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AGAPPE

CERTIFICATE OF CALIBRATION

ADL/KO/SER/0262/23-24

Instrument : **Mispa Clinia Fully Automated Biochemistry Analyser**

Customer Name : **Divine Touch Medi Clinic, Colonel Chowmuhani, Agartala,Tripura.**

Date of Installation : **05/03/2021** S/N: **YM-84001332**

Alignment Check

Motion Check	**Checked**	**Remark**
Sample Probe	□	OK
Reagent Probe	□	OK
Mixer Probes	□	OK
Reaction Disk	□	OK
Reagent Disk	□	OK
Sample Disk	□	OK
Wash Station	□	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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OPTICAL SECTION

Photometer Unit Alignments	Status	Remarks
Lamp Brightness Adjustment		
Signal Collecting Position Adjustment		
Photoelectric Gain Adjustment		

The equipment is calibrated for the different parameters by using Multi Calibrator Lot.No:_Exp:

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: **12/SEP/2023**

Next Due : **11/MAR/2024**

For Agappe Diagnostics Ltd.

AGAPPE DIAGNOSTICS LTD. Kolkata PIN:700091 TEL:40030451

Authorised signatory

Name: Debashis Bhattacharjee

Designation: Manager - Customer Service

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AGAPPE

INSTALLATION QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA CLINIA

AGAPPE DIAGNOSTICS LTD.

ADL/KO/SER/0085/23-24

ADL/FO/MCD/064/2015/R00

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

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AGAPPE

I. APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE

Both **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA** and **AGAPPE DIAGNOSTICS LTD**. are jointly responsible for the installation of **MISPA CLINIA** with serial number **YM-84001332** as per the attached Installation Qualification protocol**.**

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

Name	:	Debashis Bhattacharjee	Signature**:**
Title	:	Manager - Customer Service	Date :
Company	:	AGAPPE DIAGNOSTICS LTD.	

AGAPPE DIAGNOSTICS LTD. Kolkata PIN:700091 TEL:40030451

Validation Team from DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA

Name	:		Signature**:**
Designation	:		Date :
Department	:		

Customer Authorizations:

Name :

Title : INSTALLATION QUALIFICATION Signature :

Site : Date :

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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 **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA** 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 CLINIA** at **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA**. 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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IV. INSTALLATION QUALIFICATION

A. Instrument Identification

Verified Date: 05-03-2021

1. Model Name : MISPA CLINIA
2. Serial Number : YM-84001332

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

S No.	Component	Present (Yes/No)	Verified By	Comments
01	Analyzer Main unit			
02	Computer			
03	Printer			
04	RS232 Connector cable			
05	Power cord			
06	Waste can			
07	Water can			
08	Water connector tube			
09	Waste connector tube			
10	Water pre filter			
11	Probe assembly			
12	Mixer assembly			
13	Reagent tray			
14	Cuvette blocks			
15	Reagent bottles			

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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			
2	There is no physical damage to the components			
3	Ambient temperature is available			
4	Instrument is installed in the floor and leveled properly			
5	Power supply is correct			
6	Electric connections are tight, weatherproof & earthed			
7	Analyzer unit installed as per the manufacturers recommendations			
8	Water supply and waste drainage facilities checked			
9	Mispa Clinia Detergent Available			

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 : 05-03-2021

Installed by :

S No.	Parameter	Done by	Comments
01	Installation of the main unit		
02	Installation of the computer system		
03	Installation of the printer		
04	Connecting the waste tubing		
05	Connecting the system water tubing		
06	Installing the reagent tray		
07	Installation of the probes		
08	Installation of the mixers		
09	Installing the cuvettes		
10	Installation of Wash Station		

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. Cuvette Check

Purpose: To check the cuvettes run Cuvette Check

Procedure: Manually put more than 40ml Mispa Clinia Detergent in position D of reagent disk and more than 5ml Mispa Clinia Detergent in position D2 of sample disk. Then select **Perform Cuvette Check** and click **Continue** to proceed.

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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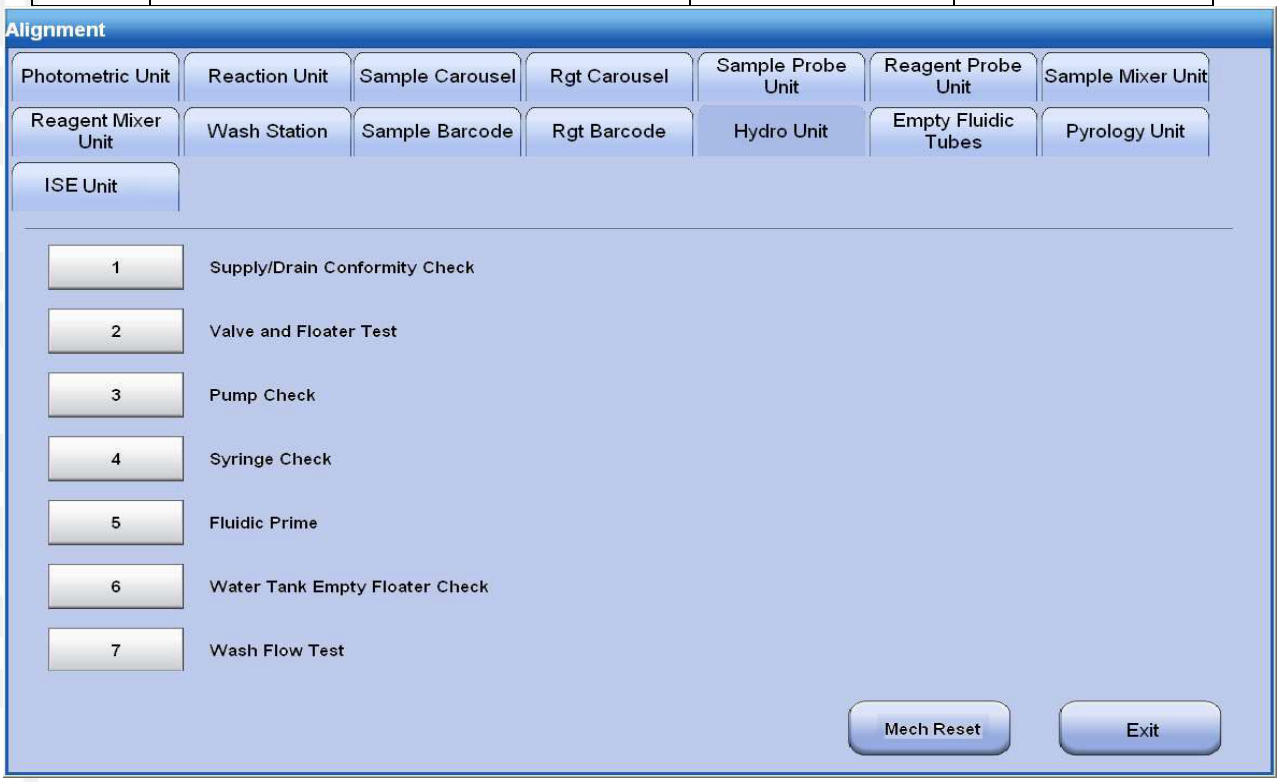
F. Priming

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

S No	Activity	Done By	Date
01	Do all checks in Hydro Unit		



Acceptance criteria:

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

PARAMETER PASS FAIL

Parameter values for verification: No Error Messages

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V. COMMENTS

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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
Signature :

Company : AGAPPE DIAGNOSTICS LTD. Date :

Customer Authorizations**: DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA**

Name :

Designation : Signature :

Title : INSTALLATION QUALIFICATION Date :

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AGAPPE

OPERATIONAL QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA CLINIA

AGAPPE DIAGNOSTICS LTD.

ADL/KO/SER/0086/23-24

ADL/FO/MCD/065/2015/R00

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AGAPPE

I. APPROVAL OF THE OPERATIONAL QUALIFICATION PROCEDURE

Both **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA** and **AGAPPE DIAGNOSTICS LTD**. are jointly responsible for the installation of **MISPA CLINIA** with serial number **YM-84001332** as per the attached OPERATIONAL QUALIFICATION protocol.

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

Name	:	Debashis Bhattacharjee	Signature :
Designation	:	Manager - Customer Service	Date :
Company	:	**AGAPPE DIAGNOSTICS LTD.**	

AGAPPE DIAGNOSTICS LTD. Kolkata PIN:700091 TEL:40030461

Validation Team from DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA

Name	:		Signature :
Designation	:		Date :
Department	:		

Customer Authorizations:

Name :

Title : OPERATIONAL QUALIFICATION Signature :

Site : Date :

ADL/FO/MCD/065/2015/R00

II. 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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III. SCOPE

This Operational Qualification protocol will be performed on the **MISPA CLINIA** at **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA.** This Operational 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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IV. OPERATIONAL QUALIFICATION

A. **Instrument Identification** Verified Date **:**

1. Model Name **:** MISPA CLINIA
2. Serial Number **:** YM-84001332

B. 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	
02	Daily maintenance	To clean appropriate modules	
03	Calibration	To calibrate the system	
04	QC check	To confirm that the system is calibrated and working within specifications	
05	Reproducibility check	To check the precision [CV %] after calibration	
06	Sample programming and Analysis	To run the samples	
07	Shut down procedure	To shut down the system	

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Test 01: <u>Starting the system</u>

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:

- Wait for the instrument to get ready after initialization
- Check the room temperature and switch on the Air Conditioner
- Check the UPS.
- Switch on the MISPA CLINIA by pressing the main switch, then switch on the computer and then the system power
- Double click the analyzer icon to initialize the system software
- Input the password and do as prompted, the system menu pops up if start up is finished
- If not, initialize by again after solving the error displayed
- 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 in the software

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

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		
02	Performing Calibration with calibration programming screen		

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		
02	Creating QC file		
03	QC sample programming and analysis		

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

PARAMETER **PASS** **FAIL**

Parameter values for verification: QC values within ± 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		
02	Running triplicates		

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		
02	Programming samples		
03	Aspirating the samples		
04	Viewing samples in process		
05	Review results: Monitoring results		

Acceptance criteria: Samples Analysis without any error

PARAMETER PASS FAIL

Parameter values for verification: Sample analysis without any error

Test 07: Shut down

Purpose: To shut down the system

Procedure:

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

Acceptance criteria: Shut down without any error

PARAMETER PASS FAIL

Parameter values for verification: Shut down without any error

V. OPERATIONAL PROCEDURE

Certificate of Training

1. 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		
2	System Operation		
3	Basic trouble shooting and Maintenance		

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2. 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

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VI. COMMENTS

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VII. 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
Signature :

AGAPPE DIAGNOSTICS LTD. Kolkata PIN:700091 TEL:40030451

Company : AGAPPE DIAGNOSTICS LTD. Date :

Customer Authorizations**: DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA**

Name :

Designation : Signature :

Title : OPERATIONAL QUALIFICATION Date :

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PERFORMANCE QUALIFICATION

For

FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

MODEL : MISPA CLINIA

AGAPPE DIAGNOSTICS LTD.

ADL/KO/SER/0087/23-24

ADL/FO/MCD/066/2015/R00

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I. APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE

Both **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA** and **AGAPPE DIAGNOSTICS LTD**. are jointly responsible for the installation of **MISPA CLINIA** with serial number **YM-84001332** as per the attached PERFORMANCE Qualification protocol.

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

Name	:	Debashis Bhattacharjee	Signature :
Designation	:	Manager - Customer Service	Date :
Company	:	**AGAPPE DIAGNOSTICS LTD.**	

AGAPPE DIAGNOSTICS LTD. Kolkata PIN:700091 TEL:40030451

Validation Team from DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA

Name	:		Signature :
Designation	:		Date :
Department	:		

Customer Authorizations:

Name :

Title : PERFORMANCE QUALIFICATION Signature :

Site : Date :

ADL/FO/MCD/066/2015/R00

II. INSTRUCTIONS

1. 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.

2. The concerned employees of **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA** 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 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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III. SCOPE

This Performance Qualification protocol will be performed on the **MISPA CLINIA** at **DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA.** 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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IV. PERFORMANCE QUALIFICATION

A. Instrument Identification

Verified Date :

1. Model Name : MISPA CLINIA
2. Serial Number : YM-84001332

B. 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	
02	Daily maintenance	To clean appropriate modules	
03	Cell blank	To check the cuvettes	
04	Priming	To check the tubing's, and flow	
05	Auto gain	To check the cuvette and photometry system	
06	Calibration	To calibrate the system	
07	QC check	To confirm that the system and reagents are acceptable and working within specifications	
08	Reproducibility check	To check the precision [CV %]	
09	Sample programming and Analysis	To run the samples	
10	Shut down procedure	To shut down the system	

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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:

- Wait for the instrument to get ready after initialization
- Check the room temperature and switch on the Air Conditioner
- Check the UPS.
- Switch on the MISPA CLINIA by pressing the main switch, then switch on the computer and then the system power
- Double click the analyzer icon to initialize the system software
- Input the password and do as prompted, the system menu pops up if start up is finished
- If not, initialize by again after solving the error displayed
- 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		
02	Check Wash solutions		
03	Check system water		
04	Check Reagents		
05	Clean Reagent Block		
06	Clean out side area		
07	Load supplies and remove outdated and empty reagents		
08	Check main menu screen		
09	Perform Quality Control		

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: Photometer Check

Purpose: To check the photometer after running some cycles of tests

Photometer Check

1. Execute **Photometer Check**.

2. Make sure that the lamp has been turned on for over 10 minutes. Operate according to screen prompts.

3. If the Status field shows Normal, it indicates that the lamp's light intensity satisfies the requirements of measurement; if it shows "Light intensity is weak" in red, it indicates that the lamp has insufficient light intensity.

4. If an alarm occurs during the check, operate as follows:
   - If an alarm indicates the lamp is off, check if the lamp has been turned on.
   - If the alarm indicates light intensity too strong
   - If the alarm indicates light intensity weak, replace the lamp immediately.

Acceptance criteria:

- No error Messages displayed
- All checks acceptance

PARAMETER **PASS** **FAIL**

Parameter values for verification: No Error Messages

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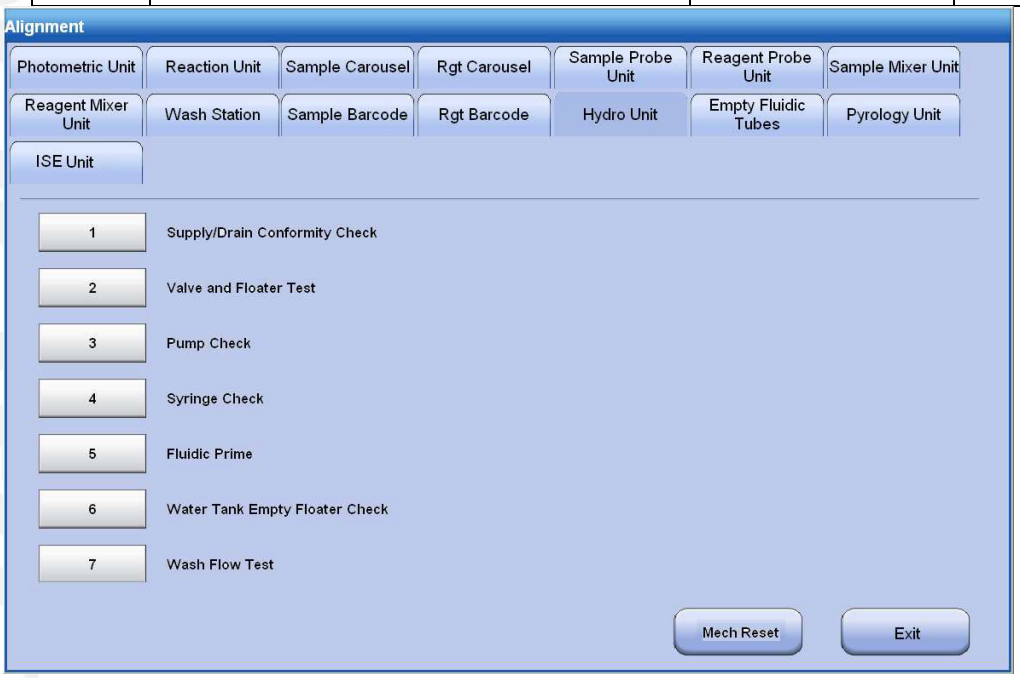
Test 04: Priming

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

S No	Activity	Done By	Date
01	Do all checks in Hydro Unit		



Acceptance criteria:

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

PARAMETER PASS FAIL

Parameter values for verification: No Error Messages

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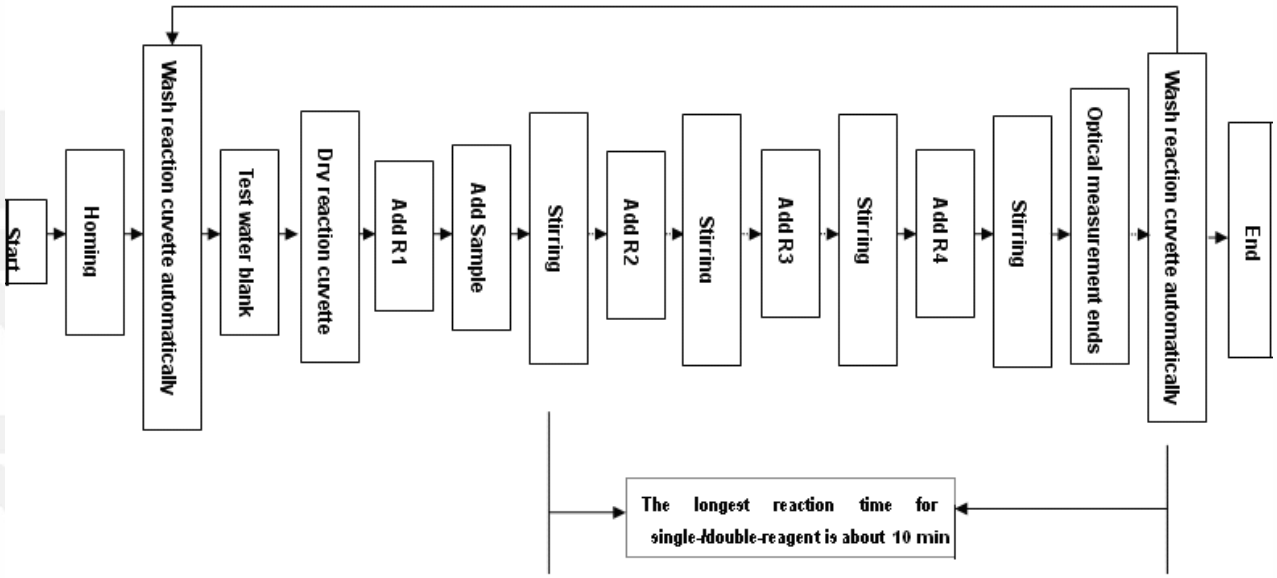
Test 05: Workflow



Acceptance criteria: The workflow should be correct in order

PARAMETER **PASS** **FAIL**

Parameter values for verification : No unwanted stopping in between

ADL/FO/MCD/066/2015/R00

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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		
02	Creating QC file		
03	QC sample programming and analysis		

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

PARAMETER **PASS** **FAIL**

Parameter values for verification: QC values within ± 2SD

Test 08: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample		
02	Running triplicates		

Acceptance criteria: Results CV within specified limits

PARAMETER **PASS** **FAIL**

Parameter values for verification: CV% within the limits

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Test 09: Sample programming and Analysis

Purpose: To run the samples

Procedure:

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

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		
02	Following the on screen instructions		
03	Switch off the instrument when prompted		

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

1. 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		
2.	System Operation		
3.	Basic trouble shooting and Maintenance		

2. 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

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V. COMMENTS

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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 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.

AGAPPE DIAGNOSTICS LTD. Kolkata PIN:700091 TEL:40030451

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

Name : Debashis Bhattacharjee

Designation : Manager - Customer Service Signature :

Company : AGAPPE DIAGNOSTICS LTD. Date :

Customer Authorizations**: DIVINE TOUCH MEDI CLINIC, AGARTALA, TRIPURA**

Name :

Designation : Signature :

Title : PERFORMANCE QUALIFICATION Date :

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