

Date: 16/02/2022

**CALIBRATION CERTIFICATE****TO WHOM SO EVER IT MAY CONCERN**

This is to Certify That The Analyzer Bearing the Serial no: **S2110167** Has Installed by us At **KG Diagnostics, Tenkasi**. Has Been Calibrated on 16-Feb-2022 And Verified To Control Values.

The Next Calibration Due is on or Before : 15-Feb-2023

For TRANSASIA BIO MEDICALS LTD

P.Ramachandran  
Sr.Application Specialist,  
Madurai

**TRANSASIA BIO-MEDICALS LTD.**

Transasia House, 8 Chandivall Studio Road, Andheri (E), Mumbai - 400 072 Tel.: (022) 40309000, Fax : (022) 2857 3030  
Email : transasia@transasia.co.in Website : www.transasia.co.in

TRANSASIA BIO-MEDICAL LTD.

CHEM 5X

SR. NO :S2110167

IQ,OQ AND PQ

For

KG DIAGNOSTICS, TENKASI

Marketed by:  
Transasia Bio-Medicals Ltd.,  
Transasia House,  
Chandivali Studio road,  
Andheri (E),  
MUMBAI - 400 072

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## Installation Qualification for Erba Chem5X NS

**Customer Name** : KG DIAGNOSTICS

**Address** : 5-294(3) A.P.S Complex, Madurai Main Road, Tenkasi

**Instrument Model** : CHEM 5X

**Serial Number** : S2110167

**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 VARAIBLE VOLUME MECHANICAL PIPETTES 5UL - 50UL (CAT. NO 720020)    | 1   |
| 13.    | PROLINE SINGLE CHANNEL VARAIBLE VOLUME MECHANICAL PIPETTE 100UL - 1000UL (CAT. NO 720060) | 1   |
| 14.    | ERBA WASH (4 X 50 ML)   | 1   |

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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. S2110167 is successfully installed and commissioned at KG DIAGNOSTICS and the Installation Protocol / checklist has been successfully completed for the above instrument.

**For TBM, Technical Services Department**

**Name** : Mr. A.GanesaMoorthi  
**Designation** : Service Engineer  
**Date** :16/02/2022

**TRANSASIA BIO-MEDICALS LTD.**



## 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:** Mr. A.GanesaMoorthi  
**Designation:** Service Engineer  
**Date:** 16/02/2022

## Installation Report for Erba Chem 5X NS

Customer Name : KG DIAGNOSTICS

Department : LAB

Contact Person : MR.LAKSHMANAN

Instrument Model : Erba Chem-5X NS

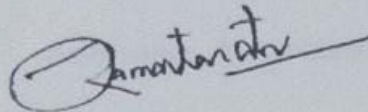
Serial Number : S2110167

Date of Installation: 16/02/2022

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 : P.RAMACHANDRAN  
Designation: Sr.Application Specialist

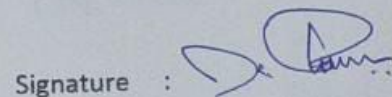


Signature :

Date :16/02/2022

### Customer Detail

Name : K.LAKSHMANAN  
Designation : LAB - TECH



Signature :

Date : 16.02.2022



## 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 : P.RAMACHANDRAN

Designation: Sr.Application Specialist

Signature :

Date :16/02/2022

### Customer Detail

Name : K.LAKSHMANAN

Designation: LAB TECH

Signature :

Date : 16.2.2022

### **TRANSASIA BIO-MEDICALS LTD.**

## 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 : P.RAMACHANDRAN

Designation: Sr.Application Specialist

Signature :

Date :16/02/2022

### Customer Detail

Name : K.LAKSHMANAN

Designation: LAB TECH

Signature :

Date : 16.2.2022

### **TRANSASIA BIO-MEDICALS LTD.**



## 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.

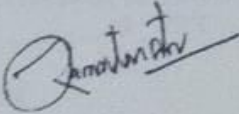
The System is ready for specific usage.

### Protocol Performed By:

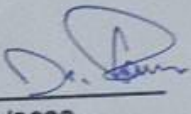
Name: P.RAMACHANDRAN  
Designation: Sr.Application Specialist

### Customer Authorization:

Name: Mr.Lakshmanan  
Designation: Lab Technician

Company Representative Sign:- 

Date: 16/02/2022

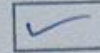
Customer Sign:- 

Date:- 16/02/2022

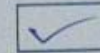
## Operational Qualification for Erba Chem5X NS

**[A] FUNCTIONAL CHECK :**
**1. PUMP CALIBRATION**

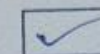
(Calibrate the peristaltic pump and record the count range from 1800 to 2700)


**2. PRINTER TEST**

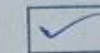
(To carry out printer function test from maintenance menu and to confirm that all characters printed w/o gap &amp; are clearly readable:- Last line must be above paper cutter)


**3. KEY FUNCTIONS**

(Confirm all keys function &amp; 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)  $37^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$ 

 (B) 57.5 K $\Omega$  to 59.0 K $\Omega$  using temperature jig)

Check temperature in RUN TEST mode for temperatures:

 1.  $37^{\circ}\text{C}$ : \_\_\_\_\_ 2.  $30^{\circ}\text{C}$ : \_\_\_\_\_ 3.  $25^{\circ}\text{C}$ : \_\_\_\_\_

**7. GAIN CHECK FOR ALL FILTERS**

| Filter | 340   | 405   | 505   | 546   | 578   | 630   | Range          |
|--------|-------|-------|-------|-------|-------|-------|----------------|
| Gains  | 38000 | 42000 | 49000 | 62000 | 69500 | 74000 | 30000-200000   |
| Offset | -5100 | -6150 | -6110 | -5980 | -5510 | -6512 | -5000 to +5000 |

8. Checked Hardware test and found OK.



9. Checked Date &amp; time and found OK.



10. Checked printer test and found OK.


**TRANSASIA BIO-MEDICALS LTD.**



TBM, Technical Services Department

Name :  
 Designation :  
 Signature :  
 Date :

Customer Details

Name :  
 Designation :  
 Signature :  
 Date:

## 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.      | 93.2                |
| 2.      | 91.8                |
| 3.      | 93.5                |
| 4.      | 90.9                |
| 5.      | 91.6                |
| 6.      | 91.8                |
| 7.      | 92.8                |
| 8.      | 92.2                |
| 9.      | 93.1                |
| 10      | 92.8                |
| Mean    | 95.59               |
| SD      | 4.78                |
| CV%     | 3%                  |

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