



Mindray BS-240

Automated Clinical Chemistry Analyzer



INSTALLATION QUALIFICATION

INSTRUCTIONS:

1. This document is to be completed at time the system in unpacked and setup for operation.
2. An authorized Avantor representative will checkout each module and verifies the alignment.
3. All deviations from normal specification to include any problems with installation will be noted in the comments section.
4. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by Mindray.

INSTALLATION QUALIFICATION PROTOCOL:

This Installation Qualification protocol will be performed on the Instrument installed at,
PRO BIOTIC DIAGNOSTICS PVT.LTD.
Add- 3rd Floor, C-4/206, Sector 6 Rd, Pocket-4, Sector 6, New Delhi -110085

This protocol will define the documentation that will be used to evaluate the instrument documented in accordance with manufacture's specifications and identified use.

Installation checks will be performed to verify that the instrumentation has been installed with proper connections and utilities.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated & appropriate course of action will be determined.

IQ/OQ/PQ -BS 240



Operational Qualification Notes:

PERFORMANCE QUALIFICATION

SYSTEM CERTIFICATION:

Study data has determined that the system described in this document meets all criteria outlined in this Performance 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: AVIENCE BIOMEDICAL

MR RAHUL PAL
SR Service Engineer-
Technical IVD-
Automation Delhi-
110058

Customer Authorization:

Ms Jiya Makkar

MS-JIYA MAKKAR

LAB INCHARGE

PRO BIOTIC DIAGNOSTICS PVT.LTD.

ADD- Add- 3rd Floor, C-4/206,
Sector 6 Rd, Pocket-4, Sector 6,
New Delhi -110085

Authorized Service Engineer's Signature



Date: 18/12/2023

Customer's Signature

Ms Jiya Makkar

Date: 18/12/2023

INSTALLATION QUALIFICATION

SYSTEM CERTIFICATION:

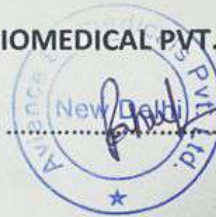
Study data has determined that the system described in this document meets all criteria outlined in this Installation. Qualification protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any have been addressed. The system is ready for specified usage.

Protocol performed by: **AVIENCE BIOMEDICAL Representative**

Mr. RAHUL PAL
Customer Service Engineer
IVD-Automation

AVIENCE BIOMEDICAL PVT.TLD. DELHI-110058

Signature:



Customer Authorization:

MS-JIYA MAKKAR
LAB INCHARGE
PRO BIOTIC DIAGNOSTICS PVT.LTD.

ADD- Add- 3rd Floor, C-4/206, Sector 6 Rd,Pocket-4, Sector 6, New Delhi -110085

Signature:

CERTIFICATION OF INSTALLATION – REPORT

INSTRUMENT NAME: BS 240

SERIAL NUMBER: YX 35007115

CUSTOMER NAME & ADDRESS: : MS-JIYA MAKKAR

LAB INCHARGE

PRO BIOTIC DIAGNOSTICS PVT.LTD.

ADD- Add- 3rd Floor, C-4/206, Sector 6 Rd,Pocket-4, Sector 6, New Delhi -110085

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

Authorized Engineer,

Mr. RAHUL PAL

Customer Service Engineer

IVD-Automation

AVIENCE BIOMEDICAL PVT.TLD. DELHI-110058

Signature



Note: Installation Service Report Should be attached with this manual for Documentation.

IQ/OQ/PQ -BS 240

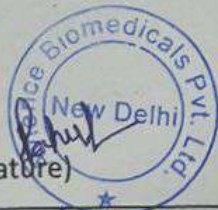
INSTALLATION VERIFICATION REPORT

This is to certify that the following checks mentioned in the installation verification protocol have been performed and found to be satisfactory.

1. Pre-Installation Check	Remark
A) Carton arrival	Checked
B) Spare and accessibility	Checked & Cleared
C) Electrical input	Checked & Passed
D) Ambient temperature and Humidity	Passed
E) Ventilation	Passed
F) Drainage	Checked
2. Unpacking & Console Installation	Passed
3. Electrical Cables Installation	Checked & Passed
4. Unpacking & Installation of the Analytical Unit	Passed
5. Setting up the analyzing unit	Success
6. Alignment Verification	Success

Mr. RAHUL PAL

(Signature)



MS -JIYA MAKKAR

(Signature)


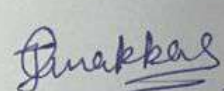
Jiyya Makkar

18/12/2023

OPERATIONAL QUALIFICATION – SYSTEM VERIFICATION REPORT

This is to certify that the following checks mentioned in the operational verification protocol have been performed and found to be satisfactory.

<u>OPERATIONAL QUALIFICATION PROTOCOL</u>	<u>REMARKS</u>
1] CHECKING THE ANALYTICAL UNIT	
A] SOFTWARE BOOTING & INITIALIZATION	Success
B] BASIC SYSTEM CHECKS & VERIFICATION	Verified
2] IMPORTING & CALIBRATING THE CHEMISTRIES	Success
3] RUNNING CONTROLS	Success
4] TRAINING THE OPERATORS	Completed

Mr. RAHUL PAL  (Signature)	MS JIYA MAKKAR  (Signature)
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OPERATIONAL QUALIFICATION PROCEDURES

The Operational Qualification procedure specifies the methodology for the installation of the specified system after successful Installation qualification. Successful completion of the specified protocols and is ready for operation and subsequent performance analysis.

OQ PROCEDURES:

1. System software loading.
2. System Booting and Initialization
3. Basic System Checks.
4. Importing Chemistries & Calibrating Chemistries.
5. Running Controls.
6. Operators Training Schedule.

References:

1. Operation Manual –BS 240
2. Service Manual – BS 240

Operational Qualification Notes:



Installation Qualification Notes & Attachments:

OPERATIONAL QUALIFICATION

SYSTEM CERTIFICATION:

Study date has determined that the system described in this document either meets all criteria outlined in this Operational Qualification protocol. All exceptional conditions if any have been addressed. The system is ready for specified usage.

Protocol performed by:

AVIENCE BIOMEDICAL REPRESENTATIVE

MR –RAHUL PAL

Customer Service Executive IVD-Automation

DELHI, -110058

CUSTOMER AUTHORIZATION:-

MS-JIYA MAKKAR

LAB INCHARGE

PRO BIOTIC DIAGNOSTICS PVT.LTD.

**ADD- Add- 3rd Floor, C-4/206,
Sector 6 Rd,Pocket-4, Sector 6,
New Delhi -110085**

Authorized Engineer's Signature



Date:

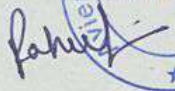

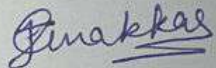
Customer's Signature

A handwritten signature in blue ink, appearing to read "Jiya Makkar", written over a horizontal line.

Date:

PERFORMANCE QUALIFICATION VERIFICATION REPORT

This is to certify that the following checks mentioned in the performance verification protocol have been performed and found to be satisfactory.

MR :RAHUL PAL  	MS JIYA MAKKAR 
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PERFORMANCE ANALYSIS

The following performance protocols have been carried out in **BS -240**, the fully automated clinical chemistry analyzer bearing the serial number : **YX 35007115** installed at GI Laboratory Services

1. With-in run precision
2. Between-run precision
3. Accuracy
4. Linearity

IQ/OQ/PQ -BS 240