

TRANSASIA
ERBA Chem 5 V210K
SEMI-AUTOMATED BIO-CHEMISTRY
ANALYZER
INSTRUMENT QUALIFICATION DOCUMENT
FOR
"Arogya Diagnostic Centre"

Installation Qualification for ERBA CHEM-5 V210K

Customer Name : AROGYA DIAGNOSTIC CENTRE

Address : JAYJAYNTI MARKET, KACHUA MORE, PIN: 743272

Instrument Model : EC5 PLUS V2

Serial Number : N121218

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 – EC5 V2 10K (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.N121218 is successfully installed and commissioned at AROGYA DIAGNOSTIC CENTRE and the Installation Protocol / checklist has been successfully completed for the above instrument.

For TBM, Technical Services Department

Name : TANMAY CHANDA
Designation : SR. SERVICE ENGINEER
Date :



Installation Qualification for ERBA CHEM-5 V210K

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: TANMAY CHANDA

Designation: SR. SERVICE ENGINEER

Date:



Installation Report for ERBA CHEM-5 V210K

Customer Name : AROGYA DIAGNOSTIC CENTRE

Department : LABORATORY

Contact Person :

Instrument Model : Erba Chem-5 V2 10K

Serial Number : N121218

Date of Installation: 13-MAY-13

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 : TANMAY CHANDA

Designation: SR. SERVICE ENGINEER

Signature :

Date :

Customer Detail

Name :

Designation:

Signature :

Date :



Instrument Setup

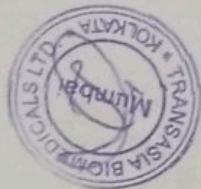
1. Assembled the instrument accessories.
2. Connected the 3/2 pin cord (with earth terminal) of the external SMPS to the mains socket & checked the output of the SMPS it should be 18V DC +/- 1.0 V DC.
3. Connected the Peristaltic Pump tubing & placed the end of the waste tubing coming out of the analyzer into the waste bottle provided for collecting the waste.
4. Mounted the printer paper.

TBM, Technical Services Department

Name : TANMAY CHANDA
Designation: SR. SERVICE ENGINEER
Signature :
Date :

Customer Detail

Name :
Designation:
Signature :
Date :



Operational Qualification For ERBA CHEM-5 V210K

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:
Designation:

Customer Authorization:

Name:
Designation:

Company Representative Sign:- _____
Date:- _____

Customer Sign:- _____
Date:- _____



Operational Qualification for ERBA CHEM-5 V210K

{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) $37^{\circ} \text{C} \pm 0.1^{\circ} \text{C}$

(B) 57.5 K Ω to 59.0 K Ω 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									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 : TANMAY CHANDA
Designation : SR. SERVICE ENGINEER
Signature :
Date :

Customer Details

Name :
Designation :
Signature :
Date:



Performance Qualifications for ERBA CHEM-5 V210K

CUSTOMER: AROGYA DIAGNOSTIC CENTRE.
INSTRUMENT: SEMI-AUTOMATIC BIOCHEMISTRY ANALYSER
MODEL: EC5 PLUS V2
SERIAL NO. N121218
DEPARTMENT: LABORATORY.
INSTALLATION DATE: 13-MAY-23

PERFORMANCE CHECK: COMPLETED SUCCESSFULLY

TBM, Technical Services Department

CUSTOMER DETAIL

TBM, Technical Services Department

Customer Detail

Name :
Designation:
Signature :
Date :

Name :
Designation:
Signature :
Date :

