

**INSTALLATION**  
**QUALIFICATION**

For

**TRANSASIA**

**ERBA H560**  
**AUTOMATED HEAMATOLOGY ANALYZER**

Manufactured by ERBA MANNHEIM  
&

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

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**I. Approval of the IQ procedure:**

Regional Ayurveda Research Institute Laboratory and Transasia are jointly responsible for the installation of the system ERBA HEMATOLOGY Analyzer, Model: H560, Serial No. K1104B2211056 in the clinical lab of the Regional Ayurveda Research Institute as per the attached protocol.

**Protocol Performed By:** Transasia Representative

**Name:** MR. AJAY SINGH  
**Title:** INSTALLATION QUALIFICATION  
**Company:** TRANSASIA BIO-MEDICALS LTD. **Date:**

**Signature:**

  
21/1/23

**Validation Team from** Transasia :

**Name** : Mr. Ajay Singh  
**Designation** : Sr. Service Engg.  
**Department** : TSD

**Customer Authorizations:**

**Name:** DR. MEENAKSHI SURI  
**Title:** INSTALLATION QUALIFICATION  
**Site:** JAMMU

**Signature:**


**Date:** 09.01.2023

  
09/01/2023

## **II. Instructions**

1. This document is to be completed at the time the system is shifted to its current location (new) and set up for operation.
2. An authorized TRANSASIA representative will check the system and enter the specific data as outlined in the appropriate Installation Qualification. Each result will be noted and dated.
3. Employee of (Customer) RARI will verify each result and sign on the last page. The members of the validation team will carry this out.
4. ALL deviations from normal specification including any problems with installation will be noted under COMMENTS. All resolutions to such problems will also be noted in the COMMENTS section. Additional space is provided at the end of this protocol for the same.
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 Transasia Bio-Medicals Ltd., Transasia House, Mumbai.

Validation Team:

Name Mr. Ajay Singh  
Designation Sr. Service Engg  
Signature 

Date

### III. Scope

This Installation Qualification protocol will be performed on the ERBA Hematology Analyzer, Model H560, Serial No. K1104B2211056 located in (add) REGIONAL AYURVEDA RESEARCH INSTITUTE. This Protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacture's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.

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:

Mv. Ajay Singh

Designation:

Sr. Service Engg.

Signature:



Date:

9/1/23

**IV. Ancillary Information.**

**a. Certification of Purchase Order Compliance**

I certify to the best of my knowledge, the instrument is purchased under Purchase Order No. GEMC-S1168770368015 Dt. 29/08/2022 sent against Quotation number Bid No. GEM/2022/3261960 dt. 10/10/22 is in compliance with the specifications of the Purchase order.

Verified By: Parmod

Date: 17/8/23

**b. Utilities**

| Sr. No. | Utility  | Yes / No | Verified By | Date   |
|---------|--|----------|-------------|--------|
| 1.      | Environmental condition as per requirement: (Ambient range of temperature 15 - 30 °C, relative humidity 30% to 85%, air conditioning facility, non-exposure to direct sunlight, non-interference from high-frequency radio waves)  | ✓        |             | 9/1/23 |
| 2.      | Adequate space for installation : (Minimum in mm. W 360 X D 410 X H 475 for the main unit clearance of around 50 cm from the back around 50cm on top and around 50 cm on the sides for the main unit)  | ✓        | ..          | 9/1/23 |
| 3.      | DIL-H560; LYSE1 & LYSE2 BOTTLES to be placed within a distance of 2 meters :   | ✓        | .           |        |
| 4.      | Power Source Requirements*<br>It should have a minimum of five 5-amp plugs. It should have proper grounding. In the case of online UPS minimum power handling capacity should be minimum of 1KVA<br>Line- Neutral voltage: <u>230v</u><br>Line -Earth voltage: <u>229v</u><br>Neutral-Earth voltage: <u>1v</u> | Yes      |             | 9/1/23 |

\* Encircle applicable source

Validation Team :

Name *Mu. Ajay Singh*

Designation *Sr. Service Crg*

Signature *[Signature]*

Date *9/1/23*

## c. The instrument has been verified for the following

| Sr.No. | Verification                                      | Yes / No | Verified By | Date |
|--------|---|----------|-------------|------|
| 1.     | Instrument is identified                          | Yes / No | Yes         |      |
| 2.     | Manufacturer's specifications are included        | Yes / No | Yes         |      |
| 3.     | Accessories / Consumables are listed              | Yes / No | Yes         |      |
| 4.     | Manufacturer's certificate of Compliance attached | Yes / No | Yes         |      |

## Validation Team :

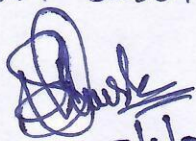
Name

Mr. Ajay Singh,

Designation

Sr. Service Engineer

Signature



Date

9/1/23



## V. Installation Qualification

### A. Equipment Description

This ERBA H560 is a fully automated five-part Hematology analyzer for in vitro diagnostic use in clinical laboratories. The instrument provides accurate and precise test results for (29) parameters including three histograms & one scatter-grams.

| Instrument identification |                       | Verified by | Date |
|---------------------------|-----------------------|-------------|------|
| Equipment Name            | Automated Hematology  |             |      |
| Model                     | H560                  |             |      |
| Manufacturer              | Erba Mannheim         |             |      |
| Marketed By               | Transasia             |             |      |
| Equipment #               |                       |             |      |
| Serial Number             | K1104B2211056         |             |      |
| Size (in mm)              | W 360 X D 410 X H 475 |             |      |
| Power                     | AC 220 V              |             |      |
| Frequency                 | 50 - 60 Hz            |             |      |
| Power Consumption         | Less Than 250 VA      |             |      |

#### Validation Team:

Name

Mr. Ajay Singh

Designation

Sr. Service Engg

Signature



Date

7/1/23



Designation *Sr. Service Engg.*

Signature *[Handwritten Signature]*

Date *9/1/23*

#### Installation Qualification

Consumables such as H-Clean, DIL H560, LYSE1 & LYSE2 were supplied along with the instrument.

Currently, a sufficient stock of the same is being maintained Yes • No •

#### C. List of Manuals, Certificates, and Drawings

Transasia provides the following with the instrument.

1. Instructions For use
2. User's Guide

#### D. Change Control Procedure

The instrument will not be altered, enhanced, modified or substituted for another system until a formal Change Control Authorization is approved from Transasia Bio-Medicals Ltd. And Regional Ayurveda Research Institute .

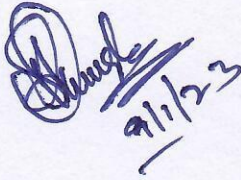
#### E. Maintenance

The instrument listed within this document will be placed under the control of the purchasing institution with respect to proper maintenance procedures as detailed in the User Manual.

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period, Transasia offers several levels of Maintenance Agreements and Performance Testing services to assist you in maintaining GLP/GMP compliance. Contacting your local representative and requesting the additional Service Agreement can supply additional information.

Validation Team : *Transasia Bio-Medicals Ltd.*  
Name *Mr. Ajay Singh.*  
Designation *Sr. Service Engg.*

Signature

Handwritten signature and date '9/1/23' in blue ink.

Date

**F. Spare Parts**

Transasia strongly recommends the end user maintain a basic of consumable parts onsite to minimize downtime due to minor failures. They have provided a list of such consumable parts and the same is also available in the Operator's Manual.

**C. Equipment Logs**

| Title | Location | Verified by | Date |
|-------|----------|-------------|------|
|       |          |             |      |

The sample page of the logbook is attached to this document

Effective date:

Validation Team :

Name


Mv. Ajay Singh

Designation

Sr. Service Cugg

Signature

Date

  
9/1/23

#### H. Installation Procedure

(These had been performed at the time of original installation at the initial location)

**1. Unpacking Checklist**

Refer to Page-16 of ERBA H560 Instruction For Use

**2. Check Before Installation**

Refer to Page-14 of ERBA H560 Instruction For Use

**3. Grounding**

Refer to Page-14 of ERBA H560 Instruction For Use

**4. Installation Environment & Space**

Refer to Page-14 of ERBA H560 Instruction For Use

Validation Team:


Name

Mr. Ajay Singh

Designation

Sr. Service Engg.


Signature

  
9/1/23

Date

**COMMENTS:**

Validation Team :

Name: Mr. Ajay Singh  
 Designation: Sr. Service Engg.  
 Signature:   
 Date: 9/1/23

**VII. System Certification**

Study data has determined that the system described in this document either meets all criteria outlined in this independent Installation 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: INSTALLATION QUALIFICATION Signature:

Company: TRANSASIA BIO-MEDICALS LTD. Date :


  
9/1/23

Customer Authorizations:

Name : DR. MEENAKSHI SURI

Title: INSTALLATION QUALIFICATION Signature:

Company: RARI

  
Date: 09.01.2023

Name :

Title: INSTALLATION QUALIFICATION Signature:

Company:

Date :

Date:

Reagent Check done

Printer checked

Analyzer switched ON at

SELF CHECK performed

RINSE CYCLE completed

Background limits within an acceptable range

Analysis start time

Analysis end time

No. of samples analyzed

Shut down procedure done

Analyzer switched OFF at

Recorded by:

Checked by:

---

*Chase*  
9/1/23



**Date:**