



• Passion With Perfection • Engineers With Dreams •

User Requirement Specification	Doc. No.	L-SJMC02-HTL-VD-URS	Effective Date	24 AUG 2022
	Rev. No.	00	Total Page(s)	1 of 12



• Passion With Perfection • Engineers With Dreams •

USER REQUIREMENT SPECIFICATION

PROJECT: NEW HOTLAB AT SUBANG JAYA MEDICAL CENTRE,
SUBANG JAYA, SELANGOR DARUL EHSAN.

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 Lufiter Sdn. Bhd.

Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Authored by: Wong Peng Peng	Validation Executive		02-Aug-2022
Reviewed by: Mohd Fahmi Abd Majid	Design, Quality & Special Projects Manager		02-Aug-2022
Reviewed by: Koh Soon Yong	Project Manager		02-Aug-2022

By signing below, Subang Jaya Medical Centre 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: Kiat Hoe	Deputy Chief Pharmacist, operations.		24-AUG-2022
Reviewed by:	N/A		
Approved by: Steven	Manager		24/8/2022

This information contained herein this document is confidential & property of LUFTER SDN. BHD. and SUBANG JAYA MEDICAL CENTRE.

No part of this documentation may be reproduced, transmitted in any forms or means, electronically or mechanically, including, without limitation, copying, photocopying and recording, for any purpose without the express written permission of LUFTER SDN. BHD. or SUBANG JAYA MEDICAL CENTRE. Violation of this prohibition shall be subjected to legal enforcement.

User Requirement Specification	Doc. No.	L-SJMC02-HTL-VD-URS	Effective Date	24 AUG 2022
	Rev. No.	00	Total Page(s)	2 of 12

TABLE OF CONTENTS

1.0	REFERENCE DOCUMENTS	3
2.0	VERSION HISTORY	3
3.0	PURPOSE.....	3
4.0	SCOPE	3
5.0	REFERENCE STANDARDS	3
6.0	ABBREVIATIONS	5
7.0	SYSTEM OVERVIEW.....	6
8.0	DESIGN REQUIREMENTS.....	7
8.1	Premises	7
8.2	Heating, Ventilation and Air Conditioning (HVAC) System	9
9.0	DOCUMENTATION.....	12
10.0	TESTING AND COMMISSIONING	12
11.0	QUALIFICATION.....	12

User Requirement Specification	Doc. No.	L-SJMC02-HTL-VD-URS	Effective Date	24 AUG 2022
	Rev. No.	00	Total Page(s)	3 of 12

1.0 REFERENCE DOCUMENTS

No.	Document No.	Document Title
1.	LSB/Q-1021/142-R3	Approved Bill of Quantity
2.	L-SJMC02-HTL-DT-01-R00 (060722)	Design Table - AHU-1
3.	L-SJMC02-HTL-DT-02-R00 (060722)	Design Table - AHU-2
4.	L-SJMC02-HTL-DT-03-R00 (060722)	Design Table - EF-4
5.	L-SJMC02-HTL-AF-01-R00 (060722)	Airflow Schematic - AHU-1
6.	L-SJMC02-HTL-AF-02-R00 (060722)	Airflow Schematic - AHU-2
7.	L-SJMC02-HTL-AF-03-R00 (060722)	Airflow Schematic - EF-4

2.0 VERSION HISTORY

Revision No.	Date	Revised By	Reason for Revision
00	24 AUG 2022	Peng Peng	New

3.0 PURPOSE

This document describes the user's requirement including design, functional and operational requirements for the cleanroom which will be operational within the New Hotlab at Subang Jaya Medical Centre. The following requirements listed in this 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 Hotlab Cleanrooms, as well as the HVAC system serving the rooms.

5.0 REFERENCE STANDARDS

The following user requirements form the basic 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 (PE010-4)

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.



• Passion With Perfection • Engineers With Dreams •

User Requirement Specification	Doc. No.	L-SJMC02-HTL-VD-URS	Effective Date	24 AUG 2022
	Rev. No.	00	Total Page(s)	4 of 12

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

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 Incorporated (SMACNA)

American Refrigerant Institute (ARI)

As well as all relevant local bureau regulations.

User Requirement Specification	Doc. No.	L-SJMC02-HTL-VD-URS	Effective Date	24 AUG 2022
	Rev. No.	00	Total Page(s)	5 of 12

6.0 ABBREVIATIONS

No.	Term/Abbreviation	Definition
1.	AHU	Air Handling Unit
2.	ARI	American Refrigerant Institute
3.	ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
4.	BIBO	Bag in/Bag out
5.	BSC	Biosafety Cabinet
6.	CFU	Colony-Forming Unit
7.	CPP	Critical Process Parameter
8.	CQA	Critical Quality Attributes
9.	D	Depth
10.	EPS	Expanded Polystyrene
11.	FH	Fume Hood
12.	H	Height
13.	HFC	HEPA Filter Chamber
14.	HEPA	High-Efficiency Particulate Air
15.	HVAC	Heating, Ventilation and Air Conditioning
16.	ISO	International Standardization for Organization
17.	NEBB	National Environmental Balancing Bureau
18.	PIC/S	Pharmaceutical Inspection Co-Operation Scheme
19.	PU	Polyurethane
20.	PUR	Polyurethane Reinforced
21.	SMACNA	Sheet Metal and Air-Conditioning Contractors National Association Incorporated
22.	t	Thickness
23.	URS	User Requirement Specification
24.	W	Width



• Passion With Perfection • Engineers With Dreams •

User Requirement Specification	Doc. No.	L-SJMC02-HTL-VD-URS	Effective Date	24 AUG 2022
	Rev. No.	00	Total Page(s)	6 of 12

7.0 SYSTEM OVERVIEW

The HVAC system for the New Hotlab 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 and ISO 14644 Cleanrooms and Associated Controlled Environments.

The scope for this URS shall cover only the classified cleanroom area of this New Hotlab. The cleanliness classification of the classified cleanroom can be found under Section 7.2.

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 ISO classified areas shall be designed to be served by two (2) units new AHU to provide the HVAC system to all cleanroom.

User Requirement Specification	Doc. No.	L-SJMC02-HTL-VD-URS	Effective Date	24 AUG 2022
	Rev. No.	00	Total Page(s)	7 of 12

8.0 DESIGN REQUIREMENTS

8.1 Premises

- 8.1.1 The premises of the New Hotlab shall include classified cleanrooms and non-classified cleanroom as listed below:

No.	Room(s)
1.	PET/CT Hotlab
2.	SPECT/CT Hotlab
3.	Airlock 1
4.	Clean Corridor
5.	Gown Room
6.	Component Prep. Room
7.	Change Room 1
8.	Radioiodine
9.	Change Room 2
10.	QC Room
11.	Transfer Room
12.	Decay Room

Table 1: Classified and Non-Classified Cleanroom in the New Hotlab Cleanroom at Subang Jaya Medical Centre

- 8.1.2 The cleanroom ceiling panel shall be of EPS panel with a thickness of 75mm and walkable type.
- 8.1.3 The wall partition shall be of EPS panel with a thickness of 75mm.
- 8.1.4 The doors type shall be EPS sandwich panel door.
- 8.1.5 The flooring system in the classified cleanrooms shall be vinyl flooring complete with self-leveling primer and PUR treatment for surface treatment.
- 8.1.6 There shall be three (3) units of active passbox and three (3) units of dynamic passbox within the classified cleanroom area for the transfer of materials for the cleanrooms specified below:

Equipment Description and Reference No.	Passbox	Adjacent Room
Active Passbox 1 (APB1)	Clean Corridor	Decay Room
Active Passbox 2 (APB2)	Component Prep. Room	Med Prep Area
Active Passbox 3 (APB3)	Clean Corridor	QC Room
Dynamic Passbox 1 (DPB1)	Radioiodine	Decay Room
Dynamic Passbox 2 (DPB2)	Clean Corridor	Component Prep. Room
Dynamic Passbox 3 (DPB3)	Radioiodine	NM-202 Inject 1

Table 2: Passbox Location



• Passion With Perfection • Engineers With Dreams •

User Requirement Specification	Doc. No.	L-SJMC02-HTL-VD-URS	Effective Date	24 AUG 2022
	Rev. No.	00	Total Page(s)	8 of 12

8.1.7 The specification for active passbox and dynamic passbox shall meet the criteria below:

Type	Description
Active Passbox (APB1, APB2, APB3)	Material: 1. External casing: Electrogavanised c/w Epoxy Powder Coated 2. Internal casing: Stainless Steel 304 – 4B Finished
	Dimension: 1. Internal size: 400mm(W) x 500mm(D) x 450mm(H) 2. External size: 850mm(W) x 590mm(D) x 1250mm(H)
	Color: White SG
	Window: 5mm(t) Clear Acrylic Sheet
	Filtration: 1. G2 Primary Filter (Washable) - 2 pieces (Side Return & Bottom Return) 2. H13 HEPA filter c/w housing - 1 unit
	Complete with electromagnetic interlocking, electric buzzer and push button.
Dynamic Passbox (DPB1, DPB2, DPB3)	Material: 1. External casing: Electrogavanised c/w Epoxy Powder Coated 2. Internal casing: Stainless Steel 304 – 4B Finished
	Dimension: 1. Internal size: 350mm(W) x 700mm(D) x 450mm(H) 2. External size: 650mm(W) x 790mm(D) x 1250mm(H)
	Color: White SG
	Window: 5mm(t) Clear Acrylic Sheet
	Filtration: 1. G2 Primary Filter (Washable) - 2 pieces (Side Return & Bottom Return) 2. Fan Filter Unit (H13) - 1 unit
	Complete with electromagnetic interlocking, electric buzzer and push button.
	Dynamic Passbox 3 with lead shield: 2mm(t) lead sheet laminated at one side of dynamic passbox

Table 3: Active Passbox and Dynamic Passbox Specification

User Requirement Specification	Doc. No.	L-SJMC02-HTL-VD-URS	Effective Date	24 AUG 2022
	Rev. No.	00	Total Page(s)	9 of 12

8.2 Heating, Ventilation and Air Conditioning (HVAC) System

8.2.1 Critical Process Parameter (CPP)

The cleanroom and active passbox design shall meet the following operating conditions:

AHU/ Exhaust Fan	Room Description	Room No.	Room ISO Class	Pressure (Pa) (reference atmosphere)	Relative Humidity (%)	Temperature (°C)
AHU-1	PET/CT Hotlab	HL01	ISO 5	55	50 - 60	18 - 22
	SPECT/CT Hotlab	HL02	ISO 5	55	50 - 60	18 - 22
	Airlock 1	HL03	ISO 5	0	50 - 60	18 - 22
	Clean Corridor	HL04	ISO 5	40	50 - 60	18 - 22
	Gown Room	HL05	ISO 5	30	50 - 60	18 - 22
	Component Prep. Room	HL06	ISO 7	30	50 - 60	18 - 22
	Change Room 1	HL07	ISO 7	15	50 - 60	18 - 22
	Active Passbox 1	APB1	ISO 7	35	50 - 60	18 - 22
	Active Passbox 2	APB2	ISO 8	25	50 - 60	18 - 22
	Active Passbox 3	APB3	ISO 7	35	50 - 60	18 - 22
AHU-2	Radioiodine	HL08	ISO 8	5	50 - 60	18 - 22
	Change Room 2	HL09	ISO 8	20	50 - 60	18 - 22
	QC Room	HL10	UNCL	-5	NC	20 - 24
	Transfer Room	HL11	ISO 8	20	50 - 60	18 - 22
EF-4	Decay Room	HL12	NC	-5	NC	NC

Table 4: Cleanroom and Active Passbox 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 5, ISO 7 & ISO 8	Non-viable count	Refer Table 6 below
	Viable count	Refer Table 7 below

Table 5: Critical Quality Attributes

User Requirement Specification	Doc. No.	L-SJMC02-HTL-VD-URS	Effective Date	24 AUG 2022
	Rev. No.	00	Total Page(s)	10 of 12

ISO class number	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 6: ISO allowable number of airborne particles of cleanrooms (Non-viable)

Grade	Recommended limits for microbial contamination ^(a)
	Air Sample (cfu/m ³)
A	<1
B	10
C	100
D	200

Table 7: PIC/S permitted limits for microbiological air sampling of cleanrooms (Viable)

- Notes: (a) These are average values
(b) ISO 5 = Grade A; ISO 7 = Grade C; ISO 8 = Grade D

8.2.3 HVAC Requirements

Two (2) units of AHUs shall be used to supply the required airflow to the respective rooms mentioned to achieve the above environmental conditions.

8.2.4 Design & Functional Constraints

8.2.4.1 The AHU shall utilize chilled water from existing chilled water plant for cooling and dehumidification.

8.2.4.2 AHU-1

The new AHU-1 shall supply single pass air to all the cleanrooms, including PET/CT Hotlab, SPECT/CT Hotlab, Airlock 1, Clean Corridor, Gown Room, Component Prep. Room and Change Room 1, as well as Active Passbox 1, Active Passbox 2 and Active Passbox 3. The exhausted air from all the cleanroom and active passbox shall be flowing towards the BIBO filtration system (BIBO-1) and will be filtered with a HEPA filter grade H13 before exhausted out by exhaust fan to atmosphere from the chimney.

The exhausted air from the BSC of PET/CT Hotlab and SPECT/CT Hotlab will be filtered with a HEPA filter grade H13 in the BIBO filtration system (BIBO-2A) and exhausted out by exhaust

User Requirement Specification	Doc. No.	L-SJMC02-HTL-VD-URS	Effective Date	24 AUG 2022
	Rev. No.	00	Total Page(s)	11 of 12

fan to minimize the discharge of contaminants carried in the air stream to the atmosphere from the chimney.

Air filters used in the air handling system shall be primary filter grade G4(B) and secondary filter grade F9. HEPA filter grade H14 shall be fitted at the HEPA filter terminal before air supplied into the cleanrooms. Air filters used in the active passbox shall be HEPA filter grade H13.

8.2.4.3 AHU-2

The new AHU-2 shall supply single pass air to the Radioiodine, Change Room 2, QC Room and Transfer Room. The exhausted air from the cleanrooms shall be flowing towards the BIBO filtration system (BIBO-1) and will be filtered with a HEPA filter grade H13 before exhausted out by exhaust fan to atmosphere from the chimney.

The exhausted air from FH Iodine of Radioiodine will be filtered with a HEPA filter grade H14 in the BIBO filtration system (BIBO-3) and exhausted out by exhaust fan to minimize the discharge of contaminants carried in the air stream to the atmosphere from the chimney.

Air filters used in the AHU-2 shall be primary filter grade G4(B) and secondary filter grade F9. HEPA filter grade H13 shall be fitted at the HEPA filter Chamber before air supplied into the cleanrooms.

8.2.4.4 EF-4

Infiltration air from outside is supplied to the Decay Room. The exhausted air from this room will be filtered with a HEPA filter grade H13 in the BIBO filtration system (BIBO-4) and exhausted out by exhaust fan to minimize the discharge of contaminants carried in the air stream to the atmosphere from the chimney.

8.2.4.5 Filtration System

Zone	Location	Type of Filter
AHU-1	AHU	G4(B), F9
	Room Terminal	H14
	BIBO Filtration System (BIBO-1)	H13
	BIBO Filtration System (BIBO-2A)	H13
AHU-2	AHU	G4(B), F9
	HEPA Filter Chamber	H13
	BIBO Filtration System (BIBO-1)	H13
	BIBO Filtration System (BIBO-3)	H14
EF-4	BIBO Filtration System (BIBO-4)	H13

Table 8: Air Filtration System

User Requirement Specification	Doc. No.	L-SJMC02-HTL-VD-URS	Effective Date	24 AUG 2022
	Rev. No.	00	Total Page(s)	12 of 12

8.2.4.6 Ducting System

Material sheet used in ducting shall be Zinalume sheet with PE insulation to prevent any condensation externally. Ducting shall be constructed based on international standard.

Duct work for all HVAC system must have undergone and passed the duct leakage testing. The test report shall be submitted as part of hand-over documents.

8.2.4.7 Differential Pressure Gauge

Calibrated pressure gauge ranging 0 to 60 Pa shall be installed at rooms for measuring room differential pressure.

Calibrated pressure gauge ranging 0 to 500 Pa shall be installed for monitoring of Terminal HEPA Filter conditions.

Calibrated pressure gauge ranging 0 to 750 Pa shall be installed for monitoring of HEPA filter chamber conditions.

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 Hotlab shall be certified to meet the PIC/S and 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 Subang Jaya Medical Centre for review and approval.

The protocols are to be executed according to the guidelines/procedures provided by Subang Jaya Medical Centre (if there is any).

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

End