



# Sigma Medicals And Diagnostic Services

## Operational Qualification:

### System Certification:

Study data has determined that the system described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional Conditions, If any Have been Addressed.

**The System is ready for specific usage.**

Protocol Performed by : **For Sigma Medicals And Diagnostic Services**

Name: Piyush Singh

Designation: Sr. Sales & Application



Customer Authorization : **Vedanta Hospital**

Bilariaganj Road Lakshirampur azamgarh-u.p.

Name:

Designation:

Company Representative Name And Sign

Customer Name And Sign

Date:

*Piyush Singh*

Date:



# Sigma Medicals And Diagnostic Services

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## Instrument Setup

1. Assembled the instrument accessories.
2. Removed the shipping Clamps.
3. Connected the Waste Tubing
4. Connected the Power cord and connection cord.
5. Initialise the machine and follow the installation procedure.

## Operational Inspection:

1. Checked and found Mechanical Movements OK.
2. Checked and found Fluidics OK.



# Sigma Medicals And Diagnostic Services

4. Checked with Controls And Samples, Results Are found OK.

For Sigma Medicals And Diagnostic Services

Technical Services Department

Name : Piyush Singh

Designation : Sr. Sales & Application





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## Operation Qualification for Semi Automated Bio-Chemistry Analyzer BD-100

- |  |        |
|--|--------|
| 1. Verified all the Mechanical Movements | : Done |
| 2. Verifeied Hydraulics                  | : Done |
| 3. Verified Electrical Systems           | : Done |
| 4. Verified the all Programming          | : Done |

For Sigma Medical And Diagnostic Services

Technical Services Department

Name : PIYUSH SINGH

Designation : SR. Sales & Application

Date : 07-10-2021





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Performance Qualification for Semi Automated Bio-Chemistry Analyser BD-100 ,  
21070300021

## Calibration Parameters

Checked and found all the control [parameters to be with in the acceptable CV limits and in range.

Checked and found all controls to be within The acceptable SD.

## System Certification:

Study data has determined that the system described in this document either meets thenecessary criteria outlined inthis Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

The system is ready for Specific Usage.

## Protocol Performed By:

Name : PIYUSH SINGH

Designation :Application



## PERFORMANCE QUALIFICATION DONE BY

Name : PIYUSH SINGH

Designation

: Application





# Sigma Medicals And Diagnostic Services

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**Performance Qualification:-**

**Instrument Name - BD-100**

**Serial No- 21070300021**

**ATTACHMENT:-**

Attachment No	Documents Title	Page No	Checked By
1	Start Up Result	1	PASSED
2	Q.C. Report	1 NO EACH	PASSED
3	Sample Repeatability Report	5 NO	PASSED

**Checked By:-**

**Verified By:-**



# Sigma Medicals And Diagnostic Services

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**Installation Qualification for Semi Automated Bio-Chemistry Analyser BD-100 Sr. No:- SS-21070300021**

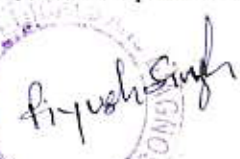
Customer Name : VEDANTA HOSPITAL  
Address : Lakshirampur, AZAMGARH – U.P.  
  
Contact Person : Mr. SHEKHAR YADAV  
Instrument Model : BD- 100  
Serial No. : 21070300021  
Date Of installation : 07-10-2021

The instrument was installed And was found to be working satisfactory. Preliminary Customer Training was provided And standardization of the parameters Were done. The results were found to be within the expected range and system found to be working satisfactorily.

For Sigma Medical And Diagnostic Services

Customer: Vedanta Hospital, lakshiram  
Azamgarh

. Technical Services Department

Name : Piyush Singh  
Designation : Sr. Sales & Aplication  
Signature : 

Contact Person : Mr. Shekhar Yadav  
Designation : Lab Incharge  
Signature :





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**Installation Qualification for Semi Auto Bio-Chemistry Analyser BD-100 Sr. No:- SS-21070300021**

Customer Name : **Vedanta Hospital**

Address : **Bilariaganj Road Lakshirampur azamgarh – U.P.**

Instrument Name : **BD-100**

Serial No : **21070300021**

**Initial Inspection of the unit carried out and the details are as follows:**

**System Condition Report:**

Found the system to have been delivered in satisfactory condition and no external physical damaged observed on the same, Package was kept in good Condition as per the directional indicators like not tilt, indicating the system has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

**Found all the required accessories as required.**

**Intallation Procedure And Checklist Attached for the records.**





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## External Requirement for Installation:

1. Input voltage of 220V-240V/50Hz or 60 Hz.
2. Recommended operating Temperature is 15-30 degree Celsius, with in Relative Humidity 30-85% and Atmospheric pressure 70-106kPa.

Installation Qualification for Semi Automated Bio-Chemistry Analyser Sr. No:- SS-21070300021

Carried out all the installation procedures as per the installation procedure and checklists.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Handover the Instrument for operatos Training And Qualifications

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Technical Services Department

Name : Piyush Singh

Designation : Sr. Sales & Application





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Installation Qualification for Semi Automated Bio-Chemistry Analyser BD-100 Sr. No:- SS-21070300021

This is to certify that the instrument BD-100 Sr. No:- 21070300021 is successfully installed and commissioned at Vedanta Hospital Azamgarh U.P.- and the Installation Protocol/ checklist has been Successfully completed for the above Instrument.

Date of Installation : 07-10-2021

For Sigma Medical and Diagnostic Services

Technical Services Department

Name : Piyush Singh

Designation : Sr. Sales & Application





# Sigma Medicals And Diagnostic Services

## Calibration Certificate, Semi Automatic BioChemistry Analyzer

Name	BD- 100 ( SEMIAUTO BIOCHEMISTRY ANALYZER)
Hospital	VEDANTA HOSPITAL , BILARIAGANJ ROAD AZAMGARH U.P.
Date	07 Oct 2021

This is certify that BD-100 (SEMIAUTO BIOCHEMISTRY ANALYZER) have calibrated & produced following data..

### Action Details:-

- AD VALUE - ( 49200 To 51550 ) Limits – 35000 to 55000
- OFFSET VALUE- ( 34 To 126 ) Limits- 0.0 to 4000
- Water Blank Abs - 0.005 Limits- < 0.01
- Temp Value - < 5% Variation Limits - < 5%

Instrument identification				QC Passed	
Serial no.	21070300021	Date of Calibration	07.10.2021	Yes	Yes
Model	BD-100	Due Date of Calibration	06.10.2022	Yes	Yes

After calibration Q.C. Test for all level passed successfully.

Test results is coming ok	✓	Remarks	Done
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Service Engineer

*Ajay Singh*  
07/10/2021