



CALIBRATION REPORT

To,
MAEER's Vishwaraj Hospital Laboratory, Pune

DATE- 30/03/22

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 – 30th Mar 2022
4. Next Calibration Due- 29th Mar 2023

Quality Control Results-

Test Type	Test Results	Range
End Point (GLU)	99.68	80.2-108.2
Fix Time (URE)	28.17	29.85-37.85
Kinetic (SGPT)	46.73	37.5-52.5

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

Yours faithfully,
For TRANSASIA BIO-MEDICALS LTD.

Swapnil Kamarike
Service Engineer





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SINCE 1979...

CALIBRATION REPORT

To,
MAEER's Vishwaraj Hospital Laboratory, Pune

DATE- 01/04/21

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.**

Swapnil Kamarikar
Service Engineer



TRANSASIA®

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TRANSASIA
ERBA Chem-7
SEMI-AUTOMATED BIO-CHEMISTRY
ANALYZER
INSTRUMENT QUALIFICATION DOCUMENT
FOR
"MAEER'S VISHWARAJ HOSPITAL LABORATORY"

Page 1 of 9



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HO : Transasia Bio - Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai - 400 072.



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Installation Qualification for ERBA CHEM-7

Customer Name : MAEER'S VISHWARAJ HOSPITAL LABORATORY

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



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 MAEER'S VISHWARAJ HOSPITAL LABORATORY 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

Installation Report for ERBA CHEM-7



Customer Name : MAEER'S VISHWARAJ HOSPITAL LABORATORY

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. Anindha Ganesh

Designation: HOD-Laboratory

Signature :

Date :

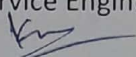


Instrument Setup

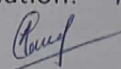



1. Assembled the instrument accessories.
2. Connected the 3/2 pin cord (with earth terminal) of the external SMPS to the mains socket & checked the output of the SMPS it should be 18V DC +/- 1.0 V DC.
3. Connected the Peristaltic Pump tubing & placed the end of the waste tubing coming out of the analyzer 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. Auneedha Camel
Designation: HOD-Laboratory
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. Anindha Kandel*
Designation: *HOD. Laboratory*

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

Customer Sign:- *[Signature]*
Date:- _____

Operational Qualification for ERBA CHEM-7

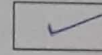


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[A] FUNCTIONAL CHECK :

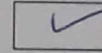
1. PUMP CALIBRATION

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



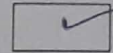
2. PRINTER TEST

(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)



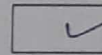
3. KEY FUNCTIONS

(Confirm all keys function & keys functioning are smooth)



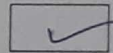
4. BUZZER

(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	12	12	12	12	12	12	12	12	30000-200000
Offset									-5000 to +5000



8. Checked Hardware test and found OK.

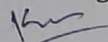
9. Checked Date & time and found OK.

10. Checked printer test and found OK.

TBM, Technical Services Department

Name : Swapnil Kamarikar

Designation : Service Engineer

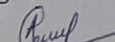
Signature : 

Date : 01/01/2021

Customer Details

Name : Dr. Anindha Khande

Designation : HOD-Laboratory

Signature : 

Date:





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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.	101.7
2.	102.6
3.	103.3
4.	104.4
5.	104.4
6.	106.9
7.	106.7
8.	107.3
9.	107.6
10	107.8
Mean	105.27
SD	2.14
CV%	2.07

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	24.48	24.48	115.7	122.4
CHOL / Urea	0.0	24.63	32.09	132.1	134.1
CRET	0.0	0.85	0.84	7.34	7.29

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



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

Name : *Dr. Anindha Ganesh*

Designation: Service Engineer

Designation: *HOD-Laboratory*

Signature : *[Signature]*

Signature : *[Signature]*

Date : 01/01/2021

Date : *[Signature]*



LINEAR TEST URE (Urea)

MODE : 2-POINT	R1/R2 VOL: 400/100
FILTERS : 340/000	SAMP. VOL: 5
STD. CONC: 50	DELAY T. : 30
FACTOR : -632.9	READ T/N : 60 /1
DEL.RG.OD: 0	NOR.MN(M): 15
ASP. VOL : 450	NOR.MX(M): 45
AIR PURGE: ON	

I.D.

TEMP: 37.0

ABS : 0.0

NO

READ

WASH

LINEAR TEST SGPT(SGPT(ALT))

MODE : RATE A	R1/R2 VOL: 400/100
FILTERS : 340/000	SAMP. VOL: 50
STD. CONC: 0	DELAY T. : 10
FACTOR : 2225	READ T/N : 240/1
DEL. RG. OD: 0	NOR. MN(M): 0
ASP. VOL : 450	NOR. MX(M): 48
AIR PURGE: ON	

I.D.

TEMP: 37.0

ABS : 0.0

ASPIRATE SAMPLE

I.D.

CHTRL

READ

PRINT

WASH

LINEAR TEST CRE (Creatinin)

MODE : 2-POINT	R1/R2 VOL: 250/250
FILTERS : 505/000	SAMP. VOL: 50
STD. CONC: 2	DELAY T. : 30
FACTOR : 20.790	READ T/N : 90 / 1
DEL. RG. OD: 0	NOR. MN(M): 0.6
ASP. VOL : 450	NOR. MX(M): 1.4
AIR PURGE: ON	

I.D.

TEMP: 37.0

ABS : 0.0

ASPIRATE STANDARD

NO

READ

WASH

01/01/21 10:26:18

Z

GLU Reagent OD 0.0160

GLU STD O.D. 0.3662

NET O.D : 0.3502

CONC : 100 mg/dl

FACTOR :285.55

0000PP GLU 101.7 mg/dl H

0000PP GLU 102.6 mg/dl H

0000PP GLU 103.3 mg/dl H

0000PP GLU 104.4 mg/dl H

0000PP GLU 104.4 mg/dl H

0000PP GLU 106.9 mg/dl H

0000PP GLU 106.7 mg/dl H

0000PP GLU 107.3 mg/dl H

0000PP GLU 107.6 mg/dl H

0000PP GLU 107.8 mg/dl H

01/01/21 10:39:36

Z

0000PP GLU 98.51 mg/dl

0000PP GLU 99.80 mg/dl

01/01/21 10:46:33

Z

0000PP SGPT 24.48 IU/L

LINEAR REACTION

0000PP SGPT 24.48 IU/L

LINEAR REACTION

0000PP SGPT 24.48 IU/L

LINEAR REACTION

0000PP SGPT 115.7 IU/L H

LINEAR REACTION

0000PP SGPT 122.4 IU/L H

LINEAR REACTION

0000PP SGPT 126.8 IU/L H

LINEAR REACTION

01/01/21 11:58:15

Z

URE DELTA STD O.D. -0.067

NET O.D : -0.067

CONC : 50 mg/dl

FACTOR : -746.3

LINEAR REACTION

0000PP URE 56.72 mg/dl H

LINEAR REACTION

0000PP URE 17.16 mg/dl

LINEAR REACTION

0000PP URE 24.63 mg/dl

LINEAR REACTION

0000PP URE 32.09 mg/dl

LINEAR REACTION

0000PP URE 132.1 mg/dl H ?

LINEAR REACTION

0000PP URE 134.3 mg/dl H

LINEAR REACTION

0000PP URE 120.9 mg/dl H

LINEAR REACTION

01/01/21 11:28:50

Z

CRE DELTA STD O.D. 0.0956
NET O.D : 0.0956
CONC : 2 mg/dl
FACTOR : 20.921

LINEAR REACTION

0000PP CRE 2.01 mg/dl H

LINEAR REACTION

0000PP CRE 7.34 mg/dl H

LINEAR REACTION

0000PP CRE 7.29 mg/dl H

LINEAR REACTION

0000PP CRE 7.28 mg/dl H

LINEAR REACTION

0000PP CRE 0.85 mg/dl H

LINEAR REACTION

0000PP CRE 0.84 mg/dl H

LINEAR REACTION

0000PP CRE 0.87 mg/dl H

LINEAR REACTION

*** CHEMISTRY PARAMETERS ***

TEST :GLU (Glucose)
MODE :1-POINT
FILTER1 :505
FILTER2 :0
FACTOR :247.46
STD. CONC:100
NOR.MN(M):74
NOR.MX(M):100
NOR.MN(F):74
NOR.MX(F):100
NOR.MN(I):74
NOR.MX(I):100
TEMP. :37
DELAY T. :5
READ T :0
READ NUM :1
RECT DIR :INC
RG.ABSLIM:0.2
RX.ABSLIM:2.5
LIN. LIM.:500
UNIT :mg/dl
SAMP. VOL:5
R1 VOL :500
R2 VOL :0
ASP. VOL :450
C1 MEAN :0
C1 SD :0
C2 MEAN :0
C2 SD :0
C3 MEAN :0
C3 SD :0
FORMULA :N/A
30/03/22 14:52:34
R

30/03/22 13:43:16

B

GLU Reagent OD 0.0274

GLU STD O.D. 0.4315

NET O.D : 0.4041

CONC : 100 mg/dl

FACTOR :247.46

0000PP GLU 99.68 mg/dl *std*

0000PP GLU 101.0 mg/dl H

---+ CHEMISTRY PARAMETERS +---

TEST : SGPT (SGPT (ALT))
MODE : RATE A
FILTER1 : 340
FILTER2 : 0
FACTOR : 2225
STD. CONC: 0
NOR. MN (M): 0
NOR. MX (M): 48
NOR. MN (F): 0
NOR. MX (F): 42
NOR. MN (I): 0
NOR. MX (I): 42
TEMP. : 37
DELAY T. : 10
READ T : 240
READ NUM : 1
RECT DIR : DEC
RG. ABSLIM: 1.8
RX. ABSLIM: 0.5
LIN. LIM.: 500
UNIT : IU/L
SAMP. VOL: 50
R1 VOL : 400
R2 VOL : 100
ASP. VOL : 450
C1 MEAN : 0
C1 SD : 0
C2 MEAN : 0
C2 SD : 0
C3 MEAN : 0
C3 SD : 0
FORMULA : N/A

URE DELTA STD O.D. -0.158
NET O.D : -0.158
CONC : 50 mg/dl
FACTOR : -316.5

LINEAR REACTION

0000PP URE 46.84 mg/dl H
std

LINEAR REACTION

0000PP URE 28.17 mg/dl

LINEAR REACTION

--*-- CHEMISTRY PARAMETERS *--*

TEST : URE (Urea)
MODE : 2-POINT
FILTER1 : 340
FILTER2 : 0
FACTOR : -588.2
STD. CONC: 50
NOR. MN (M) : 15
NOR. MX (M) : 45
NOR. MN (F) : 13
NOR. MX (F) : 45
NOR. MN (I) : 13
NOR. MX (I) : 45
TEMP. : 37
DELAY T. : 30
READ T : 60
READ NUM : 1
RECT DIR : DEC
RG. ABS LIM : 0.8
RX. ABS LIM : 0.5
LIN. LIM. : 300
UNIT : mg/dl
SAMP. VOL : 5
R1 VOL : 400
R2 VOL : 100
ASP. VOL : 450
C1 MEAN : 0
C1 SD : 0
C2 MEAN : 0
C2 SD : 0
C3 MEAN : 0
C3 SD : 0
FORMULA : N/A

30/03/22 15:32:00

B

0000PP SGPT 46.73 IU/L