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	<b>INSTALLATION / OPERATIONAL/PERFORMANCE QUALIFICATION WITH CALIBRATION &amp; TRAINING CERTIFICATE</b>		
Document No.:	IQ/OQ/PQ/ LTB/ GASTAT	Revision No.:	01
Equipment Name:	GASTAT 700 Blood Gas Analyzer		

**INSTALLATION QUALIFICATION,  
 OPERATIONAL QUALIFICATION,  
 PERFORMANCE QUALIFICATION  
 &  
 CALIBRATION CERTIFICATE**

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## VALIDATION REPORT

- Equipment Name : Arterial Blood Gas Analyzer
- Equipment Make : Techno Medica, Japan
- Equipment Model No. : GASTAT-720
- Equipment Serial No. : 01067802
- Supplier : LifeTech Biomedical.


### LifeTech Biomedical

**Address:** 604, Suchita Business Park, Nr. Patel Chowk,  
Pant nagar, Ghatkopar (E), Mumbai 400 075.

Contact Number: 9321318858

Contact Person: Sagar Satpute.

Email : [sagarsatpute@vitanmedical.org](mailto:sagarsatpute@vitanmedical.org), [info@vitanmedical.org](mailto:info@vitanmedical.org)

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**I. APPROVAL OF THE IQ\OQ\PQ PROCEDURE:**


**3.1** Both “**KRM HEALTHCARE, Laxmi Plaza, 436/437, Laxmi Industrial Estate, Suresh Nagar, Andheri West, Mumbai, Maharashtra 400053**” and **LifeTech Biomedical** are jointly responsible for the installation of **GASTAT-720** Arterial Blood Gas Analyzer (Sr. no. - 01067802 ) in the Pathology Department.

**Validation Team from (Vendor):**

Name ... Prashant Masurkar  
Designation ... Service Manager  
Company ... LifeTech Biomedical

**Validation Team from Pathology Lab:**

Name .....  
Designation ... Senior Technician  
Signature .....  
Date .....

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## **Customer Authorizations:**

### **II. INSTRUCTIONS**

1. This document is to be completed at the time the system installation (Pathology Laboratory) and setup for operation.
2. An authorized (Company) representative will check the system and enter the specific data related to installation, operational and performance qualification.
3. Employees of **KRM HEALTHCARE, Laxmi Plaza, 436/437, Laxmi Industrial Estate, Suresh Nagar, Andheri West, Mumbai, Maharashtra 400053** will verify each result and sign the results. The members of the validation team will carry this out.
4. All deviation from the normal specification to include any problems with installation will be noted under COMMENTS.

### **III. SCOPE**

This installation Qualification protocol is performed on the **GASTAT-720 Blood gas Analyzer** located in Pathology Department.


This protocol defines the documentation that is used to evaluate the instrument installation in accordance with the manufacturer's specifications and intended use.

Successful completion of this protocol verifies that this instrument has been installed & operated in accordance with the intended usage.

Installation checks are performed to verify that the instrument has been installed with proper connections and utilities.

Operational qualification will evaluate that the instrument have operational features available for the successful operation of instrument in accordance with the manufacturer's specifications.

Performance qualification will verify the actual functioning or performance of instrument.


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#### IV. Certificate of Purchase Order compliance

I certify to the best of my knowledge, the instrument **GASTAT-720 Arterial Blood Gas Analyzer** (Sr. no. - 01067802) installed on **13<sup>th</sup> June 2023** has been installed in compliance with the specifications of the Agreement order/ purchase order.

#### V. Equipment Description

S.N.	Instrument Identification	Verified by	Date
1	Equipment name: Blood Gas Analyzer	Prashant Masurkar	13/06/2023
2	Model: GASTAT 720		
3	Marketed By: LifeTech Biomedical		
4	Equipment ID : -		
5	Serial No: 01067802		
6	Size: As per the specifications given		
7	Power: As per the specifications given		


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## VI. Utilities

Sr.No	Utility	Remark	Verified by	Date
1	<b>Environmental conditions as required.</b> (Free from dust, electrical and magnetic interference), Temperature... 22 – 26 °C Humidity..... 10% to 85%, at 25°C	YES	Prashant Masurkar	13/06/2023
2	<b>Adequate space for installation:</b> ...(As per the specifications given )	YES		
3	<b>Electrical Outlets:</b> Actual voltage on site (231 VAC )	YES		
4	<b>Earthing</b> (0.1 to 3 V)	0.8 V		
5	<b>Connected through UPS</b>	YES		
6	<b>Stabilizer</b>	YES		

## VII. The instrument has been checked for the following:

Sr No.	Verification	Remark	Verified by	Date
1	Instrument is identified	YES	Prashant Masurkar	13/06/2023
2	Manufacturer's specification are included	YES		
3	Accessories /consumables are listed	YES		
4	Equipment manual from the manufacturer	YES, Online		

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### VIII. List of Manuals and Certificates.

Supplier provides the following with the instrument.

1	Operating Manual	Available - Yes Online
2	Purchase order /Agreement Order	Available - Yes
3	Calibration certificate	Available - Yes
4	Training Records	Available - Yes


### IX. Maintenance:

The instrument listed within this document will be placed under the control of **KRM HEALTHCARE, Laxmi Plaza, 436/437, Laxmi Industrial Estate, Suresh Nagar, Andheri West, Mumbai, Maharashtra 400053** with respect to proper maintenance procedures as detailed in the operator's manual. The maintenance procedures and documents will be filed separately.

A trained analyst using the manuals provided with the instrument can perform basic and operational maintenance and it will be recorded.

### X. INSTALLATION PROCEDURE

- Installation of Hardware and software: Follow the instructions mentioned in the Operator Manual.


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## XI. OPERATIONAL QUALIFICATION

- a) Following features/functions are available in the instrument as per manufacturer's specification and verified:

Test No.	Test Name	Test Purpose	Verified	Date
1	Electronic Test – startup, warm-up	Pass/ Fail	<b>Pass</b>	<b>13/06/2023</b>
2	Flow Test	Normal/abnormal	<b>Normal</b>	
3	Valve Test	Normal/abnormal	<b>Normal</b>	
4	Temperature Test	Normal/abnormal	<b>Normal</b>	
5	Calibration	Calibration Performance	<b>Ok</b>	
6	Quality Control	QC Performance	<b>Ok</b>	
7	Test Assay	Assay Performance	<b>Ok</b>	




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## XII. PERFORMANCE QUALIFICATION

Performance qualification validates the test procedure performed on the new instrument.  
Performance qualification not only validates instrument performance but also test procedure.  
All in-house protocols are validated for performance qualification of instrument and method.

**PQ Results – Pass**

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### CALIBRATION CERTIFICATE

This to certify that GASTAT 720 Blood Gas Analyzer with serial no. : 01067802 installed in **KRM HEALTHCARE, Laxmi Plaza, 436/437, Laxmi Industrial Estate, Suresh Nagar, Andheri West, Mumbai, Maharashtra 400053**, is self-calibration equipment and does not require external calibration.

The functioning of electrodes is tested by using Quality Control. Their range and value obtained is mentioned hereunder & they are found to be satisfactory.


QC	Parameter	Ranges	Value obtained in the machine
Level 02	pH	7.405 (7.355-7.455)	7.410
Gastrol	pCO2	41.2 (35.2-47.2)	42.8
QC	pO2	108 (94-122)	110
04112219	Na+	140 (134-146)	141
2023/12	K+	4.50 (4.20-4.80)	4.55
	Cl-	101 (96-106)	101.8
	Ca+	1.30 (1.10-1.50)	1.34

**Calibration Done On:-13/06/2023**

**Next Calibration Due On:-13/06/2024**

**Note: - Calibration Validity is only one year.**

For Life Tech Biomedical

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Date-13/06/2023

# Certificate of Training

This is to certify that below mentioned Staff from KRM HEALTHCARE, Laxmi Plaza,  
436/437, Laxmi Industrial Estate, Suresh Nagar, Andheri West, Mumbai,

Maharashtra 400053 have received basic user training for the GASTAT-720 Blood


Gas analyzer, Make: Techno Medica Japan;

Name	Designation
1. Kumudini Rawool	Lab Incharge
2. Ajay Junjut	Sr. Technician
3. Bhoomika Ranva	Jr. Technician
4. Divya Bomble	Jr. Technician
5. Tejal Nayak	Jr. Technician
6. Freeza Rentia	Jr. Technician
7. Katishma Mote	Jr. Technician
8. Ketan Gujat	Jr. Technician
9. Aashish Kalambate	Jr. Technician

### Topics covered:

- Application training
- Theory & hands-on

**Training given by: - Mr. Prashant Masurkar**

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**Validation procedures performed by (Vendor)**

Name :- Prashant Masurkar  
Designation: -Service Manager  
Company :- LifeTech Biomedical

**Validation procedures performed by Clinical Lab:**

Name .....

Designation: - Sr.Technician

Signature .....

Date .....

**Validation procedures reviewed by Clinical Lab:**

Name .....

Designation:- Pathologist

Signature .....

Date .....