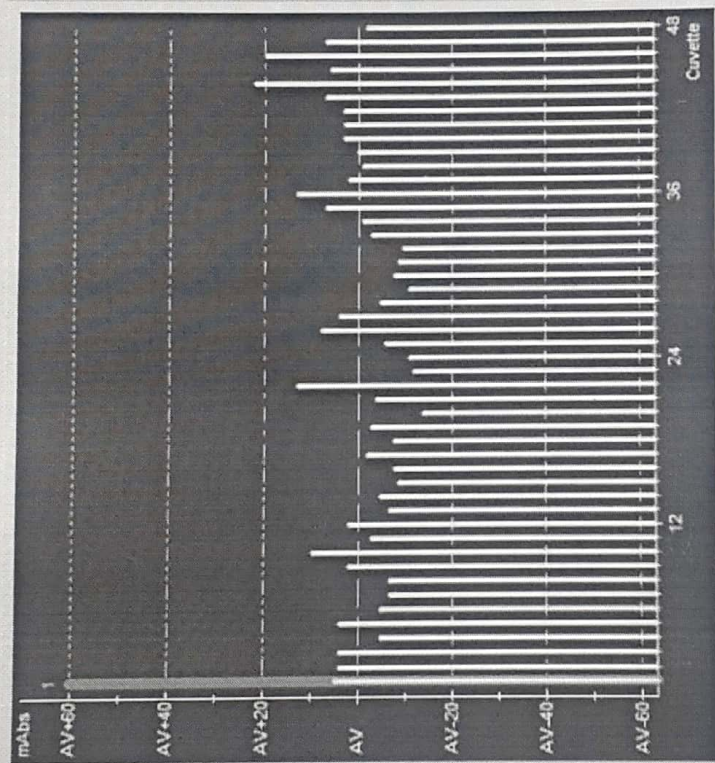
Next Calibration is due on: 8 th Jan 2022
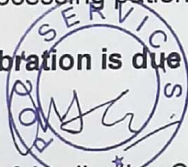
Signature of Application Specialist

Place Fatehpur
Date. 09/01/2021

Reset system

Change cuvette rotor

Change syringes

Fill/Empty system

Clean system

Rotor/Needle rinse

▶Blank rotor

mAbs

- 340 nm
- 405 nm
- 505 nm
- 546 nm
- 578 nm
- 620 nm
- 660 nm
- 700 nm

AV+60

AV+40

AV+20

AV

AV-20

AV-40

AV-60

12   24   36   48
Cuvette

Cuvette AV:	0.3576	SD: 0.0081
Lamp AV:	2.3020	SD: 0.0046

Cuvette Gain: 10.0000
Lamp Gain: 14.0000

Last blank date: 09/01/2021
time: 11:20:30 AM

F1 — Print

F2 — Blank Rotor

F4 — Exclude/Include

F5 — Previous

F6 — Next

F7 — Table Mode

F8 — Maintenance Report

F10 — Special Functions

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

Measurement date: 09/01/2021 2:10 PM
Sample type: Control
Status: UNLOADED

Test name	Value	Flags
⊞ Check R	1.756 dAbs	

Check R   1.756 dAbs

COMPLETED
TEST CHANGED

Graph   Info

Max value: 1.764 dAbs
Min value: 1.747 dAbs
Max diff: 0.017 dAbs
SD: 0.005 dAbs
CV: 0.257 %
AV: 1.756 dAbs

Target: 1.750 dAbs
Low limit: 1.500 dAbs
High limit: 2.000 dAbs

	Concentration [dAbs]	Absorbance [dAbs]
#12	1.752	1.7519
#13	1.758	1.7577
#14	1.755	1.7551
#15	1.752	1.7517
#16	1.758	1.7583
#17	1.753	1.7532
#18	1.756	1.7564
#19	1.753	1.7530
#20	1.756	1.7583

F1	F2	F3	F4	Shift+F5	F7	F8	F9	F10
Print	Graph Mode	Accept Result	Reject Result	View Test Parameters	Sample List	Request Samples	Sample Handling	Main Menu

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

Measurement date: 09/01/2021 2:15 PM
Sample type: Control
Status: UNLOADED

Test name	Value	Flags
Check S	0.069 Abs	

Check S   0.069 Abs

COMPLETED
TEST CHANGED

Graph | **Info**

Max value:	0.070 Abs
Min value:	0.068 Abs
Max diff:	0.002 Abs
SD:	0.001 Abs
CV:	0.869 %
AV:	0.069 Abs
Target:	0.080 Abs
Low limit:	0.060 Abs
High limit:	0.100 Abs

	Concentration [Abs]	Absorbance [Abs]
#12	0.069	0.0689
#13	0.070	0.0703
#14	0.070	0.0700
#15	0.069	0.0686
#16	0.069	0.0694
#17	0.070	0.0703
#18	0.069	0.0691
#19	0.070	0.0697
#20	0.068	0.0685

F1	F2	F3	F4	Shift+F5	F7	F8	F9	F10
Print	Graph Mode	Accept Result	Reject Result	View Test Parameters	Sample List	Request Samples	Sample Handling	Main Menu

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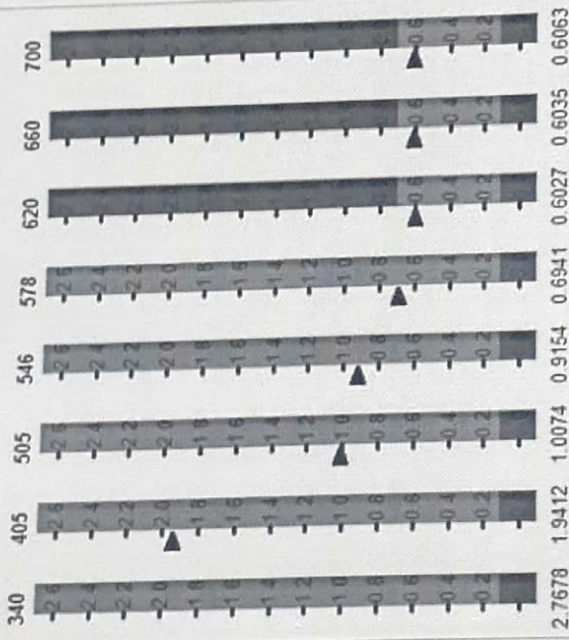Optical electronics
Electronics

Filter check

340	405	505	546	578	620	660	700
2.7678	1.9412	1.0074	0.9154	0.6941	0.6027	0.6035	0.6063

F1 — Lamp adjustment
F10 — Return

Scanned by CamScanner

▶ Adjust Lamp

Reagent Arm

Sample Arm

Reagent Disk

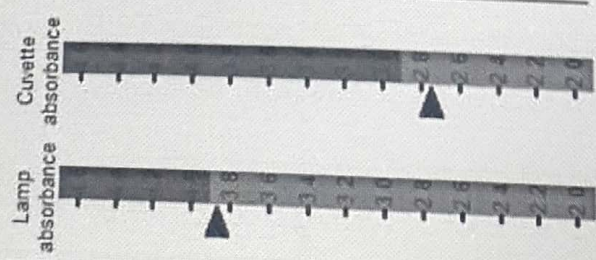Sample Disk / Barcode

Measurement Disc/Filter

Wash Arm

Pipettor

Vacuum system

Water system

Optical electronics

Electronics

Lamp adjustment

04 : 53

Lamp absorbance	Cuvette absorbance
3.8669	2.7493

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