



INSTALLATION QUALIFICATION PROTOCOL FOR ISOLATOR SYSTEM

Pre - Execution Approval

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



INSTALLATION QUALIFICATION PROTOCOL FOR ISOLATOR SYSTEM

1.0 Objective:

The purpose of installation qualification is as follows

- To provide documented evidence that the mentioned M Air T isolator system is installed as per design.
- To ensure that the M Air T isolator system installed confirms to purchase specifications and manufacturer literature, and to document the information that the M Air T isolator system meets the specification.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	M AIR T ISOLATOR SYSTEM
ID Number
Location	Incubator Room -II

3.0 Equipment / System Description:

M Air T Isolator system is an innovative concept for monitoring bacterial contamination of isolator & closed system air. System is designed to test air in Class 100 to Class 10,000 Clean Rooms. The M Air T Isolator system consists of a programmable, constant flow suction pump & an independent sampling head that is compatible with various sterilizing agents used to decontaminate isolators. The sampling head sieve has 611 micro-perforations, reducing the risk of colony overlap. The sampling head uses pre-filled, gridded, M Air T Agar cassettes.

4.0 Checklist for Preinstallation verification:

The purpose of the checklist is to confirm the availability of required documents for installation and to verify the availability of components and parts as per the approved purchase order in presence of the technical personnel of the vendor.

Preinstallation verification checklist is enclosed as Annexure - I.



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5.0 Checklist for Installation verification:

Installation of M Air T Isolator system shall be verified for the compliance with the critical parameters mentioned in the Functional Design Specification.

The purpose of this checklist is to check and document the received material and installation at site with respect to drawings, details, and data sheets approved during DQ and GEP. GEP considers the basic engineering requirements for skilful maneuvering, means those methods and practices, which the administrator determines to be consistent with scientific and engineering principles.

Installation verification checklist is enclosed as Annexure - II.

6.0 Any Changes identified towards equipment design / lay out.

Refer Annexure - III.

7.0 Recommendations and Conclusions:

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8.0 References:

- Copy of Purchase order
- Packing list supplied by vendor (Not applicable).
- List of spares (Not applicable).
- Installation Qualification submitted by vendor.
- Impact Assessment analysis.

9.0 Annexure

- Annexure - I : Check list for Preinstallation Verification.
- Annexure - II : Check list for Installation Verification.
- Annexure - III : List of Changes / Deviation.
- Annexure - IV : Installation Qualification Submitted by the vendor.
- Annexure - V : Impact Assessment Analysis.
- Annexure - VI : Summary Report of Installation Qualification
- Annexure - VII : Copy of Purchase order



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10.0 Abbreviations:

IQ : Installation Qualification

DQ : Design Qualification

Post execution approval:

	Name	Designation	Signature	Date
Compiled By				
Reviewed By				
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Reviewed By				
Approved By				



INSTALLATION QUALIFICATION PROTOCOL FOR ISOLATOR SYSTEM

Annexure - I

Checklist for Preinstallation Verification

S.No.	Main Components Accessories / Documents	Code / Doc No.	Actual	Remarks
1.	Purchase Order No.		
2.	Vendor's Name	M/s Millipore		
3.	Instrument Make	Millipore		
4.	Instrument Model No.	M Air T™ Isolator		
5.	Instrument Manual	Instrument Manual submitted by the vendor		



INSTALLATION QUALIFICATION PROTOCOL FOR ISOLATOR SYSTEM

Annexure - II

Checklist for Installation Verification

S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	Equipment /Instrument specific details			
a.	Verification of the Documents			
1.	User guide M Air T Isolator	Issue:		
2.	Certificate of Calibration of M Air T Isolator Pump	Issue: Sr. No.: Revision:		
b.	Verification of the Equipment List			
1.	M Air T Isolator Pump Catalogue	Catalogue No.: Serial No:		
2.	M Air T Isolator Sampling Head Catalogue	Catalogue No.: Serial No:		
3.	M Air T Isolator Tripod support Catalogue	Catalogue No.:		
4.	Sieve Catalogue	Catalogue No.: Serial No:		
5.	M Air T Isolator Printer Catalogue	Catalogue No.:		
6.	Micro-perforated Sieve with cover Catalogue	Catalogue No.:		



INSTALLATION QUALIFICATION PROTOCOL FOR ISOLATOR SYSTEM

S.No.	System Data	Acceptance Criteria	Actual	Remarks
c.	Verification of the utilities and operating environment Requirements			
1.	Electrical Requirements	230 V \pm 10 % - 50 Hz		
2.	Temperature	4 ⁰ C to 45 ⁰ C		
3.	Humidity	5 % to 95 % Non condensing		
d.	Verification of the Instrument Start - up			
1.	Software Release	Display Show VOMT 68		
2.	Sensor Display	Display Show OK		
3.	Main Frequenz	Display Show OK		
4.	RTC Clock	Display Show OK		
5.	Temperature	Display Show OK		
6.	Flow Sensor	Display Show OK		



INSTALLATION QUALIFICATION PROTOCOL FOR ISOLATOR SYSTEM

S.No.	System Data	Acceptance Criteria	Actual	Remarks
d.	Verification of the Instrument Start - up			
7.	Millipore M AIR T ISOLATOR auto test	Display Show OK		
8.	Last Calibration Date	Not applicable		
9.	Volume sampled since last calibration	Not applicable		
10.	Last settings for total volume and sampling cycle	Not applicable		
e.	Verification of the control key pad			
1.	Key pad	All key pad can be used correctly		
f.	Verification of the Sampling Time			
1.	M Air T clock setting (min : sec) 1 : 00 5 : 00 10 : 00	± 2 second		
g.	Verification of the Printer			
1.	Printer Checking	Printer should be work correctly		
h.	Verification of the Setting Parameter and Starting a test			
1.	Software routine "PARAM", "START" and "STOP"	Software routine should be work properly with test activities AT1 to AT 22		



INSTALLATION QUALIFICATION PROTOCOL FOR ISOLATOR SYSTEM

S.No.	System Data	Acceptance Criteria	Actual	Remarks
I.	Verification of the error message checking			
1.	Error message checking	All the key pad keys can be used correctly with test method AT1 to AT 4		
B.	Location suitability			
1.	Location	Should be place in Incubator Room - II		
C.	Utilities			
1.	Electrical Supply	230 V \pm 10 % - 50 Hz supply should be provided		
D.	Safety			
1.	Not Applicable	Not Applicable		
E.	MOC Certificates			
1.	Not Applicable	Not Applicable		
F.	Calibration Certificates			
1.	Calibration Certificates	Should be provided		
G.	Testing Certificates			
1.	Not Applicable	Not Applicable		
H.	Drawing Details			
1.	Not Applicable	Not Applicable		



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Annexure - III

List of Changes / Deviations

S.No.	Description of Change / Deviations	Justification based on impact analysis

Verified By:

Approved By:



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Annexure - VI

Summary Report of Installation Qualification

Checks	Observations (Yes / No)	Reviewed By Sign / Date
All test procedures executed and verified as per the protocol.		
All criteria set forth in the installation qualification were met.		
Deviation if any		

Summary:

Summary Report Prepared By:

Date & Sign