

### Calibration Certificate

Following voltages have been checked & adjusted on DiaSys Respons 910 (Sl. No. 121701) at Balajee Diagnostics, Near Bohar Police Station Ring Road Dubagga Lucknow 226003

**Calibration Report:**

System voltages are in the specified range –Checked by Digital Multimeter are as below:

S.No.	Module	Observed Value	Acceptable Range
1	Power supply board o/p	+24.1 VDC	+24.0 +/- 0.5 VDC
		+05.1 VDC	+05.0 +/- 0.2 VDC
2	Lamp voltage	+11.9 VDC	12.0 +/- 0.5 VDC

System Temperature values are in the specified range –Checked by Digital Thermometer are as below:

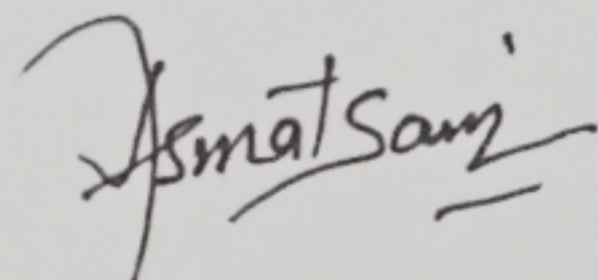
S.No.	Module	Observed Value	Acceptable Range
1	Reaction Disk Temp	37.0 C	37.0 C +/- 0.2 C

Photometer Adjustment Values are within range as recommended:

S.No.	Module	Observed Value	Acceptable Range
1	ADC Count for all Wavelengths	19,700 to 20,200	19,500 to 20,500

- All other mechanisms have been checked through field service program & Software, found OK.
- Performed calibration for End Point, Kinetic & Fixed Time Kinetic. Run control & sample. Results were satisfactory.
- Next Calibration will be performed on 10<sup>th</sup> July 2024.

For DiaSys Diagnostics India Pvt. Ltd.



**ASMAT SAMI**  
Authorized signatory



Date: 10<sup>th</sup> July 2023



**DiaSys Diagnostics India Private Limited**  
229, FIA, Patparganj Industrial Area,  
Ground and First Floor,  
New Delhi -110092



**INSTALLATION QUALIFICATION**

Instrument Name : **Respons 910 AUTO CHEMISTRY ANALYZER**

Laboratory/Hospital : Balajee Diagnostics  
Near Bohar Police Station  
Ring Road Dubagga,  
Lucknow 226003

Supported By : DiaSys Diagnostics India Pvt Ltd.  
A-821, South Central Road  
MIDC Industrial Area, Mahape  
Navi Mumbai – 400 701  
Tel.: +91-022-33714308

**Registered Office**  
Plot No. A-821, T.T.C. Industrial Area,  
MIDC, Mahape, Navi Mumbai - 400710  
Maharashtra, India

**DiaSys Diagnostics India Private Limited**  
The Specialists for diagnostic system solutions  
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CIN : U74999MH2013PTC248371  
Email : info@diasys.in  
Tel. No. : +91-022-71068331  
Toll Free : 1800 120 1447  
www.diasys-diagnostics.com



## INSTALLATION QUALIFICATION PROTOCOL

### This Installation Qualification Protocol Is Performed On the Installation Located At:-

**Balajee Diagnostics**  
Near Bohar Police Station  
Ring Road Dubagga, Lucknow 226003

The purpose of this installation qualification protocol is to define the qualifications and the acceptance standard in order to verify that instrument installation, normal operation and function of the respons910 auto chemistry analyser in the laboratory. The satisfactory outcome of this procedure assures that the system functions according to the parameters.

- ❖ DiaSys Diagnostics India Pvt. Ltd. is responsible for installation of respons910 auto chemistry analyser at **Balajee Diagnostic**, Biochemistry department per the attached protocol.
- ❖ An authorized DiaSys Diagnostics India Pvt. Ltd. representative will physically check the system and proceed for the installation.
- ❖ This installation protocol will be followed as specified by the manufacturer. Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.
- ❖ On completion of the Installation all the necessary documents of the System checks will be used to evaluate the instrument installation in accordance with the manufacturer's protocol and intended use.
- ❖ Successful completion of this protocol will verify that this instrument has been installed in accordance with the intended usage.
- ❖ Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated and appropriate course of action will be determined.
- ❖ The results of these installation activities are the base for the subsequent Operational & Performance Qualification Protocol.

### REPORT SIGN OFF:

#### Protocol Prepared By

Designated Company Persons Name: ASMAT SAMI  
Designation: RSM  
Date: 10-07-23



## INSTALLATION QUALIFICATION PROTOCOL

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Ring Road Dubagga, Lucknow 226003

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- ❖ DiaSys Diagnostics India Pvt. Ltd. is responsible for installation of respons910 auto chemistry analyser at **Balajee Diagnostic**, Biochemistry department per the attached protocol.
- ❖ An authorized DiaSys Diagnostics India Pvt. Ltd. representative will physically check the system and proceed for the installation.
- ❖ This installation protocol will be followed as specified by the manufacturer. Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.
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### REPORT SIGN OFF:

#### Protocol Prepared By

Designated Company Persons Name: ASMAT SAMI  
Designation: RSM  
Date: 10-07-23



**Protocol Prepared For**

Hospital / Institution: **Balajee Diagnostics**  
Near Bohar Police Station  
Ring Road Dubagga, Lucknow 226003

**Equipment Information: -**

Equipment Name: Respons 910 Auto Chemistry Analyser  
Model/Type: Bench Top  
Serial No: 121701  
Equipment Installed Location: Clinical Laboratory

**INSTRUMENT INSTALLATION QUALIFICATION PROTOCOL**

Respons 910 Auto-Chemistry Analyser found to be the satisfactory installation condition at biochemistry department with comply the installation requirement based on the below described items.

S. No	Installation Requirement Item	Description	Requirement Qualification	Remark
1.	Power Supply	AC220V, 50Hz Power: 350VA Circuit Breaker: 250V, 20A	Satisfactory	The department fully equipped with online UPS power supply
2.	Grounding Condition	A good grounding condition	Satisfactory	Nil
3.	Discharge Equipment	5m within mainframe Height: below 100mm,	Satisfactory	Nil
4.	Ground	The ground should be level up	Satisfactory	Nil
5.	Temperature and Humidity	Temperature: 15 - 30°C Humidity: 10 - 80%RH	Satisfactory	Nil
6.	Air condition	Air condition	Satisfactory	Nil
7.	Water Supply Equipment	De-Ionised Water	Satisfactory	Nil
8.	Communication Interface	Is there D Type USB Cable	Yes	Nil



**Verify the Pre-installation Checks: -**

If any deficiencies were noted during the pre-installation check, verify they are resolved before installation.

**Check the Supplies: -**

Make sure an adequate supply of reagents, control and calibrator are available at the site.

**Inspect Packing Box: -**

Inspect all boxes for damage. Notify shipper of damages if any.

**Unpack the Analyser: -**

- ❖ Remove the packing material of the Analyser.
- ❖ Place the Instrument on the ground/Table
- ❖ Remove fixing tapes and transportation tapes.
- ❖ Fix sample/ reagents probe.
- ❖ Connect water reservoir tank and waste water tube.
- ❖ Connect the AC Plug to Power Supply Point.
- ❖ Install operation software and communicate operation software with analyser.

**Installation Information: -**

Name of the Instrument: respons910 Auto Chemistry Analyser

Physical Verification of the instrument before installation: Satisfactory

Description of the equipment along with the components: Computer, Keyboard & accessories.

Date of Installation: 22-06-2022

Name of Engineer: MD RIZWAN KHAN

**Installation conclusion: -**

Overall instrument installation requirements found to be satisfied, handed over the instrument for operation & performance qualification.



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**OPERATION QUALIFICATION**

Instrument Name : **Respons 910 AUTO CHEMISTRY ANALYSER**

Laboratory/Hospital : **Balajee Diagnostics**  
**Near Bohar Police Station**  
**Ring Road Dubagga,**  
**Lucknow 226003**

Supported By : **DiaSys Diagnostics India Pvt Ltd.**  
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## OPERATION QUALIFICATION PROTOCOL

### This Operation Qualification Protocol Is Performed on the Installation Located At

**Balajee Diagnostics**

Near Bohar Police Station

Ring Road Dubagga, Lucknow 226003

The purpose of this operation qualification protocol is to define the qualifications and the acceptance standard in order to verify the normal operation and function of the response auto chemistry analyser in the laboratory. The satisfactory outcome of this procedure assures that the system functions according to the parameters.

- ❖ This protocol defines the documentation that will be used to evaluate the instrument and documented in accordance with manufacturer's specifications and intended use.
- ❖ Successful completion of this protocol will verify that the instrumentation identified has been operational in accordance with manufacturer's specifications and intended use.
- ❖ Operational checks will be performed to verify that the instrument operates according to specifications and to record the information/data to demonstrate its functions as expected.
- ❖ Trained knowledgeable personnel from DiaSys Diagnostics India Pvt. Ltd. along with the department personnel will perform qualification studies as mentioned by the manufacturer.
- ❖ Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated and appropriate course of action will be determined.
- ❖ The results of that installation activity are the base for the subsequent of Operational Qualification Protocol.
- ❖ The operational qualification protocol will verify the review of the start-up procedure, Operation processes, instrument routine maintenance, instrument safety handling in the laboratory.



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**REPORT SIGN OFF:**

**Protocol Prepared By**

Designated Company Persons Name: ASMAT SAMI

Designation: RSM

Date: 10-07-2023.

**Protocol Prepared For**

Hospital / Institution: Balajee Diagnostics

Near Bohar Police Station

Ring Road Dubagga,

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**Equipment Information: -**

Equipment Name: Respons 910 Auto Chemistry Analyser

Model/Type: Bench Top

Serial No: 121701

Equipment Installed Location: Clinical Laboratory

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## INSTRUMENT OPERATIONAL QUALIFICATION PROTOCOL

### 1. OPERATION QUALIFICATION PROCEDURES

- Instrument Turn on and Turn off Procedures – To check the instrument normal start up processes while login & switch on the instrument. After turning on the analyser ensure the instrument startup processes & reaction disk temperature optimization.
- Verified system “On-line” and “Off-line” communication link.
- Verified software logon & logoff options between management to operation and vice versa.
- Verified instrument complete “shutdown” and “startup” processes.
- Placed onboard “Cleaner A” & “Cleaner B”.

#### 1.1 Preliminary Operation

- Carry out the user maintenance procedures : yes
- Check the reaction disk temperature : yes
- Carry out Photometer Adjustment checkup : yes
- Carry out Cuvette Scan test : yes
- If necessary, check the probes vertical & horizontal checkup: yes

#### 1.2 Parameter Setup

- Routine parameter setting according to the reagent’s instruction : yes
- Calibration parameter set up : yes
- QC parameter set up : yes

#### 1.3 Reagent Preparation and place reagent disk

- Reagent preparation : Done
- Place the small (S) & large (L) reagents bottle : Use both the bottle
- Check the reagent positions : yes