

User Requirement Specification	Doc. No.	L-POEBS01-OT&SCR-VD-URS	Effective Date	24 MAY 2023
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USER REQUIREMENT SPECIFICATION FOR 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.			
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1.0 REFERENCE DOCUMENTS

No.	Document No.	Document Title
1.	LSB/Q-0822/078-R1	Approved Bill of Quantity
2.	L-POEBS01-OT&SCR-DT-01-R00 (020223)	Design Table – AHU-OT-02
3.	L/POEBS01/OT&SCR/DC/HVAC/05/R02	Airflow Schematic

2.0 VERSION HISTORY

Revision No.	Date	Revised By	Reason for Revision
00	08 FEB 2023	Peng Peng	New
01	24 MAY 2023	Peng Peng	Additional Heater Control and TRH

3.0 PURPOSE

This document describes the user's requirement including design, functional and operational requirements for the New Operating Theatre and Supporting Clean Room which will be operational at Nexus, Bangsar South for OasisEye Specialist Sdn. Bhd. The following requirements listed in this User Requirement Specification (URS) are the minimum requirements which must be addressed.

4.0 SCOPE

This URS describes the user specifications set for the installation and performance criteria of the new operating theatre and supporting clean room, as well as the HVAC system serving the rooms.

5.0 REFERENCE STANDARDS

The following user requirements form the basis of which the system and its component are to be designed, installed and qualified in accordance with the standards listed below:

Standards:

PIC/S - Guide to Good Practice for the Preparation of Medicinal Products in Healthcare Establishments [PE009-16 (Annexes)] and [PS INF 26 2022 (Rev. 1)]

ISO 14644-1:2015 Cleanrooms and Associated Controlled Environments – Part 1: Classification of Air Cleanliness by Particle Concentration.

ISO 14644-3:2019 Cleanrooms and Associated Controlled Environments – Part 3: Test Methods.

National Environmental Balancing Bureau (NEBB) Procedural Standards for Certified Testing of Cleanroom (3rd Edition)

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Guidelines:

ISPE Good Practice Guide – Heating, Ventilation and Air Conditioning (HVAC), (September 2009)

ISPE Baseline Guide Volume 5 – Commissioning & Qualification, 2nd Edition (June 2019)

American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE)

Sheet Metal and Air Conditioning Contractors' National Association (SMACNA)

Air-Conditioning, Heating and Refrigeration Institute (AHRI)

Ministry of Health Malaysia - Operating Theatre Management System

As well as all relevant local bureau regulations.

6.0 ABBREVIATION

No.	Term/Abbreviation	Definition
1.	AHU	Air Handling Unit
2.	AHRI	Air-Conditioning, Heating and Refrigeration Institute
3.	ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
4.	CFU	Colony-Forming Unit
5.	CPP	Critical Process Parameter
6.	CQA	Critical Quality Attributes
7.	DPG	Differential Pressure Gauge
8.	DT	Design Table
9.	DX	Direct Expansion
10.	HEPA	High-Efficiency Particulate Air
11.	HVAC	Heating, Ventilation and Air Conditioning
12.	ISO	International Standardization for Organization
13.	NEBB	National Environmental Balancing Bureau
14.	No	Number
15.	OT	Operation Theatre
16.	PIC/S	Pharmaceutical Inspection Co-Operation Scheme
17.	PU	Polyurethane
18.	Ref	Reference
19.	RH	Relative Humidity
20.	SMACNA	Sheet Metal and Air-Conditioning Contractors National Association Incorporated
21.	TRH	Temperature and Relative Humidity
22.	URS	User Requirement Specification

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7.0 SYSTEM OVERVIEW

The HVAC System for the New Operating Theatre and Supporting Clean Room shall provide appropriate working conditions in terms of particle count, temperature, relative humidity and pressure in accordance with the principles of Good Practices in Healthcare Establishments.

The scope for this URS shall cover the classified cleanroom area of this Existing Eye Centre. The cleanliness classification of the ISO classified cleanroom can be found under Section 8.2.

The design of the facility shall aim to produce an optimum material, personnel and waste flow as well as to prevent the occurrence of contamination and cross-contamination.

The classified areas shall be designed to be served by one (1) AHU to provide the HVAC system to all cleanroom.

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8.0 DESIGN REQUIREMENTS

8.1 Premises

8.1.1 The cleanroom premises of this existing facility shall include rooms as listed below:

No.	Room(s)
1	Operation Theatre 3
2	Operation Theatre 4
3	Scrub 2
4	Janitor 3
5	Packing & Autoclave Room 2

Table 1: Classified Cleanrooms in New Operating Theatre & Supporting Clean Room at Nexus, Bangsar South, OasisEye Specialist Sdn. Bhd.

8.1.2 The new wall partition and ceiling panel shall be of Polyurethane (PU) panel with a thickness of 75mm.

8.1.3 All doors shall be insulated PU panel single and double leaf swing door.

8.1.4 Three (3) units of passive passbox shall be provided for the transfer of materials.

8.1.5 The flooring system in the classified cleanroom shall be completed with self-levelling epoxy with coving.

8.2 Heating Ventilation Air Conditioning (HVAC) System

8.2.1 Critical Process Parameter (CPP)

The cleanroom design shall meet the following operating conditions:

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

Table 2: Cleanroom Parameters

8.2.2 Critical Quality Attributes (CQA)

The HVAC system shall produce required cleanroom condition as follows:

Room Classification	Attributes	Maximum permitted number
ISO 7 & ISO 8	Non-viable count	Refer Table 6 below
	Viable count	Refer Table 7 below

Table 3: Critical Quality Attributes

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ISO Class No.	Maximum Allowable Concentration (particles/m ³) for Particles Equal to and Greater Than the Considered Sizes, Shown Below					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5 µm
1	10					
2	100	24	10			
3	1,000	237	102	35		
4	10,000	2,370	1,020	352	83	
5	100,000	23,700	10,200	3,520	832	
6	1,000,000	237,000	102,000	35,200	8,320	293
7				352,000	83,200	2,930
8				3,520,000	832,000	29,300
9				35,200,000	8,320,000	293,000

Table 4: ISO allowable number of airborne particles of cleanrooms (Non-viable)

Grade	Maximum Limits for Total Particle $\geq 0.5\mu\text{m}/\text{m}^3$		Maximum Limits for Total Particle $\geq 5\mu\text{m}/\text{m}^3$	
	At Rest	In Operation	At Rest	In Operation
A	3,520	3,520	Not Specified ^(a)	Not Specified ^(a)
B	3,520	352,000	Not Specified ^(a)	2,930
C	352,000	3,520,000	2,930	29,300
D	3,520,000	Not Predetermined ^(b)	29,300	Not Predetermined ^(b)

Table 5: PIC/S maximum permitted total particle concentration for classification

Notes:

(a) Classification including 5µm particles may be considered where indicated by the CCS or historical trends.

(b) For grade D, in operation limits are not predetermined. The manufacturer should establish in operation limits based on a risk assessment and routine data where applicable.

Grade	Maximum Permitted Microbial Contamination Level		
	Air Sample (cfu/m ³)	Settle Plates (diameter 90mm) (cfu/4 hours)	Contact Plates (diameter 55mm) (cfu/plate)
A	No Growth		
B	10	5	5
C	100	50	25
D	200	100	50

Table 6: PIC/S maximum permitted microbial contamination level (Viable)

Notes:

(a) These are average values

(b) Individual settle plates may be exposed for less than 4 hours

(c) ISO 7 = Grade C; ISO 8 = Grade D

8.2.3 HVAC Requirements

One (1) AHU shall be used to supply the required airflow to the respective cleanrooms to achieve the above required conditions.

8.2.4 Design & Functional Constraints

8.2.4.1 The AHU shall utilize direct expansion (DX) type for cooling and dehumidification.

8.2.4.2 A heat recovery wheel shall be utilized to reduce the energy required for cooling and dehumidification.

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8.2.5 AHU-OT-02

- 8.2.5.1 The HVAC system supplies single pass air to all the cleanrooms, including Operation Theatre 3, Operation Theatre 4, Scrub 2, Janitor 3, and Packing & Autoclave Room 2. The exhausted air from all the cleanrooms shall be flowing towards heat recovery wheel before discharged to the atmosphere by exhaust fan instead of being recirculated. This is to prevent the cleanrooms from being contaminated by infectious particles.

8.2.6 Filtration System

- 8.2.6.1 Fresh air shall be filtered by primary filter grade G4(B) equip inside filter box located before heat recovery wheel.
- 8.2.6.2 Air filters used in the air handling system shall be secondary filter grade F9.
- 8.2.6.3 HEPA filters grade H14 shall be fitted at the HEPA filter terminal before air is discharged into all the classified cleanrooms.

8.2.7 Ducting System

- 8.2.7.1 Material sheet used in ducting shall be Zinalume sheet, insulated to prevent any condensation externally. Ducting shall be constructed based on international standard.
- 8.2.7.2 Duct work must have undergone and passed the duct leakage testing. The test report shall be submitted as part of handover documents.

8.2.8 Differential Pressure Gauge (DPG)

- 8.2.8.1 Calibrated pressure gauge ranging 0 to 60 Pa shall be installed at rooms for measuring room differential pressure.
- 8.2.8.2 Calibrated pressure gauge ranging 0 to 500 Pa shall also be installed for monitoring of terminal HEPA filter conditions.

8.2.9 Temperature and Relative Humidity Sensor (TRH)

- 8.2.9.1 There shall be three (3) units of TRH located at the exhaust ducts.

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9.0 DOCUMENTATION

The documentation package to be handed over at the end of project to user shall include system operation manual, preventive and maintenance instruction, mechanical drawings, equipment data sheet, instrument data sheet, electrical drawing, control panel diagram, calibration certificate, test reports, and validation documents (Design Qualification, Installation Qualification and Operational Qualification).

10.0 TESTING AND COMMISSIONING

The New Operating Theatre & Supporting Clean Room shall be certified to meet the ISO 14644 standard based on the performance criteria above.

Testing shall be carried out by experienced technician from a NEBB certified company.

11.0 QUALIFICATION

All validation documents are to be prepared by Lufter Sdn. Bhd. and submitted to authorized personnel from OasisEye Specialists Sdn. Bhd. for review and approval.

The protocols are to be executed according to the guidelines/procedures provided by OasisEye Specialists Sdn. Bhd. (if there is any).

Operational Qualification should only be initiated after all Installation Qualification activities, including discrepancies reported have been closed.

End