

**TRANSASIA**  
**ERBA Chem 5X NS**

SEMI-AUTOMATED BIO-CHEMISTRY  
ANALYZER

**INSTRUMENT QUALIFICATION DOCUMENT**  
FOR

**s.r.k Lab & diagnostic center Run by Shree Radhe Krishna Educational  
trust , bharatpur**

# Installation Qualification for Erba Chem5X NS

**Customer Name** : s.r.k Lab & diagnostic center Run by Shree Radhe  
Krishna Educational trust , bharatpur

**Address** : Kaptan Colony Near Reserve police Line Bharatpur ,  
( Raj. )321001.

**Instrument Model** : Chem-5x

**Serial Number** : S220302

**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. S220302 is successfully installed and commissioned at s.r.k Lab & diagnostic center Run by Shree Radhe Krishna Educational trust , bharatpur and the Installation Protocol / checklist has been successfully completed for the above instrument.

**For TBM, Technical Services Department**

Name : Ashok kumar Ashok Kumar  
Designation : service engineer

Date: 10.11.2023



## 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: ASHOK KUMAR

Designation: Service engineer

Date: 10-11-2023

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**For TBM, Technical Services Department**

**Name:** ASHOK KUMAR Ashok Kumar

**Designation:** Service engineer

**Date:** 10-11-2023

# 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 Customer Detail

Name : Ashok kumar  
Designation: Service engineer  
Signature : *Ashok Kumar*  
Date : 10-11-2023

Name : Mukut Bihari  
Designation: LT  
Signature *Mukut Bihari*  
Date : 10-11-2023



# Operational Qualification For Erba Chem5X NS

## 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: Ashok kumar  
Designation: service engineer

Customer Authorization: Ravi kuntal (president Shree Radhe Krishna Education trust, bharatpur)

Name: Ravi kuntal  
Designation: owner

Company Representative Sign:-  
Date:-10.11.23

Ashok kumar

Customer Sign:-  
Date:-10.11.23

Ravi

# 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)

2181

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

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: \_\_\_\_\_

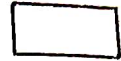
7. GAIN CHECK FOR ALL FILTERS

Filter	340	405	505	546	578	630	Range
Gains	56861	11500 0	107460	059128	107585	152533	30000-200000
Offset	0.475	0.472	0.1992	0.4586	0.1987	0.0470	0.0- 1.0

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 Customer Details**

Name : Ashok kumar  
Designation: Service engineer

Ashok Kumar

Name : Mukut Bihari  
Designation: LT

Mukut Bihari

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Signature :  
Signature :  
Date :14-08-2023

**1. 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	

PERFORMANCE TEST	DATA TRACEABILITY	REMARKS MEETS/DOES NOT MEET ACCEPTANCE
CRE		