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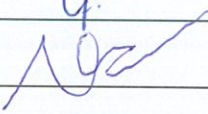
FUNCTIONAL SPECIFICATION AND DESIGN SPECIFICATION FOR HVAC SYSTEM

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.	L-POEBS01-OT&SCR-VD-URS-R00	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-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	17 FEB 2023	Peng Peng	New
01	24 MAY 2023	Peng Peng	Additional Heater Control

3.0 INTRODUCTION

Lufter Sdn. Bhd. is the contractor awarded to design, install, and commission and validate the entire HVAC system for the New Operating Theater & Supporting Clean Room, which will be operational within the Nexus, Bangsar South, OasisEye Specialist Sdn. Bhd.

4.0 GENERAL DESIGN CONSIDERATIONS

The HVAC system is designed and constructed to meet 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). 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).



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5.0 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.	ASME	The American Society of Mechanical Engineers
5.	ASTM	American Society for Testing and Materials
6.	CFU	Colony-Forming Unit
7.	cGMP	Current Good Manufacturing Practice
8.	DB	Dry Bulb
9.	DT	Design Table
10.	DX	Direct Expansion
11.	GEP	Good Engineering Practices
12.	HEPA	High-Efficiency Particulate Air
13.	HVAC	Heating, Ventilation and Air Conditioning
14.	ISO	International Standardization for Organization
15.	NEBB	National Environmental Balancing Bureau
16.	No	Number
17.	OT	Operation Theatre
18.	PIC/S	Pharmaceutical Inspection Co-Operation Scheme
19.	PU	Polyurethane
20.	Ref	Reference
21.	RH	Relative Humidity
22.	SMACNA	Sheet Metal and Air Conditioning Contractors' National Association
23.	URS	User Requirement Specification
24.	WB	Wet Bulb



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6.0 DESIGN CRITERIA

The criteria as per URS (L-POEBS01-OT&SCR-VD-URS-R01) have been taken into consideration during the design stage:

a) Temperature & Relative Humidity

The design of temperature & humidity parameters for the new operating theatre and supporting cleanrooms by Lufter Sdn. Bhd. are as below:

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 1: Lufter's Room Design Parameters



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b) Room Pressurization and Airflow Direction

The design of room pressurization and airflow direction for the New Operating Theatre and Supporting Clean Room by Lufter Sdn. Bhd. are as below:

Adjacent Room		Design Differential Pressure (Pa)
From	To	
Operation Theatre 3	Dayward 2	≥ 20
Operation Theatre 3	Scrub 2	≥ 10
Operation Theatre 3	Janitor 3	≥ 10
Operation Theatre 3	Packing & Autoclave Room 2	≥ 10
Operation Theatre 4	Dayward 2	≥ 20
Operation Theatre 4	Scrub 2	≥ 10
Operation Theatre 4	Janitor 3	≥ 10
Operation Theatre 4	Packing & Autoclave Room 2	≥ 10

Table 2: Lufter's Design Room Differential Pressure

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7.0 DESIGN CONSIDERATIONS FOR AHU DESIGN

7.1 External Design Conditions

The design of the system is done with reference to the latest version of ASHRAE and the current tropical climate condition as listed below:

Country: Malaysia
 Location: Subang, Kuala Lumpur
 Max Out Door Condition: 34.0°C DB / 28.2°C WB

7.2 Design for Air Handling Unit

No.	AHU
1.	AHU-OT-02

The above external design conditions shall be treated as the worst-case scenario. The air conditioning output fluctuates as the external condition changes, and this will subsequently impact on system performance, causing the room condition to run out of the design limit. To prevent this from occurring, a post-cooling coils is used to remove the heat and moisture content from the fresh air intake. In this Direct Expansion (DX) type, the air is directly cooled by the refrigerant in the cooling coil.

For area where relative humidity is required to be under control, air moisture will be removed by the cooling coil system in variable rate to achieve the required relative humidity. The change of internal load in the room will be controlled by the refrigerant flow rate in the cooling coil and the heater to eventually achieve the design condition as specified in the URS.

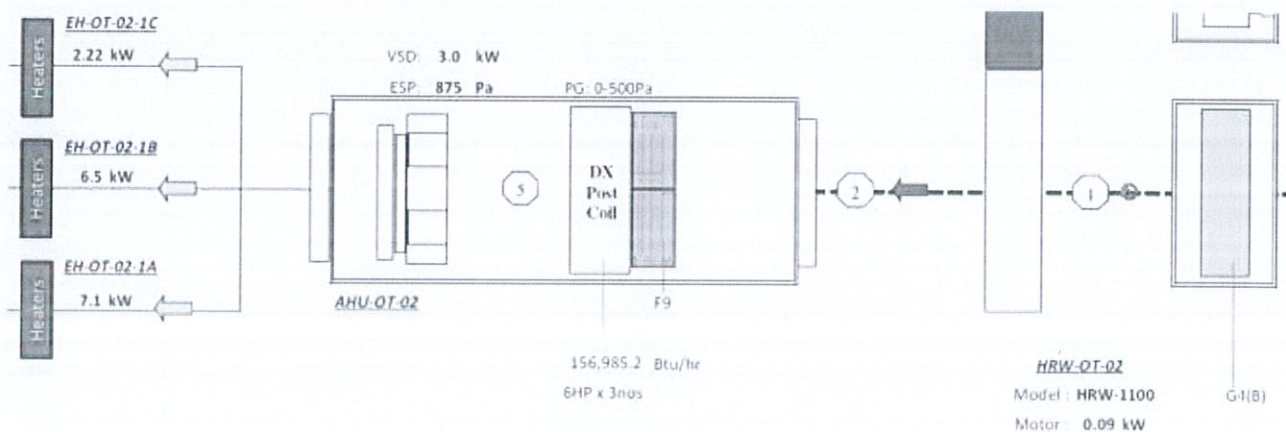


Diagram 1: AHU-OT-02 P&ID

The new AHU-OT-02 has 1 section of DX post-cooling coil to remove moisture content in the air.

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7.3 Design for AHU Supply Air Flow

The amount of supply air from AHU is dependent on the room cleanliness classification. Air circulation rate in terms of air change per hour is the basic guideline to obtain the desired room ISO class. A higher air change rate will have higher room recovery as the room is being flushed more frequently. The air change rate increases as the room ISO Class decreases or is cleaner (for example ISO 8 to ISO 7). Sufficient air circulation and air distribution is part of the consideration. The load for each room has been assessed to give a minimum airflow based upon the fresh air requirement, heat gains, minimum air change rate or extract equipment make-up whichever is the larger.

7.4 Design for Pre-Cool Fresh Air Flow and Room Pressurization

The fresh air requirement is determined by the required room pressure, human fresh air needs and the rate of air being exhausted from the room. Usually, the amount of fresh air required to pressurize the room is much greater than the human fresh need, hence the latter is negligible. The fresh air heat and moisture load is taken into consideration by the pre-cooled coil system.

As the HVAC system requires single-pass air; to reduce the capacity required for cooling and dehumidification, a heat recovery system is introduced to reduce the temperature and humidity of the fresh air before entering the AHU. The fresh air heat and moisture load will then be further conditioned by the post-cooling coil system and external electric heater.

7.5 Design for Process Equipment Heat Gains

Machine motors are some common heat sources in a facility. This room internal heat load must be taken into consideration in the heat change calculation while designing a HVAC system. The system must be designed in such a way that it is capable of overcoming the room internal heat load when the heat load is at its highest level. It is important that all required machine data such as the heat dissipation rate and frequency of machine usage are provided by the process owner for accurate design calculations.

If the frequency of machine usage with the diversity factor based on the estimated machine heat load falls within our HVAC design safety factor, we can then assume the machine heat load dissipation is negligible.

In other cases, the production machine heat load dissipation helps to increase the room sensible heat, thus the sizing of reheat HVAC system can be reduced.

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7.6 Design to Achieve Room Cleanliness

The desired room cleanliness can be achieved by adjusting the air change per hour and the selected filtration stage. The filtration stages for new HVAC system supplied by AHU-OT-02 are G4(B) and F9 for fresh air. Additionally, terminal HEPA filters H14 with efficiency of removing at least 99.995% of airborne particles 0.3 micrometers (μm) in diameter are installed at all ISO 7 and ISO 8 cleanrooms. The design air change and room classification are stated in Section 6(a).

To achieve the required cleanliness classification, the design approach needs to take into consideration the overall attributes of sufficient air circulation with appropriate filtration system, the air flow pattern, the absolute room pressure, the correct pressure gradient to the adjacent room, the architecture room layout, material selection and minimum air leakage from the room.

The design will follow the ISO classes of air cleanliness by particle concentration in ISO14644-1:2015(E), as follows:

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

As for viable particle limits, the PIC/S recommended limits for microbiological monitoring of clean areas in healthcare establishment is followed:

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 4: PIC/S maximum permitted total particle concentration for classification

Notes:

(a) Classification including $5\mu\text{m}$ 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.



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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 5: 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

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7.7 Air Circulation Rate

Air circulation rate in term of air change per hour is a basic guideline to achieve the desired room cleanliness. A higher air change rate will result in a higher room recovery as the room is being flushed more frequently. The required air change rate increases as the room ISO Class decreases (E.g. ISO 8 to ISO 7). The recommended air exchange rate requirement as stated in the Operating Theatre Management System by Ministry of Health Malaysia are 15-20 cycles per hour.

Air change rate of an area correlates with the airflow volume supplied to the area. To determine the airflow volume required, there is a need to consider the heat gains within the space, the particulate gain within the space under worst case conditions to maintain room-classification and the required recovery time of 15 to 20 minutes. Thus, the air change rate of a similar class area may be different to accommodate for the heat and/or particulate gains of the room. For example, rooms with machinery, greater activity or personnel movement and/or count will need to account for higher heat and particulate gains when designing the air change rate.

7.8 Room Air Distribution

Room air distribution is the design to obtain the best air circulation in any parts of the room. To do so, the circulation needs to be sufficient. Supply air outlet and the exhaust air grilles shall be place at the strategic place so that air can be distributed evenly to the room.

Type of exhaust air grilles for each room:

Room Description	Room ISO Class	Ceiling Exhaust	Low Level Exhaust
Operation Theatre 3	ISO 7	x	✓
Operation Theatre 4	ISO 7	x	✓
Scrub 2	ISO 7	✓	x
Janitor 3	ISO 8	✓	x
Packing & Autoclave Room 2	ISO 8	✓	x

Table 6: Type of Exhaust Air

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7.9 Design Consideration for Air Filtration System

Several filtration systems are implemented for the new HVAC system as required.

Equipment	Type of Filter	Location
AHU-OT-02	Pre-Filter (G4)	Fresh air duct (before heat recovery system)
	Secondary Filter (F9)	AHU post-cooling section
	HEPA Filter (H14)	ISO 7 & ISO 8 room terminal

Table 7: Air Filtration System

7.10 Control System Description

There are several factors taken into consideration with regards to the design of the control system for the AHU:

Temperature Control

Room temperature is controlled by modulating electrical heater. Changes in internal load will signal to the temperature sensor which will subsequently command the electrical heater to meet the desired temperature (°C).

Relative Humidity Control

Relative humidity first will be treated by the removal of latent load at the Heat Recovery Wheel (No control). Further relative humidity will be treated again by the AHU before supplying to the room. Overall room relative humidity is controlled by the post-cooling coil in AHU-OT-02. Changes in room humidity will signal the relative humidity sensor which will subsequently command the respective cooling coils via a digital indicating controller to meet the desired percentage (%).

Airflow Volume Control

Air flow control is separated into two methods. First is to control by using Variable Speed Drive (Manual input) to balance the main air flow. After balancing the main air flow, room air flow will be manually balanced by using volume control dampers.

Refer to attachment for design table and air flow schematic diagram.

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8.0 DUCT WORK

8.1 Ducting Construction, Testing and Air Diffusers

The ducting construction shall be as follow:

Ducts, plenums and fittings should be constructed of Zincalume material with medium pressure design with TDC flange joint for supply duct while Galvanised iron with slip joint for exhaust and fresh air duct. Building cavities may not be used as a duct or plenum without a sealed duct board or metal liner. Other materials are authorized if specific uses (e.g. chemical resistance) are required. The inside surface of the ducts must be smooth, except if the specific equipment is required (noise attenuator, damper, etc.).

The design of ducts with circular section is optional. The duct system must be airtight. The rectangular sections must be reinforced with folds or reinforcement to resist deformations and vibration. The duct system including elbows, change of section and other equipment must be selected and designed to minimize the static pressure losses and the level of noise. The assembly of the rectangular ducts must be executed with riveted sleeves and retractable adhesive strips. All gap opening must be sealed internally with approved duct sealant, no adhesive tape is used. The connecting of the movable parts (filters) can be executed with semi flexible metallic ducts. Their length must be as short as possible.

Before duct is insulated, the installing contractor should perform leak test on each duct system at 125% of the operating pressure for holding time 15 minutes of test sequence. For this project, leak test applicable to Supply Duct (with TDC joint) ONLY (refer to DW 143).

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9.0 HVAC EQUIPMENT

9.1 Air Handling Unit

The AHU shall be constructed with extruded aluminium profile to form a structural frame to house all internal components. Casing shall be of panel construction, double wall type packed with insulation between the walls. External and internal sheet shall be minimum 0.6mm and 0.6mm galvanized steel sheet respectively. The construction of infill panels shall not be less than 60mm and shall be selected to match both the specified sound reduction index of the casing and to prevent condensation on the exterior surfaces under the extremes of operation and ambient conditions. The infill insulation shall be of CFC-free, vermin and rot-proof, non-flammable, sound-absorbing and thermal insulating type. Framework shall be thermal-break and properly insulated to prevent formation of condensation on the exterior and intermediate surfaces of the unit casing under the extremes of operation and ambient conditions. All fixing screws/ bolts shall not result in thermal bridge of casing external/ internal surface. The density shall not be less than 40kg/m³. Thermal conductivity shall not exceed 0.02W/m°C. The insulation shall be adequately supported to prevent collapse and to eliminate the formation of cavities. The frame and the base of the unit must be made by aluminum alloy. The interior design of the panel must have round edge corner for the cleaning purposes which follow the Hygienic Standard, VDI 6022. All unit panels, including the floor panels, shall be double skin and fabricated at factory. The overall casing shall comply with the following criteria in accordance with EN1886 and EUROVENT certified test report should be submitted.

9.2 Cooling Coil

Cooling coils are manufactured from copper tubes with aluminium fins bonded to the tubes through mechanical expansion and housed in aluminium/ galvanized/ stainless steel frame; headers come with threaded male pipe connections and include drain and vent. Condensate pans will be of the dry pan design to ensure complete condensate removal and made of galvanized steel powder coated insulated with 30mm polyurethane, slope to remove the condensate. AHU coils should be of sufficient size to guarantee sufficient cooling capacity for the HVAC system. As for reference, the cooling coil may have no more than 14 fins per inch and 5-8 rows in single coil.

9.3 Heat Recovery Wheel

Heat recovery wheel use Molecular Sieve 3A (EcoSorb 300) desiccant coated on aluminium substrate in order to obtain high latent recovery, high structural strength and control on cross contamination. In-built purge sector provides strict separation of airflows, preventing carryover of bacteria, duct and pollutants from exhaust air to supply air. Non-contact labyrinth seal provides effective sealing and long lasting in term of shelf life. Highly polished surface resulting in extremely low leakage across the central divider seals. The design of the heat recovery wheel shall be bacteria-static hence it does not support microbial growth.

9.4 Exhaust Fan

The exhaust fan shall consist of single inlet centrifugal fans with high efficiency non-overloading backward curved impellers. The exhaust fan is suitable for exhaust applications in industrial buildings.

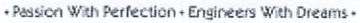
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9.5 Damper

Dampers are designed with profiled damper blades operating in opposite directions with an additional seal mounted on external, reinforced, polyamide, cogged wheels with slide bearings. All dampers to be used TROX minimum leakage dampers type only.

9.6 Fan

Fans are of direct driven type and mounted on anti-vibration supports. The motor with IP55 rating must be calculated with a sufficient over capacity and must be connected through a safety switch placed on AHU.



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10.0 LIST OF ATTACHMENTS

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

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