



# Nirmal Medical Systems

(AN ISO 9001 : 2015 & ISO 13485 : 2013 COMPANY)

MEDICAL EQUIPMENT & CONSUMABLES

Date 08-06-2023

## Installation / Qualification Report

Customer Name	Mr. Anuj Kalra,	
Address	Jain Tower, Opp. Bus Stand, Hansi-125033, Haryana	
Equipment	Electrolyte Analyzer	
Model	NuLYTE SMART	
Serial No.	NLS-4087	
Supplier Name	Nirmal Medical Systems, 521, Aggarwal Prestige Mall, Plot No.2, Road No.44, Community Centre, Pitampura, Delhi-110034	
Installation Date	08-06-2023	
Power Supply	220 V	O.K
Daily Maintenance	O.K	
Calibration Report	O.K	

### Basic Conditions:

Power Input      Ground-Neutral                      02 to 05 V  
                         Neutral -Phase                      180 to 240 V  
                         Phase-Ground                              180 to 240 V  
UPS                      3KVA pure sine wave output with 180 to 240 V

Cont..2..

521, Aggarwal Prestige Mall, Road No.44, Community Centre, Pitampura, Delhi-110034 Ph. : 011-45111923

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GSTIN : 07ADJPA2189A1Z0



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## **Location Specifications:**

1. Keep Away from or shielded from any centrifuges, X-Ray sources, Ultrasound, Nuclear and Magnetic Equipment.
2. Also keep away from direct sunlight, A.C. vent, heat vent and other heat producing equipments
3. Stable Level, Non-porous and Non-absorbing work surface.
4. 15°-32° C, Room Temperature (60°-90°F) < 85% Humidity

The location for Installation and the Equipment were checked as per specifications and the equipment was installed.

**For Nirmal Medical Systems,**

**(Authorized Signatory)**



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## OPERATION QUALIFICATION

This is for operational verification of NuLYTE SMART ELCTROLYTE ANALYZER at Mr. Anuj Kalra, Jain Tower, Opp. Bus Stand, Hansi-125033, Haryana

Purchase Order Date 06/06/2023

Equipment Received as per order Yes

Equipment Accessories O.K.

Equipment Safety and Control Provisions O.K.

This instrument operates within specified set of parameters under normal operational condition.

Equipment was checked and found to be operating satisfactorily as per the specifications (Refer Operator Manual)

All acceptance criteria are passed in the operational qualification.

For Nirmal Medical Systems,

Authorized Signatory



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## PERFORMANCE QUALIFICATION

The performance of the equipment was checked for the following:

Na<sup>+</sup>/K<sup>+</sup>/Cl<sup>-</sup> Electrode voltage verification  
Calibration Time verification

The results are well within the acceptable range.

Operational Status - Working

Equipment has been validated to perform desired parameters.

Performance for parameters (Na<sup>+</sup>/K<sup>+</sup>/Cl<sup>-</sup>) verified with commercial control.

Run Level-2, control and results are within acceptable range.

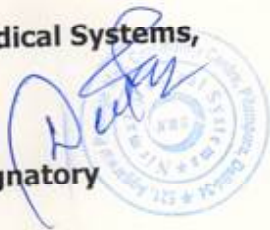
Calibration Date 08/06/2023

Calibration Validity One Year

Next Calibration due 07/06/2024

For Nirmal Medical Systems,

Authorized Signatory





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Date: 08-06-2023

## CALIBRATION CERTIFICATE

TO WHOMSOEVER IT MAY CONCERN

We hereby certify that the Electrolyte Analyzer Model NuLYTE SMART, which belong to Mr. Anuj Kalra, Jain Tower, Opp. Bus Stand, Hansi-125033, Haryana and is installed in Laboratory is Standardized and tested on 11<sup>th</sup> Sep. 2023.

Measured mV Values are:-

S.N.	Electrode	Calibration Slope (mV)	Calibration Ranges (mV)
01	Na <sup>+</sup>	62.15 mV/dec	35-100 mV/dec
02	K <sup>+</sup>	68.78 mV/dec	35-100 mV/dec
03	Cl <sup>-</sup>	39.56 mV/dec	30-100 mV/dec

QC Measurement Lot No : UQC2210A, Exp SEP 2024)

S.N	Parameter	Expected Values (mmol/L)	
		LEVEL 2	
01	Na <sup>+</sup>	136-150	
02	K <sup>+</sup>	3.72-4.72	
03	Cl <sup>-</sup>	93-107	

Measured Values are:-

S.N	Parameter	Measured Values (mmol/L)	
		LEVEL 2	
01	Na <sup>+</sup>	143.4	
02	K <sup>+</sup>	4.22	
03	Cl <sup>-</sup>	100	

Successful completion of the preceding activities and checks indicates that this instrument has been satisfactorily installed. The instrument has passed the Installation Qualification procedure. This Calibration Certificate is valid for one year. Next Calibration is due on **07<sup>th</sup> June. 2024.**

For Nirmal Medical Systems,

(Authorized Signatory)