

**Registered Office:**

**BioSystems Diagnostics Pvt. Ltd.,**  
A4, SIPCOT Industrial Park, Irungattukottai,  
Thandalam Village, Sriperumbudur - 602105.  
Ph: +91 - 44 - 3034 1911 / 12 / 13  
E-mail: customersupport@biosystems.in  
Website: www.biosystems.in  
CIN - U29297TN2003PTC051492



***BA200 – Fully Auto Biochemistry Analyser***

***Installation Qualification Certificate***


***For***

***Pace Hospitals***

***BioSystems Diagnostics Pvt. Ltd***

**Corporate Office:**

**BioSystems S.A.** Costa Brava 30, 08030 Barcelona (Spain)  
Tel +34-93 311 00 00, Fax+34-93 346 77 99  
<http://www.biosystems.es>

A large, stylized logo in the bottom right corner, consisting of overlapping grey and white circles. The text "ISO 13485" is printed in a bold, black, sans-serif font over the logo.

**ISO 13485**

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## CERTIFICATE OF INSTALLATION

Instrument Name : BA200 Fully Auto Biochemistry Analyzer

Serial Number : 832000665

Customer : Pace Hospitals

The undersigned performer certifies that the installation Qualification Protocol has been successfully completed for the instrument stated above.

**Engineer**

Signature :  
Name : Mr. Appanna Dora  
Designation : Service Engineer  
Company : BioSystems Diagnostics Pvt. Ltd.,

**Customer**

Signature :  
Name : Mr. Anjaiah  
Designation : Quality Manager  
Company : Pace Hospitals

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## **INSTALLATION REPORT**

Customer Name : **Pace Hospitals**

Department : Bio-chemistry

Contact Person : Mr. Anjaiah

Instrument Model : BA200

Serial Number : 832000665

Date of Installation : 25-07-2020

The System was installed along with the necessary accessories. All basic requirements and adjustments were checked and are found to be satisfactory Preliminary customer training was provided and standardization of all parameters was done. The Instrument is found to be working satisfactorily.

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A circular logo for ISO 13485 certification, featuring a stylized white figure inside a grey circle.

ISO 13485

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**INSTRUMENT SETUP :**

- Instrument and computer installed
- Printer Installed
- User software 5.2.3 installed
- All necessary cable connections given

**OPERATION INSPECTION :**

- No air bubbles found in the Tubing
- Temperature of the Needles/Reaction & Rotor Chamber are within range
- No unusual noises produced in the system
- Warm up procedure within time limit
- Internal Dosing of all Needle's were fine
- External Dosing of all Wash Station is perfect
- Conditioning of Machine with Air/Wash solution/Distilled water done

For Biosystems Diagnostics Pvt. Ltd

  
  
Mr. Appanna Dora  
Service Engineer

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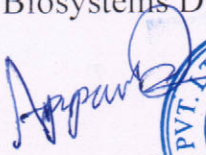
## INSTALLATION QUALIFICATION

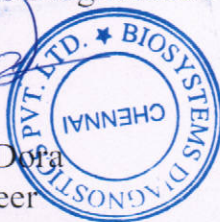
Customer Name : Pace Hospitals  
Address : Pace Hospitals  
23 Huda Techno Enclave Patrika Nagar,  
Madhapur, Hyderabad -500081  
Instrument Model : BA200  
Serial No. : 832000665

### *Operational requirement for the Instrument:*

Requirement	Acceptable Range	Observed Range
Input Voltage	220 $\pm$ 10 V	231 V
Line Frequency	50 or 60 Hz	50 Hz
Ambient Temperature	18 - 30 deg. C	25 deg. C
Distill Water	Type II NCCLS	Available

For Biosystems Diagnostics Pvt. Ltd

  
Mr. Appanna Dora  
Service Engineer



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***BA200 - Fully Auto Biochemistry Analyzer***

***Operational Qualification***


***For***

***Pace Hospitals***

***BioSystems Diagnostics Pvt. Ltd***

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## *BA200 – Fully Auto Biochemistry Analyzer*

### OPERATIONAL QUALIFICATION

1. System Performance check procedures.
2. System operational certificate.

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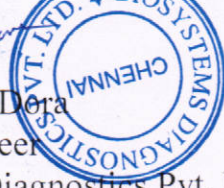
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## CERTIFICATE OF OPERATION

Instrument Name : BA200 Fully Auto Biochemistry Analyzer  
Serial Number : 832000665  
Customer : Pace Hospitals

The undersigned performer certifies that the Operational Qualification Protocol has been successfully completed for the instrument stated above.

Engineer :   
Signature :   
Name : Mr. Appanna Dora  
Designation : Service Engineer  
Company : BioSystems Diagnostics Pvt. Ltd

Customer :  
Signature :  
Name : Mr. Anjaiah  
Designation : Quality Manager  
Company : Pace Hospitals

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## SYSTEM PERFORMANCE CHECK PROCEDURE

<b>SYSTEM CHECK</b>	<b>PERFORMANCE</b>
LED Photometric Check	Done
Warm Up	Done
Mechanical Adjustments	Done
Temperature Check	Done
Internal/External Dosing Check	Done

Customer Signature:

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## OPERATIONAL QUALIFICATION

### System Certification:

Study data has determined that the System described in this document either meets all criteria outlined 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 specified usage.

Protocol Performed By:

BioSystems Diagnostics Pvt Ltd

Name : Mr. Appanna Dora

Title : Service Engineer

Company: Biosystems Diagnostics Pvt Ltd

Customer Authorization:

Pace Hospitals

Name: Mr. Anjaiah

Title : Quality Manager

ENGINEER SIGNATURE

CUSTOMER SIGNATURE

DATE:

DATE:



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***BA200 - Fully Auto Bio Chemistry Analyzer***

***Performance Qualification***

***For***

***Pace Hospitals***

***BioSystems Diagnostics Pvt. Ltd***

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## BA200 Fully Auto Biochemistry Analyzer

### PERFORMANCE QUALIFICATION:

The following parameters were checked and found to be within acceptable limits.

Parameter	Check
Vertical Motors – Sample and reagent in Home	Done
Polar Motors – Sample and reagent in Home	Done
Reaction Rotor in home	Done
Sample and Reagent rotor in Home	Done
Ceramic Dispensing pump – Sample and reagent in Home	Done
Optics Initialization: Ok	Done
Peltier cells and drivers test	Done
Rotor Peltier and Sample Reagent Rotor peltier driver test: Ok	Done
Temperature system initialized	Done
LED test: ok	Done
Hardware completely initialized	Done

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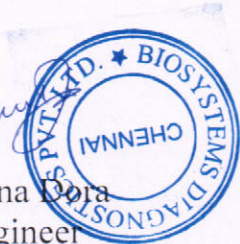


## CERTIFICATE OF PERFORMANCE

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Serial Number : 832000665  
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Date: 24/08/2021

## **CALIBRATION CERTIFICATE OF BA200**

**CUSTOMER NAME – Pace Hospitals,Hyderabad**

Serial Number = 832000665

User Software = 5.3.1

Initialization Motor

Vertical Motors – Sample and reagent in Home

Polar Motors – Sample and reagent in Home

Reaction Rotor in home

Sample and Reagent rotor in Home

Ceramic Dispensing pump – Sample and reagentin Home

Optics Initialization: Ok

Peltier cells and drivers test

Rotor Peltier and Sample Reagent Rotor peltier driver test: Ok

Temperature system initialized

LED test: ok

Hardware completely initialized

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Paremeters	Current value	Minimum	Maximum
Reading reference Position - Well 1	7892	7860	7905
Thermal adjustment of reaction rotor	37	37	39
Thermal adjustment of Wash station	46.4	42	50
Thermal adjustment of Sample & Reagent Probe	38.7	36	39
Photometric Dark Current Adjustment	3845	3300	4500
Main Photo Diode Counts 340NM	908093	600000	950000
Main Photo Diode Counts 405NM	899468	850000	950000
Main Photo Diode Counts 505NM	902320	850000	950000
Main Photo Diode Counts 535NM	896885	850000	950000
Main Photo Diode Counts 560NM	904533	420000	950000
Main Photo Diode Counts 600NM	902337	750000	950000
Main Photo Diode Counts 635NM	901197	850000	950000
Main Photo Diode Counts 670NM	897266	450000	950000

Next calibration due on: 23/08/2022

**For BIOSYSTEMS DIAGNOSTICS PVT. LTD.**

*A. Prayadhasini*

**Authorised Signatory**