



CERTIFICATE OF CALIBRATION

ADL/KO/SER/0308/23-24

S Instrument : Mispa Nano Fully Automated Biochemistry Analyser

Customer Name : Instant Diagnostic Services, Agartala

Date of installation : 28/12/2017

Serial No : WN-76106843

Alignment Check

Motion Check	Checked	Remark
Sample Probe	<input checked="" type="checkbox"/>	Ok
Reagent Probe	<input checked="" type="checkbox"/>	Ok
Mixing Bar	<input checked="" type="checkbox"/>	Ok
Reaction Disk	<input checked="" type="checkbox"/>	Ok
Reagent Disk	<input checked="" type="checkbox"/>	Ok
Sample Disk	<input checked="" type="checkbox"/>	Ok
Fluidic disk	<input checked="" type="checkbox"/>	Ok
Lamp	<input checked="" type="checkbox"/>	Ok

System	Checked	Remark
Main unit	<input checked="" type="checkbox"/>	Ok
Temp. unit	<input checked="" type="checkbox"/>	Ok
Mixing unit	<input checked="" type="checkbox"/>	Ok
Reaction unit	<input checked="" type="checkbox"/>	Ok
Reagent unit	<input checked="" type="checkbox"/>	Ok
Sample unit	<input checked="" type="checkbox"/>	Ok

Uttam Kumar Saha

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

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DR. UTTAM KUMAR SAHA, PhD
Consultant Bio-Chemist



OPTICAL SECTION

Filter	Dark Current	Background
340	102	34 107
405	102	35 302
450	101	38 397
510	100	40 147
546	98	42 147
578	100	48 109
630	101	50 108
670	102	50 109
Reference	125	45 549

Power Supply : 5V 12V 24V

The equipment is calibrated for the different parameters by using Multi Calibrator

Lot.No: 323 07089 Exp: 02/2025

This is to certify that the above mentioned product has been calibrated according to the standard operating procedure given by the MINDRAY Medical Systems.

Date of Calibration : 04/SEP/2023
Next Due Date : 03/MAR/2024

For Agappe Diagnostics Ltd,

AB
04/09/23



Authorized Signatory
Name: Debashis Bhattacharjee
Designation: Manager - Customer Service

Uttam Kumar Saha

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**CERTIFICATE OF CALIBRATION**

ADL/KO/SER/0305/23-24

S

Instrument : Mispa Nano Fully Automated Biochemistry Analyser

Customer Name : Instant Diagnostic Services, Agartala

Date of installation : 28/12/2017

Serial No : WN-76106843

Alignment Check

Motion Check	Checked	Remark
Sample Probe	✓	Ok
Reagent Probe	✓	Ok
Mixing Bar	✓	Ok
Reaction Disk	✓	Ok
Reagent Disk	✓	Ok
Sample Disk	✓	Ok
Fluidic disk	✓	Ok
Lamp	✓	Ok

System	Checked	Remark
Main unit	✓	Ok
Temp. unit	✓	Ok
Mixing unit	✓	Ok
Reaction unit	✓	Ok
Reagent unit	✓	Ok
Sample unit	✓	Ok

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Uttam Kumar Saha

Dr. UTTAM KUMAR SAHA, PH.D.
Consultant Bio-Chemist
Instant Diagnostic Services



OPTICAL SECTION

Filter	Dark Current	Background
340	102	34502
405	102	34502
450	102	34502
510	101	35536
546	100	36306
578	98	38908
630	100	33390
670	102	34502
Reference	123.	44147

Power Supply : 5V 12V 24V

The equipment is calibrated for the different parameters by using Multi Calibrator

Lot.No: 31110191 Exp: 10/2023.

This is to certify that the above mentioned product has been calibrated according to the standard operating procedure given by the MINDRAY Medical Systems.

Date of Calibration : 05/MAR/2023

Next Due Date : 04/SEP/2023



For Agappe Diagnostics Ltd,

[Handwritten Signature]
05/03/23

Authorized Signatory

Name: Debashis Bhattacharjee

Designation: Manager - Customer Service

Uttam Kumar Saha

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Consultant Bio-Chemist



AGAPPE

ADL/CO/APL/1287/23-24

15/12/2023

Customer name	Instant Diagnostic Services
Instrument	Mispa Nano
Serial Number	WN-76106843
Protocol	Precision Study
Date	15/12/2023

	<u>SGOT</u>	<u>Creatinine</u>	<u>Triglycerides</u>
	20.80	0.5	69.2
	20.90	0.5	70.1
	21.1	0.49	69.2
	21.2	0.5	68.9
	19.6	0.51	69.9
	21.20	0.5	68.9
	21.5	0.5	69.4
	21.5	0.5	69.1
	20.9	0.46	69.7
	22.2	0.5	68.1
Mean	21.09	0.50	69.25
SD	0.66	0.01	0.57
CV	3.15	2.72	0.83

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• IMPROVED HEALTH CARE

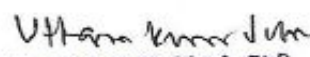
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ADL/CO/APL/2074/23-24

15/12/2023

Customer Name	Instant Diagnostic Services
Instrument	Mispa Nano
Protocol	Carryover Study
Date	15/12/23

Biorad Level 1				Biorad Level 2				Carry Over Ratio	Criteria	Judgement
Parameter	L1	L2	L3	Parameter	H1	H2	H3			
SGOT	21.8	20.6	20.5	SGOT	246.4	231.7	228.4	0.625	<1 %	Pass
Creatinine	0.52	0.51	0.52	Creatinine	2.23	2.28	2.36	0.000	<1 %	Pass
Cholesterol	159.9	156.7	157.1	Cholesterol	252.9	257.0	254.6	2.872	<1 %	Pass
Triglycerides	66.7	69.4	69.3	Triglycerides	464.0	462.6	466.0	0.655	<1 %	Pass


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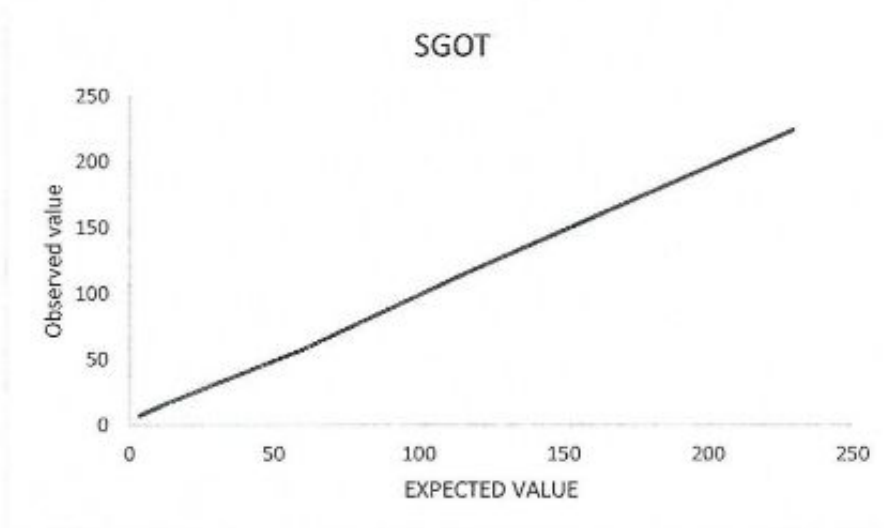


ADL/CO/APL/1214/23-24

15/12/2023

Customer Name	Instant Diagnostic Services
Instrument	Mispa Nano
Protocol	Linearity Certificate
Date	15/12/23

<u>Parameter</u>	Actual Value	Expected Value
SGOT	229.4	224
SGOT	113.00	112
SGOT	58.9	56
SGOT	26.7	28
SGOT	10.60	14
SGOT	3.8	7



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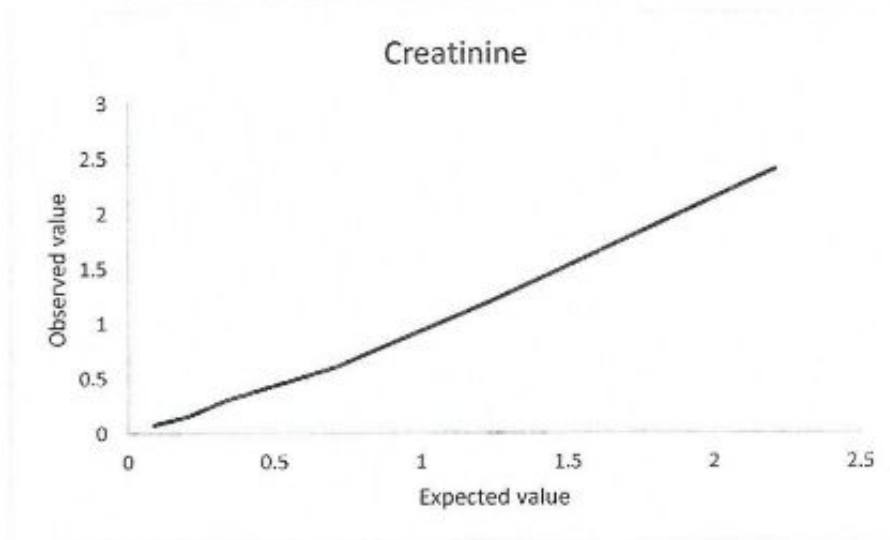
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DELHI OFFICE

BANGALORE OFFICE



Parameter Name	Expected Value	Obtained Value
Creatinine	2.21	2.4
Creatinine	1.24	1.2
Creatinine	0.71	0.6
Creatinine	0.34	0.3
Creatinine	0.20	0.15
Creatinine	0.09	0.075



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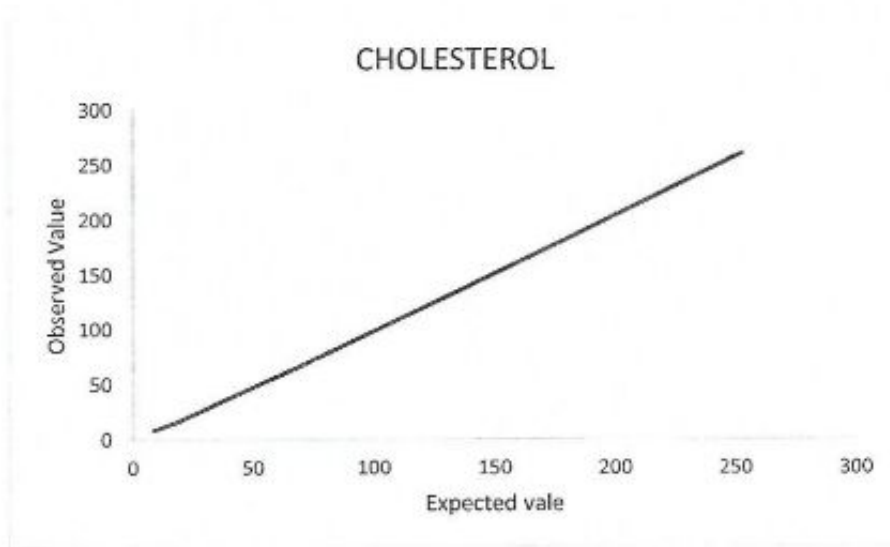
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Parameter Name	Expected Value	Obtained Value
CHOLESTEROL	252.7	260
CHOLESTEROL	130.5	130
CHOLESTEROL	68.4	65
CHOLESTEROL	35.2	32.5
CHOLESTEROL	19.0	16.25
CHOLESTEROL	8.7	8.125



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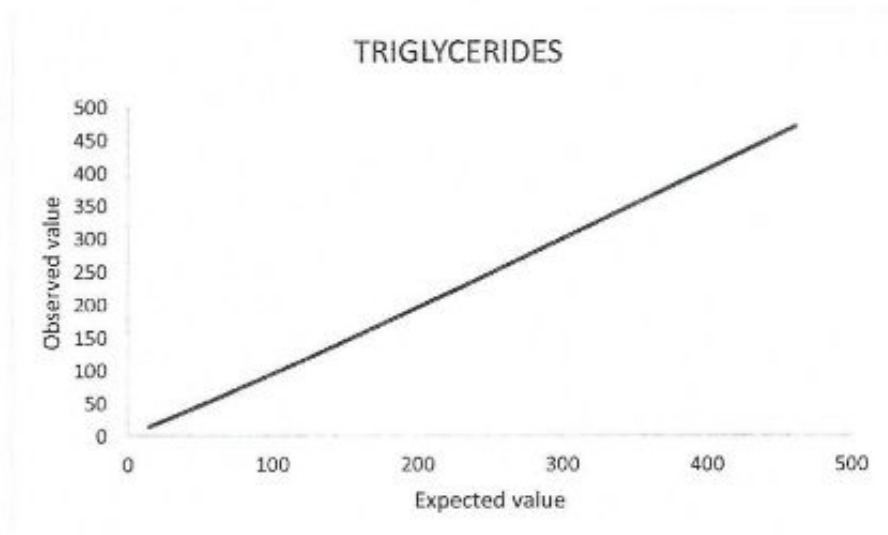
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Parameter Name	Expected Value	Obtained Value
TRIGLYCERIDES	460.9	470
TRIGLYCERIDES	239.0	235
TRIGLYCERIDES	124.0	117.5
TRIGLYCERIDES	63.0	58.75
TRIGLYCERIDES	31.1	29.375
TRIGLYCERIDES	14.9	14.6875



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INSTALLATION QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA NANO

AGAPPE DIAGNOSTICS LTD.

ADL/MO/SER/0306/23-24

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 Consultant Diagnostic Services
 Dr. Omprakash Choudhary, M.R.C.P.S.P.
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I. APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE

Both INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA and AGAPPE DIAGNOSTICS LTD are jointly responsible for the installation of MISPA NANO with serial number WN-76106843 at "Instant Diagnostic Services, Krishnanagar Road, Post Office Chowmoni, Agartala" as per the attached Installation Qualification protocol.

Protocol Performed By : Representative of AGAPPE DIAGNOSTICS LTD.

Name	:	Debashis Bhattacharjee	Signature :	
Title	:	Manager - Customer Service	Date	: 28/DEC/2017
Company	:	AGAPPE DIAGNOSTICS LTD.		

Validation Team from INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA.

Name	:	Nilay Deb .	Signature :	
Designation	:	Technician	Date	: 28/DEC/2017
Department	:	BO - Chemistry .		

Customer Authorizations:

Name : Dr. Uttam Saha.

Title : INSTALLATION QUALIFICATION

Site : Lab.

Signature

Date

: 28/DEC/2017

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II. INSTRUCTIONS

1. An authorized **AGAPPE DIAGNOSTICS LTD.** representative will check and enter the specific data as outlined in the Installation Qualification. Each result will be noted and dated.
2. The concerned employees of **INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA** will verify each result and sign in each page. The member of the validation team will carry this out.
3. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of the IQ 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.

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III. SCOPE

This Installation Qualification protocol will be performed on the **MISPA NANO** at **INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA**. This Installation 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 has been installed 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.

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Instant Diagnostic Services
Office Chowmohani, M.R. Chowmohani
Quartara Tripura (W), Pin - 799001

AGAPPE DIAGNOSTICS LTD.

ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U74239MH1998PLCE15413

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IV. INSTALLATION QUALIFICATION

AGAPPE DIAGNOSTICS
601 400 8000

AGAPPE

A. Instrument Identification

Verified Date : 28/DEC/2017

1. Model Name : MISPA NANO
2. Serial Number : WN-76106843

B. Following is a list of accessories /consumables verified:

S No.	Component	Present (Yes/No)	Verified By	Comments
01	Analyzer Main unit	Yes	Debashis Bhattacharjee	working fine
02	Computer	Yes	Debashis Bhattacharjee	✓
03	Printer	Yes	Debashis Bhattacharjee	✓
04	RS232 Connector cable	Yes	Debashis Bhattacharjee	✓
05	Power cord	Yes	Debashis Bhattacharjee	✓
06	Waste can	Yes	Debashis Bhattacharjee	✓
07	Water can	Yes	Debashis Bhattacharjee	✓
08	Water connector tube	Yes	Debashis Bhattacharjee	✓
09	Waste connector tube	Yes	Debashis Bhattacharjee	✓
10	Water pre filter	Yes	Debashis	✓

Uttam Kumar Saha
UTTAM KUMAR SAHA, PhD
 Consultant Bio-Chemist

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			Bhattacharjee	U
11	Probe assembly	Yes	Debashis Bhattacharjee	U
12	Mixer assembly	Yes	Debashis Bhattacharjee	U
13	Reagent tray	Yes	Debashis Bhattacharjee	U
14	Cuvette blocks	Yes	Debashis Bhattacharjee	U
15	Reagent bottles	Yes	Debashis Bhattacharjee	LI

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 Office Chowmohani, M R Road

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C. Installation Checks

Purpose: To make sure that the instrument is received with all the major components necessary for operation

S No.	Component	(Yes/No)	Verified By	Comments
1	Major components and accessories are present	Yes	Debashis Bhattacharjee	All are present nothing missing
2	There is no physical damage to the components	Yes	Debashis Bhattacharjee	u
3	Ambient temperature is available	Yes	Debashis Bhattacharjee	y
4	Instrument is installed in the table leveled properly	Yes	Debashis Bhattacharjee	u
5	Power supply is correct	Yes	Debashis Bhattacharjee	u
6	Electric connections are tight, weatherproof & earthed	Yes	Debashis Bhattacharjee	u
7	Analyzer unit installed as per the manufacturers recommendations	Yes	Debashis Bhattacharjee	u

Summary:

The information is recorded against each data and the deviations if any is justified / explained properly.

Acceptance criteria:

PARAMETER

PASS

FAIL

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D. Instrument Installation

Date of Installation : 28/DEC/2017

Installed by : Debashis Bhattacharjee

S No.	Parameter	Done by	Comments
01	Installation of the main unit	Debashis Bhattacharjee	Done
02	Installation of the computer system	Debashis Bhattacharjee	u
03	Installation of the printer	Debashis Bhattacharjee	u
04	Connecting the waste tubing	Debashis Bhattacharjee	u
05	Connecting the system water tubing	Debashis Bhattacharjee	u
06	Installing the reagent tray	Debashis Bhattacharjee	u
07	Installation of the probe	Debashis Bhattacharjee	u
08	Installation of the mixer	Debashis Bhattacharjee	u
09	Installing the cuvettes	Debashis Bhattacharjee	u

Acceptance criteria : System should be "Ready" after daily maintenance without any error

PARAMETER PASS FAIL

Parameter values for verification : System found "Ready" after daily maintenance

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E. Cell Blank

Purpose: To check the cuvette blank OD at different wavelength

Procedure:

S No.	Activity	Done By	Date
01	Checking the Cell blank	Debashis Bhattacharjee	28/DEC/2017
02	340 nm	Debashis Bhattacharjee	28/DEC/2017
03	405 nm	Debashis Bhattacharjee	28/DEC/2017
04	450 nm	Debashis Bhattacharjee	28/DEC/2017
05	510 nm	Debashis Bhattacharjee	28/DEC/2017
06	546 nm	Debashis Bhattacharjee	28/DEC/2017
07	578 nm	Debashis Bhattacharjee	28/DEC/2017
08	630 nm	Debashis Bhattacharjee	28/DEC/2017
09	670 nm	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER

PASS

FAIL

Parameter values for verification: No Error Messages

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 Dr. Uttam Chowdhury, M.B. B.S.
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F. Priming

Purpose: To check the internal tubing's and flow of liquids

S No	Activity	Done By	Date
01	Do wash using the maintenance screen	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria:

- No error message or air bubbles in the internal tubing's
- All the dilutor working well without air bubbles / leakage

PARAMETER **PASS** / FAIL

Parameter values for verification: No Error Messages

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V. COMMENTS

AGAPPE

Instrument installed successfully.

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VI. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline in this Installation Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Operational Qualification.

Report Performed By: **AGAPPE DIAGNOSTICS LTD.** Representative



Name : Debashis Bhattacharjee

Designation : Manager - Customer Service

Company : AGAPPE DIAGNOSTICS LTD.

Signature :

Date : 28/DEC/2017

Customer Authorizations: **INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA.**

Name : *Nitay Deb.*

Designation : *Technician*

Title : INSTALLATION QUALIFICATION

Signature :

Date : 28/DEC/2017

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• OPERATIONAL QUALIFICATION
• SUBSEQUENT REGULAR CHECKS

OPERATIONAL QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA NANO

AGAPPE DIAGNOSTICS LTD.

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III. APPROVAL OF THE OPERATIONAL QUALIFICATION PROCEDURE

Both **INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA** and **AGAPPE DIAGNOSTICS LTD** are jointly responsible for the installation of MISPA NANO with serial number **WN-76106843** at "Instant Diagnostic Services, Krishnanagar Road, Post Office Chowmoni, Agartala" as per the attached Operational Qualification protocol.

Protocol Performed By: Representative of **AGAPPE DIAGNOSTICS LTD.**

Name	: Debashis Bhattacharjee	Signature :	
Designation	: Manager - Customer Service	Date	: 28/DEC/2017
Company	: AGAPPE DIAGNOSTICS LTD.		

Validation Team from INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA .

Name	: Nilay Deb .	Signature :	
Designation	: Technician	Date	: 28/DEC/2017
Department	: Bio-chemistry .		

Customer Authorizations:

Name : *Dr. Uttam Saha.*

Uttam Kumar Saha

Title : OPERATIONAL QUALIFICATION
Site : *Lab.*

Signature :
Date : 28/DEC/2017

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IV. INSTRUCTIONS

1. An authorized **AGAPPE DIAGNOSTICS LTD** representative will check and enter the specific data as outlined in the **OPERATIONAL QUALIFICATION**. Each result will be noted and dated.
2. ALL deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end 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**.

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VII. SCOPE

This Operational Qualification protocol will be performed on the **MISPA NANO** at **INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA**. This Installation 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 has been installed 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.

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VIII. OPERATIONAL QUALIFICATION

• Instrument Identification

Verified Date : 28/DEC/2017

- Model Name : MISPA NANO
- Serial Number : WN-76106843

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

Test No.	Test Name	Test purpose	Verified By and date
01	Start up	To make the equipment ready for operation	Debashis Bhattacharjee 28/DEC/2017
02	Daily maintenance	To clean appropriate modules	Debashis Bhattacharjee 28/DEC/2017
03	Calibration	To calibrate the system	Debashis Bhattacharjee 28/DEC/2017
04	QC check	To confirm that the system is calibrated and working within specifications	Debashis Bhattacharjee 28/DEC/2017
05	Reproducibility check	To check the precision [CV %] after calibration	Debashis Bhattacharjee 28/DEC/2017
06	Sample programming and Analysis	To run the samples	Debashis Bhattacharjee 28/DEC/2017
07	Shut down procedure	To shut down the system	Debashis Bhattacharjee 28/DEC/2017

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Test 01: Starting the system

Purpose: To make the instrument READY for operation

Summary:

Instrument checks functioning of different parts of the instrument automatically. If there is an error code, initialize the system and follow corrective action instructions provided for the error message.

Procedure:

- G. Wait for the instrument to get ready after initialization
- H. Check the room temperature and switch on the Air Conditioner
- I. Check the UPS.
- J. Switch on the MISPA NANO by pressing the main switch, then switch on the computer and then the system power
- K. Double click the analyzer icon to initialize the system software
- L. Input the password and do as prompted, the system menu pops up if start up is finished
- M. If not, initialize by again after solving the error displayed
- N. Follow instructions provided for the error message

Acceptance criteria: System to display READY status

PARAMETER	<input checked="" type="checkbox"/> PASS	<input type="checkbox"/> FAIL
-----------	--	-------------------------------

Parameter values for verification: "READY" on Status Area

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Test 02: Daily Maintenance

Purpose: To clean appropriate modules so as per the daily maintenance protocol

Method:

Refer detailed procedure for Daily Maintenance

S No.	Activity	Done by	Date
01	Empty waste container	Debashis Bhattacharjee	28/DEC/2017
02	Check Wash solutions	Debashis Bhattacharjee	28/DEC/2017
03	Check system water	Debashis Bhattacharjee	28/DEC/2017
04	Check Reagents	Debashis Bhattacharjee	28/DEC/2017
05	Clean Reagent Block	Debashis Bhattacharjee	28/DEC/2017
06	Clean out side area	Debashis Bhattacharjee	28/DEC/2017
07	Load supplies and remove outdated and empty reagents	Debashis Bhattacharjee	28/DEC/2017
08	Check main menu screen	Debashis Bhattacharjee	28/DEC/2017
09	Perform Quality Control	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria: System should be "Ready" after daily maintenance without any error

PARAMETER **PASS** **FAIL**

Parameter values for verification: System found "Ready" after daily maintenance

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Test 03: Calibration of the system

Purpose: To calibrate the system

Procedure:

S No	Activity	Done By	Date
01	Preparation of the cal material	Debashis Bhattacharjee	28/DEC/2017
02	Performing Calibration with calibration programming screen	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria: Calibration data shows concordance OD values in triplicate measurement

PARAMETER **PASS** **FAIL**
Parameter values for verification : No error message in the printout

Test 04: QC check

Purpose: To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.

Procedure:

S No.	Activity	Done By	Date
01	Preparing Biochemistry control material	Debashis Bhattacharjee	28/DEC/2017
02	Creating QC file	Debashis Bhattacharjee	28/DEC/2017
03	QC sample programming and analysis	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria: QC results within specified limits mentioned on the control product insert

PARAMETER **PASS** **FAIL**
Parameter values for verification: QC values within $\pm 2SD$

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Test 05: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	Debashis Bhattacharjee	28/DEC/2017
02	Running triplicates	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria: Results CV within specified limits

PARAMETER PASS FAIL

Parameter values for verification: CV% within the limits

Test 06: Sample programming and Analysis

Purpose: To run the samples

Procedure:

S No.	Activity	Done By	Date
01	Preparing and Processing of samples	Debashis Bhattacharjee	28/DEC/2017
02	Programming samples	Debashis Bhattacharjee	28/DEC/2017
03	Aspirating the samples	Debashis Bhattacharjee	28/DEC/2017
04	Viewing samples in process	Debashis Bhattacharjee	28/DEC/2017
05	Review results: Monitoring results	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria: Samples Analysis without any error

PARAMETER PASS FAIL

Parameter values for verification: Sample analysis without any error

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Test 07: Shut down

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	Debashis Bhattacharjee	28/DEC/2017
02	Following the on screen instructions	Debashis Bhattacharjee	28/DEC/2017
03	Switch off the instrument when prompted	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria: Shut down without any error

PARAMETER **PASS** **FAIL**

Parameter values for verification: Shut down without any error

IX. OPERATIONAL PROCEDURE

Certificate of Training

4. Technician Training

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

S No.	Training program	Initials	Date
1	Instrument Setup	<i>[Signature]</i>	28/12/2017
2	System Operation	<i>[Signature]</i>	28/12/17
3	Basic trouble shooting and Maintenance	<i>[Signature]</i>	28/12/17

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5. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

S No.	Operators	Department	Initials	Date
01.	Nilay Deb.	Bio-Chemistry	<i>[Signature]</i>	28/12/17
02.	Aparna Banerjee.	Pathology.	<i>[Signature]</i>	28/12/17

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X. COMMENTS

*Training given to the technicians,
they now can perform tests.*

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XI. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline 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 Performance Qualification.



Report Performed By: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : Debashis Bhattacharjee

Designation : Manager - Customer Service

Company : AGAPPE DIAGNOSTICS LTD.

Signature :

Date :

28/DEC/2017

Customer Authorizations: **INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA.**

Name : Nilay Deb.

Designation : Technician

Title : OPERATIONAL QUALIFICATION

Signature :

Date :

28/DEC/2017

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PERFORMANCE QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA NANO

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APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE

Both **INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA** and **AGAPPE DIAGNOSTICS LTD** are jointly responsible for the installation of MISPA NANO with serial number **WN-76106843** at **"Instant Diagnostic Services, Krishnanagar Road, Post Office Chowmoni, Agartala"** as per the attached **PERFORMANCE Qualification** protocol.

Protocol Performed By: Representative of **AGAPPE DIAGNOSTICS LTD.**

Name	: Debashis Bhattacharjee	Signature :	
Designation	: Manager - Customer Service	Date	: 28/DEC/2017
Company	: AGAPPE DIAGNOSTICS LTD.		

Validation Team from INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA .

Name	: Nilay Deb.	Signature :	
Designation	: Technician	Date	: 28/DEC/2017
Department	: Bio-chemistry.		

Customer Authorizations:

Name : *Dr. Uttam Saha.*

Title : PERFORMANCE QUALIFICATION

Site : *Lab*

Signature : *Uttam Kumar Saha*

Date : 28/DEC/2017

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VI. INSTRUCTIONS

3. An authorized **AGAPPE DIAGNOSTICS LTD.** representative will check and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.
4. The concerned employees of **INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA** will verify each result and sign in each page. The member of the validation team will carry this out.
5. All deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section at the end of the 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**.

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VII. SCOPE

This Performance Qualification protocol will be performed on the **MISPA NANO** at **INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA**. This Performance 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 has been installed 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.

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PERFORMANCE QUALIFICATION

AGAPPE

O. Instrument Identification

Verified Date : 28/DEC/2017

1. Model Name : MISPA NANO
2. Serial Number : WN-76106843

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

Test No.	Test Name	Test purpose	Verified By and date
01	Start up	To make the equipment ready for operation	Debashis Bhattacharjee 28/DEC/2017
02	Daily maintenance	To clean appropriate modules	Debashis Bhattacharjee 28/DEC/2017
03	Cell blank	To check the cuvettes	Debashis Bhattacharjee 28/DEC/2017
04	Priming	To check the tubing's , and flow	Debashis Bhattacharjee 28/DEC/2017
05	Auto gain	To check the cuvette and photometry system	Debashis Bhattacharjee 28/DEC/2017
06	Calibration	To calibrate the system	Debashis Bhattacharjee 28/DEC/2017
07	QC check	To confirm that the system and reagents are acceptable and working within specifications	Debashis Bhattacharjee 28/DEC/2017
08	Reproducibility check	To check the precision [CV %]	Debashis Bhattacharjee 28/DEC/2017

Dr. Uttam Kumar Saha, PhD

Consultant Bio-Chemist

Independent Diagnostic Services

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09	Sample programming and Analysis	To run the samples	Debashis Bhattacharjee 28/DEC/2017
10	Shut down procedure	To shut down the system	Debashis Bhattacharjee 28/DEC/2017

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7. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

S No.	Operators	Department	Initials	Date
01.	Nilay Deb.	Bio-chemistry	<i>[Signature]</i>	28/12/17
02.	Aparna Banerjee	Pathology	<i>[Signature]</i>	28/12/17

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IX. COMMENTS

Operator's training given Successfully

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X. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline 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: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : Debashis Bhattacharjee

Designation : Manager - Customer Service

Signature :

Company : AGAPPE DIAGNOSTICS LTD.

Date : 28/DEC/2017

Customer Authorizations: **INSTANT DIAGNOSTIC SERVICES, KRISHNANAGAR ROAD, POST OFFICE CHOWMONI, AGARTALA.**

Name : *Nilay Deb.*

Designation : *Technician*

Signature :

Title : PERFORMANCE QUALIFICATION

Date : 28/DEC/2017

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Test 01: Starting the system

Purpose: To make the instrument **READY** for operation

Summary:

Instrument checks functioning of different parts of the instrument automatically; if there is an error code, initialize the system and follow corrective action instructions provided for the error message.

Procedure:

- XII. Wait for the instrument to get ready after initialization
- XIII. Check the room temperature and switch on the Air Conditioner
- XIV. Check the UPS.
- XV. Switch on the MISPA NANO by pressing the main switch, then switch on the computer and then the system power
- XVI. Double click the analyzer icon to initialize the system software
- XVII. Input the password and do as prompted, the system menu pops up if start up is finished
- XVIII. If not, initialize by again after solving the error displayed
- XIX. Follow instructions provided for the error message

Acceptance criteria: System to display **READY** status

PARAMETER	PASS	FAIL
-----------	-----------------	------

Parameter values for verification: "READY" on Status Area

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Test 02: Daily Maintenance

Purpose: To clean appropriate modules so as per the daily maintenance protocol

Method:

Refer detailed procedure for Daily Maintenance

S No.	Activity	Done by	Date
01	Empty waste container	Debashis Bhattacharjee	28/DEC/2017
02	Check Wash solutions	Debashis Bhattacharjee	28/DEC/2017
03	Check system water	Debashis Bhattacharjee	28/DEC/2017
04	Check Reagents	Debashis Bhattacharjee	28/DEC/2017
05	Clean Reagent Block	Debashis Bhattacharjee	28/DEC/2017
06	Clean out side area	Debashis Bhattacharjee	28/DEC/2017
07	Load supplies and remove outdated and empty reagents	Debashis Bhattacharjee	28/DEC/2017
08	Check main menu screen	Debashis Bhattacharjee	28/DEC/2017
09	Perform Quality Control	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria : System should be **"Ready"** after daily maintenance without any error

PARAMETER **PASS** FAIL

Parameter values for verification: System found **"Ready"** after daily maintenance

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Test 03: Cell Blank

Purpose: To check the cuvette blank OD at different wavelength

Procedure:

S No.	Activity	Done By	Date
01	Checking the Cell blank	Debashis Bhattacharjee	28/DEC/2017
	340 nm	Debashis Bhattacharjee	28/DEC/2017
	405 nm	Debashis Bhattacharjee	28/DEC/2017
	450 nm	Debashis Bhattacharjee	28/DEC/2017
	510 nm	Debashis Bhattacharjee	28/DEC/2017
	546 nm	Debashis Bhattacharjee	28/DEC/2017
	578 nm	Debashis Bhattacharjee	28/DEC/2017
	630 nm	Debashis Bhattacharjee	28/DEC/2017
	670 nm	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria:

- No error Messages displayed
- All Cuvettes should show acceptance

PARAMETER

PASS

FAIL

Parameter values for verification: No Error Messages

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Test 04: Priming

Purpose: To check the internal tubing's and flow of liquids

S No	Activity	Done By	Date
01	Do wash using the maintenance screen	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria:

- No error message or air bubbles in the internal tubing's
- All the dilutor working well without air bubbles / leakage

PARAMETER **PASS** FAIL

Parameter values for verification: No Error Messages

Test 05: Auto gain

Purpose: To Check the photometry system

Procedure:

S No.	Activity	Done By	Date
01	Performing the filter OD checking	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria: Data shows OD values in the acceptable range

PARAMETER **PASS** FAIL

Parameter values for verification : No error message

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**Test 06: Calibration of the system**

Purpose: To calibrate the system

Procedure:

S No.	Activity	Done By	Date
01	Preparation of the cal material *	Debashis Bhattacharjee	28/DEC/2017
02	Performing Calibration with calibration programming screen	Debashis Bhattacharjee	28/DEC/2017

*Traceability of the calibrator used is attached

Acceptance criteria: Calibration data shows concordance OD values in triplicate measurement

PARAMETER **PASS** FAIL

Parameter values for verification : No error message in the printout

Test 07: QC check

Purpose: To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.

Procedure:

S No.	Activity	Done By	Date
01	Preparing Biochemistry control material	Debashis Bhattacharjee	28/DEC/2017
02	Creating QC file	Debashis Bhattacharjee	28/DEC/2017
03	QC sample programming and analysis	Debashis Bhattacharjee	28/DEC/2017

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Acceptance criteria: QC results within specified limits mentioned on the control product insert

PARAMETER

PASS

FAIL

Parameter values for verification: QC values within $\pm 2SD$

Test 08: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	Debashis Bhattacharjee	28/DEC/2017
02	Running triplicates	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria: Results CV within specified limits

PARAMETER

PASS

FAIL

Parameter values for verification: CV% within the limits

Test 09: Sample programming and Analysis

Purpose: To run the samples

Procedure:

S No.	Activity	Done By	Date
01	Preparing and Processing of samples	Debashis Bhattacharjee	28/DEC/2017
02	Programming samples	Debashis Bhattacharjee	28/DEC/2017
03	Aspirating the samples	Debashis Bhattacharjee	28/DEC/2017

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04	Viewing samples in process	Debashis Bhattacharjee	28/DEC/2017
05	Review results: Monitoring results	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria: Samples Analysis without any error

PARAMETER **PASS** FAIL

Parameter values for verification: Sample analysis without any error

Test 10: Shut down

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	Debashis Bhattacharjee	28/DEC/2017
02	Following the on screen instructions	Debashis Bhattacharjee	28/DEC/2017
03	Switch off the instrument when prompted	Debashis Bhattacharjee	28/DEC/2017

Acceptance criteria: Shut down without any error

PARAMETER **PASS** FAIL

Parameter values for verification: Shut down without any error

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OPERATIONAL PROCEDURE

Certificate of Training

6. Technician Training

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

S No.	Training program	Initials	Date
1.	Instrument Setup	<i>[Signature]</i>	28/12/17
2.	System Operation	<i>[Signature]</i>	28/12/17
3.	Basic trouble shooting and Maintenance	<i>[Signature]</i>	28/12/17

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