

# TRANSASIA®

Transasia Bio - Medicals Ltd., Transasia House, 8 Chandivall Studio Road, Andheri (E) Mumbai - 400 072  
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## *Certificate of Conformity and Calibration*

TO WHOMSOEVER IT MAY CONCERN

### ISO 15189:2012 REQUIREMENTS REGARDING,"CALIBRATION AND VERIFICATION PROCEDURE"

All Transasia Bio-Medicals Ltd diagnostics products which are distributed and for which a certificates is issued are CE Marked. Transasia Bio-Medicals Ltd , Mumbai ,manufacturers of diagnostic devices with company quality management system in compliance with standard ISO13485:2016 ;ISO9001:2015 .This means that all the processes in development and manufacturing of TBM products are guided by quality management system.

TBM declares and assure following

- The mentioned regulations require that production system and measuring devices are qualified and manufacturing and test procedures are validated as per ISO 13485:2016 and ISO 9001:2015 standard and it is assured through schedule maintenance and by regular qualification.
- TBM declares to have established procedure and to maintain it in order to assure the post marketing surveillance according to directive of 98/79/EC.
- All physical quantities, calibrators and controls used in TBM system are fully traceable to certified standards or reference materials.
- All TBM products are factory calibrated and final qc passed at the time of release.
- The performance of TBM system at customer site is assured if regular QC measurements, cleaning and maintenance procedure as described in the instruction for use or service documentation are performed
- Additional calibration or verification procedure is not required in order to assure the specified performances of every TBM system. Only if user deviates from the manufactures recommendation does he have to establish site specific calibration and verification procedure as part of his accreditation process.

Date:-26/04/2021

Manish Airan

Head Of Quality Department & Regulatory

## INSTALLATION & TRAINING REPORT

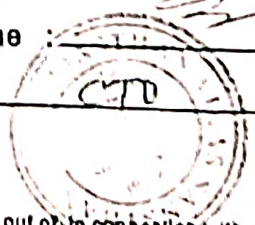
Customer Name : Vyach superspecialty Hospital  
 Department : Hospital Laboratory  
 Address : Near Kudi Had, pali Road Jodhpur  
 City : Jodhpur Pin : 342005 State : Rajasthan  
 Territory : Jodhpur Zone : CW1  
 Telephone & Fax : \_\_\_\_\_ email : \_\_\_\_\_  
 Contact Person : Mr. Krichna Mobile No. : 90461862496  
 Instrument Model : chem 7 Sr. No. : 521133  
 Installation Date : 25/02/2023

The above mentioned instrument has been satisfactorily installed by Service Engineer / Product Specialist of Transasia Bio-Medicals Ltd. Operational Training & User Maintenance of the instrument was provided to the following staff members on date (s) : 25/02/2023

Name (s)	Designation/ Dept.
1. <u>Mr. Charuwan</u>	<u>Sr. I.T</u>
2. <u>Mr. Indrajit</u>	<u>L.T</u>
3. <u>Ms. Divya bharti</u>	<u>L.T</u>

Test/ Parameters Demonstrated : \_\_\_\_\_

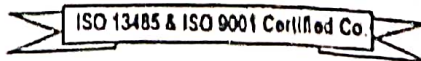
Customer Comments (If any) : \_\_\_\_\_

Engineer / Product Specialist : Upender Customer Signature : \_\_\_\_\_  
 Signature : [Signature] Customer Name : \_\_\_\_\_  
 Name : Girdharsi kaur Designation : \_\_\_\_\_  
 Date : 25/02/2023 Customer Seal : 

**Arbitration Clause**

All disputes, Differences, controversies and questions directly or indirectly arising at any time under, out of, in connection with or in relation to the payment of this instrument / reagents / service shall be referred to the sole arbitrator to be appointed by Transasia Bio-Medicals Limited under the Arbitration and Conciliation Act 1996. The venue and seat of arbitration shall be at Mumbai. The award rendered by the arbitrator(s) shall be final and binding upon both Parties.

www.transasia.co.in



CUSTOMER COPY

**TRANSASIA BIO-MEDICALS LTD.**

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Doc No. SC00-430/188-4

**TRANSASIA**  
**ERBA Chem 7**  
SEMI-AUTOMATED BIO-CHEMISTRY  
ANALYZER  
INSTRUMENT QUALIFICATION DOCUMENT  
FOR  
" \_\_\_\_\_ Lab Name \_\_\_\_\_ "



## Installation Qualification for Erba Chem7

Customer Name : Vyas Super Speciality Hospital,

Date : 25 Feb 2023

Address : Pali Road, Jodhpur

Instrument Model : Erba Chem 7

Serial Number : S211273

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-7 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-7	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. S211273 is successfully installed and commissioned at **Vyas Super Speciality Hospital, Jodhpur** and the Installation Protocol / checklist has been successfully completed for the above instrument.

**For TBM, Technical Services Department**

**Name** : Girdhari Sharma  
**Designation** : Service Engineer  
**Date** : 25 Feb 2023

## **Installation Qualification for Erba Chem7**

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** : Girdhari Sharma  
**Designation** : Service Engineer  
**Date** : 25 Feb 2023

# Installation Report for Erba Chem 7

**Customer Name** : Vyas Super Speciality Hospital, Jodhpur

**Department** : Laboratory

**Contact Person** : Mr. Sharwan

**Instrument Model** : Erba Chem-7

**Serial Number** : S211273

**Date of Installation:** 25 Feb 2023

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** : Girdhari Sharma

**Designation:** Service Engineer

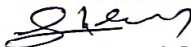
**Signature** : 

**Date** : 25/02/23

## Customer Detail

**Name** : Mr. Sharwan

**Designation:** Lab Technician


**Signature** : 

**Date** : 25/02/23

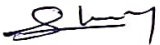
## Instrument Setup

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 : Girdhari Sharma  
Designation: Service Engineer  
Signature :   
Date : 25/02/23

### Customer Detail

Name : Mr. Sharwan  
Designation: Lab Technician  
Signature :   
Date : 25/02/23



# Operational Qualification For Erba Chem7

## 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: Girdhari Sharma  
Designation: Service Engineer

Customer Authorization:

Name: Mr. Sharwan  
Designation: Lab Technician

Company Representative Sign:- GS  
Date:- 28/02/23

Customer Sign:- [Signature]  
Date:- 28/02/23

# Operational Qualification for Erba Chem7

**[A] FUNCTIONAL CHECK :**

**1. PUMP CALIBRATION**

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

2125

**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)

OK

**3. KEY FUNCTIONS**

(Confirm all keys function & keys functioning are smooth)

OK

**4. BUZZER**

(Buzzer beeps when key is pressed)

OK

**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)

OK

**6. TEMPERATURE CHECK**

Cuvette temperature physical: 37.1° 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: 37.1° C 2. 30° C: 29.9° C 3. 25° C: 25.1° C

**7. GAIN CHECK FOR ALL FILTERS**

Filter	340	405	450	505	546	578	600	670	<i>Range</i>
Gains	85232	100549	97896	86548	102465	158744	124896	145698	30000-200000
Offset	4235	1204	2549	1457	2147	943	2349	1517	-5000 to +5000

**8. Checked Hardware test and found OK.**

OK


9. Checked Date & time and found OK.

OK

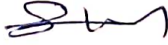
10. Checked printer test and found OK.

OK

**TBM, Technical Services Department**

Name : Girdhari Sharma  
Designation: Service Engineer  
Signature :   
Date : 28/02/23

**Customer Detail**

Name : Mr. Sharwan  
Designation: Lab Technician  
Signature :   
Date : 28/02/23

## Performance Qualifications for Erba Chem 7.

### 1. PRECISION CHECK:

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


Sr. No.	Concentration mg/dl
1.	100.5
2.	101.3
3.	98.4
4.	101.7
5.	100.8
6.	99.6
7.	101.5
8.	98.5
9.	99.6
10	101.6
Mean	100.35
SD	1.25
CV%	1.24

#### Conclusion:

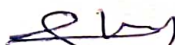
The result for all the performance tests carried out for the instrument meets/does not meet the acceptance criteria. Hence the instrument is/ is not qualified for the performance.

Protocol performed By:-

#### TBM, Technical Services Department

Name : Girdhari Sharma  
Designation: Service Engineer  
Signature :   
Date : 28/02/23

#### Customer Detail

Name : Mr. Sharwan  
Designation: Lab Technician  
Signature :   
Date : 28/2/23