

Installation Procedure and Checklist Respons-910(DiaSys)

Model : **Respons 910**
Serial Number : 170961
Customer Name : **Modern X-Ray Pathology & Polyclinic**
Address : Vill & Post : Jangipara, Hooghly- 712404, W.B.
City : **Jangipara**
Contact No. : **8145425565**

1. Inspect Shipper for Physical damage then Uncarted
 - a. Physical Damage to Shipper : No
 - b. Accessories as per packing List : Yes

2. Environmental Conditions.
 - a. Air Conditioned Environment Available : Yes
 - b. Room free of Rodents/Insects/ Pests : Yes
 - c. Humidity is less than 80% : Yes

3. Power Requirements.
Uninterrupted Power Supply Available.

- * UPS Rating- 2 KVA
- * Type of batteries- Dry
- * Back Up time- 2 Hours
- * Incoming AC Power- 230 Volts

- * Earth Voltage- 0.2 V



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MAHAPE, Navi Mumbai
Maharastra, India
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4. General Cleanliness Around Side : Acceptable
5. Verified all Instruments Components and Accessories.
6. Installed all Accessories as per the instrument Set-Up Procedure Below :
 - a. Removed all shipping screws from the system.
 - b. Assemble the User Interface Module- CPU, Monitor, Key board & Mouse.
 - c. Checked all cable connections.
 - d. Checked the Electronic Boards are properly plugged in
 - e. Checked the Dispense Angle for probe.
 - f. Installed the Software Version-4.5
7. System Calibration and Inspection.
 - a. Verified All Mechanical configuration Adjustment of the Side.
 - b. Checked the washing of Probe.
 - c. Checked the aspirate/dispense of Syringe.
 - d. Checked the Photometer adjustment.
 - e. Checked the Probe adjustment.
8. Verification of Water Requirement
 - a. Triple deionized Water
 - b. pH of the System water is between 6.0 to 7.0

ASM Signature

Chandan Banerjee

Name Mr Chandan Banerjee

Date 19/09/2017



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Installation Qualifications for Respons-910 (DiaSys)

Carried out all the Steps as well as the necessary Checks and Alignments of all Robotics were done as per Installation Procedure and Checklist.

Performed all due maintenance activities Such as Daily, Monthly Cleaning and Priming, Rinsing System with water.

Handed over the instrument for Operations Training & Qualifications.

For **DiaSys Diagnostics India Pvt. Ltd .**

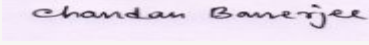
For **Modern X-Ray Pathology & Polyclinic**

Name : Mr Chandan Banerjee

Name :

Designation : Area Service Manager

Designation: Biochemist/Pathologist/Proprietor

Signature : 

Signature :

Date : 19/09/2017

Date : 19/09/2017



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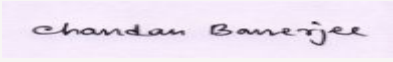
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Installation Certificate

This is to certify that the **Respons-910** (DiaSys) Biochemistry Analyser Instrument **Serial No.: 170961** has been successfully Installed and Commissioned at **Modern X-Ray Pathology & Polyclinic**, Vill & Post : Jangipara, Hooghly-712404, W.B. as per the Installation Procedure & Checklist.

For DiaSys Diagnostics India Pvt.Ltd.	For Modern X-Ray Pathology & Polyclinic
Name : Mr Chandan Banerjee	Name :
Designation : Area Service Manager	Designation: Biochemist/Pathologist/Proprietor
Signature : 	Signature :
Date : 19/09/2017	Date : 19/09/2017



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Operational Qualification for Respons-910 (DiaSys)

With reference to the Installation Procedure and Checklist and the studies carried out in the Laboratory, Respons-910 (DiaSys) meets all criteria outlined for Operational Qualification.

Exceptional conditions, if any, have been addressed.

The Flooring on which the analyser has been placed is level: Yes

Temperature and Humidity

Ambient Temperature Check Found Between 18 to 25 C: Yes

Humidity Found to be < 80 %: Yes

The Analyser is ready for Performance Qualification

Protocol Performed By: For **DiaSys Diagnostics India Pvt. Ltd.**

Signature : *Chandan Banerjee*

Name : Mr Chandan Banerjee

Designation: Area Service Manager



Customer Authorization: For **Modern X-Ray Pathology & Polyclinic**

Signature :

Name :

Designation: Biochemist/Pathologist/Proprietor

Date: 19/09/2017

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Respons-910 (DiaSys) Performance Evaluation

Following Procedure was carried out as part of the Performance Qualification.

1. Calibration of Assay.

Assays calibrated and checked – ALT, Cholesterol, TG, UA, Urea

Checked and found all calibrations be within the acceptable CV limits and in range. (<5%)

2. Internal Quality Control Performance.

DiaSys Biochemistry Control TruLab N Lot No- 25894 Exp- 12-2020

Checked and found Controls be within the acceptable SD.

3. Precision Study

A Within Run Precision for ALT, Chol, TG, UA, Urea assays for 5 replicates was carried out CV % Obtained are within the acceptable limit for the assay (<5%).



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Performance Qualification for Respons-910 (DiaSys)

With reference to the performance evaluation and studies carried out in the Laboratory have determined that analyser meets all performance criteria and has passed performance

Qualification.

The System is ready for specific usage.

Protocol performed by : For **Diasys Diagnostics India Pvt. Ltd.**

Signature :

Chandan Banerjee



Name : Mr Chandan Banerjee

Designation: Area Service Manager

Customer Authorization:

For **Modern X-Ray Pathology & Polyclinic**

Signature :

Name :

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CALIBRATION CERTIFICATE

Date: 19-09-2021

This is to Certify that the **Mechanical, Electronics and Software Calibration** has been done on **19th September, 2021** for **Respons 910 (Fully Automatic Analyser)** having serial (**Sr. No. 170961**) carried out in **Modern X-Ray Pathology & Polyclinic**, Vill & Post : Jangipara, Hooghly- 712404, W.B., India

Following Voltage have been checked & adjusted
Respons 910:-

DC Power Supply:

Target Volt	Range	Actual Volt
+24 VDC	+/- 1.0 VDC	24.12 VDC

- Checked the temperature of Incubation Bath found ok (37 Degree Celsius).
 - All other mechanism have been checked through software and found OK.
 - Checked Light Quantity for all the wavelengths and found within the Range (20000-20400).
 - Blank ADC values of all Reaction Cuvettes found within range.
 - Performed calibration for End Point, Kinetics & Fixed Point Kinetics parameters (TG, CHOL, ALT, UA, Urea etc.).
 - Run Controls and results were Satisfactory.
- Next Calibration will be performed on **18-09-2022**

For: DiaSys Diagnostics India Pvt. Ltd.

Chandan Banerjee



Chandan Banerjee

Dy-Regional Manager-Service (East)

Date: 19-09-2021

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