5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	0.3×10^3/uL or less
RBC	0.00	0.02×10^6/uL or less
HGB	0.0	0.1 g /dL or less
PLT	4	10×10^3/uL or less

SOHA BIOMEDICAL ENGINEERS

SOHA BIOMEDICAL ENGINEERS PUNE

6. PRECISION STUDY PERFORMED ON THE ANALYZER USING A BLOOD SAMPLE (ORIGINALS ATTACHED)

SMP NO	WBC	RBC	HGB	HCT	MCV	PLT
P01	5.55	5.20	13.00	39.8	76.5	292
P02	5.6	5.29	13.00	40.40	76.4	285
P03	5.66	5.19	12.80	39.7	76.5	293
P04	5.87	5.22	12.90	39.8	76.2	285
P05	5.56	5.19	12.80	39.6	76.3	287
P06	5.72	5.24	12.80	40.0	76.3	281
P07	5.58	5.26	12.80	40.0	76.0	295
P08	5.62	5.22	12.80	39.7	76.1	291
P09	5.65	5.30	13.00	40.2	75.8	290
P10	5.67	5.29	13.00	40.1	75.8	296
Mean	5.65	5.24	12.89	39.93	76.19	289.50
SD	0.094	0.043	0.099	0.254	0.260	4.859
CV%	**1.671**	**0.815**	**0.771**	**0.636**	**0.341**	**1.678**
Acceptable CV%	Within 3.0%	Within 1.5%	Within 1.5%	Within 1.5%	Within 1.5%	Within 4.0%
Result	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

CE

SCS-1000

sysmex

LOT 11940525

15-Aug-2021

Sysmex Calibrator System Assay Sheet

For Asian Pacific

	XE-Series		XT-Series		XS-Series* ✓	
Parameter	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits
WBC K/uL	7.752	7.446 - 8.059	7.979	7.664 - 8.294	7.336	7.046 - 7.626
RBC M/uL	4.587	4.516 - 4.657	4.482	4.413 - 4.551	4.569	4.499 - 4.639
HGB g/dL	12.49	12.40 - 12.59	12.30	12.21 - 12.40	12.39	12.29 - 12.48
HCT %	35.94	35.14 - 36.73	34.47	33.71 - 35.23	36.60	35.79 - 37.40
MCV fL	78.35	77.35 - 79.34	76.90	75.92 - 77.88	80.09	79.08 - 81.11
PLT K/uL	248.9	240.1 - 257.7	247.7	239.0 - 256.5	248.8	240.0 - 257.6

	K-4500 / K-1000 / K-800		pocH-100i**		KX-21		XP-Series	
Parameter	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits
WBC K/uL	7.76	7.42 - 8.09	7.46	7.14 - 7.78	7.72	7.39 - 8.05	7.12	6.82 - 7.43
RBC M/uL	4.530	4.440 - 4.621	4.565	4.474 - 4.657	4.524	4.433 - 4.614	4.485	4.395 - 4.575
HGB g/dL	12.39	12.26 - 12.51	12.10	11.98 - 12.22	12.50	12.38 - 12.63	12.07	11.95 - 12.19
HCT %	33.34	32.60 - 34.07	35.64	34.85 - 36.43	33.87	33.12 - 34.62	33.69	32.94 - 34.43
MCV fL	73.59	72.78 - 74.40	78.07	77.21 - 78.92	74.87	74.05 - 75.69	75.10	74.28 - 75.93
PLT K/uL	256.0	243.2 - 268.8	244.9	232.6 - 257.1	275.9	262.1 - 289.7	268.5	255.0 - 281.9

SCS-1000 ASSAY TERM DEFINED

Assay Target – This is the assigned value for calibration.

Acceptable Limits – These limits represent the interval around the Assay Target that can be attributed to the expanded uncertainty of the total traceability chain. A calibrator mean (n=5) that falls within these limits indicates an accurately calibrated instrument.

* **XS-1000i/XS-800i** – Assay target for WBC only for operation in CBC+Diff mode

pocH-100i – Assay Target for WBC only for systems operating under software version 00-18 and following

Date: 06-08-2021
Effective Date: 06-08-2021

Certificate of Calibration

Customer Name: **Vishwaraj Hospital, Loni Kalbhor, Pune**

Model : **Automated Hematology Analyzer Sysmex XS-800i**

Serial No. : **67641**

Calibration Done Date: **06-08-2021**

Next Calibration Due Date On or Before: **06-08-2022**

Lab In-charge: . **Dr. Aniruddha Garud**

SOHA BIOMEDICAL ENGINEERS

This is to certify that the above-mentioned product has been verified of calibration for CBC 6 parameters (WBC, RBC, HGB, HCT, MCV and PLT).

Calibration at site performed by
Er Name : Er. Khurshid M. Kazi
Designation : Technical Director

Soha Biomedical Engineers, Pune

Signature

SOHA BIOMEDICAL ENGINEERS PUNE

Encl:
1. Assay Sheet of Calibrator.
2. Printouts

Date: 06-08-2021
Effective Date: 06-08-2021

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XS-800i

2. Serial No.: 67641

3. Calibration Date: 06-08-2021

4. Material used: SCS-1000 (Lot No. 11940525, Expiry date: 15-Aug-2021)

Calibration for CBC 6 parameters using the measurement standard material (SCS-1000) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.

Soha Biomedical Engineers, Pune

SOHA BIOMEDICAL ENGINEERS PUNE

A402, Sahil-Sarvda, SR#38/5B, Opp. Maruti Sai Service Centre, A/P : Kondhwa-Khurd, Pune-411048 Dist: Pune, Maharashtra, India.
Phone: 8484 84 5154, Email: kmkazi@rediffmail.com

CRYSTAL
Diagnovision

Installation Certificate for EasyElectrolytes

This is certified that the Easy Electrolyte instrument Serial No. 119041004 is successfully installed and Commissioned at Vishwaraj hospital,Pune and the installation protocol / checklist has been successfully completed for the above instrument.

Crystal Diagnovision.

Protocol Performed By

Name : **Mr.Abhijit Jagtap**

Designation : **Service Engineer**

Signature :

Date :

Customer Authorization

Name : Dr. Aniruddha Ganed

Designation : HoD - Lab

Signature :

Date :

6th Floor, Unit No. 66, A Wing, K.K. Market, Dhankawadi, Pune 411 043.
Tel.: 020-41212844, Mob.: 9890450811, Email : crystaldiagnovision@gmail.com
www.crystaldiagnovision.in

Operational Qualification

1. REAGENT PURGE.

This Procedure was required as REAGENT PACK was newly installed. After purging, the display returned to CALIBRATE NOW?

2. CALIBRATION.

Verified proper installation, and the display showed CALIBRATE NOW?
Successfully calibrated the instrument and it displayed ANALYZE BLOOD?

Protocol Performed By

Name : **Mr.Abhijit Jagtap**

Designation : **Service Engineer**

Signature :

Date :

Customer Authorization

Name : Dr. Arinedella Ganed

Designation : HoD - Lab

Signature :

Date :

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www.crystaldiagnovision.in

CRYSTAL
Diagnovision

Performance Qualification

QUALITY CONTROL

After calibrating instrument, checked with Quality Control (Level 1,2,3) and found the result and precision within specified ranges.

Used Third party Quality Control to verify the accuracy and precision of your analyser. Results are attached.

System Certification:

Study data has determined that the System described in this document either meets all criteria outlined in this performance qualification Protocol, or exceptional conditions have been identified and documentation included.
The System is ready for specific usage.

Protocol Performed By

Name : **Mr.Abhijit Jagtap**

Designation : **Service Engineer**

Signature :

Date :

Customer Authorization

Name : Dr. Aniruddha Chaned

Designation : HOD - Lab

Signature :

Date :

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CRYSTAL
Diagnovision

Installation Qualification for EasyElectrolytes

Customer Name	**: Vishwaraj hospital**
Address	: Loni kalbhor,Pune
Instrument Name	: EasyElectrolytes
Serial Number	**: 119041004.**

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report:

Removed the Easy Electrolyte and accessories from shipping containers and place on solid wooden surface. Visually inspected EasyElectrolyte for any damage sustained during shipment.

External Requirement for Installation:

1.The power cord of the EasyElectrolyte was connected to matching grounded outlet supply of 220V AC, 50/60 Hz , as indicated on the label on the rear of the analyser.
2.Checked the mains supply and found the Earth, neutral voltage 0V
3.The environment is free from dust, mechanical vibrations, and electrical interference.
4.Ambient Conditions Maintained: 15-32 degree Celsius(60-90F), < 85% Humidity

UNPACKING

Removed the EasyElectrolyte and accessories from shipping containers and placed on solid work surface. Visually inspected EasyElectrolyte for any damage sustained during shipment.

INSTALLATION/REPLACEMENT

For installation or replacement instructions of EasyElectrolyte components, followed the procedures in this section.

1. **Building Electrode Stack**

First Reference Electrode installed. Then Spacer Electrode, Chloride, Potassium and Sodium Electrodes were installed.

2. **Installing the Tubbing**

Connected the SAMPLE TUBE to the SAMPLE PROBE.

3. **Reagent Pack Installation**

Placed REAGENT PACK into the front of the analyser, and slides the REAGENT PACK firmly to the right side, plugging it into the valve module.

4. **Power Up**

CRYSTAL DIAGNOVISION PUNE

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After assembling all the components, plugged the EasyElectrolyte into a GROUNDED outlet. The EasyElectrolyte displayed CALIBRATE NOW? installation is completed.

5. Printer Paper / Accessories Installation

To install the roll of paper into the printer, Cut the new edge to a point in the centre of the paper. Forming a V. Gently pushed this leading edge of the paper into the slot behind the printer until the paper tip reached the tear bar. Pull the paper by hand until the full width appear at the tear bar. After installing the paper, replaced the small cover on top of the housing to protect the printer paper roll.

Protocol Performed By

Name : **Mr. Abhijit Jagtap**

Designation : **Service Engineer**

Signature :

Date :

Customer Authorization

Name : Dr. Aniruddha Ranade

Designation : HOD - Lab

Signature :

Date :

6th Floor, Unit No. 66, A Wing, K.K. Market, Dhankawadi, Pune 411 043.
Tel.: 020-41212844, Mob.: 9890450811, Email : crystaldiagnovision@gmail.com
www.crystaldiagnovision.in

CRYSTAL Diagnovision

Installation Qualification for EasyElectrolytes

Customer Name	**: Vishwaraj Hospital.**
Address	**: Pune**
Instrument Name	**: EasyElectrolytes**
Serial Number	**: 119041004.**

Initial Inspection of the unit carried out and the details are as follows:
System Condition Report:
Removed the Easy Electrolyte and accessories from shipping containers and place on solid wooden surface. Visually inspected EasyElectrolyte for any damage sustained during shipment.

External Requirement for Installation:
1.The power cord of the EasyElectrolyte was connected to matching grounded outlet supply of 220V AC, 50/60 Hz , as indicated on the label on the rear of the analyser.
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Protocol Performed By

Name : **Mr. Abhijit Jagtap**

Designation : **Service Engineer**

Signature :

Date :

CRYSTAL DIAGNOSTICS PUNE

Customer Authorization

Name : Dr. Aniruddha Chand

Designation : HoD - Lab

Signature :

Date :

Operational Qualification

1. REAGENT PURGE.

This Procedure was required as REAGENT PACK was newly installed. After purging, the display returned to CALIBRATE NOW?

2. CALIBRATION.

Verified proper installation, and the display showed CALIBRATE NOW?
Successfully calibrated the instrument and it displayed ANALYZE BLOOD?

Protocol Performed By

Name : **Mr.Abhijit Jagtap**

Designation : **Service Engineer**

Signature :

Date :

CRYSTAL DIAGNOVISION PUNE

Customer Authorization

Name : Dr. Aniruddha Ranad

Designation : HOD- Lab

Signature :

Date :

Performance Qualification

QUALITY CONTROL

After calibrating instrument, checked with Quality Control (Level 1,2,3) and found the result and precision within specified ranges.

Used Third party Quality Control to verify the accuracy and precision of your analyser. Results are attached.

System Certification:

Study data has determined that the System described in this document either meets all criteria outlined in this performance qualification Protocol, or exceptional conditions have been identified and documentation included.
The System is ready for specific usage.

Protocol Performed By

Name : **Mr.Abhijit Jagtap**

Designation : **Service Engineer**

Signature :

Date :

CRYSTAL DIAGNOVISION PUNE

Customer Authorization

Name : Dr. Aniruddha Ganal

Designation : HOD - Lab

Signature :

Date :

6th Floor, Unit No. 66, A Wing, K.K. Market, Dhankawadi, Pune 411 043.
Tel.: 020-41212844, Mob.: 9890450811, Email : crystaldiagnovision@gmail.com
www.crystaldiagnovision.in

INSTALLATION QUALIFICATION

Instrument	:	**Semi-Automated Blood Coagulation Analyzer CA-101 (Serial No. M0340478)**
Laboratory	:	**Vishwaraj Hospital, Solapur Rd, Rajbaug, Loni Kalbhor, Maharashtra 412201**
Supported by	:	**Sysmex India Pvt Ltd** **1002, Damji Shamji Business Galleria,** **10th Floor, LBS Marg** **Kanjurmarg (West), Mumbai 400 078, India** **Tel: +91 (22) 6112 6666 Fax: +91 (22) 2577 6790**

INSTALLATION QUALIFICATION PROTOCOL

This Installation Qualification protocol is performed on the installation located at

Vishwaraj Hospital,

Solapur Rd, Rajbaug, Loni Kalbhor, Maharashtra 412201

Sysmex India Pvt. Ltd. is responsible for installation of CA-101 Semi Automated Coagulation Analyzer at Vishwaraj Hospital, Solapur Rd, Rajbaug, Loni Kalbhor, Maharashtra 4122011 as per the attached protocol.

- An authorized Sysmex India Pvt. Ltd. representative will physically check the system and proceed for the installation.
- This installation protocol will be followed as specified by the manufacturer.
- Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.
- On completion of the Installation all the necessary documents of the System checks will be used to evaluate the instrument installation in accordance with the manufacturer's protocol and intended use.
- An authorized Sysmex India Pvt. Ltd. representative will verify the documents of the system checks and approve the same.
- Successful completion of this protocol will verify that this instrument has been installed in accordance with the intended usage.
- Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated and appropriate course of action will be determined.

Report Sign Off

Prepared by:	**Sysmex India Pvt. Ltd.**	
Name:	**Aditya Gupta**	
Title: Application Specialist	**Sign:**	**Date: 29th Aug 2016**
Approved by:	**Vishwaraj Hospital**	
Name:	Dr. Aniruddha Kamat	
Title:	**Sign:**	**Date: 29th Aug 2016**

Installation Requirement:

Sr. No.	Description	Compliance Yes/No
1.	Environmental conditions as per required.	YES
2.	Physical Space Requirement as per required.	YES
3.	Electrical Requirements.	YES
4.	UPS connection available.	YES

1. **The instrument has been checked for the following:**

Sr. No.	Verification	Checked Yes/No
1.	Instrument is identified Instrument ID _____ M0340478_____	YES
2.	Accessories / consumables are listed	YES
3.	System checked for any External / physical damage	YES
4.	CA-101 Instruction for Use Manual provided by the Manufacturer	YES

INSTALLATION QUALIFICATION PROCEDURE

CA-101 Installation Site Requirements

General Requirements

1. Install in an indoor environment. This instrument is designed for indoor use only.
2. Ambient Temperature: 10 to 30 degree C
3. Relative Humidity: 45 to 85%
4. Install in a well – ventilated place
5. If ambient temperature and relative humidity are not in range, please use Air Conditioning
6. Instrument should not be installed at a place which is exposed to extremely high or low temperature
7. Instrument should not be installed at a place which is exposed directly to sunlight
8. Avoid Installation in place where instrument may be exposed to radio interference such as personal computer, centrifuge separator, wireless radio and communication facility
9. This instrument must be protected against splashing water.
10. Avoid shock and vibrations.
11. Avoid installation near devices causing potential interference, such as wireless communication equipment or similar devices, and centrifuges.
12. Installation of this instrument in places where chemicals are stored or hazardous gas may be present is not permitted.

Electrical Requirements

1. Input Supply: 220- 240V with proper grounding
2. **Power Supply**: Number of Three Pin Plug Points: one

Installation Space Requirements

Component	Width (mm)	Depth (mm)	Height (mm)	Weight (Kg)
CA-101 Analyzer	220	100	60	1

Installation

Verify the Pre-installation Checks

If any deficiencies were noted during the pre-installation check, verify they are resolved before installation.

Check the Supplies

Make sure an adequate supply of reagents, control and calibrator are available at the site.

Inspect Packing Box

Inspect all boxes for damage. Notify shipper of damages if any.

Unpack the Analyzer

- Remove the packing material of the Analyzer.
- Place the Instrument on the table.
- Remove fixing tapes and transportation tapes.
- Connect the AC Adaptor to Power Supply Point

Report Sign Off:

Prepared by:	**Sysmex India Pvt. Ltd.**	
Name:	**Aditya Gupta**	
Title: Application Specialist	**Sign:**	**Date: 29th Aug 2016**
Approved by:	**Vishwaraj Hospital**	
Name:	Dr. Ahmedabad Council	
Title:	**Sign:**	**Date: 29th Aug 2016**

OPERATION QUALIFICATION

Instrument	:	**Semi-Automated Blood Coagulation Analyzer CA-101 (Serial No. M0340478)**
Laboratory	:	**Vishwaraj Hospital, Solapur Rd, Rajbaug, Loni Kalbhor, Maharashtra 412201**
Supported by	:	**Sysmex India Pvt Ltd** **1002, Damji Shamji Business Galleria,** **10th Floor, LBS Marg** **Kanjurmarg (West), Mumbai 400 078, India** **Tel: +91 (22) 6112 6666 Fax: +91 (22) 2577 6790**

OPERATION QUALIFICATION PROTOCOL

This Operation Qualification protocol is performed on the installation located at

Vishwaraj Hospital,

Solapur Rd, Rajbaug, Loni Kalbhor, Maharashtra 412201

This protocol defines the documentation that will be used to evaluate the instrument and documented in accordance with manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrumentation identified has been operational in accordance with manufacturer's specifications and intended use.

Operational checks will be performed to verify that the instrument operates according to specifications and to record the information/data to demonstrate its functions as expected.

Trained knowledgeable personnel from Sysmex India Pvt. Ltd. along with the department personnel will perform qualification studies as mentioned by the manufacturer. Department personnel will record the information. The technical person from Sysmex India Pvt. Ltd. will verify the records and write the report. This protocol is to be reviewed and approved by the head of the department and QA.

Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated and appropriate course of action will be determined.

Report Sign Off

Prepared by:	**Sysmex India Pvt. Ltd.**		
Name:	**Aditya Gupta**		
Title: Application Specialist		**Sign:**	**Date: 29th Aug 2016**
Approved by:	**Vishwaraj Hospital**		
Name:	Dr. Aniruddha Gamad		
Title:		**Sign:**	**Date : 29th Aug 2016**

OPERATIONAL QUALIFICATION PROTOCOL

The operational qualification protocol specifies the methodology for the installation of the specified system and calibration after successful installation qualification. Successful completion of the procedure identifies that the system has been installed according to the specified protocols and is ready for operation and subsequent performance analysis.

REFERENCES

1. User Manual CA-101
2. Service manual CA-101

OQ Schedule

The following activities mentioned below have to be performed to complete the operational qualification

LCD Contrast

a) Adjust LCD Contrast through a hole located on bottom side of analyser.
b) Use small screwdriver for adjusting the contrast.

LCD Contrast Adjusted

☑ Yes ☐ No

Speed sensor distance

a) Adjust speed sensor distance
b) The space between magnet and speed sensor is between 3mm and 4mm. The distance can be adjusted by moving the speed sensor by hand.
c) Enter the "Service mode" and select the "mixer-test". Press the Enter key.
d) Enter the motor value "200".
e) Prepare a new cuvette with 200µl distilled water and put into the measurement channel.
f) Check the mixer spinning visually.
g) A star shaped image is observed if the adjustment is good.

Sensor Distance Adjusted

☑ Yes ☐ No

Thermal block temperature Calibration

a) Prefill a defined cuvette position (1) of incubation block ¾ with distilled water.
b) Place external temperature sensor (probe) in the water filled position.
c) Switch ON and keep cover closed until analyser is warmed up.
d) Enter the "Service mode" and select the "calib. temperature"
e) Press the Enter key.
f) Wait until the temperature has stabilized to 37.4 degree C on the internal display.
g) Check temperature at external sensor. If it is not 37.4 degree C, enter the sensor value in analyser.
h) Press the Enter key and wait until it to 37.4 degree C again.
i) If both values are identical (37.4 degree C) finish calibration, press the ESC key.

Temperature Calibration Performed

☑ Yes ☐ No

Report Sign Off:

Prepared by:	**Sysmex India Pvt. Ltd.**		
Name:	**Aditya Gupta**		
Title: Application Specialist		**Sign:**	**Date: 29th Aug 2016**
Approved by:	**Vishwaraj Hospital**		
Name:	Dr. Aniruddha Anand		
Title:		**Sign:**	**Date: 29th Aug 2016**

Deviation: None

Conclusion: This report certifies that the instrument operation is as per the specification recommended by the manufacturer.

PERFORMANCE QUALIFICATION

Instrument	:	**Semi-Automated Blood Coagulation Analyzer CA-101 (Serial No. M0340478)**
Laboratory	:	**Vishwaraj Hospital, Solapur Rd, Rajbaug, Loni Kalbhor, Maharashtra 412201**
Supported by	:	**Sysmex India Pvt Ltd** **1002, Damji Shamji Business Galleria,** **10th Floor, LBS Marg** **Kanjurmarg (West), Mumbai 400 078, India** **Tel: +91 (22) 6112 6666 Fax: +91 (22) 2577 6790**

PERFORMANCE QUALIFICATION PROTOCOL

This Performance Qualification protocol is performed on the installation located at

Vishwaraj Hospital,

Solapur Rd, Rajbaug, Loni Kalbhor, Maharashtra 412201

This protocol will define the documentation that will be used to evaluate the instrument and documented in accordance with the user specification requirements. Successful completion of this protocol will verify that the instrument performance consistently meets pre-determined specifications under normal conditions.

Performance checks will be carried out by repeatedly running the system on its intended schedule and record the information/data to demonstrate that it consistently meets the required performance, as expected.

Department personnel along with the trained personnel from Sysmex will perform qualification studies as mentioned in this protocol. Department personnel will record the information and write the report. The technical person from Sysmex will verify the records. The reports will be reviewed by head of the department and approved by QA person. This protocol is to be reviewed and approved by the head of the department and QA.

Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated and appropriate course of action will be determined.

Report Sign Off

Prepared by:	**Sysmex India Pvt. Ltd.**		
Name:	**Aditya Gupta**		
Title: Application Specialist		**Sign:**	**Date: 29th Aug 2016**
Approved by:	**Vishwaraj Hospital**		
Name:			
Title:		**Sign:**	**Date: 29th Aug 2016**

PQ Schedule

The following activities mentioned below have to be performed to complete the performance qualification

1.1 PERFROMANCE QUALIFICATION
1.1.1 REPRODUCIBILITY CHECK
1.1.2 ACCURACY CHECK

PERFORMANCE QUALIFICATION PROCEDURE

1.1.1 Reproducibility check

Perform the reproducibility check by running the Control material for 10 times and verify the CV is within the limits specified

Table B: Reproducibility Check Data

Parameters	Limit
PT/APTT	≤ 5%

Table C : Accuracy Check

Run Control and verify that all the results are within the specified limits.

Parameters	Acceptable Bias
PT/APTT	Target ± 5%

PQ Report

The following activities mentioned below have been performed to complete the performance qualification

1.1 PERFROMANCE QUALIFICATION
1.1.1 REPRODUCIBILITY CHECKS
1.1.2 ACCURACY CHECK

1.1.1 Reproducibility check

Performed the reproducibility check by running the Control for 5 times.

Table D: Reproducibility Check Data

Citrol 1 [Lot No.:548021]			
PT		**APTT**	
Lot No: 548021	Expiry: 12th April 2018	**Lot No: 548021**	Expiry: 12th April 2018
Run	**PT [sec]**	**Run**	**APTT [sec]**
1	12.9	**1**	25.7
2	13.2	**2**	25.7
3	13.2	**3**	25.4
4	12.9	**4**	26.1
5	13	**5**	26.4
MEAN	**13.04**	**MEAN**	**25.86**
SD	**0.136**	**SD**	**0.350**
CV	**1.04**	**CV**	**1.35**
Acceptable CV	≤5.0%	**Acceptable CV**	≤5.0%
Performance	**Pass**	**Performance**	**Pass**

Citrol 2 [Lot No.:548259]			
PT		**APTT**	
Lot No: 548259	Expiry: 12th July 2018	**Lot No: 548259**	Expiry: 12th July 2018
Run	**PT [sec]**	**Run**	**APTT [sec]**
1	46	**1**	50.1
2	46.3	**2**	49.7
3	46.1	**3**	49.8
4	46.6	**4**	49.5
5	46.2	**5**	49.3
MEAN	**46.24**	**MEAN**	**49.68**
SD	**0.206**	**SD**	**0.271**
CV	**0.45**	**CV**	**0.55**
Acceptable CV	≤5.0%	**Acceptable CV**	≤5.0%
Performance	**Pass**	**Performance**	**Pass**

1.1.2 Accuracy Check

Ran Control and verify that all the results are within the specified limits.

Table E: Accuracy Check Data

Citrol 1 [Lot No.:548021]			
PT		PT	
Lot No: 548021	Lot No: 548021	Lot No: 548021	Lot No: 548021
Run	PT [sec]	Run	APTT [sec]
1	12.9	1	25.7
2	13.2	2	25.7
3	13.2	3	25.4
4	12.9	4	26.1
5	13	5	26.4
MEAN	13.04	MEAN	25.86
Target	12	Target	26.3
Range	10.6 - 13.4	Range	23.1 - 29.5
Bias	-8.0	Bias	1.7
Acceptable Bias	≤15.0%	Acceptable Bias	≤15.0%
Performance	Pass	Performance	Pass

Citrol 2 [Lot No.:548259]			
PT		PT	
Lot No: 548259	Lot No: 548259	Lot No: 548259	Lot No: 548259
Run	PT [sec]	Run	APTT [sec]
1	46	1	50.1
2	46.3	2	49.7
3	46.1	3	49.8
4	46.6	4	49.5
5	46.2	5	49.3
MEAN	46.24	MEAN	49.68
Target	43.8	Target	54.1
Range	37.2 - 50.4	Range	47.6 - 60.6
Bias	-5.3	Bias	8.9
Acceptable Bias	≤15.0%	Acceptable Bias	≤15.0%
Performance	Pass	Performance	Pass

Report Sign Off

Prepared by:	**Sysmex India Pvt. Ltd.**	
Name:	**Aditya Gupta**	
Title: Application Specialist	**Sign:**	**Date: 29th Aug 2016**
Approved by:	**Vishwaraj Hospital**	
Name:	Dr Aniruddha Gaud	
Title:	**Sign:**	**Date: 29th Aug 2016**

Deviation: None

Conclusion: This report certifies that the instrument is qualified to perform as per manufacturer's specifications.

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Installation Certificate for XP-100

This is to certify that the XP100 Instrument **Serial No.A9339** is successfully Installed and Commissioned at
and the Installation Protocol / checklist has been successfully completed for the above instrument.

TRANSASIA BIOMEDICALS LTD, MUMBAI.

Protocol Performed By: TBM Swapnil Kamarkar

Name:

Designation: Service Engineer

TRANSASIA BIO MEDICALS LTD.

Customer Authorization:

Name: Dr. Aniruddha Kamat

Designation: HOD. Laboratory

Company Representative Name & Sign

Customer Name & Sign

Date: Swapnil Kamarkar

Date:

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Installation Qualification for XP-100

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 and no external physical damaged observed on the same.
Found all the required accessories as required.
Installation Procedure & Checklist Attached for records.

External Requirements for Installation:

1. Input voltage of 220V-240V / 50Hz or 60Hz.
2. Recommended Operational Temperature is +15 to +35 °C, with Relative Humidity 20-80% without condensation.

Preparation and Checks Prior to Installation:

1. In order to ensure the safety of the instrument and the operator the following conditions must be guaranteed: The power supply system (installation category II) must be "compatible" with the voltage and current specifications indicated on the name plate attached to the rear of the instrument; and it is recommended checking the efficiency of the electrical system from time to time.
2. The electrical system and relative sockets must all be fitted with efficient grounded outlet.
3. The material for the operator's safety (gloves, containers for disposing of used expendable items, detergent solutions for cleaning the instrument) must always be available.

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Unpacking and Placement of the instrument as follows:

1. Check if there are no damages to the packing.
2. Check all accessories (Refer Chapter 5 from Operator's Manual Pg. 5-2)
3. Check all reagents have received.
4. Check the installation location complies to the requirements mentioned in Chapter 5 pg. 5-4

Installation

1. Remove of Packaging material
   (Refer. Chapter 5 Pg. 5-5 &5-6)
2. Connection of reagents, Waste Bottle and Printer Paper Roll
   (Refer Chapter 5 Pg. 5-7 to 5-12)
3. Connect Peripheral Device (Optional)
   (Refer Chapter 5 Pg. 5-13)
4. Connect Power Supply Cable.

Switching on

After verification of the installation of the instrument , Switch ON the instrument.

Start up of system

Once switched on, follow the Initial Operation Process as mentioned in Service Manual Chapter 7 Pg. 7-1.This operation is essential and allows for verification of the proper functioning of all internal units and check that the moving parts are in the correct positions.

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Operational Qualifications for XP-100 Sr. No – A9339

Functional startup Procedure

1. The functional startup procedure must comply with the instructions indicated in Pg 7-1 XP-100 Service Manual

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: TBM

Name: Surajput Ramanlal

Designation: Service Engineer

TRANSASIA BIO MEDICALS LTD.

Customer Authorization:

Name: Dr. Aniruddha Ganed

Designation: HOD Laboratory

Company Representative Name & Sign

Customer Name & Sign

Date:

Surajput Ramanlal

Date:

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1. **Background Check**

   After Initial startup sequence instrument performs Background check to ensure that blank check criteria are complied.

2. **Pressure Check** (Refer Chapter 12 Pg. No. 12-2)

   Check Pressure level pressure whether it is within the acceptable range as mentioned below.

   a. 0.05MPa (Acceptable range : +/-0.01MPa)
   b. -0.0333MPa (Acceptable range : +/-0.0013MPa)

3. **Check HGB Background Error** (Refer to Service Manual, Chapter 4.)

   Check Pressure level pressure whether it is within the acceptable range as mentioned below

   HGB background convert value (Acceptable range: 2000 +/-200

4. **Precision Check** (Refer Service Manual XP100 Chapter 1 Pg. 1-7 for acceptable limit of Std. Deviation)

   Perform precision validation using Fresh Normal sample

5. **Control Check**

   a. Checked and found that the results of quality controls to be within the desired range as mentioned on the Assay Sheet of the control.
   b. Assay Sheet of controls is attached.

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System Certification:

Study data has determined that the System described in this document either meets all criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.
The System is ready for specific usage.

Protocol Performed By:

Name: Swapnil Kamble

Designation: Service Engineer

TRANSASIA BIO MEDICALS LTD.

Customer Authorization:

Name: Dr. Aniruddha Ranade

Designation: HOD - Laboratory

Company Representative Name & Sign

Swapnil Kamble

Date:

Customer Name & Sign

Date:

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SYSMEX XS800i
AUTOMATED HEMATOLOGY ANALYZER

PERFORMANCE QUALIFICATION

For

"Maharashtra Academy of Engineering and Educational Research, Pune"

Marketed by:
Transasia Bio-Medicals Ltd.,
(ISO 9002 CERTIFIED)
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI – 400 072

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
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I. Approval of the PQ procedure

Maharashtra Academy of Engineering and Educational Research, Pune and Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer, SYSMEX Model : XS800i, Serial No.67641 in the clinical lab of Maharashtra Academy of Engineering and Educational Research, Pune as per the attached protocol.

Protocol Performed By: Transasia Representative

Name : Mr. Vijay Shahu Signature:
Title : PERFORMANCE QUALIFICATION Date:
Company : TRANSASIA BIO-MEDICALS LTD.

Validation Team from :

Name :
Designation :
Department :

Name :
Designation :
Department :

Customer Authorizations:

Name : Dr. Aniruddha Ganed Signature:
Title : PERFORMANCE QUALIFICATION
Site : Pune Date:

Name : Dr. Aniruddha Ganed Signature:
Title : PERFORMANCE QUALIFICATION
Site : Pune
Date:

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
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II. Instructions

1. An authorized TRANSASIA representative will check for the performance of the instrument and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.
2. Performance checks on a regular basis described in the Further Performance Checks (vide-infra) will be responsibility of the customer's personnel.
3. Employee of Maharashtra Academy of Engineering and Educational Research, Pune will verify each result and sign in the last page. The members of the validation team will carry this out.
4. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of each PQ 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. These 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.
5. Any test data that does not meet the specified acceptance criteria will be submitted to the appropriate laboratory personnel for solution. All steps taken subsequently will be documented.
6. 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 Production Manager at Transasia Bio-Medicals Ltd., Transasia House, Mumbai.

Validation Team: Vijay Sahu

Name

Designation Sr. Appln

Signature

Date

TRASASIA BIO MEDICALS LTD

III. Scope

This Performance Qualification protocol will be performed on the Hematology Analyzer, Model XS-800I, Serial No 67641 located in Maharashtra Academy of Engineering and Educational Research, Pune. 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 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. Vijay Sahu

Designation Sr. Service Engg.

Signature

Date

IV. Performance Qualification

a. Instrument Identification

Verified Date

1. Model Name SYSMEX XS800i _____
2. Serial Number 67641 _____

TRASASIA BIO MEDICALS LTD.

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

Test No.	Test Name	Test Purpose	Verified Date
02	Sample Processing	Ability to process samples	_____
03	Further Performance Checks	Regular Maintenance	NA

Validation Team:

Name Mr. Vijay Sarn

Designation Sr. Analyst

Signature

Date

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c. Performance Testing

Test 1

Test Name: **Sample Processing**

Purpose: **Ability to Process Samples**

Method:

1. **Run the control samples five times consecutively**

Acceptance Criteria: Each of the results obtained above should be within the range as specified in the control chart.

Parameters Values for Verification:

RBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	4.2	4.1	~	
2.	4.2	4.2	–	
3.	4.2	4.2	–	
4.	4.2	4.2	–	
5.	4.2	4.2	–	

Validation Team:

Name Mr. Vijay Salvi

Designation Sr. Appn

Signature

Date

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WBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	6.1	6.2	✓	
2.	6.1	5.9	✓	
3.	6.1	6.0	✓	
4.	6.1	6.1	✓	
5.	6.1	6.1	✓	

Hemoglobin:

Test	Control Values	Results Obtained	Pass	Fail
1.	12.1	11.9	✓	
2.	12.1	12.0	✓	
3.	12.1	12	✓	
4.	12.1	12	✓	
5.	12.1	12	✓	

Platelet Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	350	340		
2.	350	345		
3.	350	343		
4.	350	333		
5.	350	352		

Validation Team:

Name vijay sun

Designation Dr.

Signature

Date

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Test 2

Test Name:

1. Tests for checking the performance of the instruments during analysis
2. Tests for checking long term performance of the instrument

Purpose:

The purpose of the above checks is to ensure the reliability of the results being obtained.

Method:

1. During Sample analysis:

To run control samples each time the instrument is used for sample analysis and verification of the results of the controls to be within the reference range to be established by performance of the precision experiments.

2. Long term Performance

This is to be checked by Levy Jennings plots to be updated once in six months

Validation Team:

Name Vijay Sawant

Designation Asst. Mgr

Signature

Date

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V. System Certification

Study data has determined that the system described in this document either meets all criteria outlined in this Performance 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. Vijay Shahu

Title : PERFORMANCE QUALIFICATION Signature:

Company: TRANSASIA BIO-MEDICALS LTD. Date :

Customer Authorizations:

Name : Dr. Aniruddha Ganed

Title : PERFORMANCE QUALIFICATION Signature:

Site : Date :

TRANSASIA BIO MEDICALS LTD.

Name : Dr. Aniruddha Ganed

Title : PERFORMANCE QUALIFICATION Signature:

Site : Date :

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SYSMEX XS-800I
AUTOMATED HEAMATOLOGY ANALYZER

INSTALLATION QUALIFICATION

For

" Maharashtra Academy of Engineering and Educational Research, Pune"

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

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
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I. Approval of the IQ procedure:

Maharashtra Academy of Engineering and Educational Research, Pune and Transasia are jointly responsible for the installation of the system SYSMEX – HEMATOLOGY Analyzer, Model: XS-800I, Serial No. 67641 in the clinical lab of Maharashtra Academy of Engineering and Educational Research, Pune as per the attached protocol.

Protocol Performed By: Transasia Representative

Name : Mr. Swapnil Kamarikar
Title : INSTALLATIONQUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD.

Signature:
Date:

Transasia Bio-Medicals Ltd. ★ Pune

Validation Team from _____:

Name :
Designation :
Department :

Customer Authorizations:

Name : Dr Aniruddha Garud
Title : INSTALLATION QUALIFICATION
Site :

Signature:
Date:

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
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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 Maharashtra Academy of Engineering and Educational Research, Pune 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:

Name

Designation Service Eg

Signature

Date

Transasia Bio-Medicals Ltd. Pune

III. Scope

This Installation Qualification protocol will be performed on the SYSMEX-Hematology Analyzer, Model XS-800I Serial No. 67641 located in Maharashtra Academy of Engineering and Educational Research, Pune 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: Swapnil Kamble

Designation: Service Engineer

Signature:

Date:

Transasia Bio-Medicals Ltd. Pune

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
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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._____. Dt._____ sent against Quotation number _____ dt._____ is in compliance with the specifications of the Purchase order.

Verified By :_____ Date :_____

b. Utilities

Sr.No.	Utility		Verified By	Date
1.	Environmental condition as per requirement: (Ambient range of temperature 15 – 35 °C, air conditioning facility, non exposure to direct sunlight, non-interference from high frequency radio waves)	Yes / No	✓	
2.	Adequate space for installation : (Minimum in mm. W 450 X D 660 X H 450)	Yes / No	✓	
3.	Cellpack DCL, SULFOLYSER.,Lysercell WDF, Fluorocell WDF and Cell Clean	Yes / No	✓	
4.	Power Source Requirements*	Yes / No	✓	

* Encircle applicable source

Validation Team :

Name Swapnil Kamnikar

Designation

Signature

Date

Transasia Bio-Medicals Ltd. Pune

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 **Fax**: +91 20 2616 2658 **Email**: wz3@transasia.co.in **CIN**: U33110MH1985PLC036198

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c. The instrument has been verified for the following

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

Validation Team:

Name Sujata Kamble

Designation Service Engg

Signature

Date

Transasia Bio-Medicals Ltd. Pune

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V. Installation Qualification

A. Equipment Description

This Sysmex XS-800I is a fully automated Hematology analyzer for in vitro diagnostic use in clinical laboratories. The XS-800I provides accurate and precise test results for ( ) parameters.

Instrument identification		Verified by	Date
Equipment Name	Automated Hematology	✓	
Model	XS800i	✓	
Manufacturer	Sysmex Corporation	✓	
Marketed By	Transasia	✓	
Equipment #		✓	
Serial Number	67641	✓	
Size (in mm)	W 450 X D 660 X H 450	✓	
Power	AC 220 V	✓	
Frequency	50 – 60 Hz	✓	
Power Consumption	Less Than 250 VA	✓	

Validation Team:

Name Swapnil Kerle

Designation Service Engg

Signature

Date

Transasia Bio-Medicals Ltd. Pune

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
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B. Accessories / Consumables

Accessories

Validation Team :

Name Swapnil Kamrikar

Designation

Signature

Date

Transasia Bio-Medicals Ltd. Pune

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
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Consumables:

Consumables such as Cellpack SULFOLYSER, Stromatlyser 4DL, Stroamtolyser 4DS and Cell Clean 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. Operator's Manual

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 Maharashtra Academy of Engineering and Educational Research, Pune.

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 operations manual Chapter 13

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:

Name

Designation Service Engg

Signature

Date

Transasia Bio-Medicals Ltd. Pune

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 **Fax**: +91 20 2616 2658 **Email**: wz3@transasia.co.in **CIN**: U33110MH1985PLC036198

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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 no.

C. Equipment Logs

Title	Location	Verified by	Date

Sample page of the logbook is attached to this document

Effective date:

Validation Team: Swapnil Kheik

Name

Designation Service engineer

Signature

Date

Transasia Bio-Medicals Ltd. Pune

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VI. Installation Procedure

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

1. **Check Before Installation**
   Refer to Chapter 7 of Sysmex XS800i Service Manual

3. **Grounding**
   Refer to Chapter 1 of Sysmex XS800i Service Manual

4. **Installation Environment & Space**
   Refer to Chapter 1 of Sysmex XS800i Service Manual

5. **Connect Air & Reagent Tubes**
   Refer to Chapter 7 of Sysmex XS800i Service Manual

6. **Connect Connection Cord & Power Cord**
   Refer to Chapter 7 of Sysmex XS800i Service Manual

7. **Turn Power On**
   Refer to Chapter 7 of Sysmex XS800i Service Manual

Validation Team:

Name Swapnil Kirik

Designation Service Eg

Signature

Date

Transasia Bio-Medicals Ltd. Pune

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VII. COMMENTS:

Validation Team:

Name Swapnil Kamarikar

Designation Service Engg

Signature

Date

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VIII. 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 : Mr. Swapnil Kamarikar

Title : **INSTALLATION QUALIFICATION** Signature:

Company: **TRANSASIA BIO-MEDICALS LTD.** Date :

Customer Authorizations:

Name : Dr. Aniruddha Ranad

Title : INSTALLATION QUALIFICATION Signature:

Site : Date :

Transasia Bio-Medicals Ltd. Pune

Name : Dr Aniruddha Ranad

Title : INSTALLATION QUALIFICATION Signature:

Site : Date :

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Date:

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: Checked by:

Transasia Bio-Medicals Ltd. Pune

Date:

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SYSMEX XS800i
AUTOMATED HEMATOLOGY ANALYZER

OPERATIONAL QUALIFICATION

For

"Maharashtra Academy of Engineering and Educational Research, Pune"

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

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 **Fax**: +91 20 2616 2658 **Email**: wz3@transasia.co.in **CIN**: U33110MH1985PLC036198

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Table of Contents

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I. Approval of the OQ procedure:

Maharashtra Academy of Engineering and Educational Research, Pune and Transasia are jointly responsible for operational check of the HEMATOLOGY Analyzer. Model: XS800i, serial# 67641 in the clinical lab of Maharashtra Academy of Engineering and Educational Research, Pune as per protocol attached.

Protocol Performed by: Transasia Representative

Name : Mr. Swapnil Kamarikar Signature:
Title : **OPERATIONAL QUALIFICATION** Date:
Company : **TRANSASIA BIO-MEDICALS LTD.**

Validation Team from _____

Name :
Designation :
Department :

Transasia Bio-Medicals Ltd. ★ Pune

Customer Authorization:

Name : Dr Aniruddha Ganed Signature:
Title : OPERATIONAL QUALIFICATION Date:
Site :

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 **Fax**: +91 20 2616 2658 **Email**: wz3@transasia.co.in **CIN**: U33110MH1985PLC036198

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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 Maharashtra Academy of Engineering and Educational Research, Pune 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.

Validation Team:

Name Swapnil Kamath

Designation Service Eng.

Signature

Date

Transasia Bio-Medicals Ltd. Pune

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III. Scope

This Operational Qualification protocol will be performed on the Hematology Analyzer, Model XS-800I, Serial No.67641 located in Maharashtra Academy of Engineering and Educational Research, Pune. 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.

Validation Team:

Name Swapnil Kanekar

Designation Service Eng.

Signature

Date

Transasia Bio-Medicals Ltd. Pune

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
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IV. Operational Qualification

a. Instrument Identification **Verified Date**

1. Model Name XS800i _____
2. Serial Number 67641 _____

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

Test No.	Test Name	Test Purpose	Verified Date
1.	Whole Blood (WB) X-aspiration motor operation	To the WB aspiration motor operation	_____
2	Sheath Motor Test.	To check Operation of Sheath Motor	_____
3.	Diagnostic Test for Auto Sampler and Bar code reader	To Check operation of Auto sampler and Barcode reader.	_____

Validation Team:

Name Swapnil Pawle

Designation Service Engg

Signature

Date

Transasia Bio-Medicals Ltd. Transasia Pune

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
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c. Operational Testing

Test 1

Test Name	:	**Whole Blood Aspiration Motor Test**
Purpose	:	**To test the Aspiration Motor movement**
Method	:	**Please follow the steps described in chapter 2, page 2.9.1 of Sysmex XN – 350 manual**

		PARAMETER	PASS	FAIL
Parameter values for verification	:	**Whold Blood Aspiration Motor Test**	✓	

Validation Team:

Name

Designation

Signature

Date

Transasia Bio-Medicals Ltd. Pune

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 **Fax**: +91 20 2616 2658 **Email**: wz3@transasia.co.in **CIN**: U33110MH1985PLC036198

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Test 2

Test Name	:	**Sheath Motor Test**
Purpose	:	**To test the Sheath Motor Operation Test.**
Method	:	**Please follow the steps described in chapter 2, page 2.9.1 of Sysmex XS800i's manual No.**

		PARAMETER	PASS	FAIL
Parameter values for verification	:	**Sheath Motor Motor Test**	✓	

Validation Team:

Name Swapnil Kurle

Designation Service Engg

Signature

Date

Transasia Bio-Medicals Ltd. Pune

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Test 3

Test Name : **Diagnostics Test for Auto Sampler & Barcode Operation**

Purpose : **To test the Operation of Auto Sampler & Barcode.**

Method : **Please follow the steps described in chapter 2, page 2.9.1&4 of Sysmex XS800i manual No.**

		PARAMETER	PASS	FAIL
Parameter values for verification	:	**Sampler & Barcode Test**	✓	

Validation Team:

Name Swapnil Kamble

Designation Service Eng

Signature

Date

Transasia Bio-Medicals Ltd. Pune

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d. Operational Procedure

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. Vijay Shahu who is certified by Transasia Bio-Medicals Ltd has conducted the training.

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

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

Validation Team:

Name Sujata Pawar

Designation Service Engineer

Signature

Date

Transasia Bio-Medicals Ltd. Pune

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
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b. Customer SOP

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

Validation Team:

Name

Designation

Signature

Date

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HO : Transasia Bio - Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai - 400 072,

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 **Fax**: +91 20 2616 2658 **Email**: wz3@transasia.co.in **CIN**: U33110MH1985PLC036198

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COMMENTS:

Validation Team:

Name

Designation

Signature

Date

Transasia Bio-Medicals Ltd. Pune

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V. 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. Swapnil Kamarikar

Title : OPERATIONAL QUALIFICATION Signature:

Company: TRANSASIA BIO-MEDICALS LTD. Date :

Customer Authorizations:

Name : Dr. Aniruddha Ganed

Title : OPERATIONAL QUALIFICATION Signature:

Site : Date :

Transasia Bio-Medicals Pune

Name : Dr Aniruddha Ganed

Title : OPERATIONAL QUALIFICATION Signature:

Site : Date :