



TRANSASIA
ERBA Chem 5X NS
SEMI-AUTOMATED BIO-CHEMISTRY
ANALYZER
INSTRUMENT QUALIFICATION DOCUMENT
FOR
"Right Care Pathology Lab, Pune"



Installation Qualification for Erba Chem5X NS

Customer Name : Right Care Pathology Lab

Address :

1st & 2nd Floor, Tanishq Building, near Sai Sanskruti Apt., Near Bank of Maharashtra, Sinhgad College Road, Ambegaon Bk Pune-46

Instrument Model : ERBA EC5X

Serial Number : S2010209

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report:

Found the System to have been delivered in satisfactory condition.

Confirmed and found all the required accessories as per dispatch note as per table below.

Sr No.	Description	Qty
1.	POWER CORD 3 PIN 250V/6A	1
2.	USER MANUAL - Chem-5X New Scheme (Domestic)	1
3.	THERMAL PRINTER PAPER ROLL (57mm x30mt.)	1
4.	RECTANGULAR POLY. MICRO CUVETTE	5
5.	ALLEN KEY 3MM	1
6.	T200y Pipet Tips Series 200ul(Yellow)	100
7.	T1000b Pipet Tips Series 1000ul(Blue)	100
8.	ROUND GLASS MICROCUVETTES	5
9.	DUST COVER FOR Chem-5 XNS	1
10.	TEST TUBE HOLDER (with O-ring)	1
11.	Pipette Stand (Plastic)	1
12.	PROLINE SINGLE CHANNEL VARIABLE VOLUME MECHANICAL PIPETTES 5UL - 50UL (CAT. NO 720020)	1
13.	PROLINE SINGLE CHANNEL VARIABLE VOLUME MECHANICAL PIPETTE 100UL - 1000UL (CAT. NO 720060)	1
14.	ERBA WASH (4 X 50 ML)	1

Installation Procedure & Checklist Attached for records.



External Requirements for Installation:

1. Input voltage of 220V-240V / 50Hz or 60Hz.
2. Perfect earthing was provided at power source with all applicable local requirement (A grounded, power plug only should be used). The voltage between earth and neutral should not exceed more than 3V.

Installation Certificate for

This is to certify that the Instrument Serial No.S2010209 is successfully installed and commissioned atAddress:-

1st & 2nd Floor, Tanishq Building, near Sai Sanskruti Apt., Near Bank of Maharashtra, Sinhgad College Road, Ambegaon Bk Pune-46 and the Installation Protocol / checklist has been successfully completed for the above instrument.

For TBM, Technical Services Department

Name : Mukund Tonpe
Designation : SERVICE ENGINEER
Date : 25/11/2020



Installation Qualification for Erba Chem5X NS

Carried out all the Installation Procedures as per the Installation Procedure & Checklists.

Connected the Peristaltic Pump tubing correctly & placed the end of the waste tubing coming out of the analyzer into the waste bottle provided for collecting waste.

Carried out all the necessary system checks and tests.

Performed all due maintenance activities.

Handed over the Instrument for Operators Training & Qualifications

For **TBM, Technical Services Department**

Name: Mukund Tonpe

Designation: SERVICE ENGINEER

Date: 25/11/2020



Installation Report for Erba Chem 5X NS

Customer Name : Right Care Pathology Lab

Department :

Contact Person :

Instrument Model : Erba Chem-5X NS

Serial Number : S2010209

Date of Installation: 25/11/2020

The instrument was installed and was found to be working satisfactorily. Preliminary Customer Training was provided and standardization of some parameters were done. The results were found to be within the expected range and System found to be working satisfactorily.

TBM, Technical Services Department

Name : Mukund Tonpe
Designation: SERVICE ENGINEER
Signature :
Date : 25/11/2020

Customer Detail

Name : Mrs. Jyoti phadtare
Designation: M.D
Signature : Jphadtare
Date : 25/11/2020





Instrument Setup

1. Assembled the instrument accessories.
2. Connected the 3/2 pin cord (with earth terminal) of the external SMPS to the mains socket & checked the output of the SMPS it should be 18V DC +/- 1.0 V DC.
3. Connected the Peristaltic Pump tubing & placed the end of the waste tubing coming out of the analyzer into the waste bottle provided for collecting the waste.
4. Mounted the printer paper.

TBM, Technical Services Department

Name : Mukund Tomorrow.
Designation: SERVICE ENGINEER
Signature :
Date : 25/11/2020

Customer Detail

Name : Jyoti phadtare
Designation: M.D
Signature : J. Phadtare
Date : 25/11/2020





Operational Qualification For Erba Chem 5XNS

System Certification:

Study data has determined that the System described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional conditions, if any, have been addressed.

The System is ready for specific usage.

Protocol Performed By:

Name: MANDAR SUMANT
Designation: APPLICATION SPECILIST

Customer Authorization:

Name:
Designation:

Company Representative Sign:
Date:-25/11/2020



Customer Sign:- [Signature]
Date:- 25/11/2020



Operational Qualification for Erba Chem5X NS

[A] FUNCTIONAL CHECK :

1. PUMP CALIBRATION

(Calibrate the peristaltic pump and record the count range from 1800 to 2700)

2. PRINTER TEST

(To carry out printer function test from maintenance menu and to confirm that all characters printed w/o gap & are clearly readable:- Last line must be above paper cutter)

3. KEY FUNCTIONS

(Confirm all keys function & keys functioning are smooth)

4. BUZZER

(Buzzer beeps when key is pressed)

5. PERISTALTIC PUMP ASSEMBLY

(Confirm rotor rotates smoothly without jerk, and placement of peristaltic tubing Remains at the centre of the bush and should not be touching the end support or rotor base)

6. TEMPERATURE CHECK

Cuvette temperature physical: 37°C

Temperature Range: (A) 37° C ± 0.1°C

(B) 57.5 KΩ to 59.0 KΩ using temperature Jig)

Check temperature in RUN TEST mode for temperatures:

1. 37° C: 2. 30° C: 3. 25° C:

7. GAIN CHECK FOR ALL FILTERS

Filter	340	405	505	546	578	630	Range
Gains	40,000	35,000	50,000	55,000	10,000	75,000	30000-200000
Offset	1000	1500	1400	1500	4000	3000	-5000 to +5000

8. Checked Hardware test and found OK.



9. Checked Date & time and found OK.

10. Checked printer test and found OK.

TBM, Technical Services Department

Name : Mukund Tonpe.
Designation : SERVICE ENGINEER
Signature :
Date : 25/11/2020

Customer Details

Name : MRS. Jyoti phadker
Designation : M.D
Signature : J. Phadker
Date: 25/11/2020





UNMATCHED SERVICE
SINCE 1979...

Performance Qualifications for Erba Chem5X NS

1. PRECISION CHECK:

(After performing Glucose calibration, prepare Glucose reaction solution of one concentration of around 5ml and aspirate this reaction 500µl 10 times and note down readings and calculate CV. CV should be below 3%)

Sr. No.	Concentration mg/dl
1.	99.74
2.	101.9
3.	99.21
4.	101.1
5.	97.50
6.	98.88
7.	96.91
8.	105.0
9.	96.81
10	95.72
Mean	99.28
SD	2.81
CV%	2.83

2. KINETIC, END-POINT MODE CHECK :

(Process the Biochemistry check with reagents and controls as per the kit insert literatures.)

TEST	BLK OD	LEVEL 1		LEVEL 2	
SGPT	0.0	54.	00		
CHOL	0.0	124.	00		
CRET	0.0	1.40.	00		



PERFORMANCE TEST	DATA TRACEABILITY	REMARKS UNMATCHED SERVICE MEETS/DOES NOT MEET ACCEPTANCE
SGPT	yes	yes
CHOL	yes	yes
CRET	yes	yes.

Conclusion:

The result for all the performance tests carried out for the instrument meets/does not meet the acceptance criteria. Hence the instrument is/ is not qualified for the performance.

Protocol performed By:-

TBM, Technical Services Department

CUSTOMER DETAIL

TBM, Technical Services Department

Customer Detail

Name : Mukund Tonpe
 Designation: SERVICE ENGINEER
 Signature :
 Date : 25/11/2020

Name : MRS. Jyoti phadtare
 Designation: M.D
 Signature : Jphadtare
 Date : 25/11/20.

