TRANSASIA®

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UNMATCHED SERVICE
SINCE 1979...

INSTALLATION QUALIFICATION

For

DIAGNOSTICA SPAN PVT LTD

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

I. Approval of the IQ procedure:

Diagnostica Span Pvt Ltd Laboratory and Transasia are jointly responsible for the installation of the system ERBA HEMATOLOGY Analyzer, Model: H560, Serial No. K1104B2142108 in the clinical lab of Diagnostica span as per the attached protocol.

Protocol Performed By: Transasia Representative

Name : Mr. Deekshith B H Signature:
Title : INSTALLATIONQUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD. Date:17-01-2023

Validation Team from : TRANSASIA BIO-MEDICALS LTD

Name : Mr.Siva Perumal Krishnaswamy
Designation : RSM
Department : TSD

Customer Authorizations:

Name : Mr.Dilip Shetty Signature :
Title : INSTALLATION QUALIFICATION
Site : Diagnostica Span Pvt Ltd
Date : 17-01-2023

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 Diagnostica Span Pvt Ltd will verify each result and sign in the last page. The members of the validation team will carry this out.

4. ALL deviations from normal specification to include any problems with installation will be noted under COMMENTS. All resolution 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 the Transasia Bio-Medicals Ltd., Transasia House, Mumbai.

Validation Team : TRANSASIA BIO-MEDICALS LTD

Name : Mr. Deekshith B H

Designation : Service Engineer

Signature :

Date

III. Scope

This Installation Qualification protocol will be performed on the ERBA Hematology Analyzer, Model H560, Serial No. K1104B2142108 located in Diagnostica Span Pvt Ltd 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: TRANSASIA BIO-MEDICALS LTD

Name : Mr. Deekshith B H

Designation : Service Engineer

Signature :

Date : 17/01/2023

IV. Ancillary Information.

a. Utilities

Sr.No.	Utility		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)	Yes	Mr. Deekshith B H	17/01/2023
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 back around 50cm on top and around 50 cm on sides for the main unit)	Yes	Mr. Deekshith B H	17/01/2023
3.	DIL-H560; LYSE1 & LYSE2 BOTTLES to be placed within a distance of 2 meters :	Yes	Mr. Deekshith B H	17/01/2023
4.	Power Source Requirements* It should have minimum five 5amps plug. It should have proper grounding. In case of online UPS minimum power handling capacity should be minimum 1KVA Line- Neutral voltage:002v Line –Earth voltage:240v Neutral-Earth voltage: 240v	Yes	Mr. Deekshith B H	17/01/2023

Validation Team : TRANSASIA BIO-MEDICALS LTD

Name : Mr. Deekshith B H

Designation : Service Engineer

Signature :

Date :17/01/2023

b. The instrument has been verified for the following

Sr.No.	Verification		Verified By	Date
1.	Instrument is identified	Yes	Mr. Deekshith B H	17/01/2023
2.	Manufacturer's specifications are included	Yes	Mr. Deekshith B H	17/01/2023
3.	Accessories / Consumables are listed	Yes	Mr. Deekshith B H	17/01/2023
4.	Manufacturer's certificate of Compliance attached	Yes		

Validation Team : TRANSASIA BIO-MEDICALS LTD

Name : Mr. Deekshith B H

Designation : Service Engineer

Signature :

Date :17/01/2023

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	Mr. Deekshith B H 17/01/2023	
Model	H560		
Manufacturer	Erba Mannheim		
Marketed By	Transasia		

Equipment #		
Serial Number		
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 : TRANSASIA BIO-MEDICALS LTD

Name : Mr. Deekshith B H

Designation : Service Engineer

Signature :

Date :17/01/2023

Installation Qualification

Consumables such as H-Clean, DIL H560, LYSE1 & LYSE2 were supplied along with 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 Diagnostica Span Pvt Ltd

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. Deekshith B H

Designation : Service Engineer

Signature :

Date :17/01/2023

F. Spare Parts

Transasia strongly recommends the end user maintain a basic of consumable parts onsite to minimize down time 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
H560	Diagnostica Span Pvt Ltd	Deekshith B H	17/01/2023

Sample page of the logbook is attached to this document

Effective date:17/01/2023

Validation Team : TRANSASIA BIO-MEDICALS LTD

Name : Mr. Deekshith B H

Designation : Service Engineer

Signature :

Date :17/01/2023

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 : TRANSASIA BIO-MEDICALS LTD

Name : Mr. Deekshith B H

Designation : Service Engineer

Signature :

Date :17/01/2023

VII. System Certification

Study data has determined that the system described in this document either meets all criteria outlined in this independently 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 : Deekshith B H

Title : INSTALLATION QUALIFICATION Signature:

Company: TRANSASIA BIO-MEDICALS LTD. Date : 17/01/2023

Customer Authorizations:

Name : Mr.Dilip Shetty

Title : INSTALLATION QUALIFICATION Signature:

Company: Diagnostica span pvt ltd. Date : 17/01/2023

Date: 17/01/2023

Reagent Check done

Printer checked

Analyzer switched ON at

SELF CHECK performed

RINSE CYCLE completed

Background limits within acceptable range

Analysis start time

Analysis end time

No. of samples analyzed

Shut down procedure done

Analyzer switched OFF at

Recorded by: Deekshith B H Checked by: Shiva perumal

Date: 17/01/2023