



TRANSASIA ERBA Chem-7

SEMI-AUTOMATED BIO-CHEMISTRY
ANALYZER
INSTRUMENT QUALIFICATION DOCUMENT
FOR

“MAHARASHTRA ACADEMY OF ENGINEERING AND EDUCATIONAL RESEARCH, PUNE”

Certificate of Operator's Training

Awarded to

MR. VIRENDAR SINGH

Armed Forces Medical College, Pune

For participation in the

“Operational training on H360”

Sr. No :- K10012022032

Held on 05th MAR 2021 at **Armed Forces Medical
College, Pune**



A handwritten signature in blue ink, appearing to read "Swapnil".

Mr. SWAPNIL KAMARIKAR.

Service Engineer

Transasia Bio-medical Ltd.



Installation Qualification for ERBA CHEM-

Customer Name : MAHARASHTRA ACADEMY OF ENGINEERING AND EDUCATIONAL RESEARCH, PUNE

Address : Pune

Instrument Model : Erba Chem-7

Serial Number : S1709178

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 (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.	TEST TUBE HOLDER (with O-ring)	1
10.	Pipette Stand (Plastic)	1
11.	PROLINE SINGLE CHANNEL VARIABLE VOLUME MECHANICAL PIPETTES 5UL - 50UL (CAT. NO 720020)	1
12.	PROLINE SINGLE CHANNEL VARIABLE VOLUME MECHANICAL PIPETTE 100UL - 1000UL (CAT. NO 720060)	1
13.	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. S1709178 is successfully installed and commissioned at MAHARASHTRA ACADEMY OF ENGINEERING AND EDUCATIONAL RESEARCH, PUNE and the Installation Protocol / checklist has been successfully completed for the above instrument.

For TBM, Technical Services Department

Name : Swapnil Kamarikar
Designation : Service Engineer
Date : 01/01/2021



Installation Qualification for ERBA CHEM-7



Carried out all the Installation Procedures as per the Installation 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 : Swapnil Kamarikar
Designation : Service Engineer
Date : 01/01/2021





Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

Installation Report for ERBA CHEM-7

Customer Name : MAHARASHTRA ACADEMY OF ENGINEERING AND EDUCATIONAL RESEARCH, PUNE

Department :
Contact Person :

Instrument Model : Chem-7
Serial Number : S1709178
Date of Installation: 01/01/2021

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 : Swapnil Kamarikar
Designation: Service Engineer
Signature :
Date : 01/01/2021

Customer Detail

Name : Dr. Anil Datta Gaud
Designation: HOD - Lab
Signature :
Date :

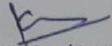





Instrument Setup

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 : Swapnil Kamarikar
Designation: Service Engineer
Signature : 
Date : 01/01/2021

Customer Detail

Name : Dr. Anandh Kumar
Designation: HOD - Lab
Signature : 
Date :





Operational Qualification For ERBA CHEM-7

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: Swapnil Kamarikar
Designation: Service Engineer

Customer Authorization:

Name: *Dr. Anindatta Ramad*
Designation: *HOD - Lab*

Company Representative Sign: *[Signature]*
Date: 01/01/2021

Customer Sign: *[Signature]*
Date: _____





Operational Qualification for ERBA CHEM-7

[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: _____

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	450	505	546	578	600	670	Range
Gains	1L	1L	1L	1L	1L	1L	1L	1L	30000-200000
Offset									-5000 to +5000




8. Checked Hardware test and found OK

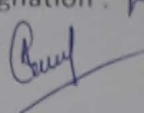
9. Checked Date & time and found OK

10. Checked printer test and found OK.

TBM, Technical Services Department

Name : Swapnil Kamarikar
Designation : Service Engineer
Signature : 
Date : 01/01/2021

Customer Details

Name : Dr. Anindha Laxmi
Designation : HOD - Lab
Signature : 
Date:





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 500µl 10 times and note down readings and calculate CV. CV should be below 3%)

Sr. No.	Concentration mg/dl
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10	
Mean	
SD	
CV%	

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					
CHOL					
CRET					

PERFORMANCE TEST	DATA TRACEABILITY	REMARKS MEETS/DOES NOT MEET ACCEPTANCE
SGPT		
CHOL		
CRET		



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.

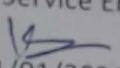
Protocol performed By:-


TBM, Technical Services Department

CUSTOMER DETAIL

TBM, Technical Services Department

Customer Detail

Name : Swapnil Kamarikar
Designation: Service Engineer
Signature : 
Date : 01/01/2021

Name : *Dr. Anand Kumar*
Designation: *HOD Lab*
Signature : 
Date :





CALIBRATION REPORT

To,

DATE- 01/04/21

**Maharashtra Academy of Engineering and Educational Research,
Vishwaraj Hospital, Pune**

Dear Sir,

As desired by you please find enclosed herewith the Calibration report

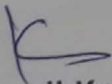
1. Instrument: Bio-chemistry Analyzer ERBA CHEM-7 S.N- S1709178
2. Range of the instrument: Optical density Linear form 0-2.5
3. Date of Calibration – 01st Apr 2021
4. Next Calibration Due- 31st Mar 2022

Quality Control Results-

Test Type	Test Results	Range
End Point (GLU)	95.8	80.2-108.2
Fix Time (URE)	33.11	29.85-37.85
Kinetic (SGPT)	41.6	37.5-52.5

Thanking you and assuring of our prompt attention at all times.

Yours faithfully,
For **TRANSASIA BIO-MEDICALS LTD.**


Swarnil Kamarikar
Service Engineer





Calibration Certificate

Date 01st Apr 2021

To,
Maharashtra Academy of Engineering and Educational Research,
Vishwaraj Hospital, Pune.

Dear Sir,

As desired by you please find enclosed herewith Technical calibration report for your Urine Analyzer Model: Laura M Sr. No. 8381160315.

1. Date of Calibration - : 01st Apr 2021
2. Next Calibration date- : 31st Mar 2022

Calibration status:

Ref	R=335	G=336	B=338
LEU	R=335	G=336	B=338
NIT	R=335	G=336	B=338
URO	R=335	G=336	B=338
PRO	R=335	G=336	B=338
pH	R=335	G=336	B=338
BLD	R=335	G=336	B=338
S.G.	R=335	G=336	B=338
KET	R=335	G=336	B=338
BIL	R=335	G=336	B=338
GLU	R=335	G=336	B=338
VTC	R=335	G=336	B=338

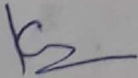
Calibration value Range 333+/- 10 (323 -343)

Calibration of instrument is ok.

Thanking you and assuring of our prompt attention at all times.

Yours faithfully,

For TRANSASIA BIO-MEDICALS LTD.


Mr. Swapnil Kamarikar
Service Engineer

