

### Calibration Certificate

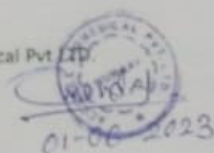
This is to certify that **SPHERA Fully Auto Biochemistry Analyzer**  
installed in Biochemistry lab with  
**Serial no. 160698001** at **Dr Amitavo Basu Smriti Raksha Committee**  
has been successfully inspected & calibrated.

The calibration details are as follows –

Particulars	Details
Installation Date	07 <sup>th</sup> November 2016
Calibration Date	01 <sup>st</sup> June 2023
Calibration due date	01 <sup>st</sup> December 2023
Electrical & Functional check	Found OK
Hardware Check	Found OK
Mechanical Calibration Check	Found OK
Wash function Check	Found OK
Sample arm movement check	Found OK
Optical Reading Test	Found OK
Parameters Checked	Controls run Found OK

All the checks & calibration done and the system is being used under recommended conditions.

For Accurex Biomedical Pvt Ltd




Chandan Mondal

{Dy. Area Service Manager}

ISO 13485 : 2016  
GST: 27AACCA3730G1Z1

212 Udyog Mandir No. 1, 7-C, Bhagoji Keer Marg  
Mahim (W), Mumbai - 400016, Maharashtra, India

 [www.accurex.net](http://www.accurex.net)

 Customer Care: +91 7400 453 000

ANNEXURE A  
Installation Qualification

Installation Report

Name of the customer: Dr. Amitavo Basu Smriti Raksha Committee

Instrument type: Biochemistry Fully Auto Analyzer

Model number: SPHERA

Serial number: 160698001

Date of receipt: 07.11.2016

Date of installation: 07.11.2016

**Power checks:**

Power supply	AC 232V-50 Hz
Plug top	16 Amps
Earth voltage	2.0 Volt

**Environmental check:**

Parameter	Working range	Site conditions
Room temperature	5-40°C	27°C
Humidity	10-90%	52%

**Physical check of the equipment:**

Check for damage	Checked	No damage found
Visual and functional inspection	Checked	OK
No damage on internal assembly	Checked	No damage found

**System configuration check:**

Positioning of the		
Equipment flat stable surface	Checked	Found OK
Adequate space around the analyzer	Checked	Found OK
Interference to other equipment	Checked	No interference

*Result*

Installed the SPHERA satisfactorily and is ready for operational verification

Installed by: Chandan Mondal Checked by:

Signature: (Signature) Signature:

Date: 07/11/2016 Date:



## Operational Qualification

### Operational Verification Report

Name of the customer: Dr. Amitavo Basu Smriti Raksha Committee

Instrument type: Biochemistry Fully Auto Analyzer

Model number: SPHERA

Serial number: 160698001

Date of receipt: 07.11.2016

Date of installation: 07.11.2016

#### Operational check:

Precision test	Checked	Passed
Quality control test	Checked	Passed

#### Result

Operational verification of SPHERA has been completed satisfactorily and it is ready for the performance verification.

Operations performed by: *Chandan Mondal*

Signature: *Mondal*

Date: *07/11/2016*




Checked by:

Signature:


Date:

ISO 13485 : 2016

GST: 27AACCA3730G1Z1

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## Performance Qualification

### Performance Verification Report

Name of the customer: Dr. Amitavo Basu Smriti Raksha Committee

Instrument type: Biochemistry Fully Auto Analyzer

Model number: SPHERA

Serial number: 160698001

Date of receipt: 07.11.2016

Date of installation: 07.11.2016

Performance check: Done

#### Result

The performance verification of SPHERA has been completed satisfactorily and instrument is ready to be placed in service.

Performance check done in presence of: Lab In-charge:

Signature:

Date:

Performance check:

Performance by:

(Service engineer)

Signature:

Date:

Checked by:


Signature:


Date:

ISO 13485 : 2016

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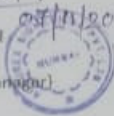
## Installation, Operational and Performance Qualification Certificate

The equipment SPHERA, serial. No: 160698001 installed and commissioned.

The operational and performance verification is done and observations are:

- (1) All system components are operating correctly.
- (2) All tests were carried out in accordance with qualification protocol and standard operating Procedure.
- (3) The performance of the SPHERA (s/n 160698001) is as per the acceptance criteria.

Mondal  
Chandan Mondal  
(Dy. Area Service Manager)



Date: 07/11/2016