

OPERATIONAL
QUALIFICATION
For

TRANSASIA

ERBA H560
AUTOMATED HEMATOLOGY ANALYZER

Marketed by:
Transasia Bio-Medicals Ltd.,
(ISO 13485 CERTIFIED)
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI - 400 072

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I. Approval of the OQ procedure:

Regional Ayurveda Research Institute and Transasia are jointly responsible for the operational check of the HEMATOLOGY Analyzer, Model: Erba H560, serial no. K1104B2211056 in the clinical lab of RARI Jammu as per the protocol attached.

Protocol Performed by: Transasia Representative

Name: MR. AJAY SINGH
Title: OPERATIONAL QUALIFICATION
Company: TRANSASIA BIO-MEDICALS LTD.


Signature : 
Date : 9/1/23

Validation Team from _____

Name : Mr. Ajay Singh
Designation : Sr. Service Engg.
Department : ASD

Customer Authorization:

Name: DR. MEENAKSHI SURI
Title: OPERATIONAL QUALIFICATION
Site: JAMMU

Signature : 
Date : 09.01.2023

II. Instructions

1. The TRANSASIA representative will check each module and enter the specific data as described in the Operational Qualification. Each result will be noted and dated.
2. Employee of RARI will verify each result and sign on the last page. The member/s of the validation team will be responsible for the same.
3. Any deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section of the OQ protocol. All resolutions to such problems will also be noted in the **COMMENTS** section and must be resolved prior to the issuance of a **SYSTEM CERTIFICATION**. This will be an additional cost to the purchasing institution (**CUSTOMER**). However, this additional cost will be waived when this test is conducted at the time of the initial performance check of new instruments.
4. Any test data, which does not meet the specified acceptance criteria, will be submitted to the appropriate laboratory personnel for a solution. All steps taken subsequently will be documented.
5. This document contains proprietary information and is in no way to be copied, photographed, or duplicated in any way without expressed written authorization by the Product Manager at Transasia Bio-Medicals Ltd., Transasia House, Mumbai.

Validation Team:

Name:

Mr. Ajay Singh

Designation:

Sr. Service Engg

Signature:



Date:

9/1/23

III. Scope

This Operational Qualification protocol will be performed on the Hematology Analyzer, Model H560, Serial No. K1104B2211056 is located in the Clinical laboratory of the Regional Ayurveda Research Institute Jammu. This Protocol will define the documentation that will be used to evaluate the instrument's installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified is performing in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

Validation Team:

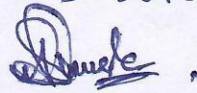
Name:

Mr. Ajay Singh.

Designation:

Sr. Service Cugg.

Signature:



Date:

9/1/23

IV. Operational Qualification**a. Instrument Identification****Verified Date**

1. Model Name H560
 2. Serial Number K1104B2211056

9/1/23
11

b. Following is a list of tests to be performed and verified and demonstrated to the user:

Test No.	Test Name	Test Purpose	Verified Date
1.	Liquid Pump	To verify pressure & vacuum generation	✓
2.	Syringe Assembly	Capacity of Blood Aspiration Diluent Aspiration, Lyse 1 & 2 Aspiration	✓
3.	Liquid Sensing PCB	To verify Liquid sensing ability Of sensors	✓

Validation Team:

Name:

Mr. Ajay Singh

Designation:

Sr. Service Engg.

Signature:



Date:

9/1/23

c. Operational Testing

Test 1

Test Name: Liquid Pump.

Purpose: To test Liquid Pump

Method: Please follow the steps described in Erba H560 "Service Manual"

PARAMETER

PASS ✓

FAIL

Parameter values for verification: LIQUID PUMP

Validation Team:

Name:

Mr. Ajay Singh

Designation:

Sr. Service Engg.

Signature:

[Handwritten Signature]

Date

9/1/23

Test 2

Test Name: Syringe Assembly
Purpose: To test the function

Method: Please follow the steps described in Erba H560 "Service Manual"

PARAMETER

PASS

FAIL

Parameter values for verification: Syringe Assembly

Validation Team :

Name

Mr. Ajay Singh

Designation

Sr. Service Engg.

Signature



Date

Test 3

Test Name: Liquid sensing PCB

Purpose: To test the liquid sensing operation.

Method: Please follow the steps described in Erba H560 "Service Manual"

PARAMETER

PASS ✓

FAIL

Parameter values for verification: Liquid Sensing

Validation Team :

Name

Mr. Ajay Singh

Designation

Sr. Service Engg.

Signature



Date

a. Certificate of Training**1. Technician Training**

This certifies that the technicians listed below have received basic user training in the following categories for the system described in this Installation Qualification.

Miss. Komal who is certified by Transasia Bio-Medicals Ltd has conducted the training.

Sr. No.	Training Program	Initials	Date
1.	Instrument Setup	<i>Komal</i>	9/1/23
2.	System Operation	<i>Komal</i>	9/1/23
3.	Basic Troubleshooting & Maintenance	<i>Komal</i>	9/1/23

2. Operator Training

The users responsible for the operation of this instrument will be trained in the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented and the training records will be filed as indicated below :

Sr.No.	Operators	Location	Initials	Date
1.	Ms. Komal	Lab	Ms. KOMAL	9/1/23
2.	Mr. Rakesh	Lab	Rakesh	9/1/23

Validation Team :

Name

Mr. Ajay Singh

Designation

Sr. Service Engg.

Signature



Date

b. Customer SOP

Title	Number	Revision #	Effective Date	Location	Verified By	Date
Operating Procedure	01	NA				

Validation Team :

Name

Mr. Ajay Singh

Designation

Sr. Service Engg.

Signature

Date

COMMENTS:

Validation Team :

Name

Designation

Signature

Date

VII. System Certification

Study data has determined that the system described in this document either meets all criteria outlined in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Report Performed By : Transasia Representative

Name: MR. AJAY SINGH

Title: OPERATIONAL QUALIFICATION

Company: TRANSASIA BIO-MEDICALS LTD.

Signature:


9/1/23

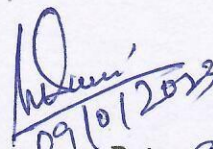
Date:

Customer Authorizations:

Name : DR. MEENAKSHI SURI

Title : OPERATIONAL QUALIFICATION Signature :

Company : RARI JAMMU
:


09/01/2023
Date 09.01.2023