Sysmex India Pvt. Ltd.
Unit No 05-07, 4th Floor, Newa Bhakti Knowledge City,
Plot No. IT-06, Airoli Knowledge Park, T.T.C. Indl. Area,
Airoli, Thane,
India, 400708
Tel. (+91) 22 6112 6666 Fax. (+91) 22 2577 6790
Email: sysmex@sysmex.co.in
Web: https://www.sysmex.co.in
GST Reg. No. 27AADCS1551J1ZC Co. Reg. No.

CSR No.: WO-100349147
Revision No.:

Customer Service Report

Customer Name	Rajasthan Vikas Sansthan		
Contact Person	Dr. Anurag Gupta		
Installation Date	22/02/2023	**Login Date/Time**	
Equipment ID	10151372	**FSR Name**	Chandramohan Kachhwaha
Model	XN-330	**From Date/Time**	20/02/2024 01:18:44 PM
Serial No.	14153	**To Date/Time**	20/02/2024 03:50:00 PM
Total Cycle Count	2,649	**Case No.**	

Defect Analysis	
Issue Code	**Cause Code**
Issue	**Cause**
Calibration Visit	Calibration Visit

Action Taken	**Action Code**	**Value Before Adjustment**	**Value After Adjustment**
Test Calibration Task	Completed		
Done sensitivity adjustment for RBC clog, HGB & Aspiration blank, Aspiration sensor span.	Adjusted		
Done sensitivity adjustment for WDF,RBC/PLT and HGB with calibrator lot no CL-40222101	Adjusted		
Now run calibration 11 times with CL-40222101	Completed		
Now run QC L1, L2, All the values found with in range.	Completed		
Now run batch of samples. Instrument is working fine.	Completed		

Sysmex India Pvt. Ltd.
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Customer Service Report

Customer Name	Rajasthan Vikas Sansthan		
Contact Person	Dr. Anurag Gupta		
Installation Date	22/02/2023	**Login Date/Time**	
Equipment ID	10151372	**FSR Name**	Chandramohan Kachhwaha
Model	XN-330	**From Date/Time**	20/02/2024 01:18:44 PM
Serial No.	14153	**To Date/Time**	20/02/2024 03:50:00 PM
Total Cycle Count	2,649	**Case No.**	

Remarks
Calibration Visit

Items Consumed

Product ID	VPN	Product Description	QTY	UOM

Name:- Chandramohan Kachhwaha	**Acknowledged By :** Dr. Anurag Gupta
Sign: Chandramohan Singh	**Sign :**
Date: 20/02/2024 03:51:54 PM	**Date:** 20/02/2024 03:51:54 PM

Customer Confidential

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XN-L Series Calibration Report

Customer : Rajasthan Vikas Sansthan Date: 20/02/2024
Model: XN-330 Serial No: 14153

1 MECHANICAL ADJUSTMENTS

Positions	Perform
Piercer/Pipette Position	Performed
Tube Holder Position	NA
Hand Position	NA
BCR Position	NA

NA- Sampler not available

2 BACKGROUND VERIFICATION

Parameters	Results	Acceptable Range	Status	
WBC	0.00	≤ 0.10 x 10*3/uL	PASS	
RBC	0.00	≤ 0.02 x 10*6/uL	PASS	
HGB	0.0	≤ 0.1 g/dL	PASS	
PLT-I	0	≤ 10 x 10*3/µL	PASS	
*RBC-O**	NA	≤ 0.02 x 10*6/uL	FAIL	NA- RET license not activted
*PLT-O**	NA	≤ 10 x 10*3/µL	FAIL	NA- RET license not activted

** Only applicable when RET license is activated*

3 OPTICAL AXIS VERIFICATION

3.1 CELLPACK DFL 10ml + DUKE 4207A 5 Drops. The diluted latex was analyzed to determine the Optical Axis of the FSC (Rough). The results are as below :

Parameters	Results	Acceptable Range	Status	
FSC (X) Rough	NA	70 - 130	FAIL	NA- RET license not activted
FSC (W) Rough	NA	Less than 0.15	FAIL	NA- RET license not activted

3.2 CELLPACK DCL 10ml + DUKE 4207A 5 Drops. The diluted latex was analyzed to determine the Optical Axis of the FSC (Fine). The results are as below :

Parameters	Results	Acceptable Range	Status
FSC (X) Fine	95	70 - 130	PASS
FSC (W) Fine	0.2	Less than 0.35	PASS

3.3 CELLPACK DCL 10ml + PS-FLUORED-L2830-4 2 Drops. The diluted latex was analyzed determine the Optical Axis of the SFL(Fine) & SSC(Fine). The results are as below :

Parameters	Results	Acceptable Range	Status
SFL (X)	117.4	For Record Purpose	
SFL (W)	0.026	lower than 0.20	PASS
SSC (X)	62.1	50 - 100	PASS
SSC (W)	0.37	For Record Purpose	

NOTE: Please attach FSC(X) rough, FSC(X) fine, SFL(X) fine, SSC(X) fine peaks screenshots.

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4 RBC CLOG LEVEL ADJUSTMENT

4.1 The RBC clog adjustment is monitored after the background check. The result is as below :

Parameters	Results	Acceptable Range	Status

RBC CLOG	100	100 ± 1	PASS

5 **HGB BLANK ADJUSTMENT**

Parameters	Results	Acceptable Range	Status
HB Blank Gain	5004	5000 ± 200	PASS

6 **ASPIRATION SENSOR BLANK ADJUSTMENT**

Parameters	Results	Acceptable Range	Status
Aspiration Sensor	5100	5000 + 200	PASS

7 **ASPIRATION SENSOR SPAN ADJUSTMENT**

7.1 *Material : XN-CHECK
Lot : 33221402
Expiry : 27/02/2024
* Cross whichever not applicable

Parameters	Results	Acceptable Range	Status
Aspiration Sensor Span	13026	13000 ± 500	PASS

8 **SENSITIVITY ADJUSTMENTS**

8.1 Material :XN-CAL
Lot : 40222101
Expiry : 25/02/2024

Parameters	Results	Assay Value	Acceptable Range	Status	Scattergram normal?
WDF-X	162.5	162.4	± 3 ch	PASS	YES
WDF-Y	104.7	103	± 3 ch	PASS	
WDF-Z / WDF-FSC	118.3	118.1	± 2.5 ch	PASS	

Parameters	Results	Assay Value	Acceptable Range	Status	Scattergram normal?
RBC-X	NA	NA	± 1 ch	#VALUE!	NA
RBC-Y	NA	NA	± 3 ch	#VALUE!	
RBC-Z	NA	NA	± 2 ch	#VALUE!	

NA- RET license not available

Parameters	Results	Assay Value	Acceptable Range	Status
MCV	80.2	80.4	± 1 ch	PASS
MPV	10.1	10.4	± 0.3 ch	PASS
HGB	12.2	12.17	± 0.2g/dl	PASS

NOTE: Please attach sensitivity adjustment screenshots.

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9 **Calibration**

9.1 **Please refer to Whole Blood Calibration Report Attached**

9.2 **PD Mode Calibration** *(NOTE: If Applicable)*

Material: XN CAL (1:7 Dilution)
Lot : 40222101
Expiry : 25/02/2024

Parameters	1	2	3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_PD_CAL	4.18	4.22	4.28	4.30	4.27	4.25	4.384	1000	1032	-3.15	PASS
PLT_PD_CAL	244	248	240	245	250	245	240.2	971	950	2.12	PASS
HGB_PD_CAL	11.9	11.9	11.8	11.8	11.8	11.8	12.17	1000	1028	-2.79	PASS
WBC_PD_CAL	8.08	7.86	8.01	8.02	8.09	8.01	8.057	1000	1006	-0.56	PASS

WBC-D/WDF_PI	8.08	7.86	8.01	8.02	8.09	8.01	7.537	1047	985	5.93	PASS			
RBC_PD_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
RBCO_PD_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
PLTO_PD_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!

NA- PET license not available
NA- PET license not available
NA- PET license not available

*NOTE: Only Applicable when PET license has been activated
NOTE: Please attach PD Mode Calibration results screenshots

9.3 Body Fluid Calibration *(NOTE: If Applicable)* Not applicable- BF license not activated

Material: NA
Lot: NA
Expiry: NA

Parameters	1	2|3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_BF_CAL*	#REF!	#####	#####	#####	#REF!	NA	NA	#VALUE!	#VALUE!	#VALUE!
WBC_BF_CAL*	#REF!	#####	#####	#####	#REF!	NA	NA	#VALUE!	#VALUE!	#VALUE!

*NOTE: Only Applicable when BF license has been activated
NOTE: Please attach BF Mode Calibration results screenshots

10 QC Verification

10.1 Please attach QC radar charts print outs for QC runs after the calibration.

11 Pipettors/Dilutors reproducibility and accuracy checked.

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12 Certification

We certify that the XN-330 Automated Hematology Analyzer S/N: 14153 has been successfully calibrated in accordance with the manufacturer's recommendations.

Report and Commissioning Performed By :

Signature (Engineer 1)

Name: Chandramohan Singh Kachhwaha
Date: 20/02/2024

NA

Signature (Engineer 2)

Name: NA

Date: NA

Report Reviewed and Accepted By :

Dr. Anuraag
MD (Path.)
RMC-008463

Signature (Customer)

Name: Dr. Anurag Gupta

Date: 20/02/2024

< XN CAL ™ ASSAY SHEET >

For XN-L series

Lot No. **40222101** Exp. Date **2024-02-25**

	RBC	HGB		HCT	PLT
	$10^6/\mu L$	g/dL	mmol/L	%	$10^3/\mu L$
TARGET	4.384	12.17	7.55	35.25	240.2

	WBC-C	WBC-D	RET%	RBC-O	PLT-O
	$10^3/\mu L$	$10^3/\mu L$	%	$10^6/\mu L$	$10^3/\mu L$
TARGET	8.057	7.537	3.157	4.264	242.6

There are some parameters which is not displayed on IPU according to the instrument.

Please refer to the package insert for the handling of the XN CAL.

Do not leave caribrator in the room temperature over an hour.

Please store it in a refrigerator (2-8°C) immediately after use.

* : This refers to the validity of the assay values for service palameters.

** : Don't calibrate ** marked palameters.

Calibrator Calibration History

Instrument Nickname: XN-L
Material: XN CAL

Calibration Date: 20/02/2024 14:52:15
Lot No.: 40222101

Logon Name: sysmex

	WBC	RBC	HGB	HCT	PLT
Target	7.537	4.384	12.17	35.25	240.2
No. 2	7.38	4.39	12.1	35.2	226
No. 3	7.35	4.38	12.1	35.1	229
No. 4	7.60	4.44	12.3	35.6	231
No. 5	7.37	4.46	12.3	35.7	231
No. 6	7.35	4.38	12.2	35.1	238
No. 7	7.28	4.45	12.2	35.7	235
No. 8	7.29	4.48	12.3	35.8	230
No. 9	7.29	4.41	12.2	35.4	231
No. 10	7.29	4.39	12.2	35.3	228
No. 11	7.47	4.37	12.2	35.1	241
Range Value	0.32	0.11	0.2	0.7	15
Max Range	0.58	0.13	0.2	1.0	26
Mean Value	7.367	4.415	12.21	35.40	232.0
Delta Percent (%)	2.31	0.70	0.33	0.42	3.53
Acceptable Limit (%)	2.27	1.25	0.78	2.64	4.16
Service Limit (%)	14.00	4.00	5.00	5.00	10.00
Current Rate (%)	100.0	100.0	101.2	100.0	100.0
New Rate (%)	102.3	99.3	100.9	100.3	103.5

Precision Check Log

Instrument Nickname: XN-L Execution Date: 20/02/2024 15:14:39 Logon Name: sysmex

	WBC	RBC	HGB	HCT	PLT
No. 2	8.01	4.40	12.2	34.2	247
No. 3	7.87	4.44	12.2	34.6	249
No. 4	7.89	4.43	12.3	34.6	247
No. 5	7.98	4.40	12.2	34.2	252
No. 6	7.87	4.39	12.2	34.3	250
No. 7	8.12	4.42	12.3	34.4	245
No. 8	7.92	4.38	12.2	34.0	244
No. 9	7.97	4.35	12.2	33.9	244
No. 10	8.04	4.44	12.3	34.5	252
No. 11	7.92	4.38	12.2	34.1	252
Mean Value	7.959	4.403	12.23	34.28	248.2
SD	0.081	0.029	0.05	0.24	3.3
CV (%)	1.0	0.7	0.4	0.7	1.3
Limit (%)	3.0	1.5	1.0	1.5	4.0

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9 Calibration

9.1 Please refer to Whole Blood Calibration Report Attached

9.2 PD Mode Calibration *(NOTE: If Applicable)*

Material: XN CAL (1:7 Dilution)
Lot:
Expiry:

Parameters	1	2	3	4	5	Average	Assay Value		Old Cal		New Cal	% Diff	Status
RBC_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
PLT_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
HGB_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
WBC_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
WBC-D/WDF_PD	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
RET_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
RBCO_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
PLTO_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!

**NOTE: Only Applicable when RET license has been activated*
NOTE: Please attach PD Mode Calibration results screenshots

9.3 Body Fluid Calibration *(NOTE: If Applicable)*

Material: XN CAL
Lot: NA
Expiry:NA

Parameters	1	2	3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_BF_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	#VALUE!	#VALUE!
WBC_BF_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	#VALUE!	#VALUE!

**NOTE: Only Applicable when BF license has been activated*
NOTE: Please attach BF Mode Calibration results screenshots

10 QC Verification

10.1 Please attach QC radar charts print outs for QC runs after the calibration.

11 Pipetors/Dilutors reproducibility and accuracy checked.

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9 Calibration

9.1 Please refer to Whole Blood Calibration Report Attached

9.2 PD Mode Calibration *(NOTE: If Applicable)*

Material: XN CAL (1:7 Dilution)
Lot:
Expiry:

Parameters	1	2	3	4	5	Average	Assay Value		Old Cal		New Cal	% Diff	Status
RBC_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
PLT_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
HGB_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
WBC_PD_CAL	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
WBC-D/WDF_PD	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
RET_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
RBCO_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!
PLTO_PD_CAL*	NA	NA	NA	NA	NA	#DIV/0!	NA	NA	NA	NA	#VALUE!	#VALUE!	#VALUE!

**NOTE: Only Applicable when RET license has been activated*
NOTE: Please attach PD Mode Calibration results screenshots

9.3 Body Fluid Calibration *(NOTE: If Applicable)*

Material: XN CAL
Lot: NA
Expiry:NA

Parameters	1	2	3	4	5	Average	Assay Value	Old Cal	New Cal	% Diff	Status
RBC_BF_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	#VALUE!	#VALUE!
WBC_BF_CAL*	NA	NA	NA	NA	NA	NA	NA	NA	NA	#VALUE!	#VALUE!

**NOTE: Only Applicable when BF license has been activated*
NOTE: Please attach BF Mode Calibration results screenshots

10 QC Verification

10.1 Please attach QC radar charts print outs for QC runs after the calibration.

11 Pipetors/Dilutors reproducibility and accuracy checked.

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12 **Certification**

We certify that the **XN-330** Automated Hematology Analyzer S/N: **14153** has been successfully commissioned in accordance with the manufacturer's recommendations.

Report and Commissioning Performed By :

Thakur

Signature (Engineer 1)

Name: Rahul Thakur
Date: 22-02-2023

Signature (Engineer 2)

Name:
Date:

Report Reviewed and Accepted By :

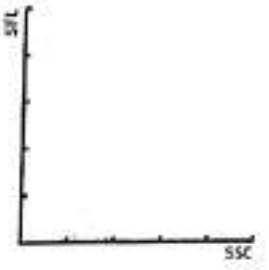
Signature (Customer)

Name: Mr. Krishna Kumal
Date: 22.2.23

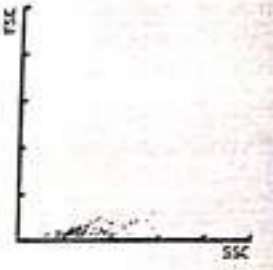
Sample No.: BACKGROUNDCHECK Adapter: Pos.: 2023/02/22 14:59:49 WE
Patient ID: Ward: Doctor:
Name: Birth: Sex:
Sample Comment: Nickname: XN-L

WBC	0.00	[10^3/uL]		
RBC	0.00	[10^6/uL]		
HGB	0.0	[g/dL]		
HCT	0.0	[%]		
MCV	----	[fL]		
MCH	----	[pg]		
MCHC	----	[g/dL]		
PLT	1	[10^3/uL]		
RDW-SD	----	[fL]		
RDW-CV	----	[%]		
PDW	----	[fL]		
MPV	----	[fL]		
P-LCR	----	[%]		
PCT	----	[%]		
NEUT	----	[10^3/uL]	----	[%]
LYMPH	----	[10^3/uL]	----	[%]
MONO	----	[10^3/uL]	----	[%]
EO	----	[10^3/uL]	----	[%]
BASO	----	[10^3/uL]	----	[%]
IG	----	[10^3/uL]	----	[%]

WDF



WDF-CBC



RBC

PLT

WBC IP Message

RBC IP Message

PLT IP Message

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We Believe the Possibilities.

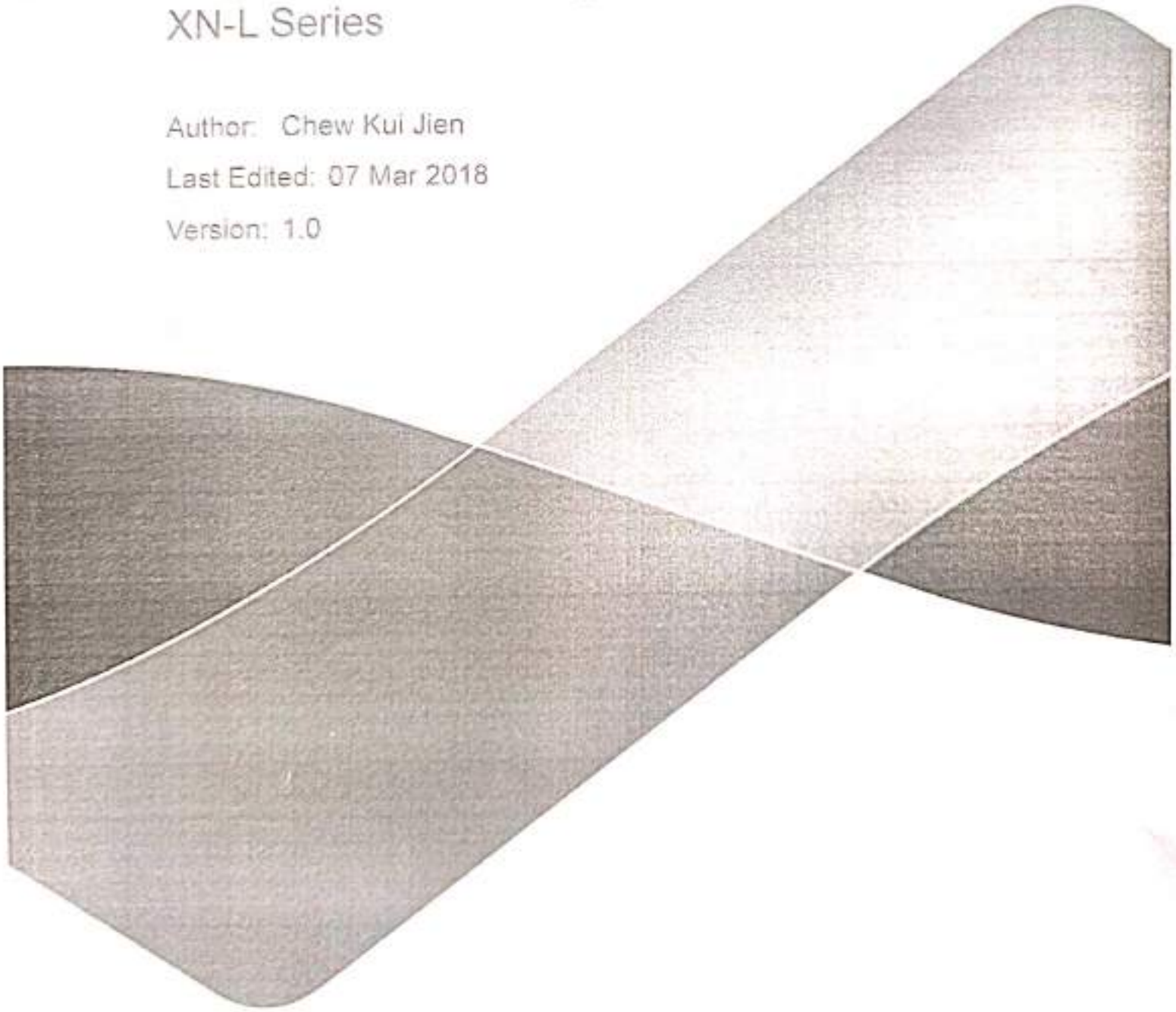
Installation Qualification

Automated Haematology Analyzer
XN-L Series

Author: Chew Kui Jien

Last Edited: 07 Mar 2018

Version: 1.0

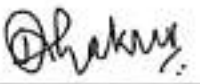


Sysmex Asia Pacific Pte Ltd

1. General Outline

1-1 Performer

The following person shall perform Installation Qualification (IQ) procedures as the person in charge of validation of the equipment in terms of calibration and testing.

Name	:	Rahul Thakur
Company	:	Sysmex India Pvt. Ltd.
Date (Day/Month/ Year)	:	22-02-2023
Signature	:	

1-2 Reviewer

People in charge of reviewing installation procedures and being representatives of the customer shall fill out the following blanks:

Name	:	
Institution OR Company	:	
Date (Day/Month/ Year)	:	
Signature / Initial	:	

Name	:	
Institution OR Company	:	
Title	:	
Date (Day/Month/ Year)	:	
Signature / Initial	:	

Remarks:

Installation Qualification

Model Number	XN – 330
Serial Number	14153
Software Version	00-24
Installation Site	22/02/2023

By the subsequent signature it becomes evident that all validation procedures for Installation Qualification (IQ) of the above stated equipment are completed by the performer.

-Performer

Name : Rahul Thakur

Signature :

Date (day/month/year) : 22/02/2023

By the subsequent signature the reviewer witnesses that all validation procedures for Installation Qualification (IQ) of the above stated equipment are completed by the performer.

-Reviewer

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We Believe the Possibilities.

Operational Qualification

Automated Haematology Analyzer
XN-L Series

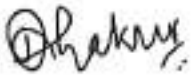
Author: Chew Kui Jien

Last Edited: 08 Mar 2018

Version: 1.0

Sysmex Asia Pacific Pte Ltd

The following person shall perform Operational Qualification (OQ) procedures as the person in charge of validation of the equipment in terms of calibration and testing.

Name	:	Rahul Thakur
Company	:	Sysmex India Pvt. Ltd.
Date (Day/Month/ Year)	:	22/02/2023
Signature / Initial	:	

1-2 Reviewer

People in charge of reviewing installation procedures and being representatives of the customer shall fill out the following blanks:

Name	:	
Institution OR Company	:	
Date (Day/Month/ Year)	:	
Signature / Initial	:	

Name	:	
Institution OR Company	:	
Title	:	
Date (Day/Month/ Year)	:	
Signature / Initial	:	

3-1 Equipment

Model Number	XN-330
Serial Number	14153
Software Version Number	00-24
Installation Site	22-02-2023

By the subsequent signature it becomes evident that all validation procedures for Operational Qualification (OQ) of the above stated equipment are completed by the performer.

-Performer

Name: Rahul Thakur

Signature: Thakur

Date (day/month/year): 22-02-2023

By the subsequent signature the reviewer witnesses that all validation procedures for Operational Qualification (OQ) of the above stated equipment are completed by the performer.

-Reviewer

Name:

Signature:

Date (day/month/year):

-Reviewer

Name:

Signature:

Date (day/month/year):

End of Document

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PERFORMANCE QUALIFICATION

Instrument	:	XNL-330 Hematology Analyzer Sr. No: 14153
Laboratory	:	Rajasthan Vikas Sansthan, Kudi Hud, City Circle Jodhpur- 342005
Manufacturer	:	Sysmex Corporation
Supported by	:	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

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PERFORMANCE QUALIFICATION PROTOCOL

This Performance Qualification protocol will be performed on the installation located at

Rajasthan Vikas Sansthan,
Kudi Hud, City Circle
Jodhpur- 342005

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:	Mr. Ravi Kumar Sah	
Title: Application Specialist	Sign:	Date: 23.05.2023
Checked By: Mr. Vikas Dagar (Manager-North)	Sign:	Date: 23.05.2023
Approved by:	Rajasthan Vikas Sansthan, Jodhpur	
Name:	Mr. Krishna Kumar	
Title: CTO	Sign: VYAS MEDICITY: CITY CENTRE Plot No. F-320-21, MIA Phase-II, AIIMS Road, JODHPUR (Raj.)	Date: 23.05.2023

sysmex

PQ SCHEDULE

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

Contents

Evaluation met Lab Managers for Whole Blood Mode

1. Precision
2. Accuracy
3. Linearity
4. Carryover
5. Limit of Blank
6. Limit of Detection and Limit of Quantitation

PERFORMANCE QUALIFICATION PROCEDURE

Performance Qualification

1. **Precision Check**

   Procedure for Precision Testing

   Requirements: - 1 Peripheral Blood sample

   1. Set the analyser to WB Mode, analyse Peripheral Blood for 11 consecutive times. The coefficient of variation of counting for each analysing parameter should meet the following condition.
   2. Input the data into the provided table. Calculate Mean, SD and CV%.
   3. Compare these values with the performance criteria for Within-run Precision Table.
   4. Acceptable Variation are as follows: