

**CERTIFICATE OF CALIBRATION FOR Mindray BS -240 Clinical Chemistry Analyzer**

Issued To: Trust -In Diagnostic-Horamavu

Certificate No: UBM/CAL/612

Location /Dept.: Laboratory

Model:BS-240

Manufacturer : Mindray

Serial No : YX-23005235

Calibration Standard used in house Performance of standards /controls using  
accepted test Proceeds.

Sl. No	Description	Test Pass/Fail	Remarks
1	<u>Mindray -BS 240 Clinical Chemistry Analyzer</u>	Pass	Working Good

Calibration Passed: Yes No: 

Calibration Date: 01-06-2024

Calibration Due Date: 31-12-2024

The above mentioned instrument has been calibrated using standards manufactures recommended Protocols, using equipment's having traceability to National Standards. Devices for which there are no National/International Standards calibrations standards are measured against in-house performance standards using accepted test procedures.

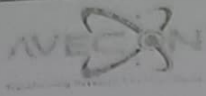
Calibration Done by

Mr. Shivakumar

Approved By

Ms. Chaithra





**AVECON HEALTHCARE PRIVATE  
LIMITED**

**OPERATIONAL QUALIFICATION (OQ) FOR  
ANALYSER ELECTROLYTE**

**Instrument Name:**

**Electrolyte Analyzer**

**Model No:**

**MaxLYTE**

# OPERATIONAL QUALIFICATION

**for**

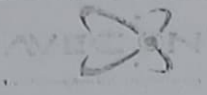
**MaxLYTE**

**Electrolyte Analyzer**

Prepared by:

**AVECON HEALTHCARE PRIVATE LIMITED**

Plot No. 338, Sector-2, Industrial Growth Centre Saha, Ambala,  
Haryana (India)- 133104

	<b>AVECON HEALTHCARE PRIVATE LIMITED</b>		
	OPERATIONAL QUALIFICATION (OQ) FOR ANALYSER ELECTROLYTE		
<b>Instrument Name:</b>	Electrolyte Analyzer	<b>Model No:</b>	MaxLYTE

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**AVECON HEALTHCARE PRIVATE LIMITED****OPERATIONAL QUALIFICATION (OQ) FOR ANALYSER ELECTROLYTE**

<b>Instrument Name:</b>	Electrolyte Analyzer	<b>Model No:</b>	MaxLYTE
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**1.0 Objective**

The aim of this OQ is to certify that the operational qualification of electrolyte analyzer according to the requirement.

**2.0 Scope:**

This Operational Qualification is intended to cover the requirements to be met by the system during the operation of electrolyte analyzers.

**3.0 RESPONSIBILITIES**

- M/s. Avecon Healthcare Private Limited.
- To prepare & review the operational Qualification protocol.
- To perform operational checks as per protocol.
- To execute OQ Documentation.
- To comply acceptance criteria.

**3.1 CLIENT COMPANY (Trust-In Hospital)**

- To provide site clearance, support and required Utilities for OQ execution.
- To participate in the execution of the Operational Qualification.
- To review the OQ documentation.

**4.0 Safety Precautions**

- 4.1 Protect from direct sunlight.

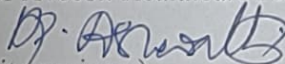
**5.0 Instructions**


- 5.1 These Instructions for Use contain vital warning and safety information.
- 5.2 This instrument is intended to be used only for the specialized purpose described in the instructions.
- 5.3 The instrument may be operated only by persons whose qualifications enable them to comply with the safety measures that are necessary during operation of the instrument.
- 5.4 Instrument repairs are to be performed only by the manufacturer or qualified service personnel.
- 5.5 The quality control requirements must be completed at least once daily for safety reasons.

**6.0 Operational Checks:**

Description	Requirement	Observation
Power supply	Self-check	OK
Electronics	Self-check	OK
Reagent pack	Self-check	OK
Hardware	Self-check	OK
Flow path	Self-check	OK

For Avecon Healthcare Private Limited

  
(Site engineer)

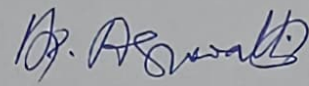
		<b>AVECON HEALTHCARE PRIVATE LIMITED</b>	
		OPERATIONAL QUALIFICATION (OQ) FOR ANALYSER ELECTROLYTE	
Instrument Name:	Electrolyte Analyzer	Model No:	MaxLYTE

### 7.0 Certification of Operational Qualification

Instrument name : MaxLYTE  
 Serial number : EL23110007  
 Customer name : Trust-In Hospital  
 Address : No.12/1, MV Appa Complex, Horamavu Road, Horamavu  
 Bengalur-560043

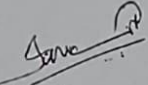
The undersigned performers certify that the operational qualification protocol has been successfully completed for the instrument stated above.

#### Site Engineer

Signature :   
 Name : Ashwath H P  
 Designation : RSM  
 Company : Avecon Healthcare Private Limited



#### Quality Manager (client)

Signature :   
 Name : Mrs. Jeena  
 Designation : Lab In-charge  
 Company : Trust-In Hospital



**AVECON HEALTHCARE PRIVATE LIMITED**

**INSTALLATION QUALIFICATION(IQ) FOR ELECTROLYTE  
ANALYZER**

**Instrument Name:**

Electrolyte Analyzer

**Model No:**

MaxLYTE

# INSTALLATION QUALIFICATION

**For**

**MaxLYTE**

**Electrolyte Analyzer**

Prepared by:

**AVECON HEALTHCARE PRIVATE LIMITED**

Plot No. 338, Sector-2, Industrial Growth Centre Saha, Ambala,  
Haryana (India)- 133104

**AVECON HEALTHCARE PRIVATE LIMITED****INSTALLATION QUALIFICATION(IQ) FOR ELECTROLYTE ANALYZER****Instrument Name:** Electrolyte Analyzer      **Model No:** MaxLYTE**Table of Content**

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## AVECON HEALTHCARE PRIVATE LIMITED

### INSTALLATION QUALIFICATION(IQ) FOR ELECTROLYTE ANALYZER

<b>Instrument Name:</b>	Electrolyte Analyzer	<b>Model No:</b>	MaxLYTE
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#### 1.0 Objective

The aim of this IQ is to certify that the installation qualification of electrolyte analyzer according to the requirement.

#### 2.0 Scope:

This Installation Qualification is intended to cover the requirements to be met by the system during the installation of electrolyte analyzers.

#### 3.0 Responsibilities

##### 3.1 M/s. Avecon Healthcare Private Limited.

- To prepare & review the Installation Qualification protocol.
- To perform Installation checks as per protocol.
- To execute IQ Documentation.
- To comply acceptance criteria.

##### 3.2 CLIENT COMPANY (Trust- In Hospital)

- To provide site clearance, support and required Utilities for IQ execution.
- To participate in the execution of the Installation Qualification.
- To review the IQ documentation.

#### 4.0 Safety Precautions

- 4.1 Protect from direct sunlight.

#### 5.0 Instructions

- 5.1 These Instructions for Use contain vital warning and safety information.
- 5.2 This instrument is intended to be used only for the specialized purpose described in the instructions.
- 5.3 The instrument may be operated only by persons whose qualifications enable them to comply with the safety measures that are necessary during operation of the instrument.
- 5.4 Instrument repairs are to be performed only by the manufacturer or qualified service personnel.
- 5.5 The quality control requirements must be completed at least once daily for safety reasons.



**AVECON HEALTHCARE PRIVATE LIMITED****INSTALLATION QUALIFICATION(IQ) FOR ELECTROLYTE ANALYZER**

<b>Instrument Name:</b>	Electrolyte Analyzer	<b>Model No:</b>	MaxLYTE
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**6.0 Installation requirements for the instrument:**

Sr. No.	Requirements	Acceptable range	Observation	Verified by (Sign & Date)
1	Input voltage	220+10vac	228	Kp. Agarwal 11/04/2024
2	Line frequency	50/60 hz	50 hz	Kp. Agarwal 11/04/2024
3	Ambient temperature	18-30 °C	23	Kp. Agarwal 11/04/2024

**7.0 Installation Checks:**

Sr. No.	Item description	Observation	Verified by (Sign & Date)
1	Software version	V1.0.6	Kp. Agarwal 11/04/2024
2	Reagent pack	LOT No. B643072	Kp. Agarwal 11/04/2024
3	Quality control	LOT No. B632302	Kp. Agarwal 11/04/2024

**AVECON HEALTHCARE PRIVATE LIMITED****INSTALLATION QUALIFICATION(IQ) FOR ELECTROLYTE ANALYZER**

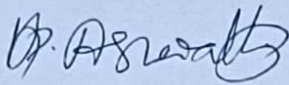
<b>Instrument Name:</b>	Electrolyte Analyzer	<b>Model No:</b>	MaxLYTE
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**8.0 Certification of Installation**

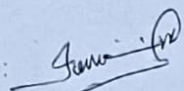
Instrument name : MaxLYTE  
Serial number : EL23110007  
Customer name : Trust-In Hospital  
Address : 12/1, MV Appa Complex, Horamavu Main Road, Horamavu  
Bengaluru-560043


The undersigned performers certify that the installation qualification protocol has been successfully completed for the instrument stated above.

Site Engineer

Signature :   
Name : Ashwath HP  
Designation : RSM  
Company : Avecon Healthcare Private Limited

Quality Manager (client)

Signature :   
Name : Mrs. Jeena  
Designation : Lab In-charge  
Company : Trust-In Hospital

	AVECON HEALTHCARE PRIVATE LIMITED		
	PERFORMANCE QUALIFICATION (PQ) FOR ELECTROLYTE ANALYZER		
Instrument Name:	Electrolyte Analyzer	Model No:	MaxLYTE

# PERFORMANCE QUALIFICATION


MaxLYTE

Electrolyte Analyzer

Prepared by:

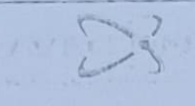
AVECON HEALTHCARE PRIVATE LIMITED

Plot No. 338, Sector-2, Industrial Growth Centre Saha, Ambala,  
Haryana (India)- 133104

	<b>AVECON HEALTHCARE PRIVATE LIMITED</b>		
	<b>PERFORMANCE QUALIFICATION(PQ) FOR ELECTROLYTE ANALYZER</b>		
<b>Instrument Name:</b>	Electrolyte Analyzer	<b>Model No:</b>	MaxLYTE

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	<b>AVECON HEALTHCARE PRIVATE LIMITED</b>		
	PERFORMANCE QUALIFICATION(PQ) FOR ELECTROLYTE ANALYZER		
<b>Instrument Name:</b>	Electrolyte Analyzer	<b>Model No:</b>	MaxLYTE

### 1.0 Objective

The aim of this PQ is to certify that the Performance qualification of electrolyte analyzer according to the requirement.

### 2.0 Scope:

This Performance Qualification is intended to cover the requirements to be met by the system during the Performance of electrolyte analyzers.

### 3.0 RESPONSIBILITIES

#### 3.1 M/s. Avecon Healthcare Private Limited.

- To prepare & review the Performance Qualification protocol.
- To perform Performance checks as per protocol.
- To execute PQ Documentation.
- To comply acceptance criteria.

#### 3.2 CLIENT COMPANY (Trust-In Hospital)


- To provide site clearance, support and required Utilities for PQ execution.
- To participate in the execution of the Performance Qualification.
- To review the PQ documentation.

### 4.0 Safety Precautions

- 4.1 Protect from direct sunlight.

### 5.0 Instructions

- 5.1 These Instructions for Use contain vital warning and safety information.
- 5.2 This instrument is intended to be used only for the specialized purpose described in the instructions.
- 5.3 The instrument may be operated only by persons whose qualifications enable them to comply with the safety measures that are necessary during operation of the instrument.
- 5.4 Instrument repairs are to be performed only by the manufacturer or qualified service personnel.
- 5.5 The quality control requirements must be completed at least once daily for safety reasons.

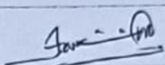
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Instrument Name:	Electrolyte Analyzer	Model No:	MaxLYTE

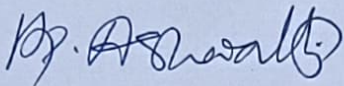
**6.0 Training certificate**

Customer                      Trust-In Hospital  
 Department                  Laboratory  
 Sr. No.                          EL23110007  
 Training date                 11-04-2024

**FOLLOWING PERSONS ARE TRAINED FOR**

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> OPERATIONS       | <input checked="" type="checkbox"/> MAINTENANCE           |
| <input checked="" type="checkbox"/> TROUBLE SHOOTING | <input checked="" type="checkbox"/> QC CONTROLS MAINTANCE |

Sr.no	NAME	DEPARTMENT	DESIGNATION	SIGNATURE
01	Jeena	Laboratory	Lab In-charge	

For Avecon Healthcare Private Limited.  
  
 (Site engineer)

	<b>AVECON HEALTHCARE PRIVATE LIMITED</b>		
	PERFORMANCE QUALIFICATION(PQ) FOR ELECTROLYTE ANALYZER		
Instrument Name:	Electrolyte Analyzer	Model No:	MaxLYTE

### 7.0 Performance analysis

The performance of the system has been verified by the following process


Three replicates of the control level 1 & level 2 & level 3 have been run and the statistical analysis of the data is performed. The results should be within control range with following precision limits.

#### 7.1 Precision with Level-1

Results / Item Times	Na <sup>+</sup>	K <sup>+</sup>	Cl <sup>-</sup>	iCa
	1	119	1.97	75
2	117	1.98	73	1.55
3	116	1.94	76	1.65
4	120	2.01	77	1.60
5	118	2.1	74	1.70
$\bar{x}$ (Mean)	118	2	75	1.6
SD	1.58	0.061	1.58	0.079
CV%	1.33	3.06	2.10	4.94

#### 7.2 Precision with Level-2

Results / Item Times	Na <sup>+</sup>	K <sup>+</sup>	Cl <sup>-</sup>	iCa
	1	138	3.9	99
2	142	3.7	97	1.14
3	142	3.7	98	1.16
4	140	3.9	97	1.15
5	142	3.8	99	1.14
$\bar{x}$ (Mean)	140	3.8	98	1.15
SD	1.78	0.1	1	0.01
CV%	1.27	2.63	1.02	0.86

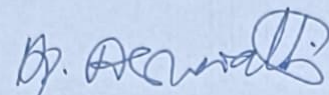
	AVECON HEALTHCARE PRIVATE LIMITED		
	PERFORMANCE QUALIFICATION(PQ) FOR ELECTROLYTE ANALYZER		
Instrument Name:	Electrolyte Analyzer	Model No:	MaxLYTE

### 7.3 Precision with Level-3

Results / Item	Na <sup>+</sup>	K <sup>+</sup>	Cl <sup>-</sup>	iCa
1	156	5.74	118	0.71
2	157	5.76	119	0.71
3	158	5.74	117	0.70
4	158	5.75	119	0.70
5	156	5.76	117	0.72
$\bar{x}$ (Mean)	157	5.75	118	0.71
SD	1	0.009	1	0.008
CV%	0.63	0.17	0.84	1.18

Engineer

Signature

: 

Name

: Ashwath H P

Designation

: RSM

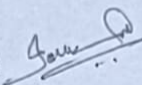
Company

: Avecon Healthcare Private Limited.



Quality manager (client)

Signature

: 

Name

: Mrs. Jeena

Designation

: Lab In-charge

Customer Name

: Trust-In Hospital