CALIBRATION CERTIFICATE

This is to certify that ADVIA CENTAUR CP bearing Serial No: ROB30006116 installed at IMPULSE DIADNOSTICS, HAILAKANDI ROAD, MEHERPUR, SILCHAR, ASSAM, has been calibrated on 17th August 2021.

The complete hardware calibration has been carried out for the best performance of the instrument as per the procedure. The following are the instrument calibration details.

System Software – Ver. 6.2

Temperature

Module	Result (°C)	Range (°C)	Status
Cuvette Ring	37.1	36 – 38	Passed
Sample Environment	23.17	18 – 30	Passed
Reagent	9.4	8 – 11.3	Passed

Luminometer

Luminometer High Voltage ON – 1000 V
High Voltage OFF – 6V
Dark Counts without Cuvettes

Position	Result (RLU)	Range (RLU)	Status
Pos # 1	33	0 – 300	Passed
Pos # 2	33	0 – 300	Passed
Pos # 3	43	0 – 300	Passed
Pos # 4	30	0 – 300	Passed
Pos # 5	46	0 – 300	Passed
Pos # 6	30	0 – 300	Passed
Average	35	0 – 300	Passed

Sample Probe Pressure Sensor Calibration

Sample Air pump = 29.0 % (The acceptable range is 25% to 40%)

Reagent Probe Sensor Test

Medium	Result (Voltage)	Range (Voltage)	Status
With Water	**0.9671**	**0.85 – 1.05**	**Passed**
With Air	**3.4755**	**3.20 – 4.20**	**Passed**

The instrument is working satisfactory as per above parameter calibrations. The next calibration due is on 16-02-2022.

Siemens Healthcare Private Limited

Kamal Kumar Baishya

Kamal Kr. Baishya

Manager: Customer Service
Silchar, Assam
17th August 2021.

SIEMENS Healthineers

CALIBRATION CERTIFICATE

Dimension EXL200 bearing serial number DE272658 at **IMPULSE DIAGNOSTICS, HAILAKANDI ROAD, MEHERPUR, SILCHAR**, Assam has been duly calibrated on 17th August 2021

Final calibration results are as follows:

PHOTOMETER DARK CALIBRATION:

Reference : 9014.57 Hz
Sample (outer on) : 8794.58 Hz
Sample (outer off) : 8796.19 Hz

LAMP CALIBRATION:

Low Calib level : 55.0%
High Calib level : 68.2%

PHOTOMETER

Filters	System Check Wavelength	Acceptable Range
293nm ----	1.22	±2.5
340nm ----	0.81	±1.5
383nm ----	0.70	±1.5
405nm ----	0.79	±1.5
452nm ----	0.69	±1.5
510nm ----	0.60	±1.5
540nm ----	0.49	±1.5
577nm ----	0.53	±1.5
600nm ----	0.53	±1.5
700nm ----	0.50	±1.5

PHOTOMETER LAMP VOLTAGE:

Set at 24.00V calibrated by DVM

PHOTOMETER ARM ALINGMENT: **set at -6** Range: -3 to -9

CHK SYSTEM CHECK RESULTS:

RESULTS FROM INTSTRUMENT

	OBSERVED	ACCEPTABLE RANGE
Reagent 1:	Mean: 396.62 SD : 0.46	Mean: 396±15 SD : 3.80
Reagent 2 :	Mean: 397.08 SD : 1.40	Mean: 396±15 SD : 3.80
Sampler :	Mean: 41.10 SD : 0.31	Mean: 39.4±2 SD : 1.6

TEMPERATURE CALIBRATION:

Reagent : 5.0°c	Range: 2°c to 8°c
Cuvette : 37.0°c	Range: 37.0 +/- 0.2°c

The instrument is working satisfactorily, subsequent to Calibrations of the above parameters, and the Next Calibration is due on 16th February. 2022.

Note: Absorbance kit (CHK) LOT NO: GA1279 is an USFDA approved kit used in performing the system check in all Dimension systems. The carton value is a predetermined value for which the limits are defined in system check screen and operator guide of Dimension.

Siemens Healthcare Pvt Ltd.

Kamal Kr. Baishya

Kamal Kumar Baishya
Manager Customer -Service
Silchar, Assam
17-08-2021

SIEMENS Healthineers

Performance Qualification for ADVIA CENTAUR CP

With reference to the Annexure 2 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 : Pinki Das.

Name : Pinki Das

Designation : Application Service

Customer Authorization : Impulse Diagnostics

Signature :

Name : J.J Purkayastha

Designation : Lab In-Charge

Date:

SIEMENS Healthineers

Annexure 2.

ADVIA CENATUR Performance Evaluation.

Following Procedure was Carried out as part of the Performance Qualification for Advia Centaur CP bearing serial No. ROB30006116Installed inImpulse Daignostics, Silchar:-

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

Three-Level Biorad Lyphocheck Immunoassays Control.
Checked and found all level Controls to be within the acceptable SD limits.
See print out Attached.

3. Precision Study

A Within Run Precisionof10 replicates werecarried out for TSH, TT3, TT4 andCV % obtained are within the acceptable limit for the assay.

See print out attached.

SIEMENS Healthineers

Operational Qualification for ADVIA CENTAUR CP

With reference to the Installation Procedure and Checklist and the studies carried out in Impulse Diagnostics, Silchar, **ADVIA CENTAUR CP Serial No. ROB30006116** meets all criteria outlined for Operational Qualification

Exceptional conditions, if any, have been addressed.

a. The Flooring on which the analyzer has been placed is LEVEL. ☐ Yes ☐ No

Temperature and Humidity

b. Ambient Temperature Check Found Between 18 to 25 C ☐ Yes ☐ No

c. Humidity Found to be < 80 % ☐ Yes ☐ No

The Analyzer is ready for Performance Qualification

Protocol Performed By: Siemens Ltd.

Signature : K Baishya

Name : Mr. Kamal Kumar Baishya

Designation : Field Service Engineer

Customer Authorization: Impulse Diagnostics

Signature :

Name : Mr. J.J Purkayastha

Designation :Lab In-Charge

SIEMENS
Healthineers

Installation Certificate

This is to certify that the **ADVIA CENTAUR CP Immunoassay System**, Instrument Serial **ROB 30006116** has been successfully Installed and Commissioned at **Impulse Daignostics**, Silchar as per the Installation Procedure& Checklist.

Siemens Ltd.

Name: Kamal Kumar Baishya

Designation: Field Service Engineer

Signature : K Baishya

Date:

Impulse Diagnostics

Name: J.J Purkayastha

Designation: Lab In-Charge

Signature:

Date:

SIEMENS Healthineers

Installation Qualifications for ADVIA CENTAUR CP.

Carried out all the InstallationSteps as well as the Necessary Checks and Alignments of all Robotics were done as per Installation Procedure and Checklist. (See Annexure 1).

Checked the Dark Counts with & without cuvettes and obtained values acceptable.

Performed all due maintenance activities such as Automated Daily Cleaning, Automated System Prime and Probe Bubble detector calibration.

Handed over the Instrument for Operations Training & Qualifications.

Enclosed:

a. Quality Certificate duly signed by the Siemens Plant Quality Assurance Manager.
b. ISO 9001:2000 / ISO 13485 : 2003
c. Declaration of Conformity.
d. QA INSTRUMENT RELEASE APPROVAL.

For Siemens Ltd.

Name : Mr. Kamal Kumar Baishya

Designation : Field Service Engineer

Signature : KBaishya

Date :

For Impulse Diagnostics

Name : J.J Purkayastha

Designation : Lab In-Charge

Signature :

Date :

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c. Checked the Reagent Probe Dispense test. ☐
d. Checked the Tip Tray Loading and Tip Pick up. ☐
e. Checked the aspirate probe. ☐
f. Checked the Acid and Base Reagent Addition. ☐
g. Checked Dark Count ☐

9. Verification of Water Requirement

a. CLSI Type II or higher Water Used: ☐

FSE Signature : KBaishya.

Name : Kamal Kumar Baishya

Date :

SIEMENS Healthineers

3. Power Requirements.
   a. Uninterrupted Power Supply Available.

      - UPS Rating ___2 _KVA
      - UPS Make _____.
      - Type of batteries _____.
      - Back Up Time __0.5Hours_.
      - Incoming AC Power: V AC.
      - Earth Voltage ___V.

4. General Cleanliness Around Site : Acceptable ☐ Not Acceptable ☐

5. Verified all Instruments Components and Accessories : ☐

6. Installed all Accessories as per the Instrument Set - Up Procedure Below : ☐
   1 Removed all shipping screws from the System
   2 Assembled the User Interface Modules – PC, Keyboard &Mouse
   3 Installed the Printer & Bar Code Scanner
   4 Installed the Top Cover
   5 Installed the Syringe Assembly
   6 Checked all cable connections;
   7 Checked all Electronic Boards are properly plugged in
   8 Checked the Dispense Test for Probes
   9 Installed the Current Software Version 6.1
   10 Installed Test Definition Version 1.0.X

7. Printer.
   a. Make: _____
   b. Installed: ☐ OK

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 and Ancillary Compartment. ☐

SIEMENS Healthineers

Advia Centur CP

Installation Procedure and Checklist – ADVIA CENTAUR CP.

Models @ Serial No : ADVIA CENTAUR CP

Instrument Sr # :ROB30006116

Customer Name : Impulse Diagnostics

Doctor / In-Charge : Jagat Jyoti Purkayastha

Address : Hailakandi Road, Meherpur

City : Silchar

Phone : 9435213188

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

SIEMENS Healthineers

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 Iakai
Print Name **Date:**

CAS Signature:

SIEMENS Healthineers

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

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3. Power Requirements.
   a. Uninterrupted Power Supply Available.

      - UPS Rating ____KVA
      - UPS Make _____.
      - Type of batteries _____.
      - Back Up Time _____Hours_.
      - Incoming AC Power: _____V AC.
      - Earth Voltage _____V.

4. General Cleanliness Around Site : Acceptable ☐ Not Acceptable ☐

5. Verified all Instruments Components and Accessories : ☐

6. Installed all Accessories as per the Instrument Set - Up Procedure Below : ☐

   1 Removed all shipping screws from the System
   2 Assembled the User Interface Modules – PC, Keyboard
   3 Installed the Printer & Bar Code Scanner
   4 Installed the Top Cover
   5 Installed the Syringe Assembly
   6 Checked all cable connections;
   7 Checked all Electronic Boards are properly plugged in
   8 Checked the Dispense Test for Probes
   9 Installed the Current Software Version
   10 Installed the Dade Behring water diluent bottle
   11 Installed the cuvette cartridge

7. Printer.
   a. Make: _____
   b. Installed: ☐ OK

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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

SIEMENS Healthineers

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

(Glass to plunger)	Observed	Adjusted	Specification
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			Specification
Top Seal	_____	_____	(.010" *)
Cuvette Form	_____	_____	(0.020" – 0.045"**)
U-Seal	_____	_____	(0.020" ± 0.010"*)
	_____	_____	

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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 : KBaishya

Date :

SIEMENS
Healthineers

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:

SIEMENS Healthineers

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.

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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, *Introducing,*
Review response to error messages using ALT M	Operator's Guide, *Introducing*
Review using Reset key to clear error messages	Operator's Guide, *Introducing*
Review active and resident error logs; including More Info and See Minor functions	Operator's Guide, *Troubleshooting*
Review troubleshooting, emphasizing system check troubleshooting guidelines	Operator's Guide, *Troubleshooting*
Review icons and using CTL Help to respond to icons	Operator's Guide, *Appendix*

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REAGENT INVENTORY SUMMARY

Attached printout

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

Mounni Lakai

CAS

CUSTOMER

SIEMENS Healthineers

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.

SIEMENS Healthineers

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 Iakai

Designation : Application Service

Customer Authorization : Impulse Diagnostic

Signature : Jantu Das

Name : Jantu Das

Designation : Technician In-charge

Date:

The DIMENSION EXL 200 s/n DE272658
has been successfully installed as of 18th Feb 2020.
(Date)

Customer Accepted: Impulse Diagnostic
Date: 18 feb 2020
Title: IO OP PA

1 Installation Completion Checklist

[ ] EM Checklist attached (Obtain FSR signature)

[ ] Calibration and QC Summary Sheets attached

[ ] Inventory Summary Sheet attached

[ ] Method Calibration / Verification / IMT Reports attached

[ ] Rating Form completed and attached

[ ] Training Checklists completed and attached

[ ] Installation Completion Statement

[ ] Software Revision Level 10 · 3 · 1 .

Signatures:

Clinical Applications Specialist	Feb 18 2020 date
Field Service Representative	Feb 18 2020 date

NOTICE TO INSTALLERS

This package contains new revisions

PLEASE READ PRIOR TO INSTALLATION

SIEMENS Healthineers

Dimension®

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:** 18/2/20

Siemens CAS

CAS's Name: Da I monmi Iakai
Print Name **Date:** 18/2/20

CAS Signature:

SIEMENS Healthineers

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

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3. Power Requirements.
   a. Uninterrupted Power Supply Available.

      - UPS Rating ____KVA
      - UPS Make _____.
      - Type of batteries _____.
      - Back Up Time _____Hours_.
      - Incoming AC Power: _____V AC.
      - Earth Voltage ____V.

4. General Cleanliness Around Site : Acceptable ☑ Not Acceptable ☐

5. Verified all Instruments Components and Accessories : ☑

6. Installed all Accessories as per the Instrument Set - Up Procedure Below : ☑

   1 Removed all shipping screws from the System
   2 Assembled the User Interface Modules – PC, Keyboard
   3 Installed the Printer & Bar Code Scanner
   4 Installed the Top Cover
   5 Installed the Syringe Assembly
   6 Checked all cable connections;
   7 Checked all Electronic Boards are properly plugged in
   8 Checked the Dispense Test for Probes
   9 Installed the Current Software Version
   10 Installed the Dade Behring water diluent bottle
   11 Installed the cuvette cartridge

7. Printer.
   a. Make: _____
   b. Installed: ☑ OK

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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

SIEMENS Healthineers

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

(Glass to plunger)	Observed	Adjusted	Specification
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			Specification
Top Seal	_____	_____	(.010" *)
Cuvette Form	_____	_____	(0.020" – 0.045"**)
U-Seal	_____	_____	(0.020" ± 0.010"*)
	_____	_____	

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Healthineers

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 : K Baishya

Date : 19/02/20

SIEMENS
Healthineers

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.

Name: Kamal Kumar Baishya

Designation: Field Service Engineer

Signature : K Baishya

Date: 18/02/20

Impulse Diagnostic

Name: Jantu Das

Designation: Technician In-charge

Signature: Jantu Das.

Date: 18/02/20

SIEMENS Healthineers

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.

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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, *Introducing,*
Review response to error messages using ALT M	Operator's Guide, *Introducing*
Review using Reset key to clear error messages	Operator's Guide, *Introducing*
Review active and resident error logs; including More Info and See Minor functions	Operator's Guide, *Troubleshooting*
Review troubleshooting, emphasizing system check troubleshooting guidelines	Operator's Guide, *Troubleshooting*
Review icons and using CTL Help to respond to icons	Operator's Guide, *Appendix*

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REAGENT INVENTORY SUMMARY

Attached printout

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

Mouni Lakai

CAS

CUSTOMER

SIEMENS Healthineers

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.

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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 Iakai

Designation : Application Service

Customer Authorization : Impulse Diagnostic

Signature : Jantu Das

Name : Jantu Das

Designation : Technician In-charge

Date: 18/02/20