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OPERATIONAL QUALIFICATION OF HVAC SYSTEM

PROJECT: NEW EXPANSION OPERATING THEATRE &
SUPPORTING CLEAN ROOM FOR EXISTING EYE CENTRE
IN NEXUS, BANGSAR SOUTH FOR OASISEYE
SPECIALISTS SDN. BHD.

APPROVAL OF PROTOCOL

Signatures below signify that both vendor and client have read, understand, and agree with the content of this document. Approval of protocol must be granted by both parties before its execution.

This document was prepared and approved by the below representatives from Lufter Sdn. Bhd.

Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Authored by: Wong Peng Peng	Validation Executive		23-May-2023
Reviewed by: Ahmad Aslam	Design Assistant Manager		23-May-2023
Reviewed by: Shawn Eng	Assistant Project Manager		23-May-2023

By signing below, OasisEye Specialists Sdn. Bhd. confirms that all their requirements for this project have been reflected in this document.

Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Reviewed by:			
Reviewed by:	NA		
Approved by:	GOO CHUI HOONG Operations Manager OasisEye Specialists		24-May-2023

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1.0 REFERENCE DOCUMENTS

No.	Document No.	Document Title
1.	L-POEBS01-OT&SCR-VD-URS-R01	User Requirement Specification for HVAC System - New Expansion Operating Theatre & Supporting Clean Room for Existing Eye Centre in Nexus, Bangsar South for OasisEye Specialists Sdn. Bhd.
2.	L-POEBS01-OT&SCR-VD-FSDS-R01	Functional Specification Design Specification for HVAC System– New Expansion Operating Theatre & Supporting Clean Room for Existing Eye Centre in Nexus, Bangsar South for OasisEye Specialists Sdn. Bhd.
3.	L-POEBS01-OT&SCR-VD-CQP-R00	Commissioning & Qualification Plan - New Expansion Operating Theatre & Supporting Clean Room for Existing Eye Centre in Nexus, Bangsar South for OasisEye Specialists Sdn. Bhd.
4.	L-POEBS01-OT&SCR-VD-DQ-R01	Design Qualification for HVAC System for HVAC System– New Expansion Operating Theatre & Supporting Clean Room for Existing Eye Centre in Nexus, Bangsar South for OasisEye Specialists Sdn. Bhd.
5.	L-POEBS01-OT&SCR-VD-IQ-R01	Installation Qualification for HVAC System - New Expansion Operating Theatre & Supporting Clean Room for Existing Eye Centre in Nexus, Bangsar South for OasisEye Specialists Sdn. Bhd.

2.0 VERSION HISTORY

Revision No.	Date	Revised By	Reason for Revision
00	16 MAR 2023	Peng Peng	New
01	24 MAY 2023	Peng Peng	Lux requirement changed

3.0 INTRODUCTION AND SCOPE

This document qualifies the new HVAC system installation for the New Expansion Operating Theatre & Supporting Clean Room for Existing Eye Centre in Nexus, Bangsar South for OasisEye Specialists Sdn. Bhd. is to be in compliance with the principle of Ministry of Health Malaysia - Operating Theatre Management System, current ISO clean room guidelines, and World Health Organization (WHO) guidelines in accordance to Current Good Manufacturing Practice (cGMP) of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). The HVAC is designed with reference to the HVAC standard for Air-Conditioning, Heating and Refrigeration Institute (AHRI), American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), American Society for Testing and Materials (ASTM), The American Society of Mechanical Engineers (ASME) and Sheet Metal and Air Conditioning Contractors' National Association. (SMACNA) and Good Engineering Practices (GEP). The system has been assessed and categorized as "Direct Impact".

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4.0 PURPOSE

This document is created to justify that the critical components have been installed as per the requirements in the design qualification and all necessary supporting documents are in place.

5.0 ROLES & RESPONSIBILITY

The following personnel have been designated to prepare, execute, review and approve the protocol.

Company	Job Title	Responsibility
OasisEye Specialist Sdn. Bhd.	Client Representative	To review the validation protocol and report. To provide approval to the submitted protocol and report. To ensure all relevant technical specifications in vendor's documents are correct.
Lufter Sdn. Bhd.	Project Manager Project Engineer Validation Executive	To evaluate vendor's design against the URS. To execute the approved validation protocol. To prepare and ensure the validation protocol is reviewed and approved before execution.
TecnicAire Services Sdn. Bhd.	3 rd Party NEBB Tester	To conduct cleanroom performance testing in accordance to NEBB standards. To provide cleanroom performance testing report and certification.



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6.0 ABBREVIATIONS

No.	Term/Abbreviation	Definition
1.	A/C	Acceptance Criteria
2.	ACR	Air Change Rate
3.	AHRI	Air-Conditioning, Heating and Refrigeration Institute
4.	AHU	Air Handling Unit
5.	ASHRAE	American Society of Heating, Refrigerating and Air-Conditioning Engineers
6.	ASME	The American Society of Mechanical Engineers
7.	ASTM	American Society for Testing and Materials
8.	Cert	Certificate
9.	cfm	Cubic Feet per Minute
10.	cfu	Colony-Forming Unit
11.	cGMP	Current Good Manufacturing Practices
12.	CQP	Commissioning & Qualification Plan
13.	DQ	Design Qualification
14.	FSDS	Functional Specification and Design Specification
15.	ft	Feet
16.	GEP	Good Engineering Practices
17.	hr	Hour
18.	HEPA	High-Efficiency Particulate Air
19.	HVAC	Heating, Ventilation & Air-Conditioning
20.	IQ	Installation Qualification
21.	ISO	International Standardization for Organization
22.	NEBB	National Environmental Balancing Bureau
23.	No	Number
24.	OQ	Operational Qualification
25.	Pa	Pascal
26.	PIC/S	Pharmaceutical Inspection Co-operation Scheme
27.	Ref	Reference
28.	RH	Relative Humidity
29.	SDA	Sabouraud Dextrose Agar
30.	SMACNA	Sheet Metal and Air Conditioning Contractors' National Association
31.	TSA	Tryptic Soy Agar
32.	WHO	World Health Organization
33.	°C	Degree Celsius

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7.0 SYSTEM DESCRIPTION

7.1 Heating, Ventilation and Air Conditioning (HVAC) System

The HVAC System designed to serve the ISO 7 and 8 area consists of one (1) unit of AHU which is:

No.	AHU
1.	AHU-OT-02

Table 1: AHUs supplying ISO 7 and 8 area

The HVAC System designed for the classified cleanroom consists of one (1) units of new AHU which are designed to supply condition air to the cleanroom of the Operation Theatre 3, Operation Theatre 4, Scrub 2, Janitor 3 and Packing & Autoclave Room 2 as per Table 1 under Section 8.2.

The new AHU-OT-02 unit consists of only one (1) section. The fresh air passes through a filter box equip with filter grade G4(B) to filter any dust before going into heat recovery wheel where energy from the exhaust air is recovered for conditioning of the air. Then, the air passing through the AHU shall then be forced through another set of grades F9 filters for filtration before it is conditioned in the direct expansion (DX) post coil to reduce its temperature and moisture content.

After exiting the AHU unit, the post-cooled air will flow through two (2) heaters to be heated to the required temperature as per the URS. The supply air is then further filtrated by H14 HEPA filters at the HEPA Filter Terminal before being released into respective rooms.

For AHU-OT-02, the supply air enters the cleanroom via a network of ducting/branch ducts and flexible duct. Air control devices like aluminum blade volume control dampers are strategically installed along the main duct and branch duct to throttle the supply, and exhaust air. Manual dampers will be installed at each of the supply air diffusers and exhaust air grilles for fine adjustment.

Air exiting from all cleanrooms served by AHU-OT-02 will then pass through the same heat recovery wheel for energy recovery before being exhausted out.

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7.2 Cleanrooms Operating Conditions

Table 2 below shows the cleanroom parameters designed to meet the design parameters required for ISO 7 and 8 areas as stated in the URS document (L-POEBS01-OT&LAB-VD-JRS; under section 8.2).

AHU	Room Description	Room No.	Room ISO Class	Pressure (Pa) (ref. atmosphere)	Relative Humidity (RH) (%)	Temperature (°C)	Air Change
AHU-OT-02	Operation Theatre 3	001	ISO 7	20	50-60	18-22	≥ 25
	Operation Theatre 4	002	ISO 7	20	50-60	18-22	≥ 25
	Scrub 2	003	ISO 7	10	50-60	18-22	≥ 25
	Janitor 3	004	ISO 8	10	50-60	18-22	≥ 20
	Packing & Autoclave Room 2	005	ISO 8	10	50-60	18-22	≥ 20

Table 2: Cleanroom Parameters

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8.0 SYSTEM BOUNDARIES

The airflow schematic diagram (L/POEBS01/OT&LAB/DC/HVAC/05) illustrates the components which comprise the HVAC System and the airflow direction.

The operational qualification covers at the minimum the following equipment/components:

- Air Parameter for AHU
- Terminal HEPA Filters

The test carried out for the rooms in this Operational Qualification will be classified as either "as-built", "at-rest" or "in-operation" as define below:

- As-built – Condition where the cleanroom is complete with all services connected and functioning but with no equipment, furniture, materials or personnel present.
- At-rest – Condition where the cleanroom is complete with equipment installed and operating in a manner agreed upon, but with no personnel present.
- In-operation – Condition where the cleanroom is complete with equipment installed and operating in a manner agreed upon with the presence of personnel.

9.0 TEST SHEETS

This section details the checks to be carried out in support of the system.

A/C Ref.	Test Sheet Title	Test No.
1	Documentation Verification– Protocol Review	OQ-01
2	Device Functionality – Filter Integrity Verification (HEPA Filters)	OQ-01
3	Performance Verification – Room Air Change Rates	OQ-03
4	Performance Verification – Room Differential Pressure	OQ-04
5	Performance Verification – Room Temperature Monitoring	OQ-05
6	Performance Verification – Room Relative Humidity Monitoring	OQ-06
7	Performance Verification – Particle Count Verification – Non-Viable	OQ-07
8	Performance Verification – Total Microbial Count Test	OQ-08
9	Performance Verification – Room Light Intensity Test	OQ-09
10	Support – Procedure Verification	OQ-10
11	Support – Change Control Record	OQ-11

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10.0 TESTING RATIONALE

Ref.	Acceptance Criteria	Rationale
1	The previous stages of commissioning & qualification have been completed; any unresolved snags/deviations must be documented and have no impact on the tests in this protocol.	To provide documented evidence that all necessary commissioning/qualification required prior to the operation of this system have been completed.
2	The HEPA filter system is properly installed with no bypass leakage and the installed filters are free of defects and pinhole leaks.	To provide documented evidence that the HEPA filters have pass the leak test and meet the design requirements.
3	Air Change Rate (ACR) in all rooms is within the acceptable range specified in the design specification	To provide documented evidence that the Air Change Rate (ACR) in all rooms meets the design requirements.
4	Differential pressure in all rooms is within the acceptable range specified in the design specification.	To provide documented evidence that the differential pressure in all rooms meets the design requirements.
5	Temperature in all rooms is within the acceptable range specified in the design specification and other details such as the test location when the test was conducted must be recorded.	To provide documented evidence that the room temperature in all rooms meets the design requirements.
6	Relative humidity (RH) in all rooms is within the acceptable range specified in the design specification and other details such as the test location when the test was conducted must be recorded.	To provide documented evidence that the relative humidity in all rooms meets the design requirements.
7	Air particle count in all rooms is within the acceptable range specified in the design specification.	To provide documented evidence that the air particle count in all rooms meets the design requirements.
8	Total microbial count in all rooms is within the acceptable range specified in the design specification.	To provide documented evidence that the total microbial count in all rooms meets the design requirements.
9	Light intensity in all rooms is within the acceptable range specified in the design specification.	To provide documented evidence that the light intensity in all rooms meet the design requirements.
10	Operation and maintenance documentations have been completed and available.	To provide documented evidence that all documentations required for operation and maintenance are complete and available.
11	Records are available for all changes made to the system throughout the execution of this checking procedure and further tests required after the changes made have been conducted.	To provide documented records of all changes made to the system upon installation.



Title:	Documentation Verification-- Protocol Review	
		Test No: QQ-01

To provide documented evidence that all necessary commissioning/qualification required prior to the operation of this system have been completed.

All documents should be reviewed and approved.

1. Locate the completed system reports and executed protocol tests/ checks.

Acceptance Criteria:

- Results:**

Protocol Type	Protocol Title	Protocol Ref.	Protocol Version	Approval Date	Verified By (Initial & Date)
Validation	Installation Qualification for HVAC system	L-POEBS01-07-discr-vd-IQ	01	08-Jul-2023	[Signature] 08-Aug-2023
		N/A [Signature] 08-Aug-2023			



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Title: Documentation Verification- Protocol Review			Test No: OQ-01		
Comments/Deviations/Supporting Documentation: Refer to Installation Qualification for HVAC system (L-POEBS01-OT&SCR-VD-IQ).					
Overall Test Outcome (PASS/FAIL)		Verified By (Signature): 		Date: 29-Aug-2023	

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Title: Device Functionality – Filter Integrity Verification (HEPA Filters)					
Objective: To provide documented evidence that the HEPA filters have pass the leak test and meet the design requirements.					
Pre-requisites: System commissioning and balancing has been completed.					
Method: 1. The filters' face velocities were determined to ensure that they were within the general design range. 2. The digital aerosol photometer and the aerosol generator were set-up according to the manufacturer's specification. 3. PAO-4 aerosol was generated with the aerosol generator and introduces at the upstream of the filter(s). 4. Upstream concentration, in µg/liter, was measured. The sampling point was immediately (subject to physical site constraint) ahead of the filters under tests. Appropriate adjustment, if necessary, was made to ensure that the concentration was within preferred range. 5. The digital aerosol photometer was setup for downstream penetration measurement once the upstream concentration was satisfied and set. 6. Rectangular sampling probe was used to scan the filters. The probe was held at approximately 25mm from frame and filter surface during scanning. The maximum concentration level was recorded. The scanning rate is approximately 50mm/s. 7. The upstream challenge concentration was sampled again to ensure consistency of the challenge throughout the test upon completion of the tests.					
Acceptance Criteria: The HEPA filter system is properly installed with no bypass leakage and the installed filters are free of defects and pinhole leaks.					

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Title:	Device Functionality – Filter Integrity Verification (HEPA Filters)				Test No: OQ-02
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Results:

No.	AHU/ Equipment	Filter Ref.	Location	Acceptance Criteria	Actual Results		Verified By (Initial & Date)
					Upstream Challenge	Downstream Penetration %	
1.	AHU-OT-02	THF-02-01	Packing & Autoclave Room 2	The downstream penetration % is $\leq 0.01\%$ of upstream concentration	18	Media: 0.003 Gasket: 0.005	✓ 08-Aug-2023
2.		THF-02-02	Janitor 3		19	Media: 0.002 Gasket: 0.003	✓ 08-Aug-2023
3.		THF-02-03	Scrub 2		15	Media: 0.002 Gasket: 0.003	✓ 08-Aug-2023
4.		THF-02-04	Operation Theatre 4		22	Media: 0.001 Gasket: 0.002	✓ 08-Aug-2023
5.		THF-02-05	Operation Theatre 4		22	Media: 0.001 Gasket: 0.002	✓ 08-Aug-2023
6.		THF-02-06	Operation Theatre 3		27	Media: 0.001 Gasket: 0.002	✓ 08-Aug-2023
7.		THF-02-07	Operation Theatre 3		27	Media: 0.001 Gasket: 0.002	✓ 08-Aug-2023
8.		THF-02-08	Operation Theatre 3		27	Media: 0.001 Gasket: 0.003	✓ 08-Aug-2023



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Title: Device Functionality – Filter Integrity Verification (HEPA Filters)					
Comments/Deviations/Supporting Documentation: Refer to CPT Report (TAS/CPT/231450)					
Overall Test Outcome (PASS/FAIL)		Verified By (Signature): 		Date: 09 - Aug - 2023	



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Title: Performance Verification – Room Air Change Rates		Test No: OQ-03
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Objective:

To provide documented evidence that the Air Change Rate (ACR) in all rooms meets the design requirements.

Pre-requisites:

System commissioning and balancing has been completed.

Method:

1. The balometer was setup with the flow hood of the appropriate size to suit the HEPA filter & supply diffuser.
2. The flow food was then placed to cover the whole HEPA filter & supply diffuser outlet. Care was taken to ensure that there was no by-pass.
3. The air volume average of the cleanroom was computed from these data.
4. Total air change rate will be calculated using the room volume and total HEPA filter & supply diffuser airflow measured in the room.

Note:

1. In some cases machinery volumetric presence may be subtracted from the total room volume to give an actual room free volume.
2. Room volume $m^3 = L \times W \times H$
3. For areas with negative pressures, air change rates should be calculated from room extract fan.
4. Hourly room air change rates $(Ac/h) = m^3/h$ (supply air)/ m^3 (room volume)

Acceptance Criteria:

Air Change Rate (ACR) in all rooms is within the acceptable range specified in the design specification.

Results:

AHU	Room Name	Acceptance Criteria	Actual Result		Verified By (Initial & Date)
		Design Air Change Rate (/hr)	Measured Room Volume (ft ³)	Total Measured Area Supply (cfm) Calculated Air Change Rate (/hr)	
AHU-OT-02	Operation Theatre 3	≥25	2,770	1,348 27	HA 08-Aug-2023
	Operation Theatre 4	≥25	2,739	1,147 25	HA 08-Aug-2023



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Title:		Performance Verification – Room Air Change Rates			Test No: OQ-03	
AHU	Room Name	Acceptance Criteria		Actual Result		Verified By (Initial & Date)
		Design Air Change Rate (/hr)	Measured Room Volume (ft ³)	Total Measured Area Supply (cfm)	Calculated Air Change Rate (/hr)	
AHU-OT-02	Scrub 2	≥25	326	173	32	<i>[Signature]</i> 08-Aug-2023
	Janitor 3	≥20	227	92	24	<i>[Signature]</i> 08-Aug-2023
	Packing & Autoclave Room 2	≥20	494	190	23	<i>[Signature]</i> 08-Aug-2023

Comments/Deviations/Supporting Documentation:

Refer to CPT Report (TMS/CPT/231400)

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): <i>[Signature]</i>	Date: 04-Aug-2023
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Title:	Performance Verification – Room Differential Pressure	Test No: OQ-04
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Objective/Purpose:

To provide documented evidence that the differential pressure in all rooms meets the design requirements.

Pre-requisites:

System commissioning and balancing has been completed.

Method:

1. All airflow volume and pressure directional was balance and met the acceptance criteria prior to this test.
2. Cleanroom component could impact the differential pressure such as doors, pass through, windows and etc. in the cleanrooms and the reference areas should be closed throughout duration of the test.
3. Permanent openings should be kept open during the test.
4. The AHU has been operated and stabilized with extraction system operable as normal.
5. Using calibrated micro manometer (record details) zero the instrumentation and connect the rubber tube to the micro manometer positive connection.
6. Lay the tube into the higher-pressure room under the door separating the areas, ensuring that any induced air leakage is minimized and that the tube end and instrument are respectively as far from the door as possible i.e., minimum of 2 meters.
7. The differential pressure between the cleanroom and the adjacent room as measured and recorded with the Anemometer.

Acceptance Criteria:

Differential pressure in all rooms is within the acceptable range specified in the design specification.

Results:

Room Ref.	Airflow Directions	Acceptance Criteria		Actual Results	Verified By (Initial & Date)
		Adjacent Room Ref.	Design Differential Pressure (Pa)		
Operation Theatre 3	→	Dayward 2	≥ 20	76.1	HA 08-Aug-2023
Operation Theatre 3	→	Scrub 2	≥ 10	18.5	HA 08-Aug-2023



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Title: Performance Verification – Room Differential Pressure					Test No: OQ-04	
Room Ref.	Airflow Directions	Acceptance Criteria		Actual Results		Verified By (Initial & Date)
		Adjacent Room Ref.	Design Differential Pressure (Pa)	Differential Pressure (Pa) Recorded		
Operation Theatre 3	→	Janitor 3	≥ 10	17.2		<i>[Signature]</i> 08-Aug-2023
Operation Theatre 3	→	Packing & Autoclave Room 2	≥ 10	17.8		<i>[Signature]</i> 08-Aug-2023
Operation Theatre 4	→	Dayward 2	≥ 20	31.6		<i>[Signature]</i> 08-Aug-2023
Operation Theatre 4	→	Scrub 2	≥ 10	26.9		<i>[Signature]</i> 08-Aug-2023
Operation Theatre 4	→	Janitor 3	≥ 10	24.6		<i>[Signature]</i> 08-Aug-2023
Operation Theatre 4	→	Packing & Autoclave Room 2	≥ 10	24.4		<i>[Signature]</i> 08-Aug-2023

Comments/Deviations/Supporting Documentation:

Refer to CPT report (TNS/CPT/231400)

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): <i>[Signature]</i>	Date: 09-Aug-2023
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Title: Performance Verification – Room Temperature Monitoring					
Objective/Purpose: To provide documented evidence that the room temperature in all rooms meets the design requirements.					
Pre-requisites: All monitoring equipment such as sensors and other devices have been fully calibrated and set-up as per site operating procedures.					
Method: 1. The HVAC system was balanced and operated continuously for at least 24 hours prior to the commencement of the test. 2. The cleanroom number of the test grid mentioned in ISO guideline. 3. The temperature meter was held at the centre of the test grid at 1 meter above the floor. 4. When an obstruction was encountered, the measurement was taken at 150mm above the obstruction 5. The readings for all the other grids were taken & recorded. 6. The average temperature of the cleanroom was computed from these data.					
Acceptance Criteria: 1. Temperature in all rooms is within the acceptable range specified in the design specification. 2. Other details such as the test location when the test was conducted must be recorded.					



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Title:	Performance Verification – Room Temperature Monitoring				Test No: OQ-05
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Results:

AHU	Room Ref.	Acceptance Criteria		Room Condition	Actual Result		Verified By (Initial & Date)
		Design Temperature (°C)	Temperature (°C) Recorded		Test Location Recorded	Temperature (°C) Recorded	
AHU-OT-02	Operation Theatre 3	18-22		At-Rest	Refer to CPT report	19.5	HA 08-Aug-2023
	Operation Theatre 4	18-22		At-Rest	Refer to CPT report	20.4	HA 08-Aug-2023
	Scrub 2	18-22		At-Rest	Refer to CPT report	19.2	HA 08-Aug-2023
	Janitor 3	18-22		At-Rest	Refer to CPT report	19.9	HA 08-Aug-2023
	Packing & Autoclave Room 2	18-22		At-Rest	Refer to CPT report	20.1	HA 08-Aug-2023

Comments/Deviations/Supporting Documentation:

Refer to CPT report (TMS/CPT/231400)

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 04-Aug-2023
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Title: Performance Verification – Room Relative Humidity Monitoring Test No: OQ-06					
Objective/Purpose: To provide documented evidence that the relative humidity in all rooms meets the design requirements.					
Pre-requisites: 1. System commissioning and balancing has been completed. 2. All monitoring equipment such as sensors and other devices have been fully calibrated as per site operating procedures.					
Method: 1. The HVAC system was balanced and operated continuously for at least 24 hours prior to the commencement of the test. 2. The cleanroom number of the test grid mentioned in ISO guideline.1 3. The relative humidity meter was held at the centre of the test grid at 1 meter above the floor. 4. When an obstruction was encountered, the measurement was taken at 150mm above the obstruction 5. The readings for all the other grids were taken & recorded. 6. The average relative humidity of the cleanroom were computed from these data.					
Acceptance Criteria: 1. Relative humidity (RH) in all rooms is within the acceptable range specified in the design specification. 2. Other details such as the test location when the test was conducted must be recorded.					

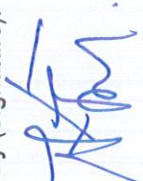
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Title:	Performance Verification – Room Relative Humidity Monitoring				Test No: OQ-06
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AHU	Room Ref.	Acceptance Criteria		Room Condition	Actual Result		Verified By (Initial & Date)
		Design Relative Humidity (%)			Test Location Recorded	Relative Humidity (%) Recorded	
AHU-OT-02	Operation Theatre 3	50-60		At-Rest	Refer to CPT report	51.3	08-Aug-2023
	Operation Theatre 4	50-60		At-Rest	Refer to CPT report	50.4	08-Aug-2023
	Scrub 2	50-60		At-Rest	Refer to CPT report	53.5	08-Aug-2023
	Janitor 3	50-60		At-Rest	Refer to CPT report	52.3	08-Aug-2023
	Packing & Autoclave Room 2	50-60		At-Rest	Refer to CPT report	51.4	08-Aug-2023

Comments/Deviations/Supporting Documentation:

Refer to CPT report (TAs/CPT/231400)

Overall Test Outcome (PASS/FAIL)	Verified By (Signature):	Date:
		09-Aug-2023

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Title: Performance Verification – Particle Count Verification – Non-Viable					
Objective: To provide documented evidence that the air particle count in all rooms meets the design requirements.					
Pre-requisites: System commissioning and balancing has been completed.					
Method: - The cleanrooms were purged for at least 12 hours before testing commences. Any additional air moving devices in the area have also been fully commissioned and set to operate normally. - The number of the test grid is determined by working area in m² as per ISO guideline. - With the particle counter at a height of 1 m and the sampling probe pointing in the direction of airflow, set the counter to the manufacturer's specifications to count 0.5 µm and 5.0 µm particles. - The sampling time was set to 25 minutes (Solair 3100) for ISO 5 and 1 minute (Solair 3100) for ISO 7 & 8 per sample with the counters' sampling rate at 28.3 lpm under at rest condition. - The sampling time was set to 7 minutes (Solair 3350) for ISO 5 per sample with the counter sampling rate at 100 lpm under at rest condition. - For under operational condition, the sampling time were set to 1 minute (Solair 3100) for ISO 5, ISO 7 and ISO 8 with the counter's sampling rate at 28.3 lpm. - A minimum of 1 sample was taken at the centre of each grid, at height of 1 meter above the floor for cleanroom or working area for machine, booths, pass boxes and clean air devices. When the count was greater than 75% of the allowable count limit, 3 samples was taken at that sample location. - When an obstruction was encountered, the sample was taken at 300mm above the obstruction. - The average particle count was computed from the collected data.					
Acceptance Criteria: Air particle count in all rooms is within the acceptable range specified in the design specification.					

Test No: OQ-07



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Title:	Performance Verification – Particle Count Verification – Non-Viable				Test No: OQ-07
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Results:

Room Ref.	Design Classification	Room Condition	Mean Particle Count/m ³ (Particle size ≥ 0.5 µm)		Mean Particle Count/m ³ (Particle size ≥ 5 µm)		Verified By (Initial & Date)
			Acceptance Criteria	Actual	Acceptance Criteria	Actual	
Operation Theatre 3	ISO 7	At-Rest	≤352,000	9,237	≤2,930	326	H 08-Aug-2023
Operation Theatre 4	ISO 7	At-Rest	≤352,000	26,601	≤2,930	451	H 08-Aug-2023
Scrub 2	ISO 7	At-Rest	≤352,000	14,526	≤2,930	401	H 08-Aug-2023
Janitor 3	ISO 8	At-Rest	≤3,520,000	9,983	≤29,300	283	H 08-Aug-2023
Packing & Autoclave Room 2	ISO 8	At-Rest	≤3,520,000	11,325	≤29,300	318	H 08-Aug-2023

Comments/Deviations/Supporting Documentation:

Refer to CPT report (TAS/CPT/231400)

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 09-Aug-2023
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Title: Performance Verification – Total Microbial Count Test					Test No: OQ-08
Objective: To provide documented evidence that the total microbial count in all rooms is within limits according to design specifications.					
Pre-requisites: System commissioning and balancing has been completed.					
Method: 1. The airborne viable micro-organism monitoring is conducted by using impactation technique (air sampling) followed by laboratory incubation on sampled test media recover & promote the micro-organism growth if there is any. 2. Total bacteria count is enumerated by using Tryptic Soy Agar (TSA) incubated at 35°C for five (5) days. 3. Total fungal count is enumerated by using Sabouraud Dextrose Agar (SDA) incubated at 25°C for seven (7) days. 4. A pre-set sampler volumetric impact flow of 100 liters/ min was used to expose the media and the respective plates incubated at the specific condition above. 5. Results are based on the number of colony form unit (cfu) that were present & counted on the media plated at the end of the incubation cycle. It is expressed in cfu/m ³ using Feller's Statistical Correction formulation.					
Acceptance Criteria: Total microbial count in all rooms is within the acceptable range specified in the design specification.					



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Title:	Performance Verification – Total Microbial Count Test	Test No: OQ-08
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Room Ref.	Design Classification	Room Condition	Total No. of Colony Form Unit from Air Sample (cfu/m ³)		Verified By (Initial & Date)
			Acceptance Criteria	Actual	
Operation Theatre 3	ISO 7	At-Rest	≤100	2	HA 08-Aug-2023
Operation Theatre 4	ISO 7	At-Rest	≤100	19	HA 08-Aug-2023
Scrub 2	ISO 7	At-Rest	≤100	5	HA 08-Aug-2023
Janitor 3	ISO 8	At-Rest	≤200	8	HA 08-Aug-2023
Packing & Autoclave Room 2	ISO 8	At-Rest	≤200	6	HA 08-Aug-2023

Comments/Deviations/Supporting Documentation:

Refer to CPT report (TAS/CPT/231400)

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 04-Aug-2023
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Title:	Performance Verification – Room Light Intensity Test	Test No: OQ-09
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Objective:

To provide documented evidence that the light intensity in all rooms meets the design requirements.

Pre-requisites:

1. System commissioning and balancing has been completed.
2. All monitoring equipment such as the lux meter and other devices have been fully calibrated and set-up as per site operating procedures.

Method:

1. Check that the electrical system has been fully commissioned.
2. Using fully calibrated test equipment (record details), place light intensity sensor at the centre of each grid and at a height of centre of work area (1 meter from floor level). If an obstruction was encountered, measurement should be taken at 300mm above obstruction.
3. Indicate the location of the light intensity sensor on a diagram of the area under test and record the intensity of the room.

Acceptance Criteria:

Light intensity in all rooms is within acceptable range specified in the design specification.

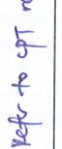
Results:

Room Ref.	Design Classification	Room Condition	Acceptance Criteria	Actual Result		Verified By (Initial & Date)
				Test Location Recorded	Light Intensity (Lux) Recorded	
Operation Theatre 3	ISO 7	At-Rest	Design Light Intensity (Lux) ≥ 500	Refer to CPT report	625	HA 08-Aug-2023
Operation Theatre 4	ISO 7	At-Rest	≥ 500	Refer to CPT report	578	HA 08-Aug-2023
Scrub 2	ISO 7	At-Rest	≥ 300	Refer to CPT report	533	HA 08-Aug-2023



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Performance Verification – Room Light Intensity Test					Test No: OQ-09		
Room Ref.	Design Classification	Room Condition	Acceptance Criteria		Actual Result		Verified By (Initial & Date)
			Design Light Intensity (Lux)		Test Location Recorded	Light Intensity (Lux) Recorded	
Janitor 3	ISO 8	At-Rest	≥ 300		Refer to CPT report	384	 08-Aug-2023
Packing & Autoclave Room 2	ISO 8	At-Rest	≥ 300		Refer to CPT report	574	 08-Aug-2023
Comments/Deviations/Supporting Documentation: Refer to CPT report (TAS/CPT/231400)							
Overall Test Outcome (PASS/FAIL)			Verified By (Signature): 		Date: 04-Aug-2023		



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Test No: OQ-10

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Title:		Test No: OQ-10			
Comments/Deviations/Supporting Documentation: Refer to Operation and Maintenance Manual (L-POEBS01-OT&SCR-VD-O&M-Pro)					
Overall Test Outcome (PASS/FAIL)		Verified By (Signature):		Date:	
				09-Aug-2023	

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Title:	Support - Change Control Record	Test No: OQ-11
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Comments/Deviations/Supporting Documentation:

NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 01-Aug-2023
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11.0 ACCEPTANCE CRITERIA SUMMARY

This section, detailing system specific Acceptance Criteria (A/C), should be completed following a review of the test sheets, within Section 8, and supporting data, contained within the referenced project files.

Pre-requisite

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? (Yes/No)	Deviation Ref.	Initial & Date
1	The previous stages of commissioning & qualification have been completed; any unresolved snags/deviations must be documented and have no impact on the tests in this protocol.	Yes	N/A	HL 08-Aug-2023

Operational

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? (Yes/No)	Deviation Ref.	Initial & Date
2	The HEPA filter system is properly installed with no bypass leakage and the installed filters are free of defects and pinhole leaks.	Yes	N/A	HL 08-Aug-2023
3	Air Change Rate (ACR) in all rooms is within the acceptable range specified in the design specification	Yes	N/A	HL 08-Aug-2023
4	Differential pressure in all rooms is within the acceptable range specified in the design specification.	Yes	N/A	HL 08-Aug-2023
5	Temperature in all rooms is within the acceptable range specified in the design specification and other details such as the test location when the test was conducted must be recorded.	Yes	N/A	HL 08-Aug-2023
6	Relative humidity (RH) in all rooms is within the acceptable range specified in the design specification and other details such as the test location when the test was conducted must be recorded.	Yes	N/A	HL 08-Aug-2023
7	Air particle count in all rooms is within the acceptable range specified in the design specification.	Yes	N/A	HL 08-Aug-2023
8	Total microbial count in all rooms is within the acceptable range specified in the design specification.	Yes	N/A	HL 08-Aug-2023
9	Light intensity in all rooms is within the acceptable range specified in the design specification.	Yes	N/A	HL 08-Aug-2023

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Support

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? Yes/No	Deviation Ref.	Initial & Date
10	Operation and maintenance documentations have been completed and available.	Yes	N/A	<i>[Signature]</i> 08-Aug-2023

Additional

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? Yes/No	Deviation Ref.	Initial & Date
11	Records are available for all changes made to the system throughout the execution of this checking procedure and further tests required after the changes made have been conducted.	Yes	N/A	<i>[Signature]</i> 08-Aug-2023



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12.0 TRAINING VERIFICATION

Training attendance record of end-user and/or other relevant personnel(s) who underwent training by Luften Sdn. Bhd. on the system operations, maintenance and brief troubleshooting methods.

Refer to Attendance List for HVAC system Training
(Attachment NO 1)

13.0 TEST INSTRUMENT RECORD

A record of all test instruments used during Operational Qualification, ensuring all instruments have valid calibration certificates.

~~N/A~~ 28-Aug-2023



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14.0 SIGNATURE RECORD

A record of all key personnel(s) involved in the completion of the Operational Qualification.

[illegible]



15.0 POST-EXECUTION APPROVAL

The system operational checks have been reviewed. All testing associated during Operational Qualification are completed with all criteria being met. Any deviations that were noted (if any) have been resolved and closed out.

16.0 DEVIATION LIST

[illegible]

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DEVIATION REPORT	Report no.:
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A. Description of Deviation:	
Documented By:	Date:

RESPONSE		
A. Reason of Deviation:		
B. Correction/preventive action to be taken:		
N/A		
08-Aug-2023		
Evaluation by:	Signature	Date (dd-mmm-yyyy)
Reviewed By:		

ACCEPTANCE		
C. Corrective/preventive action taken:		
Performed by:	Signature	Date (dd-mmm-yyyy)
Performed By:		
Reviewed By:		
Approved By:		

Note: This page to be re-printed as required



24 MAY 2023

17.0 LIST OF ATTACHMENTS

List of attachments should include all the supporting evidence and deviation reports.

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