



Instrument Installation Acceptance Statement

Account Name: Impulse Diagnostic

City: Silchar State: Assam

Instrument Installed: 13/02/2020 S/N: DE272658

S/N: _____

S/N: _____

S/N: _____


Install Completion Date: 13/02/2020

Customer:

I understand and state that the installation of the Siemens Instrument(s) has/have been completed to my satisfaction, including training of laboratory personnel on the operation and maintenance of this Instrument(s).

I also state that the Instrument(s) is/are (1) operating in accordance with manufacturing specification and (2) the Instrument(s) and consumable(s) performance has/have been validated according to Siemens protocol.

Customer's Name: Impulse Diagnostics
Print Name

Customer Signature:  Date: _____

Siemens CAS

CAS's Name: Da I monmi lakai
Print Name Date: _____

CAS Signature: _____

Installation Procedure and Checklist – Dimension EXL200.

Models @ Serial No : Dimension EXL200
Instrument Sr # : DE272658
Customer Name : Impulse Diagnostic
Doctor / In-Charge : Dr. Dipayan Saha
Address : Hailakandi, Meherpur

City : Silchar
Phone : 3482224542

1. Inspect Shipper for physical damage, then Uncrate.

- a. Physical Damage to shipper : Yes No
b. Accessories as per packing List : Yes No

2. Environmental Conditions.

- a. Air Conditioned Environment Available : Yes No
b. Room free of Rodents/ Insects/ Pests : Yes No
c. Humidity is less than 80 % : Yes No

8. System Calibration and Inspection.

- a. Verified All Mechanical Configuration Adjustment of the Site
and Back up in Disc
(Instrument Calibration Diskette provided to the User Department)
- b. Checked the Thermal Operations of Reagent compartment and Thermal Chamber.
- c. Checked the Reagent area and Automatic Flex Loader
- d. Checked Sample area.
- e. Checked the Barcode reader.
- f. Checked the Lamp Calibration
- g. Checked the Photometer alignment and mAU Offset calibration.
- h. Calibrated the Cuvette and reagent temperature

9. System Preparation: System Check

Run the System check with CHK Reagent to check the performance of Sample Probe assembly, Reagent Probe 1 and 2 assembly, Photometer alignment.

Attached System check Printout attached

Alignment: print out attached

Voltages:

	Power OFF	Power ON	Power ON
G-H	_____ V (0-1V)	_____ (90-110V)	_____ (198-264V)
	_____ V (0-1V)	_____ (110-125V)	
H-N	_____ V (0-1V)	_____ (90-110V)	_____ (198-264V)
	_____ V (0-1V)	_____ (110-125V)	
G-N	_____ V (0-1V)	_____ (Max 0.5)	_____ (< 2V)
	_____ V (0-1V)	_____ (< 2 V)	

Gaps:

Syringe

<u>(Glass to plunger)</u>	<u>Observed</u>	<u>Adjusted</u>	<u>Specification</u>
Sample Metering	_____	_____	(.005" - .010")
Sample Flush	_____	_____	(.005" - .010")
Reagent 1 Metering	_____	_____	(.005" - .010")
Reagent 1 Flush	_____	_____	(.005" - .010")
Reagent 1 Metering	_____	_____	(.005" - .010")
Reagent 1 Flush	_____	_____	(.005" - .010")
Reagent 1 Flush	_____	_____	(.005" - .010")
IF HM Instrument Chemistry Wash	_____	_____	(.005" - .010")

Cuvette Manufacture Solenoids

			<u>Specification</u>
Top Seal	_____	_____	(.010" *)
Cuvette Form	_____	_____	(0.020" - 0.045"**)
U-Sea 1	_____	_____	(0.020" ± 0.010"*)
	_____	_____	

Installation Qualifications for Dimension EXL200.

Carried out all the Installation Steps as well as the Necessary Checks and Alignments of all Robotics were done for Dimension EXL200 located in Impulse Diagnostic, Silchar bearing serial No. DE272658 as per Installation Procedure and Checklist.

Checked the System check report and the obtained values acceptable. (Printout attached)

Performed all due maintenance activities such as Daily, Weekly Maintenance, Automated System Prime.

Handed over the Instrument for Operations Training & Qualifications.

For Siemens Ltd.

Name : Mr. Kamal Kumar Baishya

Designation : Field Service Engineer

Signature : 

Date :

Installation Certificate

This is to certify that the Dimension EXL200 Clinical Chemistry **System**, Instrument Serial DE272658 has been successfully Installed and Commissioned in Impulse Diagnostic, Meherpur, Silchar, Assam as per the Installation Procedure & Checklist.

Siemens Ltd.

Impulse Diagnostic

Name: Kamal Kumar Baishya

Name: Jantu Das

Designation: Field Service Engineer

Designation: Technician In-charge

Signature : 

Signature: 

Date:

Date:

Operational Qualification for Dimension EXL200

Operator Qualification: Conducted the operator Training on the following Topic

- 1, Component Overview
- a, System Components
 - b, Keyboard, Touchscreen and Alert Keys
- 2, Calibration:
- a, Calibrated Linear Method and verify Enzyme Method
- 3, Maintenance:
- a, Daily, Weekly, Monthly Maintenance and Periodic Maintenance
 - b, Replace Cuvette Nozzle Diaphragm
 - c, Replace Cuvette film cartridge
 - d, Replace Reagent and Sample Probe tip.
- 4, Sample Processing
- a, Running sample using Sample cup, primary tube.
 - b, Manual dilution and respond to system needs.
 - c, Determine Segment status and delete Segment.
 - d, Review use of System status key
 - e, Edit samples including adding and deleting tests, rerunning test and deleting Samples.
 - f, Review use of these keys:
Pause, Exit, Shift, Reset, Backspace, Backslash, Run and Arrow keys.
 - g, Review Interpreting test report messages.
- 5, Customization
- a, Set Password
 - b, Enable automatic cartridge removal, and automatic repeat for panic
 - c, Enable Automatic Flex reagent cartridge testing.

- d, Select Plumbing configuration
- e, Define panel
- f, Define QC Status and QC ranges
- g, Review method QC results from method review screen.
- h, Enter Panic values
- i, Configure barcode choice
- j, Touchscreen and alert features
- k, Configure QC Alerts, QC ranges and QC Panels.
- l, Define calibration products and calibration alert.
- m, Setting calibration.

6, Problem Resolution

ACTIVITY	Reference
Review response to alarm ON/OFF	Operator's Guide, <i>Introducing</i> ,
Review response to error messages using ALT M	Operator's Guide, <i>Introducing</i>
Review using Reset key to clear error messages	Operator's Guide, <i>Introducing</i>
Review active and resident error logs; including More Info and See Minor functions	Operator's Guide, <i>Troubleshooting</i>
Review troubleshooting, emphasizing system check troubleshooting guidelines	Operator's Guide, <i>Troubleshooting</i>
Review icons and using CTL Help to respond to icons	Operator's Guide, <i>Appendix</i>

REAGENT INVENTORY SUMMARY

Attached printout

**THIS INVENTORY SUMMARY CONSISTS OF ALL METHODS
CALIBRATED AND INTENDED FOR USE AT TIME OF INSTALL.**

Moumi Lakai

CAS

[Signature]

CUSTOMER

Dimension EXL200 Performance Evaluation, Annexure1

Following Procedure was Carried out as part of the Performance Qualification:-

1. Calibration of Assay

Checked and found all calibrations within the acceptable CV limits and in range.
See Print out Attached.

2. Internal Quality Control Performance

Two Level Biorad Lyphocheck Assayed Chemistry Control.
Checked and found all level Controls to be within the acceptable limits.
See print out Attached.

3. Precision Study

A Within Run Precision of replicates were carried out and CV % obtained are within the acceptable limit for the assay as stated in the IFU.

See print out attached.

4, Linearity Study

Linearity study done for AST, BUN, Creatinine, GGT, Glucose.

See Print out attached.

Performance Qualification for Dimension EXL200

With reference to the Annexure 1 and studies carried out in the Laboratory have determined that the analyzer meets all performance criteria and has passed Performance Qualification.

The System is ready for specific usage.

Protocol performed by : Siemens Ltd.

Signature : *Monmi Lakai*

Name : Da I Monmi lakai

Designation : Application Service

Customer Authorization : Impulse Diagnostic

Signature : *Jantu Das*

Name : Jantu Das

Designation : Technician In-charge

Date: