

**TRANSASIA<sup>®</sup>**

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**OPERATIONAL**  
**QUALIFICATION**

For

**DIAGNOSTICA SPAN PVT LTD**

**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:

Diagnostica span pvt ltd and Transasia are jointly responsible for operational check of the HEMATOLOGY Analyzer, Model: Erba H560, serial no. . K1104B2142108 in the clinical lab as per protocol attached.

Protocol Performed by: Transasia Representative

Name : Mr. Deekshith B H  
Title : OPERATIONAL QUALIFICATION  
Company : TRANSASIA BIO-MEDICALS LTD.

Signature :  
Date : 17/1/2023

Validation Team from \_\_\_ Transasia Representative

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

Customer Authorization:

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Name : Mr.Dilip Shetty  
Title : OPERATIONAL QUALIFICATION  
Site : Diagnostica Span Pvt Ltd

Signature :  
Date :




## 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 Diagnostica span pt ltd will verify each result and sign in 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 resolution to such problems will also be noted in the **COMMENTS** section, and must be resolved prior to 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 time of 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 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.

Protocol Performed by: Transasia Representative

Name : Mr. Deekshith B H  
Title : OPERATIONAL QUALIFICATION  
Company : TRANSASIA BIO-MEDICALS LTD.

Signature:   
Date: 17/1/2023

Validation Team from \_\_\_ Transasia Representative

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



### III. Scope


This Operational Qualification protocol will be performed on the Hematology Analyzer, Model H560, Serial No. K1104B2142108 located in \_Ground floor ,deccan central , no 79,40<sup>th</sup> main. M.E.I, 2<sup>nd</sup> stage industrial suburb , yeswanthpur , Bengaluru,560022\_\_Clinical,laboratory of\_Diagnostica span pvt ltd, This Protocol will define the documentation that will be used to evaluate the instruments 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.

Protocol Performed by:      Transasia Representative

Name                               :      Mr. Deekshith B H  
Title                                 :      OPERATIONAL QUALIFICATION  
Company                           :      TRANSASIA BIO-MEDICALS LTD.

Signature:   
Date: 17/1/2023

Validation Team from \_\_\_ Transasia Representative

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

#### IV. Operational Qualification

##### a. Instrument Identification

##### Verified Date


1. Model Name                      H560                                      17/01/2023  
2. Serial Number                    K    K1104B2142108

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

Test No.	Test Name	Test Purpose	Verified Date
1.	Liquid Pump	To verify pressure & vacuum generation	17/01/2023
2.	Syringe Assembly	Capacity of Blood Aspiration Diluent Aspiration, Lyse 1 & 2 Aspiration	17/01/2023
3.	Liquid Sensing PCB	To verify Liquid sensing ability Of sensors	17/01/2023

Protocol Performed by:      Transasia Representative

Name                                :      Mr. Deekshith B H  
Title                                :      OPERATIONAL QUALIFICATION  
Company                            :      TRANSASIA BIO-MEDICALS LTD.

Signature:   
Date: 17/1/2023

Validation Team from \_\_\_ Transasia Representative

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



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"

	<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification :	LIQUID PUMP	Pass	

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Department : TSD

Test 2

Test Name : Syringe Assly


Purpose : To test function

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

	<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification :	Syringe Assly	pass	

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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"

	<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification :	Liquid Sensing	pass	

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Department : TSD

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.

Mr. Dikshith by Transasia Bio-Medicals Ltd has conducted the training.


Sr.No.	Training Program	Initials	Date
1.	Instrument Setup		17/01/2023
2.	System Operation		17/01/2023
3.	Basic Troubleshooting & Maintenance		17/01/2023

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.

Protocol Performed by: Transasia Representative

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Validation Team from \_\_\_ Transasia Representative

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Designation : RSM  
Department : TSD



## 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.Siva Perumal Krishnaswamy

Title : OPERATIONAL QUALIFICATION Signature :

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 17/1/2023

Customer Authorizations:

Name : Mr.Dilip Shetty

Title : OPERATIONAL QUALIFICATION Signature :

Company ; Diagnostica span pvt ltd

Date :